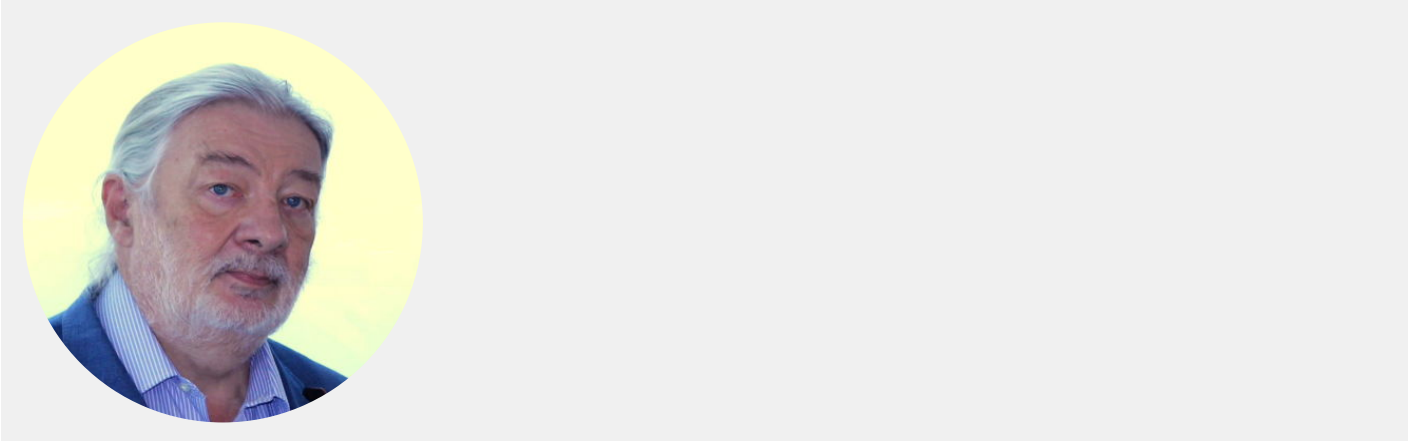
Pál Szamosújvári – Founder, Pál Szamosújvári Jr – Director, & Judit Jávor – R&D Director, Pharma Patent, Hungary



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MD Pál Szamosújvari, Judit Jávor, Pál Szamosújvari Jr—Founder, R&D Director, and Director of Pharma Patent respectively—share their insights on the activities of the company, the importance of R&D, the challenges of smaller companies, its marketing strategy of its niche products, and its internationalization strategy.

Can you introduce yourself and the activities of Pharma Patent?

Judit Jávor: I am a pharmacist and started my career in Biogal at the Debrecen site in the analytical R&D division. In 1991, I joined Teva as a registration officer and left when as a Medical Device Regulatory Office Director for Europe. At Pharma Patent as R&D Director, I oversee pharmaceutical development, manufacturing, and clinical trials. All the while, I am involved in the scientific and regulatory committee of the Association Medicine for Europe and acting Vice-Chair of the Medical Device Task Force.

Pál Szamosújvári: My speciality is in medical marketing, particularly the field of method and active agent promotional different method, medical representatives, clinical trials, other promote congress. I left a big company and built this business in 2004 own business on the idea to develop

niche products, value-added medicine in the field of rheumatology and osteoporosis. Pharma Patent is active in the Rx and reimbursed market and produces its products. It invests in R&D and continuously updates its portfolio with new indications, new formulations, new combination and packing methods.

Pál Szamosújvári Jr: The general idea was not to participate in the generic competition, as the market seemed restricted and did not seem efficient. Pharma Patent's portfolio is built around those therapeutic areas with in-licensed products and the backbone consists of our developments.

How does Pharma Patent go about setting up their portfolio?

PSJ: Pharma Patent launches their products by looking at a matrix of factors. Firstly, extensive market research is conducted, and it maps out the medical needs while assessing the reimbursement status of various European countries. If it is favourable, an appropriate molecule or product is put together for that specific niche. Pharma Patent tries to operate as efficiently as possible, and the market needs to the production line is a model that best suits our strengths. Over the last 15 years, the company developed its portfolio by carefully controlling its supply chain of APIs and build local marketing organisation in Hungary. Currently, Pharma Patent has a nationwide representative system that is promoting its products.

JJ: There exist molecular remnants of the past that have been ignored due to missing safety and efficacy data. Pharma Patent invests in forgotten molecules and revisits their potential as active ingredients in therapies. This is a competitive advantage, that benefits all stakeholders including physicians and patients: this is the special segment we are in working in.

What is Pharma Patent's overall marketing strategy?

PSJ: Its target audience is not the general public or patients, but opinion leaders and scientific specialists. The company reaches them by partnering up with medical marketing companies that have a strong presence in the market and that have a scientific reputation. Generic products are price-driven, whilst added-value products need extensive marketing efforts on a scientific basis. The process involves educating physicians and doctors about the active ingredient, and they become "ambassadors" of our products.

JJ: However, this approach is a qualitative process as each partner is carefully selected. They need to understand the added value that our products bring and the science behind it. What is important is to have partners that not only comprehend the efficacy of the product, but also know the intricacies of the market: reimbursement, regulatory framework, market knowledge, competitive landscape, and marketing strategy. These are important elements that Pharma Patent considers when finding a partner.

To what extent is Pharma Patent involved in R&D?

PSJ: The company has a turnover of EUR 15 million (USD 16.7 million) and acquired two years ago a small-sized CMO as it helped expand Pharma Patent's manufacturing capabilities. In the last 5 years, we noticed that the market had high R&D needs, yet the service offerings were limited, not only because of limited resources but also more stringent regulations with Rx products. The R&D for the field of value-added medicine is connected with the regulatory landscape. Hence, we acquired the company to boost our pipeline and be more involved in this field.

JJ: For smaller companies like Pharma Patent, when addressing R&D the issue of intellectual property is inseparable. It is a priority to retain its products, know-how, processes, regulatory knowledge and patents as much as possible as it is their competitive advantage. Resources are scarce for R&D and even more so legal recourse for smaller companies.

How supportive is the government with smaller companies when conducting R&D?

PSJ: In 2008, the Hungarian government imposed a 20 per cent tax on reimbursed products which was a heavy burden on the industry. However, there were severe pushbacks, particularly disadvantaging local marketers and manufacturers, since it is a flagship industry for the economy. In 2012, a special R&D subsidy was introduced which was a payback scheme of the previous tax, and companies were eligible if they are active in research. It is beneficial, between the insurer, the manufacturer, and the state subsidizing the insurer. This has created a stable environment. The EU funds are lacking in Hungary, but they are available to companies and mostly focus on infrastructure. Pharma Patent restraint itself from using this source of funding, to protect their IP knowledge and because we collaborate with CMOs.

JJ: In Switzerland, there is a good ecosystem between the different industries that are working together to improve the healthcare landscape. This is collaborative mentality is missing from

Hungary and needs more drive from the government. There have been some slight changes.

What is Pharma Patent’s service offering when it comes to clinical trials?

PSJ: The company conducts clinical trials in its field of expertise while partnering up in joint trials or third-party participant. Furthermore, it offers its regulatory and management expertise to help trials to be conducted. 70% of all the trials conducted in Hungary are done by third parties in the EU and the US. Albeit its international attractiveness, clinical research could be improved with legislative reforms under what circumstances trials can be conducted.

JJ: Pharma Patent collaborates with US and EU companies in our field of focus. There is a spillover of knowledge with joint partnerships. These improve future interactions with other clients, as best practices and new processes are integrated into the company’s modus operandi. Furthermore, our team is comprised of individuals that are passionate and highly skilled. They come from big pharma and bring in multinational mindset and approach and adapt to an SME.

How important are export activities to Pharma Patent?

PSJ: Pharma Patent started its export activities back in 2012 and present in almost every European country with our products. 30 per cent of revenues are generated from the Hungarian market, and 70 per cent from the export activities. For Hungarian pharmaceutical companies, it is necessary to have an internationalization strategy in place as the local market is small. The main markets are the Dutch and Belgian one within Europe, even though price erosions and Brexit have slowed down the regulatory process.

What is Pharma Patent’s internationalization strategy?

PSJ: Pharma Patent does not have many competitors as it is deliberately done this way. Markets are chosen by the lack of substitute medicine in the osteoporosis and rheumatology field. The medicine that the company produces are hedged against the existing medicine offering in a country, and the less competition there is the better. In certain instances, it takes several years to get the medicine approved and registered, but it makes it worthwhile. Hungary is the testing ground for Pharma Patent’s products. They are launched and registered here first and then launched into new markets.

JJ: Pharma Patent continuously improves its products, by refining the dosage or by introducing new formulations. Clinical studies, even ongoing ones, help the company to optimize the efficacy of their medicine.

What are the long-term vision and strategic priorities of the company in the next five years?

PSJ: In the last five years, the company has spread in the European market, however, the company is going to take a different direction. With price erosions and regulatory slowdown, Pharma Patent will move out of Europe and explore different regions. There are also new developments in the pipeline. What we see on the market. In Europe, Belgium and Switzerland are the only countries, that have established a regulatory framework that supports value-added medicine. This is mostly due that there is no legal definition of what a value-added medicine is.

What is your final message on behalf of Pharma Patent?

PSJ: Hungary is a healthy market and offers a rich ecosystem embedded in long historical traditions.

JJ: It is important to keep not only one aspect of the pharmaceutical industry healthy, but holistically by strengthening all stakeholders and peripheral industries. Innovation does not mean to invent a new product or a new process, but it can be as little as observing what other countries do and incorporate their best practices.

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