News Updates: June 04, 2014

Patents/ Compulsory licensing/ Intellectual property

Publication: The Hindu Business Line
Edition: National
Date: June 4, 2014
Opinion piece: Rudra Chaudhuri, senior lecturer in the department of war studies and the India Institute at King's College London
Headline: Time to mend fences with the US

Synopsis: With regards to immediate concerns, there is an urgent need to address differences pertaining to intellectual property standards. India is one of 10 countries listed on the "priority watch list" of the United States Trade Representative's (USTR) annual report. The key issue, according to it, has to do with India's "weak IPR legal framework and enforcement system" which hamper India's "innovation climate." This is most acute, according to the report, in areas such as pharmaceuticals and agro-chemicals, where it is difficult to secure and enforce patents. In turn, the BJP's retort is unrelenting. During the campaign, Hardeep Puri, the former Indian ambassador to the UN and now a party member, made it clear that the report is "extra-constitutional". Even special provisions such as settling matters prior to an out-of-cycle review were put down by Puri as "nonsense." The answer, according to him, lay in taking the matter to the World Trade Organisation's dispute settlement body. Rather than resort to brinkmanship, simply because this is a determined US-led initiative, it would be prudent to engage the US bilaterally to arrest such divergence.

Publication: The Economic Times
Edition: National
Date: June 4, 2014
Headline: Indian patent law very strong, at par with global standards: Maruti

Synopsis: After three major US companies - Boeing, Abbott and Honeywell - auto major Maruti Suzuki has now come in support of India's intellectual property rights (IPR) regime, saying the "very strong" domestic laws are on par with international standards. American pharma sector had alleged that Indian IPR laws discriminate against US companies and violate global norms. "Maruti Suzuki India firmly believes that the patent law in India is very strong; especially the changes that happened after the TRIPS agreement have made Indian Patent law at par with the international standards," the company said in its views submitted to the Commerce and Industry Ministry.

Similar reports in-

Business Standard- Indian patent law on par with global standards: Maruti
The Financial Express- Indian patent law very strong, at par with global standards: Maruti Suzuki
The Financial Chronicle- Indian patent law very strong, at par with global standards: Maruti
Moneycontrol- Indian patent law very strong, par with global stds: Maruti

Modi government

Publication: The Economic Times
Edition: National
Date: June 4, 2014
Headline: Gopinath Munde's untimely exit may hit BJP & Shiv Sena in Maharashtra

Synopsis: With Gopinath Munde's unexpected death, BJP has lost its only leader in Maharashtra who commanded support from rural masses. In a party dominated by urban and Brahmin leaders, Munde was seen as the only BJP leader who truly represented farmers and Other Backward Classes (OBC).

Munde was a leader who could pose a real political challenge to Maratha-dominated Congress and Nationalist Congress Party in Maharashtra. The political impact of Gopinath Munde's death is likely to be felt very soon in Maharashtra. It is expected that the seat sharing talks between the Shiv Sena and BJP for the forthcoming assembly polls could now be conducted under Nitin Gadkari's leadership. This may not augur well for the Sena-BJP alliance as the Sena is very uncomfortable with Gadkari and is suspicious of his every move.

Similar reports in-

Mint- **With Gopinath Munde's death, BJP loses its Maharashtra trump card**
The Times of India- **Gopinath Munde's death: Modi loses crucial minister, BJP key player just ahead of Maharashtra polls**
NDTV- **Gopinath Munde's Demise a Major Loss for Nation and Government, Tweets PM**
The Indian Express- **He wanted to ensure water, toilets for every poor villager**

Publication: India Today
Edition: National
Date: June 4, 2014
By-line article: Dinesh C Sharma, science editor
Headline: **Vardhan needs to clean up health**

Synopsis: New health minister Dr Harsh Vardhan has an uphill task ahead. The first and foremost is corruption. Though it is not recognised, it is a major issue in the health sector. It begins with medical education and ends up in unethical provision of services in hospitals and diagnostic centres, as highlighted in Aamir Khan's show Satyamev Jayate. Recently an Australian doctor, who had volunteered for sometime in a charitable hospital in Uttarakhand, narrated in the British Medical Journal his experience with the horrific system of diagnostic centres paying kickbacks to referring doctors. The article also illustrates the practice of drug companies paying doctors for prescribing particular drugs over others. The lifecycle of corruption in Indian health sector begins with the Medical Council of India (MCI), which is tasked with overseeing medical education in the country. The opaque, unethical and anti-patient ways of functioning of the council has been repeatedly exposed and needs no elaboration.

Drug pricing

Publication: The Economic Times
Edition: National
Date: June 4, 2014
Headline: **Injeti Srinivas appointed as NPPA Chairman**

Synopsis: Government has appointed Injeti Srinivas as the new Chairman of National Pharmaceuticals Pricing Authority (NPPA). The Appointments Committee of the Cabinet has approved the appointment of Injeti Srinivas as NPPA Chairman, the Ministry of Personnel, Public Grievances and Pensions said in a statement.

Similar reports in-

Business Standard- **Injeti Srinivas appointed as NPPA Chairman**
The Hindu Business Line- New pharma pricing authority chief (link unavailable, scan attached)

Publication: The Economic Times
Edition: National
Date: June 4, 2014
Headline: **NPPA seeks states' participation to keep drug prices under control**

Synopsis: The drug pricing regulator has urged state governments to identify expensive and most commonly used drugs for diseases prevalent in their regions, which they think should be brought under price control in public interest. This comes close on the heels of National Pharma Pricing Authority's

(NPPA) plans to lower prices of expensive medicines used for select therapeutic categories such as cancer, HIV, diabetes, cardiovascular diseases, malaria and tuberculosis, as reported by ET last month.

Drug quality/ Drug regulation

Publication: The Economic Times
Edition: Pune
Date: June 4, 2014
Headline: Generic Pharma Cos Set Eyes on New Growth Pill (link unavailable, scan attached)

Synopsis: Indian generic drug producers are devising fresh strategies to continue benefiting from the world's largest pharmaceutical market, the United States, because exclusive marketing rights for off-patent drugs are not so exclusive anymore. The US Food and Drug Administration (USFDA) has been clear ring applications to make generic drugs that are going off patent at a faster pace, which is resulting in increased competition. Moreover, the FDA has been granting joint 'first to file' (FTF) status for several generics, diluting the value of the exclusive marketing right that comes with such a status.

Publication: Forbes
Edition: Online
Date: June 4, 2014
Opinion piece: Roger Bate, Aparna Mathur, scholars at American Enterprise Institute and Ginger Zhe Jin, professor of economics at the University of Maryland
Headline: What To Do About The Deadly Threat Of Substandard Drugs

Synopsis: Concerns about US drug quality are increasing. With 80 percent of the ingredients and 40 percent of the final products coming from overseas (notably India and China), the U.S. Food and Drug Administration (FDA) faces a daunting task to ensure drug quality throughout the global supply chain. It has issued multiple warnings to myriad firms ranging from data manipulation to sanitation issues. Concerns about drug quality even drove FDA commissioner Dr. Margaret Hamburg to a high profile visit to India in February. Historically, much attention to drugs has focused on patent battles and counterfeits in developing countries as they infringe the intellectual property (IP) rights. The most widely used definition of counterfeits by the World Health Organization emphasizes IP infringement and the intent to deceive, rather than the drug's chemical content.

Website: Pharmabiz
Edition: Online
Date: June 4, 2014
Headline: IPA president calls to synchronise regulatory compliances in manufacture for export & domestic markets

Synopsis: Indian pharma industry needs to synchronize its regulatory compliance for both domestic and international markets. The only way to achieve this is to create competent human resources who comprehend the criticality of uniform compliances, said Dr Rao Vadlamudi, president, Indian Pharmaceutical Association. The industry should not separate quality norms for drugs manufactured for exports and local markets. The key reason for the current regulatory challenges faced by Indian pharma is that it is not being able to sustain the quality standards because of capability issues. IPA will take a lead in forming focussed groups and subject the human resources to external training and create Centres of Excellence in academic institutions. Since IPA is already collaborating with global bodies like the ISPE and DIA, it could chip in assistance to help industry maximise its human resources talent, said Dr Vadlamudi.

Website: Pharmabiz
Edition: Online
Date: June 4, 2014
Headline: Quality of imported APIs

Synopsis: India has been witnessing the trend of steadily increasing import of APIs, intermediates and excipients from China at very low prices for some years now. While the formulation industry felt happy in sourcing cheaper Chinese APIs, the bulk drug industry in the country has been objecting to such imports as that started hitting the very existence of bulk drug units here. According to the Department of Pharmaceuticals, almost 40 per cent APIs required in the country are being imported from China. Although the formulators were getting benefited by cheaper imports of APIs from China, the government was concerned as these imports were posing a threat to domestic API industry. In fact many small and medium scale API units had closed down during the last five years. It was in the background of this scenario, the Department of Pharmaceuticals sought stern measures including anti dumping duty on API imports from China. Even these attempts from the government did not yield the desired results and Indian bulk drug industry continues to suffer. It has to be remembered that India had emerged as a leading producer and supplier of quality APIs to the global pharma industry only two decades ago.

Website: Pharmabiz
Edition: Online
Date: June 4, 2014
Headline: Maharashtra to get first online system for speedy issue of drug manufacturing licenses

Synopsis: Pharma manufacturing units in Maharashtra would soon get licenses within 48 hours as compared to a minimum of 15 days earlier with the help of a unique online system introduced for the first time in India. Maharashtra FDA is planning to introduce the online system across the state in order to accomplish timely disposal of renewal of licenses, testing licenses, licenses for additional products, performance certificate and free sale licenses among others. The online Extended Licensing Node (XLN) system is in the initial stages of implementation at Maharashtra Food and Drug Administration's Thane division. According to an FDA official, "The system will be launched across the state in coming two months time with the technical guidance of National Informatics Centre (NIC)."

General Industry

Publication: Mint
Edition: National
Date: June 4, 2014
Headline: Biocon, Bristol-Myers Squibb extend drug discovery partnership

Synopsis: Biotechnology major Biocon Ltd and US-based Bristol-Myers Squibb on Tuesday announced a five-year extension of their drug discovery and development partnership in India. The Bangalore-based firm’s contract research subsidiary—Syngene International and Bristol-Myers Squibb (BMS) have extended their collaboration for the next five years, Biocon said in a statement.

Similar reports in-

Business Standard- Biocon expands tie-up with Bristol-Myers
The Financial Express- Biocon arm, Bristol-Myers Squibb extend drug discovery partnership (link unavailable, scan attached)

Website: Reuters
Edition: Online
Date: June 3, 2014
Headline: Cancer drug data supports advanced trials: AstraZeneca

Synopsis: Britain's AstraZeneca Plc on Tuesday said data from early-stage trials of its experimental cancer drug, MEDI4736, are encouraging and support moving the immunotherapy into pivotal-stage testing. The findings were part of a series of presentations by AstraZeneca at the annual American Society of Clinical Oncology (ASCO) meeting in Chicago. AstraZeneca had leaned on the promise of its cancer drug pipeline to fend off a $118 billion takeover bid by U.S. rival Pfizer Inc.

Similar report in-

The Financial Times- **AstraZeneca seeks to bring new cancer drugs to market**
The Guardian- **AstraZeneca unveils positive results for major new cancer treatments**

Publication: Forbes
Edition: Online
Date: June 4, 2014
Headline: **AstraZeneca CEO On His Predecessors, Rivals, And Pfizer**

Synopsis: Pascal Soriot cast aspersions on his predecessors and his competitors, saying AstraZeneca's previous management cut costs too much and allowed marketers to veto promising products. He boasted of that his lung cancer drug, AZD9291, has caught up to a rival from Clovis Oncology, and expressed optimism about embattled products like the blood thinner Brilinta and fish oil Omthera. Throughout the interview, Soriot stood by a forecast he made while fighting off Pfizer: that AstraZeneca can nearly double its annual sales from $26 billion today to $45 billion in 2023. He remains skeptical. That requires Brilinta to come back from being, so far, a failure, and AZD9291 to have a level of success few cancer pills ever have — Soriot insists the industry's pricing power will help there.

Publication: The Financial Express
Edition: Online
Date: June 3, 2014
Headline: **GSK in $350-m cancer drug deal**

Synopsis: Adaptimmune, a biotechnology company, said on Monday that it had reached a deal that could be worth more than $350 million to develop an early stage cancer drug with the pharmaceutical maker GlaxoSmithKline. The deal comes a little over a month after Glaxo agreed to sell its cancer drug business to the Swiss drug maker Novartis as part of a swap of more than $20 billion in assets.

Publication: The Indian Express
Edition: Online
Date: June 3, 2014
Headline: **In Mohali, 1,318 TB cases detected in 2012, number rose to 1,630 last year**

Synopsis: Tuberclosis cases and TB-related deaths have been rising in the district in the past few years, according to data provided by the district health authorities under the RTI Act. While 1,318 TB cases were detected in 2012, the figure shot up to 1,630 in 2013, showing an increase of nearly 25 per cent. As many as 575 cases of TB have been detected so far this year. The number of TB-related deaths has also been gradually increasing over the years. While 24 persons reportedly died due to TB in 2009, 43 TB patients died in 2013. Around 20 persons have died so far this year.