

News Updates: April 2, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Economic Times

Edition: National Date: April 2, 2014

Headline: Natco set for US launch of generic copy of Teva's drug

Synopsis: Natco PharmaBSE 6.33 % indicated it could go ahead with plans to sell the generic version of multiple-sclerosis drug Copaxone in the United States, despite the Supreme Court there agreeing to hear an appeal by Israel's Teva Pharmaceutical, which holds the patent and is attempting to block copycat versions. Natco Pharma's stock had tanked nearly a fifth after news of the US Supreme Court's decision. If the Hyderabad-based company begins selling the drug now, it may face penal damages on losing the patent battle with Teva. Copaxone, with \$3.2 billion (Rs 19,000 crore) in sales, accounts for a fifth of Teva's revenue and nearly half of its profits. On BSE, Natco shares fell nearly 17.74% on Tuesday toRs 655.55 before recovering to close at Rs 684.65, or a fall of 14.1%.

Similar reports in-

Financial Chronicle- Natco slumps on Teva's Copaxone appeal

The New Indian Express- Natco Pharma, Teva patent row now in US court

Publication: The Hindu Edition: Kolkata Date: April 2, 2014

Headline: Issue of new patents (link unavailable, scan attached)

Synopsis: The Union Government is understood to have appointed a ministerial committee to

examine afresh the question of granting patents in respect to foodstuffs and drugs.

Publication: Pharmabiz

Edition: Online Date: April 2, 2014

Headline: Licenses of several FDCs may be withdrawn, many others will be put on lifeline

Synopsis: Several fixed dose combinations currently in the market are set to lose the license and many will be put on lifeline as the expert committees started scrutinising the applications of companies for regularising those combinations, which were permitted by the State licencing authorities without concurrence from the Drug Controller General of India. The expert panel, which examined the first batch of applications as part of the massive exercise to cover thousands of FDCs, has already recommended cancellation of licenses of some FDCs sold in the market and gave a lifeline of three months to some others to prove the efficacy with additional data.

Pharma Industry

Publication: Reuters Edition: Online Date: April 2, 2014

Headline: U.S. FDA advisers back MannKind's inhaled diabetes drug

Synopsis: U.S. health advisers on Tuesday recommended approval of MannKind Corp's inhaled diabetes drug, and said the experimental treatment could help some patients, especially those wary of needles typically used with traditional insulin therapy. The Food and Drug Administration's panel of outside advisers said that while the therapy, called Afrezza, did not appear as beneficial for adults with type 1 diabetes, it was clearly safe and effective for those with the more common type 2 form of the chronic disease. Overall, it voted 13-1 to recommend approval for patients with type 1 diabetes and unanimously backed it for those with type 2, adding that longer-term studies would still be needed to monitor possible side effects such as lung cancer.

Publication: The Hindu Business Line

Edition: National Date: April 2, 2014

Headline: Natco Pharma nosedives 14% on US court's move on Copaxone

Synopsis: The Natco Pharma scrip tumbled 14.10 per cent on the BSE on Tuesday after the US Supreme Court agreed to hear a patent case on Copaxone. The stock, which opened for trading at □775, closed at □684.65. Copaxone (Glatiramer Acetate) of Teva Pharmaceuticals is used in the treatment of relapsing-remitting multiple sclerosis and had registered a revenue of \$4.2 billion in the US during 2013. Teva's Copaxone patents expiring in September 2015 were held invalid by a US court in July 2013, making generic entry possible in May this year, when the remaining patents expire. This cleared the road for Hyderabad-based Natco in partnership with Mylan Inc and Momenta Pharmaceuticals and its partners, to move in. But Teva's appeal has injected uncertainty into the future scenario.

Similar report in-

Mint- Natco shares fall on US court hearing, action on cancer drug export

Publication: The Hindu Business Line

Edition: National Date: April 2, 2014

Headline: <u>Aurobindo Pharma completes merger of Actavis in Western Europe</u>

Synopsis: Aurobindo Pharma Ltd has completed the acquisition of certain commercial operations in Western Europe from Actavis plc. In January this year, the Hyderabad-based Aurobindo Pharma had entered in to an agreement with Actavis to acquire its personnel, commercial infrastructure, products, marketing authorisations and dossier licence rights in seven European countries for €30 million. Both the companies had also inked a long term commercial and supply arrangement. The acquisition will make Aurobindo one of the leading Indian pharmaceutical companies in Europe with a top 10 position in several key markets," Muralidharan, Senior Vice-President of European operations for Aurobindo said in a statement on Tuesday.

Publication: The Pioneer

Edition: National Date: April 2, 2014

Headline: Drug importers get 3 more months to comply with re-labelling norms

Synopsis: In a relief to the drug importers, the Drug Controller General of India (DCGI) has given three more months for them to comply with the re-labelling norms for imported medicines. The move followed after drug importers apprised the top regulator of their inability to immediately comply with its recent order imposing stringent labeling norms on the drugs imported by them. "We had received representation from various stakeholders in the drug sector which had raised concern at the relabelling issue and that the drug importers need to be given some time to implement the order," a senior official from the DCGI said. He said after a recent meeting with the Union Health Ministry the importers of the drugs and drugs and devices have been given three months and six months time

respectively. "It was also felt that immediate ban on the drugs would also hamper supplies to the patients," the official added.

Publication: Deccan Herald

Edition: National Date: April 2, 2014

Headline: Aspirin's utility and heart surgery

Synopsis: Giving aspirin to patients around the time of surgery may do them more harm than good. Surgery of any kind -- not just heart surgery -- may raise a person's risk for having a heart attack, a new research has shown. Doctors often start patients on a low dose of aspirin shortly before and after their procedures to help prevent those events. But the new study, which pitted aspirin against a dummy pill ("placebo") in over 10,000 patients who were having major surgeries that didn't involve their hearts, found that not only did aspirin fail to prevent heart attacks, it also significantly increased the risk of major bleeding. The authors pointed out that many patients were already taking other drugs meant to prevent blood clots.

Drug Pricing

Publication: Pharmabiz

Edition: Online Date: April 2, 2014

Headline: <u>IMS DATA & NEW PRICES</u>

Synopsis: As in the case of earlier DPCOs, Department of Pharmaceuticals and National Pharmaceutical Pricing Authority are finding it difficult to fix and enforce new prices for 348 drugs covered under DPCO 2013 even after several months of its notification. Wherever NPPA finds scope for a reduction or only a marginal hike in prices of products, Such decisions are challenged by the pharmaceutical companies seeking higher prices. Over two dozen large companies have already disputed ceiling prices fixed for several products and approached for a review during the last six months. Some of these companies are Sun Pharma, Unichem Labs, Panacea Biotec, Win-Medicare, Albert David, Baxter (India), Indi Pharma and Gland Pharma.

General Industry

Publication: The Hindu Edition: National Date: April 2, 2014

Headline: Japan lab says stem cell research falsified

Synopsis: A Japanese government-funded laboratory said on Tuesday it found that data in a widely heralded stem cell research paper was falsified, holding the lead researcher responsible for the fabrication. The research results from the Riken Centre for Development Biology in Kobe, western Japan, were seen as a possible groundbreaking method for growing tissue to treat illnesses such as diabetes and Parkinson's disease using a simple lab procedure. Scientists at the institute said significant discrepancies in research published in January in scientific journal Nature stemmed from falsified data. They said researcher Haruko Obokata, the lead author of the paper in Nature, had manipulated or falsified images of DNA fragments used in the research.

Publication: Mail Today Edition: New Delhi Date: April 2, 2014

Headline: IIT Students win Gandhian tech awards

Synopsis: Techpedia, a consortium of college students incubated by innovation guru Anil Gupta at IIM-Ahmedabad has instituted some interesting awards for young innovators. Out of 1400 nominations

covering 60 technology fields, 13 were selected for awards this year. Awardwed innovations include low-cost cardiovascular diagnostic kit for rural areas, low cost device to increase adherence to TB medication, thermal and combustion improvements in cook stoves and low-cost diagnostic for pneumonia and herbal spermicide.