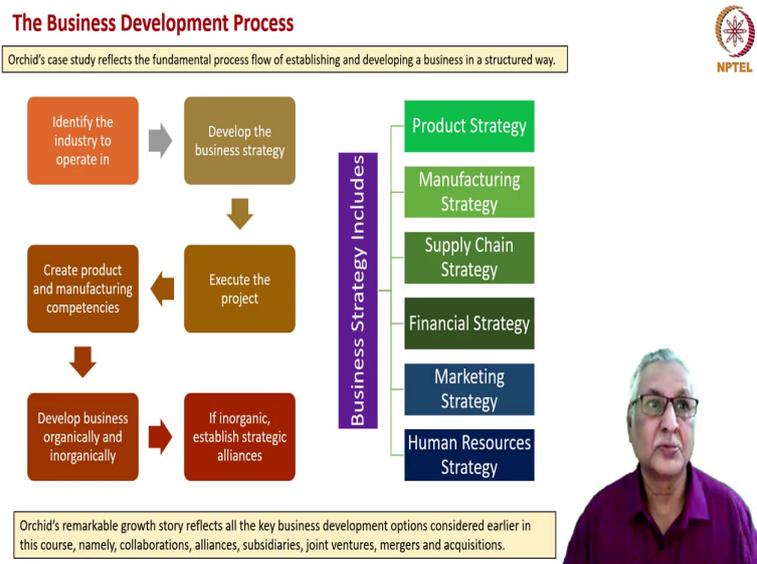


Business Development from Start to Scale
Prof. C Bhaktavatsala Rao
Department of Management Studies
Indian Institute of Technology, Madras

Week - 12
Business Development Case Studies
Lecture - 57
Pharma Strategic Alliances

Hi friends, welcome to the NPTEL course, Business Development from Start to Scale. We are in week 12 with the theme of Business Development Case Studies. In this lecture, the 57th in the series, we consider Pharma Strategic Alliances.

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The business development process that I have depicted through Orchid's case study reflects the fundamental process flow of establishing and developing a business in a structured way

based on physical assets. The first step is to identify the industry to operate in. The next step is to develop the business strategy.

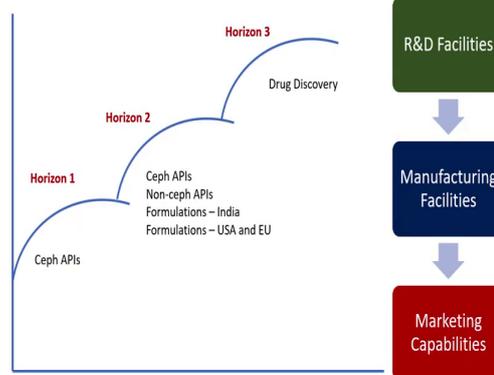
This has to be followed up by execution of the project. That involves also creating product and manufacturing competencies. Then you are ready to develop business organically and inorganically, which again is an execution activity with sharp conceptualization.

If inorganic established strategic alliances, business strategy includes product strategy, manufacturing strategy, supply chain strategy, financial strategy, marketing strategy and human resources strategy at the minimum. Orchid's remarkable growth story reflects all the key business development options that we have considered so far in this course, namely collaborations, alliances, subsidiaries, joint ventures, mergers and acquisitions.

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First, the Business Strategy

Starting from the inception period of 1992-94 with a strong product focus, Orchid diversified into a multi-horizon business strategy between 1998 and 2008, well-supported by industry-leading business development strategies.



Conceptually and operationally, the company followed a step-ladder growth strategy of rolling out product lines, some sequentially and some in parallel, each duly backed by manufacturing facilities.



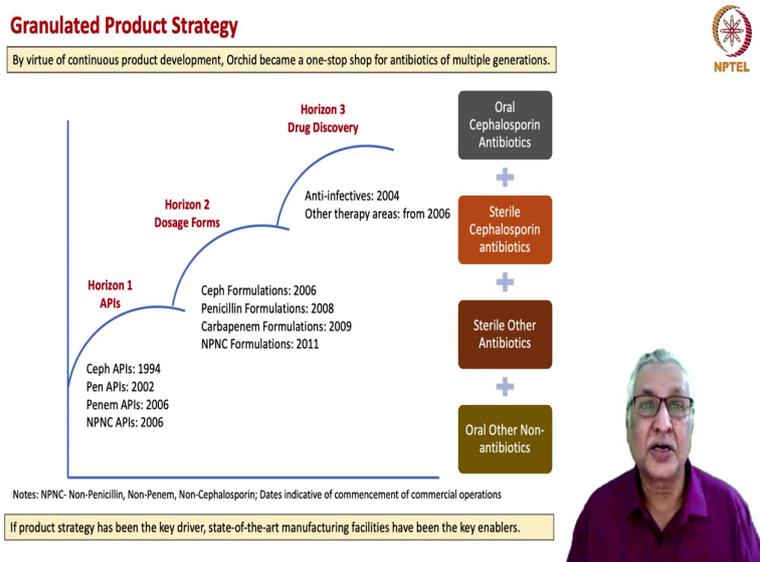
Let us look at the business strategy first. Starting from the inception period of 1992 to 94 with a strong product focus, Orchid diversified into a multi horizon business strategy between 1998 and 2009.

This was well supported by industry leading business development strategies adopted by the company. Horizon 1 comprised Cephalosporin antibiotic APIs. Horizon 2 comprised Cephalosporin antibiotic APIs. Non-Cephalosporin antibiotic APIs and non antibiotic APIs. Formulations for India and formulations for USA and European Union.

When we say formulations, we mean finished dosage forms. Horizon 3 comprises drug discovery, that is discovery of new chemical entities for the first time in the pharmaceutical space. The facilities included R and D facilities, manufacturing facilities and the capabilities included various functional capabilities, but essentially marketing capabilities to move into the export area. Conceptually and operationally, the company followed a step-ladder growth of strategy.

It rolled out product lines one by one, built confidence within itself and within the customer base by the product line success. And some of these were sequential and somewhat parallel and each of it was duly backed by manufacturing facilities. So, it was a very strong asset based model. And these assets included not only the physical assets, but also the intellectual property assets.

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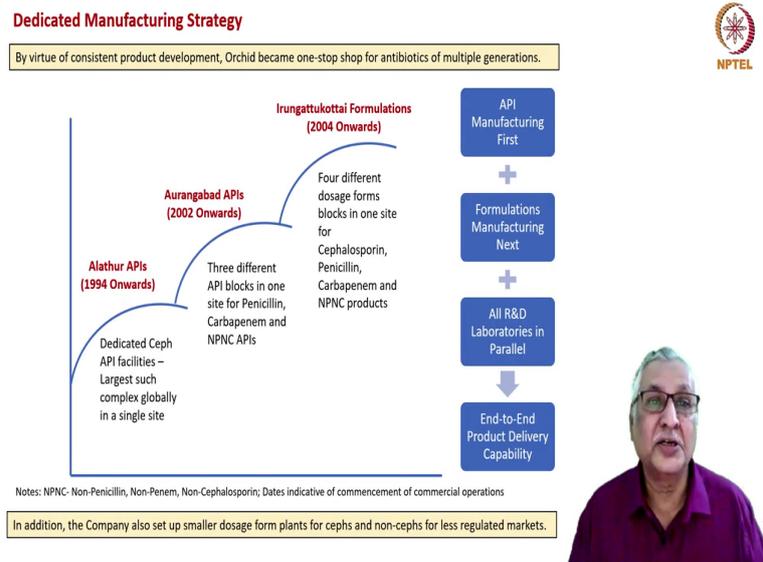
The product strategy was highly granulated. By virtue of consistent product development, Orchid became a one stop shop for antibiotics of multiple generations. Horizon 1 APIs comprised Cephalosporin APIs which were commenced in 1994, Penicillin APIs which were commenced in 2002.

Cephalosporin APIs which were commenced in 2006 and NPNC APIs which were established from 2006. The horizon 2 of dosage forms comprised Cephalosporin formulations that began from 2006, Penicillin formulations from 2008, Carbapenem formulations from 2009 and NPNC formulations from 2011. In the horizon 3 of drug discovery anti-infectives were started in 2004 and other therapy areas supplemented from 2006.

You can see this step- ladder development of various product lines and also some sequential and some parallel processing of these facility and IP creation activities as well as business development activities there for. NPNC means non-penicillin non- products.

And the dates indicated are inclusive of the commencement of commercial production in each case. The granulated product strategy included oral cephalosporin antibiotics, sterile cephalosporin antibiotics, various sterile other antibiotics and various other oral non antibiotics. If the product strategy has been the key driver, state of the art manufacturing facilities have been the key enablers.

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Let us look at the dedicated manufacturing strategy which also had a multi horizon concept. By virtue of consistent product development, Orchid became one-stop shop for antibiotics of

multiple generations. The Alathur mother plant in Chennai had APIs from 1994 onwards. The dedicated Cephalosporin APIs facility was the largest such complex globally in a single site.

The Aurangabad APIs came on to see from 2002 onwards, three different API blocks in one site for Penicillin, Carbapenem and NPNC APIs. The Irungattukottai formulation facility near Chennai came into being from 2004 onwards. Four different dosage form blocks in one site for Cephalosporin, Penicillin, Carbapenem and NPNC products. In addition, the company also set up smaller dosage form plants for cephalosporin and non-cephalosporin for less regulated markets in Chennai.

So, first of all, it was API manufacturing. Formulation manufacturing came on next. All R and D laboratories happened in parallel and therefore, an end-to-end product delivery capability was created from conceptualization of the formula to the ultimate delivery of the finished dosage form through the API support.

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API Facilities (Alathur, Chennai)

One of the key decisions taken by the company was to be as fully integrated as technologically and economically as possible. This meant that the facilities must turn out the chosen bulk drug APIs based on basic raw materials.

- | | |
|---|--|
| <ul style="list-style-type: none">▪ Largest cephalosporin API manufacturing complex▪ Approved by US FDA, UK MHRA and other international regulatory agencies▪ Variety of non-sterile and sterile (crystalline & lyophilised) APIs▪ High levels of throughput and manufacturing integration (980 MT of capacity per annum)▪ State-of-the-art infrastructure designed for highest levels of process efficiencies and environmental friendliness | <ul style="list-style-type: none">▪ GMP – Approved (WHO)▪ US-FDA – Approved (Nov '02, Sep '03 & Dec '06)▪ EDQM – Approved (Sep '03)▪ MHRA – Approved (Jan '06)▪ Hamburg Health Authority – Approved (Jan '06)▪ Australian-TGA – Approved (Feb '03)▪ ISO 9001:2000 – Certified Quality Management System (Re-certified in May '08)▪ ISO 14001 – Certified Environment Management System (re-certified in May '08)▪ Danish Medicines Agency (EU-GMP) – Approved (Jan '09)▪ Pharmaceuticals & Medical Devices Agency (PMDA, Japan) – (Oct '09) |
|---|--|



Innovative product development backed by quality-assured modern manufacturing facilities proved to be a winner.



Let us look at the API facilities at Alathur Chennai. One of the key decisions taken by the company was to be as fully integrated as technologically and economically as possible. This meant that the facilities must turn out the chosen bulk drug APIs based on basic raw materials.

Largest API manufacturing complex, a variety of products, high levels of throughput and capacity, high level of manufacturing integration and state of the art infrastructure for the highest levels of process efficiencies, quality compliance and environmental friendliness.

You can see on the right-side various approvals that have been secured from international regulatory authorities leading which was the US FDA approval series and the MHRA

approval series. Innovative product development backed by quality-issued modern manufacturing facilities proved to be a winner for Orchid's API business.

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API Facilities (Aurangabad)

In line with the evolving product strategy of different classes of antibiotics, new API production facilities were set up in Aurangabad, with high levels of technological and investment intensity.

- Multi-site API complex with dedicated facilities for
 - Penicillins
 - Sterile Carbapenems
 - Non-penicillin, Non-cephalosporins (NPNC)
- Facilities designed for automated production
- Manufacturing capacities: 48 MT for penicillins, 12 MT for Sterile Carbapenems and 120 MT for NPNC
- Approvals:
 - UK MHRA (Approved – Jan '07)
 - US FDA (Approved – Feb '07)
 - OHSAS 18001:1999
 - Danish Medicines Agency [EU-GMP] (Approved - Jan '09)
 - WHO GMP Audit (Approved – April '10)



The addition of Aurangabad as a brownfield API development facility (site acquired from Ajanta Pharma and invested for growth) took the company's capabilities a notch higher.



The API facilities at Aurangabad were even more modern. In line with the evolving product strategy of different classes of antibiotics, the new API production facilities that were set up in Aurangabad had much higher levels of technological and investment intensity.

You can see the images below. It was a multi-site API complex in this site that was acquired from Ajanta Pharma. It had three different blocks for Penicillin, sterile carbapenems and non-penicillin, non-cephalosporins. These were all designed for automated production.

Manufacturing capacities were high for those kinds of product clusters and again US and UK regulatory approvals were the important aspects for those facilities becoming recognized the

world over. The addition of Aurangabad as a brownfield API development facility took the company's capabilities a notch higher without any doubt.

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Formulation Facilities – Advanced Markets (Irungattukottai, Chennai)



Establishment of state-of-the-art formulation facilities for the advanced markets of US and Europe at Irungattukottai, Chennai, proved to be a game-changing strategic decision.

- Large state-of-the-art sterile and oral dosage form complex with multi-therapeutic facilities in antibiotics, and oral non-antibiotics)
- World-class facilities with US FDA & UK MHRA and other international regulatory approvals
- High throughput antibiotic formulations facilities (sterile cephalosporins, penicillins and carbapenems)
- Pilot and commercial scale NPNC (non-antibiotic) dosage forms plant
- Global scale capacities



The strategy helped the company establish strategic alliances with global generics players and capture value at the frontend of the formulations market.



These two API facilities, Oneata Althur and Oneata Aurangabad supported the formulation facility near Chennai. And that formulation facility was designed for advanced markets from day one. The facilities compressed large state-of-the-art oral and sterile dosage form lines with multi-therapeutic capabilities.

World-class facilities with US FDA and UK-MHRA and other international regulatory approvals. High throughput oral cephalosporins formulation facility, pilot and commercial scale NPNC non antibiotic dosage forms plant and global scale capacities. These strategy helped the company establish strategic alliances with global generic players and capture value at the front end of the formulations market.

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Orchid Chemicals & Pharmaceuticals



With the new strategy, Orchid became a fully integrated and diversified global pharmaceutical corporation, covering both APIs and Dosage Forms, in multiple therapeutic areas, catering to both regulated and less regulated markets.

Business	<ul style="list-style-type: none">Vertically integrated global pharmaceutical companyRobust research, manufacturing and marketing capabilitiesMulti-therapeutic, multi-product global businessActive pharmaceutical Ingredients (API), finished dosage forms and drug discovery
Key Product Offerings	<ul style="list-style-type: none">Fully integrated API and Finished Dosage Form product offeringsOral and sterile antibiotics (Cephalosporins, Penicillins and Carbapenems)Diverse (oral) multi-category, non-antibiotic product range (Non-Penicillin/Non-Cephalosporin)
Facilities	<ul style="list-style-type: none">2 API manufacturing sites in India and 1 API manufacturing site in China3 formulations manufacturing sites in India, and 3 research campuses in IndiaManufacturing facilities approved by US FDA, UK MHRA, EDOM, DMA, MCC and TGAR&D facility accredited by National GLP Authority of India (aligned to OECD principles of GLP)
Employees	<ul style="list-style-type: none">Human resources base of 4,000 plus – includes over 700 scientific & technical manpower in R&D and manufacturing, and around 1,000 field personnel in domestic formulations
Financials*	<ul style="list-style-type: none">FY10 turnover: Rs 13,435 Mn (US\$ 298 Mn)

*USD figures based on exchange rate of Rs 44 = 15 (Q2FY11 & H1 FY11) / Rs 45 = 15 (FY10); Financials are on consolidated basis

The combination of the entrepreneurial passion of the founder, the zeal of the leadership team and the sage counsel of the Board constituted a powerful combination to move rapidly with prudence.



As a result, Orchid chemicals and pharmaceuticals became a wholly integrated and diversified pharmaceutical cooperation. In my previous lecture, I have presented the same slide, but I am recalling for you for a quick grasp of how the business was expanded vertically in terms of integration and horizontally in terms of different product groups.

And how the product offerings were helpful in terms of different kinds of therapeutic classes and oral and sterile diversity, which would be very important in the global pharmaceutical industry. The manufacturing infrastructure has been mentioned already and the employee account has been 4000 plus including over 700 scientific and technical manpower in R and D and manufacturing and around 1000 field personnel in domestic formulations.

In FY 2010, the company club turnover of nearly 300 billion dollars. The combination of the entrepreneurial passion of the founder, the zeal of the leadership team and the sage Council of the Board constituted a powerful combination to move rapidly with prudence.

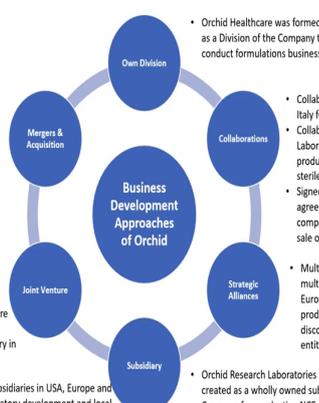
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Orchid Mega Business Development Approach

Orchid adopted multiple business development approaches to fast-track business growth.

- Orchid acquired Ajanta Pharma's API facility in Aurangabad in 2002 to develop a new base for manufacture of non-cephalosporin APIs
- Orchid acquired the domestic formulations business of Mano Pharma in 2003
- Acquired US based marketing company, Karalex Pharma for direct generics sales
- Orchid entered a 50-50 joint venture with NCPG of China to manufacture Orchid's Cephalosporin APIs in China.
- Also formed a 50-50 joint venture with Bevel Biotechnology Inc of California, USA for drug discovery in 2002
- Established subsidiaries in USA, Europe and Japan for regulatory development and local marketing knowhow

- Orchid Healthcare was formed in 1998 as a Division of the Company to conduct formulations business
- Collaboration with Sintofarm, Italy for technology in 1992
- Collaborations with SBD Laboratories, Italy for sterile production (1994) and certain sterile products (1997)
- Signed co-marketing agreements with 4 Indian companies to boost domestic sale of formulations (2003)
- Multiple alliances with multiple partners in US and Europe for distribution of products from 2004 and discovery of new chemical entities, from 2006 onwards
- Orchid Research Laboratories Limited was created as a wholly owned subsidiary of the Company for conducting NCE research in 2004



The strategic blueprint was executed with passion and diligence to accomplish a total business transformation.




Let us look at the mega development approach of Orchid. The multiple development approaches to fast-track business growth were. In fact, part of a grant strategy of business development. First of all, it started with a collaboration. The company collaborated with Sintofarm, Italy for technology in 1992, which served as the seed technology for the company. This was followed up with additional collaborations with SBD Laboratories, Italy for sterile Production 1994 and certain sterile products 1997.

The company signed at some point of time later co-marketing agreements with 4 Indian companies to boost domestic sale of formulations. That was in 2003. The other aspect was

that the company created its own division, not a separate legal entity, but its own division called Orchid Healthcare. That was in 1998. This acted as a division of the company to start the formulations business.

It also created a subsidiary called Orchid Research Laboratory Limited as a wholly owned entity for conducting new-comple entity research in 2004. The company entered into several joint ventures. One joint venture was that 50-50 joint venture with NCPC of China to manufacture Orchid's cephalosporin in APIs in China. From supplying fully finished APIs, the company moved into supplying technology, supplying basic materials and then finishing up the cephalosporin API products in China.

It also formed a 50-50 joint venture with Maxwell Biotechnology Inc of California USA for Drug Discovery in 2002. While this was happening, lots of facilities were being established in product development and manufacturing domains. Therefore, based on those kinds of capabilities, multiple alliances were struck with multiple partners in US and Europe for distribution of the products from 2004 and discovery of new chemical entities from 2006 onwards.

In terms of mergers and acquisitions, Orchid acquired Ajanta Pharma's API facility in Aurangabad in 2002. That reduced the cost of and also time of establishing a new brownfield base for manufacturing non cephalosporin APIs. Therefore, as compared to the Chennai plant which was Greenfield, the Aurangabad plant emerged as a brownfield development.

Orchid acquired the domestic formulations business of Mano Pharma in 2003, again another M and A activity. The company also acquired US-based marketing company, Karalex Pharma for direct-generics sales. The company simultaneously established subsidiaries in USA, Europe and Japan for regulatory development and local marketing know-how.

I have talked about subsidiaries being established in parallel with the strategic alliances without any conflict with the strategic alliance strategy. I said that strategic alliances would have their own purposes whereas, the subsidiaries would have other purposes which are

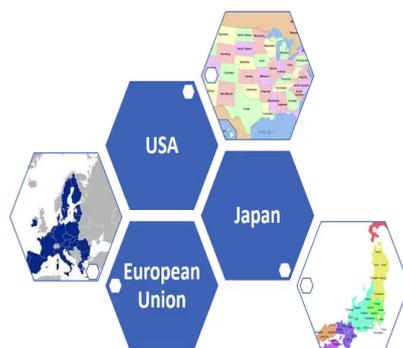
supportive to the strategic alliances. I also said that the subsidiaries would provide specific know-how in terms of drug regulatory filings and understanding of the market scenario.

So, subsidization even in parallel with strategic alliances is not a impossible thing and it could be even synergistic. This was highlighted by Orchid's strategy of business development. This vast strategic blueprint was executed with passion and diligence to accomplish a total business transformation in the company.

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Orchid Marketing Subsidiaries

It is remarkable that while Orchid pursued an aggressive, almost all-encompassing, alliance strategy for distributing its products in the regulated markets, it also established its subsidiaries in USA, EU and Japan.



These subsidiaries helped in regulatory filings, market exploration and supply chain logistics in the above markets.



Orchid's marketing subsidiaries helped the company pursue a very clear path in different geographies even in parallel to the alliance strategy. The subsidiaries were based in USA, Japan and Europe in Union. These subsidiaries helped in regulatory filings, market exploration and supply chain logistics in the above markets.

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Orchid's Strategic Alliances: Global Generics and Big Pharma R&D Model

Orchid's model of strategic alliances was an industry leading model that earned for the company global respect and trust as a partner of choice, besides earning millions of dollars in fees, royalties and profits.



Orchid's Mega Business Development Approach Earned Huge Revenues and Profits for the Company



When Business Strategy, Business Model and Business Development Work in Synergy, Results can be Amazing

Orchid's Mega Business Development Model recovered the investments made in the strategic transformation several times over. In addition, the strategy obtained for the company USD 400 million when the sterile injectables business was sold off to Hospira, a global generics player in 2010.



Let us look at the Orchid research subsidiary. In the earlier lectures I have detailed how a subsidiary strategy can help a company develop technologies and businesses of long-term value, independent of the short and medium-term imperatives of the main business. What are the mainstream technologies and ongoing businesses for Orchid?

These were APIs, dosage forms and for distribution. Innovative technologies and long-term value creators were normal drug discovery and creation of intellectual property and these were for big Pharma. Orchid research laboratories was intended to serve the big Pharma. It was a wholly owned subsidiary of Orchid chemicals and pharmaceuticals for drug discovery and development. It comprised two important ways.

One was the medical chemistry whereby you innovate and discover molecules which could have certain therapeutic effect based on identified disease pathways. Then you have in vitro

and immunobiology to prove whether the medicinal chemistry molecules are. In fact, acting in various types of cell based as well as animal based models. Orchid research laboratories also developed and executed its own multihorizon technology and business strategy.

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ORLL's Product and Services Strategy

Orchid Research Laboratories began focusing on contract development and collaborative development as short and medium term value developers while conducting proprietary drug development as long term value driver.

Project based services

- Pfizer
- Biovitrum
- Dermact etc.
- FTE or Fee for Service models

Collaborative Drug Discovery

- MNC oriented
- Therapeutic area based
- Risk-reward shared models

Proprietary Drug Discovery

- Multiple TAs
- FCC in animals
- FCC in humans
- Out-licensing

Scientific and Technological Competencies

Global Business Development Capabilities

Win-Win Alliances with Big Pharma and R&D Companies

All the three streams of drug discovery were carried out in collaboration or alliance with Big Pharma or niche R&D companies. These activities required extensive business development to structure win-win arrangements.



ORLL's product and services strategy were developed as follows. It began focusing on contract development and collaborative development as short and medium-term value developers. It also conducted proprietary drug development as a long-term value driver. So, the first horizon for ORLL was the project based services portfolio. It covered companies such as Pfizer, Biovitrum, Dermact etcetera. As a full-time equivalent service or a fee-for-service model.

Then the collaborative drug discovery constituted the second horizon. It was completely oriented towards multinational corporations. It was therapeutic area based and it shared risk

and reward with the MNC's sponsors. Then the proprietary drug discovery horizon which is the third horizon, the long-term horizon considered multiple therapeutic areas focused on proof of concept in animals, proof of concept in humans and out licensing.

This was made possible by scientific and technological competencies that were built up over a period of time. Global business development capabilities to bring the big pharma companies to Orchid for alliances and collaborative arrangements. And the win-win nature of alliances with all these big pharma companies.

All the three streams of drug discovery were carried out in collaboration or alliances with big pharma or niche R and D companies such as Biovitrum and Dermact. These activities required extensive business development to structure win-win arrangements. So, the concept of multi horizon and business development was deeply ingrained in Orchid whether it was API, dosage forms or drug discovery.

The multi horizon approach provided always a core foundation and emerging foundation and a futuristic foundation. That was the essence of business development at Orchid.

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Orchid Research Laboratories Limited (ORLL)

In respect of ORLL, one of the key objectives was to establish a scientific and technological infrastructure that connects with the business objectives of discovering and developing novel chemical entities and providing R&D services.

Business	<ul style="list-style-type: none">• A wholly owned subsidiary of Orchid Chemicals & Pharmaceuticals for drug discovery• An integrated research company with end-to-end capabilities in drug discovery and development• Among the top ranked pharmaceutical discovery entities in India, with global standing
Objectives	<ul style="list-style-type: none">• Discovery and development of New Chemical Entities (NCEs)• Custom Research and Manufacturing Services (CRAMS)
Facilities	<ul style="list-style-type: none">• Drug Discovery Centre, Biology Centre, Animal House cum Pre-clinical facility, CMC Facility, Analytical Centre, Formulation Facility in Chennai, India• R&D Facilities GLP accredited by the National GLP Authority of India, aligned with OECD Principles
Employees	<ul style="list-style-type: none">• Scientific base of 130 plus with several doctoral and post-doctoral scientists• Access to 200 plus scientists in other R&D and technical domains of the Parent organisation
Recognition	<ul style="list-style-type: none">• Partner of choice in 'Contact Research – Collaborative Drug Discovery' awarded by Frost & Sullivan





State-of-the-art laboratory facilities together with accomplished scientific manpower made ORLL a partner of choice.

So, let us look at Orchid research laboratories in greater detail. The key objective was to establish a scientific and technological infrastructure that connects with the business objectives of discovering and developing novel chemical entities and providing R and D services.

It was an integrated research company with end-to-end capabilities in drug discovery and development, ranked among the top pharmaceutical discovery entities in India with global competitiveness. There were objectives which are related to new chemical entities as also customer research and manufacturing services called CRAMS.

And the facilities were world-class covering the entire value chain of drug discovery. It had a scientific base of 130 plus people with several doctoral and postdoctoral scientists and access to 200 plus scientists in other R and D and technical domains of the parent organization.

The entity was recognized as the partner of choice in contract research collaborative drug discovery awarded by Frost and Sullivan. You can see the photographs of the state of the art facilities the Docket had. These facilities together with the accomplished scientific manpower made ORLL a partner of choice.

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A Vision within a Vision

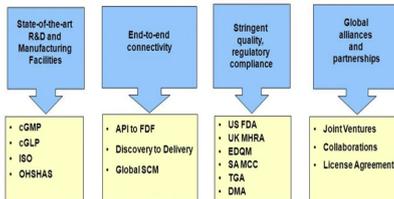
ORLL as a subsidiary had a distinct vision and focus but one which was an integral part of the broader vision for Orchid.



Orchid's Vision is to...

Become an Integrated Pharmaceutical Corporation of Global Scale and Standing, with a Comprehensive Coverage from Discovery to Delivery

Key Differentiators



The unique value proposition was that ORLL not only had strong core competence in drug discovery and development but also was an integral part of a broader US FDA approved API and Dosage Form infrastructure.



ORLL as a subsidiary had a distinct vision and focus, but that was one which was within the overall vision of the company. If Orchid's vision was to become an integrated pharmaceutical

corporation of global scale and standing with the comprehensive coverage from discovery to delivery.

The company had state of the art R and D and manufacturing facilities which are CGMP compliance, CGLP compliance, ISO compliance and OSHAS compliance. It had end-to-end connectivity from API to F FDF, discovery to delivery and global supply chain management. Stringent quality and regulatory compliance satisfying the requirements of all the international regulatory agencies.

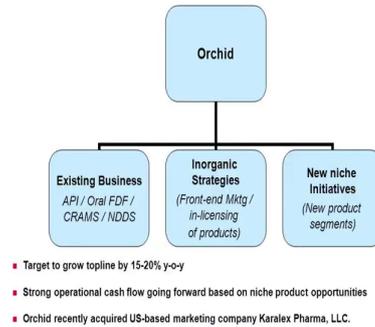
Global alliances and partnerships in form of joint ventures, collaborations and license agreements with reputed generic and bid pharmaceutical companies. The unique value proposition was that ORLL not only had strong core competency in drug discovery and development, but also was an integral part of a broader US FDA approved API in dosage form infrastructure.

Therefore, if somebody were to develop a new molecule that company would need to go anywhere else for taking the clinical trial batches and even piloting the product and stepping up to the commercial scale manufacture. That is the kind of breadth of service that was available through ORLL as well as the parent company Orchid.

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Growth Strategy

However specialised an entity is or whichever industry the entity belongs to, a corporate business strategy helps.



As a transformational company, Orchid had a clear roadmap for the future, with each facet backed by highly capable infrastructure.

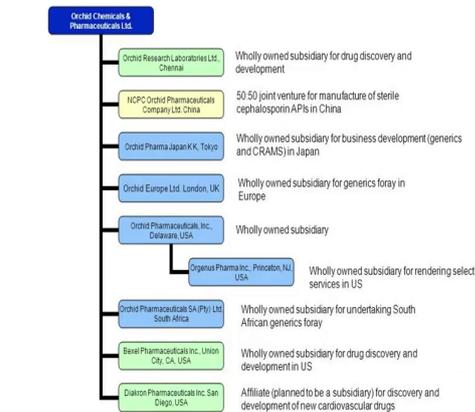


So, the growth strategy was existing businesses, in organic strategies and new initiatives and that helped the company grow top line consistently, generate operational cash flow and take up further requisitions based on the need for further market expansion.

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Orchid Group Corporate Structure

The following provides a pictorial presentation of the expansive business canvas and corporate structure of Orchid.



Of the above, three are R&D oriented subsidiaries. However, ORLL served as the lead R&D subsidiary for the firm.



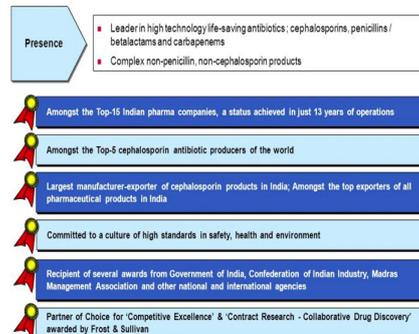
So, this was the total corporate structure of orchid. The parent Orchid Chemicals and Pharmaceuticals Limited. The subsidiaries, Orchid Research Laboratory Limited, NCPC Orchid Pharmaceuticals Company China, Orchid Pharma, Japan, KK Tokyo, Orchid Europe Limited, London, UK, Orchid Pharmaceuticals Inc, Delaware, USA which had Orgenus Pharma, a US subsidiary.

Then Orchid Pharmaceuticals in South Africa, Bexcel Pharmaceuticals in California for drug discovery and Diakron Pharmaceuticals Inc San Diego again for drug discovery. Of the above three are R and D oriented subsidiaries. However, ORLL served as the lead R and D subsidiary for the firm.

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Domain Competence: Fundamental to Business Leadership

A core driver for business development by a firm stems from the market recognition of its domain competence.



Apart from domain competence, organisational competence drives a firm's success in business development.



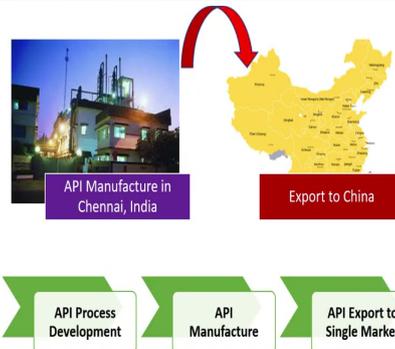
Domain Competence is fundamental to business leadership and business leadership again is fundamental for successful business development. A core driver for Orchid's business development stems from the market recognition of its domain competence in number of the rapidic areas, number of products and having ranking amongst the top 15 or top 5 whichever way you look at the company.

Also being the largest manufacturer, exporter of antibiotic products in from India also earned the company lot of global recognition. Recipient of several lovers from various government agencies, industrial bodies and selection of partner of choice by several independent consulting organizations. Therefore, at the core has been domain competence supported by organizational competence.

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Organizational Redesign: Pharmaceutical Example, the Start

Organizational Redesign in Orchid is illustrated with the movement of the firm from only Active Pharmaceutical Ingredients (APIs) to a fully integrated operation covering APIs and FDFs.



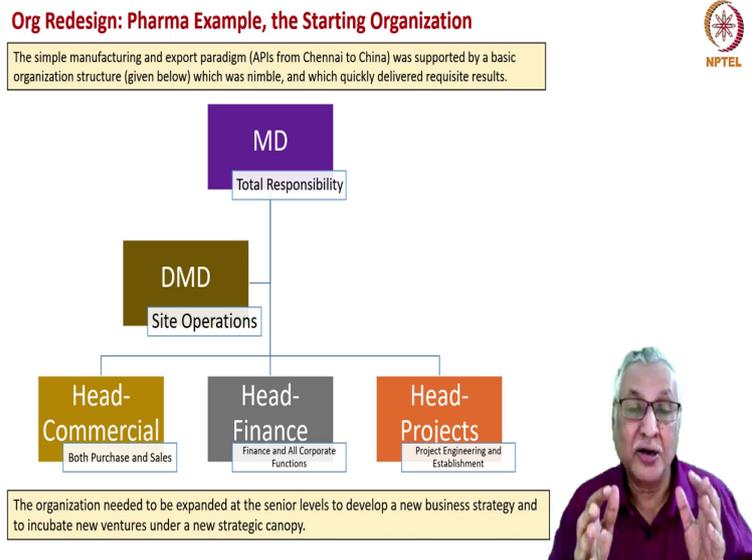
As discussed in earlier lectures, the company started its business journey with the simplest value chain which secured for the company a very effective foothold in the pharmaceutical industry, providing a base for ramp-up.



This has been carried out meticulously. Structure follow strategy, Alfred Chandler said, Orchid's case study proves this once again. As the strategy evolved, the structure followed and the structure was always established to keep the forward looking strategy happening in actual execution. So, from API manufacturing in Chennai in India to export to China, the company moved into a fully integrated operations covering APIs and FDFs.

So, API process development, API manufactured and API export to single market were of course, the core basic foundations. However, this simple value chain has been transformed into a huge value map. So, to say for the company and the foot hold that was originally brought in with the simple value chain became a global presence with a modified and expansive strategic script for the company.

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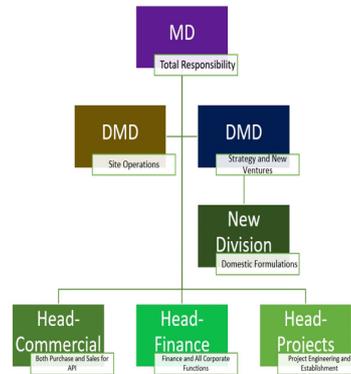
The organization structure in the beginning was very simple. MD had total responsibility for the company. There was a deputy managing director, well-versed in API technology. He was looking after the site operations at API plant in Chennai. There were only three heads, one for commercial covering both purchase and sales, one was for finance and all other corporate functions and one for projects including project engineering and establishment.

However, as the company thought about a new business strategy and a new global presence, the organization needed to be expanded at the senior levels to develop such a new business strategy and to incubate new ventures under a new strategic canopy. In any strategic transformation, incubation of new ventures, new businesses is an important task of corporate leadership.

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Org Redesign: Pharma Example, the Exploring Organization

It was important to add senior leadership capability to envision a new future, develop a new strategy and roll it out with incubation of new strategic ventures.



Creation of new leadership nucleus resulted in the development of a new strategic blueprint that required massive expansion of the strategic canvas, developing the company into an integrated and diversified global pharmaceutical corporation, operating both in Regulated Markets (RMs) and Less Regulated Markets (LRMs).



This need to add senior leadership capability was well recognized in time by the company and that has been at the base of the success of strategic expansion. MD continued to have total responsibility, but supplementing the DMT in the site operations and new DMT for strategy and new ventures came in which is the instructor.

And that also brought forth a new division called domestic formulations, division of health care for bringing up the formulations business. Then we had the three heads, head commercial, both purchase and sales for API, head finance for finance and all corporate functions and then head process for project engineering and establishment.

However, creation of the new division for strategy and new ventures started the strategic transformation program. A new strategic plan was established and new ventures began to be

incubated by the new deputy managing director. Creation of the new leadership nucleus resulted in the expanded strategic canvas.

It developed the company into an integrated and diversified global pharmaceutical cooperation, operating both in regulated markets and less regulated markets. Creation of organization is very important for accomplishing something which has not been done so far.

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Org Redesign: Pharma Example, the Strategic Drivers



There were four strategic drivers for the mammoth expansion and diversification envisaged by the company, considered ambitious (and even adventurous) for a first-generation enterprise.



To be able to undertake the above transformation, the company needed to create new value chains with multiple core competencies in the organization.

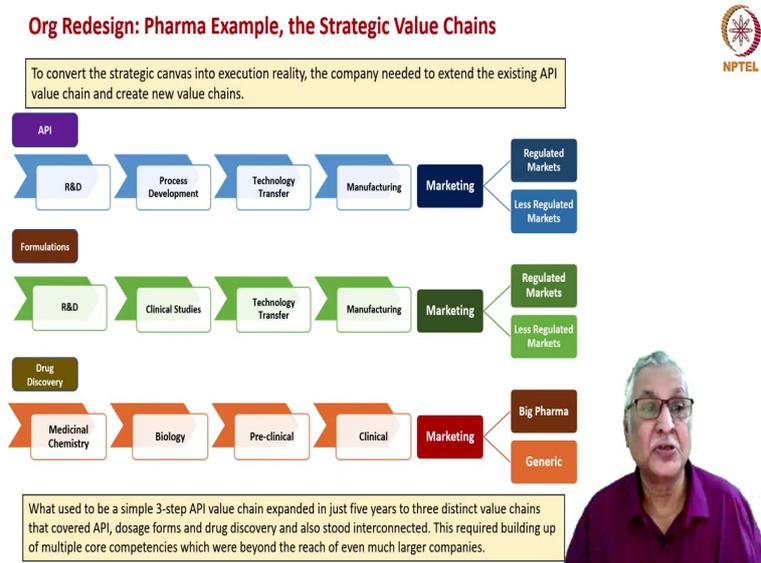


In this organization redesign, there were four key strategic drivers that supported the mammoth expansion and diversification and these were even considered ambitious and adventurous the way people looked at it. And certainly, it was very bold attempt for a first generation enterprise. Focus continued to be on sterile injectables products.

There was a forward integration into formulations. There was a simultaneous diversification into the related markets. World class R and D and manufacturing facilities with US FDA approvals were set up and diversification was carried out into new drug discovery and now alternate development.

To be able to undertake the above transformation, the company needed to create not merely people or teams of people. It created a whole new value change system with multiple core competencies in the organization.

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You can see that here. The organization redesign was metressed by creation of new strategic value change. In the API field, R and D process development, technology transfer,

manufacturing and marketing again to regulated markets and less regulated markets. The game the new expansive value chain organized in respect of each product line.

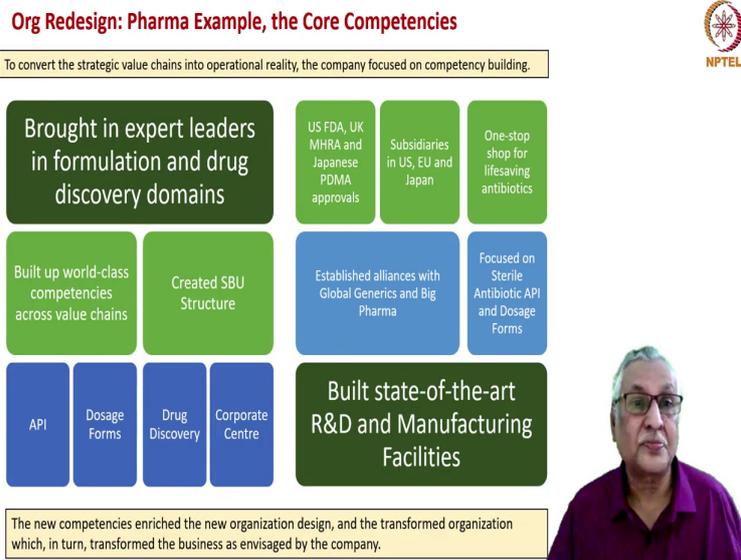
The challenge with the antibiotic API manufacture was that no antibiotic can be in the same location as another antibiotic in terms of buildings. Also, there cannot be any cross contamination of any antibiotic with another antibiotic and any antibiotic with any other non antibiotic because of the risk of an allergic shock that could exist in a very very small portion of the population.

Therefore, all these facilities have to be completely separated. People have to be separate; materials have to be separate. The logistics of movement have to be separate. It is a big challenge, but this also is an entry barrier once the company masters this capability.

Similarly, formulations were organized in terms of three distinct blocks and the fourth one being the non antibiotic block. R and D clinical studies, technology transfer, manufacturing and marketing again for regulated markets and less regulated markets. Then discovery was organized in terms of medicinal chemistry, biology, preclinical, clinical, marketing, big pharma and generic. So, you can see that a whole lot of new competencies were brought into the company and new value chains were created.

What used to be a simple three step API value chain expanded in just five years to three distinct value chains that covered API dosage forms on drug discovery and also stood interconnected. This required building up of multiple core competencies which would be behind the reach of even much larger companies at that point of time.

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To convert this strategic value chains into operational reality, the company focused on nothing, but competency building. Brought in expert leaders in formulation and drug discovery domains, built up world-class competencies across value chains created SBU structure for API, dosage forms, drug discovery and a corporate center.

Approvals were sort of very importantly, US FDA, UK MHRA and Japanese PDM approvals were obtained. Subsidiaries were established in US, Europe and Japan and the company positioned itself as the one stop shop for life saving antibiotics. Established alliances with global generics and big pharma.

The company focused on sterile antibiotic API dosage forms, built state of the art or Indian manufacturing facilities. The new competencies enriched the new organization design and transformed the organization in the overall and this transformed in turn the business as an

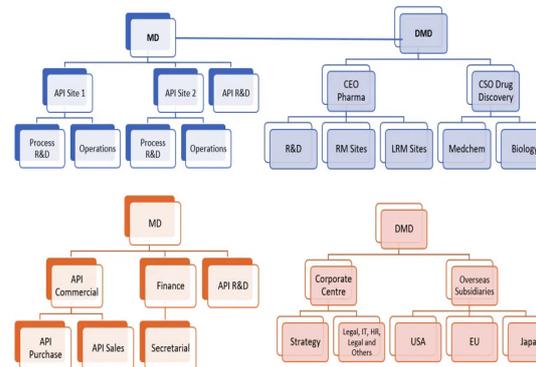
instigated by the company. So, you have the strategy then the organizational structure supported by the business and facility structure and that led to business development of the highest order possible.

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Org Redesign: Pharma Example, the Redesigned Organization



To provide the necessary growth impetus and operating autonomy within the 'one-firm' canopy, the company implemented the Strategic Business Unit (SBU) structure. This paid rich dividends.



Close collaboration between MD and DMD, and empowerment of DMD, CEO and CSO helped the company accomplish a strategic transformation in the pharma industry that had few parallels.



You can see the organization structure, how it evolved. To provide the necessary growth, impetus and operating autonomy within the one firm canopy. The company implemented the SBU structure that is strategic business unit structure this paid rich dividends. You have managing director who continue to look after API site 1, API site 2, API R and D and API site 1 had its own process R and D operations and similarly API site 2 had its own process R and D operations.

The new deputy managing director began looking after the pharmaceutical operations with a CEO to support and looking after the drug discovery operations with a chief scientific officer

to support. The CEO for pharmaceuticals had R and D, regulated market sites as well as less related market sites.

The CSO for drug discovery had medchem and biology. Not only that from a corporate point of view there was a fair allocation of responsibilities between the MD and the deputy managing director. The managing director had API commercial finance API R and D and API commercial looked after API purchase and API sales whereas, finance looked after secretarial and other functions.

The deputy managing that in terms of the corporate functions looked at the corporate center which had strategy, legal, IT, HR and others under the belt and also the overseas subsidiaries such as the USA, EU and Japan subsidiary. Close collaboration between MD and DMD and empowerment of DMD, CEO and CSO helped the company accomplish a strategic transformation in the pharma industry that had few parallels.

I must also mention that before this change started happening, the DMD who was in charge of the API operations moved over to start his own enterprise and MD began looking after the API operations in the totality whereas, the deputy managing director newly joined in 1998 started looking after all the pharmaceutical drug discovery and corporate functions.

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Orchid's Strategic Alliances: US, EU Generics Model

Orchid's model of strategic alliances for generic pharmaceutical products was based on hypotheses that visualised mutual complementarity with the partners, thus paving the way for mutual success.



Without any conflict with such strategic distribution alliances, Orchid also established its front-end regulatory and marketing subsidiaries in the advanced markets such as USA, Europe and Japan.



One of the highlights of Orchid's business development has been the era of strategic alliances. The US EU Generics model that has been pioneered by Orchid had no parallels in the industry. The hypothesis were one of mutual complementarity with the partners and mutual synergy in terms of facilities, intellectual property and marketing development capabilities.

Basically, the alliances looked at product development and manufacture by Orchid with distribution and sales by the partner. So, there were several facets of this generics model. Orchid established strategic long-term alliances with global generic players. None was for short-term requirements. Everything was for long-term. And the idea was that Orchid would develop and manufacture the products and the alliance partners would distribute Orchid's products in USA and EU.

Orchid licensed the products to the partners for distribution in return for payment of development and licensing fees by the partners. Orchid would develop and manufacture the products from the US FDA and UK MHRD facilities and supply to the partners based on pre-agreed cost of goods.

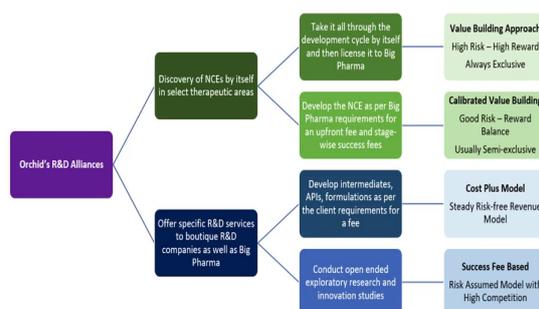
Orchid and the partners would share the net profits arising from the sale of products in the markets in pre-agreed proportions. The arrangements incorporate mutual performance parameters in terms of market share and supply performance. The typical initial term ranges from 5 to 10 years from the date of first product launch in each product case and renewable based on mutual agreement.

Typically, the partnerships offer clusters of products which can be expanded with geographical extensions as appropriate based on mutual performance. Without any conflict with such distributional alliances, Orchid also established different types of strategies as I mentioned in the earlier slide. And these were in the advanced markets of USA, Europe and Japan.

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Orchid's Strategic Alliances: Big Pharma R&D Model

Orchid's model of strategic alliances in the R&D domain was based on either providing proven novel medicines for licensing or rendering R&D services for a fee, thus making Orchid a part of Big Pharma's global R&D value chain.



Similar model as the outright licensing model was adopted by Bexel Pharma while Diakron adopted the third model.



As far as the big pharma and discovery was concerned, the model of strategic alliances was different. It was based on either providing proven novel medicines for licensing or rendering R and D services for a fee thus making Orchid a part of the big formless global R and D value chain. So, Orchid's R and D alliances were of two types. Discovery of new chemical entities all by itself in select therapeutic areas or offer specific R and D services to boutique R and D companies as well as big pharma.

In the first class, that is the discovery of new chemical entities by itself, the goal was to take it all through the development cycle by itself and then license it to big former. The other goal was to develop the NCE as per the big pharma requirements for an upfront fee and stage wise success fees. And in respect of specific R and D services, the idea was to develop intermediates, APIs, formulations as per the client requirements against a fee that is provided.

The other option was to conduct open-ended exploratory research without asking anything upfront, but offering it as and when required and as innovation studies. The first one of taking it all through the development cycle by itself and then licensing was the highest value building approach.

It entailed high risk, but also provided high reward and it was always exclusive. I mentioned in one of the earlier lectures that Orchid is indeed the first company which has developed a new antibiotic beta lactamase inhibitor which is a new chemical entity and which has gone through all the rounds of human clinical trials and is now being used in the Chinese and European markets for potentiating known cephalosporins antibiotics. And this is a great achievement by the company.

In the second category of developing NCE as per big pharma requirements, we can see this as a calibrated value building, good risk reward balance and it is usually semi-exclusive. The first one is always exclusive to the partner. In the third one of developing intermediates, APIs and formulations as per the client requirements, we have the cost plus model operating.

It is a steady risk free revenue model. And conducting of open-ended exploratory research and innovation studies is a success fee based model where the risk is assumed by orchid, but it also entails high competition within the Indian contract development and manufacturing organizations.

Similar model as the outright licensing model was adopted by Bexel pharma while Diakron adopted the third model. So, even in the exclusive field of R and D, Orchid innovated in terms of the business development approaches and came up with as many as four different approaches to cater to the requirements of big pharma or companies looking for R and D services.

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My Stint in First Generation Pharmaceutical Enterprise

Starting from the incorporation (July 01, 1992) as a non-executive board member and from August 1998 as a fulltime deputy managing director, I could lead the transformation from a bulk drug-China based company into a fully integrated and diversified pharmaceutical corporation, oriented towards sterile injectables and regulated markets.

Big Pharma Alliances

Generic Alliances

2006: FDF and API, NDD and NDDS: RM and LRM

2000: API and LRM and RM

1994: API and LRM

Subsidiaries in US, EU and Japan

Manufacture of Sterile and Oral FDF in Chennai

New Advanced R&D and Manufacturing Facilities

India Marketing Business

Manufacture of API in Aurangabad

Alliances with Global Generic Companies

R&D of API in India

Manufacture of API in Chennai

Selling in China

Big Pharma Alliances: MERCK, Pfizer, Forest Laboratories, Inc., astellas, biovitrum, zoetis

Generic Alliances: APOTEX, STADA, PAR, actavis, meynepharm, Hospira, MEKESON

Legend: API – Active Pharmaceutical Ingredient; FDF – Finished Dosage Form; LRM – Less Regulated Market; RM – Regulated Market (US, EU, Japan); R&D – Research & Development; NDD – New Drug Discovery; NDDS – Novel Drug Discovery

Strategy and structure combined to power relentless business integration and diversification at Orchid Pharma between 2002 and 2010, a period praised as transforming a first-generation enterprise into a global pharma company.



My stint in this first generation pharmaceutical enterprise has been exciting and value adding to the company. Starting from the incorporation July 1, 1992 as a non-executive board member and from August 1998 as a full-time deputy managing director, I could lead the transformation from a bulk drug China based company into a fully integrated and diversified pharmaceutical corporation oriented towards sterile injectables under related markets.

Therefore, there were three concentric boxes of development that I could drive. In 1994 it was all API unless regulated market manufactured the API in Chennai and sell it in China. In 2000 API, LRM and RM. Manufacture of API in Aurangabad alliances with global generic companies and R and D of API in India that supplemented the base model. In 2006 finished dosage forms and API, neutral discovery and all drug delivery systems both for RM and LRM.

Subsidiaries in US, EU and Japan came up. Manufacture of sterile and oral finished dosage forms in Chennai came up. New advanced R and D and manufacturing facilities came up and India marketing business came up. And the kind of generic alliances which I could bring for Orchid or BINI, Apotex, Stada, Par Pharmaceuticals, actavis, mayneformer, Hospira and Mckesson.

These are all global leading generic companies and the product portfolios for each were different. And that is the value that a company can generate when it focuses itself on product and manufacturing competencies. The big pharma alliances were with Merck, Pfizer, Forest Laboratories, astellas, Biovitrum and zoetis.

If you look at this whole scene, you can realize that strategy and structure combine to power relentless business integration and diversification at the Orchid pharma between 2002 and 2010. A period that is praised unanimously as transforming a first generation enterprise into a global pharma company.

Indian pharmaceutical industry has been the pharmaceutical capital of the world by virtue of supply of the generic products. But what Orchid demonstrated is far more than that and far greater than that it demonstrated that you can do within that product space, highly complex and highly technology oriented sterile dosage forms which required highest quality manufacturing facilities.

It could generate investments and invest in such facilities both in terms of R and D and manufacturing. It could structure alliances with globally reputed generic and big pharma companies and in fact, supply those products all over the world based on such alliances.

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Orchid's Strategic Alliances: Global Generics and Big Pharma R&D Model

Orchid's model of strategic alliances was an industry leading model that earned for the company global respect and trust as a partner of choice, besides earning millions of dollars in fees, royalties and profits.



Orchid's Mega Business Development Approach Earned Huge Revenues and Profits for the Company



When Business Strategy, Business Model and Business Development Work in Synergy, Results can be Amazing

Orchid's Mega Business Development Model recovered the investments made in the strategic transformation several times over. In addition, the strategy obtained for the company USD 400 million when the sterile injectables business was sold off to Hospira, a global generics player in 2010.



Orchid strategic alliances, big pharma R and D model combined with the big generic model was an outstanding success. Orchid's mega business development approach earned huge revenues and profits for the company. Around USD 100 million were earned in development and licensing fees and several millions of dollars were earned in profit shares.

And there has been a multi-million dollar business development outcome that happened because of the specific business development approaches that Orchid has pursued. And the lesson for all of us is that even business strategy, business model and business development work in synergy results can be amazing.

Orchid's mega business development model recovered the investments made in strategic transformation several times over. In addition, the strategy obtained for the company 400 million US dollars when the sterile injectables business was sold off to HOSPIRA in 2010.

And Hospira was a global generics player that was capable of taking up the further development of this sterile injectables business.

And the deal was done in such a manner that Orchid continued to supply its active pharmaceutical ingredients on exclusive or non-exclusive basis depending upon the product category to the height of business. Therefore, it continued to earn the revenue streams from the API. Hospira continued to do injectable formulations for itself, but it also was doing overall formulations for Orchid because the facility was part of the sterile injectables facility that was spun off.

And there was lot of synergy in terms of approaching the markets. Some markets which were not of Hospira's interest were reserved for Orchid to be carried out through the LRM facilities that the company had or any other contract manufacturing facility. Again, this proves the point that any divestment, any restructuring, any subsidization or any strategy alliance or any M and D operation can be made highly synergistic for both the parties.

If the fundamental premises are well understood by both the parties and a win-win approach is adopted during the negotiation and deal finalization process. So, this is an important lesson in business development and many of the principles that I have covered throughout this course are explicit in the way this case study has unfolded in terms of the product development, facility development, product delivery and alliance construction. In this way we come to the end of this lecture.

I thank you very much for your kind attention. We will meet again in the next lecture.