IPR & Innovation

Regulatory & Medical

Access to Healthcare

Others

IPR & Innovation

1. **Saxagliptin CL Round 1: Controller shoots down Lee Pharma** - SpicyIP

   As we'd reported a couple of days ago, the Controller of Patents has issued a prima facie finding on Lee Pharma's Compulsory License application to manufacture saxagliptin, AstraZeneca's patented anti-diabetic drug. The order [PDF], dated 12 August 2015, has just been uploaded to the IPO website. The Controller's prima facie findings seem to be almost perfectly aligned with our assessment of Lee Pharma's application. While he agrees that Lee is an interested party and has made bona fide attempts to negotiate a voluntary license, he finds that Lee has failed to demonstrate a prima facie case under any of the provisions in S. 84(1) of the Patents Act.

2. **Eli Lilly fails to get Indian patent for drug to treat alcohol addiction** – Financial Express

   The Indian patent office has refused to entertain an application by US-based pharma major Eli Lilly and company for a patent on an invention regarding a drug compound of kappa opioid receptor, used for the treatment of disorders associated with alcohol dependency. Kappa opioid receptor is a protein which has marked effects on all types of addiction, including cocaine and opiate abuse. The patent office has raised objections to the claims in the application filed by Eli Lilly, pointing out that the subject matter of invention lacks inventive steps, in the backdrop of prior-art documents available in the public domain.

3. **India, US to begin joint research on basic biology, genetics of ophthalmic diseases** – Pharmabiz

   Aiming to translate research outcomes to develop potential interventions to reduce eye disease burden in India and the USA, both the countries will soon begin joint research collaborations between the US and India that will focus on the basic biology and/or genetics of ophthalmic diseases. The key focus areas of this joint research programme, being conducted under the Indo-US collaborative programme on vision research, will be on diabetic retinopathy, genetics of ophthalmic diseases and ocular inflammation.

Regulatory & Medical

1. **As GVK drugs go off EU shelves, India sees no scope now for FTA talks** – Hindu Business Line
   India has said there is no scope at the moment to mend bilateral economic relations with the European Union as the latter has refused to withdraw the ban on the sale of over 700 generics drugs tested by GVK Biosciences. The ban will come into effect on Friday. "From tomorrow, good quality generics, most of them manufactured by Indian companies, are going to be pulled off the shelves in 28 European countries. There is no way we can discuss free trade in this back-drop," a government official told BusinessLine. India was hopeful that Brussels would revoke the marketing ban, following the loud protests by New Delhi.

Access to Healthcare

1. **'Our government's focus is first on quality healthcare and then providing this to everybody'** – Express Pharma
   An architect by profession and a founder member of Arvind Kejriwal's Aam Aadmi Party, Satyendar Jain is Minister of Home, Health, Power, PWD and Industries. He may seem an unlikely choice to handle the health portfolio but he has managed to make a fair bit of progress on the AAP's promises on the health front. In a frank discussion, he explains to Viveka Roychowdhury that Delhi's healthcare system needed a revamp and why he is betting on an ATM-like master plan for 'Anytime, Anywhere Health'

2. **BDCDA submits memorandum to include changes, additions to NPPA's amendments to DPCO 2013** – Pharmabiz
   The Bangalore District Druggists & Chemists Association (BDCDA) has now submitted a memorandum to the Union government to incorporate certain paragraphs and additions in the NPPA's proposed amendments in DPCO 2013. This includes details related to definition of drugs, trade margin covering wholesale and retail, payment policy and payment of tax, besides value added tax (VAT) and Form V. "While we appreciate NPPA for its amendments to the DPCO 2013 dated July 15, 2015, we would like to inform that our requests vide BDCDA/1532 dated July 15, 2013 and BDCDA/1893 dated November 26, 2014 are still pending," said V Harikrishnan, president, BDCDA and Karnataka Chemists and Druggists Association.

Others

1. **New strategies for growth** – Express Pharma
   After a decade of pain, there are some reassuring signs that the pharmaceutical industry may just be seeing the faint glimmers of light at the end of the R&D pipeline. A recent report from Thompson Reuters shows that 2014 had 46 new molecular entity releases, the highest in a decade. While the higher than usual number could be due to a windfall of delayed releases and approvals, what's really worth noticing is that the quality of releases has changed for the better. For instance, according to the 2015 CMR Pharmaceutical R&D Factbook, one third of 2014 launches were for rare indications, mainly in the oncology arena, with many of these receiving orphan drug status. Phase III launches grew steadily while early development pipelines thinned out, with the industry embracing a 'fail fast, fail cheaply' strategy. Sparse early pipelines could also mean that these companies will need to find replacements once these drugs hit the market.