Biocon Ltd. Case Study

BUS 282B
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Feb. 4, 2024

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Introduction & Company Background

When Biocon started operating in 1978 outside of Bangalore, it was making industrial enzymes for Unilever PLC. In this location Biocon had many bioreactors fermenting a wide range of products, including large-molecule biologics and small-molecule Active Pharmaceutical Ingredients (APIs). By adhering to current good manufacturing procedures (cGMPs), Biocon's state-of-the-art facilities set industry standards and set itself apart in the Indian pharmaceutical environment.

The managing director and chairwoman, Kiran Mazumdar-Shaw, was dubbed "India's Biotech Queen" by The Economist in recognition of her groundbreaking contributions to biotechnology. With the help of her distinct vision, Mazumdar-Shaw turned Biocon from a producer of industrial enzymes into an integrated biotechnology business, earning recognition for both the company and the Indian industry. Under Mazumdar-Shaw's direction, Biocon expanded from having just two employees when it first opened for business in 1978 to employing over 2000 people.

Beginning to change in the middle of the 1990s, the business used its platforms for fermentation to expand and create a variety of generic APIs, including enzymes and statins. In order to create generic synthetic compounds, Biocon carefully used process biotechnology techniques, such as fermentation and chemical modification of bacteria. Large molecule proteins as well as small molecule APIs were produced using this method. The business made significant investments in state-of-the-art bioreactors and bioprocessing facilities to establish itself as a prominent participant in the industry. In March 2004, Biocon Park spread across 90 acres and was India’s first and largest biologics facility.

By the end of the 2006 fiscal year, Biocon's sales were largely made up of APIs (86%) and the business had become one of the leading statin manufacturers in Europe, controlling between 30 and 40% of the market. Because of its broad fermentation manufacturing capabilities, the business stands out in the Indian pharmaceutical scene, further solidifying Biocon's position as a major player in the biotechnology and pharmaceutical industries.

Biocon's leadership claimed that its unique integrated business approach distinguished it from its competitors. The goal of the multiproduct, multiservice framework was to achieve a balance between low risk and comprehensive revenue development. Under the corporate structure of the Biocon Group, Biocon Limited served as the holding company, managing the two subsidiaries, Syngene and Clinigene, as well as the joint venture, Biocon Biopharmaceuticals Private Limited.

Even though Biocon made a smooth transition from an early-stage company to a midsized business, some industry watchers expressed doubts about the company's capacity to maintain its development trajectory driven by research. The statin and biogeneric markets were becoming more and more commoditized, and the global monoclonal antibody industry was becoming extremely competitive.

Addressing the Question

In 2007, Biocon faced major issues in the face of a rapidly-changing pharmaceutical environment in India, sitting at a major crossroads between its reliable past in API production, and its uncertain future in recombinant therapeutics. Indian biotech firms such as Biocon were now forced to deal with foreign industry pressures from both sides - within India, reliable 'cash cow' ventures such as API production (Biocon's flagship product line) were beginning to be threatened by Chinese production, and on a global scale, the biotechnology market was growing at a fast pace. While a potential Chinese overtaking of Indian production, or a move away from western companies outsourcing API production to India were years away, the writing on the wall was clear: Biocon would need to differentiate itself once again by transitioning away from basic APIs and towards more innovative solutions in order to stay competitive. With Biocon's stock whittling away year after year as investors lost confidence in their future, the urgency among top management was palpable.

Biocon's future outlook also faced issues on the managerial side, away from their manufacturing facilities. A focus on research-led growth worried investors, who doubted that Biocon could sustain their API cash cow long enough to transition into a Blue Ocean strategy in an environment that was getting redder by the minute. Their STAR quality, poised to do just that, was their service quality, which set them apart from fellow Indian competitors, and aligned well to bulwark against Chinese competitors who were prone to struggle with the language barrier and ability to satisfy foreign markets' demand for care and quality. Most notably, this enabled them to seek exclusive ventures with foreign markets, such as in Cuba. However, pursuing 'safe' deals in this way was, ironically, very risky because it relied on the successful development of products that were several years out. Even just surviving to see the entire multi-year process out was in question.

In order to complete the work needed for these new ventures, Biocon needed to attract greater scientific talents from outside the company, potentially even abroad, and also to implement better internal controls to navigate the more difficult regulatory environment associated with biologics production. Its large-molecule therapeutics being three to four years out was a very dangerous prospect, and put enormous pressure on management to find talent that could expedite that process in spite of the many hurdles involved in drug development.

All of these problems had one underlying decision: how risky was Biocon willing to be in the face of industry pressures that threatened to weaken its market share and dismantle its long-held competitive foot in the race?

Analysis Models

SWOT Analysis:

Leading biopharmaceutical corporation Biocon's strategic environment is shaped by a variety of strengths, weaknesses, opportunities, and threats (SWOT).

STRENGTHS:

1. Industrial Scale Manufacturing Capability with 12,000 sq. ft. manufacturing facility, one of the largest biotech plants in India.
2. Ability to manufacture APIs with less cost because of the low cost labor.
3. Three different subsidiaries Syngene, Clinigene and Biopharmaceuticals concentrating on research and Discovery, Clinical Trials and Developments, and Manufacturing of the Biological Drugs respectively.
4. Strong service department, renowned for its quality and support.

WEAKNESSES:

1. Very limited success in novel biotherapeutics.
2. Undiversified expertise in R&D, and lacking in research talent.
3. Inexperienced with the emerging generics market.
4. Has difficulty attracting talent from abroad.

OPPORTUNITIES:

1. The Generic Market might rise because of the patent expirations of many well-known STAR drugs and the boomer aging population.
2. Reciprocal Agreement between India and US might clear the approval for generics both in India and US simultaneously.
3. Indian Government decision to loosen the regulatory impediments to encourage the biotechnology products such as LMOs.
4. Emerging markets in the Asia-Pacific region as countries like India modernize their economy by increasing globalization efforts.

THREATS:

1. The pricing pressure for generic drugs across the globe.
2. The competition from the Chinese pharmaceuticals which are competing on the grounds of low-cost differentiation.

3. The European market is particularly strong in late-stage development, threatening Biocon's presence there.

Product Pipeline Analysis:

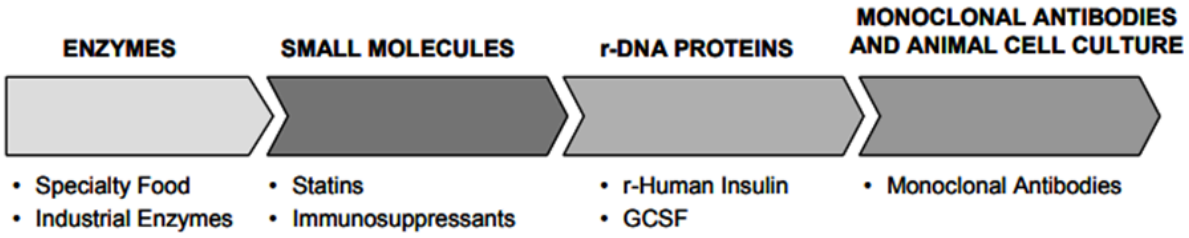

Figure 1. Biocon's Product Pipeline

Biocon's products pipeline has enzymes, small molecules, r-DNA proteins and Monoclonal antibodies and animal cell culture. Even though it has a diverse portfolio, our analysis mainly concentrates on the products API's (Statins and Immunosuppressants) and Novel Biologics. APIs were the cash cows for Biocon, whereas Novel Biologics are still in the development stage. We start analysis by product then review the industries of these products.

Ansoff Risk Matrix:

		Customer Type	
		Current	New
Product Type	Current	API's, Generics, Enzymes Market Penetration Low Risk	Market Development
	New	Biological Drugs (rDNA proteins) Product Development	Novel Biologics Product Diversification High Risk

Table 1. Ansoff Risk Matrix

The risk evaluation of the products was evaluated using Ansoff risk model. It considers the customer type (Current vs New) and the Product type (Current vs New). The risk increases from the 1st quadrant in the top left corner to the 4th quadrant in the bottom right corner in a Z shape. We identified the API's, generics, and enzymes as the low-risk products since it targets the current customer's market and products are already existing in the market. The Biological drugs or the bio generics are listed in the 3rd quadrant as they are fighting for current customers with the new product. Finally the Novel Biologics are considered as the high risk products among the Biocon's portfolio.

BCG model/Matrix:

		Relative Market Share	
		High	Low
Market Growth Rate	High	STAR (INVEST) Services (Syngene and Clinigene)	QUESTION MARK (EVALUATE) Novel Biological drugs
	Low	CASH COW (HARVEST) APIs, Enzymes (Manufacturing)	CASH HOG/DOG (DIVEST)

Table 2. BCG Matrix

API Industry Porter's Five Forces:

We analyzed the API industry with the novel biologics industry using porter five forces. There are five elements and the + sign represents the higher threat compared to the other (-). The threat of competition is higher for the APIs industry since they do not have any patent protection. The APIs were mostly sold to other Biopharmaceutical companies, they have bargaining power since they have choice over the seller. Since both APIs and Novel Biologics were synthesized using biotechnology processes the raw materials were almost the same. The possibility for new

entrants is higher for APIs industries since its low-risk products when compared to the Novel Biologics. The substitute products do not affect the APIs much since they are generic already with huge markets. But the substitutes affect Novel Biologics since they will not be competing for cost.

The APIs market was a red ocean strategy which was based on the low cost rather than differentiation. Novel Biologics market was a blue ocean whose strategy is based on the differentiation of the product.

Threats	API's	Novel Biologics
1. Competitive Rivalry	+	-
2. Customer Bargaining power	+	-
3. Suppliers Bargaining Power	=	=
4. New Entrants	+	-
5. Substitute Products	-	+

Table 3. Porter's Five Forces Comparison

Future Recommendations

Ultimately, Biocon's conservative growth approach in the face of new outside threats was, in our estimation, the incorrect choice. Other companies, such as Ranbaxy, were dedicated to more high-risk, high-reward ventures by forcing inorganic company growth by acquiring international firms, as well as their available talent. Biocon, in contrast, opted to focus on organically growing its business within India as it would slowly bleed out its API cash cow and feed its growing STAR service and biologics development over the course of several years.

Already trending downward, it seemed that Biocon's conservative growth approach would pay off too little, too late - already playing from behind, the consistent year-over-year growth of the biotechnology industry could make Biocon's resurgence into market relevancy, an already difficult task given other Indian companies' monumental expansion, a nigh-impossible one. Other cited figures, such as the European market's strong growth in late-stage development, would dampen Biocon's market penetration in Europe, as local pharmaceutical firms would be completing their clinical trials around the same time as Biocon's in three to four years. While there were market opportunities available, created by an aging population and patent expiration, these openings were primarily in developing generics.

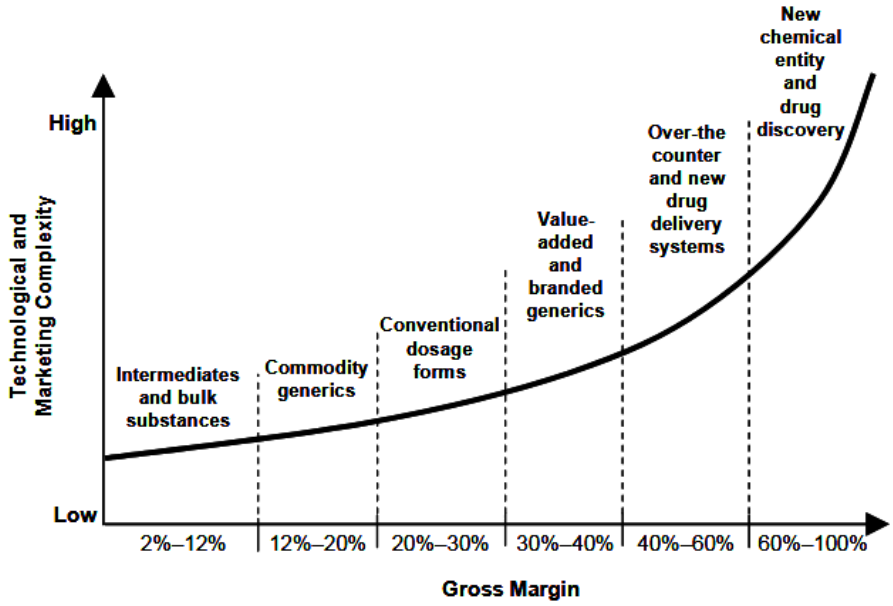

Figure 2. "Pharma Industry Value Curve" from "Going Global: Lessons from Late Movers" by C.A. Bartlett and S. Ghoshal, Mar.-Apr. 2000.

Our recommendation would be for Biocon to pursue a more aggressive approach to domestic and international growth, primarily through the acquisition of international firms with notable research talent. We would also recommend focusing on producing commodity generics, or partnering with larger international companies in developing their biologics in order to secure

the necessary capital to invest in smaller ventures while waiting for the biologics to emerge on the market. While still higher on the pharmaceutical industry value curve than API bulk substance production, generics could be produced more quickly and would require less organizational overhaul. Additionally, because APIs and commodity generics are neighbors on the value curve, it would be easier for Biocon to employ a more efficient matrix organizational structure between the two departments, given the similarities between the technological and marketing experiences required to navigate the two.

We believe that our recommendations represent the best path for Biocon to maintain and grow its industry foothold, and we can be confident in that assertion because it is directly in line with the real-life direction of Biocon after 2007. Currently, Biocon is the largest biopharmaceutical company in India, and still produces APIs as well as biosimilars both domestically and abroad. In 2008, Biocon acquired a majority controlling stake in German company AxiCorp GmbH, and in 2009, announced a strategic partnership with Mylan in entering the global generic biologics market, continuing to branch out in the Asia-Pacific market, with particular focus on producing branded generics in India.

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