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The founder of Eriochem discusses his firmâ??s ambitious technology based on a competitive IP strategy and its exciting research on a radically new oncology platform.

Today, Eriochem is a vertically integrated company producing both APIs and final dosage forms; when you started the company, what was the strategy you followed to develop the business into what it is today?

In the year 2000, Eriochem was founded and it launched its first product. Our name reflects our initial purpose, as Eriochem is an amalgamation of the words Entre Rios Chemical, and from the beginning we produced both APIs and finished dosage forms. As a small company, we had to use our limited resources efficiently and develop the more critical products first, and at the beginning APIs were often more important than finished dosage forms; we had a small API plant that started producing vinorelbine, and later on oxaliplatin and then melphalan. In 2004 the FDA approved this API plant for the production of vinorelbine, and later the other APIs were approved.

After a few years, this pattern changed and we began to focus more on developing our finished dosage forms. Even though this was our long-term plan, when the APIs prices started to fall rapidly in the mid 2000s, we decided to accelerate our plan and to begin working more on the finished dosage forms. After that, we limited development of new compounds to those that were of strategic importance to our firm, such as the polymer that we use for our microcapsulation process.

Eriochem is already selling products in around 49 countries; whatâ??s the next stage in your geographical expansion strategy?

Our export strategy has three stages. First, we entered the relatively accessible markets, in terms of regulations and territory/culture. Of course, that meant most of Latin America first, with several larger south east Asian countries (Indonesia, Philippines and Thailand) coming next. The second stage was the European market, where we introduced our first finished dosage product in 2010.

Stage three, which we are working on at the moment, is the US. This initiative is well underway as our main pharmaceuticals plant was approved by FDA just a few weeks ago; our plan is to begin by introducing our simple generics first, followed by our super generic products in a few years. In fact, our plant is the first Argentinian firm to be approved by the FDA for the production of injectable products.

Could you elaborate on your strategy for your generics and supergenerics business?

One of our reasons for moving more aggressively towards final dosage forms was that we had developed some specialized skills and capabilities of particular value in that business. These capabilities include our lyophilisation techniques, cold-chain production infrastructure, and eventually our patented microcapsulation process that allows the production of sustained release injectable products. Using these techniques, we are able to develop â??supergenericâ?? products, or generics that include some incrementally innovative features or delivery mechanisms.

Our finished dosage form strategy somewhat reflects our legal background to some extent, and relies upon these specialized skills. Generally, the generic industry operates within a box in which no one begins working on a particular product until the originators patent begins near its expiry date, and as a consequence companies tend to look only at those patents which are close to expire for possible opportunities.

Our goal at Eriochem is to find patents that we can bypass by applying or developing a new technology to a patented compound so we can get a few years ahead of the generic competition and be the first company to launch a generic version. Thus, we are continuously searching for opportunities and we keep an eye on relevant pharmaceutical patent challenges.

Our first product, which is an example of what been mentioned above, is the lyophilized docetaxel that was filed for registration with EMA in 2009. Unfortunately, Teva was able to get the patent cancelled in 2011, at least three years before its original expiry date, opening up docetaxel to the entire generics industry so we didnâ??t benefit from our privileged market position for as long as we had hoped.

I understand you are collaborating with Amega Biotech and National University of Litoral to develop â??smart nanocarriersâ?•. Could you tell us a bit about this project?

The project involves developing a lipid nanocarrier for cytostatics, such as docetaxel. This carrier will be an analog to human low-density lipoprotein, and can enter cells through endocytosis via LDL receptors. As malignant cells reproduce rapidly, they need and absorb much more cholesterol than healthy tissue to build new cell walls, to the extent that certain malignancies over-express receptor cell surface densities by more than 100 times. By attaching a cytostatic to an LDL analogue, direct absorption by malignant cells is dramatically increased, and contact between the cytostatic drug and healthy cells is decreased, lowering their secondary effects. Currently, there is no pharmaceutical product on the market that uses this cellular receptor, the specific enzymatic pathway that our research-subject uses to disassemble the lipid nanoparticle and the active drug intracellularly. Thus, this project represents a radically new treatment option for malignant cancers, and is patentable internationally. This nano/biotechnology could also be used as a platform for other drugs and other diseases related with higher r-LDL surface densities.â?•

So far the progress and results have been very positive; some of our tests have shown that this new delivery platform increases â??in vivoâ?• the activity of the docetaxel significantly. The great thing is that the finished product is very small, about 40 nanometers in diameter, and have the specific protein for transitosis via LDL receptor across the blood brain barrier. The most exciting part is that this isnâ??t just only a product, but a platform for drug delivery. However, this is the first stage of the research, not a product development; that it is many years away. We also have several other research sub-projects and ideas tied to this platform, that are in their starting phases or that we are waiting to begin.

What would you like Eriochem to accomplish over the next five years?

We have a ten-year master plan and our goal is to have half of our turnover in the US in five or six years. Right now, we are selling about USD 28 million per annum, roughly 80 percent outside of Argentina, and about 25 percent growth per year over the last few years. If we can keep that pace of growth and gain a strong foothold in the US with docetaxel within the next few years, I will be very satisfied.

As for the pharmaceutical industry in Argentina, what do you feel are the main reasons that Argentina is not currently more prominent in the international pharmaceutical market?

First, it is important to recognize that Argentina has the longest tradition of pharmaceutical manufacturing in Latin America, with several companies that are over 100 years old. I have been in the industry since 1985, and at that point there were more than 200 labs in Argentina and less than 20 in Brazil.

However, we lost most of these advantages in recent years for a variety of reasons. Argentina has fallen behind because we didnâ??t embrace globalization and trade as many of our neighboring countries and industrial competitors did; for example, relatively few pharmaceutical companies export from Argentina, and many of them only export to the smaller markets in Latin America. Partially due to these attitudes and policies, other countries like Brazil received much more foreign investment, which together with the higher levels of trade have helped them to achieve higher overall

levels of growth. Thus, while many countries outside of the US and Europe, such as China, India, Taiwan and Korea, have managed to become significant players in the global pharmaceutical market, Argentina doesnâ??t have a very strong position considering our history and technical expertise.

How competitive do you think Argentina is compared to other players?

Overall, I donâ??t think we are particularly competitive, at least not based on price alone. We can be very competitive in some markets, and perhaps with some of the more temperamental biotechnologies. Our biggest asset is our strong pool of human resources, and the cultural commitment to the excellence in work; business may not be the most efficient or professional in Argentina, but when people are expected to meet a certain level of quality in their work, they meet it. Thus, we are able to achieve and maintain the standards necessary to export to some of the more regulated markets. I hope that in the future, we will be able to leverage these strengths and take a stronger position as generic players in the more regulated markets.

The problem for other markets is that many Argentinian products lack CTD format dossiers, which are needed for registration in highly regulated countries (e.g: FDA, EMA). In Latin America where Argentinian brands are well known, we have a fairly strong presence because physicians and pharmacists understand that our products are fairly good value in terms of the quality-price relationship, but for the rest of the world we donâ??t have the brand recognition to compete in competitive markets for important products. Argentinaâ??s opportunity in these markets is as a producer of overlooked niche meds, where the competition is weaker and the price is less of an issue for payers.

Do you have a final message for our readers?

It may be a clichÃ©, but Iâ??d say: donâ??t fear challenges. My unique advice would be to look towards technology for solutions. Our company has maintained steady growth because we are continuously developing new technology that we incorporate into products and processes and we are using to accumulate patents.

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