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Daily News Monitor

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1. **AstraZeneca resolves Faslodex patent litigation in U.S.** – Reuters
British drugmaker AstraZeneca Plc said on Wednesday it has entered into an agreement with Sandoz, the generic pharmaceuticals division of Novartis AG, to resolve Faslodex patent litigation in the U.S. The company said it agreed to resolve the litigation relating to Sandoz's generic fulvestrant product, for which it is seeking FDA approval. Fulvestrant is a type of hormonal therapy drug used to treat breast cancer.

2. **UCLA study finds why some cancers stop responding to immunotherapy** - Reuters
Researchers have for the first time identified mechanisms that enable advanced melanoma to become resistant to a new class of drugs, known as immunotherapies, which work by enlisting the body's own immune system to fight the disease. "This will help us to better design the next generation of treatment," said Dr Antoni Ribas, director of the tumor immunology program at the University of California Los Angeles and a lead author of the study released on Wednesday.

3. **GE aims for $1 billion cell therapy 'tools' business with Swiss deal** – Reuters
General Electric's (GE.N) healthcare unit aims to build a $1 billion business offering vital manufacturing tools for a coming wave of cell therapies, helped by the acquisition of a Swiss firm that doubles its presence in the field. Using cells to fight cancer is a long way from GE's better-known areas like power generation and aviation, but the head of the U.S. industrial giant's $18 billion-a-year healthcare operation sees a big, high-margin opportunity. John Flannery, who leads GE Healthcare from its headquarters in Chalfont St Giles, England, reckons he has secured an important part of the supply chain by buying Biosafe Group, a supplier of cell processing systems.

4. **U.S. foreign direct investment jumps 68 percent in 2015, inversions a factor** – Reuters
   Foreign investors stepped up acquisitions of U.S.-based businesses last year, boosting foreign direct investment (FDI) to a record high, but part of the increase was due to corporate tax inversion transactions. The Commerce Department said on Wednesday FDI surged 68 percent to $420.7 billion, the highest since the government started tracking the series in 1982. Foreigners spent $408.1 billion to acquire existing business and $11.2 billion to set up new enterprises. The remaining $1.4 billion in FDI last year was for the expansion of existing foreign-owned businesses in the United States.

5. **FDA panel supports Novartis version of Amgen arthritis drug** – Reuters
   Novartis AG's cheaper version of Amgen Inc's arthritis drug Enbrel is highly similar in potency and safety to the original and should be approved, an advisory panel to the U.S. Food and Drug Administration concluded on Wednesday. The panel voted 20-O that there is no clinically meaningful difference between Novartis's drug, a biologic made of living cells, and Enbrel. Copies of biologics are called biosimilars, not generics, because they are more difficult to imitate with precision.

6. **Sun Pharma appoints Abhay Gandhi CEO of North American business** - The Economic Times
   Drug major Sun Pharma today announced a leadership recast in its Indian and North American operations, naming Abhay Gandhi as CEO of its North American business. Kal Sundaram, CEO of North American business, will move to India as CEO (India and emerging markets). AstraZeneca resolves Faslodex patent litigation in U.S.

7. **Draft rules classify medical devices** – Business Standard
   The central government has proposed that all unapproved medical devices marketed in the country would have to be licensed within six months of the draft rules, announced on Wednesday, being notified. Out of the thousands of medical devices in the market, only 15 are regulated by the Drugs Controller General of India (DCGI). This has resulted in the Indian market being flooded with low-quality medical devices. Medical devices licensed under the old rules would have to get fresh licences within 18 months. In case a licence issued under the old rules expires after 18 months, licence for a new application must be filed at that point, said the draft rules.

8. **"India has a competent enough system to check quality standards"** – Business Today
   In an interview with Business Today, Drugs Controller General of India G.N. Singh says that Indias drug regulatory mechanism is not as bad as it is often made out to be, though it may not mirror the systems that exist in the developed world. “The issue, which people often flag, is the gap that exists between the USFDA and our drug regulatory system. It is a different issue. Depending on the social, economic and other factors, each country will have its own set of regulatory system. The fundamental thing that we need to look at is whether we compromise the safety and quality of medicines or not. We don't compromise,” he added.

9. **HC imposes Rs 5000 fine on state govt** – Times of India
   The Indore bench of Madhya Pradesh high court on Wednesday imposed a penalty of Rs 5,000 on the state government for failing to reply to a PIL challenging the difference in pricing of drugs and medicines in wholesale and retail markets.

10. **Pharma cos have increased focus on quality controls: Biocon CMD** – Moneycontrol.com
    A facility of biosimilars firm Biocon has cleared inspection by the US FDA, Kiran Mazumdar Shaw told CNBC-TV18, even as she termed the development as a routine matter. "We recieve periodic inspections several times in a year from both the FDA and other regulators, which is bound to happen," she told CNBC-TV18. "We are pleased that we have a strong track record with the FDA." The unit in question that got FDA approvals manufactures statins. The pharma industry has been a bit under the cloud over the past many years, with a number of Form 483

(observations over non-compliance) and even warning letters that have led to import alerts coming through for some plants.

11. **Centre asks states to develop plans for vector borne diseases –** DDinews.gov.in
With the predicted rise in vector borne diseases like dengue and malaria during the monsoon season, the Centre has asked states to develop micro-plans for endemic districts and underlined the need for undertaking house-to-house surveillance for its prevention. The Union Health Ministry also asked states to review and strengthen coordination between municipal bodies and other departments to keep public and private buildings vector free.

12. **Workshop on patents rights** – New Indian Express
The Patent Information Centre, Kerala of the Kerala State Council for Science, Technology and Environment is organising a discussion on intellectual property rights and its enforcement. Chief Secretary S M Vijayanand will inaugurate the two day meet at Kanakakkunnu Palace on July 14 at 9.30 am. The joint partners of the programme are the Patent Facilitating Centre, Technology Information Forecasting and Assessment Council (TIFAC). Industries Principal Secretary P H Kurian will preside over the inaugural function. KSCSTE executive vice president Suresh Das will welcome the gathering and TIFAC executive director Prabhat Ranjan will deliver a special address.

13. **International collaboration to create new cancer models to accelerate research** – Pharmabiz.com
An international project to develop a large, globally accessible bank of new cancer cell culture models for the research community launched recently. The National Cancer Institute (NCI), part of the National Institutes of Health; Cancer Research UK, London; the Wellcome Trust Sanger Institute, Cambridge, England; and the foundation Hubrecht Organoid Technology, Utrecht, Netherlands, are joining forces to develop the Human Cancer Models Initiative (HCMI), which will bring together expertise from around the world to make about 1,000 cancer cell models. Using new techniques to grow cells, scientists can make models that will better resemble the tissue architecture and complexity of human tumors than the cell lines used today.

14. **How Drug-Resistant TB can show the path to tackling antimicrobial resistance –** Huffington Post
Antimicrobial resistance (AMR) is a global health threat, and it is estimated that by 2050, 10 million lives a year and a cumulative US$100 trillion of economic output are at risk due to the rise of drug-resistant infections, if we do not find solutions to tackle the problem. Since the introduction of antibiotics, microbes have evolved a variety of methods to resist them. We are now dealing with "superbugs" that are virtually untreatable, including colistin-resistant E. coli, drug-resistant gonorrhea, carbapenem-resistant enterobacteriaceae, methicillin-resistant Staphylococcus aureus, extensively drug-resistant tuberculosis, and extended-spectrum-beta-lactamase-producing strains. The antibiotic pipeline is running dry, and AMR is threatening to undo major gains made in the control of infectious diseases.