News Updates: March 22-24, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Times of India
Edition: National
Date: March 23, 2014
Headline: Changes to India's patent law will impact prices of life-saving drugs *(Interview)*

Synopsis: India's trade and investment policies, particularly balancing right to health with intellectual property and public health safeguards, are being questioned in a US investigation. With the threat of potential trade sanctions, Rohit Malpani, director of policy and analysis at Medecins Sans Frontieres (MSF) - Access Campaign, an international humanitarian organization, made a case for access to treatment before the US International Trade Commission recently.

Publication: The Hindu
Edition: National (Opinion)
Date: March 24, 2014
Headline: Friction over drug patents

Synopsis: Differences over intellectual property rights (IPRs) have emerged as a strong undercurrent in India's economic relations with the U.S. The attempt by the influential pharmaceutical lobby to stymie India's efforts to ensure the supply of medicines at affordable rates without violating existing treaty commitments, requires a principled response from New Delhi. At the core of the issue is what Columbia University Professor Arvind Panagariya calls "the hijacking of the economic policy dialogue between the U.S. and India by pharmaceutical lobbies in the U.S." Piqued by India's decision to use the flexibilities that are available in the existing TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement, big pharma in the U.S., along with other influential business groups, is using its considerable clout to pressure the U.S. Trade Representative into designating India as a "priority foreign country" in its 2014 Special 301 Report, due on April 30. That label is reserved for the worst offenders of IPRs, and as a follow-up the U.S. could impose trade sanctions such as withdrawing tariff preferences for Indian exports. In an election year, India will most likely retaliate through anti-dumping duties or tariff hikes on U.S. imports.

Publication: The Financial Express
Edition: National *(Reproduced from PTI)*
Date: March 24, 2014
Headline: Anand Sharma: India ready to discuss IPR norms at WTO if US wants

Synopsis: Rejecting US allegations related to intellectual property rights (IPR), India today said that it is ready to discuss the matter at WTO as it has not breached any international agreement. "If they (the US) want a discussion in WTO (World Trade Organization), we are more than ready because we are not in any breach. We are very clear," Commerce and Industry Minister Anand Sharma told PTI. Sharma was replying to a question over the US charges that India's IPR norms discriminate against American companies, particularly in the pharmaceutical sector.

Also Appeared
The Economic Times - India ready to discuss IPR norms at WTO if US wants: Anand Sharma
The Asian Age - India to US: Will talk IPR at WTO (no link available)
Mail Today – India Ready to take on US at WTO platform (no link available)

Publication: The Financial Express
Edition: National
Date: March 24, 2014
Headline: Delhi HC issues notice to Natco after Teva's intra-court appeal

Synopsis: The Delhi High Court on Friday issued a notice to Natco Pharma in response to an intra-court appeal lodged by Israel-based Teva Pharmaceutical. Teva was contesting an earlier single-judge order that refused to restrain Natco from "manufacturing, selling, offering for sale, export or registering Copaxone", also known as glatiramer acetate The drug, which is used to treat multiple sclerosis, currently accounts for a fifth of Teva's overall income, with sales of the drug exceeding $4 billion. For now, the court asked a further hearing on April 22. Natco has been selling the drug in India since 2007, and it has an international marketing alliance with American drug major Mylan for marketing the drug overseas, pending approval from the US FDA.

Publication: Business Standard
Edition: Chennai
Date: March 23, 2014
Headline: IPAB to take up Wockhardt plea against Novartis

Synopsis: The Intellectual Property Appellate Board (IPAB) has decided to proceed with the hearing of a revocation petition by Wockhardt against the patent of a diabetes drug of Swiss pharma major Novartis, even as a dispute between the parties on an alleged infringement of patent of the same product is pending with the Delhi High Court. The dispute is on the patent of anti-diabetes drug vildagliptin, an oral anti-hyperglycemic agent which is also marketed in combination with Metformin Hydrochloride, owned by Novartis in India. According to information available, the patent was challenged by Wockhardt in September, 2013 through a revocation petition before the IPAB. Following this, attaining information that the Indian drug manufacturer has received the drug regulator's permission for manufacture and sale of the product on May, 2013, Novartis filed a petition with the Delhi High Court, and received an interim injunction on March 5, till next hearing.

FDA

Publication: Daily News & Analysis
Edition: National
Date: March 24, 2014
Headline: Posing grave risks for patients

Synopsis: In the past few months, several Indian drug companies have been hauled up by the United States Food and Drug Administration (USFDA) for not following quality standards for drugs they export to America. Exports from as many as four facilities of Ranbaxy have been restricted. Previously, the same company had to cough up a penalty of $500 million for supplying adulterated drugs to American consumers. Another major supplier, Sun Pharma, too has been restrained from exporting drugs manufactured at one of its plants in Gujarat. Wockhardt has faced similar action against two of its manufacturing units in India, while Dr Reddy's Lab voluntarily recalled 58,000 bottles of a heartburn drug due to microbial contamination. Indian drug companies have been found guilty of charges ranging from violating standard manufacturing practices to fudging quality-related data.

Drug Quality/Drug Regulation

Publication: Business Standard
Edition: National
Date: March 24, 2014
Headline: Efficiency is key, not product portfolio

Synopsis: The Indian pharmaceutical industry is in the midst of several changes that will require

many companies to realign their business model. For the past several years, companies have benefited from the large number of drugs that have gone off-patent. Due to the steady stream of drugs going off-patent, companies focused on submitting dossiers and drug master files (DMFs) so they could take advantage of this temporary phenomenon. Although companies were increasing sales and profits, their manufacturing operations were not prioritised and became inefficient. Companies could hide their inefficiencies because even as margins fell for a particular product as the market became saturated, they could always jump onto the next product that was in the pipeline. While this model worked in the past, it is no longer sustainable because the number of drugs going off-patent is dwindling.

Publication: The Hindu
Edition: New Delhi
Date: March 24, 2014
Headline: **Pharmacists oppose sales record rule**

Synopsis: Chemists and pharmacists have threatened to launch a nationwide agitation against a government order making it mandatory for them to maintain a separate sale register for sleeping pills, antibiotics and anti-tuberculosis drugs. They will sit in dharna in the capital on March 24. The March 1 order comes even as the Health Ministry has allowed chemists to sell antibiotics listed under Schedule H1, but manufactured before February 28, without the new labelling requirements. However, they have been asked to follow other instructions for sale of these antibiotics with regard to prescription and maintenance of sale records as per the amended rule under Schedule H1, according to official sources. The pharmacists claimed it was “impractical” to maintain the register and implement the order in all 6,00,000 retail shops all over the country.

Publication: Business Standard
Edition: New Delhi
Date: March 24, 2014
Headline: **US generics benefit from pharma see-saw**

Synopsis: The rising regulatory hurdles for Indian pharmaceutical companies in the US could prove a blessing for American generic medicine manufacturers. While leading Indian drug makers are inreasingly facing enforcement action as well as reputational damage in the US because of quality concerns, companies such as Teva, Mylan, Watson, Sandoz and Valeant are gaining market share there. Analysts and industry officials are pointing at the absence of enough competition as the primary trigger for the rise of American generic companies in the largest pharma market of the world. Sources said many of these companies are even looking at creating a manufacturing base in India, by way of mergers and acquisitions, to sell products in the US. While this will allow them a cost advantage, less competition in the US will enable them to raise product prices. While Mylan recently acquired Strides Arcolab's Bangalore-based injectible manufacturing facility, Agila Specialities, others such as Teva and Watson are also reportedly eyeing buyouts in India.

Publication: The New Indian Express
Edition: Hyderabad
Date: March 23, 2014
Headline: **International Quality Control: A Challenge for Desi Pharma Cos**

Synopsis: Just as India’s generic pharma companies were just about to attain leadership position globally, the sector is witnessing a growing unrest among the medical fraternity over the quality and efficacy of drugs produced in India. To make things worse, with a series of voluntary drug recalls by Indian firms, coupled with the recent US health regulator Food and Drugs Administration’s (FDA) clamp down on manufacturing units in India, concerns about the quality of drugs are only mounting.

World TB Day

Publication: The Times of India
Edition: New Delhi
Date: March 24, 2014
Headline: Most drug-resistant TB patients in India: WHO

Synopsis: One in every three tuberculosis cases in the world goes undetected despite the advances made in medical science, according to data from World Health Organization. TB is the main cause for high morbidity and mortality in such patients. On World TB Day on Monday, doctors will stress on need to create awareness about the disease which affects one third of the world's population. India has the highest number of TB patients with an estimated 1.8 million new cases taking place every year. It has also the highest number of multi-drug-resistant tuberculosis patients, according to a WHO report.

Similar Reports:
The Times of India - After battle with MDR-TB, they emerged winners
The Hindu - A million missing patients
The Hindu - Serology testing ban needs to be enforced
The Hindu - As TB stigma lingers, awareness offers way out
The Free Press Journal - China leads the world in curbing TB, claims WHO
Deccan Herald - Technological advances in TB diagnostic tools hold promise
The Telegraph - Rulebook on TB treatment
Daily News& Analysis – HIV patients 50 times more likely to develop TB
The Indian Express- Over 4K TB relapse cases last year: Data
Zee News –India still home to quarter of global TB cases
Pharmabiz – WHO approves TB diagnostic test at reduced price, IPAQT gears up to offer these services

General Industry

Publication: Mint
Edition: National
Date: March 23, 2014
Headline: Indian pharma sector still attractive for foreign investors

Synopsis: Multinational drug makers may complain that India is an inhospitable market to do business in, but that hasn't stopped a flood of foreign direct investment (FDI) into the country's pharma industry since the start of the century. The pharma sector attracted Rs.55,986 crore in FDI in the 13 years through December 2013—half of it in the past three years, according to data compiled by the department of industrial policy and promotion (DIPP). This made the sector the fifth biggest recipient of FDI since 2000, behind financial services, construction, telecom and information technology. UK drug maker GlaxoSmithKline Plc's (GSK) investment between February and March 2014 to raise its stake in its Indian unit from 50.7% to 75% will add another Rs.6,400 crore to FDI in the sector.