

*Year at a
Glance*

PHARMA SPECTRUM
2009

SPECIAL ISSUE

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International

IPR

HIV Patent Pool Hobbles As Drug Firms Want India, China Excluded

December 9, 2009, DNA

http://www.dnaindia.com/money/report_hiv-patent-pool-hobbles-as-drug-firms-want-india-china-excluded_1321644

Efforts to bring together nine global drugmakers to pool their HIV patents in order to make available treatment to millions living with HIV/AIDS in the developing world seem to have faltered over a crucial issue -- the inclusion of middle income countries such as India and China in the list of beneficiaries.

Sun Pharma Loses Patent Battle Against Forest Labs on Alzheimer's Drug

October 23, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=52241§ionid=>

The Mumbai-based Sun Pharmaceuticals has agreed to stop manufacturing and marketing of its generic version of Namenda (memantine hydrochloride), the lucrative Alzheimer's drug patented by Forest Laboratories with the resolving of the dispute between the two firms at the US District Court for the District of Delaware.

Public Interest Groups Urge India to Oppose Moves at WIPO to Harmonise Patent Administration

September 29, 2009, Pharmabiz, Joseph Alexander, New Delhi

<http://www.pharmabiz.com/article/detnews.asp?articleid=51879§ionid=44>

A number of public interest organizations, mainly in the health sector, have urged the Centre to oppose any effort at WIPO General Assembly on harmonization of patent administration as it can fundamentally change the way in which substantive decisions about granting patents are taken by the patent offices in developing countries.

Sun Wins US Court Ruling in Eli Lilly Patent Challenge

August 20, 2009, Business Standard

<http://www.business-standard.com/india/storypage.php?autono=367573>

Sun Pharmaceuticals has succeeded in having a key patent of Eli Lilly's blockbuster cancer medicine, Gemzar, invalidated in the US market. This means the company will now be able to launch a low-cost version of the medicine in the world's largest drug market in November 2010. A district court in Michigan on Monday ruled in favour of Sun by invalidating a patent on gemcitabine, the generic name for Gemzar, which was set to expire in 2013.

WIPO Plans to Impose 'Global Patenting System' on Developing Nations Through PCT II

July 29, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=50920§ionid=44>

The US, European Union and Japan are pushing a new international patent agenda through World Intellectual Property Organization on behalf of the powerful big pharma of the developed countries. WIPO, controlled by these trilaterals, is trying hard to impose a 'Global Patenting System' at the forthcoming General Assembly session of WIPO in September.

EU Seeks Greater Commitment on IPR

June 11, 2009, Livemint

<http://www.livemint.com/2009/06/11224500/EU-seeks-greater-commitment-on.html?h=B>

New Delhi: The European Union (EU) is pressing for a greater level of commitment on intellectual property rights (IPR) protection from India in the ongoing negotiations on a free trade agreement (FTA) between the two. This has raised concerns in India over access to cheap medicines and agricultural inputs.

Regulatory

WHO Provides New Directives For Better Management Of AIDS

December 1, 2009, Pharmabiz, Switzerland

<http://www.pharmabiz.com/article/detnews.asp?articleid=52844§ionid=>

WHO now recommends earlier initiation of antiretroviral therapy (ART) for adults and adolescents, the delivery of more patient-friendly antiretroviral drugs (ARVs), and prolonged use of ARVs to reduce the risk of mother-to-child transmission of HIV. For the first time, WHO recommends that HIV-positive mothers or their infants take ARVs while breastfeeding to prevent HIV transmission.

Merck Faces 3,100 Death Claims in Vioxx Case

September 27, 2009, Business Standard

Merck & Co is paying claims by the families of more than 3,100 users of its Vioxx painkiller who died of heart attacks or strokes blamed on drug, according to a law firm administering a \$4.85 billion settlement fund. The fund will pay about 3,000 claims for heart attack deaths and at least 122 strokes, according to BrownGreer I.I.P. a claims administrator appointed by both sides. Merck introduced Vioxx in 1999 and withdraw it in 2004 when a study showed the drug doubled the risk of heart attacks and strokes.

Pfizer to Pay Record \$2.3 Billion Penalty

September 2, 2009, MSNBC

http://www.msnbc.msn.com/id/32657347/ns/business-us_business/

Federal prosecutors hit Pfizer Inc. with a record-breaking \$2.3 billion in fines Wednesday and called the world's largest drug maker a repeating corporate cheat for illegal drug promotions that plied doctors with free golf, massages, and resort junkets. Announcing the penalty as a warning to all drug manufacturers, Justice Department officials said the overall settlement is the largest ever paid by a drug company for alleged violations of federal drug rules, and the \$1.2 billion criminal fine is the largest ever in any U.S. criminal case. The total includes \$1 billion in civil penalties and a \$100 million criminal forfeiture.

WHO Backs Cervarix for Use in Developing Countries

July 9, 2009, Fierce Vaccine

<http://www.fiercevaccines.com/story/who-backs-cervarix-use-developing-countries/2009-07-09>

GlaxoSmithKline has cleared a key hurdle for gaining wider use of its cervical cancer vaccine Cervarix, winning the World Health Organization's approval to offer the jab in developing countries. That official green light is a prerequisite for non-profit groups as well as UN agencies that want to buy the vaccine.

EU Recommends Wyeth's Enbrel for New Plaque Psoriasis Treatment

June 6, 2009, Pharmabiz, Maidenhead, UK

Wyeth received positive recommendations from the European Committee for Medicinal Products for Human Use (CHMP) for two recent submissions relating to Enbrel (etanercept), the tumour necrosis factor alpha inhibitor treatment for plaque psoriasis, rheumatoid arthritis and other related inflammatory conditions.

Seizures of Indian Drugs at EU Ports Stop after India's Protest, No Seizures Last Month

April 15, 2009, Pharmabiz

The Indian government's series of proactive measures to counter the seizure of Indian drug shipments by European Union (EU) nations at their ports during its transit appears to be paying dividends as there have been no reports of such incidents during the last more than a month. As a result, the Indian authorities have put on hold its earlier decision to file complaint at WTO against the EU decision.

First Approval for Tebipenem, in Japan

February 6, 2009, SCRIP

Meiji Seika's oral carbapenem tebipenem (ME1211) has received its first approval recommendation worldwide, in Japan, for the treatment of otolaryngological and upper respiratory infections in paediatric patients. The first-in-class product, originally licensed from Wyeth, Japan, for the treatment of otolaryngological and upper respiratory infections in paediatric patients. The first-in-class product, originally licensed from Wyeth, Japan, will be marketed as Orapenem for infections from resistant strains of *Streptococcus pneumoniae*, including persistent otitis media and bacterial pneumonia.

US FDA Issues Guidance for Industry to Improve Safety of Foods, Feeds & Drugs

January 19, 2009 Pharmabiz, Maryland

The US Food and Drug Administration issued three guidance designed to help ensure the safety of FDA-regulated products in the supply chain. The document issued include, final Guidance for Industry on Voluntary Third-Party Certification Programmes for Foods and Feeds; Draft Guidance for Industry on Submission of Laboratory Packages by Accredited Laboratories; and Draft Guidance for Industry on Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages.

New Products

Ranbaxy Set To Launch Daiichi Drugs In Africa

December 21, 2009, Business Standard

<http://www.business-standard.com/india/news/ranbaxy-to-launch-daiichi-sankyo%5Cs-drug-in-africa/81332/on>

The country's largest drug maker by sales, Ranbaxy Laboratories, today said it would launch Olmesartan Medoxomil, an anti-hypertensive drug from parent company Daiichi Sankyo's portfolio, in six African countries "The companies will launch the products under the brand name 'Olvance', as soon as the necessary measures have been completed in each country," Ranbaxy Laboratories said in a statement.

Ranbaxy Launches GSK's Blockbuster Drug In US

November 2009, Yes Pharmalife

In a move that will help Ranbaxy boost its revenues from the US in the next six months, the company has launched the generic version of GlaxoSmithKline's (GSK) blockbuster Herpes drug Valtrex (valacyclovir hydrochloride) in the United States. Daiichi-controlled Ranbaxy enjoys the first-to-file status for the drug and, therefore, has a six-month exclusive marketing right to the medicine.

UCB is Making Available Again its Transdermal Patch, Neupro (Rotigotine)

July 3, 2009, SCRIP

UCB is making available again its transdermal patch, Neupro (rotigotine), in the EU, following approval by the European Commission of last month's positive opinion from the CHMP. It is indicated for the treatment of Parkinson's disease and a new indication, restless legs syndrome. Since last year, supplies of Neupro have been restricted because of the formation of crystals within the patches.

Boehringer Ingelheim and Astellas have Launched a Combination of Telmisartan and the Diuretic Hydrochlorothiazide in Japan

July 3, 2009, SCRIP

Boehringer Ingelheim and local partner Astellas have launched a combination of telmisartan and the diuretic hydrochlorothiazide in Japan, as Micombi, to treat hypertension. The product is a single once-daily tablet

containing either 40mg or 80mg of the angiotensin II antagonist with 12.5mg of HCTZ.

Bayer Schering to launch Oral Contraceptive Qlaira in Europe

May 16, 2009, Pharmabiz, Berlin

Bayer Schering Pharma AG, Germany, has launched its new oral contraceptive Qlaira (estradiol valerate/dienogest) in Europe. Qlaira will be available in several European countries, including Germany. More European countries will follow from autumn 2009 onwards, a company press release said.

Abbott Launches Two New Products for Peripheral Artery Disease Treatment

May 11, 2009, Pharmabiz, Abbott Park, Illinois
<http://www.pharmabiz.com/article/detnews.asp?articleid=49652§ionid=43>

Abbott launched two new products - FoxCross PTA Catheter and HI-TORQUE Versacore .035 Guide Wire - for the treatment of peripheral artery disease (PAD), a condition that occurs when the vessels supplying blood to the legs, arms, stomach or kidneys become narrowed or blocked by plaque, restricting normal blood flow.

Bayer Launches Betaferon Titration Pack for Multiple Sclerosis

March 30, 2009 Pharmabiz, Berlin

<http://www.pharmabiz.com/article/detnews.asp?articleid=48996§ionid=43>

Bayer will launch a titration pack for patients with multiple sclerosis (MS) that is specially designed to make it easier for them to start Betaferon (interferon beta-1b) therapy. From now on, the titration pack will be available in Germany. More European countries will follow in 2009. The four-week pack facilitates a gradual increase in dose as recommended for patients new on Betaferon.

Genzyme Canada Launches Single Injection Synvisc-One for Knee Osteoarthritis

March 19, 2009, Pharmabiz, Cambridge

<http://www.pharmabiz.com/article/detnews.asp?articleid=48858§ionid=43>

Following the February 2009 approval by Health Canada, Genzyme Canada announced the availability of Synvisc-One (Hylan GF-20), a single injection viscosupplement approved for osteoarthritis (OA) of the knee. Synvisc-One is the latest addition to a growing Synvisc family of products used to treat Osteoarthritis including: a single 2mL injection for the hip, shoulder and ankle, and a 3 X

2mL dosage format for the knee. Osteoarthritis is a common, debilitating disease that affects approximately one in 10 Canadians.

Galderma Launches Epiduo Gel to Treat Acne

February 10, 2009, YES PHARMALIFE

The FDA approved Galderma's Epiduo (Adapalene 0.1%+ Benzoyl Peroxide 2.5%) Gel - a oncedaily topical treatment for acne. The new treatment will be on pharmacy shelves nationwide in the first quarter of 2009. By combining the two effective medications into one product, Epiduo treats both inflammatory and non-inflammatory lesions with no evidence of promoting antibiotic resistance, simplifying the management of mild-to-moderate acne.

R&D/Clinical Trials

Scientists Decode Deadly Cancers

December 17, 2009, Mint

<http://www.livemint.com/2009/12/17225705/Scientists-decode-deadly-cance.html>

British scientists have cracked the genetic code of two of the most deadly cancers, a development described as a "transforming moment" in the effort to find a cure for the killer disease. Cambridge University researchers mapped the DNA mutations that lead to skin and lung cancers. The complete genetic codes of the two human cancers have been mapped for the first time, setting the stage for a medical revolution in which every tumour can be targeted with personalised therapy.

Roche, Genentech & Biogen Idec Announce Positive Results From First Phase III Trial Of Ocrelizumab In RA

December 14, 2009, Medical News Today

<http://www.medicalnewstoday.com/articles/173855.php>

Roche, Genentech, Inc a wholly owned member of the Roche Group, and Biogen Idec announced a phase-III study (STAGE) of the investigational humanized anti-CD20 monoclonal antibody ocrelizumab given in combination with methotrexate (MTX) met its primary endpoint of improving signs and symptoms (as measured by American College of Rheumatology or ACR20 response) in rheumatoid arthritis (RA) patients who had an inadequate response to MTX at both 24 and 48 weeks. The companies continue to analyze the study results and plan to submit the data for presentation at an upcoming medical meeting.

Glaxo Investing \$97 Million in AIDS Drugs for Africa

July 14, 2009, Reuters

<http://www.reuters.com/article/healthNews/idUSTRE56D7GU20090714>

GlaxoSmithKline plans to invest up to 60 million pounds (\$97 million) over 10 years to improve research, development and access to AIDS drugs in Africa, the world's second biggest drugmaker said on Tuesday. It has also agreed a new free voluntary licensing agreement for AIDS drug abacavir, or Ziagen, with South African generic drugmaker Aspen Pharmacare, in which it has a 16 percent stake. Aspen will manufacture a cheaper generic version of the drug.

Sanofi-Aventis Presents New R&D Model Project to Boost Innovation

July 1, 2009, Pharmabiz, Paris, France

Sanofi-aventis presented its new research and development model project. The model, which aims to transform R&D and increase innovation, is the first pillar of the Group's new strategy which was presented in February 2009 by Christopher A. Viehbacher, chief executive officer of sanofi-aventis.

TB Alliance, Tibotec Collaborate to Accelerate TB Drug Development

June 19, 2009, Pharmabiz, Washington

<http://www.pharmabiz.com/article/detnews.asp?articleid=50287§ionid=20>

A new landmark collaboration between the Global Alliance for TB Drug Development (TB Alliance) a not-for-profit, product development partnership, and Tibotec Inc, (Tibotec), a global pharmaceutical company, has been announced at the Pacific Health Summit in response to the urgent need to accelerate the discovery and development of new drugs to fight tuberculosis (TB).

'5-in-1 Pill Tried on Indians, May Check Heart Disease'

April 1, 2009, Indian Express

<http://www.indianexpress.com/news/5in1-pill-tried-on-indians-may-chec.../441613/>

A combination pill of five drugs, trials of which were conducted on the "Indian population", can help reduce incidence of cardiovascular events by more than 80 per cent in healthy individuals, according to new research published in The Lancet. In "double-blind" trials in 50 centres across India, as many as 2,053 individuals in the age group 45-80, without any cardiovascular disease but with one risk factor, were randomly assigned the

polypill/polycap. The trials, which went on for about two years, ended in August 2008.

Bayer Chooses China for New Global R & D Centre

February 20, 2009, SCRIP

Bayer Schering Pharma (BSP) has joined the growing roster of pharma multinationals expanding their R & D activities in China, with the announcement of a €100 million investment in a new global R & D centre in Beijing. The facility will be only BSP's third major global R & D site after Germany and the US, showing just how far perceptions of China's drug development expertise have risen over the past few years.

Mergers & Acquisitions/ Collaborations

Ranbaxy Exits China Joint Venture

December 29, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/12/30/stories/2009123051750200.htm>

Ranbaxy Laboratories Limited on Tuesday announced the transfer of its entire shareholding in Ranbaxy (Guangzhou China) Limited (RGCL) to HNG Chembio Pharmacy Co. Ltd. (HNG). RGCL was a joint venture between the Ranbaxy Group, Guangzhou Baiyunshan Pharmaceutical Company Limited, Guangzhou, China and Hong Kong New Chemic, Hong Kong. Ranbaxy had entered the JV in 1993 with a focus on the local market in China.

Sanofi-Aventis To Acquire Chattem For \$1.9 Billion

December 22, 2009, The Times of India

<http://lite.epaper.timesofindia.com/getpage.aspx?pageid=23&pagesize=&edid=TOID&edlabel=CAP&mydateHid=22-12-2009&pubname=Times+of+India+-+Delhi&edname=Delhi&publabel=TOI>

French drug major Sanofi-Aventis on Monday said it will buy US based consumer healthcare company Chattem for about \$1.9 billion. "The transaction will create the world's fifth largest consumer healthcare company measured by product revenues," the companies said in a joint statement.

Hospira Buys Orchid's Injectable Business

December 15, 2009, Financial Chronicle

<http://www.mydigitalfc.com/companies/hospira-buys-orchid%E2%80%99s-injectable-business-982>

US pharma major Hospira, the world leader in generic injectables, on Tuesday announced acquisition of the generic injectable business of Chennai-based Orchid Chemicals & Pharmaceuticals for approximately \$400 million. The US firm seeks to expand its generic injectable antibiotics operations through this deal. Orchid is among the top five generic beta-lactam antibiotics manufacturers globally.

Ranbaxy Exits Japan Venture

December 9, 2009, The Telegraph

http://www.telegraphindia.com/1091209/jsp/business/story_11840823.jsp

Ranbaxy Laboratories Ltd has pulled out of Nihon Pharmaceutical Industry, its Japan-based joint venture company. In September 2002, Ranbaxy, which is now a subsidiary of Daiichi Sankyo, and Nippon Chemiphar Company Ltd formed Nihon Pharmaceutical to market generic drugs.

Targacept Scores Blockbuster \$1.2B Deal With AZ

December 3, 2009, Fierce Biotech

http://www.fiercebiotech.com/story/targacept-scores-blockbuster-1-2b-deal-az/2009-12-03?utm_medium=nl&utm_source=internal

Backed up with some impressive mid-stage data, Targacept has inked a \$1.24 billion licensing deal with AstraZeneca for its promising new depression therapy. The Winston-Salem, NC-based developer landed a \$200 million upfront payment for TC-5214, with more than a billion dollars in development and sales milestones up for grabs. Targacept also gets "significant" double-digit royalties from any approved product from AstraZeneca, which is already partnered with the developer on two other programs. And the two companies are planning to launch a jointly designed Phase III next year as they map out plans to file for approval in 2012.

ACG Worldwide, KORSCH Ink JV For Tablet Compression Systems

December 3, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=52920§ionid=2>

ACG Worldwide, India and KORSCH AG, Germany has announced their joint venture (JV) to develop and produce tablet compression systems in India on the sidelines of the

CPhI/P-MEC/ICSE India 2009 exhibition. The JV will expand the global footprints of both companies and will benefit from the established worldwide sales channels and offices of both partners.

GSK and Pfizer launch HIV Company ViiV

November 13, 2009, SCRIP

GlaxoSmithKline and Pfizer have launched their HIV joint venture, ViiV Healthcare, and have appointed GSK's former senior Vice-President and Head of personalized medicine strategy, Dr. Dominique Limet, CEO of the new company. The two big pharma firms announced their decision to create the £250 million company in April but have waited until now to launch it officially. ViiV will be headquartered in London, but will have US headquarters in North Carolina.

Novartis Building Chinese Presence with Acquisition

November 13, 2009, SCRIP

Novartis has become the latest multinational to set its sights on the fast-growing vaccines market in China, where it has unveiled plans to acquire a Chinese manufacturer, and is also investing \$1 billion over the next five years to build up its R & D operations in the country. The Swiss group has entered into a basic agreement to pay Yuan 850 million (\$125 million) in cash for an 85% stake in Zhejiang Tianyuan Bio-Pharmaceutical, a privately held company based in Hangzhou near Shanghai. The deal remains subject to final government and regulatory approvals.

Merck, Schering-Plough Merger Gets Finalized

November 3, 2009, New Jersey Business News
http://www.nj.com/business/index.ssf/2009/11/merck_and_schering-plough_gets.html

Merck and Schering-Plough are scheduled to finalize their merger later today, marking a major consolidation of two venerable New Jersey drug makers. As the companies launch their combined operations tomorrow, the Schering-Plough name will be dropped. The new business will operate under the Merck name. The Associated Press Merck and Schering-Plough will officially begin operating as one company tomorrow. In March, Merck announced it would fortify its business by acquire fellow drugmaker Schering-Plough in a \$41.1 billion deal.

Abbott Completes Eye Care Firm Visiogen Acquisition

October 22, 2009, Pharmabiz, Abbott Park, Illinois

<http://www.pharmabiz.com/article/detnews.asp?articleid=52229§ionid=14>

Abbott has completed its acquisition of privately held eye care company Visiogen, expanding the company's vision care business with a next-generation accommodating intraocular lens (IOL) technology to address presbyopia for cataract patients. Visiogen's Synchrony accommodating IOL is a significant advancement in artificial lens technology. It is designed to mimic the eye's natural ability to change focus (accommodation), delivering improved vision at all distances, potentially eliminating the need for glasses or contact lenses, reducing glare and night time halos, and improving contrast sensitivity.

Sanofi-Aventis Closes Acquisition of Merial

September 25, 2009, SCRIP

Sanofi-Aventis has completed its \$4 billion cash acquisition of the 50% interest in Merial that it did not already own. It acquired the stake from its joint venture partner Merck & Co., which was required to sell the stake for antitrust reasons. Merial, which is number three in the animal health market with sales of \$2.7 billion, will report to Sanofi-Aventis's executive vice-president of global operations, Hanspeter Spek.

Astellas to Co-promote Caduet

September 4, 2009, SCRIP

Astellas is to co-promote Pfizer's combination antihypertensive / hypolipaeamic Caduet (amlodipine besilate plus atorvastatin) in Japan, in a deal which builds on the companies' local alliance for Lipitor. The US firm will manufacture and sell the product and book all sales, with Astellas to receive fees based on an undisclosed formula. The agreement will run until July 2016.

GSK and Concept Sign \$1 Billion Deal

June 12, 2009, SCRIP

GlaxoSmtiKline is to pay the private US company Concert Pharmaceuticals \$35 million up-front as well as future milestones and royalties to develop and commercialise three of its deuterium containing programmes. Concert may receive up to \$1 billion from GSK in total milestone and upfront payments. A \$16.7 million equity investment will be included in the up-front payment.

Bayer Acquires Rights to Bioton's Insulin SciLin

July 11, 2009, Pharmabiz, Berlin

<http://www.pharmabiz.com/article/detnews.asp?articleid=50657§ionid=43>

Bayer Schering Pharma AG, Germany, has signed an exclusive supply and distribution agreement with the Polish insulin producer Bioton S.A. and Bioton's Singaporean subsidiary, SciGen, to strengthen its pharmaceutical product portfolio. For an up-front payment of 31 million Euros, Bayer acquires the exclusive right to market and distribute insulin produced by Bioton under the trade name of SciLin in China. The contract and payment guarantee the exclusive commercial delivery of this recombinant insulin to Bayer in China with a secured supply of the product for the next 15 years.

Dr Reddy's GSK Tie Up for Emerging Markets

June 16, 2009, Business Standard

<http://www.business-standard.com/india/news/dr-reddy%5Cs-gsk-tiefor-emerging-mkts/361205/>

Hyderabad-based pharmaceutical major Dr Reddy's Laboratories (DRL) has entered into a partnership with GlaxoSmithKline (GSK) to develop and market select products across emerging markets outside India. Under the terms of the agreement, which is effective immediately, GSK will gain access to DRL's diverse portfolio and a pipeline of more than 100 branded pharmaceuticals in fast-growing therapeutic segments, such as cardiovascular, diabetes, oncology, gastroenterology and pain management.

Merck Inks Drug Discovery Deal with Xenon

June 11, 2009, Fierce Biotech

http://www.fiercebiotech.com/story/merck-inks-drug-discovery-deal-xenon/2009-06-11?utm_medium=nl&utm_source=internal

Merck has signed a deal with Canada-based Xenon to discover and develop small molecule candidates for cardiovascular disease. Xenon, a clinical genetics-based drug discovery and development outfit, will perform validation studies using its clinical genetics platform, as well as drug discovery. The company will handle certain preclinical development of small molecule compounds for selected targets. Merck has exclusive rights to any drug resulting from the collaboration, though Xenon can develop candidates which Merck passes over.

Novartis Acquires EBEWE's Generic Injectables Business

May 29, 2009, SCRIP

Novartis is to acquire EBEWE Pharma's generic injectables business for €925 million (\$1.2 billion) in cash to strengthen its generics business Sandoz. The private Austrian company will retain its smaller injectable neurological products business but will divest products such as paclitaxel, epirubicin, methotrexate, oxaliplatin, carboplatin, doxorubicin and gemcitabine. All of these were essential components of standard-of-care guidelines for treating types of cancer, Novartis said.

J&J Buys Cougar Biotech for \$1B

May 22, 2009, Fierce Biotech

http://www.fiercebiotech.com/story/breaking-news-j-j-buys-cougar-biotech-1b/2009-05-21?utm_medium=nl&utm_source=internal

Johnson & Johnson has snagged a biotech with a late-stage oncology drug in its pipeline. J&J will pay \$1 billion cash for Los Angeles-based Cougar Biotechnology, which is developing drugs for prostate cancer, breast cancer and multiple myeloma. Cougar will work with Ortho Biotech Oncology R&D, a unit of Centocor R&D.

Roche Seals \$47-B Genentech Deal

March 13, 2009, The Economic Times

<http://economictimes.indiatimes.com/International-Business/Roche-seals-47-b-Genentech-deal/articleshow/4257813.cms>

Swiss pharmaceutical giant Roche agreed to pay \$46.8 billion to buy the 44% of biotech pioneer Genentech that it doesn't already own, ending a long corporate struggle with its US-based cancer drug partner. The deal brings Roche all of the sales of Genentech's highly profitable cancer drugs as well as its promising research pipeline and scientific corporate culture.

Piramal Completes Acquisition of Minrad

March 2, 2009, The Economic Times

<http://economictimes.indiatimes.com/News/News-By-Industry/Healthcare--Biotech/Piramal-Healthcare-completes-acquisition-of-Minrad/articleshow/4211804.cms>

Pharma firm Piramal Healthcare on Monday said that it has completed the acquisition of US-based Minrad International. In a filing to the Bombay Stock Exchange, Piramal Healthcare said shareholders of Minrad would receive USD 0.12 for every share held. As a result of acquisition, Minrad would be operated as a wholly-owned subsidiary of Piramal Healthcare. Further, Minrad's share would no longer be traded on the New York Stock Exchange Alternext Exchange.

J&J Completes Acquisition of Mentor Corporation

Thursday, January 29, 2009, Pharmabiz, New Brunswick, New Jersey

Johnson & Johnson (J&J) declared the completion of its previously announced acquisition of Mentor Corporation, a leading supplier of medical products for the global aesthetic market. Mentor is expected to operate as a stand-alone business unit reporting through Ethicon, Inc, a Johnson & Johnson company and a leading provider of suture, mesh and other products for a wide range of surgical procedures.

Pricing

Drug Costs Doubled In One Decade

December 10, 2009, Fierce Pharma

http://www.fiercepharma.com/story/drug-costs-doubled-one-decade/2009-12-10?utm_medium=nl&utm_source=internal

Adult prescription drug expenditure doubled from 1996 to 2006, according to a report released by the Agency for Healthcare Research and Quality (AHRQ). "The average expense for a prescription medication purchase was notably higher for [adults 18 to 44] in 2006 than in 1996 (\$161 versus \$79)," the group found. And prescription medications accounted for a larger share of all healthcare expenses for adults in 2006 than 1996.

Pfizer Cuts UK Lipitor Price

November 13, 2009, SCRIP

The UK price for the 10 mg tablet of Pfizer's blockbuster cholesterol-lowering drug Lipitor (atorvastatin) has been lowered from £18.03 to £13.00 (excluding VAT) as of November 1st. The 28% price reduction for the 28 x 10 mg tablet pack (the only pack and dose size affected) is in line with the requirements under the 2009 Prescription Pricing Regulation Scheme (PPRS), agreed between the UK Department of Health and the ABPI, Pfizer said. Since February 1st, companies have been required to reduce the prices of their branded drugs by 3.9% and by a further 1.9% by January 1st, 2010.

GSK Plans Price Push On Cervarix

October 20, 2009, Fierce Pharma

http://www.fiercepharma.com/story/gsk-plans-price-push-cervarix/2009-10-20-0?utm_medium=rss&utm_source=rss&cmp-id=OTC-RSS-FPO

What can a latecomer do to grab market share? Cut prices, of course. And that's just what GlaxoSmithKline plans to

do as it launches the cancer vaccine Cervarix, aiming to compete with entrenched rival Gardasil. The *Financial Times* reports that Glaxo plans to undercut Merck's wholesale list price of \$399 for a three-dose course of Gardasil. Glaxo's version will be tagged at \$386.

Europe Pays 40% Less for Drugs Than U.S.

July 8, 2009, Fierce Pharma

http://www.fiercepharma.com/story/europe-pays-40-less-drugs-u-s/2009-07-08?utm_medium=nl&utm_source=internal

Decision Resources came out with a report showing that drug costs in Europe are an average of 40 percent less than in the U.S.--a price differential that shows why reimportation was ever raised in the first place. The study covered 170 of the most popular drugs and found costs to range from a low of 55 percent of the U.S. price in Italy to a high of 70 percent in Germany.

Glaxo Pools 800 Patents, Cuts Drug Prices for Poor

March 24, 2009, REUTERS

<http://uk.reuters.com/article/hotStocksNews/idUKWLA059920090324>

GlaxoSmithKline Plc will share more than 800 of its patents with others seeking to develop new medicines for neglected tropical diseases and slash the cost of many of its drugs in poor countries from next week. The world's second-largest drugmaker announced the moves on Tuesday in its annual corporate responsibility report, following a pledge by Chief Executive Andrew Witty in a speech at Harvard last month to do more to help the developing world. The \$800 billion-a-year global pharmaceutical industry has come under increasing pressure in recent years to help close the gap in access to medicines between rich and poor, particularly in Africa.

Trade & Others

Trend: E-Prescribing on the Rise Despite Problems

July 2, 2009, Fierce Healthcare

http://www.fiercehealthcare.com/story/trend-e-prescribing-rise-despite-problems/2009-07-02?utm_medium=nl&utm_source=internal

In the past, prescribing electronically was confusing to many doctors. Today, however, e-prescribing sounds like a reasonable idea and its benefits--largely improving prescription accuracy and safety--are well known to most. While the technology continues to be a bit clunky,

its use is climbing rapidly. Today, more than 120,000 doctors are using e-prescribing, or more than 20 percent of all office-based prescribers, according to industry sources.

Wockhardt Sells Its German Subsidiary

June 18, 2009, Business Standard

<http://www.business-standard.com/india/news/wockhardt-sells-its-german-subsidiary/361421/>

Debt-ridden Wockhardt Ltd today said it had sold its German subsidiary Esparma to Mova GmbH, a subsidiary of German drug major Lindopharm. Although the company did not disclose the deal size, sources said it was worth Rs 120 crore. "Wockhardt continues to be on the growth track and this initiative is the first step towards its ongoing strategy to restructure, rationalise and optimise all of its businesses and raise fresh capital by divesting some of its smaller operations and non-core businesses," said a press release.

China to Check on Fake 'Made in India' Drugs

June 14, 2009, Times of India

<http://timesofindia.indiatimes.com/World/Beijing-sends-inspectors-to-check-on-factories-making-Made-in-India-fake-drugs/articleshow/4652993.cms>

China's State Food and Drug Administration has begun an investigation into an allegation by Nigeria that a consignment of drugs labeled 'Made in India' were, actually fake Pharmaceuticals produced in China, a SFDA spokesperson has said. The matter came to light after The Times of India reported that Nigeria's Drug Regulatory Authority has seized a large consignment of fake anti-malaria drugs that were made in China but stamped 'Made in India' to escape blame. The TOI report resulted in the Indian government lodging a protest with China.

Lipitor, Nexium Still Top-Selling Brands

March 26, 2009, Fierce Pharma

http://www.fiercepharma.com/story/lipitor-nexium-still-top-selling-brands/2009-03-26?utm_medium=nl&utm_source=internal&cmp-id=EMC-NL-FP&dest=FP

Here's something for you competitive types, the ones who like to keep track of whose drug is bigger than whose. (You know who you are.) Last week's sad-but-true report from IMS Health on stagnating drug sales also included some lovely little nuggets on top brands by prescription and by dollar volume. Here we go.

The five drugs that accounted for the most dispensed scrips include four generics and just one branded product-

-and that brand saw scrips drop. Here's the list, with the number of scrips for 2008 and 2007 for comparison's sake.

- Hydrocodone with acetaminophen, generic painkiller, 124 million scrips in 2008, up from 119 million in 2007.
- Lisinopril, generic blood pressure med, 75.5 million, up from 70.5 million in 2007
- Simvastatin, generic cholesterol remedy, 66.7 million, up from 47.7 million in 2007
- Levothyroxine sodium, generic thyroid hormone, 61.4 million, up from 55 million in 2007
- Lipitor, Pfizer's branded cholesterol med, 57.9 million, down from 65.1 million in 2007

Animal Health

Bayer Animal Health, To Market Animal Healthcare Products in China and Taiwan

December 3, 2009, LIFESCIENCES INDUSTRY NEWS

Oculus Innovative Sciences, Inc. a biopharmaceutical company that develops, manufactures and markets a family of products based upon the Microcyn® Technology platform, which is intended to treat chronic and acute wounds, today announced that its development partners, Bayer Animal Health divisions in China and Taiwan, recently secured regulatory approvals in both those countries to develop and market Microcyn-based Vetericyn™ products for their respective animal healthcare markets.

New Pfizer Animal Health is Unveiled with Acquisition of Wyeth

October 21, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=52207>

A new Pfizer Animal Health was unveiled last week as Pfizer's acquisition of Wyeth, including its subsidiary Fort Dodge Animal Health, was completed. Pfizer Animal Health is now the world's leader in the discovery, development, manufacture and sales of veterinary vaccines and medicines for livestock and companion animals.

Biotechnology

Medimmune Recalls Millions Of Doses Of Swine Flu Vax

December 23, 2009, Fierce Vaccines
http://www.fiercevaccines.com/story/medimmune-recalls-millions-doses-swine-flu-vax/2009-12-23?utm_medium=nl&utm_source=internal

AstraZeneca's MedImmune is scrambling to retrieve up to about five million doses of swine flu vaccine that has lost at least some of its potency. FDA officials were quick to reassure the public that the doses--delivered in a nasal spray--were safe and that the people who had already received a shot drawn from the 13 lots now being recalled don't need to go back out and get a second jab.

GSK Backing \$60M Biotech Science Cluster

October 13, 2009, Fierce Biotech
<http://www.fiercebiotechresearch.com/story/gsk-backing-60m-biotech-science-cluster/2009-10-13#>

In an effort to create a new biotech cluster which can eventually rival Boston's, GlaxoSmithKline is joining hands with the British government, the nonprofit Wellcome Trust and the East of England Development Agency to create a new science park that will eventually become home to 1,500 scientists devoted to new drug development. Altogether, the three groups will chip in close to \$60 million in cash and facilities to create the hub at Glaxo's site near Stevenage.

Glaxo Unveils \$600M Vaccine Plant

June 10, 2009, Fierce Biotech
<http://www.fiercevaccines.com/story/glaxosmithkline-unveils-600m-vaccine-plant/2009-06-10>

GlaxoSmithKline has taken the wraps off its new, \$600 million vaccine manufacturing plant in Singapore, which will produce jabs for a range of childhood diseases such as meningitis, pneumonia and blood poisoning. And the opening ceremony featured plenty of boasting. Glaxo chief Andrew Witty called the plant "possibly the best vaccine facility anywhere in the world."

New Paediatric Vaccine Launched in Bangladesh

January 23, 2009, SCRIP

A new five-in-one combination vaccine, which will protect children in Bangladesh for the first time against Haemophilus influenzae type B (Hib), has been launched there. The vaccine, which will be administered to nearly

four million children under the age of one year as part of a routine immunization programme, will help prevent severe forms of pneumonia and meningitis associated with Hib, alongside vaccinating against diphtheria, tetanus, pertussis and hepatitis B.

Medical Diagnostics / Devices

New Cancer Research Tool from Roche

December 3, 2009, LIFESCIENCES INDUSTRY NEWS

Roche's Applied Science announces the availability of the new CIM-Plate 16 for their xCELLigence System for cell analysis, for use in cancer research. The 16-well culture plate features electronic sensors for the direct study of cell migration and invasion on the xCELLigence RTCA DP instrument. The system delivers unbiased data without disturbing cells due to labeling and allows researchers to monitor cell invasion and migration continuously in real-time throughout the entire duration of the experiment. The user can combine E-Plate 16 to measure cell proliferation and CIM-Plate 16 to quantify cell migration and invasion, thus making full use of the flexibility that the RTCA dpi INSTRUMENT has to offer.

New Cardiac Diagnostic Monitoring Device

December 3, 2009, LIFESCIENCES INDUSTRY NEWS

IntriCon Corporation, a designer, developer, manufacturer and distributor of body-worn medical and electronics devices, announced the launch of a prototype of its new Cardiac Diagnostic Monitoring (CDM) device, called the Mobile Patient ECG Telemetry System, or MPETS.

Abbott Launches Xience Prime Drug Eluting Stent in International Markets

September 1, 2009, Pharmabiz, Barcelona Spain

<http://www.pharmabiz.com/article/detnews.asp?articleid=51459§ionid=43>

Abbott announced at the European Society of Cardiology Congress the widespread availability of its next-generation Xience Prime Everolimus Eluting Coronary Stent System for the treatment of coronary artery disease. Xience Prime, which received CE Mark (Conformité Européenne) in June, offers a novel stent design and a delivery system designed for greater flexibility and enhanced deliverability. Xience

Prime is now widely available in Europe and in select countries throughout Asia-Pacific and Latin America.

Abbott Launches Real-Time PCR-Based Diagnostic Test for HPV in Europe

January 15, 2009, Pharmabiz, Des Plaines, Illinois

European clinicians will have a new weapon to combat cervical cancer with the introduction of Abbott Molecular's real-time polymerase chain reaction (PCR) based diagnostic test for human papillomavirus (HPV). The CE-marked assay can identify patients infected with specific viral genotypes known to pose the highest risk for progression to cervical cancer.

New Appointments

Carl Feldbaum Has Been Elected Chairman of BIO Ventures for Global Health

September 25, 2009, SCRIP

Carl Feldbaum has been elected Chairman of BIO Ventures for Global Health (BVGH); he has served on BVGH's board since its inception in 2004. He succeeds Rob Chess, Chairman of the Board of Nektar Therapeutics. Mr. Feldbaum is President Emeritus of the Biotechnology Industry Organisation (BIO).

Paul Pomerantz is to Join Drug Information Association (DIA)

September 18, 2009, SCRIP

Paul Pomerantz is to join the Drug Information Association (DIA) as worldwide executive director. He will move from his current position as executive vice-president of the American Society of Plastic Surgeons to the DIA on December 1st. Mr. Pomerantz succeeds William Brassington, who has served as acting executive director since July 2008, but who will resume his role as worldwide director of finance.

IPHA Has Appointed Leisha Daly

July 31, 2009, SCRIP

The Irish Pharmaceutical Healthcare Association (IPHA) has appointed Leisha Daly to its prescription medicines division strategy board. Ms. Daly currently holds the position of country manager at Janssen-Cilag; prior to this, she worked as head of technical affairs at the company. In her role with the board, she will now help define strategy and policy for the prescription medicines division.

The strategy board comprises 14 representatives, who are elected by the IPHA's prescription medicines division for a three-year tenure. Other board members currently include representatives from Wyeth, Pfizer, Abbott and Roche.

New Chairman at ERBI

July 16, 2009, SCRIP

<http://www.scripnews.com/scripnews/home/people/New-chairman-at-ERBI-169945?autnID=/contentstore/scripnews/codex/112d9767-71ea-11de-8f5f-751dc9cfc33.xml>

The UK's Eastern Region Biotech Initiative (ERBI) has appointed Jon Green, vice-president of business operations at MedImmune, as its new chairman. He succeeds Gordon Baxter of BioWisdom, who is stepping down.

IFPMA New Appointment

April 29, 2009, IFPMA

Ms. Alicia Greenidge, IFPMA's Director General, is resigning her position in order to pursue other opportunities. Ms. Greenidge came to IFPMA in 2008 after a distinguished career in the United State Government. During the search for a successor, Laurent Renaud, Director of Administration and Finances, IFPMA will take on the day-to-day administrative operations of the organisation under the direction of Michael Boyd, Vice President of Public Affairs International for Schering-Plough Corporation, who will be serving as Acting Director General.

Domestic IPR

Patent Office Braces Surge In Applications

December 24, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/12/24/stories/2009122451200200.htm>

The Indian Patent Office is set to address the shortage in patent examiners and the standardised implementation of the Patents (Amendment) Act 2005, as it braces for the increasing flood of patent applications. The number of patent applications filed in India has increased three times since the Indian Patent Law was amended in 2005 to honour product patents, and the global significance of the patent office too has since grown substantially.

Pharma Industry Seeks New Technical Committee in Place of Mashelkar Panel

October 14, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=52121§ionid=>

Pharma industry has called for further amendment to the Patents Act to strengthen the criteria of patent protection and constitution of a fresh technical expert committee on the scope of patentability of pharma products as the earlier panel headed by **Dr R A Mashelkar has run into controversy yet again.**

Wockhardt Wins Government of India Patent Award

September 24, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51841§ionid=44>

Wockhardt Limited, a Mumbai-based technology-driven global pharmaceutical and biotechnology major, has received a very prestigious award instituted by the Government of India as the 'Pharmaceutical Company for the maximum number of patent filings and grants from India.' Wockhardt has been granted 70 patents, 15 from the Indian patent office and 55 from the American and European patent offices. Anand Sharma, Minister for Commerce & Industry, will present the award on September 25, 2009 in Hyderabad, a company release said.

India Accepts Expert Group's Recommendation on Patent Issues

August 28, 2009, SCRIP

Both the Innovator and Generic Sectors in India appear satisfied with the recommendations of a technical expert group (TEG) on patent issues. Each side is claiming that the revised report supports its views on the patenting of incremental innovation in the country. The TEG's recommendations were recently accepted by the Indian government.

Cipla Can Sell Copy of Bayer's Cancer Drug

August 19, 2009, The Economic Times

In a major win for Indian Pharmaceutical companies, the Delhi High Court (HC) on Tuesday dismissed German drug major Bayer Healthcare's attempt to stop Drug Controller General of India (DCGI) from giving marketing approval to Indian company Cipla for the generic version of Bayer's patented kidney cancer drug, Nexavar. Besides, the HC asked the German firm to pay Rs. 6.75 lakh to the government and Cipla as legal cost.

India Grants 3,500 Pharma Patents in Three Years

August 3, 2009, Business Standard

<http://www.business-standard.com/india/news/india-grants-3500-pharma-patents-in-three-yrs/69759/on>

The Indian Patent Office (IPO) has granted 3,506 patents relating to pharmaceutical innovations over the last three years, the government said today. IPO has granted a total 3,506 patent to pharmaceutical innovations in the country over last three years, ranging from 2006-07 fiscal to 2008-09 and the first three months of the current fiscal, Minister of Commerce and Industry Anand Sharma said.

Drug Patent Pool Proposal Gets a Push

June 25, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/06/25/stories/2009062552380100.htm>

Concerned over the changing intellectual property (IP) environment, where medicines are getting patented across the world, UNITAID had proposed a "patent pool" to make drugs more accessible. And close to a year after getting the green signal to create the patent pool, UNITAID representatives met Indian generic drug-makers and researchers, among other stakeholders, to take on board concerns that need to be addressed when an 'implementable plan' is put in place later this year, Ms Ellen 't Hoen, UNITAID's Senior Advisor IP and Medicines, told *Business Line*.

India Needs its Hatch-Waxman Act for Healthcare

May 15, 2009, DNA Money

<http://www.dnaindia.com/report.asp?newsid=1256132>

The Hatch-Waxman Act, a legislation that transformed the American drug industry, completed 25 years last week. Over those years, the American healthcare system saved a whopping \$734 billion due to increased use of generic pharmaceuticals.

Drug Patents: India to Take EU to WTO

April 18, 2009, Financial Express

<http://www.financialexpress.com/news/drug-patents-india-to-take-eu-to-wto/448284/2>

The heat of competition against established, branded and innovative companies who are holding the patents of these drugs, Indian officials said. EC has also gone beyond what TRIPS has contemplated as the procedure followed by Netherlands, which detained the Indian consignment, was not in accordance with TRIPS, the officials alleged.

India Rejects Patent to Glivec's Second Variant

April 15, 2009, Business Standard

<http://www.business-standard.com/india/news/india-rejects-patent-to-glivec%5Cs-second-variant/355128/>

In yet another setback to Swiss drug multinational Novartis AG, the Indian patent office has rejected its application to secure a patent for an alfa crystal form of its blockbuster cancer medicine, Glivec. The patent office had earlier refused patent protection to the beta crystal form of the same medicine, a decision that has been challenged by Novartis in the Madras High Court.

Regulatory

GSK Undertakes To Withdraw Ad On Cervical Cancer Vaccine To DCGI

December 24, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53256§ionid=19>

After almost a month of advertisement blitzkrieg in several national newspapers on cervical cancer vaccine, in gross violation of Drugs & Cosmetics Act, 1940 and Drugs and Magical Remedies Act 1954, the GlaxoSmithKline (GSK) has given an assurance to the Drug Controller General of India (DCGI) that it is unilaterally withdrawing the ads, it is learnt.

Industry Concerned Over DCGI's Decision To Omit 2 Prescription Drugs From Sch H

December 21, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53198§ionid=>

The pharmaceutical industry and medical experts have raised concern over the Drug Controller General of India (DCGI)'s recent draft notification omitting two prescription drugs, 'chlorpheniramine maleate' and 'dextromethorphan hydrobromide' from the Schedule H of the Drugs & Cosmetics Act and placing them under over the counter (OTC) category.

SSIs Approach MPs Intervention To Stop Health Ministry From Centralizing Copp, Drug Licensing

December 19, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53187§ionid=19>

The small scale pharma units in the country have sought the intervention of the law makers in preventing the Union Health Ministry's efforts for export licensing (CoPP) and also the centralization of drug licensing by creation of Central Drug Authority (CDA). The SME Pharma Industries Confederation (SPIC), which claims to represent around 5000 SSI pharma units across the country, has shot off letters to more than 800 Members of Parliament (both Lok Sabha and Rajya Sabha) in this regard.

AIDCOC Opposes Move To Legalise Guidelines Attached To Spurious Drugs Act

December 17, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53151§ionid=19>

The All India Drug Control Officers Confederation (AIDCOC), an association of state and central drug control officers in the country, is opposing the industry's demand to legalise the guidelines attached to the Spurious Drugs Act. The AIDCOC has sought the enactment of the Act at its present form.

Essential Drugs List To Be Expanded

December 8, 2009, Business Standard

<http://www.business-standard.com/india/news/essential-drugs-list-to-be-expanded/378881/>

The government has begun work on expanding the country's National List of Essential Medicines (NLEM), which was last revised in 2003. The government closely monitors the prices of these essential medicines and is in the process of bringing them under price control. That would expand the ambit of price control in the Rs 60,000-crore domestic pharmaceutical industry to about 35 per cent from the current 20 per cent, according to a senior government official.

Pharma Body Opposes Govt's Export Proposal

August 25, 2009, The Economic Times

Indian Pharmaceutical Alliance (IPA), the apex body representing domestic pharma companies, is up in arms against the government's proposed action plan to boost drug exports. The department of pharmaceuticals (DoP) has proposed funding by venture capitalists (VCs), service tax exemptions, import duty waiver on pharmaceutical products and protection to clinical test data to boost exports.

Centre to Spend Rs 510 Cr on Upgrading National Institute of Communicable Diseases

August 1, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=50980§ionid=6>

The Centre has sanctioned Rs 510 crore to the National Institute of Communicable Diseases (NICD) during the 11th Five Year Plan as a new initiative for upgradation of infrastructure, modernization of equipments, and augmenting the manpower of the institute.

Pharma Port Office Opened in Bangalore

May 7, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/05/07/stories/2009050751191700.htm>

The Health Ministry has opened a new port office for pharma exports and imports at the Bengaluru International Airport. Bangalore, a hub of biotechnology, clinical trials and pharma research, will also have a sub-zonal office of the Ministry's drug quality arm, the Central Drugs Standard Control Organisation, the Drugs Controller-General of India, Dr Surinder Singh, said on Wednesday.

New Diabetes Drug Approved Without Trial

March 25, 2009, Mint

<http://www.livemint.com/2009/03/25235931/New-diabetes-drug-approved-wit.html>

A new drug to combat diabetes, which is administered orally and not injected, was given a marketing approval by the Drugs Controller General of India (DCGI) without being put through the mandatory human clinical trials, highlighting a possible lapse in Indian laws dealing with the testing and approval of drugs.

New Products

PM To Unveil New TB Drug Next Week

December 18, 2009, Business Standard

<http://www.business-standard.com/india/news/pm-to-unveil-new-tb-drug-next-week/379951/>

Prime Minister Manmohan Singh will unveil a new anti-tuberculosis (TB) drug developed by Indian scientists next week. The drug, known to be more effective than existing therapies, has been developed by Indian Institute of Integrative Medicine (IIIM), Jammu, after 12 years of research. Ahmedabad-based Cadila Pharmaceuticals will market the medicine under the brand name "Risorine".

Wanbury Launches Anti-Anaemia Drug Cpink IIC

December 11, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53040§ionid=45>

Wanbury Ltd, country's fastest growing pharmaceutical company as per the latest ORG IMS, has launched an advanced form of its anti-anaemia drug Cpink (Ferrous Ascorbate). The product is called Cpink IIC and will be used in the treatment of anaemia in pregnant women and children. Cpink IIC has been introduced with a unique Integrated Iron Complexation Technology, resulting in a significant reduction in the gastro-intestinal (GI) irritation and can result in increased absorption of iron in the body, compared to the existing ferrous ascorbate brands in the country.

Novartis Launches Nasal Decongestant Otrivin in Spray Form

August 28, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51413§ionid=45>

Novartis India Limited - OTC Business Unit, part of Novartis' operations in India, launched Otrivin in a nasal spray format. Otrivin will now be available as a topical nasal decongestant in a modern easy-to-use direct acting spray format in India. Otrivin nasal spray will be available over-the-counter (OTC) at chemist stores and is priced at Rs 44 for a 10 ml unit.

Biocon Unveils Long Play Insulin Basalog

May 30, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/05/30/stories/2009053050760300.htm>

Biocon Ltd on Friday launched its biosimilar version of human insulin analog glargine, brand named Basalog. The basal insulin is meant for type-1 and type-2 (non-insulin dependent) diabetics. Priced 40 per cent less than the market leader, the 24-hour acting Basalog will begin "a new era in diabetes management", Ms Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon, said at the launch event.

Piramal Healthcare Launches Nutritional Supplement 'Supractiv Complete'

May 28, 2009, Pharmabiz

Piramal Healthcare, one of India's largest integrated healthcare companies, has launched Supractiv Complete - a total nutritional supplement. The product is rich in many nutrients such as glutamine, zinc, vitamin B-complex,

vitamins C, vitamin E, ginseng, calcium, amino acids and antioxidants.

Astrazeneca Launches Cholesterol Drug Crestor

April 17, 2009, Hindu Business line

<http://www.thehindubusinessline.com/2009/04/17/stories/2009041751670200.htm>

Bangalore, April 16 AstraZeneca's blockbuster statin drug, Crestor, has hit the domestic market. The cholesterol-lowering Crestor, called the "original rosuvastatin" by the company, enters a domestic market that already has a handful of generic rosuvastatin versions.

Ranbaxy to Launch Daiichi Sankyo's Antihypertensive Drug in India

March 31, 2009, Pharmabiz

Ranbaxy Laboratories has set to launch Daiichi Sankyo's Olvance (Olmesartan Medoxomil antihypertensive) product in India. This follows a licensing agreement between the two companies authorizing Ranbaxy to promote and market the drug in India.

GSK Launches Cervical Cancer Vaccine, Cerverix, in India

March 16, 2009, Pharmabiz

GlaxoSmithKline (GSK) has launched cervical cancer vaccine, Cerverix, in India. The vaccine, which is proved to be effective and safe without any alarming side effects, is targeted towards the 132000 Indian women diagnosed with human papillomavirus (HPV) that causes cervical cancer. GSK is in talks with the government to make HPV vaccine easily accessible in India. At present, only two HPV vaccines are available in the market - GSK's Cerverix and Merck's Gardasil.

Merck Launches Femibion for Anaemia in Women

January 29, 2009, Pharmabiz

Aiming to reach out to women with iron deficiency in India, the Consumer Health Care division of Merck Limited (India), a subsidiary of Merck KGaA of Germany, announced the launch of Femibion - Sharp & Active capsules in the country. The product mainly targets non-pregnant women and is looking forward for the market size of around Rs 700 crore.

Solvay Pharma to Market Ethypharm's Ulcerative Colitis Drug Mesalazine in India

January 20, 2009, Pharmabiz

Ethypharm India, a subsidiary of leading French drug delivery company Ethypharm SA, announced an out-licensing cum supply agreement for Mesalazine targeted release pellets in sachet form with Solvay Pharma India Limited. The product has been developed by Ethypharm India and would be supplied from Ethypharm's manufacturing facility on the outskirts of Mumbai as finished and packaged formulation for marketing and distribution by Solvay Pharma India Ltd.

R&D/Clinical Trials

ICMR Emerges As Major Funder Of Neglected Diseases In India

December 23, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53237§ionid=6>

India has been rated among the top five government funders of research and development (R&D) in neglected disease globally with an investment of US\$ 32.5m in 2008, and 60 per cent of which was contributed by the Indian Council for Medical Research (ICMR). This was reported in the second Global Funding of Innovation for Neglected Diseases (G-FINDER) survey analyses and reports on 2008 global investment into R&D of new products for neglected diseases.

Top Pharma Cos Step Up R&D Spending To Boost Presence In Regulated, Emerging Markets

December 21, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53197>

India's pharmaceutical sector has stepped up its research & development expenditure in a bid to capture a larger market share in highly regulated and emerging markets. The R&D expenditure of the top 25 pharma companies have thus increased by almost 17 per cent at Rs.3210 crore during 2008-09 from Rs 2,747 crore in the previous year. The R&D expenditure as per cent of their standalone net sales worked out to 7.75 per cent in 2008-09 as compared to 7.60 per cent in the previous year. The same was at 8.11 per cent and 8.78 per cent during preceding two years. The Pharmabiz Study shows that very few companies are spending over 10 per cent of their net sales on R&D.

India Accounts for Highest Number of Pneumonia Cases Among Children: WHO

September 12, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51643§ionid=6>

India accounted for the highest number of pneumonia cases among children under the age of five and deaths in the world, as ten Asian countries topped the list of nations, according to the latest data with the World Health Organisation. The studies, to be published in the next edition of the Lancet, had identified two leading causes of pneumonia -- Streptococcus pneumoniae and Haemophilus influenzae type b [Hib]. The two infections take the lives of an estimated 1.2 million children under age five each year.

Biocon, Bristol-Myers Open R&D Centre

March 29, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/03/27/stories/2009032751990200.htm>

Biotechnology company Biocon and US drug major Bristol-Myers Squibb Company, on Monday opened their joint R&D facility at Biocon's SEZ in Bangalore. The two plan to start educational partnerships with universities to build research talent in India, according to a release.

Mergers & Acquisitions / Collaborations

Six Indian Companies Sign Pact With American Firms

November 25, 2009, The Times of India

<http://epaper.timesofindia.com/Repository/ml.asp?Ref=RVRELzlwMDkvMTEvMjUjQXlwMDgwMg==&Mode=HTML&Locale=english-skin-custom>

SIX Indian companies, including Tata Communications, Infosys Technologies and Apollo Hospitals, have signed separate collaboration agreements with US-based firms for joint business development at Washington on Monday. The agreement-signing ceremony, organised by industry body CII, coincides with the state visit of Prime Minister Manmohan Singh to the US.

Wyeth Becomes Part of Pfizer

October 17, 2009, Business Standard

<http://www.business-standard.com/india/news/wyeth-becomes-partpfizer/373508/>

Drug maker Wyeth today said it has become part of Pfizer Inc, following the merger of its parent company – Wyeth – with the global pharma major. Mumbai-based Wyeth Ltd was part of American entity Wyeth. The latter has been merged with Wagner Acquisition Corp, a direct and wholly-owned subsidiary of Pfizer Inc, with effect from October 15.

Merck Acquires Sanmar's Bangalore Genei

October 14, 2009, Hindu Business Line

<http://www.thehindubusinessline.com/2009/10/14/stories/2009101450610200.htm>

Drug-maker Merck KGaA has acquired Bangalore Genei (India) Pvt Ltd from the Chennai-based Sanmar Group, a Merck note said, without disclosing the financial details. Bangalore Genei specialises in developing products for proteomic and genomic research. With more than 100 employees, Bangalore Genei generated total revenues of Rs 20 crore in fiscal 2008-09, the note said.

Malvinder Singh Steps Down, Sobti New Ranbaxy CEO

May 25, 2009, Financial Express

<http://www.financialexpress.com/news/malvinder-singh-steps-down-sobti-new-ranbaxy-ceo/465223/>

Nearly a year after selling his family's entire 35% stake in the country's largest drug manufacturer, Ranbaxy Laboratories Ltd, to Japanese firm Daiichi Sankyo, Malvinder Singh on Sunday stepped down as the company's chairman, CEO and managing director. Daiichi Sankyo director and Ranbaxy board member, Tsutomu Une, has been appointed as the executive chairman of the company while, Atul Sobti, the current COO has been appointed the new CEO. The changes were announced after the company's board meeting on Sunday.

Ranbaxy Acquires Skin Care, Lifestyle Range

May 22, 2009, Business Standard

Ranbaxy Laboratories, the second largest drug company in India in terms of market share after Cipla, has acquired the entire range of skin care and lifestyle products of Ochoa Laboratories, a small to medium sized manufacturer located on the outskirts of New Delhi.

Pricing

NPPA Mulls Monitoring Launch Price Of New Non-Scheduled Drgus

December 23, 2009, DNA

<http://epaper.dnaindia.com/epapermain.aspx?queried=9&eddate=12%2f10%2f2009>

The National Pharmaceutical Pricing Authority (NPPA), the country's drug price regulator, plans to monitor the launch price of new non-scheduled drugs. Non-scheduled drugs are not directly under the price regulator's purview.

Drug Regulator Slaps Rs 20-Cr Fine On Cipla For Overcharging

December 8, 2009, The Economic Times

<http://economictimes.indiatimes.com/news/news-by-industry/healthcare/biotech/pharmaceuticals/NPPA-slaps-Rs-20-cr-fine-on-Cipla-for-overcharging/articleshow/5311913.cms>

Pharma company Cipla Ltd on Monday said it has received notices, demanding about Rs 20.15 crore, from drug price regulator for allegedly over-pricing two drugs. The company has received a notice from sectoral regulator the National Pharmaceutical Pricing Authority demanding an amount of about Rs 20.14 crore, comprising allegedly overcharged amount of Rs 11.54 crore and interest thereon of Rs 8.59 crore, in respect of the drug Ciprofloxacin, Cipla said in a filing to the BSE.

NPPA Revises Price of 887 Medicines

August 7, 2009, The Economic Times

<http://mobileet.timesofindia.com/mobile.aspx?article=yess&pageid=5§id=edid=&edlabel=ETBG&mydateHid=07-08-2009&pubname=Economic+Times+-+Bangalore&edname=&articleid=Ar00507&publabel=ET>

THE drug price regulator National Pharmaceutical Pricing Authority (NPPA) has revised prices of 887 medicines. The medicines on NPPAs list include steroids, insulins, vitamins and painkiller such as aspirin. Companies that could see prices of some of their brands being slashed include Biocon, Wockhardt, Sanofi Aventis, Nicholas Piramal and Novo Nordisk.

Trade & Others

Jan Aushadi Programme Heading For Collapse With No Progress In Opening Generic Stores

December 23, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53238§ionid=>

One year after launching the Jan Aushadi programme to provide generic medicines at affordable prices to the people, the ambitious venture seems to be getting derailed as in the case of most of the schemes in the government sector.

Sanofi-Aventis Wants To Double Market Share Through Rural Plan

December 11, 2009, Mint

<http://www.livemint.com/2009/12/10210254/SanofiAventis-wants-to-double.html>

French drug multinational Sanofi-Aventis SA is formulating a large-scale rural business strategy in India aimed at doubling its share to at least 4% of the Rs35,000 crore local drug market by 2015. The new initiative, which will also see a rebirth of its erstwhile Hoechst identity in the country, will be a three-pronged strategy involving education and training for rural doctors, facilitating diagnostics and other value-added services by partnering with clinicians, diagnostics and other infrastructure companies and non-profit organizations, besides improving access to medicines by launching low-cost generic drugs.

Industry Voices Concern over 'Unbinding' Guidelines Attached to Spurious Drugs Bill

August 20, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=51269§ionid=19>

Even as the Union Health Ministry has notified the Drugs and Cosmetics (Amendment) Bill which makes manufacturing and marketing of spurious drugs a cognizable and non-bailable offence, a section of pharma industry is upset over the fact that the guidelines attached to it is not binding on the authorities.

Bilcare Develops Scanner to Help Identify Fake Drugs

February 9, 2009, Financial Chronicle

The Pune-based Rs 650-crore Bilcare, a global player in pharmaceutical packaging and allied services, has developed an anti-counterfeit drug scanner device to combat the growing menace of fake drugs. "The pilot project is about using nano technology-based fingerprint solution to differentiate a fake drug from a genuine one," Vineet Mehrotra, vice president, finance, Bilcare, told Financial Chronicle. This technology will help in judging quality drugs through tamper-proof packaging and labels.

Unethical Pharma Promotion

January 26, 2009, DNA

Representatives of drug companies have approached the pharmaceutical secretary under the ministry of chemical and fertilisers, promising to come up with a voluntary code of ethics in the promotion of pharma products to doctors. This is a cloud with a silver lining for consumer associations and ethical doctors' bodies.

It's Time Pharma Inc Stopped Bribing Doctors to Prescribe Their Drugs

January 22, 2009, DNA

After turning a blind eye for decades, Indian drug regulators are finally trying to break the unholy nexus between pharmaceutical companies and medical practitioners in adopting unethical practices to promote drugs. The space has been getting murkier with each passing day as companies struggle to be ahead in the prescriptions race while doctors, ever pampered with goodies, extend their greed by the hour.

Animal Health

Swati Spentose To Enter Into Equine Wellness, Healthcare Segment With 10 Products

December 16, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53126§ionid=23>

The Mumbai-based Swati Spentose Pvt Ltd (SSPL), a wholly-owned subsidiary of the contract research and manufacturing firm Euresian Group, is all set to launch a range of specialised equine healthcare products for race horses in the beginning of 2010 under its veterinary division.

Bayer Animal Health To Expand Operations In India

December 11, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53046§ionid=23>

Bayer HealthCare's Animal Health division is set to grow its business in India by expanding its current portfolio and revamping its sales and distribution network. The company will increase its sales force substantially in the coming months by adding more than 100 people and developing a country-wide distribution network in the farm animal segment that covers all key agricultural regions.

Biotechnology

5-In-1 Booster Shot for Immunisation

July 20, 2009, The Economic Times

<http://economictimes.indiatimes.com/Healthcare/5-in-1-booster-shot-for-immunisation/articleshow/4796681.cms>

The government is expected to upgrade the existing three-in-one vaccine for infants to a five-in-one by the end of the year under the national immunisation programme. While the proposal has been recommended by the Expenditure Finance Committee, the government is negotiating with the World bank for additional funds to expand the programme, an official with the health ministry said.

Medical Diagnostics / Devices

Philips India To Assist Hospitals And Clinics In Establishing 130 Sleep Labs In India By End 2010

December 16, 2009, Pharmabiz

<http://www.pharmabiz.com/article/detnews.asp?articleid=53145§ionid=>

Philips Electronics India Limited (PEIL) will assist hospitals and clinics across Mumbai and Delhi in establishing 30 new sleep labs by the end of 2009. These sleep labs will help physicians accurately diagnose sleep disorders. The company will provide technology, facilities and training. The objective is to establish 130 sleep labs across India by the end of 2010 in partnership with healthcare institutions, doubling the total number of sleep labs available across the country.

GE Healthcare Launches FTA DMPK Cards For Storage Of Study Samples

December 14, 2009, Pharmabiz, Chalfont St Giles, UK

<http://www.pharmabiz.com/article/detnews.asp?articleid=53102§ionid=4>

GE Healthcare announced the launch of FTA DMPK cards for the collection and storage of blood samples for use in pharmacokinetic and toxicokinetic (PK/TK) studies. This methodology stores the samples as dried blood spots (DBS) and has a broad applicability across the entire drug discovery and development process, from research through to preclinical and clinical trials.

PMO Backs Health Ministry On Control Of Medical Devices Sector

November 30, 2009, Financial Express

<http://www.financialexpress.com/news/PMO-backs-health-ministry-on-control-of-medical-devices-sector/547770/>

The confusion prevailing over which ministry would finally get to regulate the Rs10,000-crore medical devices industry seems to be clearing up with the Prime Minister's Office deciding to intervene. The office asked the department of science and technology and ministry of health and family welfare to reconcile their differences on the issue.

Diagnostic Major Quiagen Plans Expansion In India

November 2009, Yes Pharmalife

Quiagen, the German molecular diagnostic major, is planning to expand its Indian operations in a big way. The company is considering a manufacturing facility in the country by 2010 to cater to the growth opportunity in the cervical cancer detection segment. Over 70,000 people die of cervical cancer in India each year. The ones who are diagnosed every year will come to about 150,000. Quiagen has an ongoing partnership programme with PATH, an international health NGO being funded by the Bill and Melinda Gates Foundation, to undertake demonstrative screening in select Indian towns. Quiagen's plan for a manufacturing facility in India is also linked to the growing need for diagnostic services within the country.

New Appointments

Mr. Binay Kumar Singh Appointed as Director, DoP

Mr. Binay Kumar Singh (Indian Telecom Services) has been appointed as Director, Department of Pharmaceuticals. He replaces Mr. Paresh Johri whose tenure ended on November 27, 2009. He is yet to take charge.

Mr. Om Prakash, New Member Secretary, NPPA

The Appointment Committee of the Cabinet has approved the proposal to appoint Mr. Om Prakash, CSS (77) as Member Secretary, in the National Pharmaceutical Pricing Authority (Joint Secretary level) under the Department of Pharmaceuticals. He has worked with the Ministries of Environment & Forests, Department of Industrial Policy & Promotion and Finance. Before his appointment as MS, NPPA, he was holding the post of Director, Department of Expenditure, Ministry of Finance.

Ms Aparna Sharma, Has Been Given Additional Director, Department of Health, Ministry of Health & Family Welfare,

Ms Aparna Sharma, Director, Department of Health, Ministry of Health & Family Welfare, has been given additional charge of Food and Drugs, which was earlier handled by Mr. A M Prasad, Director, who has been promoted as Joint Secretary. She will continue holding this additional portfolio till the time a full time Director is appointed.