News Updates: January 25-27, 2014

Compulsory License/Patents

Publication: The Times of India
Edition: Online
Date: January 25, 2014
Journalist: Rema Nagarajan
Headline: South African PR leak exposes how big pharma subverts govt policy

Synopsis: Pharmaceutical industry's machinations to interfere in a country's policymaking to protect their interests have been exposed yet again, this time in South Africa.
The leaked plans of a public relations firm hired by the American and South African pharmaceutical multinational companies revealed how pharma planned to launch a campaign to discredit and subvert the proposed reform of South Africa's patent laws.

Similar report in

PM LiVE - **Pharma slammed for undermining South African IP reforms**

Publication: The Times of India
Edition: Online
Date: January 25, 2014
Headline: Developed cancer drug for 'western patients' who could afford, not 'for Indians': Bayer's CEO

Synopsis: Global medical charity Medecins Sans Frontieres slammed on Friday a statement by Bayer's chief executive that the giant German firm only developed its cancer drug Nexavar for people who could afford the medicine, not "for Indians".
India's controller general of patents angered Bayer in March 2012 when he authorized a local drugmaker to produce a generic copy of Nexavar, saying the German company charged a price that was too costly for most Indians.

Similar reports in

Deccan Chronicle- Drug is not for Indians-Bayer (Scan attached. No link available)
Asian Age – Cancer drug Nexavar not for Indians (Scan attached. No link available)
Spicy IP - Update: Nexavar only for western patients
The Source - Big Pharma CEO: Cancer Drug is Only For Westerners Who Can Afford It

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Publication: The Times of India
Edition: Online
Date: January 27, 2014
Headline: Patented drugs face price caps

Synopsis: After sitting on it for years, the government is finally initiating steps to regulate the price of patented medicines and medical devices, a move that may provide relief to patients suffering from life-threatening diseases. A committee comprising representatives from the health ministry, pharmaceuticals department, the drug price regulator and department of industrial policy and promotion is scheduled to meet early next month to discuss at least three options, said an official familiar with the development.

Drug Pricing/Pricing Policy

Publication: The Financial Express
Edition: Online
Date: January 27, 2014
Headline: New medical marvel: Firms have different prices for same drug

Synopsis: Leading pharmaceutical companies are selling the same drug in the same dosage under different brand names and at widely different prices, revealed a recent data collection drive by the National Pharmaceutical Pricing Authority (NPPA). This fragments the market and creates “artificial competition” while retaining (and entrenching) bigger market shares with a few players, undermining real competition, reckons the regulator.

Publication: Pharmabiz
Edition: Online
Date: January 27, 2014
Headline: Industry wants health ministry to take action against traders who disrupt supply & distribution of essential medicines

Synopsis: Faced with strong resistance from the chemists and druggists associations over their reduction of trade margin after the implementation of the new DPCO, the pharma industry has approached the health ministry to intervene by directing the State Licensing Authorities (SLAs) to take immediate action against those who disrupt availability of essential medicines to patients.

Drug regulation/FDA

Publication: The Economic Times
Edition: Online
Date: January 27, 2014
Headline: Doctor's body to seek regulator's view on quality of Ranbaxy drugs

Synopsis: Indian Medical Association, which has nearly 78,000 doctors as members from across the country, would be seeking clarity from the Indian drug regulator on the quality of Ranbaxy Labs drugs, its general secretary Narendra Saini told ET. "We would write to the government on Monday to first seek a categorical response on the quality and safety of Ranbaxy's drugs. Our primary concern is to ensuring that the drugs are safe and efficacious," said Saini. The medical fraternity would also await clarity from the drug regulator on the exact nature of problems which is leading to repeated reprimand for the company from the US drug regulator. For doctors, the fundamental parameters of quality would mean tests of bio-equivalence, the amount of active pharma ingredient (API) in the drug, granularity and manufacturing and expiry dates, he added.

Publication: Business Standard
Edition: Online
Date: January 26, 2014
Headline: Flies in Ranbaxy's Toansa plant's sample storage room: FDA

Synopsis: Presence of flies in sample storage room, un-calibrated instruments in laboratory and non-adherence to sample analysis procedure were among the lapses found in Ranbaxy's Toansa plant that led to US health regulator FDA banning imports of drugs made at the facility. According to the report released by the US Food and Drug Administration (FDA) inspection teams, as many as eight lapses were identified, including "Too Numerous To Count (TNTC) flies" in sample storage room, inadequate control over samples and non-adherence of procedures in sample analysis, during their visit to the Toansa, Punjab facility.

Similar report in

First Post - Flies in sample storage room: What FDA report on Ranbaxy’s Toansa plant said

Publication: The Financial Express
Edition: National
Date: January 25, 2014
Headline: Editorial: Restoring Ranbaxy

Synopsis: Ranbaxy was dealt another blow by the USFDA with its Toansa unit prohibited from manufacturing and distributing Active Pharmaceutical Ingredients (API) for sales of finished drugs and formulations in the US. Given the Toansa facility makes 75% of Ranbaxy's requirements of APIs, the US regulator's action will hurt the firm's sales of formulations and finished drugs to the US estimated at roughly $400 million per annum. While Ranbaxy should be able to source APIs to supply Ohm Laboratories—its US facility— that clearly cannot be a permanent solution and Daiichi will need to work hard to restore good practices. While Ranbaxy has probably been at the receiving end of the US regulator more than any other Indian drug firm—Wockhardt has received two import alerts for its Waluj and Chikalthana facilities and also a rap from the UK drug regulator—the ratio of import alerts to the total number of USFDA-approved sites for all Indian firms is 9%, just slightly higher than China's 8%. Be that as it may, Indian firms must realise that they if they are to cash in on the growing overseas market for generics—every other month, there's a drug going off-patent—they need to stay on the right side of the regulator. Else, even their relatively share of the US generics market—estimated at roughly 10-12%—will stay just there.

Publication: Mint
Edition: Online
Date: January 26, 2014
Headline: FDA shadow on Ranbaxy stock lengthens

Synopsis: Ranbaxy Laboratories Ltd's almost suicidal behaviour must be a great mystery to its shareholders. Why would a company that is in the cross hairs of the American drug regulator allow any of its US-focused plants to slip up on the quality front? With the import alert issued to the company's Toansa plant, it is the third instance in India where the US Food and Drug Administration (FDA) has found Ranbaxy's plants to be non-compliant with its regulations.

Publication: The Economic Times
Edition: Online
Date: January 27, 2014
Opinion Article- Dinesh S Thakur
Headline: Are Indian pharma companies overdosing on lethal drug of fraud?

Synopsis: We now know that the behaviour that led Ranbaxy to sign the "unprecedented" consent decree in 2012 with the US Food & Drug Administration (FDA) was not limited to just two manufacturing sites. In 2013, the US regulator brought its Mohali facility and last week its Toansa API facility under the consent decree.
Clearly, public representations made by the company in the past citing investments in upgrading facilities and other corrective actions don't seem to have affected its operating culture. The recent FDA observations on the company's Toansa facility remind me of similar instances when I was asked to investigate the extent of data fraud back in 2005.

Publication: The Financial Express
Edition: National
Date: January 25, 2014
Headline: US import alert may hurt Ranbaxy Laboratories, says Macquarie

Synopsis: FDA has overnight put an import alert on Ranbaxy Laboratories Ltd's API facility at Toansa. According to FDA, its inspection of the Toansa facility in January identified current good manufacturing practice (CGMP) violations. As a result, Ranbaxy is now prohibited from manufacturing API for FDA-regulated drugs at the Toansa facility and from introducing API from that facility, until compliance with CGMP.

Similar reports in

The Hindu - FDA bans Ranbaxy's fourth plant in India
Indian Express - USFDA stops all Ranbaxy drugs, fourth plant banned

Clinical Trials

Publication: Business Standard
Edition: Mumbai/Ahmedabad
Date: January 25, 2014
Headline: Clinical trials and tribulations at home push companies abroad

Synopsis: As securing approvals for clinical trials becomes time-consuming under the New Drug Advisory Committee (NDAC), pharmaceutical companies are increasingly considering shifting clinical trials abroad to expedite the process. The Indian Pharmaceutical Alliance (IPA), which represents leading domestic pharma companies, expressed concern over the slowdown in decisions related to trials in India.

General Industry News

Publication: The Times Of India
Edition: Online
Date: January 26, 2014
Headline: For Gates, corruption isn't A BIG BILL TO PAY

Synopsis: Bill Gates made his reputation – and his billions – as the archetypal ruthless businessman. He then made another reputation, by giving away his billions to charitable causes through his foundation. But his charitable work has also had its share of detractors. His foundation was one of the primary funders of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), an organization that has been accused of misuse of funds – where charitable monies were diverted to pay bribes to corrupt officials from Cambodia to Uganda.

Publication: Mint
Edition: National
Date: January 25, 2014
Headline: Indian pharma firms can't be judged by US standards: G.N. Singh

Synopsis: Hours after the US drug regulator banned imports from a fourth factory of Ranbaxy Laboratories Ltd, the drug controller general of India G.N. Singh chose to back the Indian company, saying the current situation may not require withdrawal of its medicines from the local market.

Publication: Mint
Edition: National
Date: January 25, 2014
Headline: Foot Notes | Wheeling through

Synopsis: A former international president for the medical relief organization Médecins Sans Frontières (MSF), Unni Karunakara, 50 is biking across India to raise awareness and funds for health-related projects in 70 countries

Publication: The Hindu Business Line
Edition: Online
Date: January 26, 2014
Headline: Our propensity for jugaad comes in the way of developing quality'

Synopsis: The year has barely begun and Ranbaxy is already weighed down by bad news: following a regulatory observation against its plant in Toansa, Punjab, the US last week imposed a ban on imports from this facility citing manufacturing violation.

Publication: The Hindu Business Line
Edition: Online
Date: January 26, 2014
Headline: Biocon to take breast cancer drug to emerging markets

Synopsis: Bangalore-based biotechnology company Biocon Ltd is planning to take its recently launched breast cancer drug to other emerging markets. CANMAb, jointly developed with US-based drug-maker Mylan Inc, will be launched in Latin America, West Asia and North Africa, where breast cancer cases are on the rise.

Publication: Business Standard
Edition: Online
Date: January 27, 2014
Headline: Congress set to promise universal healthcare coverage in its election manifesto

Synopsis: The Congress is set to promise in its election manifesto universal healthcare coverage, including free medicines at government hospitals and health centres. Although improving healthcare cover has been on the Congress-led UPA's agenda for some time, progress on this front has been slow. The Congress manifesto will focus on ensuring universal healthcare coverage through enabling legislation and measures such as distribution of free medicines through government hospitals and health centres.

Publication: Business Standard
Edition: Online
Date: January 27, 2014
Headline: We'd like fast movement on GST, on opening the economy more: Hiromasa Yonekura

Synopsis: Hiromasa Yonekura, chairman, Keidanren (Japan Business Federation) says Japanese industry would like further liberation of the economy and fast movement on the pending Goods and Services Tax. Also the chairman of Sumitomo Chemical, he talks to Nayanima Basu on current trade issues.

Publication: Bureaucracy Today
Edition: Online
Date: January 24, 2014
Headline: Rajiv Mehrishi appointed as Additional Secretary in Ministry of Health and Family Welfare

Synopsis: According to the Bureaucracy Today sources, Rajiv Mehrishi, IAS 1978 batch, Rajasthan cadre, is appointed as Additional Secretary in Ministry of Health and Family Welfare.