

has been in the injection molding business since 1958, serving as technical director of a large company that makes molded parts in Brescia, which is outside of Milan. Andrea Venturelli recalls that his father's work was also his hobby; Luigi would come home and make small plastic model airplanes and cars for his kids. In the mid-1970s, with fiber optics becoming popular, Luigi and Andrea built a small extruder in their home to try to make fiber optic wire. While that effort was unsuccessful, they were able to manufacture a multi-lumen tube, which Luigi brought to work and hung near his desk, where it caught the attention of some visiting Sorin executives. It turns out Sorin was looking for someone to make multi-lumen tubes for the company's pacemakers and asked Luigi if he could duplicate his initial effort. "My father said, 'Yes, we can do that but we cannot invoice you because we don't have a company,'" Andrea explains. The result: Luigi Venturelli formed Fogazzi, using his wife's family name, as a small research company with expertise in all aspects of plastic processing, including extrusion, molding, welding and joining, prototyping, and small-scale production.

Sorin was Fogazzi's first customer but Luigi Venturelli's business wasn't limited to the medical field. As his reputation grew, Luigi developed relationships with Italian universities and research foundations, working on a variety of industrial applications for extruded plastics such as fuel lines. But Fogazzi's medical work continued to grow in parallel with its industrial customers, driven initially by the relationship with Sorin, which approached Fogazzi about developing catheters after the success of the multi-lumen tubes he had originally produced. "The principle was the same as for the tube we made them so we changed from making tubes to making catheters," recalls Andrea, who was in his mid-teens and would work with his father at home on evenings and weekends to produce the catheters.

Fogazzi's experience as catheter manufacturers came at a time when the small plastic tubes were not as ubiquitous as they are now, and the company's capabilities, limited as they were, placed them in demand. Fogazzi began to receive inquiries from the Italian National Research Center, from universities and from physicians and researchers about building different types of catheters. "We didn't have any medical background," Andrea Venturelli admits. "But doctors would come to us and try to explain what they wanted us to build. Often you would discover that what the doctor wanted was just not possible and it was our job to help them come up with a different design."

After Andrea finished high school, he became Fogazzi's first and only full-time employee. Luigi Venturelli used part of his pension to buy a larger extruder and worked on the research and development of projects; Andrea handled all the other aspects of the business, from the production to the pricing to the delivery.

One of Fogazzi's catheters, which included a fiber optic wire made for an Italian university, came to the attention of Giancarlo Biamino, MD, of the Rudolf Virchow

Klinikum's Department of Angiology and Laser Angioplasty in Berlin, Germany. Biamino, a pioneer in the use of laser ablation for peripheral angioplasty, approached Fogazzi about developing a catheter that included a bundle of fiber optic wires to deliver laser energy. "Professor Biamino told us, 'We have the laser, we have the patient, but we don't have the medium to move the energy into the patient,' and he asked if we could build that," Andrea Venturelli recalls. Fogazzi successfully developed some of the first laser ablation catheters, which led to a relationship with **Technolas Laser Technik GMBH**, a Munich-based company that was among the European laser pioneers and was having a similar problem finding catheters to effectively deliver laser energy.

Technolas yielded more than simply another customer for Fogazzi; it marked the Venturellis' introduction to Stefan Widensohler, President and CEO of **Krauth Medical KG (GMBH & Co.)**, one of Germany's leading medical distributors. Krauth handled Technolas, which is how Widensohler heard about this small Italian family business on the cutting edge of catheter technology and led to a longstanding relationship between Widensohler and the Venturellis that was instrumental in the launch of Invatec.

By the late 1980s, Fogazzi was receiving more requests, both medical and industrial, than its limited capabilities could handle. Luigi Venturelli retired from the plastics company to join Andrea on a full-time basis, but it quickly became apparent that the two would not be able to efficiently handle the growing business. The Venturellis decided to split the business into its two components; the industrial projects would be handled by a new entity called Vales, while Fogazzi would remain dedicated to the medical business. "Since I was not interested in spending my life making industrial tubing, I took in a minority partner and taught him the technical and commercial parts of the industrial business at Vales so I could focus on the medical projects with Fogazzi, which is what I like more," Andrea Venturelli explains.

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### One Company's Loss is Another's Birth

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The increased demand for Fogazzi's catheters on the part of device companies like Technolas changed the primary nature of the Venturellis' medical business from a specialty supplier to individual physicians, to an OEM supplier for other medical products companies. Fogazzi continued as an OEM supplier into the mid-1990s when a downturn at Krauth turned out to work to the advantage of the Venturellis. Around that time, many large cardiovascular companies began shifting their European business away from independent distributors in order to sell direct. For 13 years, Krauth had been the German distributor of Schneider's angioplasty catheters, only to find out in mid-1996 that Schneider was going direct. Facing the loss of a significant line of business, Stefan Widensohler approached Andrea Venturelli with a proposition: if Venturelli could produce a line of angioplasty catheters and balloons, Krauth would market them. It

turns out that Fogazzi was just concluding a four-year project funded by the Italian government to develop a percutaneous transcatheter coronary angioplasty (PTCA) balloon catheter to particular specifications, so the company was familiar with this product area.

Andrea Venturelli agreed to produce the catheter for Krauth and decided he needed to set up a new company to market branded products, separate from Fogazzi's OEM work. The result: the founding of Invatec in June 1996, the company's name drawn from its focus on innovative technology. Invatec was and remains privately funded by the Venturellis and Stefan Widensohler is a member of the board. Invatec delivered its first products to Krauth in the beginning of January 1997, which were *Sailor* peripheral transcatheter angioplasty (PTA) balloon catheters, and followed those with *Scuba* coronary balloon catheters six-months later. Invatec currently offers a full line of PTA balloon catheters that include rapid exchange features, PTCA balloon catheters, bypass and support catheters, clot extraction catheters, introducer sheaths, and coronary and peripheral guidewires.

From the outset, Andrea Venturelli's vision was that Invatec would not be limited to selling to a particular national or regional market, but would produce advanced technology products that are in demand worldwide. Widensohler had a similar view of the company's poten-

tial, which is why he encouraged Venturelli to sell branded products, as opposed to embarking on an OEM strategy, such as marketing products in Germany under the Krauth name. "In Germany, Krauth is known as a leading medical device distributor and service house," Widensohler explains. "We have no intention to expand to become a global manufacturer. While we could have been very successful in marketing a Krauth brand in Germany, the Krauth name wouldn't mean much beyond Germany. So we decided that, if you want to establish a global company, it makes more sense to start off with a new brand that develops its own product lines."

Krauth was taking a big chance hoping that the unproven Invatec product lines would be able to fill the huge gap created when Schneider pulled its business as of December 31, 1996. Krauth was particularly strong in peripheral and coronary angioplasty products and the loss of Schneider represented a potential to Krauth that Widensohler says could have run well into the millions of DMs. Yet, selling Invatec's products, Widensohler claims it took Krauth only three-and-a-half months to restore its peripheral angioplasty business to the same level as when Krauth was marketing Schneider's devices.

Widensohler estimates that Krauth was able to convert approximately 80% of its previous Schneider accounts to Invatec and made up the lost ground with new accounts.

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#### FEATURING:

- AbTECH S.A.
- Affitech A.S.
- Altarex Corporation
- AMGEN
- Arius Research
- Atopix Pharmaceuticals
- Bard Biopharma
- Bioscience Ventures, Inc.
- Cambridge Antibody Technology
- Cell Matrix Inc.
- Celltech Group plc
- Chiron Corporation
- Corixa Corporation
- Exelixis Inc.
- Forward Ventures
- Genentech
- Genway Biotech
- IDEC Pharmaceuticals
- Immunogen Inc.
- JPMorgan Chase H & Q
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And, he says, "I can guarantee you we didn't do it on price because we needed the higher margins that we could get now through Invatec as profits in order to build this business."

The fact that Krauth lost a major line in a mature product segment and yet was able to regain that lost business in three months selling devices from an unknown company speaks both to the value of the distributor and the importance of technological sophistication. Krauth is a well-established distribution house with close customer contacts, and Invatec was able to deliver sophisticated, high quality products that physicians immediately recognized the value of, even if they didn't recognize the brand name.

Invatec has maintained a global policy of not trying to gain market share on price. With products currently commercially available from distributors throughout Europe, in Australia, much of Asia (including Japan, China and India), and in South Africa, "we are on the high side in terms of price in many cases," acknowledges Invatec's marketing chief Bob Reeder. "And customers are still buying our products based on performance and quality." (Invatec didn't enter the Italian market until January 2001, because of Italy's notoriously slow reimbursement process and it did so by launching a separate distribution company, **Invatec Italia**.)

Andrea Venturelli credits Invatec's success in these various worldwide markets to the company's strategy of tailoring its business to its customers' needs. But the company's move into its second major overseas market had less to do with customer responsiveness than with being in the right place at the right time. Just as Krauth had seen Schneider shift from distribution to direct selling, in Japan, **Getz Bros. Co. Ltd.** distribution group was about to lose access to ACS angioplasty products because ACS was going to sell direct. Stefan Widensohler approached his long-time friend, Ray Simpkins, President of Getz, and after commiserating about how their respective distributorships were being abandoned by large cardiovascular companies, sold Getz on Invatec. Invatec then entered into a distribution agreement with Getz for Japan.

Of course, Invatec's responsiveness and flexibility has helped it sustain its share of the Japanese market. Andrea Venturelli notes that Invatec realized early on that the types of products that sell well in Europe may not necessarily be as popular in Japan due in part to differences in clinical practices. For example, in Japan there is not the same economic pressure for interventional cardiologists to finish cases as quickly as possible, as exists in the US and Europe. "There is a Japanese expression that says, 'It doesn't matter how long it takes to complete a PTCA procedure—it's enough that the physician finishes in one day,'" he says. The effect of this attitude on practice patterns is Japanese clinicians don't care so much how long a procedure takes and what it will cost; they are intent on opening up all blockages, including total occlusions when possible. So Invatec focused on developing catheters and balloons that could be used in the smallest

vessels and others that can cross total occlusions.

Stefan Widensohler argues that Invatec's emphasis on customer responsiveness distinguishes a small company like Invatec from Schneider and other large cardiovascular device companies. "We brought to Schneider the only major in-house development that company came up with, which was the monorail catheter technology, when Tassilo Bonzel, MD, the physician who developed it, contacted one of our sales reps, and yet it took us almost one year to convince Schneider of the value of this technology, which became their most important technology feature," he claims. "When we bring physicians to Invatec, the company is able to turn their questions into answers very quickly." But that, in part, defines the challenge for Invatec, particularly as it makes the transition from small designer of custom products for physicians and OEM customers to an international player serving global markets: can it retain the responsiveness and customer focus that has brought it this far? Big companies are, by nature, not by choice, less responsive than small companies, if only because high levels of customer responsiveness become difficult as a company grows larger in size and serves more customers. Like the value it places in its family roots, Invatec's high service levels will be challenged as it grows beyond a national or even European marketplace to embrace Japan and, in particular, the US.

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### Vendor Independence

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Invatec's primary core competence is in plastics, yet many of the devices the company currently markets contain important metal components. Andrea Venturelli is proud of the way Invatec has been able to add metals expertise to its plastics knowledge to expand its overall core competencies. Having this full range of in-house technical capabilities is also an attribute that distributors prize. "Where do you find manufacturers that have the expertise in both plastics and metals as core technologies that enable them to be vendor independent?" Stefan Widensohler asks. Vendor independence not only enables a company to avoid the inevitable delays inherent when relying on outside vendors, it also helps speed response times and reduce time to market, giving Invatec what it hopes is a significant advantage over big device companies that are slower to respond to market demands.

When it comes to developing new product ideas, "We are not geniuses," admits Andrea Venturelli. "We just try to produce what the market needs based on what the doctors tell us." The hard part, he explains, is in translating a physician's idea for a new or improved device into an actual product. "Often the doctor just comes to us with a feeling about how something will work, but they don't have any technical engineering background. We want the doctor to think about Invatec and Fogazzi as their in-house developer," he goes on.

One example of how this process works resulted in the development of Invatec's PTCA bifurcation balloon. Leading interventional cardiologists Antonio Colombo, MD, and Imad Sheiban, MD, approached Venturelli about de-

veloping a balloon to treat bifurcated lesions. These are very difficult to treat lesions that develop where a smaller vessel branches off of a main vessel and the lesion appears in both channels. The cardiologists' idea was to develop a new catheter system, based on Invatec's multi-lumen technology, that would have one shaft with two guidewire channels and two mounted balloons. Two months later, Invatec provided Colombo with a prototype and one month after that, the physician used the device on the first patient. "If they were to have asked the same question to any of the large companies, it would have taken them a year-and-a-half to respond," Widensohler argues.

Invatec's strategy of quickly getting individual physician's ideas translated into new products also has that neo-traditional flavor, harkening back to a time when a much larger part of the device business grew out of individual physicians working with small companies to produce new products. Yet does focusing on responsiveness to individual physicians effectively limit Invatec to building a niche, customer service-focused business, one that doesn't access the broader physician market?

Andrea Venturelli rejects that suggestion, arguing that Invatec is "creating a link to the doctors" and having that access will result in the development of new products that will be of interest to physicians as a whole. "When you create that link with the key opinion leaders, that's not easily forgotten," he adds. For a small, young company, Invatec has been remarkably successful in getting its products in the hands of leading interventional cardiologists. At this past year's Paris Course on Revascularization (PCR), the leading European interventional conference, Invatec products were used in 25 of the live peripheral cases presented. By comparison, Bob Reeders points out that Guidant products were used in 22 live peripheral cases, Boston Scientific devices in 30, and Jomed products in five.

Stefan Widensohler shares the view that Invatec's individually generated designs can translate to a larger audience, but also doesn't believe that serving niche markets is all bad. "Especially in Europe, some of the so-called niches are actually pretty large markets that the big companies have deliberately ignored because it's not worth it for them. But what is a niche for a big company is not necessarily a niche product for a company like Invatec, and with nobody else tending to these markets, these products can yield very high margins," he argues.

Reeders points to the PTCA bifurcation balloon as an example of one of those profitable niche products. Of the 1.4 million angioplasties performed worldwide each year, five-to-eight percent involve bifurcated lesions, producing approximately 60,000 cases for Invatec's new product in an area where there is no competition and therefore can provide higher margins.

### **Mo.Ma's Not Just a Museum in NY**

The product that has gotten Invatec most of its recent attention falls in a category that can hardly be classified a niche by anyone's definition. The company's *Mo.Ma* cerebral protection device, which became available in Europe in September 2001, is designed to enable interventionalists to safely perform carotid angioplasty and stenting by protecting the brain from the risk of emboli-induced stroke. The whole area of embolic protection devices is among the hottest and most competitive in interventional cardiology today, both for coronary and carotid angioplasty.

The current treatment for carotid artery disease is carotid endarterectomy (CEA), an extremely traumatic surgical procedure, but one with very high success rates.

Because of the stroke risk inherent in working on the brain's primary artery, interventionalists have been reluctant to adopt carotid angioplasty procedures, especially since these techniques have not been able to duplicate CEA's low morbidity and mortality rates. Cerebral protection devices are intended to help convert the primary therapy for carotid artery disease from surgery to angioplasty and stenting by providing interventionalists with a means to minimize the stroke risk by protecting the brain against emboli migrating up from the carotid during the procedure. The mechanism by which this is best accomplished is the subject of strenuous debate among physicians and fierce

competition in the marketplace.

The specific criteria that are important to physicians in a successful cerebral protection device include the ability to capture all size and type of emboli, avoiding inducing emboli and injuring the target vessel wall during placement and retrieval, and preserving cerebral blood flow if possible. Numerous companies are currently employing several different approaches to cerebral protection, and the marketplace has yet to pick a winner.

The initial leader in this field and the first to have a product approved in the US is **PercuSurge Inc.**, now part of **Medtronic Inc.**, with its *Guardwire Plus* system, which employs a distal occlusion balloon to block blood flow and then aspirates out the collected debris. On the other end of the embolic protection spectrum are the companies using various distal filtering approaches. The filter technologies differ but have in common the fact that all filters permit blood flow during the procedure and trap debris through retrieval systems that collect material and are removed, along with the debris, at the conclusion of the procedure. Filters have attracted the most interest in terms of the number of companies pursuing this approach. Currently, four of the top cardiovascular giants are pursuing a filter approach, including Boston

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