

IPR & Innovation

Big pharma industries gobble up NIPER patents, [India Today](#) (13 June 2015)

Patents and research findings that could have been utilised to boost the small-scale pharmaceutical companies are lying in the cold shelves of National Institute of Pharmaceutical Education and Research (NIPER) for decades. And a section of institute's top brass is allegedly busy sharing the information on patents and intellectual property rights with the big players in the industry, thereby negating the mandate for which NIPER was set up. This stark reality has come to light after a senior scientist, who worked with the institute, levelled damning allegations against the NIPER authorities. According to Dr Parikshit Bansal, the institute has the mandate to share such information with smaller companies in the industry so that affordable medicines are manufactured and made available to the people. However, he alleged that the institute has been sharing the information with big companies, who in turn, are making money by manufacturing pricey medicines.

Similar reports have appeared in:

[Yahoo! India](#)

MSF urges India not to bow to patent pressure, [PharmaTimes](#) (13 June 2015)

Médecins Sans Frontières is urging the Indian government to not relax its drug patent laws and keep the country as a source of cheap medicines. India currently sets a high bar for what deserves a patent, which has resulted in large amounts of generic competition and low drug prices compared to other countries. One of the most recent high profile examples is Gilead's hepatitis C drug Sovaldi (sofosbuvir), which was denied a patent in the country, leading to Gilead licensing it to generic manufacturers. However, the country is currently in negotiations with Japan for the Regional Comprehensive Economic Partnership (RECP) trade agreement, which contains proposals that could make it easier for pharma firms to get patents for their medicines.

Similar reports have appeared in:

[Pharma Focus Asia](#)

'Biased? India has a balanced pharma patent regime', [DNA India](#) (15 June 2015)

India has a balanced pharmaceutical patent regime in place because it needs to hold the rights and interest of a wide section of consumers who are in need of free medicines, according to Frederick Abbott, professor of international law at the Florida State University. He also suggested that Indian pharma manufacturers should collaborate with African countries to invest and set up manufacturing facilities there. On India's patent law, Abbott, an Edward Ball Eminent Scholar, told dna, "India and its courts have been doing a very good job in implementing its patent law. From my standpoint, there is relatively little from a practical or factual basis that US multinationals have to complain about. Every time Indian court or its patent office refuses a patent or validates a patent, it is treated as if this is some unfriendly act without reason, whereas in the US validating pharmaceutical patents are fairly routine."

Access to Healthcare

Soon, access to generic drugs will improve, [The Hindu Business Line](#) (13 June 2015)

Access to affordable medicine is set to improve. Generic medicines under the Jan Aushadhi scheme will soon be sold in private hospitals, thanks to a new public-private partnership model. The Jan Aushadhi scheme is being run by the Bureau of Pharma PSUs of India (BPPI), set up by the Department of Pharmaceuticals to provide drugs at affordable rates. "It has now been decided to extend the scheme through public-private partnership and partnering with individual entrepreneurs so that people take full advantage of the scheme," the Department of Pharmaceuticals said in a notification issued on Friday.

Health ministry seeks Rs 5,000 crore more, [Asian Age](#) (13 June 2015)

Dissatisfied with funds allocated for the health sector, which saw a major cut this year, the Union health ministry has sought additional funds of Rs 5,000 crore. Sources said that a meeting to this effect has already taken place in the Prime Minister's Office and they are hopeful of getting the additional funds. Sources further added that the ministry has already written to the finance ministry seeking additional funds for medical education, tertiary care, human resources, the HIV/AIDS programme etc. "Funds have been asked for the schemes and the programmes where there was no provision. We are hopeful of getting some funds so that the ongoing schemes do not get affected," sources added.

Hepatitis C medication to become cheaper, [The Times of India](#) (15 June 2015)

Roche recently announced that Exxura, the medication used for the treatment of Hepatitis C, will be available at a substantially lower price - 65% less than its original price across all government institutions in the country. The move to reduce its cost of therapy is in line with Roche's commitment to treating patients with Hepatitis C, which continues to be a substantial disease burden in the northern states of India, especially Haryana. The price reduction will also support the Haryana government's ongoing comprehensive initiatives to treat the growing number of Hepatitis C patients in the state.

Health to Finance Ministry: Not feasible to fund tertiary care costs from NHM funds, [The Indian Express](#) (15 June 2015)

A recent circular from the Finance Ministry asking the Health Ministry to dip into its National Health Mission (NHM) funds for contingency expenses in tertiary care has not gone down well with the latter. The Health Ministry has replied that it is not feasible as NHM has only been allocated the bare minimum to run existing programmes. While the estimate for Health went up by nearly 10 per cent in the 2015-16 Union the budget, it is not enough to start ambitious new plans like the National Health Assurance Mission which has five components — preventive and promotive health, free drugs, free diagnostics, hospitalisation in government hospitals/referral to private providers and tertiary care. The NHM budget for this fiscal is Rs 18,259 crore against Rs 17,000 crore allocated in the last fiscal.

NITI Aayog pinpoints glaring issues in healthcare due to limited budget allocation, [Pharmabiz.com](#) (15 June 2015)

The NITI Aayog's (National Institute for Transforming India) health division has observed glaring issues in healthcare with limited budget allocation. Disparity in healthcare exists across states and there is an excessive focus on vertical disease control programmes and inadequate attention to health system strengthening. Enormous challenges are facing the sector with limited funds. The government will need to look at maximizing returns from available financial resources and also increase investments in health, views the NITI Aayog health division.

Ethics & Compliance

Non-compliance: bitter pill of the Indian pharma biz, [The Hindu Business Line](#) (13 June 2015)

Does quality non-compliance threaten to trip-up the Indian pharmaceutical industry, growing at a steady trot of about 15 per cent in the last few years? Well, data culled by two recent reports on compliance in this industry is not very comforting. Import alerts against Indian plants in 2013 accounted for 49 per cent of the total 43 imports alerts issued by the US FDA (Food and Drug Administration) worldwide, records an EY report on data integrity compliance. And a Deloitte report on compliance management points out: "In the last two years, import ban orders have been issued by the USFDA and Canada's Health Canada to more than 25 Indian API (active pharmaceutical ingredients) and formulations."

Medical & Regulatory

India takes first step towards regulating medical devices, [Business Standard](#) (13 June 2015)

India plans to set up a regulator to oversee the country's \$4 billion medical device industry, according to a draft policy released this month, the country's first effort to regulate an industry that covers everything from thermometers to prostheses. The policy document, welcomed by many in the industry despite concerns over a lack of detail, also outlines plans to boost local manufacturing and reduce reliance on imports. While India is the world's third-largest pharmaceutical market, its share of the medical devices market is way

behind. More than 70% of medical equipment sold in the country is imported, mostly from the United States. The draft policy issued by the central Department of Pharmaceuticals proposes an autonomous National Medical Device Authority tasked with promoting the local industry and ensuring adherence to safety standards.

Similar reports have appeared in:

[Deccan Herald](#)

[NDTV Profit](#)

Strong prescription needed for e-pharmacies, [The Hindu Business Line](#) (13 June 2015)

From baby-food to bow ties, it's available online. But the sale of medicines over the internet has split the retail pharmaceutical world wide open. Despite Snapdeal getting a rap recently from the Maharashtra Food and Drug Administration for selling medicines online – several aspirants wait in the wings, ready to roll-out their online models. But waving a huge red-flag of caution here are doctor and chemist associations, who warn that it could open the door for greater misuse of cough syrups, painkillers and antibiotics, for example. "A medicine is not a phone that you can order the same product online 10 times," says Jayesh Lele, President-elect, Indian Medical Association (Maharashtra).

AICDF opposes Central govt's proposal to ban pharmacies from sale of food products, dietary & nutritional supplements, [Pharmabiz.com](#) (13 June 2015)

The All India Chemists and Distributors Federation (AICDF) has urged Union minister of state for chemicals and fertilisers, Hansraj Gangaram Ahir, not to go ahead with his reported decision to bring in a proposal banning pharmacies from sale of food products, dietary and nutritional supplements. Following the Union government's decision to ban the baby food product, Maggi, the minister, who is in charge of the Department of Pharmaceuticals, has stated that he is thinking of bringing in a proposal to ban the sale of these products at pharmacies. Reacting to his statement, AICDF has written to the minister that the association will resort to a nationwide protest if the government disallows the licensed pharmacies to sell baby food and other health products. The pharma traders' association has expressed strong objection against the reported statement of the minister.

Bulk drug business may get Rs 5,000-cr funding boost, [Hindustan Times](#) (15 June 2015)

In a bid to boost bulk drug manufacturing and cut reliance on imports from China, Narendra Modi led government is planning to invest over Rs 5,000 crore for the establishment of bulk drug cluster parks. Bulk drugs, also known as active pharmaceutical ingredient (API), are the ingredients in a drug that give it its therapeutic effect. The government estimates that currently India imports almost 90% of its bulk drugs from China. Common imported bulk drugs include painkillers such as paracetamol and aspirin, and antacid ranitidine - known by its trade name of Zantac. "The proposed plan envisions mega parks for pharma clusters through special purpose vehicles (SPV), which will be provided with a host of incentives for manufacturers," a senior official at department of pharmaceuticals (DoP) told HT. "List of incentives include a 15-year tax holiday, allocation of coal and electricity at concessional rates, soft loans to industry through interest subsidy of 5% and income-tax benefits for an initial period of 10 years."

Other News on Pharma

India's health, biopharma sectors deserve more attention, [Business Standard](#) (13 June 2015)

India's health and biopharma sectors deserve better attention from the government to realise their full potential and provide cheaper facilities to millions of patients, leading industry experts and academicians have said. During a day-long US-India BioPharma and Healthcare Summit, industry leaders, experts and academicians hoped that the new Indian government will bring in "predictable, transparent and pragmatic regulatory policies" which would positively change the country's BioPharma and Healthcare Innovation landscape.

Similar reports have appeared in:

[Financial Chronicle](#)

[Deccan Herald](#)

[Press Trust of India](#)

[The Tribune](#)

[IBN Live](#)

Cardiac stents likely to be made more affordable, [DNA India](#) (13 June 2015)

The Maharashtra Food and Drugs Administration's inquiry into complaints of exorbitant costs of cardiac stents may ultimately benefit thousands of heart patients. The National Pharmaceutical Pricing Authority (NPPA) is expected to regulate prices of these life-saving tubes in four months. Last month, FDA authorities had written to NPPA stressing the need for regulating the prices of cardiac stents. FDA said it had received several complaints from the public and non-profit organisations with regard to overpricing of stents. Acting on these complaints, a team led by FDA joint commissioner (vigilance) MM Pawar had conducted a detailed probe into the pricing mechanism of three major firms that deal in cardiac stents, in Mumbai, Pune and Nashik.

Maha FDA to facilitate modalities related to revision surgeries for patients in defective device rec, [Pharmabiz.com](#) (13 June 2015)

Against the backdrop of issues relating to delayed recall of J&J metal-on-metal ASR XL Acetabular Hip Replacement System (ASR) in India, Maharashtra Food and Drug Administration (FDA) is in the process of facilitating modalities related to revision surgeries required by patients impacted by its use, according to a senior FDA official. "We are looking into the aspect that surgeries are being done on the affected patients in a proper manner. Action can be taken on the company for not catering to the patient's grievances on the same," the official added.

New diabetes drug to slash treatment cost, [The Times of India](#) (14 June 2015)

A new anti-diabetes drug from the 'gliptin' family soon to be launched in India promises to lower treatment cost for patients by 55-60%. The launch of 'Teneligliptin' by Mumbai-based Glenmark Pharma under Ziten and Zita Plus brands at an affordable price could prove to be a game-changer with savings of over Rs 10,000 per year for diabetics. Treatment cost for the debilitating disease which gradually attacks and weakens all body organs may come down further over months, with possibly more domestic companies entering the market, experts said.

Similar reports have appeared in:

[The Economic Times](#) (15 June 2015)

Medical Device Policy mandates institutional frameworks such as common testing centres, Centers of E, [Pharmabiz.com](#) (15 June 2015)

The draft National Medical Device Policy-2015, issued recently by the Department of Pharmaceuticals (DoP), has mandated several institutional frameworks such as common medical device testing centres, Centres of Excellence, Made in India marking (BIS) specific to medical devices and a Skill Development Committee under National Medical Devices Authority. As per the policy, common medical device testing facilities, preferably in the PPP mode, should be set up by government in major medical device manufacturing hubs to facilitate testing/evaluation of medical devices. Recurring expense can be borne by the industry.

Health ministry constitutes working group to recommend governance structure for IHIN, [Pharmabiz.com](#) (15 June 2015)

Keen to realize and implement the proposed India Health Information Network (IHIN) initiative, the Union health ministry has recently constituted a working group to recommend its governance structure. Once the modalities of this network are finalized, it will provide a unique platform for the private players and the government to synergise and work together for developing a system aimed at catering key healthcare needs of the patients through eHealth. With a view to promote and establish a strong eHealth initiative in the country, the ministry via order number NO.R-14012/16/2014-e-Gov had proposed the formation IHIN early this year. The main aim behind this move was to provide a common forum to share expertise and explore opportunities to enhance eHealth experiences, discuss policy level issues, while functioning as champion of eHealth practices and standards in India.
