News Updates: March 29 - April 1, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: Business Standard
Edition: National
Date: April 1, 2014
Headline: Taking action to address Indian trade barriers: USTR

Synopsis: The Obama Administration has initiated a series of actions to address the issues posed by Indian trade barriers, the USTR said today noting that it has been successful on some issues while on the others it has dragged New Delhi to the World Trade Organization. In its 2014 National Trade Estimate Report Major Developments, US Trade Representative (USTR) said that in 2012, India began implementing the Preferential Market Access (PMA) policy, which mandated that not only government agencies but also private firms, purchase a certain percentage of domestically manufactured electronic equipment.

Clinical Trials

Publication: Business Standard
Edition: National
Date: April 1, 2014
Headline: Panel rejects clinical trial plea by some drug makers

Synopsis: Proposals from leading pharmaceutical companies such as Novo Nordisk, Cadila Pharmaceuticals, Wockhardt, Novartis, Roche and Reliance Life Sciences for conducting clinical trials were recently rejected by a regulatory committee, formed following the Supreme Court's directions to supervise tests of new medicines on human beings. The committee, headed by Health Secretary Lov Verma, evaluated a total of 47 fresh proposals, seeking permission to conduct clinical trials in India. The panel cleared 28 applications, also recommended by a technical committee.

Similar report in-

Deccan Chronicle- 'Irrelevant' clinical trials rejected

Publication: The Guardian
Edition: Online
Date: March 31, 2014
Headline: Thousands of lives put at risk by clinical trials system that is 'not fit for purpose'

Synopsis: A major outbreak of infectious disease could sweep through the country and leave thousands dead or ill because hospitals cannot test life-saving treatments quickly enough, senior doctors have told the Guardian. Profound delays in the approvals process for clinical trials mean doctors face months of form-filling and administrative checks that make it impossible to run crucial tests in good time, said Jeremy Farrar, in his first major interview as director of the Wellcome Trust.

Drug Pricing

Publication: Business Standard
Edition: National
Date: April 1, 2014
Headline: NPPA doubles recovery from drug firms in FY14

Synopsis: It has been a good year for the National Pharmaceutical Pricing Authority (NPPA) as far as recoveries from drug firms goes in matters of overcharging customers. The pricing regulator has more than doubled the amount recovered from pharma companies to Rs 40 crore during 2013-14 from Rs 14.97 crore the year before. A K Saha, director, overcharging, NPPA informed, "During the April 2013 to March 2014 fiscal, we have recovered an amount of Rs 40 crore from drug firms in the matters of overcharging. Several cases are pending in litigation. Cumulatively, till date there would be around 1,000 such cases that have been registered."

General Industry

Publication: The Times of India
Edition: National
Date: April 1, 2014
Headline: Funds dry up for drug discovery project

Synopsis: Funding for one of the foremost drug discovery projects in India came to an end on Monday as the financial year closed because the ministry of science and technology did not clear the cabinet note meant to extend funding for the project on time. The Open Source Drug Discovery (OSDD) project of the Council of Scientific and Industrial Research (CSIR), meant to discover drugs for neglected diseases, had shown enough promise in finding a new combination of drugs to treat multi-drug resistant TB for the Planning Commission to allocate Rs 650 crore for it in the 12th plan document.

Publication: The Economic Times
Edition: National
Date: April 1, 2014
Headline: US Ambassador to India Nancy Powell resigns

Synopsis: American ambassador Nancy Powell tendered her resignation on Monday night, which the US embassy described was not a sudden development, but planned. "US Ambassador to India Nancy J Powell announced in a US Mission Town Hall meeting March 31 that she has submitted her resignation to President Obama and, as planned for some time, will retire to her home in Delaware before the end of May," a US Embassy statement said on Monday night.

Similar reports in-

Mint- Nancy Powell, US ambassador to India, resigns
Business Standard- US ambassador Nancy Powell quits amid strained bilateral ties
The Indian Express- India-US chill claims Ambassador Nancy Powell's job
NDTV- US Ambassador to India Nancy Powell resigns

Publication: The Financial Chronicle
Edition: National
Date: April 1, 2014
Headline: Novartis heart drug trial successful (link unavailable, scan attached)

Synopsis: Novartis said a final-phase clinical trial on a treatment for chronic heart failure met its goal and the drugmaker plans to ask global regulators for marketing approval for the drug.

Similar report in-

Reuters- Novartis closes heart drug study early after strong results

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Publication: The Financial Chronicle
Edition: National
Date: April 1, 2014

Headline: GSK to invest $216m in African markets (link unavailable, scan attached)

Synopsis: Drugmaker GlaxoSmithKline plans to invest up to £130 million ($216 million) in Africa over the next five years as it bets on the importance of the continent in driving long-term demand for medicine.

Similar reports in-

NDTV- **GSK to invest $200 million in African factories, R&D**
Reuters- **Drugmaker GSK to invest $200 mln in African factories, R&D**

Patents/Compulsory Licensing/Intellectual Property

Publication: The Financial Express
Edition: Online
Date: March 31, 2014
Headline: **India must choose wisely on IP**

Synopsis: It is necessary to see India's troubles with the American industry and the US authorities in a wider framework. Since the pharma sector has been at the core of the ongoing dispute, it would be best to turn to an example from another field. India's motion picture industry was one wrecked by piracy, including bootlegged video cassettes and later CDs, stolen music and so on. Illegitimate activities led to massive copyright and revenue losses. In the late 1990s, the landscape began to change as film producers and music composers in Mumbai, where the Hindi film industry is located, realised the opportunity cost. The vast Indian diaspora market, especially in North America and Britain, was being exploited by contraband syndicates, including some based in the South Asian community in New York. If the situation is very different today—and if the intellectual property of the Hindi film industry is being protected in those very North American markets—it is a tribute to the cooperation between Indian and American authorities, including the New York police.

Publication: The Economic Times
Edition: National
Date: March 29, 2014
Headline: **Expand IP regime, R&D fund to boost manufacturing: DIPP**

Synopsis: The department of industry policy and promotion (DIPP) has suggested a seven pronged approach to expand India's intellectual property regime and research and development framework, which would in turn bolster manufacturing in the economy. In a discussion paper put out on Thursday, DIPP has emphasised on the need to promote transfer of knowledge and technology from universities to industry. DIPP has noted that the government needs to fund technology projects that translate scientific discoveries and cutting-edge inventions into technological innovations and accelerate advances in high-risk areas industry is unlikely to pursue independently.

Drug Pricing

Publication: Mumbai Mirror
Edition: National
Date: March 30, 2014
Headline: **No exemption, NPPA to fine drug firm for overpricing**

Synopsis: National Pharmaceutical Pricing Authority (NPPA) has refused to exempt popular paracetamol brand, Crocin Advance, from price control. Manufactured by GlaxoSmithKline (GSK), the medicine is costlier than other paracetamol brands, which violates the Drug Price Control Order. NPAA has now asked the company to reduce the market price of Crocin Advance and has also decided to fine the firm for overcharging consumers.

Clinical Trials

Publication: Pharmabiz
Edition: National
Date: March 31, 2014
Headline: Technical Committee denies permission to 19 clinical trial proposals recommended by NDACs

Synopsis: The Technical Committee and the Apex Committee, the two high-level panels to supervise the clinical trials sector, have denied clearance to several proposals of clinical trials of new drugs, including fixed dose combinations, medical devices and global trials, even though the new drug advisory committees had recommended them for permission. The Technical Committee first evaluated 47 proposals, which were forwarded by the NDACs which are supposed to go into the details with the help of experts. However, the technical committee cleared only 28 proposals out of the total 47. Later, the Apex Committee headed by the Health Secretary also accepted the recommendations by the technical committee to deny permission to 19 proposals on various grounds.

Drug Regulation

Publication: Pharmabiz
Edition: National
Date: March 31, 2014
Headline: DCGI gives more time on relabelling requirements of imported drugs

Synopsis: The Central Drugs Standard Control Organisation (CDSCO) has given three months more for the companies to comply with the relabelling norms for imported drugs, after the industry expressed concerns on the enhanced rules and tightened norms. “In the light of various representations received from OPPI, FICCI, CII, IDMA and other stakeholders on relabelling issue of imported drugs, a special meeting with the stakeholders was held on direction of the Ministry of Health and Family Welfare on March 26,” said a notice from the Drug Controller General of India (DCGI) Dr G N Singh.

Publication: The Hindu Business Line
Edition: National
Date: March 29, 2014
Headline: Pharma institute takes up specialized drugs research to combat rare diseases

Synopsis: India is set to expand its footprint into research on drugs that will help prevent as well as treat rare diseases. The National Institute of Pharmaceutical Education and Research is getting into research on ‘orphan drugs’ to combat the growing incidence of rare diseases in India. An orphan drug is a pharmaceutical agent developed specifically to treat a rare medical condition. Most of the rare diseases are “orphaned” by the global pharmaceutical industry due to commercial reasons, and are hence known as orphan diseases. The NIPER, which is under the under Council of Scientific and Industrial Research, is tying up with the University of Minnesota, which is among a handful of global research institutes that have developed expertise in this area of pharmaceutical research.“We have just signed the MoU with the University of Minnesota. In June, we will have a joint meeting here, which will include officials from the USFDA and the Indian pharmaceutical regulator, to chalk out the roadmap for orphan drugs research. We will be identifying a set of orphan drugs that can possibly be used for some rare diseases in India,” Ahmed Kamal, Director, said.

Publication: The Financial Express
Edition: National
Date: March 29, 2014
Headline: USFDA pans research that found impurities in India-made drugs

Synopsis: Even as India fights deepening perceptions about "inferior" quality drugs being exported from the country, the US Food and Drug Administration (USFDA) has not only discredited research that found

impurities in dozens of generic heart drugs made overseas, including India, but also said that investigators contaminated the samples during testing. The research conducted by Preston Mason, a researcher at Harvard-affiliated Brigham & Women's Hospital in Boston, had stated that many generic heart drugs made by India-based companies don't work as they should and contain impurities. However, a recent USFDA test of generic Atorvastatin (hypertension drug) versions approved by the regulator, showed no such problem. On the contrary, the FDA said impurities could have entered the samples during the testing process because of the methodology employed.

Publication: Western Times
Edition: Ahmedabad
Date: March 30, 2014
Headline: US bans imports from Sun Pharma's Gujarat plant (no link available, scan attached)

Scan: Drug-maker Sun Pharmaceutical Industries has received an import alert from the US Food and Drug Administration on its cephalosporin facility located at Karkhadi, Gujarat.
While an import alert virtually bans all products from the plant, the company said it had initiated corrective steps and the contribution from this plant to its consolidated revenues was "negligible". The alert was issued by the US FDA as a follow up to the last inspection of the facility, during which some non-compliance of current Good Manufacturing Practice (cGMP) regulations was identified, Sun said. Its stock-price dipped on the news by over 5 per cent, closing at ☐573 on the BSE, on Thursday. Even as Sun expects the FDA alert to have minimal impact, reflected in the fact that it has not revised its earlier sales growth projection of 29 per cent for the year ending March 2014 — the development is the latest in a string of US FDA-initiated action against India-based companies

Publication: Business Standard
Edition: National
Date: March 29, 2014
Headline: After Crocin Advance, Calpol under regulatory lens

Synopsis: After Crocin Advance, it's the turn of GlaxoSmithKline(GSK) Pharmaceutical's top-selling paracetamol brand Calpol syrup to come under the regulator's scanner for allegedly overcharging consumers. The Maharashtra Food and Drug Administration (FDA) has barred the sale of Calpol 120mg syrup in the state and issued a show-cause notice to GSK Pharmaceuticals for selling the medicine at a price higher than the ceiling. While GSK Pharma claims the product is out of price control because of its strength, Maharashtra FDA officials maintain the company has tweaked the therapeutic dosage of the original product to skip the price control ambit. The state drug regulator is also planning to write to the National Pharmaceutical Pricing Authority (NPPA), requesting action against the company.

General Industry

Publication: The New Indian Express
Edition: National
Date: March 30, 2014
Opinion piece: Kiran Mazumdar Shaw
Headline: Science and Technology Shape Economic Future

Synopsis: The new government will have to act swiftly in course correcting the stalled Indian economy. To begin with, they will have to focus on a number of regulatory reforms that will address the ease of doing business, reduce transaction costs and expedite approval timelines. The lack of rules and guidelines in taxation and business matters have deterred investment and introduced delays in project approvals. These measures alone can add a per cent or two to GDP growth through increased FDI and project implementation.

Publication: Hindustan Times
Edition: Delhi
Date: March 31, 2014

Headline: Stent prices to fall, govt beneficiaries happy (no link available, scan attached))

Synopsis: The price of drug eluting coronary stents used to prop open blocked arteries for Central Government Health Scheme (CGHS) beneficiaries is expected to come down by nearly Rs 1375. The revised ceiling rates for reimbursement is expected to be around 23625 down from the current 25000. The new drop in prices comes after the Centre took cognizance of a deal signed between Maharashtra government and two multinationals **Abbott Vascular** and Medtronic to provide the stents for 23625 apiece under a state insurance scheme.

Publication: Deccan Chronicle
Edition: National
Date: March 30, 2014
Headline: **NaMo, RaGa emerge as painkillers for businessmen**

Synopsis: Trust entrepreneurs to cash in on anything, even the election season. A pharmaceutical firm has brought out painkillers, ointments and tablets branded after BJP's PM candidate Narendra Modi and Congress vice-president Rahul Gandhi. While the brand Modi products are called 'NaMo tablets' and 'NaMoni Gel', the Rahul Gandhi brand is called 'RaGa-flam'. The Modi brand seems to have beaten the Rahul brand as far as pricing is concerned. "NaMo tablets are priced at Rs 36, while RaGa tablets are for Rs 16," says Naveen Jain, director of ICI Health Care Pvt. Ltd, which has brought out the medicine.

Publication: DNA
Edition: National
Date: March 30, 2014
Headline: **India creates own drug to treat gangrene, to be available in a year**

Synopsis: Six years of path-breaking medical research has borne fruit. India will soon have its own drug to treat bacterial infection or gangrene in deeper wounds. So far, the drugs had to be imported from overseas at exorbitant prices. The state-run Haffkine Bio-Pharmaceutical Corporation Limited has developed a 'mixed anti-gas gangrene' drug which will be used to treat patients susceptible to gangrene. After six years of research, a team of scientists from Haffkine submitted its research report to the department of biotechnology in 2012. After analysing the research and pumping in Rs1.4 crore for a more detailed study, they created the product to prevent and treat gangrene. The product has got all the necessary permissions, including those from the Food and Drug Administration, to be launched in the market. It is likely to be available within a year.

Publication: The Hindu Business Line
Edition: National
Date: March 29, 2014
Headline: **GE Healthcare to set up 25 cancer treatment centres**

Synopsis: GE Healthcare and Cancer Treatment Services International have announced plans to launch 25 cancer detection and treatment centres all over India with an investment of INR 720 crore in the next five years. These centres will have the latest technologies to diagnose and treat cancer, and will be 'affordable' , according to company executives. Both companies did not divulge the cost of diagnosing or treating cancer cases but said that it will be as per standards in developed economies. "Affordable access to healthcare requires a disruption of sorts and this partnership is a step towards that direction," John Dineen, President and CEO, GE Helathcare told reporters at its Bangalore tech centre. "There is a lack of access to affordable cancer care and with this partnership, we are precisely trying to solve this," Terri Bresenham, President and CEO GE Healthcare of South Asia.

Publication: The Times of India *(Reproduced from PTI)*
Edition: Online
Date: March 31, 2014

Headline: **Dr Reddy's eyes fresh foray into Japanese market**

Synopsis: After shrugging off its proposed joint venture with Fujifilm which was a non-starter, Dr Reddy's Laboratories Limited is back on the drawing board and is keen to make a fresh foray into the Japanese market. "We are exploring all options in the sense we have product profile. We have already gone through (with Fujifilm) which did not work. We have to be sure that we don't make those mistakes again. The priority is to get into the right plan to enter into the (Japanese) market," DRL vice-chairman and managing director, K Satish Reddy said. The Hyderabad-based company is working overtime to see that its entry next time around into the world's second largest pharma market after the US "still at works" is a success.

Also appeared in **The Hindu Business Line**, **Business Standard**, **The Financial Express**, **NDTV**