

News Updates: May 22, 2014

Patents/ Intellectual Property/ Compulsory Licensing

Publication: The Economic Times

Edition: National Date: May 22, 2014

Opinion piece: Ravi Venkatesan, Chairman, former chairman, Microsoft India

Headline: Challenges on the Economy

Synopsis: Mr. Venkatesan puts forth that the new government's top priority should be to repair our damaged economy. The foremost task is to make India a less hostile country to do business in and regain the confidence of global companies who bring much needed investment and jobs. He further highlights that while the new government must work hard to make India more business friendly , it must not cave in to pressure on other vital matters. For instance, on intellectual property protection, there is enormous pressure from global pharmaceutical companies for India to provide stronger patent protection and end compulsory licensing. These are difficult constraints for a country where 800 million people earn less than \$2 per day . India also needs to desperately revitalize its manufacturing sector. This will require many policy changes including possibly preference for locally manufactured goods in government procurement or local content requirements. In such matters, India will need to thoughtfully and courageously maintain a fine balance between being compliant with its obligations to WTO on one hand and doing what is in her self-interest on the other.

Publication: The Hindu Edition: National Date: May 22, 2014

Headline: IPR attorney association's plea to be disposed of in three months

Synopsis: The Intellectual Property Rights Attorney Association (IPRAA)'s representation seeking a provision of express request for examination of a patent application will be disposed of in three months. Counsel for the Union Department of Industrial Policy and Promotion (DIPP) made the submission when a public interest litigation petition by the association came up before a Vacation Bench comprising Justices M.M.Sundresh and K. Ravichandra Baabu on Wednesday.

Similar reports in-

The Times of India-Plea alleges patent process biased against Indians

Business Standard- HC disposes of PIL

R&D/ Clinical Trials

Publication: Daily News & Analysis

Editions: National Date: May 22, 2014

Interview: Habil Khorakiwala, chairman, Wockhardt

Headline: India can become world's fourth hub in R&D: Habil Khorakiwala

Synopsis: Mr. Khorakiwala highlights that the new government should provide incentives for research-based projects and revision in the minimum alternate tax to provide a boost for manufacturing and research. He adds that India has both the talent and capabilities. However, the present environment in clinical trials do not promote researches. Even at Wockhardt, clinical trials were done outside India. This issue needs a major change. He also spoke about the IPR issue and stated that India is completely complying with the multi-lateral agreement it has with Trips. The patents should be redeemed in India

by pharma companies in tune with the US and Europe. According to him, Indian government should stay firm on the patent act which we have agreed. Also healthcare reform is required. Private sector should be given more support in terms of land and taxation so that there could be more investments in the healthcare.

Publication: Daily News & Analysis

Edition: National Date: May 22, 2014

Headline: Clinical trials drop by 50 per cent

Synopsis: After strict regulations governing clinical trials were implemented in January last year, the quantum of tests conducted across India have reduced by less than 50 per cent. While from 2005 to 2012, there was steady increase of commercial clinical trials being commissioned by the pharmaceutical companies after a nod from Drugs Controller General of India (DCGI), the number has seen a steep decline since 2013, doctors at Tata Memorial Hospital (TMH) in Mumbai said.

Drug pricing

Publication: The Economic Times

Edition: National Date: May 22, 2014

Headline: Drug pricing regulator planning to lower prices of cancer, HIV drugs

Synopsis: The drug pricing regulator is planning to lower prices of expensive medicines used for treating cancer, HIV, diabetes, cardiovascular diseases, malaria, and tuberculosis. The National Pharmaceutical Pricing Authority (NPPA) is considering benchmarking prices of the most expensive brands in these therapeutic categories to the average price of their respective categories. It will also stipulate that the price of a new medicine should not exceed that of the most expensive drug brand in a particular therapeutic group.

Drug regulation/ Drug quality

Publication: The Economic Times

Edition: National Date: May 22, 2014

Headline: Government to spend Rs 3,000 crore to set up labs, double drug regulators

Synopsis: The government will spend about Rs 3,000 crore to double the number of drug regulators to 1,000 in three years and set up testing labs at ports to ensure that pharmaceutical export shipments meet global quality standards, a senior government official said here today. "While following a zero tolerance policy for any laxity, the government will more than double the number of regulators in three years and set up state-of-the art testing labs at ports to ensure the pharmaceuticals and drugs exports shipments meet global quality standards," Drugs Controller General (India) G N Singh told reporters.

Similar reports in-

Mint- India to double drug regulator's staffing, test drugs at ports

Business Standard- Govt to spend Rs 3k cr to set up labs, double drug regulators

The Times of India- Government to spend Rs 3,000 crore to set up labs, double drug regulators

The Hindu- Government to double number of drug regulators

The Hindu Business Line- More regulators, labs at ports to ensure quality of drug exports

The Financial Chronicle- India to double drug inspectors to boost oversight

Business Today- Govt to spend Rs 3k cr to set up labs, double drug regulators

Daily News & Analysis- <u>Government to spend Rs 3,000 crore to strengthen drug regulatory</u> Pharmabiz- <u>India to double drug regulators</u>; to set up testing labs at ports: <u>Govt officials</u> Website: NDTV Edition: Online Date: May 21, 2014

Headline: Time to Reset India-US Ties: Indian-Americans

Synopsis: With BJP leader Narendra Modi all set to become the Prime Minister, Indian-Americans feel that "policy paralysis" would be a thing of the past and they want India and the US to reset their strategic relationship. "The euphoria is over. Now the job begins. It is my belief that the two countries should look at some kind of a 100-day active effort to really build the relationship, which frankly has been at a low point (for some time now)," said Mr Rangaswami, an Indian-American entrepreneur. Based in Silicon Valley, Mr Rangaswami is the founder of Indiaspora, which hosted the first ever Indian American inaugural ball for US President Barack Obama in January 2013.

General Industry

Publication: The Hindu Business Line

Edition: National Date: May 22, 2014

Headline: India looks to reinforce image as dependable medicines producer for the world

Synopsis: Indian generically similar drugs reach almost all corners of the world and over 50 per cent of exports worth \$14.5 billion are shipped to highly regulated markets including the United States and the European Union, with Japan also holding out much potential, said Pharmexcil Chairman Ashutosh Gupta. Looking to reinforce India's capabilites as a dependable and affordable source of medicines for the world, Pharmexcil or the Pharmaceuticals Export Promotion Council of India has organised iPhex 2014, a three-day event to showcase local drug companies.

Website: Reuters Edition: Online Date: May 21, 2014

Headline: See you later? Slim Pfizer deal hopes prop up AstraZeneca

Synopsis: Pfizer's chances of striking a deal to buy AstraZeneca in the coming days look vanishingly small, but the notion it could return later this year is propping up the British drugmaker's shares. The stock rose 3 percent on Wednesday, despite AstraZeneca insisting on Tuesday there wasn't the slightest chance of Pfizer's \$118 billion offer being increased by a May 26 deadline set by UK takeover rules. While Pfizer agrees it cannot raise its final offer of 55 pounds a share, its advisers have been urging investors to speak up against AstraZeneca's decision to reject its proposal, according to several people familiar with the matter.

Similar report in-

The Wall Street Journal-Legal & General Urges AstraZeneca to Engage With Pfizer
The Financial Times-AstraZeneca deal 'in injury time' after final Pfizer offer

Website: Pharmabiz Edition: Online Date: May 21, 2014

Headline: GSK to freeze vaccine prices for 5 years for GAVI Alliance support countries

Synopsis: GSK announced that it will freeze the prices of its vaccines for five years for developing countries that graduate from GAVI Alliance support. By committing to offer GAVI Alliance prices for vaccines against pneumococcal disease, rotavirus and cervical cancer, GSK will support developing country governments as they transition to financing the full cost of their local vaccination programmes. Since its formation in 2000, the GAVI Alliance has helped to fund the immunisation of 440 million children in some of the world's poorest countries. GSK is a long-standing partner of the

Alliance and reserves its lowest prices for GAVI-eligible countries, which can be as low as one-tenth of prices in developed countries.

Publication: The Economic Times

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Headline: Supreme Court asks Andhra Pradesh High Court to look into Sun Pharma-Ranbaxy merger

Synopsis: The Supreme Court on Wednesday refused to stay a status quo order by Andhra Pradesh High Court on the planned merger of Sun Pharma and Ranbaxy for now and instead directed the high court to issue a fresh order after hearing companies' objections in two days. The high court had on April 25 issued a status quo order on the amalgamation process, holding up the biggest merger in Indian pharmaceutical industry valued at over \$4 billion, on the basis of a petition alleging insider-trading. Sun Pharma and Ranbaxy moved the Supreme Court seeking a stay on the "unreasoned" status quo order, which was passed "ex-parte" without even hearing them.

Similar reports in-

Mint- SC gives Andhra Pradesh HC two days to decide Sun-Ranbaxy issue
Business Standard- Ranbaxy-Sun Pharma deal: SC calls for ruling in two days

The Hindu Business Line- Apex court asks Andhra HC to decide on Ranbaxy-Sun Pharma merger
The Indian Express- Supreme Court refuses to stay HC order on \$4 bn Sun Pharma-Ranbaxy merger
Deccan Chronicle- Supreme Court tells Andhra High Court to decide Ranbaxy case in 2 days