Domestic Pharma companies licensed to make Roche’s “Tamiflu”

The government is likely to invoke the compulsory licensing (CL) provision in the Patents Act to allow domestic drug firms to produce and stockpile Roche’s ‘Tamiflu’ an anti-influenza drug against the possible epidemic of bird flu. It is a leading pre-emptive medicine in fighting the dreadful avian flu virus facing critical shortage in supply. The move is intended to cope with any public health emergency that might arise in case the pandemic hits India. Once the CL is issued, India’s generic drugmakers would be able to manufacture the drug not only for supply in the domestic market, but also for export. At least three firms, Ranbaxy, Cipla and HeteroDrugs, are equipped and are willing to manufacture the drug. Section 92 empowers the government to issue CL without receipt of an application from the industry. The issuance of such license would also not require third party consent, including the importing country’s prior nod. The demand for this drug has increased manifold following reports that the pandemic has reached Europe and SE Asia. CL is a provision provided for in the WTO’s trade-related intellectual property rights (TRIPS) agreement, allowing governments to sidestep patents to combat public health crises.

Acquisition of Aveca Phamacueticals by Nicholas Piramal India Limited (NPIL)

NPIL has acquired 100% equity of Aveca Pharmaceuticals Ltd., UK and likewise that of Torcan Chemical Ltd., which is a 100% subsidiary of Aveca and Reaxa Ltd., UK, which is 25% owned by Aveca. The company has paid a consideration of GBP 9.5mn (Rs760mn). NPIL will own all assets of Aveca and Torcan, including working capital of GBP 8.8mn. Aveca Pharma is a western custom manufacturing company, having a strong presence in the sector since early 90’s. It was part of ICI’s specialty chemicals business till late 90’s. Spun-out of AstraZeneca, Aveca was bought-out by private equity funds in 1999. Aveca acquired Torcan Chemical Ltd., Canada, a specialty CCS/API company, in 2000. The company has strong European and North American relationships with 5 of the top-10 innovator companies and several medium-sized pharmaceutical and biotech companies. As of now Aveca has entered into 93 CMG contracts and has 55 customers on the list. The various business segments of Aveca Pharma U.K include, North American early-phase pipeline at Torcan (Aurora Canada), Pharmaceuticals (Intermediates and API’s), Early Phase Delivery Team (EPDT) and Five High Potency Substances (HPS) laboratories at Grangemouth. NPIL believes that this merger would help in building its vision to be a global leader in CMG business and contribute to its topline through new product manufacturing. NPIL expects to break-even on the current negative EBDITA margins of Aveca’s in 12-15 months. This is possible by maintaining lower level of fixed costs, as the labour costs in India are cheap. NPIL aims to achieve turnover of US$50mn through the CMG business by 2010 and US$100mn in the long run.
Orchid and Mayne Pharma enter into distribution alliance
Orchid Chemicals and Pharmaceuticals has entered into an exclusive distribution alliance for five antibiotic injectibles with Mayne Pharma. The distribution alliance is to cover North America, Europe and Australia. Over the last two years Orchid has signed distribution alliances for a sum total of 41 molecules in the developed markets and the deal with Mayne follows the trend. The company has so far received three approvals from the US regulator (ANDAs) for the molecules covered under the distribution deals. It is expected that Mayne would be providing upfront payments as development funding and would make more payments once Orchid reaches set milestones while developing the molecules. The net profits that accrue from the distribution of the five injectibles would be shared between the partners. The company expects to begin the supply of products under the deal with Mayne in early 2007. The entire basket of five injectibles would be supplied over a three-year period.

Enaleni to sue Lupin for violation of marketing agreement
South Africa's largest generic drug company Enaleni Pharmaceuticals is planning to sue domestic major Lupin Ltd. for terminating a marketing right unilaterally in violation of an existing agreement. Specpharm and Westbury, which at the end of October become subsidiaries of the Durban based Enaleni Pharma, is now all set to defend in court their right to distribute Lupin's products in South Africa and other agreed markets. Specpharm and Westbury had signed a four-year agreement to distribute Lupin's anti-TB drugs in South Africa and other African markets in June 2002. However in September Lupin intimated Specpharm and Westbury about the termination of its marketing agreement with them owing to the change in their management and announced that it has tied up with Aspen Pharmacare, another South African company, giving Aspen the distribution rights in South Africa and the surrounding markets.

Ranbaxy entered in strategic marketing tie-up with Lupin Ltd.
Ranbaxy Labs has entered into an in-licensing agreement to market and sell Lupin Labs Tuberculosis brand named 'Akurit' in fixed dose combination. Both the companies believe that this tie-up would combine their strengths and help controlling TB in severely impacted areas of Africa. This will leverage Ranbaxy's field force and marketing strengths in West and North Africa to promote Lupin’s TB brands.
Sterling Biotech acquires Torrent Gujarat Biotech’s facility
Sterling Biotech Limited, one of the world’s largest manufacturers of pharmaceutical gelatin, has signed a MoU to purchase the manufacturing facility of Torrent Gujarat Biotech Ltd for consideration of Rs550mn in cash. The plant of Torrent Gujarat Biotech Ltd is located at Masar, Dist. Baroda, Gujarat. The transaction is subject to both the parties receiving necessary approvals under applicable laws. Sterling Biotech Ltd. will use this facility to manufacture specialized gelatins derivatives such as Fish Gelatin, Hydrolyzed Gelatin and fermentation-based nutraceuticals such as Co-Enzyme Q 10.

Glenmark Pharma receives USFDA approval and enters into strategic alliances for generics
Glenmark Pharmaceuticals Ltd has received US FDA approval for its solid dosage plant in Goa that manufactures formulations for the international regulated markets. In addition to this, the plant also has received CGMP approvals by two other international regulatory bodies, viz. Therapeutics Products Directorate, Canada (TPD) and Medicine Control Council, South Africa (MCC). These approvals would accelerate the demand for Glenmark’s generic drugs in the regulated markets. The company was privileged of receiving these approvals in a little time of over one year from commissioning. The Company has filed 7 ANDAs to date from this facility and has plans to file 13 more this financial year. In addition, the Company signed two partnership agreements with US based companies, Interpharm Inc. and Konec Inc., for marketing their generic products “Naproxen” and “Nitroglycerin” in the US. The Company also entered an exclusive license agreement with InvaGen Inc. for marketing its anti-hypertensive agent, Fosinopril Sodium oral tablets “Monopril”, for the US market. The Company had purchased two ANDA from Clonmel Healthcare Ltd in FY05 and had signed a collaboration agreement with another Indian company, Shasun Chemicals and Drugs Ltd, for the joint development and marketing of 13 generic products in the US market.

Dr. Reddy's and Ranbaxy get nod for diabetes drug
India’s Dr. Reddy’s Laboratories Ltd. and Ranbaxy Laboratories Ltd. have received approval from US FDA to sell their copy of Sanofi-Aventis’ diabetes drug Amaryl in the U.S. Dr. Reddy’s and Ranbaxy are among five companies, including Israel’s Teva Pharmaceutical Industries Ltd., which have got approval to sell tablets of Glimepiride in the world's biggest drug market.

Elder commences operations of tablet facility at Uttaranchal
Elder Pharmaceuticals has commissioned a new manufacturing facility at Selaqui, near Dehradun in Uttaranchal. The new facility is equipped to manufacture general tablets and has the capacity to produce 225 lakh tablets per month on a single shift. The plant is situated in a notified area and is eligible for excise and income tax exemptions announced by the central and state governments. The company also plans to set up two more formulation plants in Uttaranchal and Himachal Pradesh. To be set up with an investment of Rs850-900mn, the plants are expected to start commercial production by 2006-07. The expansion has been funded by issue of equity shares on a preferential basis to various foreign institutional investors (FII), debt and internal accruals.

Reliance Life plans to tie up with Otsuka
Reliance Life Sciences’ collaboration with Otsuka is part of its genome research initiative to promote personalised medicine using the expertise of outside research institutions. The objective is to develop new drugs as well as diagnostic procedures. Reliance Life Sciences is one of the leading players in the area of genome research in India and Otsuka is also in the same field of research. The two companies are expected to sign a long-term biotech research and drug development pact shortly. The tie-up between Reliance Life Sciences and Otsuka may also include a regional clinical research project for Otsuka’s latest discovery product ‘Abilify’, a prescription medicine for the treatment of acute manic and mixed episodes associated with bipolar disorder and an anti-psychotic medication for the treatment of schizophrenia. The drug research initiative planned with Reliance Life Sciences would include new biopharmaceuticals in the area of psychotropic diseases and human metabolic disorders. Once the collaboration is finalised, the project will be under the responsibility of Otsuka’s US subsidiary, Otsuka America Pharmaceutical Inc. Reliance Life Sciences conduct research in the domains of medical, plant and industrial biotechnology, whereas Otsuka a Japanese pharma group has been active in drug research and development of new innovative drugs since its opening of research arm, the Tokushima Research Institute in 1971.
**AstraZeneca’s R&D tie-up plans with Indian firms**

US-based pharmaceutical company AstraZeneca is planning to collaborate with two research-based domestic pharma companies. The company had earlier signed a research collaboration agreement with Ahmedabad-based Torrent Pharma for discovering a novel drug candidate for the treatment of hypertension. The proposed R&D tie-ups of AstraZeneca in India are in the areas of CNS and novel pain management drugs. The collaborations are part of AstraZeneca’s US$4bn annual global drug discovery programme. The company plans for two or more joined R&D projects in India in a shorter span, which would be jointly funded by the local partner. The projects would envisage success-based payments to the Indian companies and pay royalties based on the commercialisation of the drug candidate. The local research partners may also get co-marketing product rights in India. About 30% of the total R&D spend of the company is utilised for external projects and the projects in India are part of the external research programme. AstraZeneca’s R&D comprise of specialists in informatics, genomics, chemical technologies and other enabling sciences and technologies. AstraZeneca is one of the top investors in pharmaceutical R&D in the world, which spent US $3.8bn on R&D last year. AstraZeneca’s Global R&D organization is headquartered in Sodertalje, Sweden. It has generated a consistent flow of new prescription medicines to the market and has enhanced the company’s existing products portfolio globally. The company’s direct R&D operations in India based at Bangalore is now fully dedicated to tuberculosis drug research.

**Glenmark acquires Argentine marketing firm**

Glenmark Pharmaceuticals, the Swiss-based subsidiary of Glenmark Pharmaceuticals, has acquired an Argentine pharma marketing company -Servycal SA, for an undisclosed valuation. It is a cash deal, funded through internal accruals of the Swiss subsidiary, which marks the direct entry of an Indian pharmaceutical company for the first time in Argentina. Servycal, with a focused oncology portfolio, will enable Glenmark to expand its geographical scope and breadth of product offerings in the fast growing South American pharmaceutical markets. Servycal owns a basket of seventeen approved product registrations with an additional three products pending registration. Apart from Argentina, Servycal’s products are registered in 12 other South American country markets as well. The company is a marketing entity with a strong retail and hospital presence in Argentina. This acquisition would help Glenmark to achieve long term plan of emerging as a speciality company marketing novel drugs in markets outside the USA, the EU and Japan.

**Actis Biologics Inc received license for ‘Angiozyme’ an anti-cancer agent**

Actis Biologics Inc., a US based pharmaceuticals company has received worldwide license for Angiozyme. Sirna and Chiron had co-developed Angiozyme compound with Actis. Angiozyme is a ribozyme based anti-cancer agent as a therapy on colon cancer, which is in phase II clinical trials. The company has received exclusive license to develop, manufacture and commercialize Angiozyme, whereas Sirna and Chiron will receive undisclosed upfront, milestone and royalty payments. Angiozyme has been tested in over 90 advanced colorectal cancer patients in the US per FDA guidelines and has demonstrated anti-tumour activity. The company is planning to initiate additional phase II trials by the end of 2005.

**FDA approves Pfizer’s Lipitor for treatment of Diabetes**

Pfizer’s cholestrol lowering medicine Lipitor has been approved by the USFDA as a treatment to reduce the risk of stroke and heart attack in people with type II diabetes showing no evidence of heart disease. The FDA’s decision was based on the findings of the collaborative Atorvastatin Diabetes Study (CARDs), which comprised trials on more than 2800patients with type II diabetes, with normal cholestrol and one risk factor like high blood pressure. These patients when treated by Lipitor experienced nearly 50% fewer strokes than those by placebo.

**Merck KgaA and Takeda Pharma to co-develop anti-cancer drug**

Merck KgaA and Takeda Pharmaceutical company ltd. have entered into a co-development and commercialization agreement for Merck’s matuzumab (EMD 72000), a humanized monoclonal antibody for the treatment of cancer. The two companies will collaborate on development and commercialization efforts in the major pharma markets of the world, excluding Australia and Latin America. Matuzumab was developed by Merck and currently is in Phase II clinical trials in patients with non-small cell lung, gastric and colorectal cancers, claims a company release. Merck’s decision to enter into strategic alliance with Takeda was to put more resources and expertise toward this important product for the treatment of cancer and Takeda’s experience in the field of Oncology supports the plans of Merck.
J.B. Chemicals & Pharmaceuticals Ltd (JBCPL) was incorporated in Mumbai, India by J B Mody in 1976 to manufacture basic chemicals, pharmaceuticals, The Pharmaceuticals division of the company manufactures and markets a wide range of formulations, herbal remedies, bulk drugs, intermediates and radio-diagnostics. The Company ranks 38th in India as per ORG-IMS. It enjoys a strong presence in the cardiovascular, anti-infective, anti-ulcerant, NSAID and dental therapeutic segments in India and exports to more than 30 countries. One of the company’s top brand is ‘Doktor Mom’ that received the Reader’s Digest award as the "Most Trusted European Brand" award for the fifth consecutive year and the other top brands are Metrogyl, Rantac and Nicardia.

Mr. Nirav Mody is a Vice President at J. B. Chemicals & Pharmaceuticals Ltd. He looks after Strategic Marketing and Business Development activities at JBCPL. He has done his Bachelor of Science in Business Administration receiving high honors from Carnegie Mellon University in Pittsburgh, USA, with a double major in Finance and Management Information Systems. After graduation, he worked at Rodman & Renshaw, a boutique investment bank, in equity research. His internships with reputed investment banks like Salomon Smith Barney, New York and DSP Merrill Lynch, India have given him good international business exposure.

In an exclusive interview with India Infoline Pvt. Ltd, Mr. Nirav Mody spoke with Veebha Salvi and Alok Dalal, about the company’s business and its growth prospects going ahead.

**What are the top Pharmaceutical brands of the company and how much do they contribute to the turnover?**

Following are the top brands of the company contributing 90% of the total turnover wherein ‘Doktor Mom’ remains to be the biggest contributor.

- Doktor Mom (herbal cough & cold product)
- Nicardia Nifedipine (ranks 1st in Ca Channel Blocker market)
- Metrogyl Metrodinazole (ranks 1st in amoebicide market)
- Rantac Ranitidine (ranks 5th in anti-peptic ulcerant market)
- Moviz, Moviz 3D Acelofenac (NSAID) (ranks 4th in anthritis segment)
- Motiza Etopride (ranks 2nd in prokinetic segment)

[Click here for full interview](http://www.indiainfoline.com/view/261005.html)