



EPO SME CASE STUDIES | MICREL MEDICAL DEVICES

# Smart infusion pumps for treating patients at home

Micrel Medical Devices is a Greek medical technology company that develops, manufactures and markets a full range of ambulatory infusion pumps, accompanying administration sets and patient infusion control and monitoring systems. An unfortunate experience with patents thirty years ago taught the company that it pays to take IP seriously. Nowadays it uses patents strategically to safeguard future product lines, and patent information to analyse the market, monitor competitors, ensure freedom to operate and find inspiration for new technical developments.



Micrelcare allows remote reporting and monitoring of clinical and technical information and instant control of the infusion therapy.

Micrel Medical Devices is a family-owned company founded in Greece in 1980. Its first product, an ambulatory syringe pump, allowed patients suffering from thalassaemia, a rare blood disease that is prevalent among people of Mediterranean descent, to be treated at home instead of in hospital. Following that success, Micrel developed a full range of ambulatory volumetric and syringe infusion pumps for home and hospital care, all with the aim of making the treatment of patients more comfortable.

Micrel continues to specialise in the design, manufacture and marketing of “smart” drug delivery systems for hospital and home care applications. One example is a new rhythmic web-programmable ambulatory pump for clinical research. These innovative and user-friendly infusion pump systems are tailor-made for delivering specific therapies, including pain control, parenteral and intravenous nutrition, and Parkinson’s disease and cancer treatment. The products are small in size and have a low power consumption, which makes them particularly user-friendly.

The current medication practice is still to infuse drugs to unattended patients, based on preliminary tests resulting in a provisional treatment schedule. In many cases, the patient has to stay in hospital until the doctor finds a working prescription protocol. Using Micrel’s solutions, doctors can send the patient home and refine the treatment over the internet. Patients can easily inform healthcare staff about their state of health and can live a normal life while their therapy parameters are being monitored. Doctors, nurses and home-care service providers can access the status of their patients’ infusion and therapy outcome online from anywhere. Nurses receive text messages with selected notifications about the status of the infusion and therapy, enabling them to anticipate potential problems.

Micrel is characterised by a market-driven innovative culture with flexible manufacturing and a strong R&D base. Its commitment to research is a key factor in its long-term success, which has allowed the company to grow from 45 employees in 2012 to 80 in 2016 (13 of whom work in the R&D department). Micrel is currently present, directly or through distributors, in more than 30 countries around the world, covering most European markets, the Middle East, Africa, Asia, and South America. It also has subsidiaries in Germany and Sweden.

Micrel’s main competitors are large multinationals such as Smiths Medical, Becton Dickinson and Hospira. But Alexandre Tsoukalis, CEO and co-founder of the company, is confident that Micrel is prepared to face the challenges ahead, as it already has the right technologies in the pipeline, and is in the process of expanding its activities into the large volumetric pump (LVP) market.

## TECHNOLOGY PROFILE

## Rythmic™ connect

Remote control for home infusion therapies



Rythmic Connect is a real-time wireless technology which uses a GPRS device (“IP Connect”) to enable an ambulatory pump to communicate with a web server and provide its infusion status online through the MicrelCare system. The system provides instant feedback on therapy results and side-effects. This feedback can be obtained by inserting an implantable catheter tip into the bloodstream to measure parameters such as temperature, blood pressure, glucose, oxygen and certain ions via sensors embedded in the catheter or by the pump asking the patient about conditions such as diarrhoea, vomiting, nausea or pain. This web-based service enables healthcare staff to monitor clinical and technical information relating to the infusion therapy and to adjust the infusion protocol remotely.

“There is no need to be scared by the big multinational companies. Change will come from SMEs. They have the creativity and speed to innovate.”



**Alexandre Tsoukalis**  
CEO and co-founder,  
Micrel Medical Devices

## Pioneers in smart health

Micrel has a long tradition in developing pioneering technologies. These technologies create new markets and value networks but, compared with operating in established markets, the process can take longer to develop, and the accompanying risk is higher. In 2003, the year GPRS, one of the earliest communication-via-satellite services, entered Europe, Micrel exhibited the first infusion pump with a GPRS module on the market at a trade fair in Dusseldorf. At the time, vital signs monitoring through satellite communication was limited to military applications, and the terms “Internet of Things” and “smart wearables” were unknown. Micrel’s communicating drug delivery system represented a major breakthrough in monitored ambulatory patient care. However, the market and existing telecom infrastructure were not ready to implement this spearhead system. It took ten years for the technology to be successfully established on the market. Alexandre Tsoukalis assumes that the growing use of mobile phones had a large impact on the acceptance of the technology: “In 2006, doctors were still afraid of connected technologies. They were using the pumps but not the server. Now their attitude has changed.”

The fact that Micrel’s monitoring system is covered by a patent application filed in 2001 (EP 1385420), which secured exclusivity for the invention, allowed it to keep investing in the technology and moving it forward in its early years. It is very cost- and labour-intensive to establish a breakthrough technology, as there is no market or infrastructure for it initially. Without patent protection the technology leader would be copied, especially by big companies, as soon as the market understands the technology and starts to adopt it – at a fraction of the pioneer’s cost. Micrel has continuously improved and enlarged its product line. The second-generation product, providing an even better and more user-friendly server, has been on the market since 2011. In parallel, the company has been careful to protect the inventions involved. The superior quality of the products, in combination with IP protection, underpins brand creation and the setting of premium prices for Micrel’s products.

The smart healthcare market is set to experience significant growth over the next few years, particularly in the area of mobile and wireless health. Many new companies will enter the field. Micrel’s competitive edge comes from its deep understanding of patient and doctor needs: its main sources for innovation are customer requests, end-user feedback and its own market foresight.

## Smaller and connected

One focus of Micrel’s development lines is miniaturisation. Patients want greater mobility, anaesthetists want to replace existing syringe pumps with a more compact system to have more space in the operating theatre, and drug-device combinations need smaller pumps.

Linear peristaltic pumps and bedside syringe pumps are state of the art in these applications. To achieve a new dimension in miniaturisation, Micrel took the 100-year-old concept of rotary peristaltic pumps and improved it. To date, rotary pumps have not been applied in medical devices because of problems such as high friction and power consumption and poor accuracy, but they have one great advantage – you can make them very small. Micrel’s recently patented new features overcome these disadvantages, achieving a very good linearity of flow, reducing power consumption and increasing accuracy levels, and at the same time meeting user demands. The technology can potentially replace with one device both LVPs and syringe pumps in bedside applications, while being very easy to move. The first patent has been granted in the USA and is pending at the EPO; another is pending at both offices. The new pump will be on the market in 2019, integrated with the MicrelCare server support as a connected device.

### TAKEAWAY

#### MAKE INNOVATION COUNT

Continuous innovation is a major success factor. Micrel listens to patients, doctors and key opinion leaders and takes their needs seriously, as this can lead to new inventions as well as to adaptations of existing products. The ability to quickly adapt to changing market requirements distinguishes SMEs from large companies and gives them a competitive advantage.

Another of Micrel’s development focuses is drug safety. Pharmaceutical companies are moving towards “personalised” medicine, so topics such as combinations of drugs and devices, drug delivery, safety and efficiency will become even more important. Apart from pharmaceutical companies, companies engaged in pharmaceutical packaging will also move into that area for items such as prefilled bags with readymade drugs and disposable pumps. It is essential to assign the right drug to the correct pump and person. Micrel has patented specific radio frequency identification (RFID) and barcode labelling for drug, people and device identification associated with other technologies that eliminate medication error. It will combine the technology for prefilled analgesic drugs to be used in reservoirs specific to infusion pumps and RFID identification with its miniature pumps for

an ambulatory and easy-to-use drug-delivery infusion system. For general hospital fluid and drug infusions, Micrel technology will enable pharmaceutical companies to label or tag drugs directly, which will be readable anytime by Micrel's ambulatory LVPs, thereby preventing medication errors. Tsoukalis intends to approach pharmaceutical companies to establish strategic partnerships for advancing these innovations. The safety of these drug device combinations is a feature that could allow these companies to differentiate themselves from other producers. The competitive advantage they would then have could be particularly significant in markets for generic drugs, where lapsed main patents give rise to fierce price competition. In these partnerships it will be crucial to have patents, as pharmaceutical companies usually demand exclusivity.



Miniature bedside infusion pump that can be operated with one hand.

## Earning their spurs

“It could have turned out completely differently”, says Tsoukalis. In the early 1980s, Micrel was producing conventional infusion equipment for therapies, blood testing and laboratory equipment. At the time it was too expensive for a young company to consider patenting, especially in several EU countries, and Greece did not join the EPO until 1986. Even freedom-to-operate analyses were difficult and costly: all Micrel could use was patent information on microfilms.

While developing a new ambulatory syringe pump, Tsoukalis became aware of a UK patent protecting related subject-matter which was standing in the company's way.

Although Micrel did not have much experience with IP and had no patents of its own at the time, it tried to overcome this obstacle by changing features of its product to take it outside the scope of the UK patent. However, it was eventually forced to withdraw the product and as a result lost a significant market share in the UK, which amounted to fifty percent of its turnover.

Since then, Micrel has consistently patented its inventions. It has more than 21 patent families and a long-standing collaboration with a German patent attorney. Its patent portfolio includes products, methods and computer-implemented inventions. Although patenting your own inventions is no guarantee against infringing someone else's patents, Tsoukalis notes that competitors hold professionally managed IP in high regard and generally respect the IP position of other players. Micrel has not had another infringement case since.

### TAKEAWAY

#### STAY COMPETITIVE THROUGH IP

Patents allow SMEs to compete with large companies and to stay ahead of the game. Technology-based companies such as Micrel must protect their inventions and take IP issues seriously.

## Tailor-made IP strategy

Micrel takes a tailor-made approach to IP protection. Inventions with an expected high market potential are patented and the IP used offensively. To protect these promising innovations more effectively, additional patents are clustered strategically around the core patents. At the moment, Micrel has three such patent groups, all aimed at preventing competitors from entering the company's areas of interest. One example is the core patent describing a mobile and internet connected system for monitoring medical parameters (EP1385420), which laid the foundation for the Internet of Things in the health sector. It is complemented by related patent applications EP3217304 and EP2767919.

### TAKEAWAY

#### SAFEGUARD YOUR INVESTMENT

In view of the time and effort required before a new product can be successfully brought to market, patent protection can help safeguard investments and reduce risk. Without patent protection, competitors can easily copy products once they have been introduced.



Miniature bedside infusion pump hanging from medication reservoir, directly reading RFID or barcode tags.

Micrel also patents incremental improvements which have a certain value but which do not necessarily constitute a pioneering innovation. These are protected so that they can be used defensively against competitors. All other technological details, especially if they can be hidden, are kept as trade secrets.

Although it is often vital to have a patent granted as quickly as possible, in some cases, especially if the market is very dynamic, it can be advantageous for it to take longer. This allows more time for the claims to be amended within the boundaries of what is described in the application and postpones the patent validation decision, meaning that market feedback can be taken into account.

#### TAKEAWAY

##### CHOOSE YOUR FILING STRATEGY

Most patent systems offer applicants the opportunity to accelerate the patent granting procedure (for example, the EPO's PACE programme). Alternatively, filing routes are available which enable the substantive examination of the patent application to be postponed (for example, filing an international PCT patent application). Having a patent application pending allows more time to find the best claim wording, or to choose the right markets in which to validate the patent.

## Active IP management

Micrel's IP management lies mainly in the hands of Alexandre Tsoukalis. His son, Achilles Tsoukalis, Micrel's R&D and quality director, is also regularly involved in market analyses and decisions on IP. Strategic IP issues are discussed and agreed at board level. New developments begin with a strategy meeting of the board, for which a systematic market analysis is made. Ideas for novel technologies or innovative products come mainly from the R&D, sales and marketing departments.

The patenting activities of the company's main competitors are regularly monitored. Every Monday, Alexandre Tsoukalis is notified about new patents in the relevant patent classes and containing the relevant keywords, using the alert systems offered by public patent databases. With these searches Micrel can ensure that it has freedom to operate for new products and will therefore avoid infringing third-party patents. The results also yield valuable market information and inspiration for new developments. Micrel's idea for the RFID technology (EP2987517) came about as a result of analysing the published patent applications of another company. Based on the need identified in the prior art to prevent medication errors, Micrel created an improved way of achieving this aim. The improvements comprised better manufacturing properties, technology use and safety aspects, and pharmaceutical labelling and tagging.

## TAKEAWAY

**MAKE THE MOST OF PATENT INFORMATION**

It is important to perform regular searches in patent databases. In addition to allowing you to monitor your competitors, analysing new prior art can help you find “white spots” in the patent landscape which may reveal opportunities for further innovations.

## Filing strategy and considerations for Europe

In its filing strategy, Micrel concentrates on covering the larger markets. It files with the USPTO and EPO, validating in France, Germany and the UK. Although its main competitors act worldwide, Tsoukalis acknowledges that, in view of the high cost of obtaining and maintaining a patent in a large number of countries, the only reasonable way for an SME with limited resources to proceed is to protect its innovations in the larger countries only, even if this means that it has to operate without patent protection in some markets.

Tsoukalis expects that the Unitary Patent will be much better for SMEs than the existing European patent system. One of the main benefits in his view is that it will be easy to get broad territorial protection in Europe at lower cost. Due to their limited resources, SMEs typically validate their European patents in the larger countries only. “Especially for smaller countries like Austria or Greece,” says Tsoukalis, “it will be essential to take part in the Unitary Patent”. It will become especially important for Micrel when it enters into co-operation with pharmaceutical companies, as these companies usually extend their patent portfolios over a large number of European countries. With regard to the Unified Patent Court, Tsoukalis points out that having a single court that really understands patents and has jurisdiction over most of Europe will also be of great importance to SMEs as it will help reduce costs and complexity and increase legal certainty by avoiding contradictory judgments by national courts in parallel proceedings.

## COMPANY PROFILE

**MICREL MEDICAL DEVICES SA**

- › Headquarters: Athens, Greece
- › Year of establishment: 1980
- › Staff: 80
- › Turnover: EUR 17 million
- › www.micrelmed.com

**PRODUCTS/SERVICES**

Development, production and marketing of smart drug delivery systems, such as ambulatory volumetric and syringe infusion pumps for hospital and home care

**MARKET AND TECHNICAL AREA**

Medical devices

**CUSTOMERS**

Pharmaceutical firms, medical device manufacturers, medical practitioners, hospitals, home care providers, research centres and universities

**SELECTED AWARDS**

- 1994 National nominee
- European Community Design Prize

**PATENT PORTFOLIO**

21 patent families, including EP2289579, EP1385420

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EPO SME case studies | ISBN: 978-3-89605-192-9 | © EPO 2017, Munich, Germany

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