



News Updates: February 08-10, 2014

Intellectual Property/Compulsory License/Patents

Publication: The Financial Chronicle

Edition: National

Date: February 10, 2014

Headline: [‘Relaxed local norms inviting wrath of big pharma’](#)

Synopsis: Indian generic drug makers are convinced that multinational drug innovating companies have been mounting pressure on the US government and independent agencies for punitive action in retaliation against the Indian government’s patent policy that seems to favour low-cost generics over expensive patented drugs. Local pharma companies, who mostly export to the US and account for a third of that country’s generic drugs market, say that the pressure has been mounting up since March 2012 when India modified its drugs policy.

Publication: Deccan Herald

Edition: Online

Date: February 10, 2014

Headline: [US pressure on patents to hit Indian pharma](#)

Synopsis: The US Chamber of Commerce calling on the government to ratchet up pressure on India over intellectual property rights, could help prevent Indian companies from producing cheap generic versions of medicines still under patent protection. In a submission to the Office of US Trade Representative (USTR) last week, the Chamber of Commerce requested that India be classified as a Priority Foreign Country, a tag given to the worst offenders when it comes to protecting intellectual property and one that could trigger trade sanctions.

Publication: The Hindustan Times

Edition: Online

Date: February 10, 2014

Headline: Academics, activists come to India's aid as patents face US lens (No link available...Scan attached)

Synopsis: Academics and activists in the US are coming to India’s defense as its trade and patent regimes come under intense scrutiny and criticism here beginning with a public hearing this week.

Publication: The Telegraph

Edition: Online

Date: February 09, 2014

Headline: [Bitter US pill on drug patents](#)

Synopsis: The US Chamber of Commerce has advised its government to ratchet up pressure on India over intellectual property rights and prevent it from producing cheap generic versions of medicines under patent protection. In a recommendation to the United States Trade Representative (USTR), the chamber requested it to label India as a Priority Foreign Country, a tag which is given to the worst offenders of patent rights. The only country on the list is Ukraine.

Publication: Pharmabiz

Edition: Online

Date: February 10, 2014

Headline: [IPA slams methodology used by US Chamber of Commerce to rank IP environment of India](#)

Synopsis: The Indian Pharmaceutical Alliance (IPA), representing large domestic drug-makers in India, has taken exception to the methodology that the Global Intellectual Property Centre (GIPC) of the US Chamber of Commerce adopted to rank India in the recent International Intellectual Property index. "The GIPC is pushing the US government to take immediate steps to bring very serious pressures on Indian government for the benefit of American companies operating in India, even if it is at the cost of the public health," the IPA said, commenting on the second edition of IP index, prepared by GIPC in collaboration with Pugatch Consilium.

Publication: The Financial Express

Edition: Online

Date: February 10, 2014

Headline: [US trade enforcement action likely against India, pharma companies to be hit](#)

Synopsis: The U.S. trade representative on Monday will announce a trade enforcement action tied to India, his office said, a move that could further rile relations after an incident last year involving the arrest and strip-search of an Indian consul. U.S. Trade Representative Michael Froman will discuss the action at a news conference at 2 p.m. (1900 GMT), his office said on Sunday night. The Office of the U.S. Trade Representative said it could offer no additional details. On Friday, the U.S. Chamber of Commerce called on Washington to ratchet up pressure on India over intellectual property rights, a move that could help prevent Indian companies from producing cheap generic versions of medicines still under patent protection.

Publication: The Financial Express

Edition: National

Date: February 08, 2014

Headline: [Bayer can appeal against rejection of patent: IPAB](#)

Synopsis: In a reprieve for German drug major Bayer Schering Pharma, the Intellectual Property Appellate Board (IPAB) has allowed the company to appeal against a patent office order refusing patent on its claim for invention of a pharma composition used in oral contraceptives. Pharma companies Cipla and Natco had objected to Bayer filing the appeal saying the time limit to file an appeal against an order had expired. They also said there were no valid reasons and sufficient cause in allowing the appeal after a delay of two months beyond the stipulated time limit of three months.

Publication: The Financial Express

Edition: National

Date: February 08, 2014

Headline: [Novartis sues Dr Reddy's Laboratories over patent infringement on cancer drug](#)

Synopsis: Swiss drug major Novartis has sued Dr Reddys Laboratories (DRL) in an American court stating the Hyderabad-headquartered company's plan to market and sell its own version of the blockbuster cancer drug Gleevec (imatinib mesylate) would infringe Novartis' patent. Novartis said in a Delaware federal court complaint that DRL's abbreviated new drug application (ANDA) would violate the patent for Gleevec issued in 2005. Novartis Pharmaceutical Corporation (NPC) holds an approved new drug application (NDA) for Gleevec tablets containing 100 mg and 400 mg, which was approved by the US Food and Drug Administration on April 18, 2003.

Publication: Business Standard

Edition: National

Date: February 8, 2014

Headline: [Biocon squares up against Roche claims on cancer drug](#)

Synopsis: Biocon has lashed out at Roche a day after the Swiss major secured an order from the Delhi High Court barring the Indian company from marketing its new drug, co-developed with Mylan, as a biosimilar of Swiss major's blockbuster drug Herceptin, used for the treatment of HER-2 positive breast cancer.

"It is an extremely shocking, but not unexpected development. This proceeding is an attempt by Roche to protect their market monopoly and prevent Indian patients from accessing a more affordable trastuzumab," Biocon said in a statement.

Drug Pricing/Pricing Policy

Publication: Pharmabiz

Edition: Online

Date: February 10, 2014

Headline: [India to press for simplification of laws on generics during meeting with US FDA commissioner](#)

Synopsis: India is expected to press for simplifying the guidelines and clauses for generic exports to the United States during the talks with US Food and Drug Administration (US FDA) Commissioner Margaret A Hamburg, who is slated to visit India from February 10 to 18. The matter of simplification of laws for generics would be taken up in the wake of the recent instances of increased scrutiny by the US authorities on Indian companies putting pressure on the generic export. The issue is expected to come up in her meeting with her counterpart and also the industry captains from India.

Publication: Indian Express

Edition: Online

Date: February 10, 2014

Headline: [Poorest of poor should have access to sophisticated healthcare, says L-G](#)

Synopsis: Lieutenant-Governor Najeeb Jung on Sunday called for more investments in health sector to ensure the "poorest of poor have access to sophisticated healthcare". Speaking at an event to commemorate 25 years of the Fortis Escorts Research Institute in the capital, Jung said, "When I was growing up in Delhi, we had just one large hospital, which was then known as Irwin hospital. As time progressed new hospitals have come up. While talking about them, we in the outside world say (they are) five-star hotelsand that's really a problem for me.. because as a public person I am concerned about the availability of sophisticated medical facility for the poorest of the poor."

Publication: The Hindu

Edition: National

Date: February 8, 2014

Headline: [India among key players in generic drug market](#)

Synopsis: India was among key players in generic drug market with eight of its companies figuring among the top 25 companies in the world that accounted for 28 per cent of global generics market. The global generic market in 2012 was estimated at \$ 225 billion, a meeting organised by the Confederation of Indian Industry with the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers was informed.

Publication: Business Standard

Edition: National

Date: February 9, 2014

Headline: [India to flag market access of drugs and spices with US](#)

Synopsis: India and the United States will try to reach Monday a framework to deal with safety concerns and access of Indian drugs, fruits and spices in the American market that have become an irritant in bilateral relations, besides exploring new areas of collaboration. Indian policy makers will take up with visiting US Food and Drug Administration (FDA) Commissioner Margaret A. Hamburg all the issues ranging from the quality of products and safety standards in Indian pharmaceutical plants raised by the FDA and access of certain foods, fruits and spices to the US market, sources said.

Drug regulation/FDA

Publication: The Hindu Business Line

Edition: National

Date: February 08, 2014

Headline: [Govt to take up pharma issues with US](#)

Synopsis: Stung by a string of actions by the US drug regulator against Indian pharmaceutical manufacturers, the Commerce Ministry says it will put forth its concerns to US authorities. Commerce and Industry Minister Anand Sharma will take up the matter with visiting US Food and Drug Administration (FDA) commissioner Margaret A Hamburg on Monday. He also plans to raise it with the US Trade Representative (USTR). India will caution the US against using quality issues as a plank to run down the entire generic industry in the country. Generic drugs are low-priced copies of patented medicines whose patents have expired.

Publication: The Hindu Business Line

Edition: National

Date: February 09, 2014

Headline: [Pharma sector's success under appreciated story'](#)

Synopsis: Disproportionate attention is being given to the regulatory scrutiny of the US Food and Drug Administration (USFDA) on Indian drug-makers, according to G V Prasad, Chairman, Dr Reddy's Laboratories Ltd. Responding to queries at a press conference in connection with BioAsia 2014 here, Prasad said the recent surge in regulatory restrictions on pharmaceutical companies was nothing but a part of the growing-up phenomena of the Indian pharma industry.

Publication: Business Standard

Edition: National

Date: February 10, 2014

Headline: [After ban on drug facilities, regulator comes calling](#)

Synopsis: Margaret A Hamburg, the first commissioner of the US Food and Drug Administration (US FDA) to visit India officially, will meet heads of major domestic pharma companies such as Ranbaxy, Wockhardt, Cadila Healthcare and Lupin in New Delhi, sources say. While this is Hamburg's first official visit to the country, starting Monday, the event assumes greater significance as it comes in the wake of the increasing international enforcements faced by the domestic drug manufacturing industry. India happens to be the second-largest supplier of low-cost generic medicines to the US.

Similar report in

The Telegraph-[Top US drug cop recce to plug gaps](#)

Publication: Business Standard

Edition: Online

Date: February 9, 2014

Headline: [DGCI's preventive cure](#)

Synopsis: The anti-corruption movement seems to have had its impact on the country's top drug regulator as well. The Drugs Controller General of India, whose mandate is to keep a tab on the quality and efficacy of medicines available in the country, has begun monitoring movements around his office, after installing CCTV cameras in his office premises because he suspects foul play. If only that would convince the US Food and Drug Administration not to censure Indian companies for their poor manufacturing practices.

Publication: Pharmabiz

Edition: Online

Date: February 10, 2014

Headline: [Need strong regulatory framework to monitor and implement D&C Act effectively: Experts](#)

Synopsis: Stressing the need to strengthen the initiatives towards better implementation of the Drugs & Cosmetics (D&C) Act and Rules across the country, experts in the pharmacy field have asked the Drugs Controller General of India (DCGI) to take immediate steps towards reducing the problem of availability of prescription drugs without a prescription. To ensure safety and health of the patients further, they wanted the Centre to urgently work on a short and long term, multi-pronged national strategy by taking all the stakeholders into confidence. This demand comes in the wake of high incidents of improper implementation of the D&C Act and Rules, especially lack of any uniform implementation as the extent and strictness of the same varies from the competence of the state drug licensing authorities (SLAs). This they fear is leading to malpractices like medical stores and pharmacies selling prescription only medicines without any prescription or proper prescription.

Publication: The Economic Times

Edition: Online

Date: February 10, 2014

Headline: [DCGI asks Novartis to explain 'violations' in papers on drug manufacture](#)

Synopsis: India's drug regulator has asked Novartis to explain "violations" in papers relating to the manufacturing origin of a veterinary drug, with a European agency having ruled that the document the Swiss company submitted was fake. This has prompted the watchdog to begin a wider inquiry into the records submitted by the company to assess whether any of the other documents it has filed with the Indian regulator's office are "fraudulent" in nature.

Publication: Business Standard

Edition: Online

Date: February 10, 2014

Headline: [Scanner on Novartis for giving 'fake' documents](#)

Synopsis: Swiss drug maker Novartis might face tough action from the country's drug regulator for allegedly giving fake documents while seeking renewal of registration for Tiamulin Hydrogen Fumerate (80 per cent granules), sources said. The Drugs Controller General of India (DCGI) has issued a show-cause notice to the company and could even suspend distribution and marketing of the product, a senior official in the regulator's office told Business Standard. "We are evaluating strong action against the company and drug alerts to all zones, sub-zones and state drug controllers have been issued," the official said.

Publication: The Asian Age

Edition: Kolkata

Date: February 08, 2014

Headline: [Pharma MNCs eye easy entry \(scan attached\)](#)

Synopsis: Indian pharmaceutical companies having manufacturing facilities with necessary approvals from well-regulated overseas markets would be potential takeover targets as setting up greenfield facilities take two- three years to become operational.

Publication: The Economic Times

Edition: Online

Date: February 9, 2014

Headline: [Government consulting stakeholders on Bill on drugs, medical devices](#)

Synopsis: In Government does not want to rush through a legislation aimed at regulating trade, manufacture and sale of drugs and medical devices and is instead carrying out consultations with various stakeholders. "For the bill to have maximum impact, it is important for us to consider the views of other ministries, the industry and the civil society. We do not wish to hastily push forward a draft Bill without listening to the views of all stakeholders," Minister of State for Health, Abu Hasem Khan Choudhury told PTI here.

Publication: The Asian Age

Edition: Online

Date: February 10, 2014

Headline: [Medical firms to stop plastic container use](#)

Synopsis: Indian pharmaceutical companies will have to stop using plastic or PET containers in liquid oral formulations meant for paediatric formulations, geriatrics, women in reproductive age group and pregnant women. Viewing adverse effects on drug formulations packed in plastic bottles, the government has decided to ban use of plastic/PET containers in liquid oral formulations and has given six months to the companies to switch over. The decision has been taken after concerns were raised about the safety of the plastic/pet containers used in the packing of pharmaceuticals, food and water.

General Industry News

Publication: The Hindu Business Line

Edition: National

Date: February 10, 2014

Headline: [How a little blue pill changed Cipla's fortunes](#)

Synopsis: Much before Pfizer's little blue pill Viagra was making waves around the world, India had its own version of an anti-impotence medication. Called Okasa Gold, the wonder drug was a pioneer in tackling erectile dysfunction. A forerunner to Viagra, it set the company firmly on the growth path in the 1930s. Cipla Chairman YK Hamied is very proud of the fact that his family was responsible for introducing the drug, 'a tonic for male impotence', in the land of the Kamasutra. The first drugs that were rolled out from the Cipla plant were marketed only in India. Then the company started supplying for the war, and the drugs went to Burma and South-East Asian countries. Drugs for diarrhoea, dysentery, trauma and malaria all went from India. Even today, Cipla is among the biggest suppliers of drugs to the world for anti-malarial, though right now it is mainly to Africa.

Publication: The Hindu Business Line

Edition: Online

Date: February 10, 2014

Headline: [PRESCRIPTION](#)

Synopsis: The Medical Council of India has approved a draft notification which makes it mandatory for doctors to write the prescription in capital letters to avoid illegibility amid complaints that chemists sometimes give wrong medicines because of similar sounding names of drugs. The draft notification will come into effect after its approval by the Health Ministry, official sources said.

Publication: DNA

Edition: Online

Date: February 9, 2014

Headline: [Indian origin man from Britain makes cancer treatment accessible, affordable in India](#)

Synopsis: Shashi Kant Baliyan, who is in India for three years, recalls how his Diwali holiday here took a new turn after he attended a medical conference in Hisar in Haryana in 2009 with a friend, a radiation oncologist. Moved by an insight gained during a vacation in India four years ago, a British citizen of Indian origin has launched an initiative that provides 22 hospitals across the country with the latest medical equipment to make cancer treatment accessible and affordable. Shashi Kant Baliyan, who is in India for three years, recalls how his Diwali holiday here took a new turn after he attended a medical conference in Hisar in Haryana in 2009 with a friend, a radiation oncologist.

"I realized that people had to travel far for cancer treatment. Even then most hospitals in smaller towns were not equipped with the right equipment to treat them. I went back to Britain and discussed it with a few friends after which I started shuttling between London and Delhi to do something concrete about this," Baliyan told.

Publication: The Financial Chronicle

Edition: National

Date: February 09, 2014

Headline: [On the road to recovery](#)

Synopsis: The Indian pharmaceuticals industry is undergoing a difficult time. With Indian pharma companies battling regulatory issues, both foreign and domestic, the sector may take a while to return to its good old days, despite a visible growth witnessed in the quarterly numbers.

Publication: Pharmabiz

Edition: Online

Date: February 10, 2014

Headline: [Immense opportunities await Indian pharma manufacturing industry: Study](#)

Synopsis: Immense opportunities are waiting for the Indian pharmaceutical industry, both at the domestic and at the global level, and the future will be extremely promising with many more milestones, according to a research study conducted by Dr G Selvaraju, former director of drugs control, Tamil Nadu for the Vinayaka Mission University, Salem, Tamil Nadu. While there are advantages to take pride in by the industry, there are also challenges to face with by the industry players and those hurdles need to be overcome in order to achieve sustainable growth in the future. Skilled workforce, low labour cost and opportunities for export are the major advantages of the Indian pharma industry, says the study.

Publication: The Hindu Business Line

Edition: National

Date: February 8, 2014

Headline: [Cluster development scheme for pharma units soon](#)

Synopsis: The Ministry of Chemicals and Fertilisers is set to unveil within a week a cluster development scheme that will enable pharma units in different clusters across the country to set up common facilities with financial assistance from the Government. "The scheme has received all the necessary approvals and will be announced next week," BK Singh, Director of Pharmaceuticals, Ministry of Chemicals and Fertilisers, said. Under the scheme, pharma clusters will get a financial aid of 70 per cent, up to a limit of Rs. 20 crore for each cluster, to set up common facilities such as effluent treatment, R&D laboratories, logistics and training facilities.

Publication: The Financial Express

Edition: National

Date: February 9, 2014

Headline: ['If we have to provide best-quality care, I cannot compromise on the use of technology. This has a necessary cost'](#)

Synopsis: Apollo Hospitals founder and chairman Dr Prathap C Reddy talks about taking advanced healthcare to small towns and villages, launching health-related IT services, and why India needs to go a long way to become a medical tourism hub.

Publication: The Hindu Business Line

Edition: Online

Date: February 9, 2014

Headline: [Mart to take GE medical devices to rural India](#)

Synopsis: Taking a cue from the success story in Bangladesh, rural marketing consultancy firm Mart is chalking out plans to introduce low-cost ultrasound devices in Indian villages.

Publication: The Times Of India

Edition: National

Date: February 9, 2014

Headline: [Rightful remedy](#)

Synopsis: Years ago I heard a doctor in India make the case that we did not need pain relief to the extent that people in the West did, because we believe that pain helps us develop spiritually and are therefore more willing to endure it. Attitudes such as these have done a great disservice to millions of our countrymen and women.

Ask the man, woman or child who is doubled over in pain whether they want pain relief. Our home care teams, who look after people with advancing cancers, ask this question time and again. The answer, not surprisingly, is an unequivocal "Yes!" And yet, adequate pain relief still continues to elude us. Why is this so?

The villain of the piece is an antiquated and cumbersome Act that owes its origins to our colonial past. The Narcotic Drugs and Psychotropic Substances (NDPS) Bill, through the multiple licensing procedures that have governed it, has made it well-nigh impossible to obtain and dispense opioids like oral morphine, so needed for pain that does not respect the limits of human endurance.

Publication: The Times Of India

Edition: National

Date: February 9, 2014

Headline: [First step to personalized medicine](#)

Synopsis: Cancer scientists in France have made "one of the first steps" toward the creation of personalized medicines targeted to combat an individual patient's breast cancer. By scanning all of the DNA— the entire genome — of more than 400 women with late stage breast cancer for the first time, researchers have provided "proof of principle" that the technique can be used to understand the genetic cause of cancer in an individual, and help design tailor-made drugs to target it.