



How the U.S. Patent Office Got So Screwed Up

Once a haven for innovation, over the last two decades the U.S. Patent and Trademark Office has been rocked by the velocity of technological change and roiled by “patent trolls.” Could it be that the biggest impediment that innovators now face is the very system that was created to protect them?

By Scott Eden Jun 21, 2016

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Prior-art searchers go through the USPTO's nearly ten million patents, looking for anything that can be used against an inventor.

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Troy Norred was on his way home for Thanksgiving in 1998 when he had his flash of genius. It was the middle of the night, his wife was driving the family car, and his four children were asleep in the back. He'd just finished his shift at the hospital, where his workweek often exceeded a hundred hours. Two days shy of thirty-one, Norred was a fellow in the cardiology program at the University of Missouri. For more than a year he'd been stewing over an idea, and so powerful was his sudden insight now—*surface area in the aortic root!*—that he told his wife to pull over. He made a sketch on a napkin. That sketch would become the breakthrough that led to U.S. Patent No. 6,482,228, "Percutaneous Aortic Valve Replacement," granted in November 2002 by the United States Patent and Trademark Office. It would also become the basis for an idea that Norred would spend the next four years failing to interest anyone in financing the development of—not his superiors in the cardiology department at Missouri, not the venture-capital firm that flew him to Boston to hear his pitch, not the cutting-edge innovation guru at Stanford who initially encouraged him but then ended the conversation, not the product-development people he signed non-disclosure agreements with at Medtronic, Edwards Lifesciences, Johnson & Johnson, Guidant, and others. The idea was for a collapsible prosthetic aortic valve that could be fished up through an artery with a catheter and implanted in the hearts of patients who suffered from failing aortic valves.

By September 2003, Norred had all but given up on his dream when he and a colleague were strolling the exhibition hall at an important cardiology congress held annually in Washington, D.C. They came upon a booth occupied by a California startup called CoreValve. With increasing alarm, Norred studied the materials at the booth. He turned to his colleague: "That's my valve!"

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According to documents filed in a legal case that lasted more than three years and wound its way through multiple federal courts, Norred tried unsuccessfully to discuss a licensing deal with CoreValve. He says he reached out to the startup's then-chief executive, a Belgian Congo-born medical-devices entrepreneur and investor named Robrecht Michiels, who told him that a license would need to wait until after CoreValve had grown out of the startup phase. (Michiels denies saying any such thing.) Norred tried to follow up with CoreValve, but his calls and letters went unanswered. Years passed. Norred settled into private practice and then, in 2009, he saw the news online: CoreValve had sold itself to Medtronic for \$775 million in cash and future payments. Today, collapsible prosthetic valves fished up through an artery with a catheter and implanted in the aorta are well on their way to becoming the standard method of replacing worn-out heart valves. The annual market has already surpassed \$1.5 billion and is expected to grow in the coming years by orders of magnitude.

When Norred first saw CoreValve's version of his patented invention, he did not know that the U.S. patent system had entered an era of drastic change. Starting in the early 2000s, the rights and protections conferred by a U.S. patent have eroded to the point that they are weaker today than at any time since the Great Depression. A series of Supreme Court decisions and then the most important patent-reform legislation in sixty years, signed into law in 2011, have made it so. The stated purpose of the reform has been to exterminate so-called patent trolls—those entities that own patents (sometimes many thousands of them) and engage in no business other than suing companies for patent infringement. The reforms have had their desired effect. It has become harder for trolls to sue. But they've made it harder for people with legitimate cases, people like Norred, to sue, too.

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Dr. Troy Norred filed for a patent for a replacement aortic valve in 2000. Despite versions of his invention accounting for billions in sales, he has not profited.

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According to many inventors, entrepreneurs, legal scholars, judges, and former and current USPTO officials, the altered patent system harms the independent, entrepreneurial, garage-and-basement inventors, who loom as large in our national mythology as the pilgrim and the pioneer. In the words of Greg Raleigh, a Stanford-educated engineer who came up with some of the key standards that make 4G networks possible, "It has become questionable whether a small

company or startup can protect an invention, especially if the invention turns out to be important." Some call it collateral damage. Others maintain it was the express purpose of the large corporations to harm inventors. But, in the end, the result is the same. The Davids have been handicapped in favor of the Goliaths. Those who believe that innovation's richest sources lie as much in garages as in corporate R&D labs have grown fearful. "We clearly had the world's best patent system, based on the results," says Palo Alto venture capitalist Gary Lauder. "And that is going away."

As a resident at the University of Oklahoma Health Sciences Center in the mid-1990s, Troy Norred saw an elderly male patient who was in all ways healthy except for a failing valve in his aorta. At the time the only way to treat that condition was to open up the man's chest, stop his heart, bypass it, carve out the old valve and suture in a rigid artificial one. The patient was too old for such a procedure. He died. "Why can't we replace his valve in a way that would not create such havoc on his system?" Norred asked himself. "What would such a replacement look like?" Most important, he realized, the valve would need to withstand the tremendous pressure of blood pumping constantly through it.

On that Thanksgiving drive, he thought he had figured it out. His idea involved the surface area of the tubular aortic root and an expandable nitinol stent, also tubular, with a pig valve attached to it. The stent would expand against the tissue wall of the ascending aorta, anchoring the new valve in place and creating a seal without the need for barbs or staples or sutures, which tend to break over time. The surface area was the key. The more area the stent could expand against, the stronger it would adhere and the better it would keep the valve in place.

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BASED ON THE RESULTS. AND THAT IS GOING AWAY."**

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