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In Focus – Lipitor patent case: Adverse rulings for Ranbaxy continues

On December 16, 2005, Indian multinational pharmaceutical company, Ranbaxy's dream of hitting the US market with the generic version of Pfizer's globally largest selling drug Lipitor was shattered when US District Judge ruled that Ranbaxy's generic drug would infringe Pfizer's Lipitor patent. He also upheld the validity of Pfizer's two key patents, one on Lipitor's basic patent and the other covering the calcium salt of Lipitor against the Indian pharmaceutical major Ranbaxy Laboratories.

Challenging Lipitor patent is like tasting sweet poison

Ranbaxy continues its challenges against Lipitor in most of the countries inspite of unfavorable rulings because it is a multi billion drug with an annual sale of US\$10.86 billion in 2004 and the patent cover on Lipitor was scheduled to expire in 2006; but Pfizer got extensions till 2010 on the main compound and till 2011 on a calcium salt. Ranbaxy claims that these are ever greening tactics and seeks to invalidate both patents.

Rulings mostly in favour of Pfizer

Ranbaxy has received a favourable ruling only in Austria, but it is not a significant market and Pfizer has appealed against this ruling in Austria. In UK, the patent of the main drug was protected by the ruling but it claimed that the patent covering the calcium salt of the main drug was invalid. Pfizer has appealed against the ruling for the calcium salt and Ranbaxy against the ruling for the main drug. In US, the market which accounted for 54% of the Lipitor sales in 2004 the ruling was in favour of Pfizer for both the patents.

Lipitor – An attractive option

- World's largest selling drug
- 18 million patient base in US alone
- Approved in 70 countries
- US\$5.9 billion revenue in US – for the first generic company during the 180 days exclusivity period.
- Approval for new indications like stroke
- Extended patent

Source: Cygnus Research

Status of Lipitor challenges in different countries

Country	Ruling in favour of	Higher appeals by
US	Pfizer	Ranbaxy
UK	Pfizer for main patent	Ranbaxy & Pfizer
Norway	Pfizer	Ranbaxy
Austria	Ranbaxy	Pfizer

Source: Cygnus Research

A Joint Initiative of **IPA** and **Cygnus** to enable Pharma Professionals to be more successful

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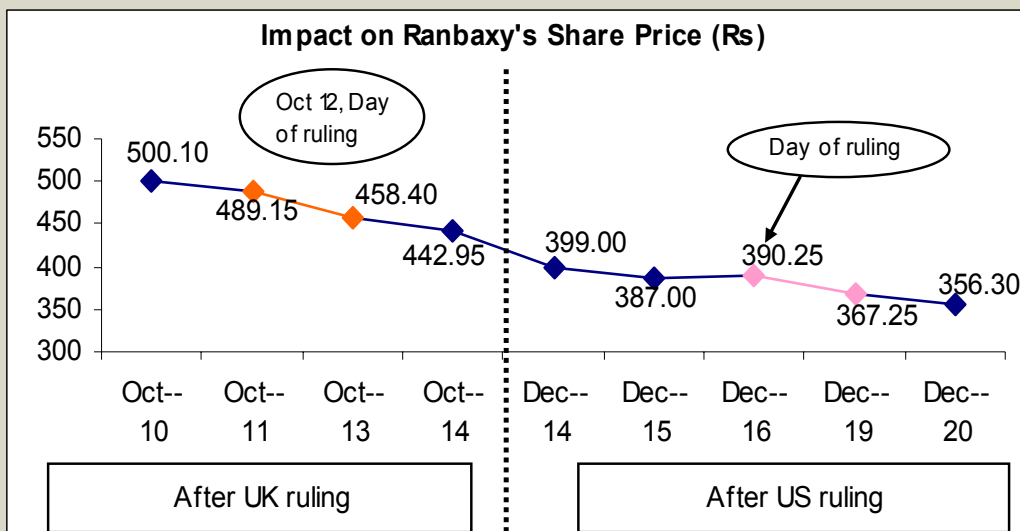
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Immediate stock market reaction

Share prices declines by over 5% on a single day because of unfavourable rulings

The stock price of Ranbaxy has declined by 6% to Rs 367.25 on December 19. The stock further declined by 9% on December 20 with the stock touching Rs 356.30.

This decline was the result of unfavourable ruling against Ranbaxy in Lipitor patent challenge case in the US. Similar thing happened when Ranbaxy received an unfavourable ruling on October 12, 2005. The share price of Ranbaxy fell by 6% from Rs.489.15 on October 11 to Rs.458.40 on October 13. The stock further declined by 9% on the next day with the share price reaching Rs.442.95. On December 19, Ranbaxy shares had fallen 43% in 2005, under-performing a 41% jump in the BSE index.



Source: BSE India & Cygnus Research

Note: BSE was closed on October 12, December 17 & 18.

Impact on profit

Unfavourable ruling likely to hit the bottom-line growth

The US ruling has come at a point when Ranbaxy is already fighting sharp price erosion in the important US market amidst heavy competition, a slowdown in new product launches and higher research and development and legal or litigation costs. For the quarter ending September 2005, Ranbaxy's net profit slumped by 91% per cent to Rs.184 million as competition in the US generic market ate into its profit margins. Moreover revenues were down 3% due to fierce competition in the U.S. generics market. It is estimated that for a single Para IV filing, the cost incurred would be between Rs.600 to 800 million. If the company loses in the patent challenge case, then for further appeal it has to invest some money and the results are uncertain. Ranbaxy has lost the case in three countries and has gone for a higher appeal in all those three countries. These additional litigation costs will impact the bottom-line growth of Ranbaxy if it does not get a positive ruling in any of these cases. The NCE pipeline has significantly come down. Presently, the company has only two molecules in clinical trials as against six a year ago.

Para IV filing: High Risk game

Of the 11 key patent litigations during 2004, there were 9 unfavourable (6 losses and 3 reversals) and two favourable decisions for the generics industry. So the success rate in 2004 was around 18%.

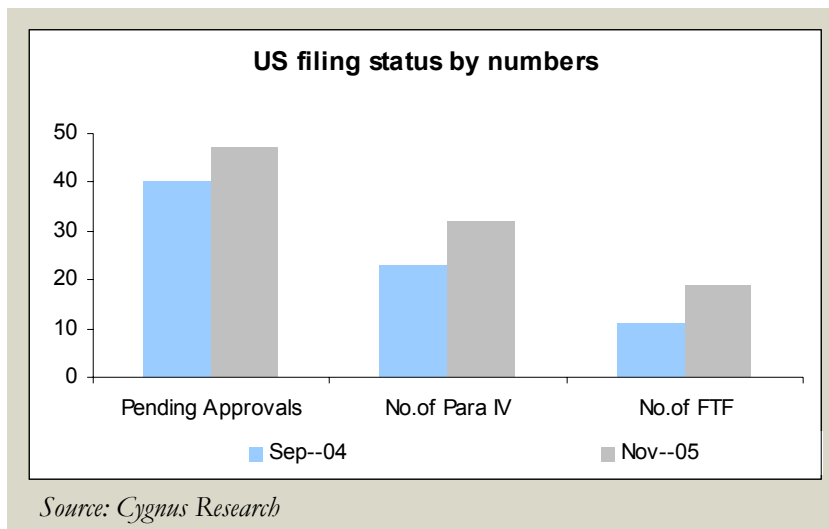
When a company makes a Para IV filing, a lot of research goes into it to find out the loopholes in the patents and approximately US\$15-20m goes into it. If unsuccessful, the entire amount invested in filing goes waste. Para IV filings are very risky business models and cannot be depended on always to bring in the revenue.

Moreover, the patent holders have a number of ways to prevent the generics from entering the market like monopoly extension beyond patent term for a maximum of 5 years by the law; rewards for paediatric trials as six month exclusivity period by the law; and merging with direct competitors to retain monopolies and recombining drugs in different ways to claim new patents. Off late the trend is of authorised generics wherein the patent holder is granting the license to a generic player of his choice to market the drug in the fag end of the patent period to prevent the litigant of taking the benefits of the Para IV litigation.

Ranbaxy filing status in US

Para IV filings grew by 39 percent

The number of filings awaiting approvals increased from 40 to 47 growing at a rate of 18%. The number of First to File (FTF) has increased significantly by 73% from 11 in September 2004 to 19 in November 2005 and the value of FTF increased by 67% from US\$13.5 billion to US\$22.6 billion during the same period. The number of Para IV filings grew by 39% from 23 to 32 during the same period.



Ranbaxy's Para IV filings with FTF status value US\$16.54 billion

Ranbaxy has challenged many blockbuster drugs like Pfizer's Lipitor with an annual sale of US\$10.86 billion in 2004, Takeda's Actos, GSK's Valtrex, Boehringer's Flomax. These are the blockbuster drugs against which litigations are going on between Ranbaxy and the respective companies. Other blockbuster drugs that were challenged by Ranbaxy but not sued for it include AstraZeneca's Nexium, Merck's Zocor and BMS's Pravachol.

Outlook

Undeterred by these unfavourable rulings Ranbaxy has plans of continuing with challenging patents as one of their business strategies in the regulated markets. It is planning for higher appeals in UK, Norway and US. It has recently challenged patent of another blockbuster drug -- AstraZeneca's anti-ulcer drug Nexium. It looks like Ranbaxy is still maintaining its aggression in Para IV filing. Ranbaxy has 47 products in the pipeline, however, out of these products, 32 are under the Para-4 filings. Ranbaxy forecasts a much better position in 2006 with plans to launch 15 products in the United States and expects sales to rise 18%, compared with a forecast of low single digits for 2005. It also expects an operating margin of more than 16 percent in 2006 against 8 percent expected for 2005.

Ranbaxy's FTF Status			
Filings sued	Company	Brand	2004 sales (US\$ mn)
Atorvastatin	Pfizer	Lipitor	10860
Pioglitazone	Takeda	Actos	1874.81
Valacyclovir	GSK	Valtrex	1098.16
Tamsulosin	Boehringer	Flomax	1004.19
Modafinil	Cephalon Inc.	Provigil	439.7
Fenofibrate	Abbott	Tricor	779*
Ibuprofen + Pseudo sofgels	Wyeth	Advil	490.4
Filings not sued			
Esomeprazole	AstraZeneca	Nexium	3900
Simvastatin	Merck & Co	Zocor	5200
Pravastatin	BMS	Pravachol	2635
Others			5030
Source: Annual Report & Cygnus Research			*US Sales



News Briefs

AMERICAS

US: United States Pharmacopoeia (USP) to start Indian operations

The United States Pharmacopoeia (USP) is a non-profit, non-governmental, standards-setting organization that improves public health and patient safety by ensuring good pharmaceutical care. It has started its maiden site overseas with the establishment of the United States Pharmacopoeia-India Private Ltd in Hyderabad at the ICICI Knowledge Park. It will provide its wide range of pharmacopoeial services to USP customers in India and the neighboring countries.

US: Elite Pharma & Orit Labs enters into development and commercialization agreement

Elite Pharmaceuticals, Inc. has entered into a development and commercialization agreement with Orit Laboratories, LLC with the objective to develop and commercialize an extended release drug product for treatment of anxiety. This agreement will bring both the companies to position in the generic drug industry. This development agreement expands Elite's diversified R&D portfolio of controlled release products which addresses niche segments of the market and include, pain, allergy anti-infectives, cardiovascular, and now anxiety.

US: Mylan Technologies foray into strategic agreement with Cephalon

Mylan Technologis Inc., subsidiary of Mylan Laboratories Inc. has entered into strategic agreement with Cephalon Inc. to utilize Mylan Technologies innovative transdermal technology to address certain pain and central nervous system disorders. As per agreement, Mylan and Cephalon will collaborate with the aim to create branded transdermal products to develop and commercialize in exchange for payment of milestones and ongoing royalties to Mylan based on net sales of the products. This agreement will influence MTT's state-of-the-art technology and expertise and has the potential to allow Mylan to participate in branded commercial opportunities without additional R&D net costs.

US: Dusa Pharmaceuticals signs definitive merger agreement

Dusa Pharmaceuticals Inc., developer and marketer of Levulan photodynamic therapy (PDT) has signed a definitive merger agreement to acquire all of the common stock of Sirius Laboratories Inc. for US\$30 million. The combination of Sirius and DUSA is a major step forward in DUSA's plan to become a leading provider of dermatological pharmaceuticals. Now Sirius will look forward to bringing their products to more dermatologists enabling the combined enterprise to be stronger than either company prior to the merger.

US: Guidant & Johnson & Johnson enters into agreement

Johnson & Johnson will acquire Guidant Corporation for US\$24.2 billion in fully diluted equity value. As per agreement, Johnson & Johnson will pay US\$40.52 in cash and 493 shares of Johnson & Johnson common stock for each outstanding share of Guidant common stock. This agreement with Johnson & Johnson provides significant financial value and certainty for shareholders. Both the companies' plans to focus on creating the world's broadest and most comprehensive cardiovascular device company that will bring meaningful technology solutions to address this devastating disease.

US: Pfizer to acquire Sanofi-Aventis worldwide rights to inhaled human insulin

Pfizer Inc. has entered into an agreement to acquire the Sanofi-Aventis worldwide rights to inhaled human insulin under the trade name Exubera. The total deal was US\$1.3 billion. Exubera is a fast-acting dry powder formulation of human insulin. It is inhaled into the lungs via the mouth pre-meal through a simple-to-use, hand-held inhalation device which does not require batteries or electricity. Pfizer plans to make Exubera available to patients as soon as possible. This acquisition will scale up their ability to invest in new product opportunities that will drive their future growth.

US: Nastech finds four new classes of lipids

Nastech have found four new classes of lipids that can be used to increase transmucosal drug delivery and open up new opportunities for non-injectable forms of drugs that would otherwise require injections. New non-injectable forms of drugs have the potential to revolutionise the lives of countless people. Among seven groups of lipids (sterols, sphingolipids, ceramides, glycosylated sphingosines, alkylglucosides, oxidized lipids, and ether lipids) tested by Nastech, the latter four were identified as tight junction modulators (they can open tight junctions) and were thus shown to significantly enhance peptide permeation through epithelial tissue.

Canada: Generex expanding its diabetes treatment pipeline

Generex is developing a new metformin chewing gum for diabetes that aims to avoid the significant gastrointestinal side effects often accompanying the use of metformin tablets. It may provide relief for the approximately 30 percent of metformin users who develop significant adverse gastrointestinal effects from taking metformin tablets, including diarrhea and nausea/vomiting. Metformin is used with or without insulin for the treatment of Type-2 diabetes and is also used to prevent the development of diabetes in people at risk, as well as treating polycystic ovary syndrome (PCOS), and non-alcoholic steatohepatitis (liver disease). It increases the sensitivity of liver, muscle, fat and other tissues to the uptake and effects of insulin, and lowers blood glucose levels.

EUROPE**UK: Schering re-acquired the rights of Bonefos in UK**

Schering AG has brought the bisphosphonate Bonefos (sodium clodronate) back under its umbrella in the UK and Ireland. It has re-acquired the rights to the product from Boehringer Ingelheim, which licensed Bonefos in the 80s. Bonefos is available as three formulations in the UK, with the oral tablets and capsules being licensed for managing osteolytic lesions, hypercalcaemia and bone pain associated with skeletal metastases in patients with breast cancer or multiple myeloma.

Germany: Qiagen N.V. and Eppendorf AG foray into an agreement

Qiagen N.V. and Eppendorf AG have entered into an agreement to form a strategic alliance that includes co-development and co-marketing of complementary and optimized products. The alliance is intended to link two of the strongest brands and product lines in the industry to ensure the highest compatibility of their products targeting the research, applied testing and molecular diagnostics. Through the strategic alliance, both the companies aim to concentrate on improving biological sample management and analysis.

Switzerland: Roche, Amira enters into agreement

Switzerland based healthcare group Roche and San Diego-based Amira Pharmaceuticals have entered into an agreement to form research alliance. Amira plans to license two clinical stage compounds from Roche. As per agreement, Roche will use its screening capabilities to investigate three mutually agreed targets in the field of inflammatory diseases. This alliance reinforces the proven pharmaceutical background of Amira's scientists and positions Amira to develop an outstanding pipeline of novel drug candidates for a broad array of inflammation-based disorders.

MIDDLEEAST**Israel: Israeli Pharma Company enters into agreement with JB Chemicals**

JB Chemicals and Pharmaceuticals have signed an agreement with Israeli Pharma Company to jointly develop products to increase its competitive edge in the US and other world markets. This strategic arrangement is intended to enable the Israeli company Taro Pharmaceutical Industries to utilize JB Chemicals' pharmaceutical expertise to enhance their competitive position in the US and other countries with regard to certain products.

ASIA PACIFIC**China, equipping itself to produce huge quantities of human bird flu vaccine**

China has established a store of NIBRG-14 virus strain to vaccinate against H5N1, the biological properties of the virus strain remain the same as the original even after developing a tenth generation which displays a steady inheriting process, indicating that the virus strain can be used in large quantity vaccine production. The Beijing-based Sinovac Biotech Co Ltd and the Chinese Centre for Disease Control and Prevention in 2004 jointly developed a human bird flu vaccine in November 2005 which is currently under clinical tests that will last about 12 months.

China plans to manufacture one billion doses of bird flu vaccine for animals

China intends to manufacture one billion doses of a new bird flu vaccine for animals in order to vaccinate the country's billions of farm birds. The vaccines prepared can be given as injections or nasal sprays, eye drops or put into water supplies. It immunizes the birds against bird flu and Newcastle disease.

China: Shanghai Brilliance increases its stake in the local drugmaker

Shanghai Guoxin investment and Development Co., Ltd. had transferred 32,145,041 shares or a 20.17% stake in the Shanghai No.1 Pharmacy Co. to Shanghai Brilliance (Group) Co. for free. Similarly Hualian Group and another Shanghai-based brokerage firm also transferred 283,140 shares and 2,453,880 shares to their parent company Brilliance Group. After these deals, Brilliance Group became the second-largest shareholder of the drugmaker, with its stake reaching 21.89%. During December 2005, Shanghai New World (Holding) Co., the biggest shareholder of the drugmaker, sold a 26.01% stake to an affiliated company of Brilliance Group for CNY 1.524 per share. The Shanghai-based retailer and its affiliated companies now hold a total of 52.56% stake in the local drugmaker.

China: BioPro Pharmaceutical acquires Nexmed Medical Co Ltd

BioPro Pharmaceutical Inc (BioPro) acquires 80% ownership of Nexmed Medical Co Ltd, a Chinese distributor of pharmaceutical products based in Beijing. The new company will be known as BioPro Pharmaceutical China Ltd (BioPro China) and will be operating in two divisions one, the logistics division which will provide logistical services to hospitals in Beijing and increasingly in the other major urban areas of China. The other is the novel oncology division will pursue Chinese regulatory approvals of two products namely Gliadel (brain cancer drug) and Vantas (prostate cancer drug) licensed by BioPro Pharmaceutical for Asia.

Japan: BSD Medical foray into distribution agreement with Ktec Corp

BSD Medical Corp. has entered into a distribution agreement with Ktec Corporation to sell BSD's cancer treatment systems in Japan. This agreement brings a lengthy search and negotiation process as part of BSD Medical's global strategy to establish a chain of distributors in the Pacific Rim as an important segment of the company's world market.

India: Periyar College of Pharmaceutical Sciences organized a national seminar on IPR

A national seminar on Intellectual Property Rights was organized by the Periyar College of Pharmaceutical Sciences for Girls, Tiruchirapalli, Tamil Nadu on January 20th and 21st, 2006. The Ministry of Human Resource Department had sponsored the seminar. Eminent professionals delivered informative lectures covering various aspects of Intellectual Property Rights at the seminar.

India: IIT Kharagpur and George Washington University collaborate to set up IP law school in India

IIT Kharagpur and US-based George Washington University (GWU) have entered into a collaboration to start a comprehensive formal education in the intellectual property laws in India. A new law school by GWU is to be established in the campus of IIT-Kharagpur which will offer a three-year Bachelor of Law in Technology and IP Law and an 18-month part-time PG Diploma in IP Law course. This law school which is likely to be set up in July 2006 will be recognized by the Bar Council of India and those students, who have successfully completed the three-year course, can practice in the Indian courts.

India: Drug for malaria from marine sources

University and the Department of Science and Technology, New Delhi, have signed a Memorandum of Understanding on a research project to come up with an effective drug for malaria from marine sources. 'Isolation and Study of Molecules from Marine Herbals for the Treatment of Malaria', will also involve Pharmafabrikon, a Madurai-based company, making various categories of dosage formulations in the past 24 years.

The Department of Science and Technology has sanctioned the project at a cost of Rs10.70 million. It will contribute Rs6.8 million for buying equipment and meeting the recurring cost. Pharmafabrikon will give 30% of the recurring cost - Rs15.47 lakh - to the university. The Department has released the first-year instalment of Rs4.336 million. This was the first project conducted in the university under the public-private partnership programme of the Department of Science and Technology.

India: Malnutrition in kids leads to diabetes, low IQ

Diabetes and cardiovascular diseases may be due to malnutrition during childhood. Malnourished children also have low IQ. Not many would know this, but such chronic diseases in later stages of life have a link with malnutrition in early childhood. Even though there was no food shortage, all had a perennial problem of malnutrition among women, and child. It was not restricted to families living below the poverty line, but is seen in well-to-do families also. For the growing children, non-vegetarian diet is very important and most of the population has micro nutrient malnutrition - iron deficiency or anaemia, vitamin A deficiency, and iodine deficiency disorders.

India: Strides Arcolab enters into agreement with Clinton Foundation

Strides Arcolab, Indian drug maker has signed an agreement with the Clinton Foundation to provide anti-retroviral drugs for the treatment of AIDS. As per company statement, Strides would supply the ARV efavirenz at US\$240 per patient per year.

India: Mission Pharma to set up a Solid Oral Dosage form and Ointment manufacturing facility

Mumbai-based Mission Pharmaceuticals Limited is setting up a Solid Oral Dosage form and Ointment manufacturing facility at North-East India. The company plans to invest about Rs 30 crore in the project and the facility would be set up in a built up area of about 50,000 square feet. This manufacturing facility would meet the quality standards of regulatory agencies like US FDA. In future, the company plans to tie-ups with multi national companies in USA and UK.

India: Ventiv Health, SIRO Clinpharm enters into joint venture

US-based Ventiv Health, Inc.'s Ventiv Clinical Services division and SIRO Clinpharm Pvt. Ltd has entered into joint venture and formed Ventiv-SIRO (India). The new company Ventiv-SIRO (India) brings together Ventiv's broad statistical analysis, data management services and premier client portfolio with SIRO's strength conducting large-scale Phase II-IV clinical trial data management projects. It will provide pharmaceutical and biotech companies access to a broad pool of outsourced offshore talent who will design databases, conduct data, statistical analysis and analyze medical images and scans. The joint venture will broaden their capabilities, allowing them to deliver high-quality clinical research and statistical analysis services both domestically and now offshore through this joint venture with SIRO.

India: Jubilant Organosys enters into five year agreement with Eli Lilly

Jubilant Organosys Ltd along with its subsidiaries viz. Jubilant Biosys Ltd and Jubilant Chemsys Ltd has entered into a five-year agreement with the US based Eli Lilly and Company. According to company officials, Jubilant will provide a range of collaboration drug discovery services to Eli Lilly.

India: Indian Dishman Pharma to establish a manufacturing base in China

Dishman Pharmaceuticals plans for an initial investment of US\$10 million to set up a manufacturing facility in China to produce quats and intermediates in the first phase and is also in talks with Japanese companies for production of active pharmaceutical ingredients (API) in Japan. Dishman Pharma had already acquired an 80,000 sqm plot in Shanghai Chemical Industry Park at an approximate cost of US\$4 million as a part of its phase I activities. It also plans to contract manufacturing facilities including USFDA compliant API plants in the second phase within the next two years.

India: Matrix Labs for investment in Chinese and South African pharma companies

Hyderabad based Matrix Laboratories Ltd intends to invest in many pharmaceutical companies in China like Mchem Pharma Group Ltd, Dafeng Mchem Pharmaceutical Co Ltd and Xiamen Mchem Laboratories Ltd and one in South African firm called Fine Chemicals Corporation Ltd.

India: Bal pharma to foray into Pakistan

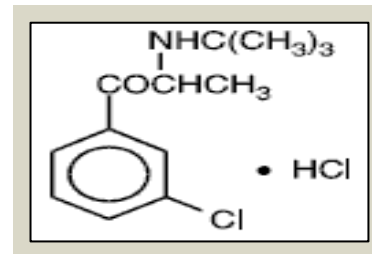
Bal Pharma, a major provider of APIs for leading multinational companies is planning to increase presence in Pakistan with its range for bulk drugs. Players like Bal Pharma find it easy to export to Pakistan as the pharmaceutical market in Pakistan, does not demand product registrations. Some of the major products exported to Pakistan includes gliclazide, an anti diabetic and ebastine which is an anti histamine, topiramate for epilepsy, amiloride, a diuretic and benzydamine anti pyretic.

Product Focus – Wellbutrin (Bupropion Hydrochloride)

Wellbutrin, with the active ingredient Bupropion hydrochloride from GlaxoSmithKline is used as a stimulant for a person who suffers from depression. Wellbutrin is an anti-depressant. Wellbutrin pills are available in three forms: immediate release, sustained release (SR) and extended release (XL). Generic forms of immediate and sustained release are also available.

Chemical structure

The chemical name for Bupropion hydrochloride is (\pm) -1- (3-chlorophenyl)-2-[(1, 1-dimethylethyl) amino]-1-propanone hydrochloride. Its molecular weight is 276.2 and the molecular formula is $C_{13}H_{18}ClNO \cdot HCl$. Bupropion hydrochloride powder is white, crystalline, and highly soluble in water. It has a bitter taste and produces the sensation of local anaesthesia on the oral mucosa.



Mechanism of Action

Neurotransmitters are chemical substances within the brain that nerves use to send messages to each other. Some of the neurotransmitters are dopamine, serotonin and norepinephrine. These neurotransmitters that are released by nerves are taken up again by them for reuse and this process is referred to as reuptake. Wellbutrin acts by inhibiting the reuptake of these neurotransmitters majorly dopamine. As a result of this inhibition, more neurotransmitters are available to transmit messages to other nerves.

Indications

Management of depression
Attention deficit hyperactivity disorder (ADHD)
Seasonal affective disorder
Adjunctive in tobacco withdrawal

Dosage form and dose

Wellbutrin is available in both standard 75 mg and 100 mg tablets and in 100 mg and 150 mg sustained-release tablets. The recommended starting dose for adults is 100 mg per day twice daily. Once the patient is found to be tolerant, the typical dose for Wellbutrin is 300 mg per day taken as 100 mg thrice a day. No single dose should exceed 150 mg, and the maximum recommended daily dose for the drug is 450 mg.

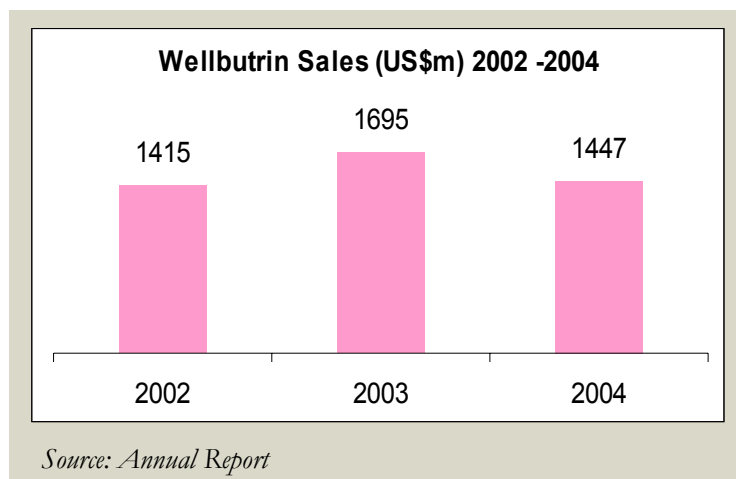
Side effects

Seizures
Fast or irregular heartbeats
Allergic reaction
Abdominal pain
Agitation and anxiety

Market

Generic launches impinge upon the sales

Burroughs Research synthesized bupropion in 1966. Burroughs-Wellcome, now GlaxoSmithKline patented it in 1974. It was approved by the FDA in 1985 and marketed under the name Wellbutrin. The sales grew by 20% in 2003 compared to the previous year. In 2004, there was a negative surge in Wellbutrin sales by 15% as a result of launch of generic versions of the drug from January 2004. Generic equivalents of Wellbutrin and Wellbutrin SR hit the US market in January 2004, whereas Wellbutrin XL is still protected by the patent.



Competition

The major branded competitors for Wellbutrin though not in the same category include Forest's Celexa & Lexapro, Pfizer's Zoloft and Eli Lilly's Prozac. Generic versions of Wellbutrin are eating up its market share drastically and had seized a 6% share of the total Wellbutrin market by the end of 2004.

Outlook

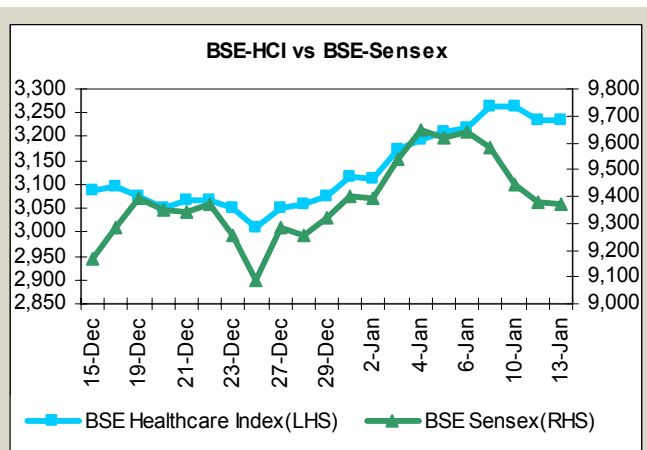
Though the generic launch of Wellbutrin in January 2004 has drastically affected its sales, the sales of Wellbutrin XL launched in September 2003, with a novel drug delivery system (once-daily formulation) is increasing considerably. This formulation contributed 40% of branded Wellbutrin prescriptions in early February 2004 and increased to 62% by the end of 2004. Wellbutrin XL has been protected by patents till 2018. If patent challenges are not successful, the future of Wellbutrin XL seems to be very bright.

Brand	Company	2004 US Sales (US\$m)
Wellbutrin	GSK	1447
Celexa	Forest	980
Lexapro	Forest	1600
Zoloft	Pfizer	3361
Prozac	Eli Lilly	182

Source: Cygnus Research

Stock Scan

During the period December 15, 2005 to January 13, 2006, BSE Sensex has recorded a marginal growth of 2.22% to 9374.19 points. On 4th January, 2006, the Sensex saw a new intra-day lifetime high of 9648.08. From January 5, the Sensex witnessed the selling pressures ahead of the results announcements. The indices started their decline as most frontline stocks came under selling pressure. The downtrend persisted throughout the week as traders unwound their positions. Lack of buying support was evident as most institutional investors are waiting for the quarterly numbers before taking fresh positions. BSE Healthcare Index has recorded a growth of 4.87 percent to 3236.29 points. This was driven by strong inflow of funds from FIIs and expectations of robust quarterly performance.



Source: BSE India, Cygnus Research

Regulatory Issues

US: Cipher Pharmaceuticals receives USFDA approval of CIP-Fenofibrate

Cipher Pharmaceuticals Inc. has received an approval of CIP-Fenofibrate, the company's novel formulation of the active ingredient fenofibrate from US Food and Drug Administration. CIP-Fenofibrate is used in the treatment of hyperlipidemia and it is approved under the label as Lipofen. It is the first product that company receives FDA approval. CIP-Fenofibrate received approval for three unique fenofibrate dosages: 50, 100 and 150 mg, with the 150 mg strength equivalent to Tricor 160 mg under fed conditions. With CIP-Fenofibrate, the extent of absorption is increased under high-fat conditions relative to low-fat conditions.

US: USFDA approves tentative approval for divalproex of Teva Pharmaceuticals

Teva has received tentative approval for divalproex sodium delayed-release tablets USP, 125 mg, 250 mg and 500 mg from US Food and Drug Administration. Teva's divalproex sodium delayed-release tablets will be the AB-rated generic equivalent of Abbott's Depakote tablets. It is used for the treatment of manic episodes associated with bipolar disorder, prophylaxis of migraine headaches, and as therapy in several types of epileptic disorders.

China: Jewin Pharma wins the license to sell drugs to the public on the Internet

Beijing-based Jewin Pharma, the eighth largest medicine chain store in Beijing in 2005 became the first medicine chain store to win a license to sell drugs online to the public. Online sale of drugs was earlier banned in 2004. Applications were invited for online drug sales from last October by the State Food and Drug Administration (SFDA) in order to lower medicine prices, a big problem in the Chinese health industry. The SFDA also focuses more on online drug sales because pharmaceutical e-commerce is already relatively developed overseas and it improves drug distribution capabilities.

India: Department of Chemicals announces new drug policy

On December 28, 2005, the Department of Chemicals has announced the draft drug policy. The first part of the policy lays highlights inter-alia on strengthening of Drug Regulatory System, Public Private Partnership Programme for anti-cancer and anti HIV/AIDS drugs, reduction in the Excise Duty on all Pharmaceutical products from 16 to 8 percent, health cess at 2 percent etc. The second part, which will deal with price control issue like mechanism, various options is also under preparation. After bringing out the views from various stake-holders and general public, the New Pharmaceutical Policy will go for Cabinet in the middle of February 2006.

India: Pharma associations ask for a one year extension for complying with Schedule M norms

Marathwada Pharmaceuticals Manufacturers Association (MPMA) and Small Scale Industries (SSI) Pharmaceutical Association representing small and medium scale pharmaceutical units, whose licenses have been cancelled or suspended by Maharashtra FDA for non compliance with the Schedule M norms, have filed a petition in Aurangabad High Court, pleading to direct the FDA to withdraw the cancellation orders and have asked for a one year extension for complying with Schedule M norms.

India: Department of Chemicals and Fertilisers allocates Rs 5 lakh for pharma export promotion

The budgetary provision for the pharma export promotion scheme had been raised from Rs.3 lakh to Rs.5 lakh in 2005-06. Further increase is expected in the revised estimates. The Parliamentary Standing Committee on Chemicals and Fertilisers was doubtful whether the allocated amount can achieve any concrete objective wanted the government to consider the matter seriously and provide reasonable funds for the drug export promotion.

India: Health Ministry commissions JWT to develop awareness programme for drug consumption

The Union Health Ministry has commissioned J Walter Thompson Co (JWT), a leading consultancy, to prepare a national strategy for successfully carrying out the Information, Education and Communication (IEC) programme in the medicine sector, part of the World Bank funded capacity building project in the food and drugs sector. JWT has been asked to understand and analyze the consumer patterns in the purchase of medicines to evolve the advertising and awareness programme strategies. The centre has asked all the states to come out with state level strategies to improve the safety levels in medication.

India: Pharma SMEs to receive technology upgradation fund

The Pharmaceutical Technology Upgradation Fund (PTUF) proposed by the Union Chemicals Ministry is meant to subsidise the interest component of loans taken by the small and medium scale pharma units for implementation of Schedule M. It is likely to be effective from April 1, 2006 and is expected to be part of the Union Budget 2006-07 announcements. It is to be implemented by Small Industries Development Bank of India (SIDBI). The ministry has proposed to give 5% interest subsidy to a maximum limit of Rs.1 crore on a single application and expects that over 3,000 SMEs would be benefited by this programme.

Upcoming Events

National

1.	Event	India-CIS Pharma Conference
	Date	Mar 3-5, 2006
	Venue	Hotel Leela Kempenski, Mumbai
	Highlights	India-CIS Pharma focuses on Indian Pharma industry, drug regulatory system in India, drug registration requirements of CIS countries and status of Pharma markets in CIS countries.
2.	Event	Focus India- 2006
	Date	Mar 15-17, 2006
	Venue	Hyderabad, India
	Highlights	The conference will focus on five areas like business forum, partnership table, discovery biology, discovery chemistry and clinical research.
	Contact Details	Email: contactus@kasyaptech.com
3.	Event	Infra Medica
	Date	Apr 20-22, 2006
	Venue	Pragati Maidan, New Delhi
	Highlights	The event highlights the swiftly progressing scenario of the Indian pharmaceutical industry. Indian and a large number of international companies will provide the global overview of pharma sector with new innovations and research techniques that are already on or in the anvil.
	Contact Details	Friendz Exhibitions and Promotions Pvt. Ltd.I-11, First Floor, Lajpat Nagar- II, New Delhi, India.Phone: +(91)-(11)-51721891/51721892/51721893/51721894 Fax: +(91)-(11)-51042716

International

4.	Event	Pharmaceutical cGMPs and FDA Inspections
	Date	Feb 8-10, 2006
	Venue	Academic Center in the Hyatt Regency, New Brunswick, NJ, USA
	Highlights	It will introduce the Current Good Manufacturing Practice (cGMP) in the pharmaceutical and allied industries.
5.	Event	2nd Annual Summit on Post-Marketing Studies
	Date	Feb 13 - 14, 2006
	Venue	London, UK
	Highlights	It focuses on the design of post-approval studies for improved safety and risk assessment while meeting clinical, marketing and regulatory objectives.
	Contact Details	The Center for Business Intelligence, 500 W. Cummings Park, Ste 5100 Woburn, MA 01801, Toll Free: 800-767-9499, Phone: 781-939-2400
6.	Event	Pharm Tech
	Date	Feb 22-23 , 2006
	Venue	EXPO XXI, Warsaw, Poland
	Highlights	The event provides a unique opportunity for the interaction of vendors, delegates visitors and the media.
	Contact Details	Nicola Papaphillipou Phone: +357 22 849 359 Email: NicolaP@marcusevanscy.com

7.	Event	INTERPHEX2006
	Date	Mar 21-23, 2006
	Venue	Jacob K. Javits Convention Center in New York, USA.
	Highlights	It will provide visitors with product and technology resources, potential partnerships, world class expertise and networking opportunities for professionals involved in every aspect of the pharmaceutical manufacturing process.
	Contact Details	Ed Williams, Sales Executive at +1 203 840 5319 or email ewilliams@reedexpo.com
8.	Event	Pharma Development Summit China 2006
	Date	Mar 23 - 24, 2006
	Venue	Shanghai, China
	Highlights	Pharma Development Summit China 2006 will focus on business development in China's pharma industry.
	Contact Details	Phone: +86 21 5063 4538. Email: enquiry@iqpc.com.cn.
9.	Event	CPhI Japan 2006
	Date	Apr 24-26, 2006
	Venue	Tokyo Big Sight Exhibition Centre, Japan
	Highlights	It will provide a platform to business-partners to introduce their company to the Japanese market, reinforce their company's position in the Japanese market, bolster Japanese distributor marketing activity, launch new products in the Japanese market and make new contacts and expand their Japanese network.
10.	Event	Pharmaceutical R&D Global Summit
	Date	May 21-24, 2006
	Venue	Shangri-La Hotel, Beijing, China
	Highlights	It will highlight the immense opportunity and challenge the Chinese pharmaceutical market.
	Contact Details	Strategic Research Institute, Jon E. Liong, Email: jliong@srinstitute.com