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Intellectual Property Law

Keywords: **public use; on-sale bar; ready for patenting; experimental use; 102(b)**

General: **An invention is not "ready for patenting" until the invention has been tested in a variety of settings and is known to work for its intended purpose.**

Mark A. Barry v. Medtronic, Inc.
Appeal no. 2017-2463
Fed. Cir. January 24, 2019

I. Facts

In 2014, Dr. Mark A. Barry brought suit, asserting that Defendant Medtronic, Inc.'s CD Horizon Legacy spine surgery system indirectly infringed two patents, U.S. Patent No. 7,670,358 ("the '358 Patent") and U.S. Patent No. 8,361,121 ("the '121 Patent"), which relate to a system and method of aligning spinal vertebrae to correct common spinal deformities like scoliosis. At trial, the jury a verdict finding in favor of Dr. Barry on every issue, including indirect infringement, various theories of invalidity, and willfulness, which the district court upheld. Medtronic appealed the decision based on several grounds, principally concerning the public-use and on-sale statutory bars, but also concerning prior invention, inequitable conduct, and induced infringement and associated damages.

Dr. Barry began work in late 2002 or early 2003 on a method of aligning spinal vertebrae to correct common spinal deformalities like scoliosis. During 2003, he worked with a sales representative from the DePuy medical device company to adjust standard DePuy tools for Dr. Barry's purposes and in accordance with Barry's ideas. Dr. Barry also spoke about his ideas with representatives from another company, Spine-Vision. By July 2003, Dr. Barry had a tool that allowed him to link screw-grabbing and vertebrae-moving wrenches together.

Dr. Barry used the tool in three surgeries on August 4, August 5, and October 14, 2003. Dr. Barry testified that the three surgeries represented the three most common types of scoliosis-caused spinal deviation conditions that surgeons typically see. Between August 2003 and January 2004, Dr. Barry had follow-up appointments with his patients where Dr. Barry viewed x-rays of the patients' spines (after they had been able to stand up and walk following the three-month acute phase of recovery) to determine if the curvature conditions had been successfully ameliorated by the surgery. According to Barry's testimony, it was only in January 2004 that he felt confident his invention functioned for its intended purpose and was ready to publicize it. By February, Barry prepared and submitted an abstract for an international conference. On December 23, 2004, the application that would become the '358 patent was filed, and thus, making December 2003 the critical date for purposes of the public-use and on-sale bar issues under 35 U.S.C. § 102(b).

II. Issue

1. Was Dr. Barry's invention in public use prior to December 30, 2003?
2. Was the invention on sale prior to December 30, 2003?

III. Discussion

1. No. "The public use bar is triggered when, before the critical date, the invention is in (i) public use *and* (ii) ready for patenting." *Polara Eng'g Inc v. Campbell Co*., 894 F.3d 1339, 1348 (Fed. Cir. 2018) (emphasis added) (annotations added).

i. **Was the invention ready for patenting?**

No. "Ready for patenting" is shown by (a) a reduction to practice or (b) drawings or descriptions enabling an ordinarily skilled artisan to practice the invention. *Pfaff*, 525 U.S. at 67-68. Under the test for a reduction to practice, the challenger must show that "the inventor (1) constructed an embodiment or performed a process that met all the limitations *and* (2) determined that the invention would work for its intended purpose." *In re Omeprazole Patent Litig*., 536 F. 3d 1361, 1373 (Fed. Cir. 2008) (emphasis added).

With respect to point (a), Medtronic relied on the August and October 2003 surgeries as showing reduction to practice. However, as noted above, it was not until January 2004 that Dr. Barry completed his standard-practice follow-up for the three most common types of scoliosis. Further, testimony from Dr. Lenke, Dr. Barry, and Dr. Barry's expert confirmed that it is important for a surgeon to evaluate a patient after some time, particularly when the patient can stand. Thus, the evidence allowed a reasonable finding that Dr. Barry did not know that his invention would work for its intended purpose until he completed all three follow-ups.

Medtronic argued that the "intended purpose" of the invention, as recited in the preamble of the claims, was for "the amelioration of aberrant spinal column deviation conditions." The courts rebutted that an "intended purpose" recited in a preamble is not limiting, *i.e.*, it does not state a requirement that must be proved to establish infringement. Further, the courts cited case law, such as *Polara, Manville,* and *Honey International v. Universal Avionic Systems*, which established that an inventor could not know if an invention worked for its intended purpose until it had been tested in a variety of setting where it would operate. As such, the court concluded that Dr. Barry could not confirm that the invention would work for its intended purpose until following up with all three surgeries.

With respect to point (b), and to answer the dissent, the court noted that while drawings prepared in November 30, 2003, by a device company, Spine-Vision, based on conversations with Dr. Barry existed, there was no expert testimony that these drawings meet a required enablement showing. Accordingly, the court found that the '358 patent's invention was not ready for patenting before the critical data.

ii. **Was the invention in public use?**

No. The court found that Dr. Barry was the only one who actually practiced the invention- performing the surgery using the claim-required manipulation of linked derotators. While other people were present in the operating room, there was sufficient evidence to show that very few of the people in the operating room had a clear view of the surgical field, where Dr. Barry was using his invention, because they were either not permitted near the sterile field or because there was a drape blocking the view. The court

found that those in the operating room were under an implied duty of confidentiality as this was considered a demonstration of a prototype to colleagues.

Additionally, the court found that and the August and October 2003 surgeries were within the experimental use exception. The host of factors that can be relevant to assessing whether a use is experimental include: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers. The court found that the facts of case would allow the jury to reasonably find that the experimental use exception applies.

2. No. To be rendered invalid under the on-sale bar, an invention "must be the subject of a commercial offer for sale" in the United States and "it must be ready for patenting." *Pfaff*, 525 U.S. at 67. Because the invention was not ready for patenting, the court found that the on-sale bar did not apply.

IV. Conclusion

The court affirmed the district court's rulings regarding public-use and on-sale statutory bars, the meaning of "ready for patenting," and experimental use exceptions.

V. Dissent

In dissent, Judge Prost argues that though sufficient, reduction to practice is not necessary for § 102(b)'s on-sale bar to apply. Rather, the standard is whether the invention was "ready for patenting"—that is, whether the inventor could have obtained a patent. Judge Prost reviewed the evidence and found that regardless of when the inventions were reduced to practice, Dr. Barry could have obtained a patent before the critical date because by the end of the surgeries, Dr. Barry could have satisfied the enablement and written-description requirements of § 112 and credibly claimed utility under § 101. Judge Prost argues that by focusing only on reduction to practice, the majority misses *Pfaff*'s point—readiness for patenting is broader than reduction to practice and is meant to answer whether the inventor could have obtained a patent on his or her invention. Judge Prost also argues the findings of the majority regarding reduction to practice for the inventions intended purpose and whether the intended purpose was only met subsequent to the follow-up visits.