



**News Updates: February 22- 24, 2014**

**Patents/Compulsory Licensing/Intellectual Property**

**Publication: The Times Of India**

**Edition: National**

**Date: February 23, 2014**

**Headline: [India hardens trade stance against US, wants disputes to go to WTO](#)**

**Synopsis:** The government is set to ask all its officials to stay away from any interaction with a delegation from the US International Trade Commission (USITC), a quasi-judicial agency, probing the impact of India's trade and investment regime on the American economy in what is seen as the latest sore point in economic ties between the two countries. The move follows a meeting in the ministry of external affairs on Friday and comes after the government took the view that its laws and policies are its sovereign functions, while the US actions are unilateral. "The hearings relate to our patents regime and industrial and trade policies, which are governed by multilateral agreements, of which the US is also a signatory. So, if there is a dispute, it has to be settled at a multilateral forum like the WTO. No country can apply its own law extra-territorially," said an official privy to the discussions.

Similar report in-

**The Indian Express- [Govt officials decline to meet USITC members](#)**

**Publication: Business Standard**

**Edition: National**

**Date: February 24, 2014**

**Headline: [India set to take on US over probe into IPR laws](#)**

**Synopsis:** The government appears to have decided not to grant visas to the US officials planning to visit India and investigate the country's trade and industrial practices, especially related to laws governing intellectual property rights (IPR). This was decided at a meeting attended by representatives of the external affairs, commerce & industry and finance ministries, besides the Planning Commission.

**Publication: The Times Of India**

**Edition: National**

**Date: February 24, 2014**

**Headline: [India-US ties are under stress again, this time over trade and investment](#)**

**Synopsis:** India-US ties are under stress again — this time over trade and investment — according to the government. With calls in the US for designating India a priority foreign country (PFC), the worst downgrading of status by the US trade representative for inability to protect IPRs, the government is accusing US authorities of intimidating the Union health ministry over the issue of compulsory licences — which allow local firms to manufacture patented drugs - and simultaneously preventing other developing countries from acting against evergreening of drug patents.

**Drug Regulatory/ Access**

**Publication: The Times Of India**

**Edition: National**

**Date: February 24, 2014**

**Headline: [Cheaper drug-eluting stents save 100 lives](#)**

**Synopsis:** The public health department's crucial decision to negotiate with leading firms to halve the price of drug-eluting stents has helped well over 100 poor patients in just a fortnight. The cheaper stents were launched on February 5. Public health minister Suresh Shetty had taken a lead in launching the Rajiv Gandhi health scheme for below poverty line individuals on August 16, 2012. A few months after the project was made operational, Shetty found that they had not benefitted in real terms due to the prohibitive cost of such stents. The scheme had a provision for Rs 18,000 to Rs 20,000 for angioplasty. Quality stents were not available for Rs 20,000 though, as their prices ranged from Rs 45,000 to Rs 50,000.

**Publication: The Hindu**

**Edition: National**

**Date: February 23, 2014**

**Headline: [For an affordable healthcare model](#)**

**Synopsis:** The story of women suffering from cancer in India is remarkably similar, and the lack of progress in making healthcare fair and equitable has only worsened the lot of womenfolk, who have traditionally occupied the lower perches on the social totem. Technological progress in communication and transportation has reduced barriers to international trade and revolutionised modern life; though healthcare remains a largely domestic pursuit.

#### FDA

**Publication: Business Standard**

**Edition: National**

**Date: February 23, 2014**

**Headline: [Not targeting Ranbaxy or Indian companies: US FDA](#)**

**Synopsis:** The US is not targeting Ranbaxy or any other Indian company but only ensuring quality control and compliance with norms to see drugs sold in the country are safe for patients, Margaret Hamburg, commissioner, US Food and Drug Administration (FDA), told the international media while briefing on her recent India visit this morning.

Emphasising that increased inspections in India is the fallout of the fact that India is a large supplier of medicines and food products to the world's largest pharmaceutical market, the FDA chief said she was also set to visit other countries soon.

Similar report in-

**The Hindu Business Line- [FDA chief says US not targeting Indian drug companies](#)**

**Publication: The Financial Chronicle**

**Edition: Delhi**

**Date: February 24, 2014**

**Headline: [US safety lens on 80 generic drugs \(link unavailable, scan attached\)](#)**

**Synopsis:** Generic drugs that make up almost 80 per cent of US prescriptions are being tested in the first widespread safety and quality evaluation run by the food and drug administration.

**Publication: The Hindustan Times**

**Edition: Delhi**

**Date: February 23, 2014**

**Headline: [US browbeating Indian pharma firms: Azad](#)**

**Synopsis:** Union health minister Ghulam Nabi Azad has come down heavily on the US Food and Drug Administration (FDA), saying the United States, fearing the challenge posed by Indian drug manufacturers, is trying to impose its own will on the local pharmaceuticals' industry and India would strongly retaliate to this at international forums. His statement came a day after FDA commissioner Margaret Hambrug said the

US was not targeting Indian pharma major Ranbaxy, whose drugs were recently banned from being imported into the US, or other Indian companies, but only ensuring quality control and compliance with FDA norms. "India is exporting drugs to 212 countries, which includes many developed countries. US companies are unable to accept this fact as they are losing out on competition, thus resorting to highhandedness towards Indian pharma companies," said Azad, who was here to lay the foundation stone of the Rs. 150-crore super-specialty cell of Rajindra Medical College and Hospital.

**Publication: Deccan Herald**

**Edition: National**

**Date: February 23, 2014**

**Headline: [Stamping out spurious drugs](#)**

**Synopsis:** On November 25, 2013, Wockhardt group CEO Habil Khorakiwala received a letter from the US Food and Drugs Administration flagging several shortcomings of the company's two drugs manufacturing units at Chikalhana and Waluj, both in Aurangabad district of Maharashtra. The two units were inspected by an FDA team simultaneously between July 22 and 31, 2013, to prepare the warning letter on the deficiencies of the plants that manufacture drugs, which Wockhardt exports to the USA. The company is expected to comply with the FDA norms to remain in the US market.

**Publication: Deccan Herald**

**Edition: National**

**Date: February 23, 2014**

**Headline: [Testing, quality norms differ](#)**

**Synopsis:** The quality issues arise because of various factors. It could be storage conditions in the importing country, approved by local FDA and/or cold storage provided in the supply chain, etc. The methods of testing, adopted by the exporters and the regulatory agency as standard may differ and become a factor. It is also noted that in cases where regulated markets are involved, most of the observations relate to data integrity. India has over 1300 World Health Organisation GMP (Good Manufacturing Practice) certified manufacturing units. This endorses India's pharmaceutical chemistry skills as of the same order as seen in developed countries and does not give room for any doubt on its capabilities.

#### FDI

**Publication: The Indian Express**

**Edition: National**

**Date: February 24, 2014**

**Headline: [Govt okays 12 FDI proposals worth over Rs 2,609 crore](#)**

**Synopsis:** The government today said it has approved 12 FDI proposals, including that of pharma firm Claris Otsuka, totalling over Rs 2,609 crore. The Foreign Investment Promotion Board (FIPB) also cleared the proposal of Decathlon Sports India's proposal for induction of foreign equity worth Rs 700 crore to engage in single brand retail. "Based on the recommendations of FIPB in its meeting held on February 13, the government has approved 12 proposals of foreign direct investment amounting to Rs 2,609.27 crore approximately," the finance ministry said in a statement. The biggest proposal that was cleared was Ahmedabad-based Claris Otsuka Ltd's plan to hive off its infusions business into a new JV with FDI worth Rs 1,050 crore. The board also cleared Mumbai-based Glynwed Pipe Systems's proposal to receive foreign investment worth Rs 800 crore for making downstream investment.

#### Union Health Minister

**Publication: The Times Of India**

**Edition: National**

**Date: February 23, 2014**

**Headline: [MCI babu who blocked Desai comeback removed](#)**

**Synopsis:** Former health secretaries and several other eminent persons have written to the Prime Minister expressing concern over the abrupt transfer of Keshav Desiraju from the post of union health secretary in violation of the Supreme Court's order to ensure a two-year tenure to all senior officers in the interests of good governance. The letter alleged that Desiraju was transferred for opposing the re-entry of corruption-tainted former Medical Council of India president Dr Ketan Desai into MCI.

### General Industry

**Publication:** The Times Of India

**Edition:** National

**Date:** February 24, 2014

**Headline:** [MCI puts doc bodies out of ethics code](#)

**Synopsis:** In a bizarre move, the Medical Council of India, the apex regulatory body of doctors and the medical practice in the country, has decided to shrink its own jurisdiction. It has reinterpreted its code of ethics regulations as being applicable only to individual doctors and not doctors associations. Clause 6.8 of the Code of Medical Ethics Regulation 2002 states that it pertains to Code of conduct for doctors and professional associations of doctors in their relationship with pharmaceutical and allied health sector industry. The executive committee of the new medical council in its meeting on February 18 decided that the term association of doctors be deleted. It added that any action taken by the MCI against any association of doctors by virtue of clause 6.8 shall be nullified.

**Publication:** Deccan Herald

**Edition:** National

**Date:** February 23, 2014

**Headline:** ['MNCs and lobbyists campaign against Indian drugs industry'](#)

**Synopsis:** A Fulbright scholar and a post-doctoral fellow at Harvard School of Public Health, Shaktivel Selvaraj is an adjunct assistant professor at the Public Health Foundation of India. He was a Health Economist at the National Commission on Macroeconomics and Health in 2004-05. Engaged in teaching and research at PFHI, Selvaraj spoke to Deccan Herald's Kalyan Ray on sub-standard medicine.

**Publication:** The Times Of India

**Edition:** National

**Date:** February 24, 2014

**Headline:** [India to adopt global financial standards from April 2015](#)

**Synopsis:** The corporate affairs ministry is likely to notify within a month all sections and rules of the new Companies Act and start immediately thereafter the process of converging Indian accounting standards with the International Financial Reporting Standards (IFRS), which have to be implemented from April 2015 for companies with a net worth of more than Rs 1,000 crore.

**Publication:** The Hindu

**Edition:** National

**Date:** February 23, 2014

**Headline:** [Centre issues new guidelines to check malpractice in stem cell treatment](#)

**Synopsis:** Any use of stem cell in patients will, from now on be considered research and not therapy, according to the fresh National Guidelines on Stem Cell Research issued by the government. Stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offer it as therapy, the guidelines issued on Saturday said. "In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial shall be considered malpractice. It is hoped that this clear definition will serve to curb the malpractice of stem cell 'therapy' being offered as a new tool for curing untreatable diseases," according to the Indian Council of Medical Research and

the Department of Biotechnology.

Similar report in-

**The Hindu-** [ICMR redefines stem cell use to curb malpractice](#)

**Publication: The Times Of India**

**Edition: National**

**Date: February 24, 2014**

**Headline: [Three PSUs producing vaccines at snail's pace](#)**

**Synopsis:** The three public sector units producing primary vaccines might have resumed operation, but they are hardly making any contribution to the vaccines procured for the Universal Immunisation Programme (UIP). In 2012-13, the PSUs' share in UIP procurement worth Rs 887 crore was just 2.4% and in 2013-14, it was just 3.6%. According to the health ministry's reply to an RTI application in January 2014, the PSUs accounted for well over a quarter of the money spent on vaccine procurement for UIP before being shut down in 2008. They produced almost the entire requirement of BCG, DTP and TT vaccines in the country.

**Publication: The Economic Times**

**Edition: National**

**Date: February 24, 2014**

**Headline: [Devi Shetty opens low-cost healthcare venture in Cayman Islands outside US regulatory reach](#)**

**Synopsis:** Devi Shetty, the Indian cardiac surgeon renowned for making cutting-edge medical care affordable to the masses, is set to begin his overseas innings this week. Health City Cayman Islands will start receiving patients this week as the first leg of Shetty's Caribbean venture becomes operational with a 104-bed multispecialty tertiary hospital.

**Publication: Business Standard**

**Edition: National**

**Date: February 24, 2014**

**Headline: [Online portal offers social media networking tools to pharma SMEs](#)**

**Synopsis:** Social media networking seems to be picking up even among small and medium enterprises pharmaceutical firms. An Ahmedabad-based portal pharmaneed.com has thought of offering social networking platform for its registered users. City-based mid-sized pharma firm West Coast Pharmaceuticals Ltd, recently launched a website pharmaneed.com as a solution for pharma companies and professionals to network amongst themselves. Parth Patel, chief executive officer of pharmaneed.com said that a special feature in the website is the social networking tool. "Pharmaceutical professionals can get their own Template Personal Website or webpage on pharma need through which they can blog, submit articles, advertise and promote their products," Patel added.

**Publication: The Times Of India**

**Edition: Bangalore**

**Date: February 23, 2014**

**Headline: Endorsement strictly prohibited by MCI (link unavailable, scan attached)**

**Synopsis:** In effect, the MCI said that the action it took against the India Medical Association (IMA) for endorsing products of Pepsi and Dabur in exchanges for crores of rupees or against the India Academy of Pediatrics for accepting funding from pharmaceutical companies will no longer be valid.

**Publication: The Hindu Business Line**

**Edition: National**

**Date: February 23, 2014**

**Headline:** [Fantastic pharma](#)

**Synopsis:** Fears of blockbuster drug patent expiry, generics competition and price erosion aside, mutual funds investing in US pharma stocks have outperformed the rest of the global industry in the past one year. These funds have not only bettered the MSCI Global Pharma Index, but have also raced ahead of their Indian counterparts. While the MSCI Global Pharma Index managed to gain 24 per cent during this period, US pharma-focused funds saw their NAVs rise between 34 per cent and 71 per cent. This is much higher than the 29-34 per cent gains clocked by India-based mutual fund schemes investing in pharma and healthcare stocks listed on Indian bourses during the same period.

**Publication:** The Times Of India

**Edition:** National

**Date:** February 24, 2014

**Headline:** [Corporate Social Responsibility rules soon, will include 10 major areas](#)

**Synopsis:** The government has identified 10 major areas including education, gender equality, environment, national heritage and the Prime minister Relief fund where India Inc can spend to claim credit for the mandatory 2% Corporate Social Responsibility (CSR) expenditure. Under the new Companies Act, mid and large companies have to spend 2% of their three-year annual average net profit on CSR activities. The government expects a significant step up in spending on CSR projects by companies.

**Publication:** The Times Of India

**Edition:** National

**Date:** February 23, 2014

**Headline:** [MR Rajagopal: The man who spearheaded efforts to improve access to morphine](#)

**Synopsis:** The Lok Sabha that just came to the end of its five-year term last week will go down in history as one of the least productive. But they got one thing right. The amendment of the controversial Narcotic Drugs and Psychotropic Substances (NDPS) Act marked the culmination of years of efforts by MR Rajagopal and others to ease the needless suffering of cancer and HIV patients, many of them terminally ill, by improving access to morphine-based medicines, which are among the cheapest and most effective treatments for chronic pain.