News Updates: November 26, 2013

FDI

Publication: The Economic Times
Edition: National
Date: November 26, 2013
Opinion: Habil Khorakiwala, Founder, Chairman and Group CEO, Wockhardt
Headline: Govt should not interfere with cross-fertilisation in Indian pharma sector

Synopsis: The last 10 years in the Indian pharmaceutical industry have been characterised by many events that led to its stellar performance. A strong aspect of this growth has been the process of inorganic growth, both in terms of outbound acquisitions and domestic consolidation by Indian firms as well as inbound acquisition of Indian firms by multinational companies. Unfortunately, the latter has been a matter of much concern with the government since this will impact the availability and affordability of off-patent medicines in India due to a high multinational presence and, hence, there should be a curb on the FDI in pharmaceutical industry. The share of Indian companies is about 73% of the market while the rest 27% is held by MNCs. Additionally, India has the highest generic medicine penetration at over 99%, with equal market access to large and small players of both domestic and foreign origin. The Indian pharmaceutical industry is one of the most globalised industries and this aspect has benefited a lot more than just the source nation of the medicine. It is a two-way street and restricting the inflow will surely impact the outflow. The policy of restricting participation of foreign MNCs is very defensive and more of a counterproductive move, which may impact assessment of India as a strong pharmaceutical destination. This stand on curbing M&A threatens the very premise of globalisation of the pharmaceutical industry, with which India has benefited significantly. In fact, we have earned a net foreign exchange of $70 billion through M&A and exports in the last 10 years. Allowing globalisation of the industry as it moves forward is a true win-win situation for the industry.

Publication: The Economic Times
Edition: National
Date: November 26, 2013
Headline: Cabinet defers decision on FDI in pharma

Synopsis: The Union Cabinet deferred a proposal for changes in the foreign direct investment (FDI) policy for the pharmaceutical sector that seeks to bar foreigners from taking control of manufacturing facilities for critical care drugs. "The commerce and industry ministry requested for the deferment of all the three proposals. Most likely, the Cabinet will take up these issues later this week," an official said. The strategy for the WTO ministerial conference in Bali next month was also not discussed. Several departments, including the Department of Industrial Policy and Promotion (DIPP), have raised concerns about Indian drugmakers being acquired by global firms.

Publication: NDTV Profit
Edition: National
Date: November 25, 2013
Headline: Cabinet may restrict pharma FDI as drug costs rise

Synopsis: The UPA government may be trying its best to attract foreign direct investment, or FDI, but there is, at least, one sector where the government wants to bring it down. The Cabinet will decide on FDI limit in existing pharmaceutical companies producing critical medicines. The Department Industrial Policy & Promotion (DIPP) of Commerce Ministry wants to bring down FDI limit in existing pharma companies to 49 per cent from the current norm of 100 per cent. The pharma FDI issue is listed on the Cabinet's agenda for today's meeting but sources told NDTV that it could be deferred due to opposition from the Prime Minister's Office and Finance Ministry.

Currently, India permits 100 per cent FDI in the pharma sector through automatic approval route. The Cabinet note, accessed by NDTV, argues its objective is two-fold. One, it is to prevent hostile take-overs of Indian companies by MNCs and two, to keep prices of critical medicines affordable.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Economic Times
Edition: National
Date: November 25, 2013
Headline: Pfizer-Wyeth merger good for shareholders: Ranjit Kapadia, Centrum Broking

Synopsis: In an interview with ET Now, Ranjit Kapadia, Sr VP-Pharma, Centrum Broking Ltd, shares his views on the Pfizer-Wyeth merger.
ET Now: Do you like the Pfizer business because many analyst have criticised MNC pharma companies in the past and their view is that MNC companies are not really launching some of their blockbuster drugs in India because there is no patent protection?
Ranjit Kapadia: I defer with this statement because Pfizer has already launched Champix, which is a smoking cessation drug. The drug is still under patent in the Indian market through a listed entity and this was launched about two years back.

Publication: The Economic Times
Edition: National
Date: November 25, 2013
Headline: Govt not lax on pharma policy: Anand Sharma

Synopsis: Commerce minister Anand Sharma said that the government is not lax on Indian pharma policy. Government is committed to protecting Indian generics and pharma sector

Publication: The Economic Times
Edition: National
Date: November 25, 2013
Headline: Ipca wins trademark case against Anrose Pharma

Synopsis: In a major relief to Ipca Laboratories, the court has ordered Anrose Pharma not to use words 'Zerovolp' or 'Zerovol' which are identical to Mumbai-based pharmaceutical firm's popular painkiller drug "Zerodol".

Publication: Business Standard
Edition: National
Date: November 25, 2013
Headline: European Patent Office to slash fee to euro 5,000 by 2015

Synopsis: The European Patent Office (EPO), the second-largest European public service organisation with Euro 2-billion budget for 2013, is planning to cut the patent filing costs to Euro 5,000 (Rs 4.25 lakh), according to its director Dieter Tzschoppe. “It (slash in patent fee) is currently in construction. This move is expected to increase the number of patent filings, especially from small and mid-sized companies and also from universities globally,” he said. Speaking to Business Standard on the sidelines of a seminar on the European patent system organised by the CII in Hyderabad on Monday, Tzschoppe said the EPO had so far received 500 patents from India, with the biggest sectors being pharmaceuticals and fine chemistry, followed by computer inventions. “I think India has quite a good growth rate in terms of patent filings in Europe. This, however, is not as high as China. At present, China has a growth rate of 5 per cent and it intends to publish two million patents by 2050,” he added.
Tzschoppe said most of the companies were not making use of IPRs (intellectual property rights) because of the absence of complete database on Indian patents, which was slowing down patent filing by local inventors and creating road blocks to transfer of technology in the country.

Publication: The Hindu Business Line
Edition: National
Date: November 25, 2013
Headline: Gilead to respond to opposition on hepatitis C drug

Synopsis: US-based drug-maker Gilead Sciences has said that its Indian patent application for hepatitis C drug sofosbuvir complies with domestic patent laws. “We will respond to the opposition in due course,” Gilead said in a response to Business Line, following the pre-grant opposition filed against its drug at the Kolkata patent office by US-based lawyer group I-MAK (Initiative for Medicines, Access & Knowledge). “Gilead is currently conducting the necessary clinical trials that are required to register sofosbuvir in India, which we hope will be completed by the end of 2014,” the company said. In a pre-grant opposition, the patent application on a product is opposed before the Patent Office takes a decision. Health advocacy groups are also concerned that the drug will be priced beyond the reach of people, especially in developing countries like India. On its part, Gilead said it is committed to helping ensure access to its HCV medicines in “resource-limited settings, including India”. It further added that “IP should not be a barrier to access and used responsibly can drive medical innovation while also enabling access to treatment for patients in need.”

Publication: The Hindu Business Line
Edition: National
Date: November 25, 2013
Headline: Suggestion of WTO complaint irks public health workers in India

Synopsis: A US trade lawyer’s observation on the possibility of hauling India to the World Trade Organisation, “for violating international patent treatises”, has ruffled feathers back in India. The lawyer’s observation was made at a US Chamber of Commerce event in New York, a foreign media-report said, adding that the lawyer felt it was time countries exercised their rights under the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This development is more than just an individual’s observation. In fact, it is the latest addition to the string of criticism heaped on the Indian patent regime, ever since foreign drug-majors lost a few cases here. There is a perception problem and the Indian Government needs to explain to counterparts in other countries and counter the misrepresentation of India’s patent enforcement, say patent-experts and public-health workers, concerned at the pressure being put on India by global trade and policy circles. The backlash against the Indian patent regime saw an increase after judgments in some high-profile cases, including Novartis’ blood-cancer drug Glivec and Bayer’s advanced kidney cancer drug Nexavar, to name just a couple, went against the multinationals. The criticism of India’s Patents Act has been relentless, coming from US-based industry associations and sections of its Congress-men. In one instance, a critical submission by a Pfizer executive to a US trade sub-committee on India’s patent enforcement was countered by the Indian Pharmaceutical Alliance, representing domestic drug-majors.

Publication: FirstPost Business
Edition: National
Date: November 25, 2013
Headline: Branded drugs: How Lupin plans to grow in US and beyond

Synopsis: Lupin Ltd, India’s No. 4 drug maker by revenue, may come from the land of cheap generics but it is betting on high-margin branded drugs in the United States to drive growth. It also wants to expand beyond its core U.S., Indian and Japanese markets into Latin America, Eastern Europe and China, and is prepared to spend as much as $1 billion to buy brands and companies in coming years. A decade ago Lupin was another Indian “me-too” maker of cheap versions of off-patent drugs and was a late entrant, in 2004, to the United States. Gupta’s older sister Vinita, now Lupin’s CEO, was its first U.S. employee and remains based at its U.S. headquarters in Baltimore.

FDA / Drug Regulatory / DCGI / Drug Policy

Publication: The Economic Times

Edition: National
Date: November 26, 2013
Headline: Will Ranbaxy Labs be the next turnaround story?

Synopsis: Ranbaxy Laboratories, India's biggest pharmaceutical company by sales, is trading at a steep discount to its peers due to concerns over legal troubles with the US Food and Drug Administration (USFDA). Its market capitalisation is less than one sixth that of Sun Pharma, the biggest Indian pharmaceutical company by that measure. The FDA triggered concerns among investors when it imposed an import alert on Ranbaxy's factory in Mohali recently, saying the plant had not met "good manufacturing practices" norms. All three Ranbaxy plants in India dedicated to the US market, which accounts for more than 40% of its sales, have now been barred from making shipments to the country. However, some analysts are optimistic about an early resolution of the issue at the Mohali plant as they believe the plant's quality standards are sound and the import alert issued is not as severe as in the case of other companies such as Wockhardt.

Publication: Bangalore Mirror
Edition: National
Date: November 25, 2013
Headline: Call your doc, right away

Synopsis: Doctors prescribe medicine, of which they know little, to patients of which they know less. This has been a well-known statement. It should be rephrased to "doctors prescribe medicine, of which medical science knows little to patients of which medical science knows even less". The database of evidence changes from time to time and what we might have prescribed yesterday may be considered disastrous today. I remember a colleague had gone to see a patient who had a urinary infection. This man also had a neck and spinal surgery done for early compression of his cervical spine. During the course of his therapy for urine infection, he developed fits and became incontinent. In the United States, the Food and Drug administration regulates OTC medication. It has a category of restricted OTC substances as well. Such drugs are sold only in stores which are registered by the state. One such drug is pseudo ephedrine. It is used as a cold medication. In Europe it is available as an OTC. Because of the risk of hemorrhagic stroke in young women at a study done by Yale University and cases of psychiatric disturbances of acute mania, organic psychosis and even paranoid schizophrenia, the US FDA issued a public health advisory in 2000 against the use of this drug.

Publication: Telegraph India
Edition: National
Date: November 25, 2013
Headline: Mylan-Biocon Receive First Indian Biosimilar Regulatory Approval for Herceptin

Synopsis: Mylan Inc. (Nasdaq: MYL) today announced that its partner Biocon has received approval for a Mylan-Biocon trastuzumab product from the Drug Controller General of India. This is the first regulatory approval for a Mylan-Biocon developed biosimilar product. The product is a biosimilar to Roche's Herceptin®, indicated for the treatment of HER2 overexpressing breast cancer. Mylan intends to market its trastuzumab product under the trade name Hertraz.

Publication: Pharmabiz
Edition: Online
Date: November 26, 2013
Headline: All irrational combinations will be weeded out from the domestic market soon: DCGI

Synopsis: The office of the Drug Controller General of India (DCGI) is determined to go ahead with the process of weeding out all irrational combinations from the Indian pharmaceutical market soon. This would happen even if some of the pharmaceutical companies are constantly trying to oppose the government's initiative, according to Dr GN Singh, the DCGI. Speaking to Pharmabiz on the sidelines of a meeting organised as part of Pharmacy Week celebration in Chennai, the national regulator said his office is now formulating a special strategy to clean the Indian pharma market giving no space for irrational combinations. However, Dr Singh did not explain how would

the strategy be worked out and what it was. He added that provided the pharma companies failed to submit the safety and efficacy data, all the fixed dose combination drugs would be banned in the country. The DCGI gave away the 'Best Pharmacist Award' to M Sulaiman, managing director of Madras Pharmaceuticals. Tamil Nadu IPA president MM Yusuf, secretary, J Jayaseelan, IDMA president elect S Veeramani, state drugs controller, Abdul Khader, associate professor of Pharmacy from US Christine Birnie and CDSCO deputy drugs controller S Manivannan attended the meeting.

General Industry

Publication: The Economic Times
Edition: National
Date: November 26, 2013
Headline: Mylan, two Indian companies line up to buy Bafna Pharmaceuticals

Synopsis: US-based generic drug maker Mylan and two Indian pharma companies are in the race to acquire Chennai-based Bafna Pharmaceuticals, which makes haemoglobin drug 'Raricap' among other products, said two people privy to the transaction. Founded in 1981, Bafna Pharmaceutical, which makes indictable, generic drugs and haemoglobin drug 'Raricap', is in talk where promoters are intending to divest their stake from the company. "The talks are primarily for a slump sale in nature," said one of the person, who is directly involved into the talk. If Mylan completes the transaction, this will be the second acquisition by the US company in India after it had completed $760-million acquisition of vaccine and injectable-drug unit of Strides Arcolab in current year.

Clinical Research / Trials

Publication: The Indian Express
Edition: National
Date: November 26, 2013
Headline: Audiovisual consent of subject mandatory for clinical trials

Synopsis: All clinical trials in India will henceforth have to take subject consent audiovisually and preserve the records. Acting on a directive of the Supreme Court, the drug controller has issued an order making audiovisual recording mandatory for all trials. While industry has raised objections, officials in the Health Ministry say that the order will not be applicable for ongoing clinical trials. In all clinical trials in addition to the requirement of obtaining written informed consent, audiovisual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding of such consent is required to be done while adhering to the principles of confidentiality.

Publication: Pharmabiz
Edition: Online
Date: November 26, 2013
Headline: ISCR raises concern over hasty introduction of audio-visual recording of informed consent

Synopsis: The Indian Society for Clinical Research (ISCR), a professional body representing the interests of clinical research professionals in the country, has expressed concern over the haste with which the union health ministry has introduced the audio-visual recording of informed consent in clinical trials without the requisite clarity and an appreciation of the logistical issues in its implementation. Fully supporting the need for a more robust and regulated environment for the conduct of clinical trials in India ensuring the practice of the highest standards of ethics and quality, the ISCR asked the regulators to provide more clarity and address concerns of stakeholders to ensure that an important step taken to safeguard the interests of patients does not act as a deterrent to stakeholders.

Publication: Sahara Samay
Edition: National
Date: November 25, 2013
Headline: New drug may ease pain in arthritis

Synopsis: In a breakthrough, a new drug that can ease the crippling symptoms of arthritis has been developed. Patients who used the drug Sarilumab in trials were able to move more freely and suffered less damage to their joints. Manufacturers have announced promising late-stage data for an experimental rheumatoid arthritis (RA) drug. The Phase III clinical trial evaluated sarilumab in combination with MTX in adult patients with active RA who were inadequate responders to MTX. The trial consisted of 1,200 patients who were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week.

Innovation

Publication: BusinessWorld
Edition: National
Date: November 26, 2013
Headline: A Step Forward In Cancer Research

Synopsis: Medical experts from various fields in India and abroad discussed the various aspects of cancer at the Indian Cancer Congress 2013 held in New Delhi (date/period?). This was done with the hope that oncology practitionars will adopt the multimodal approach as the standard of care. Dr Harit Chaturvedi, Organiaing Secretary, Indian Cancer Congress said, "It will act as a catalyst of true integration of clinical and research innovations. With a large input from world leaders in cancer care, we are certain this is going to inspire the new generation towards taking oncology to an international level".