Who invented the miraculous artificial blood vessel?

It took 30 years and armies of lawyers fighting through a landscape of lies, corporate intrigue, and personal misery to find the $400 million answer.

BY ALISON FRANKEL
couple of weeks after he was selected as C.R. Bard, Inc.'s new trial lawyer in its patent infringement case against W.L. Gore & Associates, Inc., Steven Cherny had a momentary panic attack. It was a perfectly reasonable reaction. In fact, if the Fish & Neave partner had really understood what he was getting into when he took over the Bard case in 2004, he’d have panicked even sooner.

He’d known, of course, that the case had a very long history. For almost three decades, Gore had been fighting for ownership of the artificial blood vessel, known as a vascular graft, that revolutionized vascular surgery. Only after a contentious 12-year proceeding to determine the true inventor of the device and two trips to the U.S. Court of Appeals for the Federal Circuit did the Patent and Trademark Office finally reject Gore’s ownership claim in 2002.

And even then Gore would not concede defeat. The company, which earned tens of millions of dollars a year from the sale of vascular grafts, refused to pay Bard (which owned rights to the patent) a licensing fee, claiming—with no concession to the irony of its argument—that the patent it had struggled for 30 years to obtain was actually invalid. Finally, to gain control of its patent rights, Bard sued Gore for infringement. The March 2003 filing came 29 years after the vascular graft was invented.

The stretch of time didn’t daunt Cherny, who’d worked on plenty of long-running suits. Nor was he worried about the case’s technological complexity; Cherny has an undergraduate degree in mechanical engineering from the Massachusetts Institute of Technology. When his friend Charles Krauss—a former...
BROTHERS-IN-ARMS (from left): Max Grant, Charles Krauss, and Steven Cherny had little time to master Bard’s complicated patent case.
Fish & Neave associate who’d recently gone in-house at Bard—called to ask if he’d be interested in taking over the Gore case, Cherny regarded it as a great opportunity. But after he went to Boston in 2004 to meet with the lawyer he was succeeding, retiring Foley Hoag partner Peter Ellis, and with Wolf Greenfield partner Lawrence Green, who’d been in charge of Bard’s patent application since the 1980s, Cherny began to understand: The 30-year war between Gore and Bard was no ordinary patent dispute. “That was my ‘aha’ moment,” he says. “They started throwing around names, theories, things that had happened in 1978. My head was spinning.”

What Cherny realized at the meeting in Boston—and what sets the fight over the artificial blood vessel apart from typical patent suits—was that the technology underlying the invention wasn’t the most complex aspect of the case. Not by a long shot. This case was all about how the revolutionary device came to be created, who actually created it, and what happened afterward.

At first Cherny and Krauss, who was in charge of the case at Bard, wondered if they’d ever master the details. “It was as if someone gave us the script for one episode of As the World Turns and said, ‘Okay, figure out the last 30 years of its history,’” says Krauss. “You didn’t know who was a spectator, who was real.”

Meanwhile, Gore’s lawyers from Morgan Finnegan and Phoenix’s Osborn Maledon seemed to be at a distinct advantage. Some of them had been involved in the case since the 1980s. They didn’t have to learn the story; they’d already lived it. (Citing ongoing appeals, Gore declined to comment for this story or to permit its lawyers to comment.)

But as the case proceeded, the Bard lawyers discovered, to their surprise, that they were better off unencumbered by personal involvement and emotional entanglement. Unlike Gore’s team, they were able to show jurors a sensible path through the thicket of the case’s history when they went to trial in Phoenix federal district court at the end of 2007. They were also much better than the Gore lawyers at making their arguments to federal district court judge Mary Murguia in posttrial proceedings. The result: $410 million in damages, attorneys’ fees, and interest for Bard so far, with rulings still to come from Judge Murguia on supplemental damages and enforced royalties for the grafts, which Gore continues to sell. Those issues, which have been fully briefed and should be resolved in the next few months, are expected to add $100–$300 million to the total judgment—which will make Bard’s win one of the biggest in patent litigation history.

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Goldfarb was the first of the researchers using Gore-Tex to achieve optimal and consistent tissue growth. His breakthrough, he would later tell jurors at the patent trial in Phoenix, came when he realized that Gore-Tex, under the microscope, was a thick lattice of interspaced nodes and fibrils. Goldfarb believed that the space between them, which became known as internodal distance, was the key to encouraging red blood cells and fibroblasts to grow tissue into the vascular grafts. He began ordering tubes of specific internodal distance from the Gore plant for testing.

Gore, meanwhile, had hired a man named Dan Detton to travel around the country, coordinating the work of researchers testing Gore-Tex vascular grafts. (Detton also worked with Peter Cooper, who oversaw requests for materials from the Gore plant he managed in Arizona.) The first doctor Detton visited was a University of Utah researcher named Jay Volder, who would later figure prominently in the feud between Gore and Bard. The second was Goldfarb in Phoenix.

Detton’s exact role in the invention of the vascular graft later became a matter of no small dispute. Though he was not trained as a physician or scientist, he would claim that he was instrumental in developing the graft’s molecular structure. Goldfarb, on the other hand, referred to Detton at trial as “sort of a messenger, in a way.” Detton, he said, would visit his lab about once a week and relay his specification requests back to the Gore plant.

In the spring of 1974 Detton came to Goldfarb’s lab with disturbing news. Gore, he said, had filed a patent application for a vascular graft, specifying the same internodal distance that Goldfarb had derived through his experiments. The Gore patent application, filed in April 1974, named Cooper, the plant manager, as the graft’s inventor. It’s almost impossible to provoke a strong emotional reaction from Goldfarb, who is supremely unflappable. But he says he was surprised by what Gore had done in 1974. “I just didn’t understand on what basis Peter Cooper was the inventor,” says Goldfarb, who is now in his seventies. “I just didn’t think it was right.”
immediately, Detton complained to his superiors that Cooper—who’d dropped out of Middlebury College before joining the Gore company—hadn’t invented anything. Detton later testified that he was then asked to leave the company. He and other disenchanted Gore employees asked Goldfarb if the doctor would join them in establishing a new company to manufacture and market vascular grafts. Goldfarb, who testified that his priority was continuing his research on the grafts, agreed to join the board of the start-up company, which was called International Medical Prosthetics Research Associates, Inc., or Impra.

In May 1974 Impra hired Arizona patent lawyer Sam Sutton to counsel the company on a patent application that would challenge Gore’s claim. In the course of his investigation, Sutton interviewed Detton, Goldfarb, and Jay Volder, who had moved from the University of Utah to join Goldfarb’s lab and the Impra board. At a long meeting on September 9, 1974, Sutton reviewed his findings with Goldfarb, Volder, and the three former Gore employees who were also on Impra’s board. (Detton was not among them.) At the end of the meeting, all five—including Volder—agreed without objection that Goldfarb had invented the vascular graft and should be named in the patent application.

In October 1974 Sutton filed the application. Goldfarb, who had resigned from Impra’s board because he didn’t think it was proper for him to be involved with the business, assigned Impra the right to make and sell a product based on his patent application. In exchange, Impra was to help fund his continuing research.

But in 1976 Goldfarb sued Impra. He accused the start-up’s executives of failing to fulfill their promise to fund his research, and sought the return of his patent rights.

Impra’s response in the years of litigation that followed was to stir up doubt about Goldfarb’s claim to have invented the vascular graft. His patent application, Impra argued, was doomed because Dan Detton and Jay Volder (among others) had contributed too much to the development of the vascular graft for Goldfarb to be named the sole inventor.

Neither Volder nor Detton ever filed competing patent applications on the device. Nevertheless, by the time Goldfarb sued Impra—as the revolutionary impact of the vascular graft became clear—both had begun hinting that they wanted a bigger share of the credit for the vascular graft. Detton, who was at first a staunch supporter of Goldfarb, had supplied a 1976 affidavit to the patent office attesting that Goldfarb was the inventor of the vascular graft. A year or so later, however, Volder entrusted a lab notebook to Impra counsel Sam Sutton, asking him to keep it confidential. Volder would eventually claim that the notebook proved that he—not Goldfarb—had invented the graft, providing powerful ammunition to lawyers challenging Goldfarb’s inventorship, first from Impra, then from Gore.

Goldfarb’s suit against Impra eventually settled, with Impra returning patent rights to the doctor. Goldfarb then licensed his pending patent to C.R. Bard, a medical device company that was eager to compete with Gore and Impra in the burgeoning market for vascular grafts.

(It’s worth noting that Goldfarb, who has always said he wasn’t interested in the money from his invention, gave most of the licensing fees he earned from Bard to charity.) Bard hired the Boston patent firm Wolf Greenfield to prosecute Goldfarb’s application at the patent office.

In 1983, nine years after the dueling vascular graft patent applications were filed, the patent office declared an “interference.” The patent examiner, in other words, had determined that the
THE ROAD TO VICTORY

APRIL 1974 W.L. Gore files a patent application for a revolutionary medical device known as a vascular graft. The application names Gore plant manager Peter Cooper as the inventor.

SEPTEMBER 1974 Arizona cardiac surgeon David Goldfarb files a competing patent application on the vascular graft.

SEPTEMBER 1983 After nine years without issuing a patent on the vascular graft, the Patent and Trademark Office finally rules that the vascular graft is a patentable invention and that both Gore and Goldfarb have filed valid applications. The PTO sends the case to the Board of Patent Appeals and Interference to determine whether Gore or Goldfarb is the true inventor.

OCTOBER 1995 Twelve years after beginning its investigation, the patent interference board declares Goldfarb the inventor of the vascular graft. Its ruling is upheld twice by the U.S. Court of Appeals for the Federal Circuit in appeals by Gore.

MARCH 2003 With Gore continuing to sell vascular grafts, C.R. Bard files a patent infringement suit against Gore in federal district court in Phoenix.

NOVEMBER 2007 Trial begins before Judge Mary Murguia and a federal jury in Phoenix.

DECEMBER 2007 The jury finds for Bard on all counts and awards damages of $186 million. It also finds Gore’s infringement to have been willful.

MARCH 2009 Gore’s claims of inequitable conduct against Bard were denied by Judge Murguia. She doubles damages against Gore, adds nearly $20 million in attorneys’ fees for Bard’s lawyers, and tacks on prejudgment interest, bringing the total to $410 million—with an additional ruling still to come on licensing fees for Gore’s continuing sales of vascular grafts. The final judgment is expected to be one of the largest in patent litigation history.

—A.F.

AS STEVE CHERRY AND MAX GRANT LEARNED the case’s history, they were constantly surprised at what they didn’t know. It wasn’t until a couple of months before trial, for example, that Cherny found out, from an offhand remark by Goldfarb, that the doctor had once sued Peter Cooper for stealing his laboratory slides. “I said, ‘What?’ ” Cherny recalls. “I’ve been working on this case for three years, and no one ever told me this?” Cooper ended up returning the slides.

The Gore strategy, meanwhile, depended on its lawyers’ thorough knowledge of the vascular graft. Gore appeared to be intent on introducing characters and issues to create confusion, suggesting to both Judge Murguia and the jury that Goldfarb did not deserve the vascular graft patent because too many others had claims on the invention.

Both Detton and Volder were intrinsic to Gore’s plan. Detton, who later told jurors that he had received pretrial payments from Gore, would testify that Impra named Goldfarb as the inventor only because the company was worried that if Volder or Detton were named, their former employers would assert ownership claims. Through Detton, the Gore lawyers also planned to show that Goldfarb’s lawyers had withheld evidence from the patent office—including Detton’s supposed repudiation of the 1976 affidavit in which he affirmed Goldfarb’s inventorship.

Illness prevented Volder from testifying at trial. But the lab notebook he’d entrusted to Sam Sutton in the mid-1970s—which was presumably destroyed with the rest of Sutton’s files when the lawyer retired in the 1990s—was a mystery through which Gore intended to cast doubt on Goldfarb’s patent.

By contrast, Cherny, Krauss, and Grant hacked Bard’s case down to a simple theme: David Goldfarb saw what other researchers had not. He invented the vascular graft, and in more than 30 years, he never wavered in his account of how he did it. “The Gore guys were never able to weave together an explanation of what motivated David,” says Grant. “They made a terrible decision in trying to beat him up.”

Goldfarb, who was Bard’s first witness, was physically spent by the hours of testimony, but was undamaged in the cross-examination by David Pfeffer of Morgan Finnegan. Detton, on the other hand, was badly battered during Max Grant’s cross-examination a few weeks into the trial. Grant asked repeatedly about inconsistencies in Detton’s stories over the years, pointing out that Detton had by his own admission perjured himself when he signed the 1976 affidavit in support of Goldfarb’s patent application, which he later tried to disavow. Grant was trying to goad Detton to lose his composure, and he succeeded. “It’s never pleasant to have to sit in front of a group of people and say, ‘Guess what, I told lies under oath,’ ” Detton testified. “That’s never pleasant. And you know that, which is why you keep asking me . . . again and again . . . did you lie, did you lie, did you lie. Because what you really want to say is, since you lied 32 years ago, we all know that you’re lying today.”

The Gore trial team also asked at least five witnesses about the missing Volder notebook. But their testimony never answered two key questions. If Volder had invented a successful vascular graft, why didn’t he publish his findings? And why hadn’t Gore obtained a sworn statement from Volder before he became ill? Volder’s only sworn statement addressing the inventorship of the vascular graft was his 1976 affidavit in support of Goldfarb.
The jury deliberated only a day and a half before returning with a verdict for Bard on almost every question. Jurors agreed that Goldfarb was the inventor of the graft, that his patent was valid, and that Gore had willfully infringed it in a wide array of products. (The only area in which jurors did not side with Bard was a reasonable royalty rate; they found that Gore owed Bard only 10 percent, not the 15 percent Bard wanted.)

For the Bard lawyers, there was no time to enjoy the verdict. They were already in the middle of the next phase of the case, presenting testimony to Judge Murguia on Gore’s claims that Goldfarb’s patent was invalid because he and his lawyers had committed inequitable conduct by deceiving patent office officials. If Murguia found inequitable conduct by Goldfarb, the jury verdict would be meaningless. “There was no enormous joy,” Grant says. “We knew there was more to do.”

Judge Murguia’s denial of Gore’s inequitable conduct allegations, which came in a monumental 83-page ruling in July 2008, was the cause for celebration that Cherny, Krauss, and Grant had been waiting for. Gore had presented seven different inequitable conduct theories, citing instances in which Goldfarb’s lawyers allegedly failed to advise the patent office of relevant evidence or misled the patent office with testimony they knew to be false. Murguia analyzed the evidence in painstaking detail and rejected all of Gore’s arguments. “Gore has failed to present sufficient evidence to establish that plaintiffs have not fulfilled their duty of candor, good faith, and honesty to the PTO,” she wrote. The jury verdict would stand: Judge Murguia entered judgment for Bard.

Cherny received word of the ruling on an Acela train to Boston. He scanned the decision, sent a text message to Grant, and sat back to savor the moment. “Then I knew we had won,” he says.

But the most resounding affirmation was still to come. With the jury verdict and the inequitable conduct ruling, it was obvious that the Bard lawyers’ machete-cuts through the case’s history had been the right strategy. Judge Murguia’s subsequent ruling on damages and attorneys’ fees, in March 2009, showed just how big a mistake Gore’s team made when they refused to let go of that history. Murguia discussed Detton’s credibility problems, and Gore’s failure to obtain a sworn statement from Volder. She dismissed Gore’s continued assertions that Goldfarb’s patent was invalid, observing that the company fought for almost 30 years to obtain the very patent it was now calling invalid. “There comes a time,” Judge Murguia wrote, “when a defendant’s zealous advocacy runs so contrary to reality that such continuing reliance on its opinions, without change or reevaluation of those positions, becomes reprehensible.” The judge doubled Bard’s damages, and ordered Gore to pay almost $20 million in Bard’s attorneys’ fees.

Cherny, Grant, and Krauss like to say that they still don’t know everything about the history of the vascular graft, though Cherny has come a long, long way from the head-spinning 2004 meeting in Boston. It may even be possible that Gore’s lawyers know things about the case that the Bard team doesn’t. That doesn’t matter. The Bard lawyers knew enough to see what would ring true to a judge and jury. They knew enough to win.

E-mail: afrankel@alm.com.

Vascular grafts are implanted to replace weak or damaged veins and arteries. Often used in bypass and aneurysm surgery, they act as artificial blood vessels. Properly functioning grafts become a part of the patient’s body through a process called tissue in growth, in which red blood cells and fibroblasts promote the growth of tissue on the walls of the graft.