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Crossing the Rubicon and tapping into a niche drug delivery system

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Rubicon is the Italian word for Rubico, the Latin name of a small river in Northern Italy. To protect the republic from internal military threat, the Roman law forbade any general with a standing army, from crossing that river, as it formed a boundary between the Roman province of Cisalpine Gaul and the Roman heartland. When Julius Caesar crossed the river in 49 BC, supposedly on January 10 of the Roman calendar, in pursuit of Gnaeus Pompeius Magnus, thus breaking the law and making armed conflict inevitable, he uttered the famous phrase 'the die is cast'. Today, the phrase 'crossing the Rubicon' refers to a person committing himself irrevocably to a risky course of action.

And that's what three scientists committed to, when they set up Rubicon Research in Mumbai in 1999. With no personal fortune or company backing, Maharukh Rustomjee, Sudhir Pilgaonkar and Pratibha Pilgaonkar decided to set up a research company, with a mission to provide formulation development services to global pharma companies.

In a country filled with generic drug makers and bulk contractors, Rubicon has developed novel drug delivery systems that could be used by innovator companies in the West to make their patented drugs in newer formats. "We saw a great need for contract research in the formulation area, and one has to have the innovative skill sets, competency and be cost effective to compete," said Ms Rustomjee.

The company started as a contract research organisation providing generic formulation development services to Indian and European companies. "We developed non-infringing processes for various generic products, stability data and worked on technology transfers," she said.

Ms Rustomjee had already undertaken projects for international development while working with Novartis Enterprises and GlaxoSmithKline. Sudhir Pilgaonkar had over 30 years experience in manufacturing value-added speciality pharmaceutical products, and handled activities such as manpower management, production planning, inventory control, safety and cost reduction in production management.

Pratibha Pilgaonkar had worked with Sun Pharmaceutical Industrials as vice-president for product development, and added significant value to the team. But setting up Rubicon proved to be a challenge.

"Recruiting people initially was very difficult and competition is tough," she explains. "In the first two to three years, we spent a lot of time training people. Research is a way of thinking, it can't be taught in a class room, it only comes with experience, while working on projects."

Funding the venture was another problem. “We were three scientists, with no company backing and no personal fortune, so we needed bank loans to start operations,” she said. While the company soon started working on small projects, which provided funds to further scale up the business, Rustomjee realised that to add value to the company, they needed to work on their own technology. “In pharma research, unlike IT, scaling up operations is very difficult. Each project requires a different approach and a small dedicated and vibrant team,” she explains.

In 2003, Rubicon Research started working on new drug delivery platforms like extended release systems, orally disintegrated tablets and drug coating technologies. The same year, Rubicon Research received approval as a commercial R&D company from the government of India’s directorate of science and technology, and filed its first international patent.

“Today, Rubicon Research develops pharmaceutical and consumer products and licenses out technologies to improve the convenience, side effect profile or the therapeutic efficacy of pharma company’s new and existing drugs,” said Rustomjee.

In 2005, it licensed out its first controlled release product to a US-based company. Along with its own technology, Rubicon started developing drug delivery technologies for the specific needs of its global pharma customers. “Pharma companies come to us with a problem relating to drug delivery that we help them solve. For sponsored projects, the IP rights remain with the pharma company,” she clarified. Rubicon now has a team of 120 people in Mumbai, including 80 scientists.

In a significant milestone for the company, in 2007, Kotak Mahindra Bank’s private equity fund picked up a stake in Rubicon Research. “This is a new business model,” said Alok Gupta, country head for life sciences and technology at Yes Bank. While there are companies similar to Rubicon in the Western world, like Penwest Pharmaceuticals, Ethypharm or Azopharma, few Indian companies are present in this segment, points out Ms Rustomjee.

Rubicon is still at a very ‘early stage company’, admits Rustomjee. But as big pharma struggles to keep its head above water while swimming from one blockbuster drug to another, incremental innovation may play a significant part in their R&D strategy. And as the number of new drug approvals in the US and in Europe decreases, the demand for technology that may improve existing drugs, may soar.