



News Updates: April 12-14, 2014

Patents/ Compulsory Licensing/ Intellectual Property

Publication: The Hindu

Edition: Online

Date: April 10, 2014

Headline: [Developing countries concerned about U.S.-EU economic treaty](#)

Synopsis: Even as a fourth round of negotiations on the Transatlantic Trade and Investment Partnership between the U.S. and European Union was concluded recently, experts from developing countries as well as within the U.S. have underscored concerns emerging from the powerful trade bloc that this new treaty would represent, if successful. The forward momentum on the TTIP comes even as India and the U.S. find themselves enmeshed in an ever-deepening cycle of trade disputes, on everything from solar panel manufacturing to compulsory licensing in pharmaceuticals and telecommunications sectors.

Sun Pharma- Ranbaxy deal

Publication: Mint

Edition: National

Date: April 14, 2014

Headline: [Sun Pharma, Ranbaxy merger: Layoffs, supply synergy key to \\$250 mn savings](#)

Synopsis: The merger of Sun Pharmaceutical Industries Ltd and Ranbaxy Laboratories Ltd will create the world's fifth biggest generic drug maker, but it will also result in job redundancies. Sun Pharma has estimated that it will save \$250 million (Rs.1,505 crore) in the third year of the merger because of operating synergy, which will likely come from trimming the field force of the two companies and integration of its supply chain. Sun Pharma agreed to acquire Ranbaxy last week in a \$3.2 billion all-stock purchase.

Similar reports in-

Business Standard- [Ranbaxy may have to pay huge fine, again](#)

Business Standard- [Premature to talk of changes in Ranbaxy management team now: Dilip Shanghvi & Israel Makov](#)

The Economic Times- [Investors bet Sun Pharma can restore Ranbaxy to health](#)

The Financial Express- [Another deal from turnaround expert](#)

The Financial Chronicle- [Signs of revival](#)

Clinical Trials

Website: Pharmabiz

Edition: Online

Date: April 14, 2014

Headline: [CDRI planning to launch Phase-1 trials on 2 candidate drugs to fight malaria, diabetes](#)

Synopsis: The Central Drug Research Institute (CDRI), the public sector premier institution for drug discovery, will soon start Phase 1 clinical trials of a candidate drug against malaria and another one to fight diabetes. The institute has developed and licensed the anti-hyperglycemic candidate drug (CDR134F194) to TVC Sky Shop Ltd., Mumbai. The process of formulation of the drug in a GMP

certified company is in progress. The single dose and multi-dose Phase- I clinical trial will be initiated soon at KEM Hospital & Seth GS Medical College in Mumbai. The permission for the trials was already given by the Drugs Controller General of India (DCGI), sources said.

FDA

Publication: Deccan Herald

Edition: National

Date: April 14, 2014

Headline: [Inspectors hard-pressed to scrutinise drug factories](#)

Synopsis: G L Singhal, chief regulator of Haryana, a drugs manufacturing hub, says he needs double the number of inspectors if he is to properly scrutinise factories there. "We literally have skeletal services. We are struggling in the present system. Inspectors are so overburdened, and their nature of duty is very serious," Singhal said. There are just 1,500 drug inspectors responsible for more than 10,000 factories in India, where one in every 22 locally made samples was of sub-standard quality according to a study carried out two years ago.

Drug regulation/ Drug quality

Publication: Business Standard

Edition: National

Date: April 13, 2014

Headline: [Indian drugs: hard to swallow](#)

Synopsis: India-made medicines, which are much cheaper than imported drugs and have, therefore, been the lifeline for various developing countries so far, have come under the regulatory lens, more so in the past one year. Ranbaxy, which gained much negative publicity after pleading guilty in America to fraud and admitting to charges of producing fake data to get fast approvals for generic medicines, hurt the industry the most. Faced with criminal charges, the company had to pay a fine of \$500 million to US authorities. But this was just the beginning of the troubles for Ranbaxy and for others in the business. While more Ranbaxy facilities were proscribed by the US, other leading generic players such as Wockhardt, Agila Specialities, RPG Life Sciences and a facility of Sun Pharma too came under the US Food and Drug Administration's scanner. Many batches of the medicines were recalled from America, the world's largest pharmaceutical market. Some factories of Ranbaxy and Wockhardt also faced strict scrutiny in Europe.

Publication: The Hindu Business Line

Edition: National

Date: April 12, 2014

Headline: [Regulator starts examining the safety of combination drugs](#)

Synopsis: The drug regulator's fight to weed out potentially unsafe combination drugs is picking up pace. The Central Drugs Standards and Control Organisation which is headed by the DCGI, has started examining the safety of fixed-dose combination drugs, which are formulations used for a variety of medicines ranging from antibiotics to painkillers. The CDSCO, which intends to regularise this segment, wanted both small and large manufacturers to get its approval. But, despite the directive, many continued to get it done at the local level. Some of the known FDC manufacturers include smaller entities such as Restech Pharma, Naxpar Pharma, Unix Biotech, as well as big names like Cipla.

Drug pricing

Website: Pharmabiz

Edition: Online

Date: April 14, 2014

Headline: [Maha FDA inspectors to seize stocks of over priced Calpol suspension from market](#)

Synopsis: After the issue of the stop sale order for overcharging Calpol 60 ml suspension marketed by GlaxoSmithKline (GSK), the Maharashtra FDA has now directed drug inspectors to seize the product from the trade channels across the state. FDA officials maintain that action can be taken against the retailer for selling and stocking the drug at the overpriced rate as it amounts to violation of Drug Price Control Order (DPCO). Penalty may range from suspension of license to prosecution.

General Industry

Publication: The Western Times

Edition: Ahmedabad

Date: April 14, 2014

Headline: Indian groups urge Govt to resist US pressure over economic policies (link unavailable, scan attached)

Synopsis: A host of Indian groups have urged the outgoing Manmohan Singh government to resist and challenge US pressure to change its economic policies at the behest of Corporate America and its misleading allegations. As a counter move to the intense lobbying by US business groups that want India to be designated a Priority Foreign Country under its Special 301 provisions for possible sanctions over restrictive economic and trade policies, the Indian groups have asked New Delhi, to challenge the US' unilateral threats in a multilateral forum.

Publication: The Times of India

Edition: National

Date: April 14, 2014

Headline: [1 million new cancer cases being diagnosed in India each year: Study](#)

Synopsis: Latest estimates announced on Friday have revealed some worrying findings about the growing burden of cancer in India. The latest figures published in the British medical journal The Lancet show that around one million new cancer cases are being diagnosed in India each year, projected to nearly double to 1.7 million new cases in 2035. Around 700,000 people are dying from cancer in India annually, projected to rise to around 1.2 million deaths in 2035. Fewer than 30% of cancer patients in India survive for more than five years after their diagnosis.

Similar reports in-

The Economic Times- [China and India face huge cancer burden: Experts](#)

The Indian Express- [India is facing huge cancer crisis: Experts](#)

Deccan Herald- [India is facing huge cancer crisis: experts](#)

Deccan Chronicle- [India faces huge cancer crisis: Experts](#)

Daily News & Analysis- Shortage of cancer patients scarier than the disease itself (link unavailable, scan attached)

Zee News- [China, India face huge economic and human costs from cancer: Experts](#)

Publication: The Hindu

Edition: National

Date: April 13, 2014

Headline: [Natco moves to oppose Gilead hepatitis C drug patent](#)

Synopsis: Natco Pharmaceuticals, the Hyderabad-based generic pharmaceutical company, has filed a

'pre-grant opposition' with the Indian Controller General of Patents, Designs & Trademarks to prevent the granting of a patent to U.S. pharmaceutical major Gilead Sciences for its breakthrough drug for treatment of Hepatitis C, Sovaldi, which is proposed to be introduced here. Confirming the same, Natco Pharmaceuticals said it had filed the opposition about 10 days ago on the grounds that the patent would not be valid as the pro-drug and compound, sofosbuvir, was a known product and 'not inventive' enough.

Publication: Business Standard

Edition: National

Date: April 14, 2014

Headline: [Pharma sector expects strong FY15](#)

Synopsis: The country's pharmaceutical industry expects to be back on a strong growth path in 2014-15, after a tough year battling price control and trade issues. On the whole, it expects growth of 12-14 per cent. Pankaj Patel, chairman and managing director, Cadila Healthcare, said: "We expect the market to pick up after June-July and the growth should be in double digits. Last year, there was some shrinkage in revenue as prices of several essential drugs came under control."

Publication: The Financial Express

Edition: National

Date: April 14, 2014

Headline: [We don't just sell products here](#)

Synopsis: GE Healthcare, a unit of General Electric Company, is focusing on some of the toughest healthcare challenges of India—lowering maternal and infant deaths, enable early detection of cancer for early treatment, addressing heart disease burden etc. It has committed \$1 billion over the next five years to developing molecular technologies for cancer diagnosis and imaging. In partnership with Cancer Treatment Services International (CTSI), GE Healthcare will be setting up 25 world-class centres across India to improve access to cancer care.