

BioWorld MedTech

Expert Opinion Seen As Carrying The Day In Patent Scrum Between Ethicon, Intuitive

May 27, 2022 [\[Link\]](#)

Ethicon Endosurgery Inc. and Intuitive Surgical Inc. have been sparring in the courts over patents for robot surgery systems for some time, and the U.S. Court of Appeals for the Federal Circuit has ruled on yet another of those disputes. **Intuitive prevailed in this latest case because a “person of ordinary skill” would have been motivated to combine several references in the prior art related to the Ethicon patent, but Courtland Merrill, a partner in the Minneapolis office of Saul, Ewing Arnstein & Lehr, told BioWorld that a key factor in this outcome is that expert testimony for Intuitive was more persuasive than that offered by Ethicon.**

The lawsuit revolved around the first three claims of Ethicon’s 9,884,379 patent (the ’379 patent), which is directed toward a surgical stapling tool. Surgical stapling tools patents were also the subject of prior litigation between the two parties, although Ethicon managed to prevail in that matter at the Federal Circuit. In the instance of the ’379 patent, the device features an I-beam firing mechanism and a no-cartridge safety lock-out mechanism, the latter of which suppresses the former when no staple is loaded.

Sunnyvale, Calif.-based Intuitive had filed for two inter partes reviews (IPR) at the U.S. Patent and Trademark Office in October 2019, during which two elements of prior art were highlighted. Patent no. 4,429,965 (the Green patent) and patent no. 5,413,267 (the Solyntjes patent) were offered as evidence of prior art in these proceedings, with the Green patent providing prior art for elongated jaws that constitute a staple and an anvil. Solyntjes was described as having suggested the benefits of adding a locking pin to a surgical stapler to prevent a firing of the stapler in the absence of a staple.

Cincinnati-based Ethicon is said to have conceded during the IPR that these two earlier patents disclosed all the elements of the first three claims of the ’379 patent, although Ethicon nonetheless asserted that a person of ordinary skill would not have been motivated these two earlier items of prior art. Ethicon also said that such a combination would not have carried any reasonable expectation of success. The expert witness for Ethicon had argued that there would have been no motivation to combine Green and Solyntjes because the Green patent already provided a source of tactile and visual feedback that would have alerted the surgeon as to the absence of a staple cartridge.

The Patent Trial and Appeal Board, which hears IPR proceedings, had determined that Ethicon’s witness had relied too heavily on speculation regarding the user’s awareness of whether a staple cartridge had been loaded. The PTAB ruling was that Solyntjes highlights the need for a locking mechanism by drawing attention to the hazards associated with the firing of the mechanism without a staple cartridge, which would include tissue trauma, loss of hemostasis and loss of time during the surgical procedure. The PTAB decreed that it “defies reason to conclude that a skilled artisan would not have recognized readily the benefit of employing a locking mechanism” to avoid an actuation without a staple cartridge.

BioWorld MedTech

Ethicon's expert witness apparently conceded the hazards associated with a stapler discharge without a staple cartridge during the IPR proceedings. The Federal Circuit indicated that the PTAB found correctly when it determined that a trained mechanical engineer with three years of experience in the field would have been reasonably expected to successfully combine the elements of Green and Solyntjes.

Judge Pauline Newman wrote a dissenting opinion, stating that her two colleagues at the Federal Circuit were incorrect in assuming that the two items of prior art would necessarily have been readily combined to produce the '379 patent. Newman cited the landmark 2007 Supreme Court patent case of *KSR v. Teleflex* – which overhauled the U.S. court systems' treatment of obviousness – in asserting that a patent claim is not necessarily invalidated simply by virtue of the fact that prior art in some way resembles a patent's claims. Newman said the Supreme Court had declared in *KSR* that the majority of inventions “rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”

Merrill noted that this case “does not provide any new legal pronouncements or holdings,” but that the Federal Circuit’s role as jury in IPR proceedings hinges as much on facts as it does on questions of the law. The problem for Ethicon is that it is difficult in some instances to reverse a PTAB’s findings of fact when appealing the outcome at the Federal Circuit, and thus it is perhaps less difficult to make a successful argument regarding the facts during the IPR.

“The take-away I received from this decision is the importance of expert testimony re the underlying factual issues supporting or refuting an obviousness argument,” Merrill said, noting that the PTAB had clearly found Intuitive’s expert testimony more credible than the expert testimony provided by Ethicon. Merrill made note of the fact that the PTAB had cited Ethicon’s expert testimony as speculative, and while he said Newman’s dissent “seemed factually compelling,” Merrill nonetheless stated that there was little reason to conclude that the PTAB’s decision “was unsupported by substantial evidence, as the [Federal Circuit] majority concluded.”