1. India Calls for flexibilities in IPR to combat AIDS – PTI

With over 80 per cent of the affordable and quality antiretroviral drugs used globally to treat AIDS supplied by Indian pharmaceutical industry, India has sought flexibilities in IPR under a global trade agreement to back its endeavour of ending the deadly disease by 2030. "We are well aware of the role that generic pharmaceutical manufacturers from India have played in initiating antiretroviral (ARV) treatment for over 17 million people by providing affordable and high quality ARV drugs. We will continue to provide this support to the global community in ending AIDS by 2030," Minister for Health and Family Welfare J P Nadda said at a panel discussion on the sidelines of the high-level General Assembly meeting on HIV/AIDS.

2. Why India-US engagements get patently jittery? – The Hindu Business Line

Coming against the backdrop of the IPR Policy unveiled by India a month ago, India's PM, Mr Narendra Modi's visit to US assumed a greater significance. And its outcome is being closely watched by health groups and industry representatives, their IP orientation notwithstanding. Explaining some of the apprehensions, Third World Network's KM Gopakumar says that the Policy has "kept the door open" for a possible review of existing IP laws. And the worry is whether New Delhi will accommodate American drug companies' demands against compulsory licensing (CL) or for data exclusivity. **The Organisation of Pharmaceutical Producers of India's (OPPI) President, Shailesh Ayyangar**, says that the industry owes it to the country to bring in medicines. "This is not about pleasing the Americans" or any other country, he said at a recent OPPI event. "This is for my nation and my scientists here," he says, elaborating how countries like India can benefit from making incremental developments on medicines. At present, Section 3 (d) of the Patent Act disallows protection on incremental developments, unless if can prove greater efficacy than an existing medicine.

Reason for jitters

The CL concern is because India does not have a clearly-spelt-out stand and the ambiguity creates anxiety for people wanting to invest, he says. It is the sovereign right of any country to issue a CL during a public health emergency, and no one disputes that, **he says**. The concern is when it is used and how. It should not be for the commercial benefit of a third party, **he says**. "Make no mistake," **says Ayyangar**, generic medicines are a lifeline of every country even the US, as it keeps the cost low. But the generic industry exists only if innovative medicines are made, he says, explaining how an innovative patented drug is allowed a period of exclusive time to sell and recover its research cost, before it is opened up to competitors to make it. The Policy should have also addressed marketing approvals given to a company by the Indian regulator on a drug that is patent protected by another company, says **Krishna Sarma, Managing Partner with the Corporate Law Group**. She also expresses disappointment on specialised courts for IP cases not getting a mention in the Policy. This would have meant speed in disposing cases, a criteria in the ease of doing business, besides bringing in greater domain knowledge, she explains.

Middle path

Making a practical suggestion, **Komal Kalha, Senior Counsel, US Embassy**, says that modifications to the law should be made after getting stakeholders to talk to officials so that the outcome is more comprehensive. That would take out the bickering, she says. In fact, health advocacy groups too have asked the Government to bring in greater transparency and table a white paper in Parliament on its IP engagements with the US. With IP being as divisive as it is, the Government may do well to take on board both suggestions and chart a middle path of consensus.

3. **Merck, Pfizer double size of diabetes drug study to catch rivals – Mint**
   Two pharmaceutical companies - Merck & Co. and Pfizer Inc. are doubling the size of a study of their joint diabetes treatment to keep up with smaller competitors in the fast-growing market that already have proven their drugs can reduce the risk of death from heart complications. The trial will be expanded to 8,000 people at high risk for heart disease to determine whether the treatment helps the heart. The companies, the largest two in the US, are developing the drug ertugliflozin for use alone and in combination with Merck's best-selling Januvia.

4. **Why you just can't have a one-size-fits-all IPR Policy – The Financial Express**
   During an interaction with the former chairperson of the Intellectual Property Appellate Board of India, Justice Prabha said how we cant have one-size-fits-all IPR Policy. "The government will not do anything to make medicines more expensive. India's strength as a leading generic drug manufacturer has been well-acknowledged and must be leveraged," she said. She further said that India has committed itself to the obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Therefore, it was necessary for the country to look at its patent laws again. In 2005, the Indian Patents Act was amended—section 3(d) being one of the amendments. It was the basis of the Novartis case.

5. **Madras HC orders in favour of Sun Pharma in trademark dispute – Business Standard**
   The Madras High Court has issued an order in favour of Sun Pharmaceuticals in a trademark dispute it has raised against Cadila Healthcare for the trademark of its depressive disorder drug VENIZ. The Court issued a permanent injunction against the latter using marks similar to Sun Pharma's particular trademark. Cadila Healthcare was also ordered to pay to Sun Pharma a sum of Rs 3 lakh as liquidated damages for committing acts of infringement against the latters' registered trademark so as to pass off their products as and for the plaintiff's products.

6. **Govt ban on 350 drugs hits Rs3,800 cr of pharma market – ET Healthworld.com**
   The ban on "irrational" 350-odd fixed dose combination (FDC) drugs including wide-selling pain-killers, anti-diabetic medicines and respiratory therapies, will impact nearly 4% or Rs 3,800 crore of the organised pharma retail market. The ban on FDCs over safety and efficacy concerns will adversely affect MNCs like Pfizer and Abbott and domestic companies including Alkem, Ipca and MacLeods, and is likely to be contested by companies, sources say.

Similar news in **Indian Express:** **Pharma sector grows 7.7% in May; FDC ban weighs**

7. **Rise in medicinal drugs seizure alarms NCB – The Times of India**
   The seizure of medicinal drugs and arrest of suppliers is increasing with each passing year in Chandigarh. The recent seizure of more than 250 prohibited injections, which can be sold only on a valid prescription, from Rajeev Kumar, a slum dweller, has alarmed premier anti-narcotic agency Narcotics Control Bureau (NCB), which has started conducting a special vigil on medical stores and pharmaceutical companies. Kumar was arrested by Chandigarh police on June 7.

8. **Land of opportunity woos Indian investors – The Hindu**
   In the U.S. capital Washington D.C, the perception about the strength of Indian companies is changing among top government officials. They are now on a mission to promote and facilitate business investment from these firms. India became the fourth fastest-growing source of Foreign Direct Investment (FDI) in the U.S. in 2014, according to Select USA, a government programme to attract and retain business investment in the country. FDI by Indian firms into the U.S. has touched $11 billion. The U.S. affiliates of Indian-owned firms employed 45,100 American workers in 2013 mainly in industries such as software and IT services, financial services, pharmaceutical and industrial machinery.

9. **National intellectual property policy suffers from a lack of conceptual clarity – The Indian Express**
   It was a surprise when the Department of Industrial Policy and Promotion (DIPP) of the ministry of commerce and industry released a document on the National Intellectual Property Policy on May 13 seeking to promote “creative and innovative” India. The surprise is that only a few years ago India undertook massive legislative measures to amend the patent, copyright, and trade mark and design acts and no new measures are on the anvil. Further, recent years witnessed wide ranging and contentious debates over issues relating to “compulsory licensing” and “ever greening” of patents by foreign drug majors. Unfortunately, India has continued to be under pressure from the US pharmaceutical lobby and the US Trade Representative with suggestions to tighten IPR laws and regulations beyond India’s international obligations. In response to fears expressed by non-governmental organisations the government of India reassured critics that it would not succumb to foreign pressure in instituting IPR amendments. Unfortunately, the current document on IPR, especially its reframing of the objectives of IPR, seems to send a different message.

10. **Dr Reddy’s in $350 million deal to buy 8 US drugs from Teva, Allergan – The New Indian Express**
    Dr Reddy's Laboratories Ltd will buy eight generic drugs from Teva Pharmaceutical Industries and Allergan Plc for $350 million in cash to bolster its U.S. business. The deal is among Dr Reddy's largest acquisitions, and comes at a time when the company has been facing slowing growth in the United States, its largest market, due to regulatory troubles and fewer new drug approvals. Some formerly lucrative emerging markets have also taken a hit over the past year, and caused the company's March quarter profit to slump 86 percent.

11. **States to get low-cost Amrit medical stores – The New Indian Express**
    In a letter sent to all state governments, Union Health Minister J P Nadda has said the Centre was ready to provide training and partly fund to set up Amrit stores in all government hospitals. The scheme will make medication for cancer and cardio-vascular diseases less expensive. The letter also asked State governments to ensure that there was at least one Amrit store in each State. “The Centre will provide training to pharmacists as well as share the cost of setting up the stores,” the letter said.

12. **USFDA issues guidance on facility definition for outsourcing plants, Indian cos view it a positive move – Pharmabiz.com**
    The US Food and Drug Administration (FDA) has issued a guidance on facility definition for outsourcing plants. Indian pharma which has chipped in a lot of manufacturing capability to

global drug majors sees the need for this regulation which could provide specific requirements for manufacturing units as the way forward in outsourcing services. The global regulatory authority now seeks the comments from the industry before July 30, 2016. Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines an outsourcing facility, at each geographic location.

13. **PHDCCI asks govt to desist from move to replace gelatin capsules with HPMC capsules – Pharmabiz.com**

    The PHD Chamber of Commerce & Industry (PHDCCI) has asked the government to desist from its proposal of replacing gelatine capsules with cellulose-based capsules, as the gelatin capsules have technical advantage over HPMC capsules. Gelatine capsules are being used world over for the past 100 years without any health issues being reported by the virtue of capsule shell. In highly regulated markets like USA, UK, Japan, Australia etc, gelatin based capsules are widely accepted in oral formulations for different ailments, it said.