

Business India

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Yogesh: driving force behind R&D

While many of the largest pharmaceutical companies in India are struggling to cope with the double whammy of increased US FDA inspections and pricing pressures both in the US and within the country, a few companies such as Ajanta Pharma are going against the tide. In the past year, the Mumbai-based medicine maker has actually seen its US sales jump from a minuscule ₹14 crore to ₹185 crore! But this is not a mere flash in the pan. The company has recorded consistent growth over the past decade; its total sales in 2008 was just ₹317 crore (PAT: ₹22 crore), which has increased almost 10-fold to the 2016-17 figure (sales: ₹2,026 crore, PAT: ₹507 crore). Accordingly, its share price has zoomed from a modest ₹295 in January 2012 to ₹1521.85 at present! Its market capitalisation therefore works out to about ₹13,000 crore, with a promoter holding of 73.7 per cent and a free float of 26 per cent.

Ajanta has travelled a long way from its modest beginning, way back in 1973, when it was set up as a repackaging unit for generic medicines. During the years that followed, it launched a series of OTC (over the counter) products, the most famous

of which was named '30-Plus'. These medicines could be sold without a doctor's prescription, thus bypassing one of the biggest challenges that pharmaceutical companies all over the world face even today.

The other reason for this strategy was that the patent laws, in force until the 1970s, allowed the sale of prescription medicines only by the company holding the patent for that product. The law was changed in 1972 with the new Indian Patents Act, under which pharmaceutical companies could only patent the manufacturing process of a drug and not the product itself. And it took a while for Indian companies to develop the technological expertise to take advantage of the new patent provisions.

The real transformation of the company began in the 1990s with several changes that took place almost simultaneously. First, it reached to international markets, starting with Mauritius, where it established a manufacturing facility in 1996, and became a publicly listed company in 2000. Side by side, it began preparing to enter the fiercely competitive field of prescription drugs, though a full decade would pass before they could consider themselves ready.

In addition, a new generation of the promoters' family took over the reins of the company – Yogesh Agrawal as managing director in 1995, and his younger brother, Rajesh Agrawal, who joined as joint managing director four years later. Both brothers have MBAs from reputed US universities, Yogesh from Johnson & Wales and Rajesh from Bentley University, and they decided as far back as the mid-1990s to create a research-based foundation for their business.

With this mindset, the two brothers set about building a team of scientists to create a strong portfolio of intellectual property. At the same time, they reached out to markets in the Middle East, Africa and the CIS countries (which had just started becoming independent after the Soviet Union broke up in 1989). Besides, a change of US laws in 1995 enabled companies from all over the world including India to sell their generic pharmaceutical products (whose period of patent protection had expired) in the US. In that sense, it was a time filled with new opportunity on the global scenario and the youthful management of Ajanta Pharma took full advantage.

Yogesh Agrawal is the driving force behind the company's powerful R&D thrust. Though he inherited the team of only 30 scientists, he ramped up the R&D team to over 800 talented scientists, who continuously work on developing niche products and complex molecules. In 2007, Ajanta Pharma opened a large R&D Centre in Kandivli, a Mumbai suburb. As a whole, the company has doubled its R&D budget from 4 per cent of sales in 2012-13 to 7-8 per cent in the year ended March 2017.

Their conviction and focus on R&D enabled the company to launch many complex and difficult products in each of these countries and enjoy leadership in most of its market segments. Today, Ajanta is ranked the fourth largest drug maker in 19 African countries and fifth largest in Iraq. In 2016-17, the company's sales from these territories contributed 53.9 per cent to its overall turnover. Another 10 per cent of sales came from Asian countries other than India as well as the US (where they entered as recently as 2013!).

R&D initiatives

Among the notable achievements of Ajanta's R&D initiatives is in the anti-malarial segment, where the company's flagship brand is Artefan. It was the first generic treatment for malaria to be granted pre-qualification by the World Health Organization (WHO), which meant that it could be supplied all over the world through health programmes funded by multilateral agencies. Even today, Artefan is Ajanta's most successful and widely used product in the export market, and fetches the company a lion's share of its export revenue.

This might soon change, as the sustained R&D effort begins to yield results and the extent of its US foray begins to grow. Ajanta has filed 17 ANDAs (abbreviated new drug applications), with the US FDA to seek marketing permission for each product, of which eight were filed in 2016-17. Of these, 12 products have



Rajesh: building a team of scientists

been approved, while the company plans to file 18 applications in the current fiscal year. However, going by the experience of other leading pharmaceutical companies competing for the US pie, most of the ANDAs filed last year and this year could be accorded marketing permission only by 2020-21 and not earlier. That is if the manufacturing facilities are also cleared simultaneously.

Among the most interesting opportunities for Ajanta Pharma in the US are the two products which have already received tentative approval from the US FDA: one is generic Relpax, the patent for which expires next month, and generic Viagra, which would lose its patent protection in April 2020. Interestingly, Pfizer is the

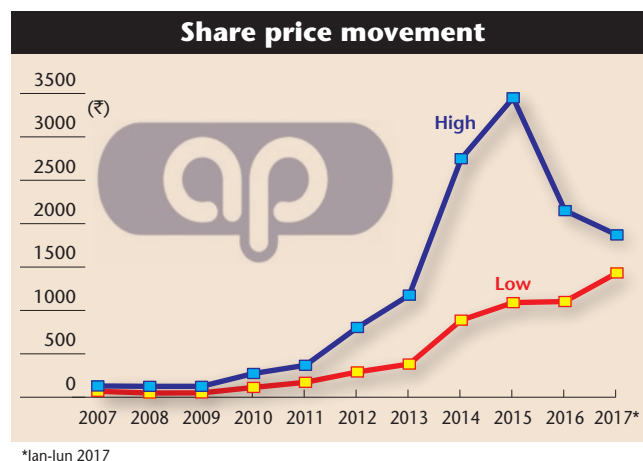
patent holder for both products. Relpax (chemical name: Eletriptan) is used for the treatment and prevention of migraine-related headaches and had recorded annual sales of \$250 million (almost ₹175 crore). Though global generic leaders including Teva, Apotex and Mylan also have tentative approvals for Eletriptan, because of which there could be a price erosion of 70 per cent, equity research analysts estimate that the product could still fetch as much as \$15 million in sales for Ajanta.

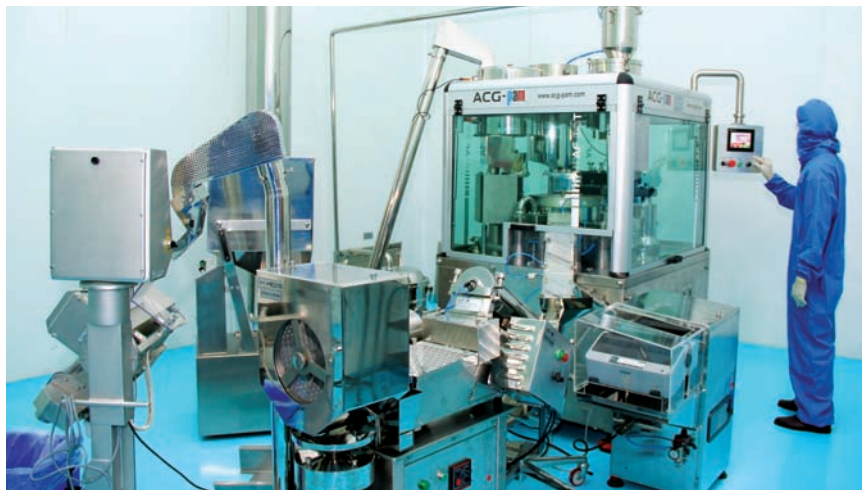
In the case of Viagra, the scenario is more interesting. Though there are still over two years left for the product patent to expire, Teva and Ajanta Pharma have received tentative approval to launch the drug in December 2017, while at least three

others may also be given a similar opportunity. This would mean that one or more of these companies would challenge the subsidiary patents associated with Viagra in what the international pharmaceutical industry describes as a 'Para IV' challenge. Assuming the generic companies win the patent litigation, there would possibly be a price erosion of 90 per cent. Despite this, the potential market for Ajanta is worth about \$34 million, according to industry sources.

Put together, the company has seven manufacturing facilities, four of which are near Aurangabad (Chikalthana, Paithan, Chitegaon and Waluj), one in Dahej (Gujarat), one in Guwahati (the most recent) and one in Goodlands, Mauritius. The one in Waluj is an API (active pharmaceutical ingredient) plant, which produces bulk drugs in the form of powders or liquids in large quantities. The entire output of this unit is consumed by the company's other factories that fashion the APIs into medicinal formulations (tablets, capsules, syrups, etc).

One of the conditions





for approval of formulations (also known as ‘finished dosage forms’) from the US FDA is that they have to be produced from APIs that are required to be approved separately with the help of drug master files (DMF). Besides, the factory at which the APIs are produced also has to be FDA-approved! Now Ajanta Pharma’s production unit in Paithan has been approved by the US FDA, but its one and only API unit is probably not approved by them. In addition, its brand new factory in Dahej, which began commercial operations in April 2017, has already undergone an FDA audit. The company has informed the stock exchanges that it was issued a Form 483 with no adverse comments, which means the US regulatory approval could come through sooner rather than later.

While obtaining over 60 per cent of its sales from overseas markets, Ajanta has also captured a 0.7 per cent share of the Indian market, having climbed from the 88th position in March 2005 to a respectable 33rd in March 2017. Its sales figure of ₹614 crore in 2016-17 represents 30.3 per cent of its total revenues and a 12 per cent growth over the previous year (compared to 9 per cent in the overall domestic market). It has also got into the Top Five in the segment of eye care medicines, and within the Top 20 in dermatology (skin disorders) and cardiology. In eye care and skin care as well as in pain management, which are high growth areas for quite a few Indian companies, Ajanta has

recorded a modest 11-12 per cent growth over the previous year.

Data sourced from QuintilesIMS, a global information and technology healthcare services company, reveals that Ajanta’s closest competitors in the domestic market include: Himalaya Drugs (ranked 31), Franco (32), Blue Cross (34), Unique (35), Raptakos (36) and Medley (37). In specific segments, too, Ajanta has managed to make its presence felt. Thus, in the dermatology segment, Ajanta’s 2016-17 sales of ₹142 crore constituted 23.1 per cent of the total India sales of ₹614 crore, which is substantially higher than the average of 7-9 per cent share that dermatology commands in the entire domestic market (all companies put together).

“APL’s main distinguishing factor is the uncanny knack of launching maximum number of first time launches with focus on New Drug Delivery System (NDDS),” says an equity research report from ICICIDirect, released in May 2017. “Of the 200-plus actively marketed brands, 70 per cent brands were introduced first time in India. The focus on specialty therapies and niche product led APL to post a strong growth at a CAGR of 22 per cent during 2012-17 – far higher than industry growth of about 12 per cent. Going ahead, we expect domestic formulations to grow at a CAGR of 15 per cent between 2016-17 and 2018-19E to ₹813 crore, driven by a mix of existing products and new launches”.

Hence, ICICIDirect has accorded a

‘BUY’ rating to the scrip with a target price of ₹1,880, which represents a 13 per cent upside from its current price (May 2017) of ₹1,659 over the coming 12-15 months. This is in fact a downward revision from the target price of ₹1,960 mentioned by the same analyst at the end of Q3 2016-17.

Superior track record

Motilal Oswal, another equity research house, is however more optimistic. “We value Ajanta Pharma at a premium compared to P/E multiple of 20-21x for mid-cap pharma companies, at 25x 2018-19E earnings, on the back of its proven superior track record in terms of revenue growth and profitability,” says its latest report, issued on basis of 2016-17 results. “We also note that peers with a higher exposure to the US market are facing pricing pressure in the base business, with some also facing regulatory headwinds. Ajanta has a low US base business and minimal regulatory risks over the medium term. We thus initiate coverage on the company with a BUY rating and a target price of ₹2,028”.

In terms of its portfolio mix and the geographies that it operates in, Ajanta is probably well placed for strong growth. Its relatively low base could be an advantage because the struggles that companies with a larger US presence are facing are some distance away. Besides, its focus is as much on African and Latin American countries where regulation is not as stringent as the US or Europe. These so-called emerging markets are where the fastest growth would continue in the near future, while growth in the developed markets is not likely to pick up any time soon.

In the Indian market, too, price control applies mostly to mature products while new launches are given a holiday for the first few years. Hence a company like Ajanta with a system of quick-fire product launches would have a distinct advantage. With an army of over 3,000 field representatives all over the country, it is surely well equipped to benefit from its regular pipeline of new products.

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