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IPR and Innovation

1. **Commerce Ministry considering proposal for CL to anti-cancer drug** – Economic Times
Commerce and Industry Ministry is considering a proposal of the health ministry for grant of compulsory licence (CL) to an anti-cancer drug - Dasatinib, Parliament was informed today. The ministry has received a proposal from the Ministry of Health and Family Welfare for grant of CL in respect of the drug. Commerce and Industry Minister Nirmala Sitharaman said the matter was examined and accordingly the Health Ministry was requested to furnish full particulars in respect of existence of circumstances of - national emergency; or extreme urgency; or a case of public non-commercial use, as required under Section 92 of the Patents Act 1970.

   Also appeared in Mint

2. **BIO, PhRMA lobby for IPR fix to insulate their patents from challenge** – IP Watchdog
In a recent op-ed published by The Hill, Jim Greenwood, President and CEO of the Biotechnology Industry Organization (BIO) and John Castellani, President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), argue that something must be done by Congress to stop IPR trolls from attacking biotech and pharma patents. In support of their position Greenwood and Castellani point out, “When Congress created the IPR process as

part of the America Invents Act of 2011, it never intended for IPR to be used to kill valid biopharmaceutical patents…"
An immediate problem is that the inter partes review (IPR) process at the U.S. Patent and Trademark Office (PTO), which is intended to provide a faster and cheaper process for people to challenge patents, is being abused by outside interests, including hedge funds, seeking to undermine and exploit it for short-term financial gain.

3. **Compulsory licensing: A nightmare awaiting pharma MNCs?** – Biospectrum
Hyderabad-based Lee Pharma, a manufacturer of intermediates and APIs, has taken the global pharma world by storm after aggressively filing its application requesting for the grant of compulsory licensing for the manufacture of Saxagliptin in India. Saxagliptin (Onglyza) is a drug used in treating type-2 diabetes. Initially, the molecule was discovered and developed by Bristol-Myers Squibb (BMS) and was later, in 2007, joined by AstraZeneca (AZ) to further develop and commercialize the product.

Access to Healthcare

1. **Government reviews Drug Order 2013 to sort implementation issues** – Economic Times
The government is reviewing the Drug (Prices Control) Order, 2013, to sort out implementation issues and make it more efficient -- both for consumers and the industry. The idea is to make the price control order easy to implement, they added. The government, according to the sources, has sought inputs on DPCO from all stakeholders, including the industry and the civil society. Meanwhile, a task force constituted by the Department of Pharmaceuticals has also recommended review of DPCO 2013.

Also appeared in Business Standard & NDTV Profit

2. **Prices of 98 Drugs Not Fixed Due to Lack of Information** – Business Standard
The government has not fixed the ceiling price of 98 drugs used for treating various diseases such as tuberculosis, cardiac conditions and infections due to non-availability of information. The National Pharmaceutical Pricing Authority (NPPA) has asked various stakeholders to provide related data in 30 days. At present, the government caps prices of essential drugs based on the simple average of all medicines in a particular therapeutic segment with sales of more than 1 per cent. In the case of non-scheduled drugs, companies are allowed to hike prices by only up to 10 per cent in a year.

Also appeared in NDTV Profit

3. **'Scheduled medicine sale above notified price not authorised'** – Economic Times
Government today said no one is authorised to sell any scheduled medicine to a consumer at a price exceeding the one notified by the drug price regulator NPPA under DPCO, 2013. As per the provisions of Drugs Price Control Order (DPCO, 2013) the National Pharmaceutical Pricing Authority fixed the ceiling prices of essential medicines contained in Schedule-I.

Also appeared in DNA & Business Standard

Medical & Regulatory

1. **Question of ethics: protecting patients... and doctors** - Hindu Business Line
Late last month a committee of medical professionals looking into ethical and legal challenges facing healthcare sat for their first meeting. The discussion revolved around medical malpractice, negligence and self regulation. Key concerns for the fraternity as they witness an increase in the number of law suits and compensation amounts, following the historic Kunal Saha verdict on medical negligence. A strong framework is needed to tackle malpractices and implement self-regulation.

2. **Prescription format needs to be mandatory to avoid incomplete & illegible prescriptions: IPA** – Pharmabiz

   The Indian Pharmaceutical Association (IPA) wants the Centre to take proactive steps towards adopting and implementing a model format for prescription of medicines to avoid complications arising out of incomplete and illegible prescriptions. Experts pointed out that currently there is lot of confusion among pharmacists while dispensing medicines due to lack of any uniform prescription format or model in the country which is leading to either delay in services, difficulty while dispensing and in some cases even medication error.

Others

1. **Under the weather** – Financial Chronicle

   India's pharma sector has been presenting mixed growth trends. On the one hand, growing demand is presenting an opportunity, while on the other, many factors are impacting the non-homogeneous sector. Some recent key developments included fixing of price caps on many drugs by the national pharmaceutical pricing authority, USFDA's observation on some plants, mixed signals on the earnings front and consolidation efforts within the industry. National drug price regulator NPPA has fixed the prices of 39 formulation packs, including drugs used to treat diabetes, infections, digestive disorders and pain, among others. With this, prices of several formulations will fall between 5 per cent and 40 per cent, affecting margins of the companies to a great extent.

2. **Centre to set up Rs.500-cr pharma upgradation fund** – The Hindu

   The government will be setting up a Rs.500-crore fund for small and medium players in the pharmaceutical sector for upgradation of their manufacturing facilities to boost drug production in the country. The fund is being set up following recommendations submitted by a task force on pharmaceutical sector last month to Union Chemicals and Fertiliser Minister Ananth Kumar.