

# Daily News Monitor July 21, 2015

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#### **IPR** and Innovation

Draft IPR policy vetted by ministerial group: Sitharaman – The Hindu Business Line
 The draft Intellectual Property Rights (IPR) policy is being vetted by an inter-ministerial group
 following which it will be sent to the Union Cabinet for approval, said Commerce Minister
 Nirmala Sitharaman. The new policy, which incorporates views of stakeholders, including the
 US, is unlikely to make any changes on controversial laws such as Section 3(d) of the Indian
 Patents Act — a major demand of multinational pharmaceutical companies. Section 3(d)
 discourages patents being granted for incremental innovations.

Click here to read Business Standard story
Click here to read The Economic Times story
Click here to read The Times of India story

2. Lee Pharma revives the CL debate – The Financial Express

With little known Lee Pharma filing India's third compulsory licensing (CL), legal eagles and everyone interested or connected to pharmaceutical IP are gearing up for yet another discussion on this topic. In a battle that is going to look like a David versus Goliath, the Hyderabad-based API maker has chosen to go after an anti-diabetes molecule, saxagliptin, which is covered by Patent No. 206543. Originally granted to Bristol-Myers Squibb in 2007, it later passed on to AstraZeneca in 2014 when the latter acquired BMS' interests in the companies' diabetes alliance.

#### **Access to Healthcare**

1. Price Controls for Drugs in India Fail to Improve Access for Patients: Report – Wall Street lournal

As public and private payers grapple with rising costs for many prescription drugs, there is increasing debate over the extent to which some form of price controls may be warranted. In India, however, the government has already taken such a step, although a new industry-sponsored report finds the move has not achieved the key goal of improving access to medicines for the neediest citizens.

2. A sick system – Business Standard

Full details are yet to emerge of the reform of the Employees State Insurance Corporation of India, or ESIC, as indicated by Prime Minister <u>Narendra Modi</u> at a labour conference in New Delhi on Monday. The question that is being asked is: will reform of the <u>ESIC</u> mean an expansion of its coverage to those hitherto not covered by it? Earlier media reports suggested that, for example, on-site construction workers would gain access to ESIC benefits. If so, what will be the contributory system? Will there be a difference in the contributory pattern?

# **Medical & Regulatory**

 Centre needs to define & list OTC drugs, fix prescription validity of 48 hours in D&C Act: Dr Jagashetty – Pharmabiz.com

Union government will need to define and prepare a list of over-the-counter (OTC) drugs with caution and fix a 48-hour validity period for prescriptions as per a new amendment to the Drugs & Cosmetics Act & Rules, said Dr BR Jagashetty, former national advisor (drugs control) to ministry of health & family welfare and former Karnataka drugs controller. In the wake of the Drugs Consultative Committee meet to be held on July 24, 2015, with a focus on online pharmacy, Dr Jagashetty is of the view that the government is expected to include pharmaceuticals into online trade. Here legal and ethical issues have to be considered carefully since the safety of patient is most important.

2. As Parliament session begins on July 21, several Bills related to health & pharma waiting for final nod – Pharmabiz.com

Even as the monsoon session of Parliament is scheduled to begin on July 21, several Bills related to the health and pharma sectors are waiting for Parliament's final nod. In fact, several of these Bills have been pending for quite some time for introduction and passage in Parliament. The three-week monsoon session of Parliament will conclude on August 13. The major Bills which have been waiting for Parliament's final nod in pharma and health sectors include Drugs and Cosmetics (Amendment) Bill, Biotechnology Regulatory Authority of India Bill (NBRA Bill), ART Bill, HIV/AIDS Bill, Ethical Guidelines for Biomedical Research on Human Subjects Bill, etc.

3. No changes in foreign investment limits in banking, defence: Govt – Hindustan Times
The government on Monday clarified that the recent announcement regarding foreign
investment norms for companies will not apply to banking and defence sectors. Portfolio
investment limits in both the sensitive sectors will be retained at existing levels to prevent 'flyby-night operators or quick money coming in and going out," commerce minister Nirmala
Sitharaman said. In banking, portfolio investments will be limited to the current 49%. However,
FDI can be raised to 74%. In defence, the portfolio investment cap will be 24%, although the FDI
limit can go up to 100% on a case-to-case basis.

#### Others

How pharma stocks helped the healthcare index soar – Business Standard
 More than a dozen pharma stocks, including Dr Reddys, Aurobindo Pharma and Glenmark,
 touched 52-week highs last Friday, helping the healthcare index on the Bombay Stock Exchange

grow over 16% in the last five weeks. While the fundamentals remain strong for the industry, concerns continue to linger in the form of USFDA crackdown on quality issues at exporting plants, domestic regulatory issues related to price control and product approval.

# India can become major exporter of pharma products to ASEAN countries, Dr Somphone – Pharmabiz.com

India has the potential to become an export hub for all kinds of pharmaceutical products, including traditional drugs, throughout the ASEAN countries if the exporters are willing to compete with other nations in terms of quality and price, commented Dr Somphone Phonh Axa, managing director of Palamy Pharma in Lao People's Democratic Republic (LAOS), a member of the ASEAN. The production of medicines in the country is very less. There are three government companies and three private companies which are not manufacturing all the essential medicines. In the trade sector, about 50 distributors are operating and most of them are importers.