News Updates: April 23, 2014

Patents/ Compulsory Licensing/ Intellectual Property

Website: Moneycontrol
Edition: Online
Date: April 22, 2014
Headline: IPR mess: US to name India as an offender?

Synopsis: In just over a week from now, the United States Trade Representative will release the Special 301 report, an annual exercise of the US administration, where countries with poor intellectual property rights (IPR) compliance are named and shamed. This year, there are concerns across the Indian industry and the highest levels of the government, that India could be designated as a serious IPR offender, which could lead to sanctions. However, experts believe it won't be easy for the US to put trade restrictions on India citing IPR violations.

Similar report in-

Pharmabiz- India not to budge under US pressure on IPR issues

Clinical Trials

Publication: The Hindustan Times
Edition: National
Date: April 23, 2014
Headline: There's a lot at stake

Synopsis: The controversy regarding clinical trials in India is far from over. A new chapter was added to the saga on Monday when the Supreme Court pulled up the Union government for not ensuring that foreign pharmaceutical majors compensate those who suffer adverse effects during trials. The court was hearing a public interest litigation filed by a Pune-based NGO, Swasthya Adhikar Manch, which alleged that many patients in India have been used by pharma giants as "guinea pigs" for clinical trials of new pharmaceutical compounds with not enough emphasis on the safety of patients and whether the compounds being tested on volunteers are needed by India. While the Union health ministry's lawyer conceded that the ministry had not looked into this aspect and sought time to revert to the apex court with explanations from the ministry, the advocate appearing on behalf of one of the complainants observed that rules had been in place since 2005, mandating payment of compensation to those seriously affected by such trials.

Similar reports in-

The Times of India (Kochi)- Clinical trial deaths: SC pulls up govt (link unavailable, scan attached)
Pharmabiz- Supreme Court asks Centre to submit details on deaths, SAEs during clinical trials
The Western Times (Ahmedabad)- Government must facilitate compensation for clinical trial victims: SC (link unavailable, scan attached)

Drug pricing

Publication: Business Standard
Edition: National
Date: April 23, 2014
Headline: GSK slashes price of Crocin tablets

Synopsis: GlaxoSmithKline Asia has slashed the price of fever and pain-relief pill Crocin Advance

tablets across the country by around 50 per cent in order to conform to the price notified under DPCO, 2013. GlaxoSmithKline Asia (GSKAP), which takes care of all non-nutrition products, has decided to reduce the price of the drug after getting a response from National Pharmaceuticals Pricing Authority (NPPA) on the application seeking exemption for Crocin Advance Paracetamol Fast Release 500 mg tablet under the provisions of the Drugs Price Control Order (DPCO), 2013.

Similar reports in-

The Hindu Business Line- **Cheap Crocin Advance likely to be on sale soon**
The Hindu- **Crocin Advance in short supply**
The Financial Express- **GlaxoSmithKline Asia slashes price of Crocin tablets**
The Financial Chronicle- GSK slashes price of Crocin tablets (link unavailable, scan attached)
Pharmabiz- **Crocin Advance at DPCO price may take some time to reach retail outlets**

Drug quality

Publication: Business Today
Edition: Online
Date: April 22, 2014
Headline: **DCGI to look into drug quality issues flagged by Vietnam**

Synopsis: In the light of Vietnam raising concerns over quality of drugs being exported by some of Indian pharma companies, G N Singh, the Drug Controller General of India (DCGI), said the matter is being looking into. Vietnam has reportedly voiced these concerns in over 40 companies, mostly tier-II pharma companies.

FDA

Website: Reuters
Edition: Online
Date: April 23, 2014
Headline: **FDA proposes program to speed approval of medical devices**

Synopsis: The U.S. Food and Drug Administration on Tuesday proposed speeding up medical device approvals for patients who have no other treatment options through a new program focused on earlier and more frequent interactions between companies and FDA staff. The Expedited Access Premarket Approval Application program is a response to criticisms by policymakers, patient groups and industry that the FDA process for approving medical devices is inefficient and slow, delaying patients' access to new, helpful products.

General Industry

Publication: The Economic Times
Edition: National
Date: April 23, 2014
Headline: **Novartis buys GSK's cancer drugs for $14.5 billion in a 3-way deal**

Synopsis: Amidst a flurry of consolidation in the pharma industry, global pharmaceutical giants GlaxoSmithKline and Novartis announced a massive threeway deal that will see the rivals exchanging asset portfolios, and merging the consumer health businesses in a new joint venture. GSK will sell its portfolio of cancer drugs to Novartis for $14.5 billion, plus another $1.5 billion, depending on trials in progress.

Similar reports in-

Mint- **Novartis, Glaxo in deal to transform firms, industry**
The Times of India- **Novartis buys Glaxo's cancer arm for $16 billion**
The Hindu Business Line- **Pharma giants Novartis, GSK swap assets in $23-b deal**
The Hindustan Times- **GSK, Novartis unveil major billion-dollar drug deal**

Business Standard- Novartis-GSK-Eli Lilly deal may affect Indian market
The Financial Express- GlaxoSmithKline swaps oncology for vaccines with Novartis AG
The Indian Express- Novartis, GSK, Eli Lilly trade assets as global pharma industry reshapes

Website: Pharmabiz
Edition: Online
Date: April 23, 2014
Headline: Bearing Ranbaxy Burden

Synopsis: The takeover of Daiichi Sankyo owned Ranbaxy Labs by Sun Pharmaceuticals for $4 billion including a $800 million liability early this month surprised quite a few in the Indian pharmaceutical industry. There was hardly any indication of such a move in the industry circles especially when Ranbaxy has been grappling with a steady rise in losses over the years and mounting regulatory issues with the US FDA with regard to its exports to the US market. When Ranbaxy was first sold to the Japanese giant, Daiichi, in 2008 it gave a shock to the domestic pharmaceutical industry as the company has been doing extremely well and many thought that a sell off was uncalled for. Now with the management control shifting to Sun Pharma, consolidated net sales of both the entities could be above Rs. 26,000 crore in the current year. Under the transaction, expected to be completed by this year end, shareholders of Ranbaxy will receive four shares of Sun Pharma for every five they hold. Daiichi will become the second largest shareholder in Sun Pharma with around 8.9% stake. The merger of Sun Pharma and Ranbaxy will make the combined entity the fifth largest generics company in the world and the largest pharmaceutical company in India.