

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

ETHICON LLC,
Appellant

v.

INTUITIVE SURGICAL, INC.,
Appellee

2021-1995, 2021-1997

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00050, IPR2020-00051.

Decided: May 23, 2022

ANISH R. DESAI, Weil, Gotshal & Manges LLP, New York, NY, argued for appellant. Also represented by ADAM BANKS, ELIZABETH WEISWASSER; PRIYATA PATEL, CHRISTOPHER PEPE, Washington, DC.

STEVEN KATZ, Fish & Richardson PC, Boston, MA, argued for appellee. Also represented by KENTON W. FREEMAN, JR., Washington, DC; RYAN PATRICK O'CONNOR, JOHN C. PHILLIPS, San Diego, CA.

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

Opinion for the court filed by *Circuit Judge* REYNA.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

REYNA, *Circuit Judge*.

Appellant Ethicon LLC appeals a final written decision issued in two consolidated inter partes review proceedings where the Patent Trial and Appeal Board concluded that the challenged claims are unpatentable as obvious. Ethicon contends that the Board committed legal error by placing the burden of proof on Ethicon, the patent owner. Ethicon also contends that the Board’s finding of a reasonable expectation of success in combining the asserted prior art is unsupported by substantial evidence.¹ We affirm.

BACKGROUND

Ethicon owns U.S. Patent No. 9,844,379 B2 (the “’379 Patent”), titled “Surgical stapling instrument having a clearanced opening.” The ’379 Patent relates to an endoscopic surgical stapling tool. The purported novelty of the claimed invention is the use of both an I-beam firing member and a no-cartridge safety lockout, such that the lockout blocks the advancement of an I-beam firing member when there is no staple cartridge loaded in the stapling assembly. *See* Appellant’s Br. 1–3. This safety mechanism is particularly useful for endoscopic procedures, which require a

¹ Ethicon also argued in its opening brief that the Board’s finding of a motivation to combine is unsupported by substantial evidence. Appellant’s Br. 56–69. Ethicon conceded this issue at oral argument, so we do not reach the question here. Oral Arg. 8:00–8:30. We note, however, that the absence of that waiver would not affect our disposition in this case.

surgeon to work with reduced visual and tactile feedback as compared to open surgery. *Id.*

On October 16, 2019, Appellee Intuitive Surgical, Inc. (“Intuitive”) filed two petitions for inter partes review (“IPR”) of claims 1–3 of the ’379 Patent. *Intuitive Surgical, Inc. v. Ethicon LLC*, Nos. IPR2020-00050, IPR2020-00051, 2021 WL 1158290, at *1 (P.T.A.B. Mar. 26, 2021). On March 31, 2020, the Board instituted the IPRs on the ground that claims 1–3 are unpatentable as obvious over U.S. Patent No. 4,429,695 (“Green”) in view of U.S. Patent No. 5,413,267 (“Solyntjes”).² *Id.*

Green, titled “Surgical instruments,” describes a “surgical stapling instrument” with “upper and lower elongate jaws for receiving a staple cartridge and an anvil respectively.” J.A. 5157. Green accounts for the majority of the claimed features in the ’379 Patent, including a frame, a distal end, a first jaw with a channel, and a channel retainer. *See Intuitive Surgical*, 2021 WL 1158290, at *6–7.

Solyntjes, titled “Surgical stapler with spent cartridge sensing and lockout means,” is directed to surgical stapling instruments “for applying linear parallel rows of staggered staples through compressed living tissue.” J.A. 5146. Solyntjes teaches that there are benefits to equipping a surgical stapler instrument with a locking pin to prevent the instrument’s firing when it is loaded with an empty stapler cartridge, as doing so “reduces the chances of unnecessary tissue trauma, blood loss, inadequate hemostasis, and squandered time during surgery.” Solyntjes col. 2 ll. 65–68.

² The Board also instituted IPR on other grounds. *See Intuitive Surgical*, 2021 WL 1158290, at *1. We do not address those grounds, as they are not at issue on appeal.

BOARD'S FINAL WRITTEN DECISION

During IPR, Ethicon conceded that Green and Solyntjes disclose all the elements claimed by the challenged claims. *Intuitive Surgical*, 2021 WL 1158290, at *7. Ethicon argued, however, that a person of ordinary skill in the art (“POSITA”) (1) would not have been motivated to combine Green with Solyntjes, and (2) would not have had a reasonable expectation of success in doing so. *Id.* On March 26, 2021, the Board issued a consolidated final written decision addressing both issues.

Motivation to Combine

With respect to the question of a motivation to combine, Intuitive relied on testimony from its expert, Dr. Knodel, to argue that a POSITA would have recognized Solyntjes’s locking mechanism would make Green’s instrument safer and more efficient. *Id.* at *6–8. Ethicon, on the other hand, relied on testimony from its own expert, Dr. Fronczak, to argue that there would be no motivation to combine the references because Green already provides the user with tactile and visual feedback as to the presence or absence of a staple cartridge. *Id.* at *7–8. The Green instrument was for use in open surgery whereby the instrument was in the surgeon’s field of vision. *See* Appellant’s Br. 3.

The Board determined that Dr. Fronczak’s expert opinion relied too much on “speculation as to a user’s awareness or cognizance during use of Green’s surgical stapler instrument as to the presence or absence of a stapler cartridge.” *Id.* at *7. The Board instead found that a POSITA would have been motivated to combine the references because:

In particular, Solyntjes clearly sets forth that a locking mechanism is valuable, as the dangers of firing a surgical stapler instrument without a stapler cartridge being present are significant, including the risk of “unnecessary tissue trauma, blood

loss, inadequate hemostasis, and squandered time during surgery.” [Solyntjes col. 2 ll. 65–68].

[. . .]

It defies reason to conclude that a skilled artisan would not have recognized readily the benefit of employing a locking mechanism specifically directed to preventing such firing. That is logically so even if a user may already have an avenue to recognize the presence or absence of a staple cartridge, such as through visual or tactile feedback, as mere recognition in that regard is not understood to actually prevent the firing of a cartridge-less stapler. [Suppl. Decl. of Dr. Knodel ¶¶ 15–20].

Id. The Board also noted that Dr. Fronczak admitted it would be “catastrophic” and a “hazard” if a user failed to notice the absence of a stapler cartridge before attempting to fire the instrument. *Id.* Accordingly, the Board found that Intuitive sufficiently established a motivation to combine Green with Solyntjes.

Reasonable Expectation of Success

With respect to the question of a reasonable expectation of success, Ethicon proffered testimony from Dr. Fronczak supporting its contention that a POSITA “would be incapable of implementing a ‘spring-and-pin lockout mechanism,’ such as that disclosed in Solyntjes, into a surgical stapler instrument having the particular structural characteristic of Green’s instrument.” *Id.* at *8. The Board discredited this testimony because it was “based on little evidentiary support in the record” and “instead largely premised on Dr. Fronczak’s speculation that physical difficulties or impediments in modifying Green’s instrument would have been insurmountable.” *Id.*

The Board credited the testimony of Dr. Knodel that a POSITA would know how to modify Green’s stapler with the lockout taught in Solyntjes. *Id.* at *9. The Board found

Dr. Knodel’s testimony “logical and credible,” as “appropriately reflect[ing] the types of design assessments that such a skilled artisan would have employed in seeking to improve Green’s instrument based on Solyntjes’s teachings as to a locking pin mechanism so as to harness the benefits of such a mechanism.” *Id.* Recalling that “[b]oth parties agree[d] that the level of ordinary skill in the relevant art includes someone with a degree in mechanical engineering and at least three years of design experience in surgical instruments,” the Board found that a motivated POSITA would be able to “account for routine considerations, e.g., location, positioning, and robustness of a locking mechanism, as a part of Green’s instrument.” *Id.*

Ultimately, the Board concluded that Intuitive established by a preponderance of the evidence that claims 1–3 of the ’379 Patent are unpatentable as obvious. *Id.* at *10. Ethicon appeals. We have jurisdiction pursuant to 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) (quoting *Consol. Edison Co., Inc. v. NLRB*, 305 U.S. 197, 229–30 (1938)).

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*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); *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 in an obviousness determination is a pure question of fact, which we review for substantial evidence. *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (quoting *Alza Corp. v. Mylan Lab'ys, Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)). Whether a skilled artisan would have had a reasonable expectation of success in combining references is also a question of fact. *Id.* (citation omitted).

DISCUSSION

On appeal, Ethicon argues that the Board improperly placed the burden on Ethicon as the patentee to disprove that a POSITA would have had a reasonable expectation of success in combining Green and Solyntjes. Appellant's Br. 41–51. Ethicon also argues that the Board's finding of a reasonable expectation of success is unsupported by substantial evidence. *Id.* at 51–56.

I

We first address whether the Board improperly placed the burden of proof on Ethicon. The fact that the petitioner bears the burden of proof in a Board proceeding does not eliminate the patent owner's burden to proffer opposing evidence against the petitioner's showing of unpatentability. *See Novo Nordisk A/S v. Caraco Pharm. Lab'ys, Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013). In resolving a claim of obviousness, the Board should consider the totality of evidence proffered by both parties to resolve any subsidiary factual inquiries, such as the scope and content of the prior art, the existence of a motivation to combine, the existence of a reasonable expectation of success, or the existence of any objective indicia of non-obviousness. The petitioner bears the burden to demonstrate by a preponderance of the evidence that the patent is invalid. *See* 35 U.S.C. § 316. And while the unpatentability inquiry must remain focused on whether the petitioner has borne its burden, that the Board addresses the patentee's counterarguments is not an improper shifting of burdens. *See, e.g., Bos. Sci.*

SciMed, Inc. v. Iancu, 811 F. App'x 618, 626 (Fed. Cir. 2020) (citing *Novo Nordisk*, 719 F.3d at 1353).

Here, the Board received competing expert testimony and found Intuitive's expert, Dr. Knodel, more credible than Ethicon's expert, Dr. Fronczak. The Board found that Dr. Knodel logically and credibly opined that a POSITA would have had a reasonable expectation of success in combining Green with Solyntjes because an individual with a mechanical engineering degree and at least three years of experience designing surgical instruments would have been capable of performing routine modifications to implement Solyntjes's lockout mechanism in Green's stapler. The Board also found Dr. Fronczak's testimony unsupported by the record and largely speculative. This is not indicative of a situation where the Board improperly shifted the burden of proof on the patent owner to establish non-obviousness in the first instance, as Ethicon argues. Rather, the Board weighed competing evidence and made its determination on the record as a whole.

II

We also conclude that substantial evidence supports the Board's finding that a POSITA would have had a reasonable expectation of success in combining Green and Solyntjes. 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) (citing *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996)).

Here, as discussed above, the Board credited Dr. Knodel's testimony that a POSITA would have had a reasonable expectation of success in modifying the surgical stapling instrument of Green to include the lockout mechanism of Solyntjes. *Intuitive Surgical*, 2021 WL 1158290,

at *9. The Board acknowledged Ethicon's argument that the combination would require some modifications to fit pieces of the invention together. The Board relied, however, on Dr. Knodel's testimony that a POSITA would know how to account for "routine considerations" such as "location, positioning, and robustness of a locking mechanism, as a part of Green's instrument." *Id.* And although Dr. Fronczak testified that a POSITA would be "incapable" of combining the references, the Board discredited his testimony as speculative and unsupported by evidence in the record. *Id.* at *8. In view of the foregoing, we conclude that the Board's finding of a reasonable expectation of success is supported by substantial evidence, especially in light of the parties' stipulation regarding the relative skill and experience level of a POSITA in this case.

CONCLUSION

In summary, we hold that the Board did not misplace the burden of proof on the patentee and that substantial evidence supports the Board's finding that a POSITA would have had a reasonable expectation of success in combining the asserted references. Thus, we affirm the Board's final written decision concluding that claims 1–3 of the '379 Patent are unpatentable as obvious.

AFFIRMED

COSTS

Costs to Appellee.

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NEWMAN, *Circuit Judge*, dissenting.

I respectfully dissent. The court reconstructs a novel surgical device from components of known devices, using the '379 patent as a template for the reconstruction. The court finds that an engineer with at least three years of experience in designing surgical instruments would have been capable of designing the claimed device. However, the patentability question is not whether such an engineer would be capable of designing the instrument of the '379 patent. The patentability question is whether the prior art teaches or suggests the structure of the '379 instrument as a whole. Although the court finds that it would have been obvious to combine the Solyntjes and Green reference

mechanisms, it is not disputed that the Solyntjes' spring-and-pin mechanism is not a spent-cartridge lockout, and that a simple combination does not produce the '379 instrument.

There is no teaching or suggestion in the prior art of the '379 patent's structure as a whole, although the prior art shows closely related surgical instruments. No reference shows or suggests a spring-and-pin lockout within the jaws of an endoscopic cutting and stapling instrument. And the inventors' description in the '379 specification of the problem to be solved is not prior art against their solution. Although my colleagues now find it obvious to make the '379 instrument, no one did so despite the advantages and benefits here achieved.

The '379 instrument has advantages and benefits not possessed by prior endoscopic instruments. Such an achievement is of particular relevance in the field of medical technology, where afflicted patients may be benefitted by any technological advantage. Such opportunity for benefit is a purpose of the patent system, thereby serving the public interest. The purpose of encouraging development of new technology warrants recognition of the varied attributes of the myriad fields of technological e-commerce.

The panel majority finds the elements of the '379 invention in assorted prior art references, which the majority then plugs into the claims. Such judicial hindsight was negated in *KSR International*, where the Supreme Court observed that "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–19 (2007).

From my colleagues' analysis and conclusion, I respectfully dissent.