



News Updates : March 4, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Indian Express

Edition: National

Date: March 4, 2014

Opinion piece: Ritu Kamal, medical technology professional focusing on medical technology innovation for emerging markets and a former Stanford-India Biodesign Fellow

Headline: [Outside the patent monopolies](#)

Synopsis: Recently, there were rumours that the United States Trade Representative (USTR) was getting ready to announce “trade enforcement actions” or sanctions against India over its intellectual property rights regime. The Obama administration has been under pressure from the US Chamber of Commerce and lobby groups, like the Pharmaceutical Research and Manufacturers of America, to take a tough stance against Indian rulings that have vetoed several multinational pharmaceutical company patents. The lobbyists are pushing for India to be classified as a “priority foreign country”, a label associated with the worst offenders of patent law. The row blew over, but not before the USTR had filed a case at the World Trade Organisation (WTO) against India’s domestic content requirements for its solar programme.

Publication: The Financial Express

Edition: National

Date: March 4, 2014

Headline: [Is the Indian patent regime weak?](#)

Synopsis: “India misuses its own IP system to boost its domestic industries,” US Senator Orrin Hatch commented while introducing the 2014 report of the Global Intellectual Property Centre (GIPC) on ‘International Intellectual Property (IP) Index’. In this report, India featured at the bottom of a list of 25 countries, scoring only 6.95 out of 30.

The reasons for this low score, especially true in the case of the pharma sector, are the US view that India's patentability requirements are in violations of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the non-availability of regulatory data protection, non-availability of patent term restoration and the use of compulsory licensing (CL) for commercial, non-emergency situations.

Publication: The Times Of India

Edition: National

Date: March 4, 2014

Headline: [Indo-US ties hit low as New Delhi fights back trade and business onslaught](#)

Synopsis: On the ground, the atmosphere is not congenial. Indian officials say US is using India for target practice on trade, tax and IPR issues. India has decided to fight back. In both capitals, political leaders have signed off- in India due to coming elections, and in the US due to other more pressing crises at hand. Jaishankar said, "The results are there for all of to see - a de-strategising of foreign policies in favour of bread and butter concerns. A globalized world is also an infectious one and it should come as no surprise if others respond in an equally hard-headed manner to the diplomacy of demands."

FDA

Publication: The Hindustan Times

Edition: Delhi

Date: March 4, 2014

Headline: Wockhardt moves to cure itself of FDA woes (link unavailable, scan attached)

Synopsis: Hit by the recent US ban on its two plants, drug major Wockhardt plans to shift the company's focus to research and development (R&D) instead of only manufacturing drugs. The company will spend Rs 500 crore on R&D this year against Rs 220 crore two year back.

Website: Pharmabiz

Edition: Online

Date: March 4, 2014

Headline: [Maha FDA to implement model medicine prescription format for patient safety](#)

Synopsis: Maharashtra Food and Drug Administration (FDA) has become the first state drug regulatory body in the country to come out with a model medicine prescription format to address the compelling need for safe and efficacious supply of medicines for patient safety. The format was formally issued by Maharashtra Chief Minister Prithviraj Chavan on February 28, 2014 in the presence of State FDA officials.

Website: Pharmabiz

Edition: Online

Date: March 4, 2014

Headline: [AstraZeneca's Bydureon Pen gets US FDA approval for once-weekly treatment of adults with type 2 diabetes](#)

Synopsis: The US Food and Drug Administration (FDA) has approved AstraZeneca's Bydureon Pen (exenatide extended-release for injectable suspension) 2 mg as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. The Bydureon Pen is a pre-filled, single-use pen injector, eliminating the need for the patient to transfer the medication between a vial and syringe during the self-injection process.

MCI

Publication: Business Standard

Edition: National

Date: March 4, 2014

Headline: [An ailing health ministry](#)

Synopsis: The Union health ministry, which has been run for five years by Ghulam Nabi Azad, has consistently been in trouble of late. The Supreme Court ordered an overhaul of the regulation of clinical trials; and the United States Food and Drug Administration has questioned the manufacturing practices of Indian pharmaceutical companies. Both trials and pharmaceutical companies are the ministry's bailiwick. Now, developments related to the Medical Council of India (MCI), the national regulator for medical education and practice, have hit the headlines. The Aam Aadmi Party (AAP) has alleged that political patronage from the Congress, Gujarat Chief Minister Narendra Modi and the Samajwadi Party has together tried to return its former head, Ketan Desai, to the MCI - and that the government even transferred a health secretary who objected. Mr Desai lost the position in 2010, along with his medical licence, after he was arrested for taking a bribe to favour a particular medical college.

Publication: The Tribune

Edition: National

Date: March 4, 2014

Headline: [MCI amends its ethical code](#)

Synopsis: If the Medical Council of India (MCI) has its way, professional associations of doctors like the Indian Medical Association will not be accountable to it for unethical practices in future. In a development that has attracted widespread criticism, the MCI has amended its existing Code of Ethics Regulations in a way to exempt professional associations of doctors from its reach.

Drug Regulation

Publication: The Indian Express

Edition: National

Date: March 4, 2014

Headline: [Facing staff crunch, drug control dept unable to up quality checks](#)

Synopsis: Licences of over 300 chemists were cancelled in Delhi till December 31 last year because they did not meet various regulatory guidelines of the Drug Controller General of India (DCGI). During the same period, 16 of 300 drug samples tested in surprise checks from various private chemists, and three of 42 samples tested from government pharmacies were found to be of sub-standard quality. According to data from the Delhi drug control department, all three have been the lowest in the last five years.

General Industry

Publication: The Economic Times

Edition: National

Date: March 4, 2014

Headline: [Lupin seeks biosimilar, lung drug partners](#)

Synopsis: Lupin Ltd is seeking new partnership agreements as it moves into the promising fields of inhaled lung drugs and copies of biotechnology drugs, its managing director said. The United States and Japan were the most interesting regions for so-called "biosimilar" developments by Lupin and the company is actively seeking partners with the right drug development expertise, Nilesh Gupta told Reuters in an interview.

Similar report in-

Reuters- [India's Lupin seeks biosimilar, lung drug partners](#)

Publication: The Times Of India

Edition: National

Date: March 4, 2014

Headline: [Zydus R&D unit served closure notice over pollution](#)

Synopsis: The Gujarat Pollution Control Board (GPCB) has issued closure notices to the research wing of pharma major Cadila Healthcare— Zydus Research Centre (ZRC)—at Changodar on the outskirts of Ahmedabad. The notice was issued on March 1 after the company was found allowing waste water from its laboratories to percolate through a dead borewell into an underground aquifer. The development could have far-reaching consequences for the BSE-listed company, which is betting big on the US market. A company spokesperson sought time to respond to an e-mailed query on the issue.