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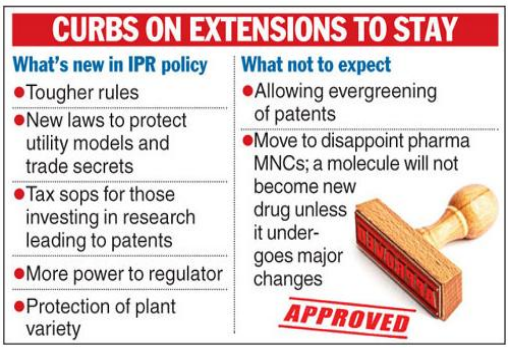
IPR and Innovation

1. **IPA, Natco withdraw opposition to Gilead's drug** – Business Standard
   September 14: Indian Pharmaceutical Alliance (IPA) withdrew its opposition to the patent application for Gilead Pharmasset's Hepatitis C drug sofosbuvir, marketed as Sovaldi, after the latter entered into a voluntary licensing agreement with 11 companies to sell the generic version at a lower price. Hyderabad-based Natco Pharma, which had filed a pre-grant opposition with the Indian Patent Office, also pulled out from the litigation after entering into a licensing agreement with Gilead. IPA's position is that it would oppose patents that block access to medicine. In this case, the company offered an unconditional voluntary licence to 11 companies, which means the patent would not block access to medicine.

2. **Drill to widen patent domain** – The Telegraph
   September 13: The Union cabinet will be considering a new policy on intellectual property rights (IPR) later this month that will protect innovators by toughening some patent rules as well as make it easier for companies to file for patents. However, the new regime will not change the provisions prohibiting the evergreening of a patent, which will disappoint US and European pharma giants.



   Officials said the final note on the new policy, initially drafted by a committee headed by Justice Prabha Sridevan and submitted last winter, has been circulated to all the concerned ministries and is likely to be taken up by the cabinet soon.

3. **Government readies 'improved' IPR policy before PM Modi's US visit** – Business Standard
   September 12: Hectic parleys are on to get the National National Intellectual Property Rights (IPR) Policy rolled out before Prime Minister Narendra Modi sets foot in the US by the end of this month even as a "much better and improved version" is expected compared to the draft policy. The policy, which is now awaiting the approval of the Cabinet, is going to be launched after much delay. The government had made an announcement in September last year that it will be released by February 2015. However, now that the PM is going to visit US again and will also have a bilateral meeting with President Barack Obama, the government was keen that India should "have something in hand" to show it to them before both leaders met.

4. **Patent Controller to hear Lee Pharma's plea on compulsory licence for diabetes drug** – The Hindu Business Line
   September 11: Hyderabad-based Lee Pharma has approached the Patent Controller on the award of a compulsory licence for manufacturing patented diabetes drug saxagliptin. Its application for a compulsory licence (CL) – a permission given by the government to an interested party to manufacture a patented product without permission of the patent holder – was 'prima facie' rejected by the Patent Office, Mumbai, in August. "As the request for the hearing has been made within a month of 'prima facie' rejection of the application, the company will now be given the opportunity to present a more detailed case," a government official told BusinessLine. The hearing is likely to take place by the end of September.

Access to Healthcare

1. **A balance between public and private is required** – Hindustan Times
   September 12: Private versus public, should the private sector or the market provide services — that hoary debate emerged again last month in two sectors of the economy, health and education. These are crucial sectors if India is to correct its lop-sided growth and grow inclusively.In the health sector the Niti Aayog criticised the government's draft health policy, which has emphasised the importance of the public sector. The policy has suggested "it would be desirable but ambitious" for India to aim at spending 4% of GDP on health. Most of that money, the policy recommends, should be spent on "public providers" with the private sector's role limited to "supplementation".

2. **WHO urges SE Asian nations to focus on affordable healthcare** - The Economic Times
   September 11: WHO today urged South East Asian nations including India to focus on providing affordable and quality health services to those who need them even as it said that nearly 400 million people still did not have access to essential health services globally. "Health is critical to development. Access to safe, affordable and good quality health services enables people to be more productive and active contributors to their families, communities and nations," said Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region.

Ethics & Compliance

1. **Doctors Flouting Prescription Fiat to Favour Pharma Companies?** – New Indian Express
   September 13: Even though the Medical Council of India (MCI) directed physicians in 2013 to write only the generic name of drugs in their prescriptions and not the trade name of a drug, the practice of mentioning the trade names of drugs continues among private doctors in Coimbatore. The MCI had also issued circulars to deans of all medical colleges, directors of post graduate institutes and presidents of state medical councils on this as per the the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. However, gross violation of this rule has been the norm in Coimbatore.

Medical & Regulatory

1. **Hopes that gave us mandate to rule for 5 yrs should give us 5 yrs to implement plans: Nirmala Sitharaman** – Business Standard
   September 14: Commerce & Industry Minister **Nirmala Sitharaman** believes the popular mandate, based on which her party came to power last year, should also be considerate enough to give the government five years to fulfil promises. In an interaction with *Business Standard*, the minister said she felt a little let down that industry did not voice its support for some of the reforms undertaken by the government. Edited excerpts:

   On the EU, let me tell you that I had gone ahead with the negotiations. Each time I met the EU's former ambassador, João Cravinho, I said we would like to start it. Then I met the EU trade commissioner and asked her to let the chief negotiators meet. And, it was agreed they could meet by August 28. The chief negotiators had met in early 2015 and understood where the negotiations stood. But I insisted on formal talks. We took a studied call on a matter. But, brand India came under question when they imposed a ban on 700 drugs clinically tested by GVK. The prime minister raised the issue on the ban, his enquiries were not answered. We said, 'Sorry, the environment is not conducive if they are not even ready to reply'. My questioning did not get an answer... we raised it all levels.

2. **Medicine Prices- Part3: Have Indians been taken for a ride?** - Moneylife
   September 11: India could definitely relook into medicine pricing issues and save thousands of crores while bringing more drugs under NPPA. Germany has led the way by coming up with an effective, citizen-friendly and rational drug pricing regime - first in drafting a unique policy and then in standing up to the pressures from vested interests. Interestingly, countries that find German model worthy of emulation but are unable to afford it, have still taken conscientious, rational and citizen-friendly approach of benchmarking to German drug prices to benefit from German diligence. In case the German principles of pricing are applied in the Indian context, would it save our system hundreds of crores of rupees?

Others

1. **'Healthcare BPO sector in India facing competition from U.S. and Philippines'** – The Hindu
   September 13: Players engaged in business process outsourcing (BPO) in healthcare sector in India are facing stiff competition from their Filipino counterparts, according to a recent joint study. "The Philippines and other low-cost locations are emerging as a big challenge to Indian BPO industry including the healthcare vertical," pointed out the study —Medical Process Outsourcing in India — jointly conducted by The Associated Chambers of Commerce and Industry of India (Assocham) and global professional services organisation EY. "Competition from leading healthcare BPO companies in the U.S. is a big challenge for Indian vendors, since most of them are specialists in the healthcare sector and provide an increased gamut of services as compared to Indian vendors," the study highlighted.

2. **Others'Generics to double in five years'** - The Hindu
   September 12: India ranks fourth in pharmaceutical production in the world with a production output of about $31 billion in 2014.

   The domestic generic drug market is expected to cross $27.9 billion from the current level of $13.1 billion registering compound annual growth rate (CAGR) of about 16.3 per cent particularly due to approval accorded by USFDA makers and 21 drugs patent losing patent by 2019, according to a joint study by the Associated Chambers of Commerce and Industry of India (Assocham) and RNCOS.

   Generics would account for 85 per cent share in the domestic pharma market by 2020, fuelled by cheap labour, patent cliff of blockbuster drugs and prevalence of lifestyle diseases, according to a study on 'Generic Medicines in India - Promulgating Growth & Access.'

3. **Indian pharma sector surges in global market: IBEF report** – Pharmabiz.com
   September 12: Public-private partnerships, an increased penetration of healthcare facilities in non-metro cities, involvement of multinationals in setting up facilities in the country and establishment of educational institutions, are some of the prime reasons which has enabled India to surge in the global market, according to a report by India Brand Equity Foundation (IBEF). Other key assets which have played a role in India becoming a leading pharma market are a thorough know-how in the manufacture of generics, rapidly developing research and development facilities with talented technical staffing, internationally recognised systems of pharmacy education, and a broad patient population pool enabling intense clinical trials, the report adds.

4. **Can Indian generic makers find gold with a blockbuster Hepatitis C drug?** – The Economic Times
   September 12: For patients with Hepatitis C, Dr Parveen Malhotra prescribes a tablet that doctors say is revolutionising the treatment paradigm for the dreaded liver ailment. The hepatologist from Haryana's Rohtak town too has reported a higher cure rate since switching to the orally administered sofosbuvir from the injectable interferon five months ago. According to World Health Organization data, hepatitis C kills half a million people a year and infects 150 million globally. Screening often includes costly multiple tests without which the ailment often goes undetected. In this backdrop, say doctors, sofosbuvir, is proving to be a magic bullet, unlike some of the alternatives that came with a host of side effects.

5. **Pharma firms to go for more big buys in US** – Business Standard
   September 12: At the end of the past financial year, the top-10 Indian pharmaceutical companies had free cash flow of Rs 15,666 crore, more than double the Rs 7,195 crore reported five years ago. In the same period, the 10-year US treasury yield dropped to 2.18 per cent from 3.87 per cent, bringing down the cost of finance for doing acquisitions in the US substantially. This explains how the two most valued acquisitions by Indian pharma companies in the US were

achieved in the past couple of months. First, Lupin acquired US-based Gavis Pharmaceuticals and Novel Laboratories for $880 million in July, followed by Cipla with its $550-million acquisition of InvaGen and Exelan earlier this month.

6. **Novartis heart failure drug should have 17 percent discount: analysis** - Reuters
September 12: A new Novartis AG drug to treat heart failure should cost 17 percent less than its list price of $4,560 per year to keep health costs in line with growth in the overall U.S. economy, according to the nonprofit ICER. In a draft report released on Friday, the Boston-based Institute for Clinical and Economic Review set its "value-based" price for Entresto at $3,799 annually. The independent ICER evaluates clinical and cost effectiveness of new medicines. The group found that Entresto extends patients' lives and decreases the risk of hospitalization, but said the budget impact of the drug, which could be used by nearly 2 million Americans in its first five years, is too high at its current price.