News Updates: June 24, 2014

Patents/ Compulsory licensing/ Intellectual property rights

Publication: The Times of India
Edition: Online
Date: June 24, 2014
Headline: US company denied patent on anti-cancer drug

Synopsis: The Indian Patent Office has refused a patent on US firm Abraxis BioSciences' anti-cancer drug Abraxane, paving the way for domestic companies to launch affordable versions in the local market. The application was refused on the grounds of the US firm's claims lacking of inventive step, not being patentable and insufficiency, legal sources say. One of the main grounds under which the patent was rejected is Section 3 (d) - the provision under which Novartis lost protection on its blockbuster drug Glivec last year. The Patent Office relied on the decision of the Supreme Court in the landmark Glivec case while hearing the application.

Clinical trials

Publication: The Indian Express
Edition: National
Date: June 24, 2014
Headline: Centre plans to clip wings of drug regulator

Synopsis: The Union Health Ministry is working on a proposal to provide accreditation to clinical trial centres, investigators and ethics committees — all of which will kept be out of the purview of Central Drugs and Standards Control Organisation, the country's highest drug regulatory body. Thus, the role of CDSCO will be limited only to granting permission for testing new pharmaceutical products. Clinical trial permissions have been stalled for months after the Supreme Court last year rescinded the regulator's nod for 157 clinical trials. Based on the recommendations of the Professor Ranjit Roychowdhury Committee, the new regulatory model would take several aspects of clinical trials away from the CDSCO.

Similar report in-

The Financial Express- Clinical trials: Narendra Modi govt plans to clip wings of drug regulator

Essential drugs/ Generics/ Drug pricing

Publication: The Economic Times
Edition: National
Date: June 24, 2014
Headline: Pharmaceutical firms find it hard to exit essential drugs market

Synopsis: Pharmaceutical companies having more than a 1% market share for any essential drugs may find it difficult to stop manufacturing those products. Since May, when the government brought into force a new drug-pricing system after a gap of 18 years, the National Pharmaceutical Pricing Authority has denied such requests whenever the market share of the essential drugs the companies wanted to discontinue was more than 1%, government officials told ET. "If we allowed one such player with a significant market share to withdraw, we cannot stop other such players from doing it. This may create an exodus of many players from essential drugs, change the market dynamics drastically and even create a shortage," an official said. The pricing authority has internally set a 1% mark beyond which it refuses to grant permission for companies to exit unless it is assured that there would be no shortage of the drug in the market, he added.

Publication: The Financial Chronicle
Edition: National
Date: June 24, 2014
Headline: US begins to probe pharma deals of generic drugs (link unavailable, scan attached)

Synopsis: US regulators, armed with a year-old Supreme Court decision, are stepping up probes of pharmaceutical deals that delay the sale of generic drugs, arrangements they view as illegally hurting competition. The federal trade commission has opened new investigations into agreements between generic and brand-name drugmakers that may lead the agency to sue for disgorgement of revenues, said Markus Meier, head of the agency's health-care division. Companies under scrutiny include Forest Laboratories and Endo International, according to regulatory filings this year.

Website: Reuters
Edition: Online
Date: June 24, 2014
Headline: India may extend caps to more drugs

Synopsis: The health ministry has formed a committee that will meet for the first time on Tuesday to consider raising the number of drugs deemed essential and subject to price caps, people directly involved in the process said. The committee will consider adding more drugs to the National List of Essential Medicines (NLEM), all of which would then come under price controls.

Universal Health Coverage

Publication: Mint
Edition: Online
Date: June 24, 2014
Headline: Government plans universal healthcare, to focus on social indicators

Synopsis: The government is working to overhaul the health system with an aim to advance the universal health coverage and focus on social indicators of healthcare. Speaking at the release of the World Health Organization (WHO) bulletin on "(Brazil, Russia, India, China) BRICS and Global Health," C.K Mishra, additional secretary, health and family welfare ministry said that India has been hit by a double burden with the emergence of non-communicable diseases even as communicable diseases persist. "In the endeavour to address the double burden of disease we face due to combination of rapid emergence of non-communicable and persistence of communicable diseases, we are seeking to reform our health systems, advance universal health coverage and focus on social determinants of health," he said.

Similar report in-

The Economic Times- 'Collaboration on heath priority for BRICS nations'

Publication: Mint
Edition: National
Date: June 24, 2014
Headline: Big Data: affordability factor is the key

Synopsis: Universal health coverage is an issue that the Indian government has been taking steps towards, but with little progress. Big Data—collecting and analysing vast amounts of data—can help realize that goal, for example, by helping understand disease patterns so that optimal treatment plans can be designed. But Big Data can become big in the Indian healthcare industry only if it is made accessible to all, according to experts at the Mint Healthcare Conclave held in New Delhi. The first step, of course, is to collect data so it can be analysed. "The idea of allowing affordable access to Big Data is central to this particular tenet," said Kanav Kahol, team leader (affordable health technologies) at Public Health Foundation of India. "But if you want to get information from all the devices that are affordable, that's when you generate data with which you can ask unstructured questions."

Cancer

Publication: The New Indian Express
Edition: Online
Date: June 24, 2014
Headline: Cheaper. But cheap enough?

Synopsis: With the government proposing to bring cancer and AIDS drugs under price control, the pharmaceutical industry is up in arms. But the cost of cancer treatment is so high, and patients dropping out of treatment so widespread, that many medical experts feel government regulation is warranted. A doctor said 30-40 per cent of the drugs released in the world market now target cancer, but most are not available in India. Any drug released in the US or Europe takes six months to two years to enter the Indian market. Most cancer drugs are imported, and are taxed heavily. Only a lucky few have the resources to afford these under an individual import licence scheme.

Modi Government

Publication: Business Standard
Edition: National
Date: June 24, 2014
Interview: Nirmala Sitharaman, Commerce & Industry Minister
Headline: Budget will bring a simpler tax system for businesses: Nirmala Sitharaman

Synopsis: Talking about the Special 301 report and taking up the matter of the proposed out-of-cycle reviews (OCRs) by the US in the upcoming trade policy forum meeting, Commerce & Industry Minister Nirmala Sitharaman affirms that the Indian intellectual property law is well within the WTO rules and that there is a need to keep our national interests intact. She will engage with them to assert that every nation is allowed to protect its IPR and India's position is well within WTO rules and not in violation.

Similar report in-

The Hindu Business Line- 'SEZ policy requires a comprehensive review'

FDA

Publication: The Free Press Journal
Edition: National
Date: June 24, 2014
Headline: US Food and Drug Administration warnings to Indian cos

Synopsis: Indian pharmaceutical companies have been in the news for all the wrong reasons recently. Increased scrutiny of plants and processes has led to prohibitions and alerts by US Food and Drug Administration. The most famous case being that of Ranbaxy Laboratories for deviation in good manufacturing practices at its Toansa and Dewas plants, which led the company to voluntarily suspend shipments from the same. The Drug Controller General of India, too, has woken up to the threatening situation the Indian industry faces.