News Updates: February 19, 2014

Intellectual Property/Compulsory License/Patents
Publication: Hindustan Times **Edition: National** **Date: February 19, 2014** **Headline: Indian firms under pressure on drug patent regime, as global majors mount lobbying** **Synopsis:** India is defending its patent regime more aggressively than ever before from attacks in the US that have come to define the state of ties between the two countries lately. The first sign of this came at a US International Trade Commission hearing last week with a telling push-back from trade bodies from India. They were supported by activists such as Medecins Sans Frontiers (Doctors without Borders), that have historically supported easy access to medicines, and US academics.
Publication: Pharmabiz **Edition: Online** **Date: February 19, 2014** **Headline: THE US BLACKMAIL** **Synopsis:** India's pharmaceutical exporters seem to have received a major shock when the US Chamber of Commerce asked the Barack Obama Administration to classify India as a Priority Foreign Country, a worst classification given to an exporting country. The US government may take the advisory of the Chamber seriously considering its tremendous influence on the US government and it will have to act accordingly against India.
Publication: Mail Today **Edition: Delhi** **Date: February 19, 2014** **Headline: An end to patent problems (No link available…Scan attached)** **Synopsis**: The issue of drug patent is still a matter of debate. Multinational drug companies whose patents are being revoked feel that it will hit innovation, while patient rights groups developing countries see it as an issue of access.
Website: Intellectual Property Watch **Edition: Online** **Date: February 18, 2014** **Headline: Battles Over Patents: Is India Changing The Rules Of The Game?** **Synopsis:** Over the last couple of years, news of pharmaceutical patents and India's attempts to protect and manage its market has caught the attention of intellectual property observers everywhere and the pharmaceutical industry in particular. High-profile developments have included India's awarding of its first compulsory licence for a patented drug and Swiss pharmaceutical giant Novartis' long-running court battles challenging India's patent law.
Website: Money Morning **Edition: Online** **Date: February 18, 2014** **Headline: This Patent Cliff 2014 Chart Shows How Much Revenue Big Pharma Will Lose**

Synopsis: More pharmaceutical companies will lose drug patents to the patent cliff in 2014, threatening billions of dollars in revenue for Big Pharma. Once a drug is off patent, other pharmaceutical companies are free to replicate the product. That can drastically slash the revenue of pharmaceutical companies that have been making billions of dollars from their patented products.

Drug Pricing/Pricing Policy

Website: Reuters
Edition: Online
Date: February 18, 2014
Headline: Germany's stance on pricing threatens drug firm profits

Synopsis: Germany, in order to curb rising healthcare costs, plan to publish price discounts agreed with drug makers. The aim is to stop wholesalers and pharmacies from basing their margins on list prices rather than the discounted prices. The pharma industry fears that this decision poses a risk to profits and could trigger price falls elsewhere.

Also appeared in The Financial Express. Scan attached.

Drug regulation/FDA

Publication: The Times of India
Edition: National
Date: February 19, 2014
Headline: 'Indian drug companies must meet US standards'

Synopsis: When US Food & Drug Administration commissioner Margaret Hamburg signed off her 9-day visit to India on Tuesday, she praised everything Indian with a steely demand for quality. Throughout her 45-minute meeting with the Indian media in Mumbai, she used the 'Q word' several times to convey the USFDA's main concern vis-a-vis growing exports of medicines and food from India

Similar reports in:

The Economic Times - If you want our market, meet our standards, says Margaret Hamburg, US FDA chief
Bloomberg News - India Drugmakers Carry Onus of Knowing Rules, U.S. FDA Head Says

Publication: The Economic Times
Edition: Online
Date: February 19, 2014
Headline: US Food and Drug regulator to deploy more inspectors in India

Synopsis: The US Food and Drug regulator said on Tuesday that it will increase the number of its inspection staff in India. Currently, the FDA deploys 12 officials in India, which the regulatory body plans to increase by 19, said Margret Hamburg, Commissioner, US Food and Drug Administration in the course of an interaction in Mumbai.

Similar report in

Indian Express - USFDA chief calls for coalition of regulators

Publication: Business Standard
Edition: Online
Date: February 18, 2014
Headline: Working with India to improve drug quality, safety: USFDA

Synopsis: The US Food and Drug Administration (USFDA) today said it was working with regulators here to enhance the quality and safety of drugs as 40 per cent of generic drugs exported to America were from India. Margaret Hamburg, the visiting Commissioner of the US health regulator, termed India as a very important partner for her country in the pharma sector.

Clinical Trials

Publication: The National
Edition: Online
Date: February 18, 2014
Headline: India clamps down on clinical drug trials, at a cost

Synopsis: India has introduced restrictions on clinical trials following concerns about the safety of test patients, and it has become a much more complex and lengthy process to secure permission for trials. It has reached the point where some Indian companies are moving trials abroad to locations in Europe and the US, at a much higher cost.

General Industry News

Publication: The Economic Times
Edition: Online
Date: February 19, 2014
Opinion article - Barry Werth, From "The Antidote: Inside the World of New Pharma"
Headline: Malady Diagnosing

Synopsis: The modern pharmaceutical industry emerged from one of the great triumphs of 20thcentury science. Before the 1940s, there were medicines and companies that made them, but no one had invented a method for actively finding and developing new drugs. Profits in medicine were disdained as suspect — immoral —and the companies were essentially manufacturers of fine chemical compounds. Since their products could do as much harm as good, integrity was key. Then university laboratories advanced a new approach: microbial screening.

Publication: The Economic Times
Edition: Online
Date: February 19, 2014
Opinion article - Seema Sirohi, Geopolitical analyst
Headline: India, US in danger of losing the big picture of strategic partnership

Synopsis: The big picture of Indo-US strategic partnership is getting blurred just as the strategic necessity for the two countries to converge increases. The focus is diffused, high-level attention has withered and in the absence of political oversight, a series of unfortunate events overseen by small sheriffs has begun to define the relationship. The Indo-US bilateral scene is not cheery either. Two years of US complaints on market access, intellectual property protection, compulsory licensing and taxation were topped by a corrosive spat over the mistreatment of Indian deputy consul general Devyani Khobragade by US authorities.

Publication: The Economic Times
Edition: National
Date: February 19, 2014
Headline: Actavis to buy Forest Labs in $25 billion deal

Synopsis: Irish drugmaker Actavis PLC plans to buy Forest Laboratories Inc. for about $25 billion, catapulting little-known Actavis into the world's No. 15 drug company, with an unusual one-stop-shopping model giving it an edge: more face time with doctors.

Publication: The Hindu Business Line
Edition: Online
Date: February 18, 2014
Headline: GSK-Dr Reddy's to file for joint drug this year

Synopsis: The first drug being jointly developed by GlaxoSmithKline (GSK) and Dr Reddy's Laboratories will be filed for registration in this year. Speaking to newspersons on the sidelines of the ongoing BioAsia 2014 here on Tuesday, Rogerio Ribeiro, Senior Vice-President & Head of Emerging Markets and Asia Pacific, GSK, said the registration would be initially done in Europe. "We will be introducing the product through Europe in the emerging markets which has been a focus area for us,'' he said. Generally, it takes a couple of years for a product to hit markets after filing for approval.