



## Pharmaceuticals

### ANDA approvals in February 2011

In this report, we have summarised the abbreviated new drug application (ANDA) filings and Para IV challenges made by pharmaceutical (pharma) majors in the US generics market and we analyze the trends/recent developments in the sector.

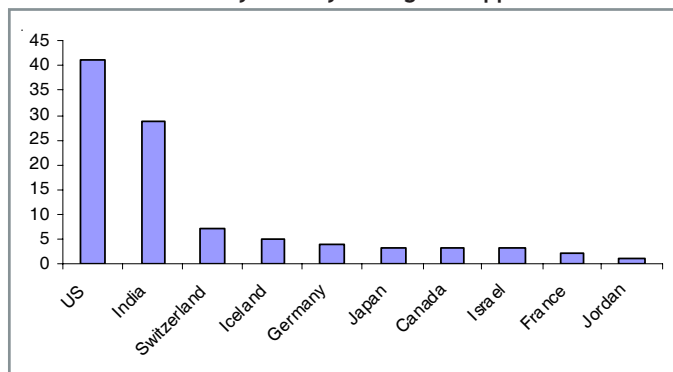
#### Sector overview

Industry pressures are continuing to mount for innovators as a number of blockbusters are losing exclusivity with few new launches to fill up the gap. In light of that, it is not surprising that the pharma majors continued their foray into the generics sector and into the emerging markets. Companies also continued their pursuit of patent challenges, geographic and portfolio diversification, and positioning for biosimilars.

Among the notable recent deals are: Sanofi acquiring Genzyme for \$20 billion (biotech), Pfizer acquiring Aurobindo's drug pipeline for \$28 million (emerging market), and Reckitt Benckiser Group acquiring Paras Pharma for \$724 million (filling portfolio gap). At home, Piramal Healthcare (Piramal) acquired a majority stake in a discovery services firm - Oxygen bio research for Rs51 crore (76% stake), while Sun Pharmaceutical Industries (Sun pharma) is on its way to de-list Caraco.

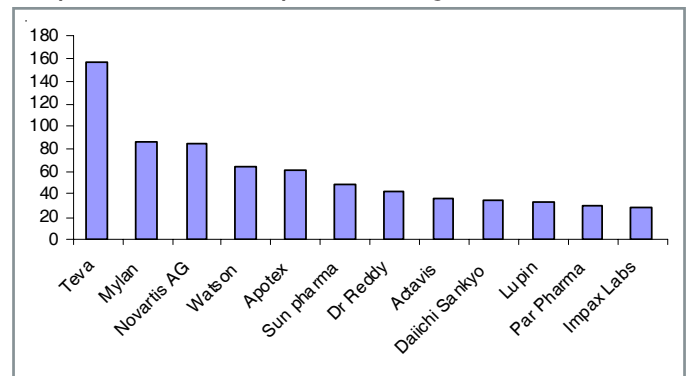
Meanwhile, we remain robust on the US generics growth story. We believe that the growth in the pharma sector is now focused on specialist/niche therapy areas. In the boom of off-patent drugs, generic companies like Sun pharma, Dr Reddy's Laboratories (Dr Reddy's), Lupin and Glenmark Pharmaceuticals (Glenmark) would be able to weather the future downturns.

Total A-rated ANDAs by country of origin of applicant



The US-based companies received the most ANDA approvals, with 41 approvals going to 24 different US companies. The Indian groups were in the second place, with 29 final approvals going to nine companies.

Companies with the most patent challenges on record as of 2010



Teva continued to be by far the most prolific filer of ANDAs with patent challenges. Mylan claimed the second spot with challenges on 86 products, while Novartis (Sandoz) dropped to the third place with links to 84 challenges. Amongst the Indian pharma companies, Sun pharma ranks the highest with major concentration towards dermatology and controlled substances, followed by Dr Reddy's and Lupin (oral contraceptives, ophthalmics, modified release).

#### Key events/updates in pharma sector

- The US Food and Drug Administration (USFDA) imposed an import alert on Aurobindo Pharma (Aurobindo)'s cephalosporins plant after its initial inspection in December 2010. The facility would contribute ~5% of the total revenues. Currently Aurobindo supplies ten products to Pfizer. A delay in the clearance of the ban would impact the earnings from this deal. Pfizer confirmed four of its injectable products—cefazolin, cefotaxime, ceftazidime and ceftriaxone—would be affected by this import alert.
- Sanofi Aventis has entered into a definitive agreement to acquire Genzyme for \$20 billion (~\$74 per share). In addition to cash, Genzyme's shareholders would also receive one contingent value right for each share held. The CVR would entitle the shareholders to receive additional cash payments relating to developments and milestone achieved for Cerezyme and Fabrazyme. We believe that apart from earnings benefits, the acquisition would also help Sanofi strengthen its biotech portfolio.

We present below the ANDA approvals by the Indian pharma companies from February 5, 2011 till March 4, 2011.

| Generic Name                           | Brand Name          | Innovator company    | Company type          | Approval         | Indication          | Market size (\$mn) | Marketing Timeline               | Key players   |
|--|---------------------|----------------------|-----------------------|------------------|---------------------|--------------------|----------------------------------|---|
| Levocetirizine Dihydrochloride Tablets | Xyzal               | UCB Inc.             | Glenmark              | Final            | Allergic rhinitis   | 231                | Immediate                        | Dr Reddy, Synthron  |
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| Venlafexine ER Capsules                | Effexor XR Capsules | Wyeth Pharma         | Aurobindo             | Tentative        | CNS                 | 2400               | -                                | -   |
| Lamotrigine Tablets                    | Lamictal            | GSK Pharma           | Alembic               | Final            | CNS                 | -                  | Immediate                        | Apotex, Cadista, Dr Reddy, Lupin, Mylan, Sandoz, Sun, Teva, Torrent, Watson, Cadila, Aurobindo  |
| Lamotrigine Tablets                    | Lamictal            | GSK Pharma           | Jubilant Lifesciences | Final            | CNS                 | -                  | Immediate                        | Apotex, Cadista, Dr Reddy, Lupin, Mylan, Sandoz, Sun, Teva, Torrent, Watson, Cadila, Aurobindo  |
| Pantoprazole Sodium                    | Protonix            | Wyeth Pharma         | Dr Reddy's Lab        | Final            | GI                  | 2000               | -                                | -   |
| Carboplatin                            | Paraplatin          | BMS                  | Strides Arcolab       | Final, EU market | Ovarian Cancer      | 138                | Immediate                        | Teva  |
| Gabapentin Tablets                     | Neurontin           | Pfizer               | Matrix Labs           | Final            | Epilepsy            | 300                | Immediate                        | Actavis, Alkem, Amneal, Apotex, Aurobindo, Cadila Invagen, Teva, Ranbaxy, Sun, Watson, Glenmark |
| Gabapentin Tablets                     | Neurontin           | Pfizer               | Cadila                | Final            | Epilepsy            | 300                | Immediate                        | Actavis, Alkem, Amneal, Apotex, Aurobindo, Matrix Invagen, Teva, Ranbaxy, Sun Watson, Glenmark  |
| Naratriptan Tablets                    | Amerge              | GSK Pharma           | Sun pharma            | Final            | CNS                 | 60                 | Immediate                        | Paddock, Roxane, Sandoz, Teva   |
| Lithium Carbonate ER Capsules          | Lithobid            | Noven Therapies      | Glenmark              | Final            | Psychotic           | 10                 | Immediate                        | Roxane, West ward, Sun Pharma   |
| Zidovudine                             | Ziagen              | VIIV Healthcare      | Matrix Labs           | NDA approval     | Anti-retroviral-HIV | -                  | -                                | Cipla, Strides - tentative approvals  |
| Ondansetron                            | Zofran ODT          | GSK pharma           | Ranbaxy               | Final            | Oncology            | 300                | Immediate                        | Glenmark, Mylan, Sandoz, Sun Pharma, Teva   |
| Galantamine Hydrobromide               | Razadyne ER         | Ortho Mcneil Janssen | Cadila                | Final            | Alzheimer           | 50                 | Immediate                        | Barr, Impax, Mylan, Watson, Sun Pharma  |
| Irbesartan and Hydrochlorothiazide     | Avalide             | Sanofi Aventis       | Cadila                | Tentative        | Anti-Hypertensive   | 2100               | Patent expires in Sep 11/ Mar 12 | -   |
| Abacavir Sulphate Solution             | Ziagen              | VIIV Healthcare      | Cipla                 | Tentative        | Anti-retroviral-HIV | -                  | Patent expires in Dec 2011       | Strides Arcolab, Matrix labs  |

## Valuation table: Sharekhan pharma universe

| Company                  | CMP<br>(Rs) | EPS (Rs) |       |       | P/E (x) |       |       |
|--------------------------|-------------|----------|-------|-------|---------|-------|-------|
|                          |             | FY11E    | FY12E | FY13E | FY11E   | FY12E | FY13E |
| Glenmark Pharmaceuticals | 300         | 17.6     | 19.5  | 24.1  | 17.0    | 15.4  | 12.4  |
| Sun Pharma               | 432         | 16.9     | 21.8  | 26    | 25.6    | 19.8  | 16.6  |
| Lupin                    | 397         | 19.1     | 23.1  | 27.2  | 20.8    | 17.2  | 14.6  |
| Nicholas Piramal         | 463         | 9.2      | 15.7  | -     | 50.4    | 29.5  | -     |
| Cadila Healthcare        | 767         | 33.5     | 41.0  | 50.6  | 22.9    | 18.7  | 15.2  |
| Ipca Laboratories        | 273         | 20.0     | 23.8  | 30.5  | 13.7    | 11.5  | 9.0   |
| Opto Circuits            | 258         | 18.4     | 22.3  | 27.3  | 14.0    | 11.6  | 9.5   |
| JB Chemicals             | 138         | 15.3     | 18.3  | 22.2  | 9.0     | 7.6   | 6.2   |
| Torrent Pharmaceuticals  | 510         | 34.6     | 45.7  | 50.9  | 14.7    | 11.2  | 10.0  |

The author doesn't hold any investment in any of the companies mentioned in the article.

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