



News Updates: May 9, 2014

Patents/ Compulsory Licensing/ Intellectual Property

Publication: The Economic Times

Edition: National

Date: May 9, 2014

Headline: [Pfizer, Roche end association with US-India Business Council](#)

Synopsis: Tension over intellectual property rights (IPR) between the US and India has led to cracks in the US India Business Council (USIBC), a grouping of hundreds of companies present in both countries, to the extent that a section of Big Pharma has chosen to end its association with the organisation seemingly in a huff.

Pfizer Inc and Roche are no longer part of the lobby group. This followed the USIBC urging US government agencies against punishing India for perceived deterioration of the IPR environment in the country, two persons with direct knowledge of the matter told ET. Pfizer is headquartered in the US and Roche is based in Switzerland.

Clinical Trials

Publication: Daily News & Analysis

Edition: National

Date: May 9, 2014

Opinion piece: Dinesh C Sharma, science journalist based in New Delhi

Headline: [When errors can turn fatal](#)

Synopsis: Nobody can deny that testing new drugs, treatment methods and health technologies among humans is necessary for overall progress of health science and for the resulting benefits to flow to the general population. This is the only way health science has progressed and given us new medicines, vaccines and diagnostic tools. Scientific evidence emerging from field trials in different settings is also necessary for governments to take key decisions relating to health policies such as screening for different diseases, preventive vaccination or introduction of new drugs in publicly funded programmes. However, clinical trials involving human subjects have to be conducted in an ethical manner and in a way that does not potentially harm people who volunteer to participate in such trials. This is the biggest challenge facing health research today.

FDA

Publication: The Economic Times

Edition: Online

Date: May 8, 2014

Headline: [Pharma exports to US unaffected by import alerts: Ind-Ra](#)

Synopsis: Indian pharmaceutical exports to the US is expected to keep growing despite a spate of import alerts issued by the US Food and Drug Administration (US FDA) in 2013, according to India Ratings & Research (Ind-Ra) report here. Ind-Ra believes that potential for the domestic pharma industry to grow at around 20 per cent CAGR over the next five years is intact. This is despite the agency's expectation of an increase in US FDA inspections in line with the US' increasing dependence on Indian pharmaceuticals and the bad press attracted by them in recent times, the report said.

Similar reports in-

Business Standard- [Pharma exports to US unaffected by import alerts: Ind-Ra](#)

The Financial Express- [Pharma exports to US unaffected by import alerts: Ind-Ra](#)

Drug regulation/ Drug pricing

Publication: The Hindu Business Line

Edition: National

Date: May 9, 2014

Headline: [Drug price regulator going after major violators](#)

Synopsis: Less is more seems to be the mantra of the central authority that monitors drug prices in India, especially when it comes to rapping companies for overcharging on medicines. Two years ago, the National Pharmaceutical Pricing Authority (NPPA) initiated 103 cases against drug companies for overcharging on medicines, demanding ₹128 crore as the overcharged amount. In 2013-14 though, the NPPA initiated just 89 cases but demanded Rs.384 crore, more than double the previous year's penalty, as the overcharged amount. So, was the NPPA less active last year? Or did it just change tack to go after major violators?

Publication: The Hindu

Edition: National

Date: May 9, 2014

Headline: [Drug authority cracks down on errant pharmacies](#)

Synopsis: As part of a special drive, inspectors from the Drug Control Administration (DCA) initiated legal action against 45 pharmacies that were apparently selling habit-forming drugs, and six other shops selling antibiotics without a prescription. During the course of the raids, taken up between Wednesday and Thursday, the DCA team also identified drug companies selling drugs more than the ceiling price fixed under the Central Government's Drugs Price Control Order (DPCO). These include FDC Ltd, Goa (Zocon-50 DT 50mg – Fluconazole), Alkem Laboratories, Sikkim (Ondem 2 ml Injection – Ondansetron), Torrent Pharma, Sikkim (Betacard-100 – Atenolol), Torrent Pharmaceuticals, Sikkim (Dilzem-60 tab – Diltiazem) and Cipla, Solan (Azee-500 – Azithromycin) tablets.

Drug quality

Publication: BusinessWorld

Edition: Online

Date: May 8, 2014

Headline: [Indian Drug Cos Get Foreign Experts For Quality Check](#)

Synopsis: Like Wockhardt, many Indian drug makers are increasingly using the services of global standard quality assurance companies like Intertek, SGS and BV to ensure the products they manufacture conform to the quality benchmarks set by regulators like the US FDA. Their role is to find shortfalls in manufacturing processes from sourcing to data maintenance and across the drug supply chain.

General Industry

Publication: The Economic Times

Edition: National

Date: May 9, 2014

Headline: [Sun Pharma recalls over 4 lakh bottles of two drugs in US](#)

Synopsis: Drug major Sun Pharmaceuticals is recalling over 4 lakh bottles of anti-depressant and anti-allergy drugs in the US for failing to meet specifications. The recalls of anti-depressant Venlafaxine Hydrochloride extended release tablets of different strengths and anti-allergy Cetirizine Hydrochloride chewable tablets are being made by Caraco Pharmaceutical Laboratories, the US arm of Sun Pharma.

Similar reports in-

Mint- [Sun Pharma recalls 400,000 bottles of drugs in US: FDA](#)

The Times of India- [Sun Pharma recalls two drugs in US](#)

The Financial Express- [Sun Pharmaceuticals recalls over 2.5 lakh bottles of anti-depressant in US](#)

Website: Pharmabiz

Edition: Online

Date: May 9, 2014

Headline: [Protectionist steps by foreign countries led to fall in exports of pharma products from India](#)

Synopsis: Increased restrictions and protectionism by several countries have led to the fall of exports in pharmaceutical sector in the last financial year, according to Pharmexcil which recently held an assessment on the scenario with the industry. "Every country is trying to bolster their capabilities in generics sector and wants to be self-sufficient. They are encouraging investments, but discouraging imports with rigid regulatory regimes and by delaying registrations for our products," said Pharmexcil director general Dr P V Appaji.