News Updates: February 21, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: Mint
Edition: National
Date: February 21, 2014
Headline: India has to indicate its position on certain aspects of IPR: Kiran Mazumdar-Shaw

Synopsis: US lobby groups such as the US Trade Representative and the International Trade Commission are demanding trade sanctions against India if it does not take a tough stand on intellectual property rights, or IPR, after receiving several complaints from US pharmaceutical companies and government representatives against India's trade policies, particularly concerning the Indian Patents Act (2005). Local drug makers say the Indian government should not be bullied into taking decisions based on demands by such lobby groups. Kiran Mazumdar-Shaw, chairman and managing director, Biocon Ltd, in an interview said the US should not take action based on a trade body's request, while also explaining that India will have to find a middle path of working with big pharma.

Cipla's Partnership with MSD

Publication: The Hindu
Edition: National
Date: February 21, 2014
Headline: MSD, Cipla to co-market AIDS drug in India

Synopsis: In a significant development to help treat HIV/AIDS patients in India, U.S. pharmaceutical giant, MSD (Merck & Co), a leading player in HIV innovative treatment, and Cipla, the Indian pharmaceutical major, entered into an India-specific strategic partnership under which Cipla will have a non-exclusive licence to market, promote and distribute MSD's Raltegravir 400 mg tablet under a different brand name in India.

Similar reports in-
The Economic Times- Cipla to market MSD's HIV drug 'raltegravir' in India
Mint- Cipla to partner with US drug maker Merck to sell HIV drug in India
Business Standard- Cipla to market MSD's HIV drug 'raltegravir' in India
The Hindu Business Line- Cipla to sell MSD's HIV drug in India
The Times Of India- MSD and Cipla announce partnership for life-saving HIV drug

FDA

Publication: The Financial Chronicle
Edition: National
Date: February 21, 2014
Headline: Big pharma plans shift to electronic mode

Synopsis: Some of the large pharma companies in India are soon likely to move to an electronic training mode from the present manual system to have a higher accuracy while documenting data. This is an after effect of several probes initiated by US FDA and MHRA that eventually banned exports from various domestic drug manufacturers. Former deputy drug controller Kapil Bhargava pointed out "documentation" deficiencies are the most reported observation by the regulators compared with the total non-compliance reports (NCRs) which are almost 50 per cent. Another major concern according to him is that of data integrity.

FDI

Publication: The Times Of India
Edition: National
Date: February 21, 2014
Headline: Govt clears GlaxoSmithKline's Rs 6,400 crore FDI proposal

Synopsis: The government on Thursday cleared Rs 6,400 crore FDI proposal of global healthcare company GlaxoSmithKline to acquire additional 24.33 per cent stake in its India arm. The Cabinet Committee on Economic Affairs (CCEA) has approved the proposal of GlaxoSmithKline Pte Limited, Singapore for acquisition of 24.33 percent shares in existing Indian subsidiary company of GSK Group. The said acquisition "would be done by way of a voluntary open offer under SEBI (SAST Regulations) in the pharmaceutical sector," an official statement said on Thursday.

Similar reports in-
The Financial Express- GlaxoSmithKline's Rs 6,400 cr FDI proposal cleared by govt
The Financial Chronicle- GSK buyback, Hitachi's Prizm deal get cabinet go-ahead
The New Indian Express- Govt Clears GlaxoSmithKline's Rs 6,400 Cr FDI Proposal

Clinical Trials

Publication: The Pharma Times
Edition: National
Date: February 20, 2014
Headline: ACRO warns on Indian clinical-trial regulations

Synopsis: A "confusing, inconsistent and arbitrary" regulatory environment has seen the number of industry-sponsored clinical trials conducted in India fall by 66% from 256 in 2010 to 86 in 2013, says the US-based Association of Clinical Research Organizations (ACRO).
Citing data from the clinicaltrials.gov registry at a hearing on trade, investment and industrial policies in India organised by the United States International Trade Commission in Washington, John Lewis, ACRO's vice president of public affairs, called for a regulatory framework that "is reasonable and rooted in science, not politics".
He also warned that research "can be relocated to more hospitable countries to mitigate the direct economic damage".

Publication: The Times Of India
Edition: National
Date: February 21, 2014
Headline: Indian-origin doctor finds 'solution' to problem of organ preservation

Synopsis: A Mumbai-born doctor could well revolutionize the world of organ transplants. Dr Hemant Thatte, a senior cardiovascular surgeon at Harvard University who was born in Dadar and raised in Pune, has worked out a 21-chemical solution that could preserve a donated organ for up to a week before a transplant. "Preliminary studies have shown that hearts stored in SOMAH solution (as the new preservative is called) for 24 hours can be resuscitated without medicines as against other solutions that allow for only four hours," said Dr Thatte via email. In studies conducted on pigs, the solution has been effective in preserving tissues for up to a week.

Drug Regulatory/ Access

Website: Pharmabiz.com
Edition: Online
Date: February 20, 2014
Headline: IDMA & UL form alliance to help cos mitigate global regulatory scrutiny and boost compliance levels

Synopsis: Furthering its efforts to help Indian pharmaceutical companies mitigate regulatory scrutiny

and increase compliance levels, UL, a global leader in safety science, has entered into an alliance with the Indian Drug Manufacturers' Association (IDMA). Under this alliance, UL and IDMA will equip the industry with tools and training to enable Indian companies straddle rapid global growth in a highly competitive environment, while navigating complex regulatory issues.Through this alliance, UL and IDMA are hosting a summit to share best practices and trends in critical areas including GMP (Good Manufacturing Practices), CGMP (Current GMP), GCP (Good Clinical Practices), BiMo (Bio-medical research), Quality System Regulation (QSR), US FDA and regulatory compliance.

Similar report in-
Business Standard- IDMA ties-up with UL to help pharma cos meet compliance levels

---

Publication: The Times Of India
Edition: National
Date: February 21, 2014
Headline: Healthcare Alliance draws up strategies to address challenges

Synopsis: India's premier industry bodies and top global consulting firms will collectively draw up strategies to provide recommendations which will help address the crucial healthcare challenges of the nation and other countries. The conglomeration of industry leaders will work together under the initiative 'The Healthcare Alliance,' an entity developed by Dr Prathap C Reddy, chairman of Apollo Hospitals Group. The conglomeration would promote collaborative thinking, collective expertise and experience to lay the foundation for tomorrow's healthcare which would need to be collaborative, connected, accessible and smart, said Dr Reddy.

Publication: Mint
Edition: National
Date: February 21, 2014
Headline: Lok Sabha clears amended narcotics legislation

Synopsis: In a breakthrough for cancer patients, the Lok Sabha on Thursday cleared the amended narcotics legislation, getting terminally ill patients in India one step closer to unrestricted access to pain relief medicines including morphine.
The draft law simplifies licensing procedures for storage of morphine. If the Rajya Sabha clears it on Friday, cancer patients in India will have easier access to morphine for the first time since 1985 when the country enacted its narcotics law.

Publication: The Times Of India
Edition: National
Date: February 21, 2014
Headline: Stem cell bank, now affordable

Synopsis: The state health department admitted on Thursday that the unit for regenerative medicine, popularly known as stem cell therapy, at the School of Tropical Medicine (STM) does not have the mandatory permission from central agencies such as department of biotechnology (DBT), Indian Council of Medical Research (ICMR) and Drug
control General of India (DCGI).

Similar reports in-
The Hindustan Times- Health dept admits stem cell unit has no approval from central agencies (link unavailable, scan attached)
The Statesman- Mamata inaugurates medicine centre

General Industry

Publication: The Statesman

Edition: National
Date: February 21, 2014
Headline: More jobs in academics than industry: Survey

Synopsis: While there is an overall slowdown in the job market, the maximum number of high-end white collar vacancies being filled up at this point of time are in the area of academics ~ schools and colleges ~ followed by healthcare and engineers required in infrastructure projects.
An Assocham survey showed that almost 50 per cent of the jobs being advertised in newspapers relate to academics, although the trend may stay short-term since teaching jobs are mostly filled at the end of academic sessions, so that the schools and colleges re-open for new sessions with full faculty strength.