News Updates: December 5, 2013

OPPI

Publication: The Economic Times
Edition: Mumbai, Online
Journalist: Soma Das
Date: December 5, 2013
Headline: New caveat in drug FDI policy worries MNCs

Synopsis: Valuations of Indian pharmaceutical companies may drop with the government deciding to bar non-compete clauses in takeovers by foreign companies. This would allow sellers to re-enter the business without the usual hiatus that acquirers usually insist upon following a sale. Multinationals said they are worried by the new caveat in the foreign direct investment policy, while experts feel that this could mean 'super valuations' of domestic drug makers may become rarer. Late last week, the cabinet decided that the current FDI policy "in brownfield and greenfield projects in the pharmaceutical sector will continue subject to the additional condition that in all cases of FDI in brownfield pharma, there will not be any noncompete clause in any of the inter se agreements". The move is "worrying", said Ranjana Smetacek, director general of the Organisation of Pharma Producers of India, a grouping of foreign drug makers. "Business is a two-way street and if FDI is to be encouraged, it is important to protect the interests of both parties," she said. "Our concern is that the buying company could be in a disadvantaged situation if the seller uses its knowledge and expertise to foray into the same line of business." The grouping, however, welcomed the government's move to continue with the existing policy of allowing 100% FDI in the sector. Moves to impose stake limits in acquisitions in the rare and critical subsector and not allowing non-compete clauses were based on the concern that overseas drug makers may gain a monopoly in essential drugs and that prices may rise. The stake-limit plan was abandoned but that the proposal on the non-compete clause was accepted.

Publication: Mint
Edition: Mumbai, Online
Journalist: C H Unnikrishnan
Date: December 5, 2013
Headline: Govt may issue compulsory licences on diabetes drugs

Synopsis: Health ministry panel may suggest compulsory licences for at least two patented drugs that are yet to be identified. India, with at least 60 million diabetes patients, may consider issuing compulsory licences for some patented diabetes management drugs sold in the country in an effort to make them accessible and affordable. A committee formed by the ministry of health and family welfare to recommend ways to ensure access to essential drugs to patients will suggest that compulsory licences be issued for at least two patented therapeutic drugs, according to two people familiar with the development. “OPPI believes that compulsory licensing of a patented invention is not a sustainable or viable solution to addressing India’s healthcare challenges. We believe compulsory licences should be used only in exceptional circumstances, such as in times of a national health crisis. If used arbitrarily, compulsory licences will serve to undermine the innovative pharmaceutical industry and will be to the long-term detriment of the patient,” said Ranjana Smetacek, director general, Organisation of Pharmaceutical Producers of India (OPPI), in an emailed response. OPPI is a lobby of foreign pharmaceutical companies in India.

PhRMA

Publication: The Hindu Business Line
Edition: National
Date: December 4, 2013
Author: Kristina M. Lybecker, Assistant Professor of Economics at Colorado College in Colorado Springs

Headline: In medicine, every little innovation matters

Synopsis: But Section 3 (d) of the Indian Patent Act does not understand this. In the past few months, India's Ambassador to the US, Nirupama Rao made some declarations aimed at allaying concerns over the country's stringent patent regime. Her statements notwithstanding, India seems to have failed to create an environment to nurture and protect innovation, as recent court decisions indicate. The much debated Section 3(d) of the Indian Patent Act forbids patenting new forms of existing drugs, unless they markedly improve efficacy and generate therapeutic benefits. Consequently, much of the incremental innovation done on existing treatments will no longer be patentable in India. This is disastrous for medical progress and for patients.

FDI

Publication: The Hindu Business Line *(Reproduced from PTI)*
Edition: National
Date: December 5, 2013
Headline: USIBC applauds Indian decision to reject FDI limits in pharma

Synopsis: The US-India Business Council yesterday applauded India's decision to reject a proposal limiting pharmaceutical investment caps to 49 per cent in the brownfield investment sector. Such a reversal would have sent chilling signals to investors, chased capital to other markets, and prevented domestic companies from growing and collaborating, USIBC said welcoming the decision of the Indian Government in this regard, adding that this reassures investors that India is not going back on reforms. The decision will encourage competition and investment in the pharmaceutical sector which will continue to create jobs and ensure that patients receive access to important medicines, USIBC said in a statement.

Publication: The New Indian Express
Edition: National
Date: December 4, 2013
Headline: FDI Inflows Fall 38% to $2.91 bn in Sept

Synopsis: In what is being seen as a reflection of the investment climate in the country, foreign direct investment (FDI) fell by 38 per cent to $2.91 billion in September. According to data available with the Department of Industrial Policy and Promotion (DIPP), in September last year, the FDI number stood at $4.67 billion. And for the April to September period this year, FDI inflows have fallen 11 per cent to $11.37 billion from $12.84 billion in the corresponding period of the last fiscal.

Publication: The New Indian Express
Edition: National
Date: December 5, 2013
Headline: 'Drug Price Control a Gimmick'

Synopsis: Kerala Medical and Sales Representatives Association (KMSRA)(CITU) has opined that the new price control policy to regulate the prices of medicines was a big gimmick. They said while 26 of the multinational companies literally took over the country's pharma giants they was really aiming to stop Indian companies from exporting medicines at a cheaper rate to the global market from the year 2015 when the patent of products of several companies will expire. Moreover, these MNCs could gain control over India's Rs 60,000 crore drug manufacturing industry. They said the multinationals introduced over 700 drugs at exhorbitant prices. When the government listed several medicines to be sold at controlled prices, these companies stopped their production and introduced new medicines which were priced heavily. They pointed out that when the BJP Government allowed 100 percent FDI the main claim was that it would attract greenfield ivestsments. However, no new manufacturing unit have come up. Instead, 26 prominent Indian companies have been taken over by multinationals.

Publication: Zee News

Edition: Online
Date: December 4, 2013
Headline: 'Low FDI cap in insurance an issue in India-EU trade pact'

Synopsis: Low FDI cap in the insurance sector is an 'outstanding issue' for India-EU free trade pact and the EU is waiting for the Indian Parliament to pass the bill that aims to raise the limit, a European Union official has said. The Insurance Laws (Amendment) Bill 2008, which seeks to raise FDI cap in the sector from 26 percent to 49 percent, is much awaited by global investors but has been pending for long in Parliament.

Publication: India PR Wire
Edition: Online
Date: December 4, 2013
Headline: India's Top Doctors & Industry Stalwarts to debate at historic 6th Annual Pharmaceutical Leadership Summit & Leadership Awards 2013

Synopsis: The state of the indian pharmaceutical & healthcare industry is definitely not in good shape as the nation has witnessed series of policy paralysis & the stand-off between the industry & the government. The latest blow to this is in in FDI in Pharma where the government has decided to continue with the existing policy on foreign direct investment in the pharmaceutical sector and not implement the revised policy proposed by the industry ministry. However, an additional condition has been imposed that in all cases of FDI in Brownfield pharma projects, there will be no non-compete clause in any of the inter se agreements. There is also a deep concern with regard to the image of the pharma industry in india due to the severe attack from the regulatory bodies such as US FDA. Pricing continues to be the challenging factor as majority of essential drugs are controlled by the pricing mechanism of the government. Healthcare insurance again is a concept in womb in India. India's branded formulation market has become fiercely competitive due to the pricing mechanism, regulatory challenges & FDI in Pharma sector" said Satya Brahma.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: Business Standard
Edition: National
Date: December 5, 2013
Headline: Pharma: Strong pill in medium doses

Synopsis: Large-cap pharma companies have been major outperformers over the last few years, trumping both the broader markets and smaller peers. Even in the calendar year to date, large cap pharma companies have posted returns over 30 per cent while mid cap pharma has given returns under 10 per cent. The company with sales of $414 million in FY13 is looking at more than doubling the same to $1 billion by FY2018. While the domestic pharma business (14 per cent of revenues) is growing at 30 per cent annually and listing of its contract research subsidiary Syngene could unlock value, the bigger trigger is the opening up of the regulated markets to its biosimilars post patent expiries of key drugs in CY15.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Economic Times
Edition: National
Date: December 5, 2013
Headline: Low Valuations May Work in Favour of Cadila Health

Synopsis: The recent run-up in the stock of Cadila Healthcare is likely to be sustained due to indications of imminent improvement in the companys performance.The Ahmedabadbased drugs manufacturer reported a revenue growth of 12% in the quarter to September that was largely driven by its performance in the United States and Brazil.Its revenues from the domestic market,which accounts for nearly 40% of its consolidated sales,grew just 5% during the three-month period because of the standoff between the distributors and manufacturers over implementation of the new drug pricing policy.This also adversely impacted its operating margin,which,at a little over 15%,remained almost the same as the year-ago level.Cadila has 20 abbreviated new

drug application (ANDA) approvals lined up in the US over the next 12-15 months.It is set to launch products in niche segments that will boost its top line growth as well as margins.

Publication: The Economic Times
Edition: National
Date: December 4, 2013
Headline: Johnson & Johnson faulty implants: Indians left in lurch due to 'differential treatment' compared to US counterparts

Synopsis: Pharmaceutical giant Johnson & Johnson recently agreed to pay $2.5 billion (over Rs 15,000 crore) as compensation to around 8,000 US citizens who had sued the company after being fitted with its faulty hip implants. The settlement, touted as one of the biggest in pharma history, came three years after the metal-on-metal Articular Surface Replacement (ASR) implant, manufactured by J&J subsidiary DePuy Orthopedics, was recalled globally in 2010.

Publication: The Economic Times
Edition: National
Date: December 4, 2013
Headline: Firm that learns from others' mistakes is more successful: Dilip Shanghvi, Sun Pharma

Synopsis: Sun Pharma's stock has been on a tear this year. It has risen 61.94% so far this year as investors chased defensives with a strong export presence. Lupin, the nearest big competitor, has jumped 42.87% while Dr Reddy's Labs has risen 36.66%. Sun is one of the fastest-growing pharmaceutical generics firms globally. Its three-year compounded annual growth rate of 41% is higher than global majors such as Teva and Mylan. In the past one year, it has added a market cap of more than Rs 50,000 crore. Dilip Shanghvi, who built Sun into a global giant, is not slowing down the pace of expansion. He wants Sun to invest in innovative products and not just be known as only a generic player. He is putting in place systems and processes that will make Sun a global pharma company. Already, more than 70% of Sun's sales come from the US and Shanghvi recently hired Israel Makov, former president and CEO of Teva as chairman of the company, while he himself has stepped down to be the CEO.

Publication: The Economic Times
Edition: National
Date: December 5, 2013
Headline: Why foreign investors are staying the course

Synopsis: Indian policymakers have concluded that the worst of India's economic woes are behind us. One only wonders where such optimism stems from. When the economy started to weaken in 2011, policymakers persuaded us that India had seen much worse and told us not to self-flagellate. However, when things began to look considerably worse than expected, policymakers convinced us that things are so bad that they could only get better.

Publication: The Times of India
Edition: National
Date: December 5, 2013
Headline: Free Trade Agreement with European Union in suspended animation till new govt takes over

Synopsis: The long-negotiated ambitious Free Trade Agreement (FTA) between India and its largest trading partner European Union (EU) will remain in the doldrums till a new government takes over in New Delhi next year. India wants EU to provide greater market access in the services and pharmaceutical sectors, data security status for its IT sector and liberalised visa norms for its professionals. EU, in turn, is pressing India hard for "reforms" in the banking & insurance, wines & spirits, intellectual property regime, automobile and public procurement sectors.

Publication: Mint
Edition: National
Date: December 5, 2013
Headline: Strides Arcolab may not get $250 million from Mylan for Agila deal

Synopsis: Strides Arcolab Ltd. won't get $250 million of the $1.75 billion anticipated from the sale of its injectable drugs unit to Mylan Inc. unless regulatory concerns at one of the Indian drugmaker's factories are resolved. In September, the US Food and Drug Administration (FDA) told Strides there were significant violations of current good manufacturing practice at a plant in Bangalore. Mylan's purchase has been restructured to hold back $250 million unless certain regulatory conditions are resolved, the Canonsburg, Pennsylvania-based company said on Thursday in a statement announcing completion of the acquisition.

Publication: The Financial Express
Edition: National
Date: December 5, 2013
Headline: Ministries differ over competition policy coverage, delay rollout

Synopsis: The proposed national competition policy rollout, which has been in the works for over two years, may see further delay with no resolution of inter-ministerial differences on who will drive its implementation and which departments and ministries will need to be kept out of its purview. The draft policy has been under the scrutiny of a committee of secretaries where the department of industrial policy and promotions (DIPP) and ministries such as commerce, defence, railways and finance have expressed their views that they should be kept out of its provisions, government sources said.

Publication: The Financial Express
Edition: National
Date: December 4, 2013
Headline: FDI inflows decline 38% in September

Synopsis: Foreign direct investment into the country declined by about 38%, year-on-year, to $2.91 billion in September, according to the department of industrial policy and promotion (DIPP).

Publication: The Financial Express
Edition: National, Online
Date: December 5, 2013
Headline: Wockhardt needs global assessment: FDA

Synopsis: The US Food and Drug Administration (USFDA) has hauled up Wockhardt's senior management for failing to take "appropriate actions" to resolve problems identified by the regulator at the company's Waluj facility and "elsewhere within Wockhardt's organisation". The regulator, in a warning letter dated November 25, outlined its responses to the corrective actions sent by Wockhardt following the USFDA inspection conducted at the company's Waluj and Chikalthana facilities in July 2013.

Publication: Business Standard
Edition: National
Date: December 5, 2013
Headline: US FDA tells Wockhardt to evaluate its plants

Synopsis: Trouble for Mumbai-based drug maker Wockhardt has increased as the US Food and Drug Administration (FDA) has raised concerns over the reliability and accuracy of tests conducted by the company at its plants in Waluj and Chikalthana in Maharashtra. In a warning letter on Novemeber 25, FDA asked the

company to conduct a global assessment of its plants to ensure its products conformed to FDA requirements for safety, efficacy and quality. FDA has also expressed concern about Wockhardt's inability to implement a robust and sustainable quality system.

Publication: Daily News and An alysis
Edition: National
Date: December 5, 2013
Headline: Medical shops to go on 3-day strike again

Synopsis: The Food and Drug Administration (FDA) and chemists are once again at loggerheads in Maharashtra over the issue of non presence of pharmacists in chemists shops and FDA's action against the same. The Maharashtra State Chemists and Druggists Association (MSCDA) has yet again announced to go on strike for three days starting from December 16. The chemists are protesting against the alleged harassment and raids by FDA regarding selling of drugs under the supervision of registered pharmacist and billing for every drug sold. Though these rules are not new, but the strict implementation has provoked MSCDA to go on strikes.

Drug Pricing

Publication: Pharmabiz
Edition: Online
Date: December 5, 2013
Headline: Hearing on case against new pharma policy to come up only in January, under new bench

Synopsis: The ongoing case on the pharmaceutical pricing policy in the Supreme Court will come up for hearing only in January, possibly with a new bench, putting pressure on the petitioners to begin the process afresh.

Disease

Publication: Pharmabiz
Edition: Online
Date: December 5, 2013
Headline: HIV/AIDS Bill likely to be introduced in winter session of Parliament that begins on Dec 5

Synopsis: The much delayed HIV/AIDS (Prevention and Control) Bill, 2013 is likely to be introduced in the winter session of Parliament which begins on December 5 as it has found a place among the tentative list for transaction of business during the winter session. The Bill aims to end discrimination to the HIV patients and ensuring access to treatment to them.

Clinical Trials

Publication: Mint
Edition: National
Date: December 4, 2013
Headline: Wockhardt manipulated clinical trials data: US FDA

Synopsis: The US drug regulator has accused Wockhardt Ltd of manipulating data related to clinical trials of drugs at its two Indian factories, which had earlier been banned from shipping medicines to the US. The Wockhardt factories located at Waluj and Chikalthana in Aurangabad district of Maharashtra had halted exports to the US, a market that contributed at least 30% of its revenue in fiscal 2011 and 2012.

Publication: The Hindu
Edition: National
Date: December 5, 2013
Headline: 'Children metabolise TB drugs much faster than adults'

Synopsis: Dr. Peter R. Donald, Emeritus Professor in the Department of Paediatrics and Child Health of the Faculty of Health Sciences at Stellenbosch University, South Africa was awarded an A-rating by the National Research Foundation, South Africa. He says 'It would be very difficult to conduct efficacy trials in children. Because children are often culture negative and smear negative it would be quite difficult to find enough children to carry out efficacy trials of TB drugs in children. Very large numbers would have to be enrolled. In adults microbiological endpoints are used to judge efficacy....the fall colony forming units of M. tuberculosis or culture positivity.'

General Industry

Publication: The Economic Times
Edition: National
Date: December 4, 2013
Headline: India to showcase drugmaking facilities to global regulators

Synopsis: India is showcasing its best pharmaceutical manufacturing facilities to regulators from emerging economies to counter adverse publicity the country's drug industry has endured in recent times. Health ministers and officials from countries including Kenya, Ghana, South Africa, Vietnam, Egypt and the Philippines are being hosted by India, which is keen to dispel notions that Indian pharmaceutical companies do not adhere to the highest quality standards.

Publication: The Economic Times
Edition: National
Date: December 4, 2013
Headline: Pharma giant GSK's sign-on bonus demand leaves Ad world divided

Synopsis: UK pharma major GlaxoSmith-Kline's demand for sign-on bonus from advertising firms to do business with it seems to have divided the Indian advertising and marketing fraternity into two camps on the social media. While GSK's move is being condemned by international advertising agencies that have termed it 'scandalous', 'lazy' and 'bullying', some industry veterans in India support the rebate, saying it will put a leash on media agencies that, they allege, discreetly charge over 10% commission and show 2-3% on record.

Publication: The Times of India
Edition: National
Date: December 5, 2013
Headline: Lack of incentive major hurdle in setting up industry, tycoon says

Synopsis: Anisha Anand caught up with the pharmaceutical giant to know his plans for Bihar and Biharis. A friend suggested me to opt for pharmacy business since it was related to my earlier ambition of becoming a doctor. In 1953, I opened a small chemist shop on Ashok Rajpath. In 1960, I started pharmaceutical distribution under the banner of 'Magadh Pharma' and came into contact with the big bosses of pharma industry, like Dolphin Labs and Abbot Labs. Realizing the limitations in distribution business in Patna, I moved to Mumbai and set up my own pharmaceutical company, 'Alkem Laboratories', in 1973. Since then we have been helming the company across the country. An important thing for a pharmaceutical company is adequate land and getting that in Bihar is an uphill task. The third and most important factor is lack of tax incentives.

Publication: The Economic Times
Edition: National
Date: December 4, 2013
Headline: Egypt seeks investment from Indian pharma players

Synopsis: Egypt today invited Indian pharma companies to invest and manufacture final product in that country. "Indian pharma industry has proceeded and progressed well. We invite pharma industry in India to invest in Egypt. This kind of mutual cooperation and investment is very beneficial to both the sides.

Publication: Business Standard
Edition: National
Date: December 3, 2013
Headline: Curtains raised for pharma ingredients show CPhI in Mumbai

Synopsis: With over 1000 plus exhibitors from 95 countries, pharma ingredients exhibition CPhI – along with other concurrent events P-MEC, ICSE and BioPh India – is likely to offer global pharma industry an opportunity to explore India as destination for sourcing and consumption, claims the organiser of the event, UBM India. Being held from December 3-5, 2013, in Mumbai, the event is expected to be attended by nearly 30,000 attendees from 109 countries.

Innovation

Publication: Pharmabiz
Edition: Online
Date: December 5, 2013
Headline: India's know-how in genomics attracts US collaboration as Strand partners with El Camino Hospital for pharmacogenomics

Synopsis: India's expertise in genomics and personalized medicine is opening up avenues for several bioinformatics and bio-pharma entrepreneurs to offer their expertise. The effort enables rapid and effective interpretation of pharmacogenomics to analyze genetic structure affecting an individual's response to drugs.