News Updates: February 12, 2014

Intellectual Property/Compulsory License/Patents

Publication: Business Standard
Edition: National
Date: February 11, 2014
Opinion article - Amit Gupta, Advocate on Record, Supreme Court of India and Attorney, New York State Bar.
Headline: Big Pharma's profiteering protests

Synopsis: The US Chamber of Commerce has recently asked the Barack Obama Administration to designate India a Priority Foreign Country. This is the worst classification given to foreign countries that "deny adequate and effective" protection of intellectual property rights. The US industry trade group Pharmaceutical Research and Manufacturers of America (PhRMA) has expressed a similar view. Last year, the chamber wrote to Obama urging him to hold detailed discussions with the Indian prime minister on the issue. According to US lobbyists, India has failed to recognise international intellectual property rights, which is deterring investments in the country. During a hearing, "A tangle of trade barriers"' before the US Energy and Commerce Committee in June 2013, the Chief Intellectual Property Officer of Pfizer Inc criticised developments in India's intellectual property regime. Some critics have gone to the extent of stating that there is potential cause for a World Trade Organisation (WTO) complaint against India for violating intellectual property treaties.

Publication: The Economic Times
Edition: National
Date: February 12, 2014
Headline: US International Trade Commission to hear cases of bias against American companies in India

Synopsis: The US International Trade Commission would begin public hearing on Wednesday as part of its probe into Indian policies that allegedly discriminate against US trade and investments. The quasi-judicial body set up by the US Congress is currently investigating whether and to what extent Indian polices discriminate against US players. Among those listed to depose on the first day are Mark Eliott, executive vice president, Global Intellectual Property Centre, US Chambers of Commerce, Michael Schlesinger, counsel of Washington based International Intellectual Property Alliance, Brian Pomper, executive director of Washington based Alliance for Fair Trade among other academics.

Publication: The Hindu Business Line
Edition: Online
Date: February 11, 2014
Headline: India patent regime not about access to medicine: US body

Synopsis: With U.S Trade Representative Michael Froman set to announce a trade enforcement action tied to India, the highly influential U.S Chamber of Commerce has lashed out at India's recent pattern of pharma patent denials, pointing out that the country's actions "are not about access to medicine." In the case of Swiss drug-maker Novartis, whose cancer drug's patent protections were dismissed by the Supreme Court, the chamber has argued that the patent revocation led to the drug actually becoming "more expensive for Indian patients."

Publication: The Financial Express
Edition: National
Date: February 12, 2014
Headline: **Editorial: Patent problems**

Synopsis: While the agreement between the US FDA and its Indian counterpart to share information and perhaps coordinate action is good news as both regulators will now be on the same page, the need of the day is for the Indian regulators to be more stringent and conduct more surprise tests in the manner the FDA does. Indeed, since Indian regulators are not contesting the US findings in the case of, for instance, a Ranbaxy, it is worrying that they have not detected such problems themselves. That said, the Indo-US problem goes deeper, to the US belief that India's IPR laws, particularly Section 3(d) of the Patents Act that deals with what is not patentable—and brings in the question of increased efficacy—are inadequate to protect US intellectual property.

Drug regulation/FDA

Publication: Business Standard
Edition: National
Date: February 12, 2014
Headline: **Let the US not buy drugs from India if they're not satisfied: Yusuf Hamied**

Synopsis: Regulations in the Indian pharmaceutical sector are under the scanner. These have come under fire after the US Food andDrug Administration (FDA)'s alleged non-compliance by manufacturing units, while they also deal with strict clinical trial guidelines at home, set by the Supreme Court. Yusuf Hamied, chairman of Indian drug manufacturer Cipla Ltd and a veteran in the pharmaceutical industry, talks with Antonita Madonna about the regulatory framework in India and advocates "pragmatic" changes.

Publication: Business Standard
Edition: National
Date: February 11, 2014
Headline: **Compliance does not end with approval, says US FDA chief**

Synopsis: Compliance does not end with approval, visiting US Food and Drug Administration (US FDA) Commissioner Margaret Hamburg told Business Standard, replying to a question on tough and repeated enforcements on Indian pharma companies. While pointing out that pre-approval inspection is a snapshot in time, she said companies would have to continuously maintain quality practices at every level to be able to supply to the US market. Indicating frequent inspections and stringent quality checks in future, Hamburg stressed the regulator would expand its presence in the country.

Publication: The Indian Express
Edition: National
Date: February 11, 2014
Headline: **Pharma Inc calls for alignment with US rules**

Synopsis: US Food and Drug Administration (USFDA) Commissioner Margaret Hamburg on Tuesday met representatives of pharma companies and tried to assuage apprehensions anc called for strengthening the relationship between the two countries.
The companies called for aligning India's regulatory standards with the US to avoid the adverse impact on the industry caused by the USFDA inspections. Hamburg, who is in India till February 18, met chiefs of pharma companies, in an event organised by industry chamber Ficci.

Similar report in

The Hindu Business Line- **US FDA to speed up approvals for Indian drug-makers**
The Financial Express - USFDA rejigging system to speed up drug approvals, says Hamburg

Publication: The Economic Times
Edition: National
Date: February 12, 2014
Headline: USFDA to hold workshops across India on quality requirements

Synopsis: The US health regulator plans to conduct workshops across India in the next one year in order to sanitise Indian drug companies about the changing quality requirements in the American market. The matter came up during a meeting between chief executives of various drug companies and US Food and Drug Administration (USFDA) Commissioner Margaret A Hamburg.

Publication: The Hindu
Edition: National
Date: February 12, 2014
Headline: Ranbaxy rejects sabotage theory

Synopsis: Rejecting sabotage theory at Toansa plant that faces USFDA ban, drug major Ranbaxy on Tuesday denied blaming the company's voluntary retirement scheme for the problem it faces. "I do not support sabotage theory for Toansa plant. I have never said the problem is on account of voluntary retirement scheme (VRS), this is the official position that I have maintained. I will maintain that," Ranbaxy CEO and Managing Director Arun Sawhney told reporters in New Delhi.

Publication: The Economic Times
Edition: Online
Date: February 12, 2014
Headline: US FDA refuses to allow Ranbaxy to export from banned units

Synopsis: The head of the US drug regulatory body has turned down Ranbaxy Laboratories' plea to allow drugmakers to continue exporting from banned manufacturing facilities while they take remedial measures to rectify the issues flagged. This request was made on Tuesday by Ranbaxy Managing Director Arun Sawhney at a closed-door meeting of CEOs of leading Indian pharmaceutical companies with US Food and Drug Administration (US FDA) Commissioner Margaret Hamburg, who is currently visiting India.

FDI

Publication: The Hindu Business Line
Edition: National
Date: February 11, 2014
Headline: India is still a top destination for FDI: Sharma

Synopsis: Union Minister for Commerce and Industry Anand Sharma has asserted that India remains one of the top destinations for foreign direct investment, despite the economic slow down.
Speaking at a students' interactive session at Sophia College in Mumbai on February 11, Sharma said India's foreign direct investment (FDI) policy has been progressively liberalised to make the regime more investor friendly. He said in a recent review of the policy the Government has amended the sectoral caps in some key areas to stimulate FDI inflow.

Publication: The Financial Express
Edition: National
Date: February 12, 2014
Opinion article - Kewal Handa, Managing director, Pfizer Ltd

Headline: Poor pharma policy

Synopsis: The Union Cabinet rejected the proposal of the Department of Industrial Policy and Promotion (DIPP) to limit Foreign Direct Investment (FDI) in domestic manufacturers in rare and critical drugs. The Cabinet decided that the current policy in brownfield and greenfield projects in the pharmaceutical sector will continue to be subject to the additional condition that in all cases of FDI in brownfield pharmaceuticals, there shall be no non-compete clause in any of the inter se agreements.
The DIPP and the Cabinet are of the opinion that if a promoter sells one facility or operation, he should not be barred from starting another venture.

General Industry News

Publication: The Economic Times
Edition: National
Date: February 12, 2014
Headline: Pharma sector battling with fraud among job applicants: Report

Synopsis: It's not just the US Food & Drug Administration (US FDA) that the Indian pharmaceutical sector is wary of, but it has a rather unusual problem to deal with back home. A staggering 35 out of every 100 job applicants in the pharmaceutical or clinical trial space are lying about their credentials either by furnishing incorrect educational information or, what's even worse, creating fake companies, the highest among any other sector, according to a report released by AuthBridge, a Delhi-based employee screening firm.