News Updates: January 28, 2014

Compulsory License/Patents

Publication: The Times of India
Edition: Online
Date: January 27, 2014
Journalist: Rema Nagarajan
Headline: Pharma drug development only for wealthy countries?

Synopsis: The Bayer CEO's has been reported as saying that the company did not develop a cancer medicine for Indians, only for western patients who can afford it. His statement has evoked wide-spread condemnation. Medecins Sans Frontieres (MSF) issued a statement saying that Bayer CEO, Marijn Dekkers' statement summed up everything that was wrong with the multinational pharmaceutical industry. "Bayer is effectively admitting that the drugs they develop are deliberately going to be rationed to the wealthiest patients. This is a side-effect of the way drugs are developed today. Pharmaceutical companies are singularly focused on profit and so aggressively push for patents and high drug prices," said Dr Manica Balasegaram, Executive Director of MSF's Access Campaign.

Publication: Scrip (No link available)
Edition: Online
Date: January 27, 2014
Headline: India's compulsory licensing radar spies fresh meat

Synopsis: An Indian government-appointed panel is believed to be working on plans to evaluate a clutch of patented drugs, which may be beyond the reach of ordinary people, as potential candidates for compulsory licensing (CL). What makes the current exercise significant is that India may be looking beyond what have been seen as the traditional CL-ripe segments such as HIV and cancer, towards new territory like diabetes and even cardiovasculars, an industry source told *Scrip*. "They [the panel] may look at one or two products for compulsory licensing in segments that go beyond HIV/AIDS, TB, etc, to establish that India means business when it comes to ensuring access. But they are unlikely to do so for a large basket of products…. no question on that," the source indicated. An official government response was not immediately savailable.

Drug regulation/FDA

Publication: The Hindu Business Line
Edition: National
Date: January 28, 2014
Headline: 'Drugmakers need to learn to comply with FDA rules not once, but every time'

Synopsis: A rush to hit the market, culture-mismatches, blind spots in senior management, lack of training… Pharma industry representatives are reeling out a host of reasons for drugmaker Ranbaxy's woes. One after another, the company's Indian plants have been banned from selling to the US by that country's regulator, the FDA.
Wockhardt has faced similar troubles. However, companies such as Lupin and Sun Pharma, which have got warning letters from the US regulator in the past, have managed to resolve its concerns.

Publication: The Hindu Business Line
Edition: National
Date: January 28, 2014
Headline: Bitter medicine

Synopsis: The US Food and Drug Administration's (USFDA) ban on import of active pharmaceutical ingredients from Ranbaxy's plant at Toansa in Punjab – in addition to three other of its earlier blacklisted manufacturing sites — has implications for more than just the beleaguered company. To start with, Ranbaxy Laboratories is not alone. The USFDA has also identified "significant violations of current good manufacturing practice (cGMP) regulations" at two facilities belonging to Wockhardt, apart from issuing warning letters to a host of other firms such as Dr Reddy's, Lupin, Sun Pharma and Aurobindo Pharma. While Ranbaxy may be the only company to have been prohibited from manufacturing drugs from all its Indian plants for the US market, the matter is serious enough for the Centre to sit up and take notice. The Drug Controller General of India and other authorities must work closely with the pharma industry to evolve systems for enforcement of compliance with global cGMP standards. At stake is India's $15 billion-a-year pharma exports, over a quarter of which goes to the US.

Publication: Business Standard (Editorial)
Edition: National
Date: January 28, 2014
Headline: **Indian pharma's twin woes**

Synopsis: The Indian pharmaceutical industry is beset by two adverse conditions - one is a recent development and the other a long-standing malady. Most recently, leading pharmaceutical company Ranbaxy met with yet another regulatory mishap: the United States Food and Drug Administration, or FDA, withdrew approval for the firm's Toansa plant because of significant lapses in manufacturing practices. The fourth Indian plant of the company to suffer such a setback from the US regulator, Toansa is the major supplier of low-cost active pharmaceutical ingredient, or API, a key raw material for some Ranbaxy products marketed in the US. Maintaining both volumes and margins in a market accounting for more than a third of consolidated global sales will now be difficult, if not impossible.

Publication: The Hindu Business Line
Edition: National
Date: January 28, 2014
Headline: **Damage-control: Ranbaxy 'may outsource or buy' a drug-maker**

Synopsis: As part of a damage-control exercise, Ranbaxy Laboratories Ltd, whose fourth plant in India was recently banned by the US drugs regulator, may outsource production or even acquire a manufacturer, say industry watchers. And while the company is working on a Plan B, other local manufacturers of active pharmaceutical ingredients (API) will have a clear shot at the US opportunity. On January 23, the US Food and Drug Administration (FDA) prohibited imports of drugs made at Ranbaxy's Toansa facility in Punjab. With the US-based Ohm Labs being the only Ranbaxy unit in the good books of the FDA, the Toansa ban has opened up a huge market for the company's peers, say analysts.

Publication: The Indian Express
Edition: National
Date: January 28, 2014
Headline: **Jolted by US ban, Indian regulators wake up to review Ranbaxy units**

Synopsis: DRUG Controller General of India (DCGI) inspectors are set to inspect pharma giant Ranbaxy's Toansa unit in Punjab this week, days after the US Food and Drug Administration banned import of products made there for manufacturing violations."We will be sending a team of officials to inspect the plant to test the product. If there are any violations, we will take action," DCGI G N Singh told The Indian Express.

General Industry News

Publication: Mint
Edition: National
Date: January 28, 2014
Headline: **Zydus Cadila to exit from Japanese business**

Synopsis: Cadila Healthcare Ltd on Monday said it has decided to close its Japanese subsidiary set up in 2006

to tap the world's second-largest pharmaceutical market. "The company has recently completed portfolio and strategy review of its business and has decided to exit from its business in Japan, which is through a 100% subsidiary company," Cadila Healthcare said in a statement to the stock exchanges on Monday, without specifying a reason.

Publication: The Hindu Business Line
Edition: Online
Date: January 27, 2014
Headline: Govt launches India Inclusive Innovation Fund

Synopsis: The National Innovation Council and the Ministry of Micro, Small and Medium Enterprises (MSME) have jointly announced the creation of the India Inclusive Innovation Fund (IIIF). Approved by the Union Cabinet, the fund was conceived as a unique concept that seeks to combine innovation and the dynamism of enterprise to solve the problems of citizens at the base of the economic pyramid in India.