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In a lawsuit, Medinol Ltd. of Tel Aviv accuses Boston Scientific, a Natick company, of taking its cutting-edge stent-making machine, pictured here, and making an unauthorized copy of it.

The Boston Globe

Suit accuses stent-maker of copying designs

By Jeffrey Krasner and Ross Kerber, Globe Staff | September 27, 2004

Boston Scientific Corp., the Natick medical device company that parlayed its heart stent business into billions of dollars of revenue, created a secret company overseas that dismantled a partner's stent-making machine and built its own version, according to unsealed court documents.

Boston Scientific's 'Better Deal'

High points in Boston Scientific's three-year effort, called Project Independence or Bringing a Better Deal (BBD), to set up a secret operation to copy technology from Medinol Ltd., its Israeli partner.

April 1997 Lawyers set up a company called Forwich Ltd.

July 1, 1997 Boston Scientific orders a stent-making machine from Medinol for \$369,837.

July 1997 Forwich sets up a "ghost office" with a receptionist in Dublin and leases separate manufacturing space there. It does business under the name BBD.

July 25, 1997 Stent-making machine arrives at Boston Scientific's plant in Galway, Ireland. The crate is loaded onto another truck and shipped to Dublin.

August 1997 BBD gives Medinol's stent diagrams to steel etchers to try to replicate Medinol stents.

Sept. 10, 1997 BBD buys a laser welding system for 186,000 (pounds sterling) as part of its effort to reverse-engineer Medinol's stent-making machine.

Nov. 26, 1997 BBD orders enough stainless steel to

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Boston Scientific went so far as incorporating a firm, Forwich Ltd., leasing office space in Dublin, and hiring a receptionist. The operation, known internally as Project Independence, oversaw the reverse engineering -- dismantling and re-creation -- of a machine that made cutting-edge coronary stents. The alleged goal, according to partner Medinol Ltd.'s court filings: to learn how to build Medinol stents so Boston Scientific could walk away from a 10-year supply agreement and earn the 90 percent profit margin on the products.

Boston Scientific confirms in interviews and court filings that it ran the secret company and duplicated the machine, but says it had to because Medinol was an unreliable

supplier. Boston Scientific asserts the project was permitted under the terms of the agreement with Medinol.

EXHIBIT

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But the Natick firm denies a more explosive allegation that it copied a set of Medinol's blueprints to help create Boston Scientific's best-selling Express and Taxus stents.

Medinol sued Boston Scientific in US District Court in New York in April 2001, claiming Boston Scientific had violated its agreement. Boston Scientific countersued several weeks later. A federal judge could soon rule whether Boston Scientific attempted to steal Medinol's stent-making technology and eliminate its partner from the lucrative business, as Medinol contends, or whether Project Independence was a clandestine but legitimate way for Boston Scientific to ensure its supply of stents as the partnership unraveled, as the company claims in its countersuit.

Medinol in 2002 estimated that it lost future profits through 2005 of \$1.35 billion from Boston Scientific's alleged contract breaches. Boston Scientific argues that Medinol wasn't damaged at all by Project Independence.

The outcome could hit Boston Scientific's revenues from its blockbuster Taxus stent system, which dominates the market for drug-coated stents despite three recalls. Boston Scientific predicts Taxus will generate as much as \$1.3 billion in revenue in the last six months of 2004 alone. Stents are wire-mesh tubes that doctors implant to prop open coronary arteries that have been cleared of blockages.

Medinol has asked a federal judge to issue an injunction barring Boston Scientific from selling any stents that make use of the allegedly purloined technology. While an injunction seems unlikely because the stents are a popular medical advance, the judge could order Boston Scientific to pay Medinol royalties on Taxus sales.

Medinol first learned about the secret operation in April 2000, when Boston Scientific chief executive James R. Tobin confessed the details to Medinol founders Judith and Jacob "Kobi" Richter.

"I do not believe that there is any other CEO in corporate America who has to make a disclosure like this," Tobin acknowledged saying, according to a deposition he gave. Project Independence, he said, "was a stupid thing."

The three-year legal battle provides a rare glimpse into the cutthroat world of the medical-device business. Both sides produced stacks of confidential inside information to each other under a protective court order, but the judge later made many of those documents public.

A Globe review of those filings found a remarkably detailed picture of the extraordinary measures Boston Scientific took to keep the operation hidden. Even Tobin wasn't told about Project Independence when he took the helm in June 1999, according to his sworn testimony.

Both sides have asked Judge Alvin K. Hellerstein to rule in their favor on central issues in the case. The judge's decision will determine whether the disputed issues go to trial.

In the past 15 years, Boston Scientific has grown from a small player in medical devices to become the second-largest company headquartered in Massachusetts, with a stock market valuation of \$32.2 billion. A big part of its growth came from its venture into stents, which began when it acquired SciMed [Life Systems Inc.](#) of Minneapolis in 1994 and continued when it signed a 10-year supply agreement with Medinol in 1995.

But as it grew, Boston Scientific made costly missteps. The company recalled one stent system, made with Medinol, shortly after it was introduced in 1998 because of leaks in balloons used to position the stents in arteries. This year, Boston Scientific issued three recalls of its Taxus stent system, which it launched in March, because of problems with balloons. The Food and Drug Administration is reviewing the Taxus problems, which have been linked to one death and more than 20 serious injuries.

In sworn testimony, Tobin said the secret Project Independence was another blunder. "It's another of a series of dumb things that the company did to itself that had subsequent effects that should never have happened, could have been avoided, should have been avoided," he said in a deposition.

The Richters, who are majority owners of Medinol, founded the privately-held firm in Tel Aviv in 1992. Medinol was looking for a US partner to distribute its stents. It signed an agreement in 1995 with Boston Scientific, which also purchased a 22 percent stake in Medinol.

Under the agreement, Medinol was to become Boston Scientific's primary source of stents for at least 10 years. The only exception, according to the agreement and other court documents, was a backup manufacturing line that was to be installed by Medinol engineers at a Boston Scientific

make about 1 million stents.

December 1997 Boston Scientific's chief financial officer, Larry Best, and chairman and chief executive, Peter M. Nicholas, sign capital expenditures totaling \$960,035 for BBD.

July 1998 BBD transfers its duplicate of Medinol's machine to Boston Scientific's official facility in Galway. Dublin operation is shut down.

April 21, 2000 Boston Scientific chief executive James R. Tobin tells Medinol founders Judith and Jacob Richter about BBD.

Sources: Company documents filed in the lawsuit between Medinol and Boston Scientific

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facility and kept dormant unless Medinol couldn't supply enough stents.

Relations between the two companies soured soon after the pact was signed, Boston Scientific says. The firm alleges Medinol had regrets and sought to extract higher payments by limiting the number of stents it supplied to Boston Scientific. Boston Scientific also alleges Medinol was late in setting up the alternative line.

According to the Natick company's filings and a company spokesman, the Richters cut off supplies at some points and threatened to do so at other times. The Richters also exhibited "irrational and erratic" behavior, including swearing and screaming at Boston Scientific executives, the suit contends.

Eventually, Boston Scientific says in a court filing, "Their behavior was so outrageous" that Boston Scientific hired a firm to provide counseling for its workers who had to deal with the Richters. According to a Boston Scientific e-mail, the firm provided three-hour training sessions on "ways to deal with Medinol employees and other 'difficult' people."

Medinol, in its court filings, says Boston Scientific never complained about the supply of stents and invented those claims to support its lawsuit. Medinol alleges that Boston Scientific officials made numerous comments, written and verbal, praising the relationship with Medinol and the Richters. In an April 17, 2000, letter, Boston Scientific's chairman, Peter M. Nicholas, wrote to the Richters, "The relationship with Medinol is fundamental to us, and as you and Kobi know, near and dear to me personally."

In its court filings, Medinol denies that it cut off supplies or threatened to do so and contends that Boston Scientific wanted to end its supply contract prematurely and make its own stents after it learned that the Israeli company was earning profit margins of up to 90 percent on the stents.

Medinol cites a quarterly conference call with analysts on Oct. 17, 2000, in which Tobin said: "The history of the relationship has been that the Medinol folks have been reliable. Their history is that they've been reliable in the supply of product." A Boston Scientific spokesman said Tobin was referring only to late 1999 and 2000.

At the least, Boston Scientific wanted out. In October 2001, six years into the partnership, Lawrence C. Best, the chief financial officer of Boston Scientific, said in an interview with an Israeli newspaper that he knew he had made a mistake right after the deal was signed, adding: "The relationship with Medinol is like cancer. It's a terrible thing, you don't know how you got it, but you know you have to get rid of it." Best, in a deposition, has confirmed making that statement.

At the heart of Project Independence was Medinol's unique machine that makes stents by folding flat wire-mesh panels into cylindrical tubes and welding the edges together. Medinol was to supply one of its proprietary folder-welders to Boston Scientific. The machine was to be part of a backup manufacturing facility run by Boston Scientific in case terrorism or some other catastrophe prevented Medinol from supplying stents.

Boston Scientific alleges the Israeli firm was intentionally slow to deliver the machine and that it was "subject to daily breakdowns" while it was being tested in Israel, according to a Boston Scientific company memo among the court filings.

Boston Scientific had no choice but to surreptitiously build its own machine, it asserts in court filings and interviews. The company argues that when Medinol failed to deliver the machine as agreed, Boston Scientific had the right to "cover," or arrange for substitutes for the goods that a seller had promised, according to the Uniform Commercial Code, a series of state laws that govern contracts.

Boston Scientific launched the secret project in April 1997, when its lawyers incorporated an Irish firm called Forwich. That June, Forwich hired an outside consultant to run the company "to shield Boston Scientific from being associated with the project activities," according to an internal company chronology that Tobin gave the Richters in April 2000 when he told them about the secret project.

Forwich conducted business under the name BBD "as another level of protection," according to the chronology and other documents. The name BBD was chosen "to signify 'Bringing a Better Deal' " to Boston Scientific, according to the official company chronology. Throughout the Boston Scientific documents, the names Project Independence and BBD are used interchangeably.

Forwich set up a bank account, registered with local tax authorities, and leased a "ghost office with phone receptionist," according to the chronology. Another company document said there needed to be "no traceable links" to Boston Scientific Ireland Ltd., the company's official

subsidiary in Galway.

In June 1997, Paul Redmond, director of engineering and research and development at Boston Scientific Ireland, told Aiden Flanagan, an engineer who worked on much of the secret operation, that the purpose of the exercise was "to copy the machine," Flanagan said in his deposition.

Boston Scientific Ireland ordered the folder-welder from Medinol on July 1, 1997, according to a purchase order in the court filings. It was shipped on July 20, according to a packing slip filed in court documents, and arrived in Ireland July 25.

When the machine arrived at the official facility at the Ballybrit Business Park, it wasn't even unpacked from its crate, Flanagan said in a deposition. Instead, it was immediately reloaded onto another truck and shipped 135 miles to Dublin. Only two people in the Galway facility even knew the machine had arrived from Israel, Flanagan said.

In Dublin, officials from BBD hired two engineering companies to take the machine apart and reverse-engineer the complex device. BBD also sought suppliers for the steel panels that would provide the raw material for the stents. To hide that it was making stents, BBD told its suppliers it was making "heat exchangers," a common engineering term for devices such as those used to keep electronics components cool.

Besides replicating Medinol's machine, BBD sought to duplicate Medinol's stents so it could test whether the copy could actually manufacture stents. Eric Stenzel, the lead engineer on the BBD project, said in a deposition that he copied diagrams of two types of Medinol stents, the NIR and the NIR Conformer, but altered three pieces of information in his drawings. He changed the name of the device from "stent" to "heat exchanger," the company name from Medinol to BBD, and replaced "Medinol Confidential" with "BBD Confidential."

In late August 1997, BBD shipped the original Medinol machine back to a Galway suburb where Boston Scientific has a facility. The following summer, Boston Scientific shut down the secret office in Dublin but kept developing the unauthorized machine in Galway. BBD kept its version of the folder-welder in a locked, windowless room in the back of a warehouse, according to court documents. The only person with a key to the room was Stenzel, according to his deposition.

At times, Boston Scientific officials involved in the secret project had to deceive fellow employees. Stephen R. Paidosh, a manufacturing manager at the Galway facility who managed the secret Dublin operation, wrote in an e-mail to project participants: "Eric [Stenzel] and I spend an increasing amount of time telling white lies about this activity to our people to keep them in the dark."

While Project Independence was a carefully concealed secret within Boston Scientific, it was known to some senior managers. Best, the chief financial officer, and then-chief executive Nicholas both signed capital expenditure forms totaling \$960,035 in September 1997 to buy a variety of welding equipment and other support for Project Independence. Best has declined the Globe's requests for an interview.

Asked about the project during a deposition, Nicholas, now Boston Scientific's chairman, said it "was a proper, correct thing for us to do in light of the circumstances." Tobin and Nicholas have also both declined to be interviewed for this article.

Medinol charges that Boston Scientific also used cloak-and-dagger methods to build its best-selling Express cardiac stents and its follow-on Taxus drug-coated stent system, which now account for the bulk of the Natick company's stent sales. Besides the Medinol stent designs that Stenzel allegedly duplicated in Ireland, Boston Scientific copied other stent designs, according to court filings. In 1997 at its Minnesota plant, Boston Scientific secretly started to make "knockoffs" of Medinol's NIR line of stents, according to court documents.

At first, Boston Scientific's knockoffs seemed to be part of a cost-saving strategy. Medinol charged Boston Scientific \$75 apiece for stents used for internal research and development. Michael Berman, president of Boston Scientific's SciMed division, said in a deposition that his company was "looking for ways of making cheaper stents that would be equivalent for testing purposes." According to a memo written by Stenzel, the knockoffs would cost only \$25 each.

But between 1997 and 2000, the secret stent-making operation became something larger, Medinol alleges: Boston Scientific used the knockoffs of Medinol's NIRflex stent to develop its Express stent and its drug-coated stent, Taxus. In particular, Medinol alleges that in 2000, a SciMed senior engineer named Graig Kveen copied the design of Medinol's NIRflex stent by "cutting and pasting drawings of the NIRflex" on a computer file, creating purportedly new designs, according to a filing seeking summary judgment.

In court filings, Boston Scientific acknowledges it made knockoffs of Medinol stents, but says Medinol knew about the effort. As with copying Medinol's machine in Ireland, Boston Scientific in court documents argues it had to make knockoff stents "because Medinol was unable to provide" Boston Scientific with sufficient quantities. Medinol charges that under its supply agreement, Boston Scientific was not permitted to make copies of its stents even for research purposes.

Boston Scientific said its top-selling Express and Taxus stents are unique. The company had instructed its engineers to "develop a design that is entirely independent of Medinol patents or intellectual property," it said in a filing.

Ultimately it was the chief executive, Tobin, who told the Richters about all the work his firm had been doing behind their backs. That came after a Department of Justice investigation into Boston Scientific's 1998 recall of the NIR stent system had triggered questions to Boston Scientific executives about Forwich. Tobin, in a July 11, 2000, letter to his board of directors, said that's when he decided to tell the Richters.

"Rather than have the Richters find out about it from the Feds, I told them," Tobin wrote in his letter.

A Boston Scientific spokesman added that Tobin told the Richters mainly because he wanted to make a fresh start with them.

In a 2001 deposition, Tobin recalled that the meeting with the Richters was "very painful." He added, "The emotion I was feeling was just acute embarrassment."

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