



News Updates: April 4, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Financial Express

Edition: National

Date: April 4, 2014

Opinion piece: Biswajit Dhar, director general, Research and Information System for Developing Countries (RIS), New Delhi

Headline: [Patently partial](#)

Synopsis: The past several weeks have seen an orchestrated move by the industry lobbies in the US to challenge India's intellectual property (IP) laws (read 'patent laws'). The trigger for the orchestration is the annual review of the IP laws of its partner countries that the US Trade Representative (USTR) is conducting. These reviews began in 1989, after the enactment of the Omnibus Foreign Trade and Competitiveness Act of 1988. 'Special 301' provisions of this Act authorises the USTR to annually identify 'priority foreign countries' whose failure to protect IP is the most onerous and has the greatest adverse impact on US products and which are not making significant progress in providing adequate and effective protection of IP rights (IPR). The USTR has the rights to retaliate against any country if it "refused to reform its practices satisfactorily".

Clinical Trials

Publication: The Indian Express

Edition: National

Date: April 4, 2014

Headline: [Permissions for clinical trials delayed, bio pharma firms plan to leave country](#)

Synopsis: With more than a year's delay in getting permission for starting Phase 3 of the rotavirus vaccine trial among 7,000 infants, Serum Institute of India is in no mood to ask for the government's approval for testing other vaccines in clinical trials "Be it dengue or meningitis vaccine, we are now moving out to other countries in Asia," said Adar Poonawalla, executive director at Serum Institute of India. At Lupin Pharmaceuticals' research park in Pune the scene is similar, with scientists fed up due to delay in conducting trials and have already moved out to other countries.

Drug Pricing

Publication: Business Standard

Edition: National

Date: April 4, 2014

Headline: [Medicines to cost more](#)

Synopsis: The next time you go to your chemist, you are likely to notice an increase in your medicine bill. In keeping with the new pharmaceutical pricing policy, the regulator has allowed companies to raise maximum retail price (MRP) of essential medicines by 6.32 per cent, while all other product prices can go up by 10 per cent annually.

Website: Pharmabiz

Edition: National

Date: April 4, 2014

Headline: [NPPA revises prices of 33 more formulations under new DPCO norms](#)

Synopsis: Continuing further its process of revising the prices of essential medicines in line with the new

Drug Price Control Order (DPCO), the National Pharmaceutical Pricing Authority (NPPA) has fixed the prices of 33 more formulation packs. With this, the NPPA has already covered nearly 440 formulations as per the provisions of the new pricing policy and the DPCO which mandated the revision of prices based on the simple average of the prices of all brands of the drugs having a market share of more than one percent. The national list of essential medicines lists 348 bulk drugs, which are sold as 650 formulations, has been brought under the price control.

FDA

Publication: The Economic Times

Edition: National

Date: April 4, 2014

Headline: [After Ranbaxy and Sun Pharma, US FDA bans imports from Canadian drugmaker Apotex's India plant](#)

Synopsis: The US Food and Drug Administration banned imports from Canadian drugmaker Apotex Inc's manufacturing plant in India for not complying with quality standards, the latest in a series of sanctions against medicines produced in India. Drugs made at the plant, based in the southern Indian city of Bangalore, will be detained without physical examination because the factory did not meet the FDA's good manufacturing practices, the agency said on its website on Wednesday.

Similar reports in-

Mint- [FDA bans imports from canadian drugmaker Apotex's India plant](#)

The Financial Express- [Canadian drug firm Apotex Inc's Indian manufacturing unit gets import alert](#)

General Industry

Publication: The Hindu Business Line

Edition: National

Date: April 4, 2014

Headline: [Novartis files patent infringement suit against Biocon](#)

Synopsis: Swiss drugmaker Novartis has locked horns with Biocon over the alleged infringement of the patent on its diabetes drug Galvus, which reportedly had global sales of over \$1.2 billion last year. The legal action seeks to prevent Biocon from launching a similar version of the drug. It comes a year after a high-profile patent case involving Novartis' blood cancer drug Glivec ended.

Similar reports in-

The Economic Times- [Novartis files patent suit against Biocon over Galvus](#)

Mint- [Biocon in patent suit with Novartis over Galvus diabetes drug](#)

Business Standard- [Novartis sues Biocon for patent breach](#)

The Times of India- [Novartis files patent suit against Biocon](#)

The Financial Express- [Novartis files patent suit against Biocon over diabetes drug Galvus](#)

The Indian Express- [Novartis files patent suit against Biocon over diabetes drug](#)

Business Today- [Novartis patent suit: Biocon denies any court injunction](#)

Reuters- [Drugmaker Novartis files patent suit against Biocon over Galvus](#)

Publication: The Hindu Business Line

Edition: National

Date: April 4, 2014

Headline: [Novartis top Japan executives quit over cancer drug scandal](#)

Synopsis: Swiss pharmaceutical giant Novartis said today it was replacing the top executives at its Japanese unit over allegations the division hid serious potential side effects of leukaemia treatments from regulators. The company also said it was freezing funding for clinical trials in the country in the wake of the scandal, which David Epstein, head of the firm's pharmaceutical division, branded "unacceptable and a clear

violation of our code of conduct“.

Publication: The Financial Express

Edition: National

Date: April 4, 2014

Headline: [Not everyone happy with Indian rupee recovery; IT, pharma suffer](#)

Synopsis: Market observers feel pharma companies could take a hit on their margins if rupee strengthens further. “In FY14, 50% of the margin expansion was due to a sharp depreciation of the rupee. If the rupee appreciates meaningfully, earnings will see a correction as most companies are unhedged. However, companies with better product pipeline and leverage opportunities would be able to absorb the cross-currency headwinds,” said an analyst with a leading domestic brokerage. “Sharp appreciation of rupee against major currencies could add to cost pressure and result in lower profitability,” UBS analysts added in a report.