

The IP Battleground

Generally speaking, professional experts are loath to predict the future. However mild they may be, such “forward-looking statements” are the stuff of the legal caveats that flesh out every company press release and occupy page upon page in every corporation’s annual report.

So perhaps it should be no surprise that analysts have so far had little to say about the remarkable run of triumphs enjoyed by stent manufacturer Medinol Ltd. (Tel Aviv, Israel) in European intellectual property (IP) litigation against market leaders Johnson & Johnson and Boston Scientific (see sidebar, page 26). Since the middle of this year, Medinol has won a number of key cases, forcing J&J to withdraw its BX Velocity and Cypher drug-eluting stents from the Dutch market and compelling Boston Scientific to withdraw its Express and Taxus stents from the German market and submit accounts for damage calculations.

But a number of suits are still to be heard, including the first such case with potential for pan-European application, and another that may set the tone for future developments in the U.S. market. With the outcome of such important litigation still hanging in the balance, it’s far too early to predict the effects that Medinol’s victories may have on the emerging market for drug-eluting stents.

Whatever the outcome of such future cases, however, Medinol has successfully made its mark as a player to be reckoned with in the future of the cardiovascular marketplace. In this excerpted interview with *MX* editor-in-chief Steve Halasey, Medinol’s senior executives Judith Richter, PhD, CEO; and Kobi Richter, PhD, chairman and CTO; discuss how they built their company and its technology into a cardiovascular IP powerhouse, and what they expect will come from current and future rounds of IP litigation in the field. The complete transcript of the interview can be accessed via the *MX* Web site at www.devicelink.com/mx.

MX: *You once said that when you first founded Medinol, you were really focused on the technology more than the business. How has that changed over the years?*

Judith Richter: Yes, that’s true. Both Kobi and I spent extensive periods of time in academia. Kobi has a PhD from the medical school of Tel Aviv University and has done a lot of research in the area of brain studies. Before we founded Medinol he had previously spent time as a postdoctoral research fellow in the vision group of the artificial intelligence lab at MIT.

I have a PhD in social or organizational psychology, which is a combination of the knowledge of management and psychology, and I’ve

been a professor in the business school of Tel Aviv University for many years.

When we founded the company, we were both very much interested in developing a technology—but also in using up-to-date methods of management.

Together, the two of you also brought to your new company some significant and particularly relevant professional background.

Judith: Yes. In the past I worked at Teva Pharmaceutical Industries Ltd. (Petach Tikva, Israel), which is the largest pharmaceutical company in Israel. Today it is also one of the largest generic pharmaceutical companies in the United States.

Kobi Richter: My background was not only academic. I founded with a few other, very talented people a more-traditional high-tech company called Orbotech, which is still a world leader in the field of automated visual inspection machines for the microelectronics industry. That application of digital image processing grew out of my experience in brain research at MIT.

In addition, I spent many years leading the R&D department of the Israeli air force, where I was exposed to many diverse technologies.

With your backgrounds, you might have gone into computer sciences, telecommunications, or a similar area. Why did you choose to create a

With their recent IP victories in European courts,
Medinol's **Kobi Richter and Judith Richter**
are shaking up medtech's cardiovascular sector.

Interview by
Steve Halasey

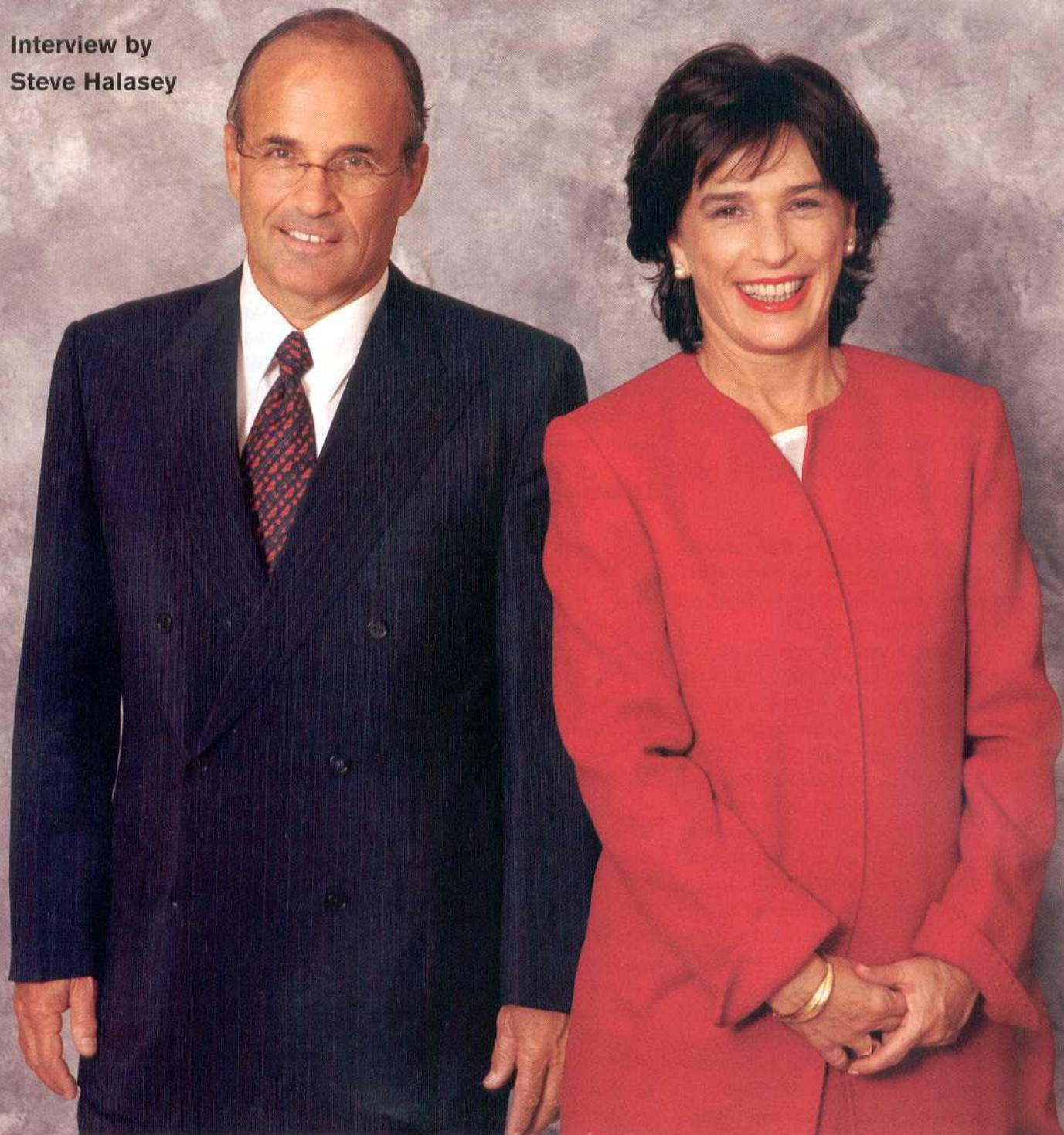


Photo courtesy Medinol Ltd.

medical products company?

Judith: Because both of us love the medical field. I had just come out of Teva, from the pharma side, and Kobi had a very extensive background in the medical field. After spending some years in the microelectronics and computer sciences fields, he came back to the medical field. That was a field in which we could join forces and create a company together.

Kobi: After our earlier experiences, we felt that we were standing at an intersection. We had developed significant knowledge about available cutting-edge technologies, but also had an understanding of the need for new medical applications that could lead to new businesses and new products. That was also a part of our decision to go in this direction. We wanted to take advantage of our ability to apply technologies that were not yet part of the portfolio of medical device manufacturers and could improve that field or take that field to another level.

How did that happen? Was it partly based on your sense of the market opportunities for coronary stents, or was there more to it?

Kobi: I find the opportunity to intervene in a helpful way much more exciting than the opportunity to monitor, even if in a very sophisticated way. So my personal bias is more toward interventional medicine than toward the diagnostic or monitoring areas. Those areas are definitely important, but on a personal level, intervention is more attractive to me.

But at the end of 1993 or beginning of 1994, when we decided that a part of Medinol would focus on stents—and before the first coronary stent was approved in the United States—no analyst saw a market of more than a few hundred million dollars worldwide by the year 2000.

So when we came in with a busi-

ness plan that said the market for coronary stents in 2000 would be a little over \$2 billion, everybody laughed. We then had to say, 'Guys, all you're seeing is how the uses that we know about today can develop. What we see is what is there to be done. And, in three or four years, those uses will bring to the market things that you can't even dream about today.'

This is why our view is different.

Have the results of your recent IP litigation changed your company strategy for the future? Are there particular opportunities that have opened or been closed off by the decisions?

Judith: I don't think any opportunities have been closed off. On the contrary, I think new opportunities have opened up. But as far as our strategy goes, we continue to be focused on invention and technology. We think that we have the right resources to be creative and invent innovative solutions.

Technology Development*How was your initial R&D funded?*

Kobi: We were in the fortunate situation that Orbotech—the company that I founded 10 years earlier, in 1983—had already become successful. So Judith and I had enough private resources to fund the growth of Medinol until companies that we thought were worthy strategic partners began to take an interest in teaming up with the company.

How did you turn the corner from your market projections of 1993 or 1994 into a business plan for your company?

Judith: I don't think that was the way we developed. We became very excited about the product that we were developing and the results we observed in animal trials. At that stage we were very much absorbed by the application, and I don't think we were

as aware of the economic aspects as one might expect.

Kobi spent a lot of time in catheterization labs watching procedures and visiting with cardiologists who would comment about the procedures they were engaged in. And it was there that he observed firsthand the advantages and disadvantages of those procedures. Eventually, that led us to look for solutions to the real problems that physicians were encountering.

Maybe in this sense we were a little bit different from others. We didn't outsource any of our development activities. We were really interested in the product and in the efficiency of manufacturing it.

How does that process differ from the way that other companies work?

Kobi: I'm not sure I know how all companies work. But many companies have talented engineers, and many physicians know what they are lacking, and these two groups almost never speak the same language.

The most limited commodity in medical device companies today is the group of people who can serve as a bridge between the engineers and the physicians—people who are at the same time versed in the technology and knowledgeable about medical applications. These people are the most essential and least available resources necessary for developing new approaches and new technologies.

We were fortunate, in that we happened to start from that position. We started with a very small group that already had the capability to integrate technology with medicine. And if you are going to create a medical device company, I think this is certainly the right place to begin. From this base, it is much easier and faster for the company to identify additional engineers that it wants to recruit, or physicians that it wants to work with.

What was the process that led to Medinol's unique stent design?

Judith: Medinol designed each stent based on observations that Kobi made when visiting with physicians working in catheterization labs. Kobi frequently visits cath labs, and since he has a medical background and understanding of biological mechanisms, he is able to grasp the needs of both physicians and patients.

Did the process of designing a stent involve a large number of the company's engineering staff?

Judith: No, the process would usually be limited to Kobi and Grisha Pinchasik, who is Medinol's chief engineer and one of the company's founders—as well as a good friend. In other words, it would most often be just these two people working on new designs.

The result is that Medinol has IP related to its stent designs, all of which are patented under Medinol's name. Medinol's unique manufacturing process is also protected by patents.

How is Medinol's manufacturing process unique?

Judith: All of the other stents on the market are manufactured by taking a slotted tube and cutting it with a laser. Medinol is the only manufacturer using a manufacturing process that is common in the microelectronics field but is completely new to the medical field.

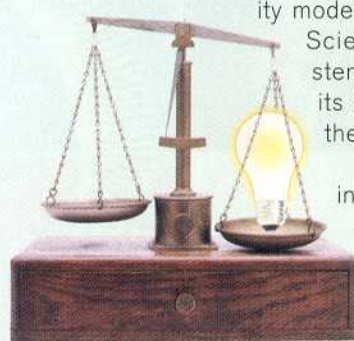
Medinol manufactures multiple stents simultaneously using flat panels of stainless steel, which are then photochemically etched with a design pattern. Each stent is then cut out from the flat panel, folded, and welded. In the next step, the stents are put through electropolishing in order to smooth out their surfaces.

It is relatively easy to adopt changes in this manufacturing process in order to accommodate new

A Run of Favorable Rulings

Experts in international intellectual property litigation are traditionally cautious about predicting the ultimate outcome of IP disputes, since rulings that seem to be running in one direction can too readily be overturned in other courts. Whatever the ultimate outcome of current disputes over IP for the design and manufacturing of cardiac stents, Medinol has enjoyed a remarkable run of favorable decisions in European courts and patent offices. Following is a synopsis of the key court decisions issued since the middle of 2003.

June 24: The patent chamber of the district court in Düsseldorf, Germany, rules in favor of Medinol in a suit against Boston Scientific alleging patent infringement of Medinol's German patent EP 0 762 856 and utility model 295 21 206. The court orders Boston Scientific to withdraw its Express-design stents from the German market, and to open its books to Medinol in order to determine the amount of further damages to be paid.



In a press release, Boston Scientific initially maintains that the decision relates only to its Express stent, not to the Taxus stent; and that it applies only to its German subsidiary, not to other subsidiaries or to the parent company. In a letter to Medinol on July 18, however,

Boston Scientific acknowledges that the court ruling applies to the parent company and to all Express-design stents—including the Taxus stent. The court subsequently issues a clarification, confirming that its original decision covers all of Boston Scientific's stents, including the Express, Express², and Taxus models; and that the decision applies to all Boston Scientific companies.

July 3: The court of appeals in The Hague, The Netherlands, rules in favor of Medinol in a suit alleging that Johnson & Johnson's BX Velocity stent infringes Medinol's intellectual property. The court orders Cordis B.V. and Cordis Europe N.V. to cease all infringing activity in The Netherlands within 48 hours and sets penalties of approximately \$45,900 per breach.

In a follow-up to this decision, J&J asks the court to remove the Cypher stent from its earlier action, arguing that it should not be included in the injunction. On August 26 the court denies J&J's request, ruling that the Cypher is included and barring J&J from conducting any infringing activity related to that stent.

July 9: The cancellation division of the German Patent and Trademark Office (Munich) rules in favor of Medinol, in an action originally filed by J&J (joined by Boston Scientific) to invalidate Medinol's German utility model 295 21 206. When Boston Scientific had the license to market Medinol's stents, in May 2001, it won a similar case against J&J based on the same utility model. The July ruling permits the utility model and pertinent claims to stand.

September 10: The district court in The Hague, The Netherlands, rejects a suit by Scimed Life Systems, a Boston Scientific subsidiary, alleging that Medinol had infringed its balloon catheter patents. The decision also invalidates the Boston Scientific patent on which the suit was based.

stent designs or to manufacture the same stent in different dimensions. You can therefore expect us to be very fast in implementing new ideas.

The IP Picture

With regard to its stent products, how did Medinol's IP portfolio develop?

Kobi: Medinol's IP package is very broad and quite impressive. Each of the patents in that portfolio began as a functional definition; not a design for a device or process, but a description of what functions such a device or process would perform, and how it would behave. Only when the functional definition was complete did we reduce it to patentable form as the design for a specific device or advance relative to the existing art. And those designs were then reduced to patents in the important territories.

So the reason our IP package developed so broadly and so quickly is that we didn't just say, 'here's a neat little device, let's protect it.' Instead, we attacked a field and tried to identify what we thought were deficiencies or processes that could be improved upon. From that we deduced the family of devices that we started protecting.

Medinol's recent litigation has involved two forms of intellectual property rights: patents and utility models. The latter concept is not used in the United States; can you explain it?

Kobi: Yes, the rights that were issued to Medinol took the form of both a patent and a utility model.

A utility model is a tool that conveys patentlike rights, and is available in Germany and a number of other European countries. When a company files for a utility model, the patent office reviews the disclosure and claims in the filing to determine whether the claims are properly emerging from the disclosure. If those elements are in order, the office issues

the utility model.

The key difference between a patent and a utility model is that for the latter, the patent office does not look into prior art to determine the inventiveness or validity of the filing over other, previously issued patents. So unlike a patent, a utility model is not presumed to be valid. It's only presumed to be a correct disclosure of an alleged invention.

When one party sues another for infringement of a patent, the court is entitled to presume that the patent is valid, and only the defendant can challenge that presumption.

By contrast, when one party sues another for infringement of a utility model, the court cannot simply assume that the IP is valid and deal only with the issue of infringement. First, it has to attend to the issue of whether the IP is valid over prior art. And only if the court determines that the IP is valid can it continue to consider the issue of infringement.

How did you handle additional IP filings as Medinol further developed its stent technology and manufacturing processes? Were all of those filings made directly by Medinol?

Kobi: Always. The rights to our IP were always left as belonging to us, and were never shared with others. In our agreements with Boston Scientific, for example, it was stated clearly and explicitly that Medinol's IP rights belonged exclusively to Medinol and would always remain as such.

Partnering

How was it that you came to the attention of Johnson & Johnson and Boston Scientific?

Kobi: We began conducting pre-clinical animal trials in the summer of 1994, working with Martin B. Leon, MD, at the Washington Cardiology Center of Georgetown University Medical Center (Washington, DC).

Up to that time, Dr. Leon had been instrumental in guiding Johnson & Johnson Interventional Systems, which was the group that was leading J&J toward a marketable stent product.

When Dr. Leon saw our product, he asked if we would be interested in being introduced to Marvin Woodall, who was then president of Johnson & Johnson Interventional Systems. He then called Woodall and told him, 'I'm now experimenting with a device that is a major advance relative to your devices, and I think you should see these people.'

Shortly after that we met and started to work with Johnson & Johnson.

Was the Boston Scientific contact also a personal one, or did your work with J&J bring you to their attention?

Kobi: After we started working with J&J we also began presenting at various conferences. Boston Scientific heard about us mainly a year or so later, in June 1995, when we reported on our first and very successful human trials, which were conducted in Italy.

They noticed that the performance of our device was way, way out of the box. And that was when they began to approach us more aggressively.

However, we did not start talking seriously with Boston Scientific until our possible deal with Johnson & Johnson did not go forward.

IP Litigation

Your relationship with Boston Scientific has disintegrated into widespread IP litigation. What is the key issue of that litigation?

Kobi: Well, among other things, what became the key issue is the fact that Boston Scientific decided to copy without permission our stent design and our manufacturing process, both of which are the subjects of many

In the Pipeline

Medtech companies frequently live and die according to the strength of their ability to innovate—to develop new products that can be readily adopted into clinical practice. Few events are more likely to undermine those abilities than protracted IP litigation such as that in which Medinol has become embroiled since 2001.

In spite of such obstacles, Medinol has continued to press ahead with its product development activities, filling its pipeline with stents designed for a variety of applications. The latest version of the company's coronary stent, called Nirflex, is available in Europe and undergoing clinical trials around the world. A version of the stent called Nirside flex, designed for use in bifurcated coronary arteries, is also under development.

Medinol is also conducting extensive research into other stent applications, including those for peripheral, neurovascular, and renal use. A number of such products are currently in various stages of clinical trials.

Perhaps just as boldly, considering the company's recent experiences, Medinol is continuing to partner with other medtech companies for the advancement of

its stent products. Medinol and W. L. Gore & Associates (Flagstaff, AZ) will soon launch their NOA system, the first product to result from their collaborative alliance relating to



Cutaway illustration of the NOA coronary stent system by Medinol and W. L. Gore & Associates.

Illustration courtesy W. L. Gore

stents and stenting solutions. Announced in September 2002, the alliance is intended to make use of Medinol's leadership position in cardiovascular stent technology and Gore's recognized capabilities in expanded polytetrafluoroethylene (ePTFE) processing and materials.

The NOA system combines Medinol's Nirflex stent with Gore's ePTFE Aptera balloon. The system is designed to permit "complete stenting," allowing for direct stenting and postdilatation with a single system.

The first clinical implant using the system was performed in May at the London Chest Hospital (UK). Over the course of two days, a total of eight NOA systems were used to treat six patients. More than 50 systems were subsequently used in leading hospitals in Germany, Italy, and France. The NOA system will soon be available for sale in Europe.

patents.

In many ways, the issue of copying our devices directly is even more acute than the issue of happening to infringe our patents. It's not a surprise that Boston Scientific's stents and process infringe on Medinol's IP, because the company had access to our articles under an agreement. And contrary to the terms of that agreement, they actually copied the articles and used them improperly.

Now, when you take a company's product and copy it, of course you

will also happen to infringe its patents. It's not surprising.

What is the position of Medinol's intellectual properties relative to other stent manufacturers?

Judith: We believe we have a strong intellectual property position, which has recently been confirmed by several courts in Europe.

Medinol recently won a patent case in Germany, in which the court ruled that Boston Scientific's Express stent infringes on Medinol's IP, and

ordered Boston Scientific to stop selling the Express, Express², and Taxus stents in Germany.

In The Netherlands we have just won an IP battle against Johnson & Johnson, in which the court ruled that J&J's drug-eluting stent, the Cypher, is infringing Medinol's patents. The court of appeals in The Netherlands ruled that Johnson & Johnson cannot sell the Cypher stent in The Netherlands.

Is it your hope that Boston Scientific and J&J will agree to license your technologies, or do you hope to force them to withdraw from the market?

Judith: We always look first to what is best for patients. Whatever agreement the companies may reach, we would be happy to adopt it so long as it serves the best interests of the healthcare community.

Conclusion

Many medtech companies are finding it necessary or desirable to enter into partnerships of various kinds. On the basis of your experience, what advice would you offer those companies?

Judith: Medinol is a very passionate company, and when an idea is presented we are very quick to react. We process the proposal in the quickest way possible, and action quickly follows. This is an area that we are looking into as it relates to evaluating the compatibility of another company with Medinol.

Personally, I believe that the cultural environment of an organization is a major factor in the success or failure of a collaboration. This applies not only to a company's technical capabilities, but also to the business culture of the organization—its philosophy, beliefs and, most importantly, people. In order for a collaboration to succeed, the business culture of your partner should align with your set of values and ethics. ■