News Updates: February 15 - 17, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Financial Times
Edition: National
Date: February 17, 2014
Headline: Novartis puts pressure on India over patent abuse

Synopsis: The report talks about Novartis urging US and European governments to "apply pressure" on India to protect intellectual property and encourage investments. Joe Jimenez, chief executive of the Swiss drugmaker, urged India to follow China's example and embrace strong IP rights as a way to develop its economy.

Publication: The Economic Times
Edition: National
Date: February 17, 2014
Headline: Biocon, Mylan challenge ban on using Roche data

Synopsis: Bangalore-based and US generic drugmaker Mylan have challenged Delhi High Court's interim order which barred them from using Swiss drug innovator Roche's data to sell their jointly developed biosimilar version of breast cancer drug Trastuzumab.
In a relief of sorts for Biocon and Mylan, the court on Friday said it was not taking an immediate position on whether the two firms had the drug regulator's approval for the package insert they were using to sell their biosimilar version. "At present, there are two versions of the parties which are contrary to each other," said the court order.

Similar reports in-

The Financial Express - Mylan, Biocon move HC against order on biosimilar drug trials

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Website: Firstpost
Date: February 15, 2014
Headline: Doctor's group tells US, big pharma to get off India's back

Synopsis: A Geneva-based non-profit doctors association has criticised the US and its pharma lobby for exerting pressure on India over its patent laws, saying such actions undermine the global trading system. "Every country has the right to take steps to increase access to medicines and implement a patent system in line with its public health needs. We strongly object to the pressure exerted by the US on developing countries, including India, for using legal flexibilities to protect public health," Rohit Malpani of the Doctors Without Borders told the US International Trade Commission yesterday.

Publication: Business Standard
Edition: National
Date: February 14, 2014
Headline: Failing the smell test

Synopsis: Such is the general preoccupation with domestic issues, economic and political, that

even business people are mostly unaware of how much the rest of the world's (especially American) perceptions of India have changed in the last couple of years - in particular, its loss of attractiveness as a place for doing business. This is not because of one or other isolated issue; rather, it is a range of issues that have come to sour the international business mood - from policies that mandate local sourcing to massive tax disputes, from the violation of intellectual property rights to poor quality regulation, and from delayed and/or arbitrary government decision making to (yes) widespread corruption.

Union health secretary Keshav Desiraju

Publication: The Economic Times
Edition: National
Date: February 17, 2014
Headline: The curious case of health secretary Keshav Desiraju's transfer

Synopsis: The report talks about Mr. Desiraju's transfer seen as an unexpected decision by senior ministry officials, given the fact that he had been health secretary for just a year. According to them, by transferring him, the government appeared to be violating a Supreme Court order last October directing the government to ensure fixed tenures for bureaucrats -- to insulate them from political pulls and pressures.

Publication: The Hindu
Edition: National
Date: February 17, 2014
Headline: Centre draws flak over Health Secretary's transfer

Synopsis: The Centre has drawn flak from the public health community over the transfer of the former Health Secretary, Keshav Desiraju, last week. Medico Friend Circle, a national network of medical professionals and health activists, has demanded transparency in the government's handling of sensitive matters having wide-ranging implications on public health policies. The forum said it was deeply disturbed by the sudden transfer. "The claim that this is a routine transfer does not hold water given the recent events overseen by Mr. Desiraju for ensuring public and national health security interests are protected," the forum said in a statement issued at its 40th annual meet here.

Clinical Trials/ Drug Pricing

Publication: Business Standard
Edition: National
Date: February 15, 2014
Headline: Pharma companies shouldn't conduct clinical trials: Peter C Gøtzsche

Synopsis: Allowing pharmaceutical companies to conduct drug trials is the equivalent of a defendant alone presenting all the evidence to determine whether he is guilty or not, argues Peter C Gøtzsche, co-founder of The Cochrane Collaboration, a global independent network of health practitioners, researchers, patient advocates and others, and author of the recently released Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare. In a candid email interview with *Indulekha Aravind*, Denmark-based Gøtzsche, who is a specialist in internal medicine and has also worked with clinical trials and regulatory affairs in the pharma industry, explains what motivated him to write his controversially titled book, and why we need to be wary of Big Pharma.

Publication: The Times Of India
Edition: National
Date: February 17, 2014
Headline: Generic medicines ineffective: Raipur Medical College doctors

Synopsis: Doctors at Raipur Medical College (RMC) have complained to authorities about the ineffectiveness of certain free generic medicines being administered to patients in hospital. According to sources, several doctors and heads of departments (HoDs) have complained to the dean about generic medicines, including diclofenac (non-steroidal anti-inflammatory drug taken or applied to reduce inflammation and as an analgesic reducing pain in certain conditions). Complaints have also been received about pentazocine injection, used to treat pain and for anaesthetic purposes. Doctors say that pentazocine injection is totally ineffective and does not provide relief to patients. Confirming the complaints, Dr Vivek Choudhary, secretary of medical college council said they were being looked into.

FDA / Drug Regulatory / DCGI

Publication: The Economic Times
Edition: National
Date: February 14, 2014
Headline: FDAs Bitter Medicine has a Capsule of History

Synopsis: Three letters of the English alphabet are causing much pain of late to the Indian pharmaceutical industry: FDA. The Food and Drug Administration of the US is imposing bans on sales of drugs from Indian companies in America that do not meet its strict standards. Given the FDAs status, a negative decision has a global impact, so it's not surprising that its head, Dr.Margaret Hamburg, was treated with a mixture of grovel and resentment when she visited India this week. If Indian drug companies want to understand the spirit driving the FDA, perhaps they should consider the F part of its name as much as the D.

Publication: The Financial Express
Edition: National
Date: February 15, 2014
Headline: US may exclude Indian pharma cos from alerts in case of shortage

Synopsis: USFDA commissioner Margaret A Hamburg says problems encountered by FDA investigators in India are similar to those around the world. In an email interview to FE's Jayati Ghose, Hamburg says quality will be one of the highest priorities in 2014 for the FDA, adding that US may exclude Indian firms from import alerts if drugs are in shortage, albeit without compromising on their safety and efficacy.

Publication: The Times Of India
Edition: Chennai
Date: February 15, 2014
Headline: Nearly 7% of drug samples found to be substandard (link unavailable, scan attached)

Synopsis: Sample this bitter pill: Around 7% of the drug samples collected by the Directorate of Drugs Control last year were found to be either spurious or substandard.
Drug inspectors took samples of more than 5,500 drugs for testing from across the state from January to December 2013, of which 200 were found to be substandard. More than 20% of the substandard drugs were made by pharmaceutical companies in Puducherry and Himachal Pradesh.

Publication: The Hindu Business Line
Edition: National
Date: February 15, 2014
Headline: 'Made in India' no longer sounds good

Synopsis: In the past few days, one of India's top pharmaceutical companies had its last remaining

recognised plant de-recognised by the US Federal Drug Administration (FDA); the US Federal Aviation Administration downgraded India's aviation regulator leading to negative financial consequences for two of India's leading airlines; and an independent testing agency in Europe said that India's top-selling small cars don't meet international safety standards.

Publication: Business Standard
Edition: National
Date: February 15, 2014
Headline: Hamburg set to wrap up India trip on tough note

Synopsis: Margaret Hamburg, commissioner of the US Food and Drug Administration (US FDA), seems to be wrapping up her Indiatrip on a tough note. Hamburg, who met government as well as industry officials in New Delhi and Kochi through the week and visited the Taj Mahal too, has reiterated in her latest blog that "lapses in quality" are "unacceptable" and indicated that going forward the US regulatory agency will increase inspections of "foreign facilities". "In recent years, the FDA has identified significant lapses in quality by some companies operating in the US and around the world. As a result, American consumers have had to endure greater risk of illnesses, recalls, and warnings about the products many of them rely on each day. This is unacceptable," Hamburg said in her latest blog, posted on Friday.

Similar report in-
The Indian Express- **USFDA talks tough on lapses in quality standards**

Publication: The Economic Times
Edition: National
Date: February 17, 2014
Headline: Rx for Indian Pharma (link unavailable, scan attached)

Synopsis: The decision of the USFDA to put Ranbaxy's bulk drug unit in Toansa under import alert is a big blow to it. A lot has to be done if India is to be called the global pharmacy of the world, now and in future. Daiichi-Sankyo, the Japanese innovator company, is in control of Ranbaxy for almost five years but regulatory problems continue to plague the company. The USFDA is looking at Ranbaxy with a magnifying lens. Of the 21 warning letters issued by the USFDA in 2013, 10 were sent out to Indian companies. In comparison, of the 23 warning letters issued in 2012, only one was sent to an Indian company With almost 40% of generic drugs dispensed in the US coming from India, the USFDA has to look at Indian pharma more closely.

Publication: Pharmabiz
Edition: Online
Date: February 17, 2014
Headline: Indian pharma companies to soon get GMP compliant as mandated by US FDA

Synopsis: In the wake of a spate of warning letters on Indian pharma companies by US FDA, US-based online compliance and regulatory learning solutions company Underwriters Laboratories (UL) Eduneering, which trains drug regulators to ensure safety of FDA related pharma products is planning to equip leading Indian pharma companies on maximising compliances related to consent decree, Form 483, data integrity and quality management systems. This would entail maintenance of electronic records for inspection readiness of Indian companies.

Publication: The Financial Express
Edition: National
Date: February 16, 2014
Headline: Drug quality linked to product safety: USFDA commissioner

Synopsis: Emphasising on the "quality" of craftsmanship depicted in the Taj Mahal, US Food and Drug Administration (USFDA) commissioner Margaret A Hamburg wrote in her blog that the "quality (of drugs) is linked to product safety and without a direct focus on quality, the potential for patient harm increases significantly". "As one of the Seven Wonders of the World, the Taj Mahal is not only one of India's most sacred symbols, but one of the finest, most carefully designed architectural structures in the world. It was evident as I walked along with hundreds of other visitors in socked feet that those responsible for building the Taj and those that are preserving the centuries-old structure are committed to extraordinary quality," Hamburg wrote on FDA's official blog (blogs.fda.gov), adding that this vision of quality and care remained with her when she met executives from pharmaceutical and food exporting companies operating in India.

Publication: The Indian Express
Edition: National
Date: February 17, 2014
Headline: Medicines made in India set off safety worries in US

Synopsis: India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators for safety lapses, falsified drug test results and selling fake medicines.
Margaret A Hamburg, the commissioner of the United States Food and Drug Administration (USFDA), arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms".

Publication: Business Standard
Edition: National
Date: February 17, 2014
Headline: What regulation, when man is vile?

Synopsis: Last week, Margaret Hamburg, commissioner of the United States Food and Drug Administration (FDA), delivered a tough message to the Indian pharmaceutical sector. Inspections carried out by the FDA of drug manufacturing plants in India had allegedly uncovered major quality issues, triggering this step. Last May, Ranbaxy Laboratories pleaded guilty to felony charges related to drug safety and agreed to pay half a billion dollars in civil and criminal fines under a settlement agreement that had been in the works since late 2011. One might have thought that this tough stance would have signaled what lay ahead unless the Indian pharmaceutical industry and its regulator got their act together. If so, one would be mistaken.

Publication: Deccan Herald
Edition: National
Date: February 17, 2014
Headline: Unease growing in US over medicines made in India

Synopsis: India, the second largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by US regulators for safety lapses, falsified drug test results and selling fake medicines. Dr Margaret A Hamburg, the commissioner of the US Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms." India's pharmaceutical industry supplies 40 per cent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for US consumers.

Publication: The Financial Express
Edition: National
Date: February 17, 2014
Headline: FDA surprise checks on, but DCGI will be kept in loop

Synopsis: India wants to observe first-hand the processes undertaken by the US Food and Drug Administration (FDA) when the latter points out lapses in manufacturing processes of pharmaceutical companies operating in the country to rule out any attempts of a witch-hunt by the US regulator. The agreement of collaboration signed between the FDA and its Indian counterpart last week, however, doesn't allow the Indian regulator to inform the company in advance of the FDA's inspection plans. The surprise element of such inspections would be retained.

Publication: Pharmabiz
Edition: Online
Date: February 17, 2014
Headline: DCGI to allow import of drug with residual shelf life less than 60% under special conditions

Synopsis: The drug controller general of India (DCGI) will henceforth allow import of drugs with residual shelf life less than 60 per cent under special conditions and the importers who import such drugs shall have to give proper justification for the import.

Publication: Business Standard
Edition: National
Date: February 14, 2014
Headline: Pharma exports growth from Gujarat may dip 2-3% in FY14

Synopsis: As pharmaceutical exports from the country go on a slow lane, exports from Gujarat, which contributes to almost a quarter of the national pharma exports, is also likely to decline by 2-3 per cent this fiscal.
Industry insiders claim that the major reasons behind the dip in export growth are several exporting units coming under the US Food and Drugs Administration (USFDA) scanner, apart
from slowdown in bulk drug exports. Pharmexcil sources indicated that while the target was to clock a 15 per cent growth in pharma exports, from what it looks like, pharma exports would manage to register a 10-12 per cent growth over last fiscal.

General Industry/ Diseases

Publication: Business Standard
Edition: National
Date: February 15, 2014
Headline: Misplaced priority

Synopsis: Indians are taught early that science is only a means to an end. All the bright young people who enter the "science stream" of various schools are told to have their eyes set not on that ever-receding horizon of scientific discovery, but on the more mundane, if more monetarily rewarding, prospect of a career in engineering. Lost in this mindset is this basic fact: for a country, basic science is as essential as engineering. If anything, for a country struggling to lift itself up the value chain, basic science is perhaps more important than engineering. Sadly, the present state of Indian science does not measure up to its potential. Nor is it quite as much of a priority as it should be. The recently-held 101st session of the Indian Science Congress bore this out amply - it largely failed to generate the same kind of interest in scientific circles and the media as many of its predecessors. One possible reason: a perceptible drop in the participation of outstanding scientists from across the globe, as well as in the quality of papers presented there. And, if there's a root cause for this, it's that the Indian state has for many years failed

to prioritise basic science properly. Dismay over state apathy and meagre funding for science and technology was recently articulated, with great emotion, by the distinguished scientist C N R Rao - himself chairman of the Prime Minister's scientific advisory council - soon after being conferred the country's highest honour, the Bharat Ratna. He squarely blamed the bureaucratic stranglehold over science policy and scientific institutions.

Publication: The New Indian Express
Edition: National
Date: February 17, 2014
Headline: Mentoring Medicine Men

Synopsis: Pharmacy studies, a viable option for those who can't afford the high cost and long duration of a medical education, trains students for an important role in the healthcare industry, alongside doctors and nurses.

Publication: Millennium Post
Edition: National
Date: February 15, 2014
Headline: Drugging the world

Synopsis: Why is the United States so paranoid about India's pharma industry? How genuine are its concerns over oft-alleged laxity in manufacturing processes and practices followed by India's drug manufacturers? Can India's drug industry afford to take the concerns of the powerful US Food and Drug Administration (FDA) lightly? These broad questions along with several more specific and less irritant others are crucial to the future progress and survival of India's roughly Rs 1,70,000-crore drugs and pharmaceuticals industry leaning sizably on export with the US being the most important destination. Export accounts for nearly 45 per cent of the industry's turnover. Lately, exporting India-made drugs to the US market is becoming increasingly difficult with the US continuously raising procedural and legal hurdles affecting the trade. Fighting legal disputes in the US for a market space could be really expensive and struggle some in future.

Publication: Business Standard
Edition: National
Date: February 16, 2014
Headline: Pharma sales in India to touch $27 bn by 2016: Deloitte

Synopsis: Pharmaceutical sales in India are expected to rise by 14.4 per cent to USD 27 billion in 2016 from last year, but the life sciences and health care industry is up against challenges such as quality management and meeting global standards, says a report.
According to "2014 Global Life Sciences Outlook" by consultancy firm Deloitte, pharmaceutical sales in India stood at USD 22.6 billion in 2012, which is expected to rise to USD 23.6 billion in 2013.

Publication: Mint
Edition: National
Date: February 16, 2014
Headline: Entrepreneurs—which path to choose?

Synopsis: The young in India—15% below the age of 15; 50% below 25; 65% below 35—have an opportunity to make a difference for the future. This is more than 700 million young people. In spite of the growing job opportunities in traditional industries (research, academics, hotels, medicines, pharmaceutical, automobile, shipping, information technology, etc.), there is still a need to create avenues for employing a large number of young talent pools in India. Also, much of the young population resides not in the big cities and metros but in smaller cities across the country. And it is very important to create opportunities for all.

Publication: The Pioneer
Edition: Delhi
Date: February 16, 2014
Headline: Global Docs' Body Defends India Against US Pharma Lobbby

Synopsis: Doctors Without Borders", the Geneva-based international humanitarian body, has come down hard on the US's powerful pharmaceutical lobby for pressuring India over its intellectual property laws in disregard of the country's right to implement a patent system to serve its public health needs.
At the ongoing US International Trade Commission hearing on Indian policies, the doctors' body highlighted the importance of India's generic drugs industry to cater to the medical needs of hundreds of millions of poor people.