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IP and Industry News

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

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Beijing Higher Court Rules in Patent Owner

The Beijing High Court, Beijing, China has affirmed a lower court's decision against RephiLe Bioscience for copying and selling purification cartridges for lab water systems, infringing on patents owned by EMD Millipore. The Court determined that RephiLe's accused products fall into the protection scope of EMD Millipore's patent. The decision upholds the permanent injunction against RephiLe to discontinue making, selling and offering to sell the infringing products. The decision also confirmed the award of damages to EMD Millipore originally set by the lower court.

Clinical Data Falsified In Japan

A report by the Japanese health found that Novartis used falsified data to promote its widely used heart drug Diovan, <http://www.mhlw.go.jp/file/05-Shingikai-10801000-Iseikyoku-Soumuka/0000024587.pdf>, based on the revelations that data was manipulated by Kyoto Prefectural University of Medicine and Jikei University. The panel noted Novartis marketing literature – such as brochures for physicians and handouts

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for lectures - often featured research papers by the universities. Kyoto Prefectural and Jikei University conducted their own probes and found that data had been manipulated and moved to retract the studies published in The Lancet and The European Heart Journal.

Recently, Shiga University of Medical Science found 10.1 percent of patient data in its reports released in 2007 failed to match original data in clinical records, i.e., the data was manipulated to bolster Diovan. The Shiga Prefecture conducted the study between 2003 and 2006 to determine whether the drug could lower blood pressure and protect kidneys in 150 hypertensive patients.

The government report also found a conflict of interest involving nearly \$6 million Novartis gave to the universities. In addition, a Novartis Pharma employee was listed as a statistician on the Jikei heart trial that was published in The Lancet, listed as being affiliated to Osaka City University, which has received more than \$1 million in donations from Novartis. This is not going to help already struggling Pharma with reputation problem.

Industry sponsors 90% of published clinical trials, and industry-sponsored trials are four times as likely to produce positive results than independently run experiments, according to Pharma Gossip_ <http://pharmagossip.blogspot.com/2013/09/why-big-pharma-is-bad-for-your-health.html>. It is clear there is a deep conflict of interest in pharmaceutical companies' sponsoring trials on their own drugs. But, that is the only way, because no governmental or non-profit organization can handle the billions of dollars involved, while the entire NIH budget is only about \$60 billion.

In the above Japanese case, who falsified the results? Is it Novartis or the researchers from the universities for funds from the Pharma or that falsified the research? Whether it is the scientists at the University or at Pharma, they are all driven by the need for their survival, keep the job, keep the funding, survive the year end reviews, publish to succeed etc. That is why we have checks and balances, in the form of government regulatory entities and private entities for profit to make sure there is R&D to develop new products and to make sure only good products are marketed. The blame and the responsibility must be shared. <http://www.forbes.com/sites/johnlamattina/2013/10/02/pharma-controls-clinical-trials-of-their-drugs-is-this-hazardous-to-your-health/>

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Precautionary Recall

The Medicines and Healthcare products Regulatory Agency (MHRA) had found problems with the manufacturing process during an inspection of Wockhardt's manufacturing site in Chikalhana, India, in July. They included, poor record keeping relating to the manufacture and testing of the medicines made at the site and inadequate validation and production controls for medicines. MHRA is asking chemists and wholesalers to return the medicines made by Wockhardt Limited. The recalled drugs are used for pain relief and to treat type 2 diabetes. The affected medicines are, in most cases, available from alternative manufacturers. Ten prescription-only medicines can continue to be made at the Chikalhana site and used in the UK.

The MHRA has stressed there is no risk to patients and people should continue to take their medication as prescribed. The agency's decision follows a precautionary recall from retail outlets by the manufacturer. The MHRA said it was working with Wockhardt and other international regulators to resolve these issues.

The recalled drugs are:

- Amiloride HCl 5mg tablets
- Clarithromycin 250mg tablets
- Clarithromycin 500mg tablets
- Gliclazide 80mg Tablets
- Quinine Sulphate 300mg tablets
- Tamsulosin Pinexel 400mcg tablets

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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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