



News Updates: March 6, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Times Of India

Edition: National

Date: March 6, 2014

Headline: [‘Lobbies shouldn't hurt Indo-US ties: Rajeev Kher’](#)

Synopsis: Mr. Kher in his interview highlighted that India-US trade relations should not be held hostage by lobby groups, in what is a veiled attack on the pharma industry. He also discussed his strategy to boost exports.

Publication: Bloomberg Businessweek

Edition: Online

Date: March 6, 2014

Headline: [Life-Saving Medicine, High Costs, and the Intractable Patent Puzzle](#)

Synopsis: The report highlights that the problem of affordable medicine goes far beyond India and Egypt, reaching into even the wealthiest economies. The monthly costs of many cancer drugs now exceed \$10,000 and a few are more than triple that amount. Patents on drugs give the manufacturers a monopoly—in the U.S. it lasts 20 years from the date of filing—so the costs of research and development can be recouped and revenues can be invested in new innovations (along with profit for shareholders). The U.S. has pushed to broaden patents and other intellectual-property protections around the globe through trade agreements.

Publication: The Hindu Business Line

Edition: National

Date: March 6, 2014

Headline: [India-US trade stand-off: a tale of two reports](#)

Synopsis: The television drama The West Wing, set in the White House, bears an uncanny resemblance to the trade tug-of-war seen at present between India and the US. Recent episodes of the programme show US officials getting involved in heated back-room activity on intellectual property (IP) and protests from US knowledge-worker unions as jobs get “vacuumed” out to India. The political drama may not be too far from the truth, as India finds itself in the eye of a trade-related storm in the US, with much of the fury directed at India’s track-record of protecting IP, after the country amended its Patents Act in 2005.

Publication: The Economic Times

Edition: Mumbai, Pune

Date: March 6, 2014

Headline: [Cos Need to Review Drug Discovery Strategies, Says J&J's Hait \(link unavailable, scan attached\)](#)

Synopsis: Pharmaceutical companies, which are stuck with patent issues, need to take a relook at their strategies when it comes to drug discovery Bill Hait, global head, Janssen Research and Development, the research arm of Johnson and Johnson, told ET. Hait, who was in India last week, asserted that drug companies still don’t understand the science and biology behind diseases, which are leading to failures in drug discovery.

Publication: The Times Of India

Edition: National

Date: March 6, 2014

Headline: [Patent filing fees doubled for cos, up 60% for individuals](#)

Synopsis: Invention and innovation will now cost more. In one of the largest increases, fees for patent filings made with the Indian regulatory authorities have doubled for companies, while those made by individuals have seen a 60% increase. Also, to give a leg-up to innovation in small and mid-sized companies and startups, a new category of 'small entity' has been introduced as an amendment in the Indian Patent Rules. This is the first major increase in fees for patent filings since 2004, industry experts say. While patent filings for individuals have increased to Rs 1,600 by 60%, those for large firms doubled to Rs 8,000 for every application filed with the Indian Patent Office.

Publication: The Telegraph

Edition: National

Date: March 6, 2014

Headline: [Strategic Miscalculations](#)

Synopsis: The United States of America is, once again, not managing its relations with India well. Gains made during George W. Bush's presidency in building strategic trust between the two countries are being steadily frittered away by wrong steps taken by the Obama administration, which seems to have taken its eyes off the India ball. Blame for this is being laid at India's door, with the argument that India has not lived up to American expectations, that we have been sitting on the fence, unwilling to grasp firmly the hand extended by the US because of our non-aligned obsessions resurfacing as "strategic autonomy".

Clinical Trials

Website: Moneycontrol

Edition: Online

Date: March 5, 2014

Headline: [Delay in clinical trials approval affecting pharma sector](#)

Synopsis: India's pharma sector, which has the potential to be one of the best in the world of innovation is nowhere in dispute but players say delays in approvals for clinical trials, which is crucial to launch a new drug in the market, is holding the industry back. Launching a new drug in India, whether a completely new molecule or a generic one, has become a herculean task. The Supreme Court's recent dictat that the government review 157 clinical trials has delayed fresh approvals.

Publication: The Times Of India

Edition: Online

Date: March 5, 2014

Headline: [Johnson & Johnson hands over clinical trial data to Yale University to be publicly accessible](#)

Synopsis: The campaign to bring all clinical trial data into the public domain got a shot in the arm with Johnson & Johnson making all its drug trial data available to Yale University. J&J is the first company to hand over all its trial data to a completely independent third party, the Yale University Open Data Access (YODA) project. Pharma giants like GSK, Pfizer and Roche had earlier announced that they would make their trial data available, but only on their own web portals where researchers would have to apply to be given access to the data. Harlan Krumholz, principal investigator on the YODA project has stressed that YODA's advantage lay in its credibility as an independent body that would not impede access to data, but would ensure its responsible use.

FDA

Publication: The Economic Times

Edition: National

Date: March 6, 2014

Headline: [India criticizes US whistleblower policy; says it may lead to policy abuse by sore staff](#)

Synopsis: India has called for a review of the US whistleblower policy as it feels that the generous incentives offered by the US drug regulator to employees for revealing malpractices in their companies may encourage disgruntled executives to tamper with data to use against their employers. "We feel the whistleblower policy may be suitably reviewed to avoid a possible misuse of it just to earn high rewards," said a government official. The government has, in a 'non-paper' issued to the US Food and Drug Administration, said some aggrieved employees may fudge data in the hope of reaping huge rewards. A non-paper is an informal paper to discuss sensitive issues without elevating it to a formal or final position.

Drug Regulation

Publication: The Times Of India

Edition: Delhi

Date: March 6, 2014

Headline: [Antibiotics, syrups need prescription](#)

Synopsis: Now, you will need a doctor's prescription for buying common antibiotics, certain pain-relievers, anxiety-busters and sleeping pills. Retail chemists have started asking for prescriptions while dispensing 46 medicines across therapies—these cover over 7,000 formulations in the domestic market. The sale restrictions apply to popular antibiotics, best-selling cough syrups like Corex and certain anti-tuberculosis medicines, all of which used to be easily available over the counter. The new rules kicked in this month, following a government notification to restrict abuse of antibiotics and anxiety depressants. That's not all. These medicines will undergo a change in packaging and will be sold with a boxed warning. Firms are in the process of changing the packaging so as to display the drug formulation with the symbol 'Rx' in red conspicuously displayed in the left top corner of the label.

Generics

Publication: The Economic Times

Edition: Mumbai

Date: March 6, 2014

Headline: [Drug Cos Switch Focus to Complex Generics for Higher Margins \(link unavailable, scan attached\)](#)

Synopsis: Indian pharmaceutical companies are increasingly shifting their focus to complex generics in regulated markets, attracted by high margins and less intense competition in that space. They are also increasing their R&D spending significantly to line up a healthy complex generics pipeline, analysts and industry experts said.

Innovation

Publication: The Hindu Business Line

Edition: National

Date: March 6, 2014

Headline: [Learning to expect the unexpected](#)

Synopsis: Why is it that some companies continue to find themselves being pushed out of the marketplace, their competitive edges eroded and their margins under increasing pressure? Why is it that every once in a while, a perfectly good, innovative, profitable company suddenly finds itself out of business, displaced by something completely unexpected? Welcome to the world of disruptive innovation.

General Industry

Publication: The Hindu Business Line

Edition: National

Date: March 6, 2014

Headline: ['Need more PPP projects in healthcare'](#)

Synopsis: India's rising healthcare needs require quality infrastructure — about 6.5 lakh additional beds — which entail an investment of Rs 1.65 lakh crore by 2017, a white paper on public-private-partnership in healthcare said. The paper 'Public-Private People Partnership: Winning in Collaboration,' which calls for more and better collaboration between private and public entities in healthcare, was presented to President Pranab Mukherjee by the Healthcare Alliance on Tuesday.

Publication: The Hindu Business Line

Edition: National

Date: March 6, 2014

Headline: Prescription drug abuse is growing in India, says UN report (link unavailable, scan attached)

Synopsis: Prescription drug abuse is growing in India and the problem is serious in South Asia, according to a UN report, which said drugs enter the region's illicit markets through various channels, being diverted from India's pharma industry and smuggled from Afghanistan.

Similar reports in-

The Economic Times- [Prescription drug abuse growing in India: UN report](#)

The Indian Express- [Prescription drug abuse growing in India: UN report](#)

Firstpost- [Growing prescription drug abuse in India says UN report](#)

Publication: The Financial Express

Edition: National

Date: March 6, 2014

Headline: [Top cos to shell out Rs 10K cr for CSR; ONGC, Reliance Industries big spenders](#)

Synopsis: The country's top listed companies belonging to S&P BSE 500 index would have to shell out nearly Rs 10,054 crore on corporate social responsibility (CSR) activities in the coming fiscal. Going by the recently notified CSR norms that come into effect starting next month, 441 of the BSE 500 companies would be required to mandatorily contribute 2% of their average total net profit for last three fiscals towards CSR activities in the fiscal 2015.