
Generics growth in the USA and the EU: The role of India

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Abstract This paper examines issues impacting the global generics sector and the role of Indian generics companies. The USA, which has been the primary regulated market focus for Indian companies, and the EU, are covered. Key success factors for generics companies are described. Various approaches by Indian companies to selling in the regulated markets are discussed, including partnership and direct selling models, and Indian competitive advantages and weaknesses compared to global and regional generics companies described.

Keywords: *India, generics competition, USA, EU, consolidation, pipelines, partnerships*

GLOBAL GENERICS OPPORTUNITY: ATTRACTIVE GROWTH

Generic drugs represent a large and growing opportunity. Generics sales represented some 23 per cent by volume of the total global pharma market in 2004, increasing at a compound average growth rate (CAGR) of 17 per cent in the five years leading up to 2004, greater than the growth rate for branded pharmaceuticals, according to IMS. Despite price erosion, especially in the USA, IMS forecasts that generics will grow by 10–15 per cent in the current five year period, or US\$66bn to US\$82bn in 2009.¹ Generics demand is fuelled by demographic trends and economic growth in the regulated markets, as well as the need for cost control by payors.

Furthermore, the top generics companies — such as Teva and Sandoz — are now huge, global players, themselves driving demand and inspiring confidence in generic drugs as high-quality, therapeutic equivalents produced by reputable companies. The current robust

forecast for generics prescription volume growth is supported by the next wave of patent expiries on blockbusters.

GENERICS OPPORTUNITY: USA ESPECIALLY ATTRACTIVE

Six of the top selling prescription drugs by volume in the USA in 2004 were generics.² Generics had a 35 per cent share of the total US market by volume in 2004.³ Five of the ten largest US product launches in 2004 were generics, including Watson's bupropion SR, Teva's oxycodone ER and bupropion SR, Eon's bupropion SR and Ivax's glyburide/metformin.³ Generics have been outpacing big pharma earnings performance for years, as shown in Table 1.

GLOBAL GENERICS OPPORTUNITY: CYCLICAL AND HIGHLY COMPETITIVE

The generics opportunity cycle of products losing exclusivity in major markets follows the life cycle of new drug launches as

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Table I: Generics outperforming big pharma

Diluted EPS growth from continuing operations	Three-year compound annual growth rate (CAGR, %)	Five-year compound annual growth rate (CAGR, %)
US generics performance	25.5	39.2
US brand performance	-12.1	-6.0
European brand performance	6.3	13.6
US generics outperformance vs US brand	37.7	45.3
US generics outperformance vs European brand	19.3	25.7

Source: Lehman Brothers, July 2005

EPS, earnings per share; CAGR, compound annual growth rate

products' patents expire or exclusivity ends due to patent challenge or circumvention. 2005 is a lean year for loss of exclusivity. The upcoming period from 2006–2008 is more fruitful for generics, and painful for brand name companies, with many large selling products losing exclusivity in major markets. The number of new entrants and desperation for growth in 2006 after the leanness of 2005, however, are likely to make 2006 a tough year for market share growth and profitability for generics companies in the USA, EU and India. Longer term, the dearth of new drug launches — so problematic for and encouraging of consolidation by big pharma — will also negatively impact the opportunities for and increase consolidation in generics companies.

There is growing interest in and competition from established and emerging Indian companies for a share of the next generics cycle, while consolidation among global and regional US and EU generics companies is reducing the number of Western generics players; longer term, fewer new drugs launched means fewer available for generics.

BIG PHARMA'S DECREASING R&D PRODUCTIVITY IMPACTING GENERICS

Pharmaceutical sector growth is slowing, and there are fewer new drug launches. According to IMS, the global

pharmaceutical market is projected to grow at 6.5 per cent a year from 2004 to 2007, compared with more than 10 per cent annual growth from 1999 to 2003. The US market is projected to grow at 6 per cent a year from 2004 to 2007, compared with a growth rate of 10 per cent a year from 1999 to 2003. The slowdown in growth is in part due to fewer new product launches, with an average of 45 new drug launches forecasted annually from 2004 to 2007 vs 54 new drug launches annually from 1999 to 2003.³ Therefore, over the long term, there will be a decrease in the number of products available to generics. Given the long lead times for generics development, which often starts seven to ten years prior to patent expiry for the active pharmaceutical ingredient (API), one can argue that the slowdown in new product launches is already impacting the generics sector's R&D and pipeline development. It should be noted that sales of a generic drug commence, on average, seven to ten years after investments have begun to be made and risk undertaken confidentially in R&D, while long-term investors have a time horizon of around 12–18 months.

GROWING COMPETITION TO SUPPLY THE EU AND THE USA

Many Indian companies are targeting regulated markets, especially the USA. Seventy-two Indian companies have active

drug master files (DMFs) on file with the US Food and Drug Administration (FDA), some of these DMFs will never be referenced. Leaders Cipla, Dr. Reddy's Labs (DRL), Ranbaxy, Matrix, Sun, Wockhardt and Lupin each have 25 or more active DMFs.⁴

The Indian API and integrated finished dose form (FDF) suppliers are now a large source of APIs for the US market, whether supplied as APIs or manufactured into FDFs. India has displaced some of the traditional Italian and Spanish API suppliers. In 2004, approximately 45 per cent — the largest percentage by far — of DMFs reviewed by the FDA were filed by Indian-based companies. Western European firms filed only ~15 per cent of the DMFs reviewed by the FDA in 2004. Of the DMFs reviewed by the Agency in 1999, none were filed by Indian-based companies and the largest percentage, ~45 per cent, were filed by Western European API manufacturers.⁵ It should be noted that several Indian companies, notably Cipla and Ranbaxy, filed DMFs to supply the USA as far back as the 1980s.

Most of the original Indian API suppliers to the generics side of the industry, including Ranbaxy, Cipla and DRL and later entrants such as Wockhardt and Orchid, are now entering with FDF drug products. Some, such as Sun/Caraco, followed Ranbaxy's example of attempting to build direct sales to US customers under their own names after acquiring a US manufacturer. Companies such as Strides are selling to generics companies via the partnership model used by Cipla. Companies in the third wave from India that are attempting to compete directly with the US wholesalers and chains that control the vast majority of business in the USA without a US-based manufacturing entity include Zydus and Glenmark.

Growing numbers of new Indian companies are offering lower-cost APIs

and FDF products for the USA, contributing to a highly competitive business where margins are under pressure, particularly with fewer generics products available to launch in 2005 and in development for the longer term post-2008.

Indian companies generally have started by selling APIs in the EU, where the barriers to entry are lower because EU authorities do not inspect API facilities on a regular basis as the US FDA does. Some Indian companies have acquired smaller FDF companies or obtained approval for dossiers in the EU in order to forward integrate into FDFs. Examples of API manufacturers that sell FDFs in the EU include Matrix — with the announced acquisition of Belgian generic Docpharma, Jubilant through its acquisition of a majority of Belgian dossier house PSI plus Wockhardt, IPCA, Lupin and, of course, Ranbaxy, DRL and Cipla — the latter following its partnership model. Most Indian companies hedge their bets and remain open to choosing a direct sales or partnership option on a product-by-product and country-by-country bases.

The first Indian companies to target the regulated markets, Ranbaxy and DRL, started by selling APIs to US generics, each then did different sorts of business development deals with US companies to launch their first FDF products. Only after significant time and significant investments in and understanding of the USA did Ranbaxy and DRL launch their own generics. DRL's strategy was driven by patent challenges, only one of which, paroxetine, has thus far been successful. DRL in the past built a sizeable API business in the USA, however. Ranbaxy acquired a small US FDF manufacturer, Ohm, and with that platform used its R&D capabilities to build a base business and a solid pipeline over many years. Ranbaxy employs several hundred people in the USA, its largest market. Cipla

entered more cautiously with its partnership business model, and now reportedly has eight alliances in the USA — with Watson, Ivax, Morton Grove, Eon (being acquired by Sandoz) and others — and over 200 products in its pipeline.⁶

US customers are using offers from new Indian FDF manufacturers to negotiate better prices, but mostly from their existing major generics suppliers. Other than APIs, it is not clear that any Indian companies other than Ranbaxy and, to a lesser extent, DRL and Sun/Caraco are yet getting meaningful market share in the US FDF generics market. The net result of Indian forays into the US FDF market and the increasingly competitive API market thus far is that margins are under pressure throughout the supply chain, while new entrants are as yet gaining little FDF market share in their own names.

For example, citalopram, where first generics were launched in October 2004, had multiple abbreviated new drug applications (ANDAs) approved, precipitous price declines and rapid generics penetration. New Indian entrants included Aurobindo and Matrix as well as Jubilant as an API supplier. Aurobindo had only 1.2 per cent market share under its own name and Caraco/Sun only achieved a 2 per cent share as of the week of 24th June, 2005. DRL has a market share of 17 per cent for the same time period.⁷

So, there is growing competition to supply the USA, the largest and therefore most attractive regulated market, at a time when there are fewer products losing exclusivity in the immediate and long term and consolidation on the part of major US generics and the customers — the large chains and wholesalers. The large chains and wholesalers, huge companies themselves, require large, sophisticated companies to serve them and do not buy from boutiques. Indian companies can make money in the USA at lower prices

than US or EU companies and are usually quick to drop prices even if they are not ultimately winning significant market share, fuelling the downwards spiral of prices and margins. DRL Chief Operating Officer Satish Reddy stated that DRL was making money on citalopram, even at prices lower than 8 per cent of the brand price, in response to a question from Lehman Brothers analyst Rich Silver at the IGPA Conference in Malta in June 2005.

USA: LOW PRICES DO NOT WIN THE BUSINESS

‘Generics manufacturers need to differentiate themselves to the drug retailers by consistency of product and supply, distribution and logistics, capabilities and the pipeline of future products. Price is not usually a significant negotiating tool, as most generics are multi-sourced and priced similarly.’ These comments by Dennis O’Dell, Senior Vice President of Pharmacy Service at the large US drug store chain Walgreens were made on a conference call hosted by Rich Silver and Meredith Alder of Lehman Brothers NY with Teva’s George Barrett, Chief Executive Officer (CEO) North America, and Bill Marth, CEO USA, on 9th December, 2004.

In the same interview Dennis O’Dell elaborated that the big US drug store chains such as Walgreens switch generics suppliers infrequently. As O’Dell put it, ‘How frequently do we switch suppliers . . . we could switch suppliers in a multi-source situation often, but we don’t . . .’. The reasons provided by Dennis O’Dell to explain why Walgreens does not switch suppliers include the following:

- Patient trust in continuity of care: important to have no changes to pills, etc.

- Relationship with generics supplier: ability to work together is key.
- Logistics: very important. Speed to market and speed of adoption of generics are important to retailers.
- Distribution: making sure the product is where it is supposed to be at the right time, having product available from the get-go without interruption (from one supplier) through the end cycle.
- Communication, information, continuing medical education (CME) materials.

Generally, US buyers like to buy one product at very low prices from a new supplier, in order to have a relationship, and to use the leverage of a new, low-priced offer to help in negotiating the best deal from their preferred suppliers. Some large chains have started using reverse auctions to obtain the lowest price on their largest products. US chain and wholesale buyers have complex, long-term relationships with their large, long-time generics suppliers, involving in-depth understanding and meeting of their logistical and profit needs, especially on large, new launches.

The sentiments of Walgreens call into question the tactic of filing ANDAs and DMFs for older generics products by Indian companies, especially Indian companies with weak US sales and marketing. Of the 195 DMFs filed in the USA by Indian companies in 2004, 58 were for products that were already generic, according to DRL's Satish Reddy at the IGPA Conference. It remains to be seen how many of these late DMFs will actually result in significant inroads into the USA.

Large drug store chains and wholesalers, the customers for drug products in the USA, have also consolidated. Buyers have thereby increased their clout and demand sophisticated logistics and supply chain management to meet their exacting needs.

Large buyers prefer to be served by large, established suppliers, as in most industries.

Some large US chains, wholesalers and other members of the buyer side have approached large Indian and Chinese companies directly to contract for generics products at lower prices. The buyers' goals are to lower costs and thereby increase their own margins. The cost/benefit for these customers of the investment and resource commitment of building sophisticated commercial and technical capabilities to safely purchase FDF generics directly from low cost overseas manufacturers vs the cost savings from going direct are not analysed herein, nor is the risk of inexperienced organisations making mistakes from buying lower quality products or mismanaging the in-bound supply chain.

The growing number of generics companies driven to license deals for FDF drugs due to lack of internal R&D performance may well find themselves marginalised as their customers go direct to the sources of R&D in India. The most sophisticated generics companies — notably Teva — with high-performing R&D, aggressively low costs and sophisticated customer relationship and supply chain management, are expected to continue to add value to the customer side, whereas smaller companies — those without attractive pipelines or the ability to understand how their customers make money and add value — are expected to suffer from strong Indian competition and the efforts, while ultimately successful or not, of big buyers to go direct.

EU wholesalers/customers remain fragmented and mostly national, which, combined with the differing packs, rules, and brands in each markets make it difficult for a large generics company or large volume Indian producer to make money in the EU. Opportunities in Europe must be approached on a country by country basis, with manufacturing of

small batch sizes to make the often differing presentations for each market. The EU therefore represents a more difficult opportunity for Indian companies than the large, uniform US market and one that high-volume US and Indian FDF manufacturers are ill-equipped to serve profitably from their traditional large volume FDF factories. Pricing in the EU, however, is more stable than in the USA. Pricing varies broadly between the competitive market in the UK and the price-controlled market in Germany, with true prices often less than those reported because of discounts and rebates. While even the UK does not yet usually feature the kind of rapid discounting to around 90+ per cent off the branded price a couple of months after a generics launch that is now routine in the USA, the EU remains a difficult environment for a generics company to achieve good margins.

WHAT DO GENERICS NEED TO PERFORM IN THE USA?

There are six key success factors (KSFs) for a generics company in the USA or any truly generic, regulated market. Each KSF is examined in turn and then Indian competence in these key areas is evaluated in general:

- pipeline;
- sales and marketing;
- APIs;
- breadth of product line or unique niches;
- low costs;
- timing.

Generics performance: Pipeline

Generics companies need a strong, growing pipeline of products in which the company has a competitive advantage. Underlying the building of a strong pipeline is product selection: companies must build a pipeline that supports

company strategy in terms of core focus on blockbusters or niche, specialty-type products. A successful generics company must focus and execute in R&D and business development and licensing (BD&L) in order to enable the build pipeline to deliver approval and launch on time. No generics company can sustain major market leadership based on BD&L alone, without high-performing, internal R&D.

An attractive pipeline is essential in part because it underpins sales of existing products. New entrants without an attractive new product pipeline have difficulty selling older products, irrespective of cost.

If [a US generics company's] pipeline is deep and attractive, both quantity and quality, it further strengthens their competitive position on existing products — they have more leverage with customers. It's mutually beneficial if the supplier has an attractive pipeline that helps the customer's profitability and long term planning. That customer is more likely to do more long term business with a company that can offer an attractive pipeline. The converse is true — if a company doesn't have much of a pipeline, doesn't have something good to offer, then the customer will do less business on existing products and likely be a tougher negotiator.

These comments were made by Rich Silver, Senior Vice President and Specialty Pharmaceutical Analyst at Lehman Brothers NY, in an interview with the author on 21st February, 2005.

Table 2 shows known pipelines for companies in the USA. The current expedient fix in both the USA and Europe for generics companies with weak R&D, such as Alkermes, to license a pipeline from India is likely to further weaken these companies and diminish their ability

Table 2: US generics pipelines

	ANDAs	Value US\$bn	Number FTF	Source
Teva	140	82+	26	R&D
Ivax	61	40	12	R&D, Cipla, BD&L
Par	50	30		BD&L, R&D Kali
Ranbaxy	50	10–11		R&D
Barr	46	10		R&D, BD&L
Mylan	41	32	10	R&D
Dr Reddys	39			R&D
Watson	34	20		Cipla, BD&L
Andrx	≈30			R&D
Sandoz/Eon/Hexal	?+27	14+		Sandoz — weak R&D; Eon — R&D, Hexal, Cipla
Taro	20			
APP	20	2		
Impax	16	6	1	R&D, BD&L
Alpharma	≈14	<5		BD&L, weak R&D

Sources: Company reports, Lehman estimates updated 6th March, 2005, Q Street assessment. ANDA, abbreviated new drug applications; FTF, first to file; BD&L, business development and licensing

to compete long term. With integrated Indian companies going direct to the markets, and buyers such as chains and wholesalers looking to cut costs, what is the rationale for giving margin to a US company effectively acting as a sales agent for an Indian R&D powerhouse? In the long term, such companies are unlikely to survive but may become useful acquisitions for Indian or European regional companies dedicated to building the sales and marketing infrastructure they need to compete in the USA. While a powerhouse in US sales and marketing, one might argue that Watson has a similar problem, and must either fix or acquire internal R&D capabilities adequate for its size.

In the EU, a dossier licensing business model prevails for generics companies seeking to broaden their product lines or make up for R&D delays as well as for companies that neither manufacture nor perform R&D. Every company in the EU seems to license in at least some dossiers, often but not always with finished goods supplied. This business model, which was not common in the USA until recently, is now supported by the differing presentations and market models in the various member states, which gives advantage to national companies with

generic brands and sales forces but which cannot support broad R&D. The national companies, even if they do some R&D, do not have the breadth of pipeline of the big global players such as Teva and Sandoz/Hexal/Eon. Effective political and regulatory advocacy for generics by the European Generics Association (EGA), and the presence of global and regional generics companies, will likely lead to more pro-generics policies and market changes in the EU over the medium to long term. With the eventual growing harmonisation of rules, market models and perhaps presentations may come an EU market more similar to the USA in favouring generics manufacturers with the broad R&D pipelines and low costs possible only with internal FDF manufacturing and access to low-cost APIs. Global and strong regional generics, such as ratiopharm, are undermining the competitiveness of many of the national companies that lack true R&D and manufacturing capabilities.

Indian speed and high performance in R&D

High-quality Indian pharma companies have significant competitive advantages in

R&D to build a pipeline. R&D is India's key advantage. Indian scientists can develop products and transfer technology to and build API plants to make the products faster, on average, than other companies. Indian advantages include high technical skill levels in the development of non-infringing processes and difficult non-infringing, bio-equivalent formulations, and development of regulatory submissions, at lower cost. Some Indian companies can even perform their own bio-studies at dramatically lower cost than in the USA or Europe. Core competencies in rapid, non-infringing development and regulatory submission of low-cost, equivalent products on time for launch at loss of exclusivity (LOE) are extremely well developed in many Indian generics companies. The impact on Indian R&D companies of the recently implemented amendments to the patent act remains to be seen.

Generics performance: Sales and marketing

To succeed in the USA, generics companies need strong relationships with customers and a deep understanding of the levers of profitability at the customer level. Flawless execution of launch and supply chain management in a pure generics market is required. Shipping late, not having enough product to fill the channel at initial launch, not delivering on time to the customer's warehouse site are not acceptable. Large generics launches in the US market are extremely complicated and achieving rapid uptake of a new generic drug is important to chains' and wholesalers' profits. American customers are unlikely to want to take a chance with an unfamiliar generic supplier with which they have not done profitable business managing the logistics of new launches for years.

Branded generics markets such as Germany require a salesforce with

excellent relationships, high productivity and knowledge of the local prescribing environment. In branded generics markets, access to a pipeline that will deliver launches of new, attractive products helps to pull sales of older products as well.

Indian weaknesses in sales and marketing

Sales and marketing is the weak area for Indian companies attempting to compete in regulated markets. Indian companies with the exception of Ranbaxy are still learning the requirements of Western generics companies and are not experienced working with the US customers. Ranbaxy has reportedly greatly improved its service levels in recent years, as evidenced by its recent receipt of a Supplier Award from Wal-Mart, the largest chain drug store in the US, for outstanding performance in the first quarter of 2005. '[Ranbaxy] has been outstanding in meeting the criteria for this award, based upon improvement in areas of on-time shipping, performance, innovative programs and partnership', according to Dave Dible, Executive Vice President, Wal-Mart.⁸ Ranbaxy's service and customer integration levels, while impressive for a relatively new entrant, still lag behind those of the top US generics companies such as Mylan, Watson and Teva, and they are often the leader in dropping prices below even levels needed to make a competitive offer, according to several senior industry sales and marketing executives with whom the author has spoken.

Indian weakness in sales and marketing requires sustained investment and learning about working with customers and the establishment of relationships that take time, as Ranbaxy has done. Alternatively, a partnership model can be used. The Indian weakness in sales and marketing

and the weakness of numerous US and EU companies in R&D is likely also to lead to mergers between strong Indian R&D companies and Western generics with strengths in marketing in specific countries. For instance, the partnership between Cipla, a world-class R&D and manufacturing powerhouse with no marketing infrastructure in the regulated markets, and Watson, a US marketing powerhouse with poor-performing R&D and higher manufacturing costs, is a strategic alliance. Even in the Watson–Cipla alliance, however, there is not full risk and profit sharing and information is not fully disclosed by either side. Partnerships, like marriages, require openness, trust and time to grow, and no true marriages yet exist between Western and Indian companies in the USA.

Generics performance: APIs

Either internal API manufacturing and development or strong sourcing partnerships are essential to generics companies' abilities to develop products early enough, have non-infringing products and low costs. Products must not infringe the intellectual property (IP) of either innovators or aggressive, IP-intensive generics such as Teva and Ranbaxy. API manufacturers must be ready very early — seven to ten years prior to LOE — in order to support FDF R&D and regulatory submissions in order to launch on time at LOE. The API side must have a perfect technical package and support for regulatory filings, including rapid, complete responses to any deficiency letters, in multiple markets.

High-performing internal API capabilities is a competitive advantage in circumventing or challenging patents, being first to file/first to launch and solving complex technical problems for products that are difficult to manufacture or formulate. Internal API manufacture

lowers costs, since the margin of the API manufacturer is kept inside the company. As Chaim Zalmonowitz of Israel-based ARZ Chemical says, however, 'If you need milk, you do not have to own the cow. If you need a lot of milk, you can buy a cow, but a professional farmer must manage it, not a pharmacist.'

India: World leader in APIs

Indian companies entering the regulated markets have internal API manufacturing and development capabilities. Strong API companies, such as Matrix and Aurobindo, have forward integrated and are trying to compete in regulated markets selling FDFs. Companies originally lacking API manufacturing have either acquired or built, such as Glenmark and Strides.

Clearly, either strategically managed internal API development and manufacturing or strategic sourcing partnerships are essential to generics company success. American or European generics companies without API capabilities almost always have to source from India and 'understand the cow', as Ranbaxy's CEO Brian Tempest put it during his presentation at the ABN AMRO Global Generics Conference in Mumbai, in order to compete.⁹

Generics performance: Breadth of product line or niches

Customers want a full line, so breadth of product line is important. Unless offering first to file (FTF) generics for an important part of the customer's budget, having one, two or five product approvals will not lead to meaningful market share in the USA. It is useful to note that small shares of products in the US market can translate into meaningful profits and sales for smaller Indian companies, even while not being meaningful as a percentage market share in the USA. New product offerings are likely to be used by buyers to leverage price negotiations with their preferred

suppliers rather than leading to meaningful purchases from the new entrant. With a first approval, which is difficult to win, since many players are targeting almost every product, a new entrant can gain some share but other factors must be flawless to gain and retain significant market share unless the product is unique. Generics companies, especially new entrants, must always focus on how much money they are helping their customers to make. Many Indian companies focus on low prices as their competitive advantage, without understanding that wringing profits out of the entire supply chain leaves money on the table and does their customers no good at all.

Indian capabilities: Breadth of product line

Ranbaxy, Cipla, DRL, Sun, Lupin and Aurobindo have large numbers of manufactured products and deep R&D capabilities and pipelines potentially available for the US and EU markets. Other Indian companies are building and some have impressive product pipelines but are a long way away from the breadth of the leaders. Ranbaxy and Cipla have particularly deep and attractive pipelines supported by experience and a track record of regulatory success in regulated markets.

A niche strategy, on the other hand, requires partnership with a company having marketing relationships and experience in the niche therapy or delivery area. So far, niche product licensing deals have come more commonly from European manufacturers than from India, perhaps in part due to Indian weakness in marketing and tendency to go it alone.

Biocon is notable among Indian companies for having a focused strategy around a group of large volume APIs, the statins. So far, Biocon has achieved greater success in the EU, where it is easier to

change suppliers, than in the USA, where longer lead times and more complex and costly regulatory requirements make using an untried API supplier or changing suppliers more problematic.

Generics performance: Low costs assumed, not a competitive advantage

Low costs are assumed to be part of the generics business model. Low cost is therefore less important than other factors such as pipeline attractiveness and performance, API capabilities and marketing, and is overrated as a competitive advantage. Companies with high costs cannot compete but companies with lower costs cannot compete on lower costs alone.

India's low-cost scientists are a competitive advantage

Indian cultural traits of complexity, adaptability, entrepreneurialism and creativity in working around hardships are well suited to the complexities of operating in the highly competitive, highly complex, global pharma industry. India has low-cost and high-calibre scientific and technical personnel and a growing cadre of managers, scientists and workers experienced in current Good Manufacturing Practices (cGMPs). Many experts who have visited both Indian and Chinese factories say that the depth of Indian understanding of cGMP manufacturing is significantly beyond that of China. Chinese workers have been described by one API business development manager at a leading generics firm as 'robotic' in their adherence to whatever is taught them, but without the deep, nuanced understanding by workers or managers to be both reliable and flexible in meeting cGMPs seen in India.

India's cost advantage is based on low-cost, high-calibre scientific and technical

talent. Labour costs in India represent a small portion of API costs, on average 5–10 per cent of sales, vs an average 25–30 per cent of sales for a European API producer, according to Guy Villax, CEO of Portugal-based API and custom synthesis manufacturer Hovione. ‘The operating profit margin (sales minus raw materials and direct costs) is lower in India (40–50 per cent) than in Europe (75–60 per cent) primarily because Indians tend to compete with each other and Chinese producers to erode each other’s margins; thus the savings in labour, plant and overhead costs are promptly transferred to the clients’, according to Guy Villax. High-calibre Indian pharma companies supplying regulated markets have invested hundreds of millions of dollars in infrastructure and ‘software’ related to compliance, raising costs. With leading global generics manufacturers such as Sandoz locating significant R&D and manufacturing facilities in India and leading Indian companies such as Ranbaxy locating significant manufacturing facilities and sales, marketing and regulatory personnel in the USA, the perceived cost advantages of Indian companies are likely to even out over time.

Generics performance: Timing

In the pharmaceutical industry, timing is a key factor in profitability. Authorised generics are undercutting the profitability of the 180-day exclusivity reward to successful patent challenges in the USA. Launching on time and with full support and enough products for the customer, however, is important to retaining customers and making money, as is being committed to outlasting the competition. Teva’s motto to ‘be first, stay last’ is a key success factor often overlooked by other companies who enter late and exit when products become highly competitive. Indian companies have not been

established in the US market long enough nor have any besides Ranbaxy demonstrated significant enough commitment to and understanding of the market for a large chain or large wholesaler to rely on them to be first or stay last.

Generics: Partnership model

A partnership model, whereby the Indian company performs R&D and manufactures the API and possibly the FDF, and the EU or US company handles sales and marketing, offers advantages for Indian companies weak in sales and marketing and Western companies weak in R&D in building a portfolio faster for both partners. Cipla is the premier alliance partner due to its core strengths in R&D, non-infringing process development and rapid scale-up of extremely high-quality, low-cost manufacturing. Moreover, Cipla’s unique strategy of not entering many markets directly means that partners have faith that Cipla will not compete against them. Even Cipla’s partnerships are not yet full, risk-sharing alliances, however. Whether Cipla moves to a deeper, broader partnership model and how it navigates the consolidation and changing capabilities of its partners remains to be seen.

Issues with the partnership model being used by many Indian and US/EU generics include the following:

- No deals yet involve true partnership and full risk and information sharing. Trust between Indian and Western companies is lacking and interests are not fully aligned.
- US companies hold back development and marketing strategies and tactics — they do not educate Indian companies about generics customer needs, market competition and opportunities.
- Indian companies hold back their costs and R&D strategies, leading to

inefficient allocation of resources and limiting the ability to think and compete strategically as partners.

- Partners must build trust and establish performance and profits slowly, a product or a deal at a time. The number of large, multi-product deals being announced is too large to support the long, careful process of building trust.
- Profits are divided between two companies and neither company is as profitable or as competitive as a fully integrated manufacturer or a generics company that strategically sources APIs. It is unlikely, for instance, that Ivax could compete on the basis of products licensed from a partner against Teva or Sandoz/Hexal/Eon on the basis of internally developed products.

Many of the announced alliances will not succeed for the above reasons. Partnership may only be achievable within a unified company. So far, Indian companies have been acquirers of small generics companies in the USA and EU. Those companies are using acquisitions to partner with local management and learn how to compete in those markets.

In the EU, acquisitions such as the recently announced purchases of Docpharma by Matrix (reported by ABN AMRO as the largest acquisition by an Indian company) and Heumann by Torrent, as well as acquisitions by Ranbaxy, IPCA, Wockhardt, Jubilant and others, give Indian manufacturers the regulatory infrastructure to file marketing authorisations (MAs) in the EU member states and sales and marketing capabilities in individual countries.

In the USA, Ranbaxy has made the most progress in sales and marketing, starting with selling APIs, then acquiring old products from Lilly and later acquiring Ohm and building an organisation in the USA. So far, only Ranbaxy and DRL

have achieved a meaningful share in direct sales in the USA; however DRL has stumbled in the last few years and has few products under its own name. Building a presence in the USA takes time and investment. Few companies will succeed as the large US generics are well established with the big buyers who, as previously discussed, use new entrants more to keep prices low than as meaningful suppliers. Zydus, with its experienced US team, headed by former Apothecon and Geneva executive Joe Renner, and Invamed founder Dr Mahendra Patel on the Board, might succeed but Zydus is as yet a start-up in the USA.

CONCLUSIONS

There is increasing competition created by the number of Indian companies trying to compete in the USA and EU, while long term the number of products available for generics is declining and overall pharmaceutical industry growth is slowing. Considerable variation in long-term growth prospects among Western and Indian companies exists, based on R&D pipelines and ability to deliver on the key success factors. Companies with fewer capabilities for building a product pipeline to deliver quality earnings and growth are, like their big pharma brethren whose pipelines fail to deliver new launches, more likely to need to be involved in mergers and acquisitions (M&As). Companies with strong pipelines and good cash flow that are strong in M&As are more likely to acquire for expansion into new markets, profitable branded/specialty businesses with supporting sales forces and new platform technologies.

Smaller companies with limited R&D, limited or no API capabilities and limited scale to attract API manufacturers into exclusive alliances are especially dependent on licensing and likely to be acquired. Consolidation is likely to be led by global

and regional companies, including selected Indian companies, and to continue at a measured pace. There will probably be failures among Indian companies over-investing in facilities for regulated markets with borrowed money but which are unable to gain significant market share in selling to the large chains and wholesalers in the USA.

While the pipeline, sales and marketing competence, API access, breadth of product line, low costs and mastery of timing are Key Success Factors, people are the most important ingredient in success.

Exceptional leaders are rare in any industry. India's pharma industry has a disproportionate number of talented, committed and passionate entrepreneurial leaders, plus highly skilled, creative scientists and technical personnel who are driving R&D and manufacturing. Future leading global pharma companies will include at least one and probably two or more India-based, global generics companies who excel at the key success factors. Many of the Indian companies entering the USA and EU now will not succeed at building their own sales in either market and will end up being acquired or taking their places in the supply chains of the successful global companies, Western and Indian.

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