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Internationalization of Indian Pharmaceutical Industry

By Dr. Amisha Gupta
Delhi University

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Internationalization of Indian Pharmaceutical Industry

Dr. Amisha Gupta

Abstract- **Entry strategies are one of the important decisions in the process of internationalization. Decision on entry mode is one of the most critical decisions having significant and far-reaching consequences on a firm's performance and survival in the target foreign market. This study focuses on the path of internationalization of Indian Pharmaceutical industry and makes an attempt to identify the major determinants influencing entry mode decision. The study concludes that both firm specific as well as the policy changes at the country levels, host country's as well as domestic policies together influences the decision of the firm on entry mode.**

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I. Introduction

Indian economy is currently booming. More and more Indian industries and companies are expanding their activities in foreign markets. It is seen that the destination, mode of internationalization and motivations for global expansion are changing. Literature has established the factors that are most influential in deciding the modes of internationalization for Indian pharmaceutical companies. It was considered important to validate the results by evaluating the current scenario and trends for modes of internationalization in the industry. Therefore, a detailed analysis of five leading pharmaceutical companies of India is conducted. These companies have extensive experience in both domestic as well as foreign markets and therefore warranted a detailed study on their approach and experience in various modes of internationalization.

This paper lays out the detailed internationalization efforts of top 5 Indian pharmaceutical companies. These companies were ranked based on their revenue (2013-14). Top 5 companies by revenue were selected from the big size category. These companies are Sun Pharma, Dr. Reddy's laboratories, Cipla, Lupin and Aurobindo Pharmaceuticals. This category is the most active in internationalization efforts and have gone through multiple modes of internationalization in their evolution. Complete history of the companies is studied to understand the reasons for various modes of internationalization decisions during different stages of the company's life. Table 1 below details out some general characteristics of these companies.

Table 1: General characteristics and performance of Big size companies

Name of the firm	Aurobindo	Cipla	Dr. Reddy's	Lupin	Sun Pharmaceuticals
Year of Incorporation	1986	1935	1984	1968	1983
location of the firm	Hyderabad, Telangana, India	Mumbai, Maharashtra, India	Hyderabad, Telangana, India	Mumbai, Maharashtra, India	Vadodara, Gujarat, India
R&D facilities	8	14	8	6	10
Product specialization	Antibiotics, Anti-Retroviral, CVS, CNS, Gastroenterological, and Anti-Allergic.	Inhalation therapy	Diabetes, cardiovascular, inflammation and bacterial infection.	specializes in anti -TB medications	Neuro-Psychiatry, Cardiology
Manpower,	9,500	20,000	19,000	14,000	30,000
Sales	$1.25 bn	$1.6 bn	$ 2.2bn	$ 1.89 bn	$ 2.56 bn
Exports as a share of total sales	70%	60%	85%	78%	75%

II. Aurobindo Pharma

Aurobindo Pharma was founded in 1986 by Mr. P.V. Ramaprasad Reddy, Mr. K. Nityananda Reddy and a small group of people. The company commenced operations in 1988-89 with a single unit manufacturing Semi-Synthetic Penicillin (SSP) at Pondicherry. Table 2.1 lists some basic facts about the company.

Author: Business Economics Department, Delhi University.
e-mail: amisha005@gmail.com

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Table 2.1: Aurobindo Pharma – basic facts

Headquarters	Hyderabad, India
Public or Private	Public
Year of Establishment	1986
Revenues (2013-14)	$1.25 bn
Specialties	R&D, Manufacturing Capabilities, Regulatory Approvals

a) Synopsis of the Company

Aurobindo Pharma became a public company in 1992 and listed its shares in the Indian stock exchanges in 1995. It has a presence in key therapeutic segments such as neurosciences, cardiovascular, anti-retrovirals, anti - diabetics, gastroenterology and cephalosporin, among others.

The company entered the specialty generic formulations segment through cost effective manufacturing capabilities. Today, after a decade or so, it has evolved into a global company manufacturing API's and formulation products based on its innovation capabilities. Aurobindo's R&D capabilities has resulted in filing of multiple patents, Drug Master Files (DMFs), Abbreviated New Drug Applications (ANDAs) and formulation dossiers across the world. In fact, AurobindoPharma is among the largest filers of DMFs and ANDAs from India.

Aurobindo exports to over 125 countries across the globe. Around 70% of its revenues are derived out of international operations. It's manufacturing units have been approved by leading regulatory agencies such as USFDA, EU GMP, UK MHRA, South Africa-MCC, Health Canada and Brazil ANVISA.

Aurobindo Pharma Ltd. has evolved into a knowledge driven, R & D focused company, with its manufacturing and marketing infrastructure spread across many countries. Aurobindo has invested significant resources in regulated markets by designing five of its units for APIs and five units for Finished Dosages. These units are approved by US FDA, UKMHRA, WHO, MCC-SA, ANVISA-Brazil, and TGI-Australia. Aurobindo has a robust product portfolio of over 400 generic specialties.

b) Path to Internationalization

Aurobindo has been very active in the international pharmaceutical space. Aurobindo started internationalizing in the 1990's by setting up subsidiaries in various countries. This was followed by doing strategic acquisitions in 2000's to enhance company's product portfolio and access new markets. Table 2.2 below details the international operations of Aurobindo.

Table 2.2: International Operations History – AurobindoPharma

Year	Modes of internationalization	Company Name	Country	Motivating Factor
1998	Subsidiary		USA	International presence
1998	Subsidiary		China	International presence
1999	Subsidiary	Aurobindo (H.K.) Limited	Hong Kong	Market access
1999	Subsidiary	APL Pharma Thai Limited	Thailand	Market access
1999	Joint Venture		Brazil	Resource seeking
1999	Joint Venture		China	Resource seeking
2000	Joint Venture		USA	Resource seeking, Facilitating manufacturing of formulations
2001	Subsidiary	AB FarmoQuimicaLimitada	Brazil	
2002	Joint Venture		USA	
2003	Joint Venture	Shanxi Tongling Pharmaceuticals	China	Resource seeking for manufacturing of Penicillin.
2004	Subsidiary	Aurex Generics Ltd	UK	
2004	Joint Venture		USA	This deal helped the company to locally manufacture in USA.
2005	acquisition	USFDA approved manufacturing facility		The basic purpose was to facilitate the growth platform.
2006	Acquisition	Milpharm	UK	inorganic growth in Europe to reduce the time to market and enhance the relationships in the generic value chain
2006	Acquisition	Pharmacin International B.V.	Netherlands	Market seeking
2007	Subsidiary		Japan	Market seeking for generics
2008	Acquisition	TAD	Italy	Italian operations of German pharmaceutical major TAD Pharmaceuticals

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2009	Licensing Agreement	Pfizer		Aurobindo has strong manufacturing facilities. This agreement will help Aurobindo with a support in marketing and sales.
2011	Licensing Agreement	Astra Zeneca		This agreement accelerates the growth plans of the company and also increases the range of branded medicines.
2012	Joint Venture	Diod	Russia	Helps in international expansion and maintain relationships with local companies in target markets.
2013	Acquisition	Actavis	Western Europe	This acquisition will help Aurobindo to attain strong position in European market.
2014	Acquisition	Natrol	USA	Market penetration in U.S. A

Aurobindo has been present in the US market for quite a long time. It set up its first ever subsidiary in the US in 1984 and followed it up by multiple agreements, joint ventures and acquisitions in that market.

Aurobindo was a late entrant in the European market. It first acquisition was that of UK based Milpharm in 2006. This acquisition was to kick start inorganic growth in Europe to reduce the time to market and enhance the relationships in the generic value chain.

Aurobindo Pharma concluded a strategic deal to acquire Italian operations of Germany based TAD Pharmaceuticals in 2007. This acquisition gave Aurobindo access to more than 70 ready to market products. This strategic acquisition is expected to jump start the business for Aurobindo in Italy where the market and the regulatory procedures are considered as the one of the toughest in all EU. Aurobindo also acquired high profile OTC brands - Mapooro and Carmiooro from TAD as a part of this deal. This was company's third acquisition in Europe, after acquiring Milpharm Ltd in UK and Pharmac in International B.V., in Netherlands. The Company believes that such acquisitions reduce the time to market and enhance the relationships in the generic value chain in addition to building a broad and formidable product portfolio.

c) Analysis & Conclusion

Fig. 2.1 and 2.2 below show the correlation of Aurobindo's export intensity with R&D expenses and total assets. In both the cases, it can be said that they are positively correlated with Aurobindo's export intensity.

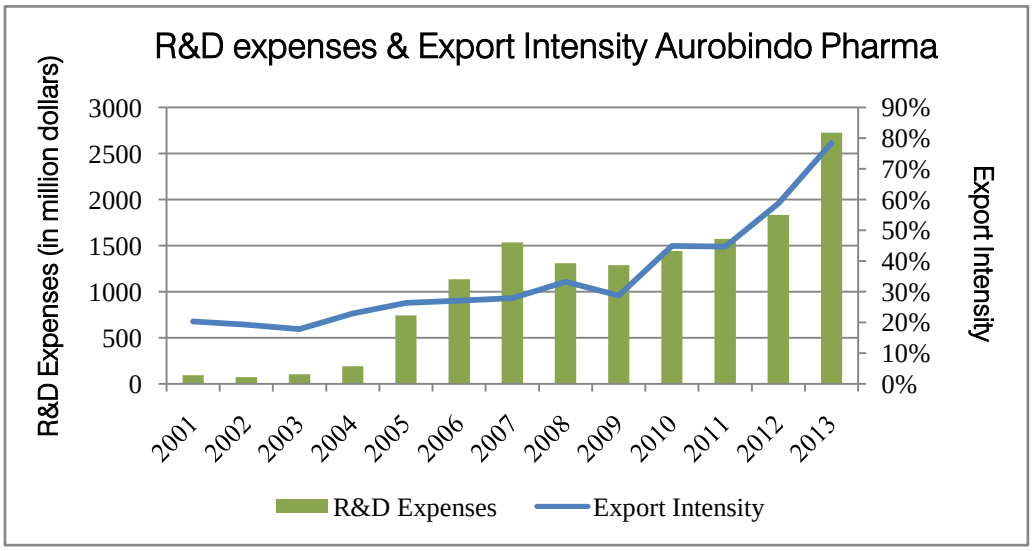


Figure 2.1: R & D expenses & Export Intensity – AurobindoPharma

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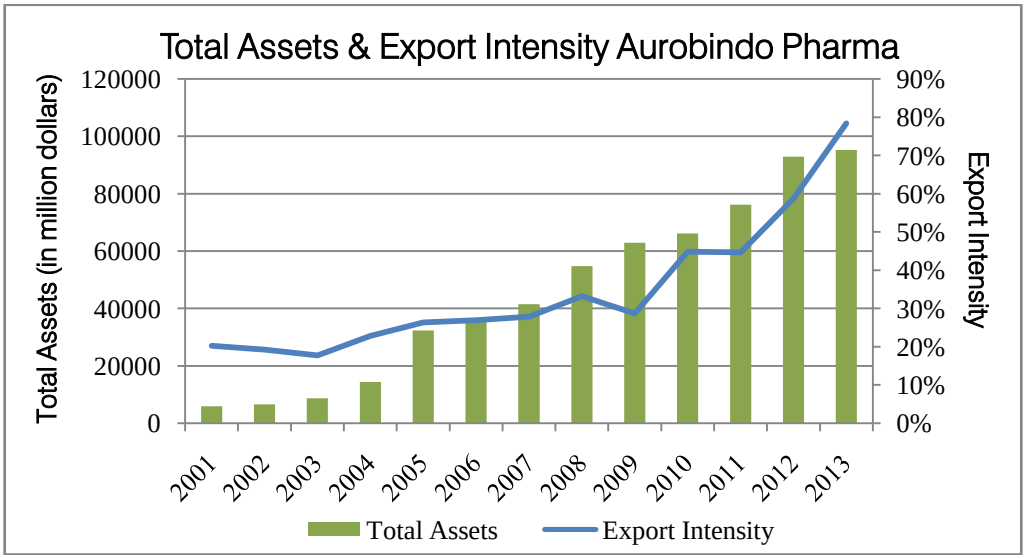


Figure 2.2: Total Assets & Export Intensity – AurobindoPharma

To conclude it can be said that Aurobindo-Pharma has identified international operations as a major part of its growth strategy. It has been gradually expanding its global network of marketing and manufacturing operations. Geographically, its focus has been majorly on China, Brazil, Japan, Netherlands, South Africa, Thailand, UK, USA and Russia. It can be said that subsidiary has been its most preferred modes of internationalization. Aurobindo is today well positioned to surmount any further challenge in international expansion.

III. Cipla Pharmaceuticals

Cipla is a global pharmaceutical company. It is one of the oldest pharmaceutical companies in India and is present in more than 170 countries across the world. The list of countries includes the U.S., Canada and countries in Europe, Africa, Australia, Latin America and the Middle East.

Table 3.1: Cipla – Basic Facts

Headquarters	Mumbai, India
Public or Private	Public
Year of Establishment	1935
Revenues (2013-14)	$1.6 bn
Specialties	Pharmaceuticals

a) Synopsis of the Company

Cipla have 34 manufacturing facilities that make Active Pharmaceutical Ingredients (APIs) and formulations, which have been approved by major international Regulatory Agencies. They have 2000 products in 65 therapeutic categories with over 40 dosage forms.

Cipla's research and development focuses on developing innovative products and drug delivery systems. It has been responsible for creating multiple new products that are accepted in India as well as globally. Despite the tightly regulated environment of foreign countries, Cipla today has more than 30 manufacturing facilities across India that have been approved by major international regulatory agencies including US FDA, MHRA-UK, WHO, Department of Health-Canada, MCC – South Africa, ANVISA – Brazil, and PMDA – Japan.

The company engages in R&D and also offers technical consultancy services. CIPLA's R&D focuses on innovation, both product and process, that result in cost and time saving. CIPLA has gained expertise in producing generics of very complex molecules. The company has given many generic solutions to India and to the world.

b) Path to Internationalization

The core of Cipla's international business is strategic alliances for product development, registration and distribution of the products. Its international business continues to be a major revenue driver for the company. Their overseas sales represent 53% of the total income. Cipla continues to expand and modernize its manufacturing and Research & Development facilities. Table 7.13 lists out the international operations history of Cipla since inception.

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Table 3.2: International Operations History - Cipla

Year	Modes of internationalization	Company Name	Country	Motivating Factor
1984	Subsidiary	Cipla USA Inc.	USA	first Indian company to receive US FDA approval
2002	Exports		Anglo America, South Africa	Market Seeking
2002	Strategic Alliance	MedproPharma	South Africa	Strategy alliance to enter the African market
2011	Acquisition	Manufacturing unit	Uganda	Market Expansion
2012	Acquisition			Integration of value chain and strategic asset seeking
2012	Joint Venture	Aspen Pharma	Australia	First Mover Advantage
2013	Acquisition	Celeris	Croatia	
2013	Acquisition	CiplaMedpro	South Africa	Low Cost Advantage, expansion and recognition
2014	Collaboration	TevaPharma Industries Ltd.	South Africa	Low Cost Advantage
2014	Licensing Agreement	Gileed Sciences Ltd.	USA	To sell and manufacture low cost medicines.
2014	Joint Venture	S&D Pharma	U.K.	Market seeking, Strategic Asset seeking
2014	Marketing Agreement	BioQuiddity		to market One Dose Ready fusORTM in regional anesthetic applications
2015	Joint venture	Cooper Pharmaceuticals.	Morocco	Market seeking
2015	Acquisition	Okasa Pharmaceuticals.	Satara	Operational and financial efficiency

Cipla has been one of the largest exporters of pharmaceutical products from India, exporting API and formulation products to over 170 countries. This includes the U.S., Canada and countries in Europe, Africa, Australia, Latin America and the Middle East.

Cipla started in USA in 1984, when it became the first Indian company to receive US FDA approval. United States of America is a key market of the company. Cipla USA Inc., the US subsidiary of Cipla Limited, is based in Miami, FL. The company has executed over 20 US partnerships and currently has over 40 commercialized products in the US. Cipla has supported the development of more than 170 ANDA's and has received 89 final approvals plus 2 NDA's approved and marketed in the US.

CIPLA also has partnerships and alliances for product development, technical support and marketing. Medpro Pharmaceuticals, South Africa's first generic drug producer formed a strategic alliance with Cipla around 2002. This strategic alliance gave CIPLA an outlet to sell its products in African markets. The strategic alliance was later converted into a joint venture. Recently, in July 2013, Medpro Pharmaceuticals was acquired by CIPLA for US $440 million and the company is now known as CIPLA Medpro.

As part of their growth strategy, Cipla acquired Celeris in 2013. It is a pharmaceutical distribution company based out of Croatia and was recently renamed as Cipla Croatia.

In July 2014 Cipla signed an exclusive partnership with BioQuiddity (Europe based company) to market One Dose Ready fusORTM (a drug used in regional anesthetic applications for post-surgical pain management). Cipla also entered into an alliance with Serum Institute of India to launch vaccines in Europe.

Currently, CIPLA is one of the world's largest generic pharmaceutical companies with its products sold in over 180 countries. So far, the main mode of international business is exports of formulations, Pharmaceutical ingredients, prescription and over-the-counter drugs, and veterinary products. However, going forward CIPLA is looking to make a shift in its business model.

c) Analysis & Conclusion

Cipla is the oldest company amongst its Indian peers. It did not realize the benefit of mergers, acquisitions soon enough and so got left behind a little but is now catching up fast. Just like its peers in Top pharmaceutical companies of India, and as can be seen in Fig 3.1 and 3.2 below, the export intensity has been directly correlated with R&D expenses as well as Total Assets.

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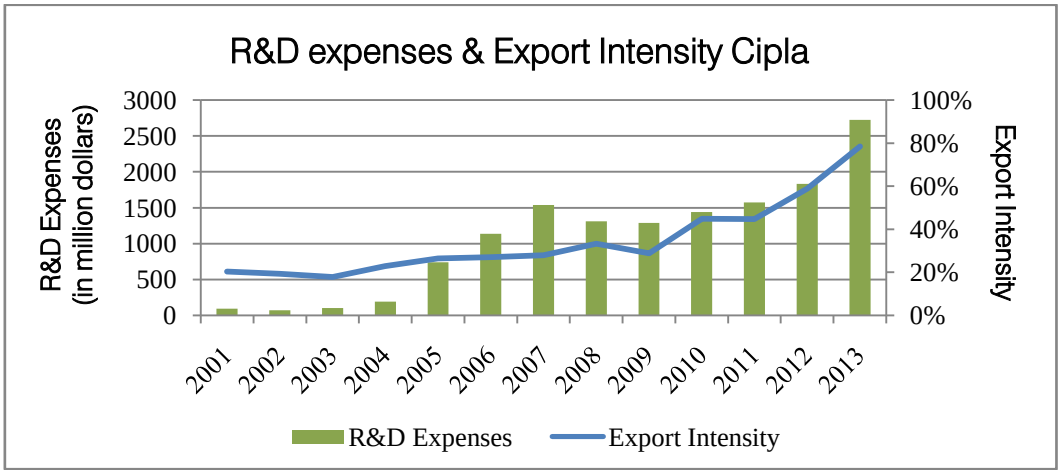


Figure 3.1: R & D expenses & Export Intensity – Cipla

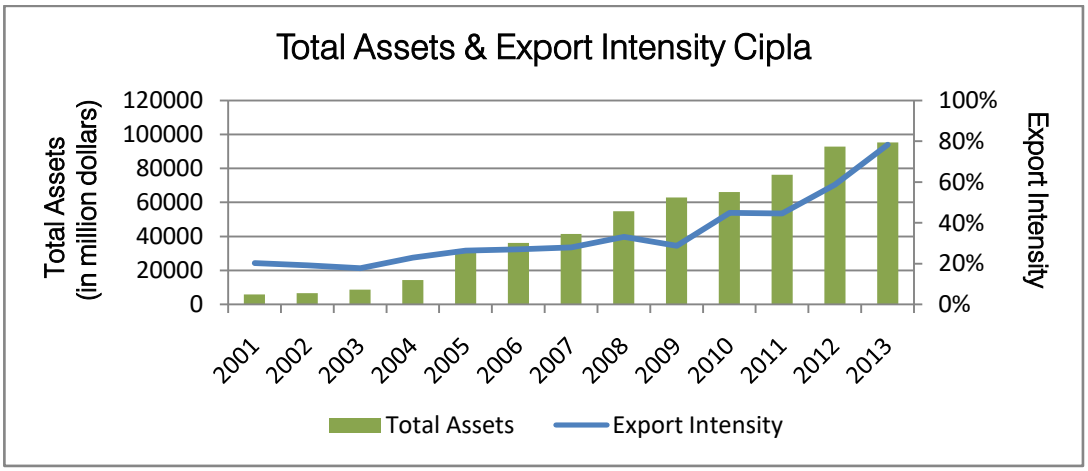


Figure 3.2: Total Assets & Export Intensity – Cipla

Apart from Medpro's acquisition, CIPLA did not grow inorganically through mergers and acquisitions. The company has always expanded organically. Further, except Medpro, CIPLA's physical expansion always took place within India. This may be because any expansion outside India might have made CIPLA vulnerable for legal suites for the previous breach of intellectual property rights.

Therefore, while operating from India, CIPLA conducted its international business through indirect exports. However, the company hopes that it will not face too many challenges when it moves abroad in the near future because it has partners across the globe to help with whom it has long standing relationships. Company is planning to undertake foreign direct investment for expansion in near future. The expansion is most likely to be a forward expansion as the company aims to build marketing and sales network in abroad.

IV. Dr. Reddy Labs

Dr. Reddy's Laboratories is an emerging global pharmaceutical company. It has three core businesses: Pharmaceutical Services and Active Ingredients, comprising Active Pharmaceuticals and Custom Pharmaceuticals businesses; Global Generics, which includes branded and unbranded generics; and Proprietary Products, which includes New Chemical Entities (NCEs), Differentiated Formulations, and Generic Biopharmaceuticals. Table 4.1 lists out some other basic facts about the company.

Table 4.1: Dr. Reddy Labs – basic facts

Headquarters	Hyderabad, India
Public or Private	Public
Year of Establishment	1984
Revenues (2013-14)	$2.25 bn
Specialties	Pharmaceuticals, Specialty, Bigeneric, API, Generic Formulation

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a) Synopsis of the Company

Dr. Reddy's began as a supplier to Indian drug manufacturers. It soon started exporting to other less-regulated markets. This meant not having to spend time and money on a manufacturing plants or seek approval from a drug licensing body such as the U.S. Food and Drug Administration (FDA). This was a great advantage and helped spur the phenomenal growth of the company.

By the early 1990s, bolstered by the expanded scale and profitability in unregulated markets, the company started focusing on tightly regulated markets. It started getting approvals from drug regulators for their formulations and bulk drug manufacturing plants in more-developed economies. This allowed their movement into regulated markets such as the US and Europe.

In 2001 Reddy's completed its US initial public offering of $132.8 million American Depositary Receipts (ADR) issue and also listed on the New York Stock exchange. Funds raised from the US initial public offering helped Reddy's move into international production – and take over technology - based companies.

By 2007, Dr. Reddy's had six FDA-plants manufacturing active pharmaceutical ingredients in India. It also had seven FDA-inspected plants making patient-ready medications – five of them in India and two in the UK.

Reddy's also invested heavily in building R&D labs and is the only Indian company to have significant R&D being undertaken overseas. Dr. Reddy's Research Foundation was established in 1992 and dedicated to research in area of new drug discovery. At first, the foundation's drug research strategy revolved around searching for analogues but its changed focus to innovative R&D by hiring new scientists.

b) Path to Internationalization

Reddy's path into new drug discovery involved targeting specialty generics products in western markets to gain drug discovery abilities. This led Dr. Reddy to adopt aggressive merger & acquisition strategy to explore the international markets. Table 4.2 below lists out the internationalization history of the company.

Table 4.2: International Operations History - Dr. Reddy's Labs

Year	Modes of internationalization	Company Name	Country	Motivating Factor
1992	Joint venture	Biomed	Russia	Market Access
1993	Joint venture	-	Middle East	Created two formulations units
1994	Exports	-	Kazakhstan	Representative office was opened.
1994	Joint Venture	-	Uzbekistan	Representative office was opened.
1994	Subsidiary	Dr. Reddy's Laboratories Inc.	USA	Target USA generic market
1995	Exports	-	Belarus	Representative office was opened.
2000	Subsidiary	Reddy US Therapeutics Inc.	USA	discovery and design of novel therapeutics
2000	Marketing Alliance	Triomed	South Africa	begins its Generic business operation in South Africa
2000	Joint Venture	KunshanRotam Reddy Pharmaceutical Co., Ltd. (KRRP)	China	-
2002	acquisition	BMS Labs and its wholly owned subsidiary, Meridian UK	U.K.	To expand geographically and gain access to the European market.
2003	Joint venture	Par- Pharma Inc.	USA	to market hypertension products
2003	Subsidiary	-	Russia	pharmacy warehouse for better service on the territory of Russia
2004	Agreement	Eurodrug Labs	Netherlands	-
2004	Agreement	Pharmaplan	South Africa	for hiring sales force after Triomed was acquired by Aspen
2004	Joint Venture	Venturepharm	South Africa	
2004	Acquisition	Trigenesis	USA	To access strategic assets in dermatology segment.
2005	Sales & Development Agreement	Rheoscience A/S,	Denmark	-
2006	acquisition	Betapharma	Germany	For the purpose of brand building
2006	Licensing Agreement	MERCK AG	Germany	-
2006	Licensing Agreement	Molteni	Italy	-

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2006	R& D, Commercialization Agreement	Argenta Discovery Ltd.	U.K.	-
2007	Subsidiary	Dr. Reddy's Laboratories SA	Switzerland	provides custom pharmaceutical services for starting materials, intermediates, active ingredients, and finished dosage forms
2008	Acquisition	Affordable Healthcare Ltd.	New Zealand	gaining tenders from the New Zealand govt. body, Pharmac and supplying the pharmaceutical drugs for the prescription market
2009	Subsidiary	Dr. Reddy's Laboratories Australia Pty Ltd	Australia	launch of new Generics Medicine lines
2010	Subsidiary	Dr. Reddy's Laboratories (Pty) Ltd	South Africa	Joint Venture with Venturepharm became the wholly owned subsidiary
2010	Licensing Agreement	Cipla (Senade)	Russia	-
2010	Licensing Agreement	R-Pharm	Russia	Collaboration in the areas of high technology and knowledge sharing.
2011	Licensing Agreement	Novartis (Famvir)	Russia	

Dr. Reddy was a very early mover into the Russian market, forming a joint venture with the country's biggest pharmaceuticals producer Biomed in 1992. In 1993, Reddy's entered into a joint venture in the Middle East and created two formulation units there and in Russia. Reddy's exported bulk drugs to these formulation units, which then converted them into finished products. In 1994, Reddy's started targeting the US generic market by building state of art manufacturing facility.

By 1997, Reddy's was ready for the next major step. From being an API and bulk drug supplier to regulated markets like the USA and the UK, and a branded formulations supplier in unregulated markets like India and Russia.

In 2000, Dr. Reddy's Research Foundation set up a US lab in Atlanta, dedicated to discovery and design of novel therapeutics Reddy's merged Cheminor Drug Limited (CDL) with primary aim of supplying APIs to the technically demanding markets of North America and Europe. This merger also gave Reddy's entry into value added generics business in the regulated markets of APIs.

In 2001 Reddy's became the first Indian company to launch the generic drug, fluoxetine (a generic version of Eli Lilly and Company's Prozac) with 180-day market exclusivity in the USA. The fluoxetine marketing success was followed by the launch of ibuprofen in US under its own brand name, in January 2003. It was the first step in building Reddy's fully fledged distribution network in the US market.

In March 2002, Dr. Reddy's acquired BMS Laboratories, Beverley, and it is wholly owned subsidiary Meridian Healthcare, for EUR 14.81 million. Recently, Dr. Reddy's entered into an R&D and commercialization agreement with Argenta Discovery Ltd., a private drug development company based in the UK, for the treatment of COPD.

With growing success in the generics market, Reddy's also came to realize the need for developing marketing and distribution capabilities in the USA. The company already had one tie-up with Pharmaceutical Resources, Inc. to market Fluoxentine 40 mg tablets. It also had a tie-up with Par Pharmaceuticals Inc., to produce and market over-the-counter drugs in the U.S. In addition to the United States, Reddy's generics business had established a presence in the UK as well. Reddy's also plans to expand its presence in Canada and South Africa. Its API business had sales in over 60 countries, with the US and India being the most significant revenue contributors. The branded formulations business was active in over 30 countries and Reddy's was a significant player in the Indian and Russian markets. The business planned to significantly increase its presence in China, Brazil and Mexico in the near future.

In 2004, Reddy's acquired Trigenesis Therapeutics Inc.; the US based private dermatology company. This acquisition gave Reddy's access to certain products and proprietary technologies in dermatology segment.

In March 2006, Dr. Reddy's acquired BetapharmArzneimittel GmbH from 3i for EUR 480 million. This is one of the largest-ever foreign acquisitions by an Indian pharmaceutical company.

c) Analysis & Conclusion

Dr. Reddy's Labs has been a very aggressive player in the international acquisition space. Its initial success came through exports of generics which continue to be the growth drive to this date. Fig. 4.1 and 4.2 below show the plot of Reddy's export intensity vs R & D expenses and Total Assets respectively.

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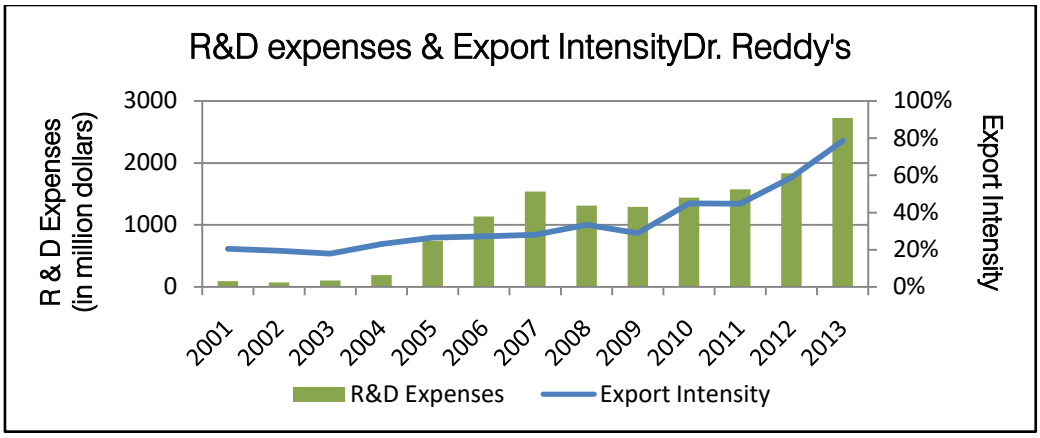


Figure 4.1: R & D expenses & Export Intensity – Dr. Reddy's

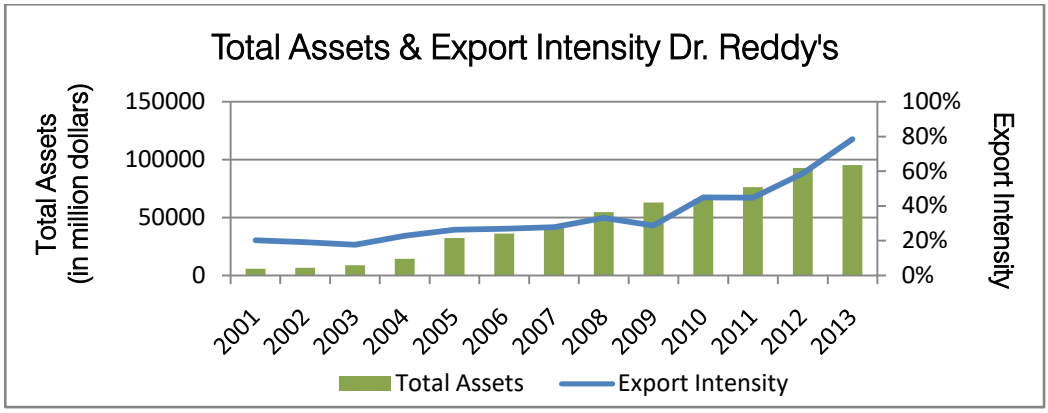


Figure 4.2: Total Assets & Export Intensity – Dr. Reddy's

Reddy's successful growth into a fully integrated pharmaceutical company in less than a decade was founded on a successful and targeted program of inorganic growth and investments in process R&D. It had chosen a high risk-high gain strategy to growth by going into direct competition with existing patent holders.

A major challenge for Reddy's is to find ways to de-risk its overall strategy. One way may lie in managing the cash flows from the 'safer' API and formulations businesses. Another way may be to seek out more experienced partners for the R&D business or use acquisitions to boost R&D resources and revenues. It has chosen the global route and went on an acquiring spree.

V. Lupin

Lupin is an innovation led transnational pharmaceutical major producing and developing a wide range of branded and generic formulations as well as biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatrics, CNS, GI, Anti-Infective and NSAID space and holds global leadership positions in the Anti-TB and Cephalosporin segment.

Table 5.1: Lupin – basic facts

Headquarters	Mumbai, India
Public or Private	Public
Year of Establishment	1968
Revenues (2013-14)	$1.89 bn
Specialties	Formulations, APIs, Generics, Biotechnology, Novel Drug Discovery and Development, Drug Delivery Systems, Specialty Pharmaceuticals

a) Synopsis of the Company

Lupin is the 5th largest and fastest growing top 5 generics player in the US (5.3% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan and South Africa (IMS).

Lupin benefitted from the cost arbitrage between India and developed countries as all of Lupin's manufacturing plants initially were located in India. From

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the international footprint table of Lupin it is clear that Lupin wanted to leverage this cost arbitrage internationally by entering into strategic marketing alliances with firms.

Lupin continues to invest heavily in its R&D programs. The Company invested 8.6% of its net sales in R&D and related spends, amounting to Rs. 9,583 million in 2013-14. Lupin has designed a very successful research program which continues to ensure the delivery of a sustainable pipe line of high - value opportunities that are maximizing growth for the Company across markets.

b) Path to Internationalization

Lupin is one of the largest and fastest growing pharmaceutical companies in India. It is present in more than 70 countries. Lupin has used a mix of international expansion strategies which reflect the need and stage in the growth life cycle of Lupin itself. Table 5.2 below shows the internationalization history of Lupin.

Table 5.2: International Operations History - Lupin

Year	Modes of internationalization	Company Name	Country	Motivating Factor
2003	Subsidiary	Lupin Pharmaceuticals Inc.	USA	Market Access
2004	Subsidiary	Lupin Australia Pty Ltd., Australia	Australia	Market Access
2004	Strategic alliance	Baxter	USA	Will provide Lupin access to the US ceftriaxone vial market.
2005	Strategic agreement	GSK	Philippines	Geographical expansion
2006	Acquisition	51% equity in DafraPharma ltd	Belgium	strategic initiative
2007	Subsidiary	Lupin Atlantis Holdings SA	Switzerland	-
2007	acquisition	Kyowa	Japan	Kyowa has major strengths in product development, manufacturing and marketing of its products nationwide. Lupin will be able to add significant value through its strengths in R&D and global marketing, leading to major synergies.
2008	Acquisition	Generic Health	Australia	Business expansion
2008	Acquisition	Pharma Dynamics	South Africa	3rd largest generic company in the SA prescriptions market.
2008	Strategic Agreement	ASCENA	USA	Extend Suprax franchise and enhance the value of brand business in the U.S."
2008	Acquisition	HormosanPharma	Germany	-
2009	Subsidiary	Lupin (Europe) Ltd.	UK	-
2009	Subsidiary	LupinPharma Canada Ltd.	Canada	-
2009	Acquisition	Multicare Pharmaceuticals	Philippines	acquisition offers Lupin an entry into this $2.5 billion market
2010	Subsidiary	Lupin Mexico S.A. de C.V	Mexico	-
2011	Acquisition	I'Rompharmaceuticals	Tokyo	IP's strong presence in the DPC hospital segment in Japan, through its line of injectable products, is an ideal fit with our existing oral business portfolio in Japan.
2011	Licensing agreement	Sydney	Australia	-
2011	Supply agreement	farmanguinkos	Brazil	providing comprehensive therapeutic care in the areas of conventional TB and MDR-TB,
2013	Licensing Agreement	Romark Lab	USA	grow its brand franchise
2014	Joint venture	yoshindo	Japan	First step forward to establishing Lupin's global Biosimilar portfolio".
2014	acquisition	Laboratorios grin	Mexico	Specialty Ophthalmic Company; Enters the Latin American Market.
2014	acquisition	Nanomi B.V.	Netherlands	use of Nanomi's proprietary technology platform,
2014	Joint Venture	YL Biologics Ltd.	Japan	-
2015	Acquisition	Biocom	Russia	-
2015	Acquisition	Medquimica	Brazil	-

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In 2002-03 Lupin had already made inroads into the active pharmaceutical ingredient or API supplies in the US and Europe, but was a fringe player in most other markets.

Lupin Pharmaceuticals, Inc. entered the U.S. generic pharmaceutical market in 2003. Since then company have received more than 75 FDA approvals and have become one of the fastest growing pharmaceutical companies in the US.

Lupin operates a globally integrated network of 11 manufacturing facilities. Their world class facilities are built to manufacture and deliver a wide range of finished products to the US market. USA is the main market fir Lupin's operations. Lupin has experienced a wide degree of transformation. It has started with opening a subsidiary in USA to sell its product, while the same team is selling some other companies product in the country.

Medicines in Japan have different specifications from other markets. The percentage of residual impurities and the raw material strengths are different from that of US or European requirements and therefore, cannot be clubbed together with those markets. As a result, Lupin revealed the first step in its strategy—a co-operation agreement with a 50-year old local drug firm Kyowa Pharmaceutical to market medicines in Japan. The agreement turned out to be pivotal. While Lupin had to develop and manufacture the medicine, Kyowa was supposed to conduct regulatory testing, obtain approvals and market the drugs in Japan. Two years later, Lupin acquired a majority stake in privately-held Kyowa, and in 2008, turned it into a 100 per cent subsidiary. Kyowa gave Lupin lot of insights into the working of the Japanese generic market. Company added new products in the Kyowa pipeline, and in less than three years, doubled its turnover.

c) Analysis & Conclusion

Again, just like its peers in Top pharmaceutical companies of India, and as can be seen in Fig 5.1 and 5.2 below, the export intensity has been directly correlated with R&D expenses as well as Total Assets.

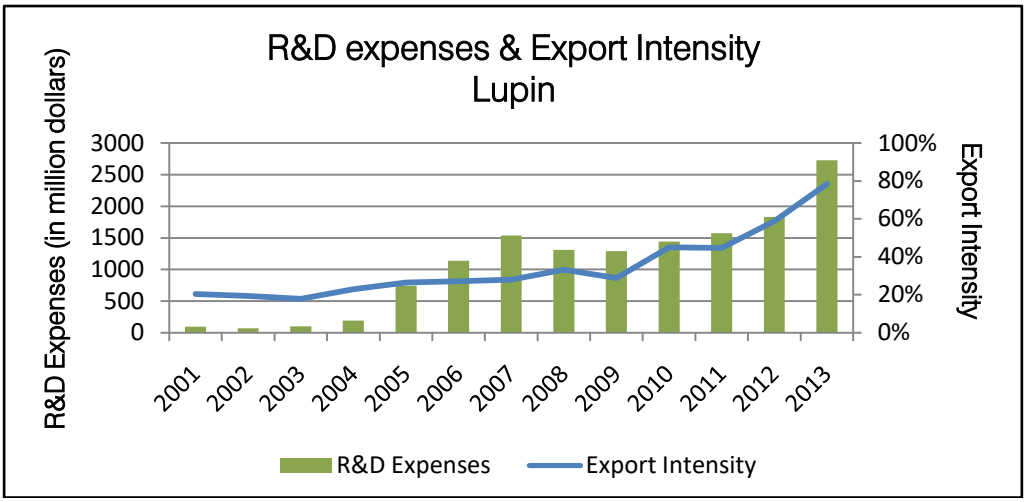


Figure 5.1: R & D expenses & Export Intensity – Lupin

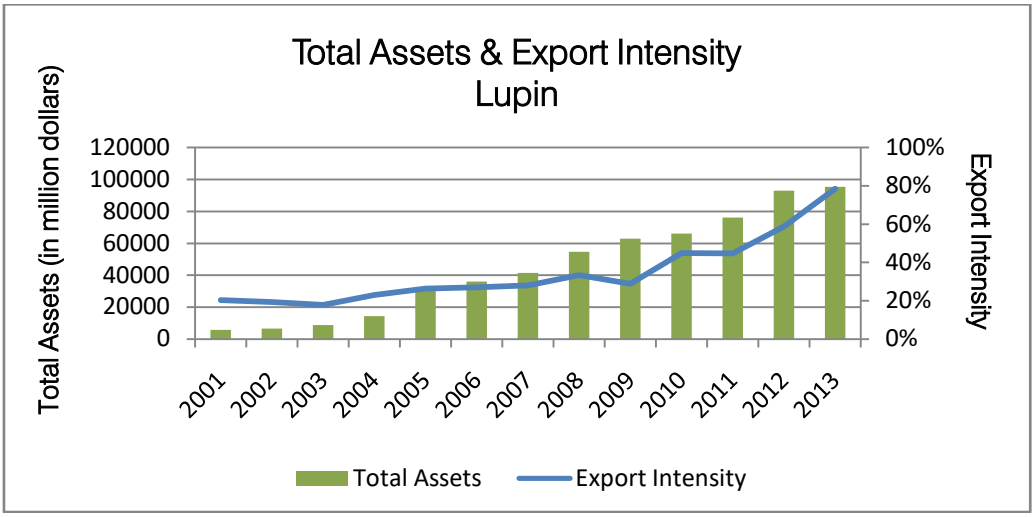


Figure 5.2: Total Assets & Export Intensity – Lupin

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Lupin started with the organics entry in international market. but with its strengths and capabilities it moved to other non- organic modes of expansion as well.

Thus, it can be said that Lupin is set to emerge as a transnational enterprise from a purely Indian operation leveraging its ownership resources of low cost manufacturing and acquired R&D capabilities, tuning its strategies to enter markets with best location advantages and using its core competencies to internalize key functions and actually magnetizing these strategic assets.

VI. Sun Pharmaceuticals Laboratories LTD.

Sun Pharma is a global, integrated, specialty pharmaceutical company. It manufactures and markets a large basket of pharmaceutical formulations in India, US and several other markets across the world. In India, the company manufactures products in niche therapy areas of psychiatry, neurology, cardiology, diabetology, gastroenterology, orthopedics and ophthalmology.

Table 6.1: Sun Pharma – basic facts

Headquarters	Mumbai, India
Public or Private	Public
Year of Establishment	1983
Revenues (2013-14)	$2.56 bn
Specialties	Formulations, API, US Generics, Specialty brands, Technically complex formulations

a) Synopsis of the Company

Over 72% of Sun Pharma sales are from markets outside India, primarily in the US. The US is the single largest market. It accounts for about 60% turnover in all be it in the form of formulations or finished dosage. It manufactures across 26 locations, including plants in the US, Canada, Brazil, Mexico and Israel.

Several regulatory agencies, including FDA-USA, EMA-Europe, MHRA-UK, MCC-South Africa, TGA-Australia, ANVISA-Brazil, WHO-Geneva, BfArM-Germany, KFDA-Korea and PMDA-Japan, have certified their facilities.

Their track-record of successful collaborations includes various in and out licensing of products and technologies, joint ventures, as well as mergers & acquisitions.

Their early investments in R&D began three decades ago. It enabled the company to make technology as their key differentiator and develop a basket of robust products for diverse markets across the world. The company have around 1800 research scientists working in multiple R&D centers. Their scientists have expertise in developing generics, Active Pharmaceutical Ingredients (APIs), Novel Drug Delivery Systems (NDDS) and New Chemical Entities (NCEs).

b) Path to Internationalization

Sun pharmaceutical started exporting products to neighboring countries of India in 1989. Table 6.2 below summarizes the internationalization history of the company

Table 6.2: International Operations History – Sun Pharma

Year	Modes of internationalization	Company Name	Country	Motivating Factor
1989	Exports		Neighboring countries of India	
1996	subsidiary	Sun Pharma Global Inc.	British Virgin Islands	
1997	Acquisition	Caraco Pharmaceutical Laboratories	USA	Technology and R&D seeking
1997	Equity Stake	MJ Pharma	UK	
2001	Subsidiary	Sun Pharmaceutical (Bangladesh) Limited	Bangladesh	Market access
2004	Subsidiary	Sun Pharmaceutical Industries, Inc.	USA	Market access
2004	Acquisition	Niche brands from Women's First Health care	USA	To enrich the product portfolio
2005	Subsidiary	Sun Pharmaceutical UK Limited	UK	Market access

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2005	Acquisition	Manufacturing Unit in Bryan, Ohio	USA	
2005	Acquisition	Able Laboratories	USA	Expansion, to make presence in controlled substances.
2005	Acquisition	ICN	Hungary	Band building and to make presence in controlled substances.
2008	Subsidiary	Sun Pharmaceutical Industries Pty Ltd (Australia)	Australia	Market access
2008	Acquisition	Chattem Chemicals Inc.	USA	To enrich the product portfolio and become more active player in pain management.
2009	Subsidiary	Sun Pharmaceuticals Germany GmbH	Germany	Market access
2009	Acquisition	Products from Forest Inwood	USA	Through Coraco
2010	Acquisition	Taro pharmaceuticals	USA	Expansion in USA
2012	Acquisition	Dusa pharmaceuticals	USA	DUSA's business will bring an entry into dermatological treatment devices, where Sunpharma see good growth opportunities.
2012	Acquisition	Generic business of URL pharmaceuticals.	USA	
2014	Acquisition	Ranbaxy	Various countries	Brand building. Sun pharma became world fifth largest generic pharma company.
2014	Acquisition	Pharmalucence	USA	Manufacturer of human injectable pharmaceuticals.
2014	Licensing Agreement	Merck & Co. Inc.	USA	Enrich the product portfolio
2015	Acquisition	GSK'S opiates business in Australia.	Australia	Expansion in the niche segment of controlled substances.

Then in 1991, fall in bulk drug prices was a setback for the company. It realized the mistake of depending on a single product line so it started to diversify across multiple formulations. Russia became the biggest export market for Sun but the 1998 collapse of the Russian economy came as a big jolt for the company. Sun has become too focused on Russia as country and lost a big chunk of business due to the political upheaval. That's when Sun decided to focus on three key therapeutic areas by employing similar production technology. This allowed Sun to serve different market segments while using the same technology and thereby allowing them access to the best of both worlds.

In 1997, Sun did its first international acquisition. The main purpose of the acquisition was to acquire the technology. As a result, Sun acquired many companies with equity stake. MJ Pharma, TDPL were few of them. Apart from acquisition as a mode of internationalization Sun also focused on exports. In 1997, Sun reported the exports as 18 percent of their total sales. Although Sun was present in many regulated and unregulated markets, USA still remained the single most important country.

In 2004 Sun Pharma bought a few exclusive brands to consolidate its positions as a leader in the segment. The brands were purchased from the US based company Women's First Healthcare (WFHC). Acquisition of WFHC was the foundation stone for entering the branded generic space in the US at a reasonable cost. In same year Sun Pharma increased its stake in Coraco to over 60% from 44% by acquiring a common stock and options from 2 large shareholders of Caraco.

In 2005 Sun acquired a Hungarian firm to operate in the controlled substance market. Company bought raw materials and dosage form manufacturing operations of ICN Hungary from Valeant Pharmaceuticals. In the same year, Sun acquired a manufacturing plant at Bryan, Ohio, USA, and work begun on increasing the capacity and making operations more efficient.

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c) Analysis & Conclusion

Sun although being a new company of the selected sample, manages a broad scope of operations. It is actively pursuing mergers, acquisitions and other strategic tie-ups. Sun pharmaceutical targets API market in Europe and US as these markets are gradually opening up to the use of low cost generics. There is intense competition from API manufacturers in many other developing countries. Therefore, the company is trying to diversify its product offerings by targeting specialty API. The company's acquisition of Knoll's bulk drug facility and its purchase of controlling stakes in Gujarat Pharma, MJ Pharma, and Caraco (U.S.) provide Sun with additional R&D capabilities and access to U.S. FDA approved factories.

As can be seen in Fig 6.1, increase in R&D had a positive impact on export intensity of the company.

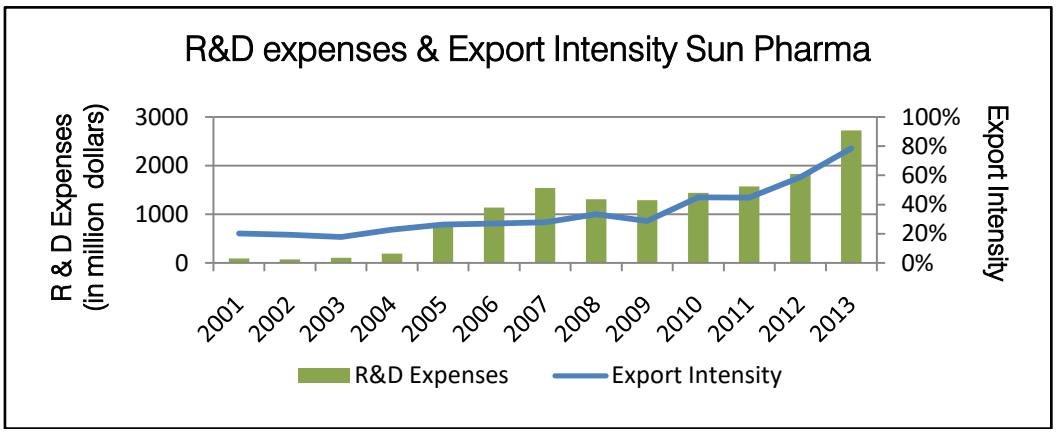


Figure 6.1: R & D expenses & Export Intensity – Sun Pharma

Fig 6.2 shows a plot of Sun Pharma's assets plotted against its export intensity. Company's export intensity seems to be having a positive correlation with its total assets.

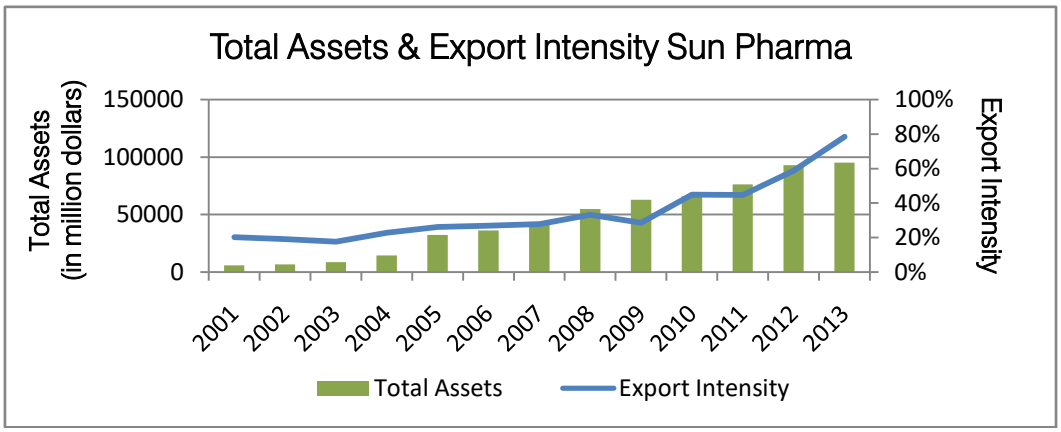


Figure 6.2: Total Assets & Export Intensity – Sun Pharma

After the thorough analysis it can always be said that Sun Pharma is internationalizing with a high pace, but still challenges are on the way. Sun is taking corrective measures to eliminate the threat of increased patent protection. It is investing heavily in sales and marketing capacities and plans to implement its branded generic strategy in multiple markets.

VII. Comparative Analysis of Findings From Case Studies

The first step in internationalization for a small company is always exports. This would mainly be achieved by entering into an agreement with another company in that country. The guiding factor behind it is the philosophy of the company to count on quality. The small company prefers in investing in quality rather than marketing and distribution. Moreover, to encourage the exports they get various incentives from Indian government in form of duty drawbacks, duty free imports of raw materials etc. So it is not only the enthusiasm of the entrepreneur, but also the encouragement on behalf of government that leads to internationalization.

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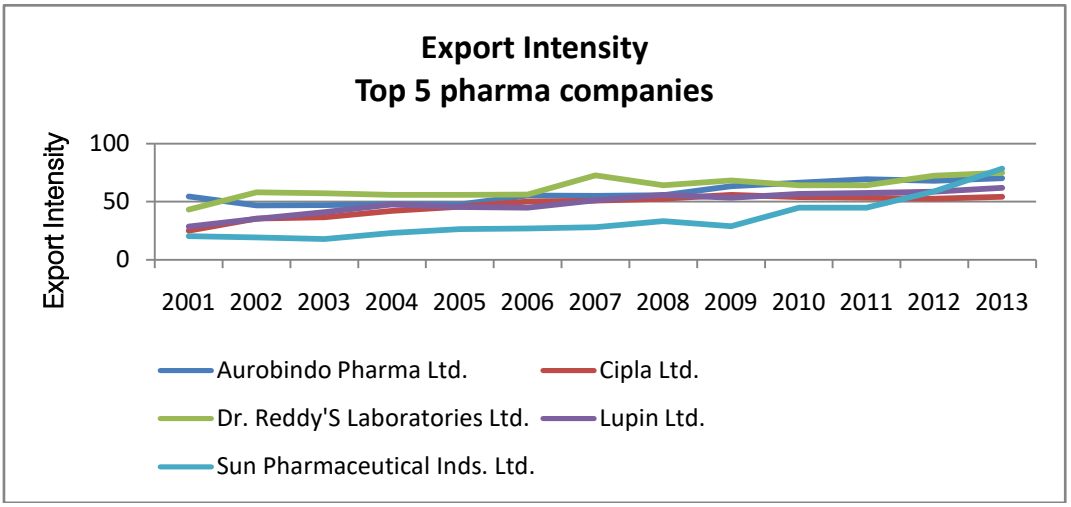


Figure 7.1: Export Intensity of top 5 pharmaceutical firms

Looking at Fig. 7.1 it is clear that Dr. Reddy has maintained an overall lead in export intensity over the years, but, Sun Pharma has seen a spurt in growth in recent years and is all set to taken over Dr. Reddy now.

Table 7.1 below summarizes the internationalization efforts of top 5 pharmaceutical companies by modes of internationalization.

Table 7.1: Modes of internationalization - Summary for top 5 companies

Name of the firm	Aurobindo	Cipla	Dr. Reddy's	Lupin	Sun Pharma
No. of countries exporting to	100	170	130	100	150
No. of Acquisitions	6	5	3	11	13
No. of Joint ventures	7	3	6	2	0
No. of subsidiaries	3	1	6	6	6
No. of Agreements	2	3	10	6	1

Sun Pharma and Lupin have been very active in acquisitions. Aurobindo has relied more on joint ventures whereas Dr. Reddy's has explored multiple modes of internationalization almost equally. Table 7.2 further details out the reasons for selecting a particular modes of internationalization by these companies. It is a comparative analysis on these companies as to what was a significant modes of internationalization and what was factor influencing the decision.

Table 7.2: Comparative Analysis for Modes of internationalization strategy for top 5 pharmaceutical companies

Company Name	Key Modes of internationalization taken	Factor that influenced modes of internationalization	Explanation
Aurobindo	Acquisition	Market Size	The Company believes that such acquisitions reduce the time to market and enhance the relationships in the generic value chain in addition to building a broad and formidable product portfolio.
Cipla	Strategic Alliance	Regulatory framework of host country	Cipla is one of the oldest pharmaceutical companies based in India. During it's early evolution years, it copied many patented drugs due to lax regime in India and exported them to less regulated markets. This prevented Cipla from expanding in the West as it always feared for patent infringement lawsuits due to tight regulatory framework in those countries.
Dr. Reddy's	Joint Venture	Market Size	Dr. Reddy's was the first mover in Russian market. It's first ever joint venture was with Biomed of Russia and it gave Dr. Reddy unparalleled access to the Russian market.

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	Acquisition	R & D	Reddy's successful growth into a fully integrated pharmaceutical company in less than a decade was founded on a successful and targeted program of inorganic growth and investments in process R&D.
Lupin	Strategic Alliance followed by Acquisition	Market Size	Lupin recognized the tremendous opportunity that the Japanese market provided. Even though Japan is a small country but it is a highly developed country. Also cost of living is quite high which makes it very lucrative for any pharmaceutical company with reasonably priced generic medicines. Nobody from India had been able to penetrate the Japanese market before. Lupin entered into a co-operation agreement with a 50-year old local drug firm Kyowa Pharmaceutical to market medicines in Japan. The agreement turned out to be pivotal and had such a good impact on company's financials that is acquired Kyowa eventually.
Sun Pharma	Acquisition	R & D	Acquisition of Knoll's bulk drug facility and its purchase of controlling stakes in Gujarat Pharma, MJ Pharma, and Caraco (U.S) provide Sun with additional R&D capabilities and access to U.S. FDA approved production facilities. Sun is going for major acquisitions to augment its R&D capabilities.

As is evident from the table above that regulatory framework, R & D and Market Size have been some of the factors that have influenced the modes of internationalization decisions for these companies. Fig. 7.2 below further shows the R&D expenses at these 5 pharmaceutical firms.

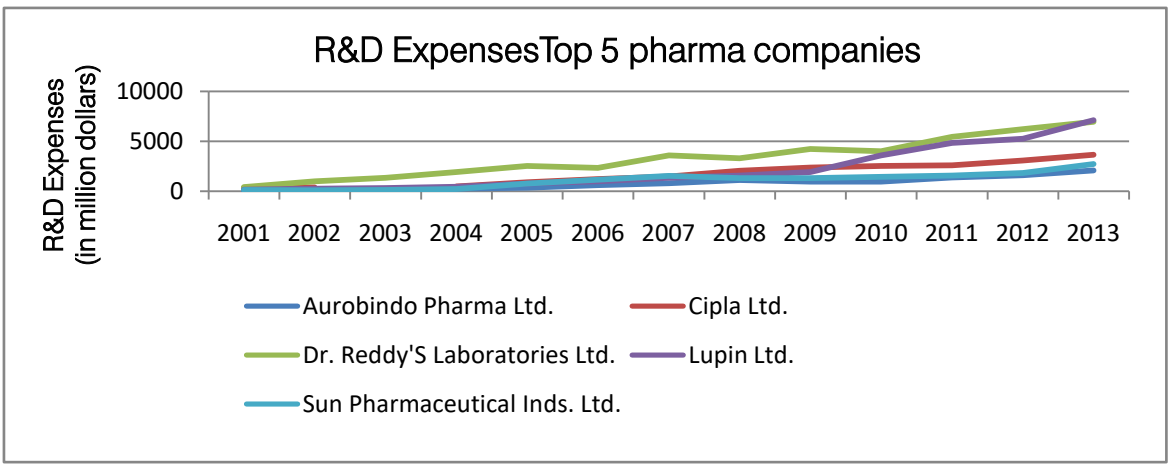


Figure 7.2: R & D expenses of top 5 pharmaceutical firms

Dr. Reddy has once again been a leader in R & D activities over the years. In fact, as stated in the case study for Dr. Reddy, the company has always looked to augment its R & D capabilities through active mergers and acquisitions.

Mergers & Acquisitions are generally followed by larger companies. The guiding objective is either to enter a new market quickly or gain a dominant position in an existing market. Through acquisitions, company generally looks for market expansion and operational efficiency. Perhaps it can be said that mergers and acquisitions are generally guide by an objective of resource seeking. In the global world we live in today, there is cut throat competition at every level and it becomes imperative for firms to go for continuous product expansion and market expansion. This product and market expansion is achieved through mergers and acquisitions.

Subsidiary route or establishing a manufacturing plant in the foreign country is followed by even fewer and largest companies as it is the most cost and time intensive approach. Setting up a new unit takes time as it requires getting all the approvals from local authorities.

Acquisition has emerged as a dominant strategy for internationalization in Europe compared to the US and developing countries. Indian companies are acquiring firms in Europe in order to gain experience in regulatory skills. Use of generics in European market is growing quickly due to government's price controls and

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other regulations. DRL's acquisition of Betapharm provides the company with access to that market. DRL's strength in the product segment combines with Betapharm's front-end presence and thus enhancing DRL's domestic manufacturing advantage. Another factor aiding acquisition in Europe is the wider range of companies available compared to US where acquisition is more expensive and risky for Indian companies.

VIII. Conclusion

To conclude, the changes in US regulations and liberalization of Indian economy have played a key role in aiding Indian firms internationalization strategies. Thus findings of the primary study support the argument that changes in world economy and its interlinked character is responsible for driving the new approaches and patterns of internationalization.

Moreover, the leading Indian pharmaceutical firms show that strategy of acquisitions and direct foreign entry can result in higher profits as long as it is supplemented with superior technology. The insights from the primary study suggest that the motive behind overseas expansion of Indian firms is the need to improve global competitiveness and acquisition of assets including research.

US remains the most attractive market for companies taking the export mode. Given the cost difference between India and US in terms of manufacturing, it is highly beneficial for a company to manufacture in India and export to developed nations.US remains the toughest market to enter too. Getting approval from US FDA opens the floodgates for the company to export its products to multiple countries across the world. But getting US FDA approval requires lot of time and money investment as the requirements for approval are very stringent. The second largest Pharma market in the world is Japan. Japan is supposed to be the most difficult Pharma markets to access. However, Lupin's success in establishing significant presence in Japan shows that building a footprint in this market is not impossible. Indian companies are also look at establishing their foothold in other managed but less regulated markets such as South East Asia and Africa. Liaisons in these developing markets can be facilitated more efficiently by collaborating with international agencies or via government intervention.

After the thorough analysis of the pharmaceutical companies and pharmaceutical industry of India it is found that Indian Pharmaceutical companies are capitalizing on export opportunities in regulated as well as semi regulated markets. Changes in the global arena in terms of increasing healthcare cost have been able to create space and opportunities for Indian pharmaceutical players. Further change in regulatory as well as business perspective is pushing the companies to adapt and change their business strategies. As a result, companies are trying to tap newer markets for their expansion. Company size remains a big factor in determination of modes of internationalization. Size determines the financial and operational capabilities of the company. which further enables the company to take the decision of being risk averse or risk taker.

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