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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq
Editor: Miss Krishna Claudia Vepachedu

Issue 118

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Perils of Drug Development

Sanofi Pays to Shareholders

France's largest drugmaker, which once expected the medicine to generate about \$3 billion in annual revenue, pulled its application for U.S. approval after a committee of FDA advisers found that Sanofi's safety data were insufficient and that the weight lost in clinical trials didn't justify the danger of psychiatric or neurological side effects. Sanofi agreed to pay \$40 million to settle a lawsuit by investors who alleged they were misled about the likelihood that the company's Zimulti weight-loss drug would win regulatory approval. The money will go to investors who bought the French drugmaker's American depository receipts from Feb. 24, 2006, to June 13, 2007, according to the settlement agreement filed today in federal court in Manhattan. Sanofi, based in Paris, was accused in the November 2007 complaint

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of violating U.S. securities laws by failing to disclose data about Zimulti's link to suicidal behavior. A Food and Drug Administration panel in June 2007 rejected the pill, sending company shares to their biggest drop in three years.

Sanofi embarked on an aggressive effort to dissuade these folks from showing any interest in the forthcoming competition. Sanofi, however, appears to have gone a bit too far, at least according to the Competition Authority, which has just issued a \$52.7 million fine for a smear campaign that essentially denigrated generics. How so? Sanofi reps made remarks not only casting doubt on the safety and efficacy of generic forms of Plavix "without relying on any proven fact," but also raised questions about potential liability that physicians and pharmacies may encounter if patients developed medical problems after using a generic. The Competition Authority included comments from physicians and pharmacists, in fact, to illustrate the extent to which Sanofi tried to convince them to stick with Plavix. The drugmaker "terrorized doctors" and "pharmacists cannot be fooled" by the tactics that were used, according to a translation.

Teva and Sun to Pay to Settle

Teva Pharmaceuticals Industries Ltd and Sun Pharmaceutical Industries Ltd would pay \$2.15 billion to settle a patent infringement lawsuit related to its acid-reflux drug Protonix. Japan's Takeda Pharmaceutical Co Ltd, Pfizer's partner on the drug, will receive 36 percent or about \$774 million from the settlement. Pfizer won a protracted 10-year legal battle in April 2010 when a New Jersey jury ruled that Teva had infringed the Protonix patent. Teva started selling a generic version of the drug in 2007.

EU Fines Drugmakers

In 2013, European antitrust regulators fined nine drugmakers, including Denmark's Lundbeck, a total of 146 million euros (\$195 million) for blocking the supply of a cheaper anti-depressant to the market, the first EU sanction against such deals. The punishments follow a 2009 report by the European Commission on the pharmaceutical sector, which said "pay-for-delay" agreements between companies lead to consumers paying as much as 20 percent more for their medicines.

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Boehringer Ingelheim Faces 2,000 Lawsuits

German drugmaker Boehringer Ingelheim is facing more than 2,000 lawsuits in the United States over claims its blockbuster drug Pradaxa, the first in a new class of stroke prevention pills, caused severe and fatal bleeding. The unlisted company confirmed the number of cases reported by German newspaper Handelsblatt, adding the risk of side effects was known and had to be weighed against the drug's life saving potential. Pradaxa was the first to market in a promising new class of medicines designed to replace decades-old warfarin to prevent strokes in patients suffering from atrial fibrillation, a form of irregular heartbeat common among the elderly. Like other blood thinners, Pradaxa's benefit of cutting the rate of fatal or debilitating strokes in the elderly comes at the risk of internal bleeding, which can also cost lives. Boehringer cited a recent study by the U.S. Food and Drug Administration as showing that Pradaxa users ran a lower risk of severe bleedings than patients on warfarin.

<http://www.reuters.com/article/2014/02/13/us-boehringer-pradaxa-idUSBREA1C0PW20140213>

Data Protection in EU

A legal case brought by AbbVie and InterMune over access to details of clinical trials held by Europe's drugs regulator has been hit by delay after the EU's top court sent it back to be re-examined by a lower body. The decision leaves in limbo a high-profile fight that has pitched the European Medicines Agency (EMA), Europe's equivalent of the U.S. Food and Drug Administration, against the two companies.

<http://www.businessweek.com/news/2013-12-05/eu-top-court-orders-review-of-abbvie-data-release-injunction-2>

Abbott/Abvie Sued

AbbVie Inc., the company it spun off last year, hid the dangers of using the testosterone replacement drug AndroGel, five men claimed in lawsuits. Their complaints, filed in the federal court in Chicago, came four days after the U.S. **Food and Drug Administration** said it will re-

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examine the safety of testosterone replacement drugs after two studies showed a higher risk of heart attacks and strokes in men who use them. The men range in age from 50 to 63, according to their complaints. Three claim they had heart attacks after they started using AndroGel, and a fourth said he had a stroke. The fifth man said he had a mini-stroke.

<http://www.bloomberg.com/news/2014-02-05/abbott-labs-sued-by-five-men-claiming-androgel-injuries.html>

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!

(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

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