



News Updates: November 14, 2013

Fire In The Blood

Publication: The New Indian Express

Edition: National

Date: November 14, 2013

Headline: [Film Festivals: Crossing the thresholds of entertainment](#)

Synopsis: Dylan Mohan Gray, director of Fire in the Blood, says "Film festivals are essential for independent films, especially if you want to reach global audiences. Of course, it's very difficult to get selected for the top festivals, so this option is not open to every film. Fire in the Blood has played in a lot of festivals in about 25 countries, winning a number of awards, and this has made a huge difference, both in terms of the profile of the film as well as international sales of the rights."

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: Mint

Edition: National

Date: November 14, 2013

Headline: [US Supreme Court rejects Teva stay request in Copaxone case](#)

Synopsis: A US Supreme Court justice on Wednesday declined a request from Teva Pharmaceutical Industries Ltd for a stay of an appeals court ruling that would strip the company's \$4 billion-a-year multiple sclerosis drug Copaxone of patent protection in 2014, rather than in 2015. In July, the US Court of Appeals for the Federal Circuit issued a decision in a patent fight that pits Teva against two teams developing cheaper generic forms of Copaxone: one with Novartis AG and Momenta Pharmaceuticals Inc.; and another between Mylan Inc. and Natco Pharma Ltd.

Publication: The Financial Express

Edition: National

Date: November 14, 2013

Headline: [Wockhardt wins trademark battle against Kameron Labs](#)

Synopsis: The Intellectual Property Appellate Board (IPAB) has revoked the 'Zecodex' mark given to Gujarat-based Kameron Laboratories on an appeal filed by Wockhardt, saying that the trademark is deceptively similar to the one owned by the latter. The applicant, Wockhardt, during the course of its business started using various distinctive trademarks in order to distinguish its goods from those of its competitors and one such trade mark is 'Zedex', which the applicant adopted in the year 1983.

Publication: Daily News and Analysis

Edition: National

Date: November 14, 2013

Headline: [Good governance is key to a healthy, wealthy India](#)

Synopsis: The appalling state of the medical industry was discussed at a forum in the city, with a focus on improving healthcare accessibility and affordability. The gathering on the final day of the Forum and Workshops on Affordable Healthcare and Water in India at Indian Institute of Management, Bangalore were exposed to the gory state of affairs in healthcare industry as well as the roadmap to a better future. India spends 4.1% of its Gross Domestic Product on healthcare and only 1% is by the state, stated Ashok GC, advocate and managing partner at

CorLit Legal, who also explained the role of patenting in clinical research.

Publication: The New Indian Express

Edition: National

Date: November 14, 2013

Headline: [DRL Anti-blood clot drug to hit canada](#)

Synopsis: Dr Reddy's Laboratories Ltd (DRL) will launch its complex generic drug Fondaparinux sodium injection in Canada and two other emerging markets. Fondaparinux is used for treatment and prevention of deep vein thrombosis and is sold under the brand name Arixtra by GSK. DRL will manufacture the drug under licence using a patented process developed by Alchemia. "In addition, the company is pleased to note that Dr Reddy's has filed generic applications for Fondaparinux with local regulatory authorities in two additional emerging markets," it added. In July 2010, DRL signed an agreement with Alchemia and as per the agreement, DRL will pay Alchemia a royalty on sales at an agreed proportion besides having an option to market the drug itself or enter into agreements with third parties.

Clinical Research / Trials

Publication: Daily News and Analysis

Edition: National

Date: November 14, 2013

Headline: [Frequent fatigue in children a warning signal](#)

Synopsis: Juvenile diabetes occurs when an autoimmune disorder in the body stops the release of insulin. "There is an urgent need to develop more effective technologies for diabetes. It is only through clinical research that we will be able to find cures," says Dr Vyankatesh Shivane, joint director of the Research Health Institute in Diabetes Endocrinology and Metabolism in Mumbai.

Publication: Pharmabiz

Edition: Online

Date: November 14, 2013

Headline: [DBT launches INCRE programme to create pool of trained clinical researchers in neuroscience](#)

Synopsis: Aiming to create a pool of trained clinical researchers in the area of neuroscience, the department of biotechnology (DBT) has launched a fellowship programme called 'Initiative on Neuro-Clinical Research Education (INCRE)'. According to senior officials in the DBT, the department is keen towards creating of a pool of trained clinical researchers in the area of neuroscience. The shortfall of clinical researchers is a crisis that will heavily impact the research scenario of neuroscience research. Recognizing this critical need for neuro-researchers, the department has dedicated its HRD efforts towards investing in young clinicians with an aptitude and interest in neuro-clinical research.

Publication: Pharmabiz

Edition: Online

Date: November 14, 2013

Headline: [ISCR concerned over lack of new drugs for juvenile diabetics on Children's Day & World Diabetes Day](#)

Synopsis: Indian Society for Clinical Research (ISCR) is concerned about stalling of clinical trials which prevents access to novel drugs for juvenile diabetics in the country. On the occasion of both Children's Day and World Diabetes Day observed annually on November 14, the irony is that there is no permanent cure for juvenile diabetes and at the best, the disease can only be kept under control with drugs. There have been several global juvenile diabetic trials conducted in India. However for the future these human studies look doubtful going by the current unpredictable regulatory environment in the country which has derailed the clinical research. All efforts to

carry out human studies to find safer and better cures for existing diseases including juvenile diabetes are stalled, said Suneela Thatte, president, ISCR told Pharmabiz in a telecon. "We are in a situation in the country where new clinical trials have almost come to a standstill due to regulatory and other external challenges. In this regard the ISCR was distressed on the kind on future or hope of better treatment or cure that could be offered growing diabetic population and when India had already earned the dubious distinction of being termed the 'diabetes capital of the world'," she pointed out.

Publication: Pharmabiz

Edition: Online

Date: November 14, 2013

Headline: [Public interest groups demand review of legal framework for trials to protect subjects](#)

Synopsis: Public interest groups, which moved the Supreme Court over the unethical trial of HPV vaccine by PATH, have sought re-examination of the current ethical and legal framework to conduct drugs/vaccine trials in India to secure stronger protections for human subject participants. The NGOs, armed with the report of the Parliamentary Standing Committee on the matter, alleged that violation of the right to health of thousands of young girls happened during the unethical conduct of HPV vaccine in Andhra Pradesh and Gujarat, between 2009 and 2010 by PATH in collaboration with the ICMR. Apart from addressing the doubtful claims about the safety and efficacy of the vaccines involved, the NGOs have also sought to hold PATH and others liable for their illegal actions under the current ethical, penal and regulatory framework to protect subject of biomedical research provided under Schedule Y of the Drugs and Cosmetics Rules, 1945 and the Good Clinical Practice Guidelines and ICMR Guidelines, which has led to the violation of the right to health of thousands of young girls involved in the vaccine trials.

Drug Pricing

Publication: MoneyControl

Edition: Online

Date: November 14, 2013

Headline: [H1 inline; Cipla Medpro fully integrated: Cipla MD](#)

Synopsis: Cipla MD & Global CEO Subhanu Saxena says he had signaled that the first 12-18 months in its roadmap was investing in the business for the future - particularly on people and also the pipeline to get in a position where it'll have sustainable platform for growth for the decade and beyond. With a very difficult operating environment in India in the second quarter with all the difficulties with Drug Pricing Control Order (DPCO) implementation etc, the market there grew just around 7 percent, our business grew 11 percent. So, what we have been able to do is to keep the focus on the key deliverables within the business and really look at managing our assets and our resources and costs effectively.

Publication: MoneyLife

Edition: National

Date: November 14, 2013

Headline: [Medicine prices: DPCO loopholes will deny cheaper essential drugs-Part2](#)

Synopsis: While market based pricing can potentially reduce rates for two-third essential medicines, there are far too many loopholes in the move. Pharma companies have exploited such escape routes in the past. According to the Drug Prices Control Order (DPCO), 2013 the ceiling price of essential medicines is fixed based on the simple average of the prices of all brands of that drug that have a market share of at least 1%. The national list of essential medicines lists 348 bulk drugs, which are sold as 650 formulations. The DPCO itself covers only 14 %-17% of the Rs75,000 crore pharma market, which means only a small subset of the market will be impacted. The good news is that for two-third essential medicines, there can be average price reduction of 22% (even though some reports claim reduction by 30%-40%). The bad news is that there are far too many loopholes to really see reduction in your chemist bill.

FDI

Publication: The Economic Times

Edition: National

Date: November 14, 2013

Headline: [India, Ukraine seek to broaden bilateral ties](#)

Synopsis: Seeking to broaden bilateral ties, India and Ukraine today explored ways to expand cooperation in diverse sectors such as trade, nuclear energy, coal mining, pharmaceuticals, healthcare and science and technology. Both sides held wide-ranging discussion to enhance cooperation in these sectors at the fifth session of the India-Ukraine Inter-Governmental Commission on Trade, Economic, Scientific, Technological, Industrial and Cultural Cooperation here. The session was chaired by Minister of State for External Affairs E Ahamed while the Ukrainian delegation was led by Ihor Mykolayovych Prasolov, Minister of Economic Development and Trade. Both sides agreed that there was vast untapped potential to increase trade beyond the existing level of USD 3.2 billion annually. They felt that removing temporary obstacles of visas and problems being faced by Indian pharmaceutical companies in export of medicine to Ukraine would help both the countries forge a truly comprehensive partnership. Pharmaceuticals constitute the bulk of India's exports to Ukraine amounting to about USD 375 million per annum. An MoU for cooperation in joint ventures and research in pharmaceuticals and bio-pharmaceuticals between the Ministry of Chemicals and Fertilisers and Ukrain's State Administration on Medicinal Products was also signed.

FDA

Publication: Mumbai Mirror

Edition: National

Date: November 14, 2013

Headline: [Now, pills missing from TB drug strips](#)

Synopsis: After wrong dosage was discovered in Sandoz's tuberculosis drug 4D, packs of its stronger variant have three pills instead of the stated four. Pharma major Sandoz, under government scrutiny over a faulty batch of tuberculosis combination drug '4D', is set to face more questions as another serious lapse in the company's quality control has come to light. Mirror had reported on Tuesday how some strips of Sandoz's 4D drug had wrong, and potentially damaging, dosage. The state Food and Drug Administration (FDA) has already ordered a recall of the suspect batch. The lapse was discovered even as the FDA wrote to the Drug Controller General of India, the national body that regulates pharmaceutical products and medical devices, asking it to recall the suspect 4D batch from across the country.

Innovation in India

Publication: Forbes

Edition: National

Date: November 14, 2013

Headline: [K Anji Reddy: Innovator Forever](#)

Synopsis: Anji Reddy himself never stuck with the routine. He would start something, pass it on, give directions for scaling up, and then move on to things that excited him. In the late 1980s, when their formulations business was about Rs 40 crore and DRL was ranked 45th in the country, he set the five-year revenue target at Rs 200 crore, the ranking for number 5, and himself moved on to build the drug discovery unit. If there was one person who embodied innovation, it was Dr Reddy, says Sanjiv Kaul, who leads the pharmaceutical and health care sector at private equity firm ChrysCapital India. Kaul's association with the late entrepreneur goes back 20 years. He finds it remarkable how absolutely consistent Dr Reddy's belief was in innovation and how in many ways, he was ahead of his time. "He believed he could have done so much more for pharmaceutical innovation in this country. He fought a lone battle in making India, not just DRL, a centre of excellence in pharmaceutical innovation, says Kaul. Even when he had retired from active business, Dr Reddy held a strong view on drug price control which the government was then contemplating, and which since his death has been put into practice. He thought it would hurt the cause of innovation. He believed the government should focus on lowering the prices of expensive drugs,

not of drugs that already cost below a rupee.

Publication: The Times of India

Edition: National

Date: November 14, 2013

Headline: [Docs' diagnosis: Integrated medicine is future](#)

Synopsis: Foreign doctors shared the stage with Sidda and Unani practitioners. There were discussions on wet cupping, mud bath, pancha kosha, antibiotics and angioplasty. The talks ranged from Obama's new medical care system to new innovations in health care in India's villages. Simply put, it was the West embracing the East. The international conference on Global Health Futures, organized by College of Medicine, UK and Soukya Foundation in collaboration with the Times Foundation at Whitefield reiterated that integrated medicine is the way forward in days to come. Doctors from across the globe flew down to Bangalore to discuss different healing traditions for chronic diseases.