



News Updates: March 8-10, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: Business Standard

Edition: National

Date: March 9, 2014

Headline: [USIBC opposes move to designate India Priority Foreign Country](#)

Synopsis: A top American trade advocacy group has vehemently opposed any move by the US to designate India a Priority Foreign Country, saying the Indian Government has been responsive to issues raised on the intellectual property rights (IPR) front over the past year. The US India Business Council (USIBC) has told the US Trade Representatives (USTR) that it strongly recommends against India being designated a Priority Foreign Country as being advocated by influential pharma lobbying groups.

Similar reports in-

The Economic Times- [USIBC opposes move to designate India Priority Foreign Country](#)

The Indian Express- [USIBC opposes IP violator tag for India](#)

Publication: The Hindu Business Line

Edition: National

Date: March 10, 2014

Opinion piece: Mike Palmedo, Researcher at the American University Washington College of Law

Headline: [A flimsy case against Indian pharma](#)

Synopsis: Trade tensions between the US and India are on the rise. Multiple trade organisations have asked the US Trade Representative to designate India a Priority Foreign Country in its annual review of countries that “deny adequate and effective protection of intellectual property rights.” This would trigger an investigation under the Trade Act that could ultimately lead to sanctions. Additionally, the US International Trade Commission has been instructed by Congressional leaders to investigate “Indian industrial policies that discriminate against US imports and investment for the sake of supporting Indian domestic industries”. Much of the controversy surrounds flexibilities in Indian patent law designed to promote access to generic medicines. The medicines at issue tend to be expensive cancer treatments priced far out of reach for most of the Indians.

Publication: Business Standard

Edition: National

Date: March 10, 2014

Headline: [US leaders to woo Indian industry amid trade spat](#)

Synopsis: Amid mounting tensions between both countries, senior US leaders are arriving here on Monday with several American business heads in an effort to woo Indian industry, even as the threat of the US labeling India as 'Priority Foreign Country' in its 'Special 301 Report' looms large. US Energy Secretary Ernest Moniz and USAID head of climate change division, Kit Batten, are all coming here this week with several senior US delegates to participate in a US-India dialogue. On Tuesday, the US-India Energy Security Coalition will be launched by Moniz.

Publication: The Financial Express

Edition: National

Date: March 9, 2014

Headline: [WTO to the rescue](#)

Synopsis: Tough ostensibly committed to the WTO process, over the years, India has been on a spree to sign bilateral free trade agreements—sometimes Comprehensive Economic Cooperation Agreements—with a host of countries. Over the past decade, India has signed such pacts with 10 countries, including Singapore and Mauritius, and is currently negotiating a pact with the European Union. Everyone knows the multilateral process is better for developing countries like India, in the sense that it gives them more time to, say, open up their agriculture markets to imports. But, given how the WTO process has been so badly stuck for years—it has been 12 years since.

Publication: The Hindu

Edition: National

Date: March 10, 2014

Headline: [U.S. pharma companies benefit from large Indian generic market](#)

Synopsis: The tirade by the U.S. against India with regard to its 'unfriendly' business environment, particularly the Indian pharmaceutical sector, is largely misplaced according to the Indian Pharmaceutical Alliance (IPA). The U.S. International Trade Commission (USITC) last month started public hearings in Washington DC as part of its investigation 'Trade, investment and industrial policies in India: effects on the U.S. economy.' Representatives from software and pharmaceutical industry associations among others from India appeared before it.

Publication: Business Standard

Edition: National

Date: March 9, 2014

Headline: [MEA says Khobragade issue caused 'misunderstanding' between India, US](#)

Synopsis: The diplomatic row that emerged between India and US concerning Indian diplomat Devyani Khobragade did create "misunderstanding" even though the relationship between both countries continue to "grow" according to Foreign Secretary Sujatha Singh. "The issue (concerning Devyani Khobragade) caused a certain degree of misunderstanding for a certain period of time ... The India-US relationship is strong and will continue to grow from strength to strength," Singh said here today while addressing women reporters on the occasion of the International Women's Day.

FDA

Publication: The Hindustan Times

Edition: National

Date: March 10, 2014

Headline: [US fumes, but UK agency OKs Indian pharma \(link unavailable, scan attached\)](#)

Synopsis: Concerns about quality control in India's Rs 86,800-crore drug industry have worried the US industry regulators, but its British counterpart finds no such concern on a significant scale. "The majority of inspections of Indian manufacturing sites result in a satisfactory outcome," Jennifer Kyne, press officer at UK's Medicines and Healthcare Products Regulatory Agency told HT by e-mail. "There is not a significant difference in the number of critical findings identified at UK sites versus those in India or other third countries."

Publication: The Statesman

Edition: National

Date: March 10, 2014

Headline: [India for review of US pharma policy](#)

Synopsis: Taking up the case of domestic pharma sector with the USA, India has pitched for review of America's whistle blower policy and lowering of registration charges to help Indian firms seek greater market access. The concerns over four major issues were raised in a 'non-paper' (a kind of a discussion document) presented to the US authorities by India.

Publication: The Times Of India

Edition: National

Date: March 9, 2014

Headline: [Ranbaxy calls back cholesterol drug in US](#)

Synopsis: Ranbaxy Laboratories, facing a host of regulatory issues, has recalled over 64,000 bottles of the generic version of a cholesterol-lowering drug, Lipitor, in the US after a dosage mix-up was detected. It recalled the tablets of atorvastatin calcium after a pharmacist found a 20mg tablet in a sealed bottle marked for 10mg tablets, the US Food and Drug Administration said on its website.

Similar reports in-

Business Standard- [Ranbaxy gets prescription wrong on Lipitor, again \(link unavailable, scan attached\)](#)

The Financial Express- [Ranbaxy Laboratories recalls some batches of generic Lipitor in latest quality blow](#)

Publication: The Economic Times

Edition: National

Date: March 8, 2014

Headline: [US FDA asks Sanofi, Regeneron to assess cholesterol drug's cognitive risks](#)

Synopsis: The US Food and Drug Administration has asked Regeneron and Sanofi to assess potential neurocognitive side effects of their experimental cholesterol drug, Sanofi said in its annual report on Friday. The regulatory filing sent shares of Regeneron down 6 per cent in Nasdaq trading. US-listed shares of France-based Sanofi were down 1 per cent.

Similar report in-

Reuters- [FDA probes cognitive impact of new cholesterol drugs](#)

DCGI

Publication: The Times Of India

Edition: National

Date: March 9, 2014

Headline: [Allegations of fake India-made medicines baseless: DCGI](#)

Synopsis: The drugs controller general of India has contradicted a New York Times report reprinted in TOI on February 16 — 'India-made drugs trigger safety concerns in US'. The report made some "baseless, irresponsible and malicious" claims by stating that WHO estimates that one in 5 drugs made in India is a fake, a release issued by the public information cell of DCGI said. The fact is that the WHO had clarified as recently as on August 31, 2012 that there was no such study carried out by the WHO. They have also "regretted that occasionally some individuals in the media and the organizations use WHO references incorrectly and even irresponsibly", the release said.

Similar report in-

Pharmabiz- [Health Min slams media reports against DCGI office as 'baseless' and 'harmful'](#)

Drug Pricing

Publication: The Times Of India

Edition: National

Date: March 10, 2014

Headline: [Chemists want review of order on drug prices](#)

Synopsis: Drug distributors on Sunday reiterated their demand to the government to help pharmacies that have taken a hit after the implementation of the new Drug (Prices Control) Order 2013. According to the order the ceiling price of essential medicines has been fixed based on the average price of all brands of that drug that have a market share of at least 1%.

Access

Publication: Western Times

Edition: Ahmedabad

Date: March 8, 2014

Headline: Poor access to medicines due to unreliable support: Report (link unavailable, scan attached)

Synopsis: Inadequate financing, inefficient procurement and unreliable supply are responsible for poor access to medicines in India, said a new report released Thursday. The current spending on medicines both by the central and the state governments are a meagre 0.1 percent of the Gross Domestic Product (GDP). This needs to be scaled up to at least 0.5 percent of the GDP in the next five years, said the report by the Public Health Foundation of India (PHFI) and The Institute for Studies in Industrial Development (ISID).

General Industry

Publication: The Financial Chronicle

Edition: National

Date: March 8, 2014

Headline: [Do good INC.](#)

Synopsis: The responsibility of any government to herd the masses out of their misery may have been well established since the civil state concept came into being. Even for cash-rich companies across the world, being charitable is a way of life, though not legal. But for companies in India, sharing the obligation with the state comes with a diktat. It is no longer voluntary. It is for the first time that the Indian government has legalised the term corporate social responsibility (CSR) by making it mandatory for the companies to deploy 2 per cent of their profits towards the upliftment of the society, environment and economic development by enforcing the CSR recommendations under Schedule 7 of the Companies Act 2013.

Publication: The New Indian Express

Edition: National

Date: March 10, 2014

Headline: [Women Promoters Rule India's Life Sciences Sector, say Industry Experts](#)

Synopsis: The Rs.75,000-crore Indian pharmaceutical industry has a distinctive feature. Unlike other male-dominated sectors, women play a major role in shaping this industry. Kiran Mazumdar Shaw of Biocon, Swati Piramal of Piramal Healthcare, Reddy sisters of Apollo Enterprises, Vinita Gupta of Lupin, Suchitra Ella of Bharat Biotech and Viloo Morawala Patell of Avesthagen Ltd, to name a few,

not only contribute significantly to their company topline, they are also the voice (and face) of their sector.