



News Updates: March 12, 2014

Patents/Compulsory Licensing/Intellectual Property

Publication: The Economic Times

Edition: National

Date: March 12, 2014

Headline: [How to strengthen India's case on intellectual property rights](#)

Synopsis: New Delhi is well within its rights to rebuff the US pharma lobby's attempt to label India a habitual intellectual property rights (IPR) offender. India's patent law is far from being weak on protecting IPR. Yet, it must sort out some things for its IPR regime to have credibility: the legal system must work fast and use of compulsory licensing (CL) must be seen to be restrained. It must use price control, rather than CL, to make drugs affordable. A complementary step would be an institutional arrangement for purchase commitments that will help pharma companies submit to price control with grace.

Publication: The Financial Express

Edition: National

Date: March 12, 2014

Headline: [US defence giants back India's IPR regime as Big Pharma frets](#)

Synopsis: At a time when Washington is considering trade sanctions against New Delhi for 'ineffective' Intellectual Property Rights (IPR) regime, two of America's major defence and civil aviation firms, Honeywell and Boeing, have come out strongly in support of India's IPR regulations.

Publication: The Economic Times

Edition: National

Date: March 12, 2014

Headline: [Indian patent laws sound, unchallenged: Drug companies tell US International Trade Commission](#)

Synopsis: The World Health Organization (WHO) has strongly endorsed India's patent laws and no country, including the United States, has challenged these laws at the WTO claiming that these infringe trade-related intellectual property rights, Indian drugmakers have told the US International Trade Commission.

The commission, a quasi-judicial body set up by the US Congress, is investigating whether Indian policies discriminate against American manufacturers and is due to submit its views later this year.

Publication: The Financial Express

Edition: National

Date: March 12, 2014

Opinion piece: Ron Somers, President, US-India Business Council (USIBC)

Headline: [Why the US needs India](#)

Synopsis: American business stands to gain from a robust US-India commercial & strategic partnership. Technology and innovation will be key for both our future economies. To achieve greater collaboration in these important areas, it is essential to develop shared ecosystems that reward and protect IP. On issues concerning water & energy security, research & development, diabetes & other health challenges, food security, space exploration, or defence & homeland security, collaboration in technology and

innovation will be crucial. Certainly, more work needs to be done strengthening the protection of IPR. That said, America's most precious technology, its defence technology, has grown in trade with India from \$250 million in 2003 to over \$12 billion today. The US government is exchanging and sharing technologies with India that previously it has shared with its closest allies: Great Britain, Australia and Japan. The growing trust in sharing such technology and the IP that goes along with this demonstrates a trust and appreciation on behalf of both governments of the issues at stake concerning sensitive technology and the importance of the protection and safe-keeping of IPR.

Website: Moneycontrol

Edition: Online

Date: March 11, 2014

Headline: [Health Min's compulsory license proposal hits DIPP hurdle](#)

Synopsis: Health ministry's proposal for a compulsory licence for anti-cancer drug Dasatinib has hit a hurdle. The Department of Industrial Policy and Promotion (DIPP) is not convinced about the proposals submitted by the ministry. Compulsory licence is a tool through which developing countries like India can produce patented drugs, can allow companies to produce patented drugs in a much cheaper and affordable way.

Clinical Trials

Publication: Daily News & Analysis

Edition: Mumbai, Pune, Bangalore, Ahmedabad

Date: March 12, 2014

Headline: Tough medicine (link unavailable, scan attached)

Synopsis: The Supreme Court's dismay at the statistics regarding deaths and adverse events among clinical trial volunteers highlights an issue that could impact the Indian pharmaceutical sector as much as the ongoing intellectual property rights kerfuffle. The struggle over how best to regulate the trial process has been going on for a year now, and with good reason. The affidavit filed by the union health ministry with regard to a PIL by NGO Swasthya Adhikar Manch shows that 3,458 deaths and 14,320 serious adverse (SAEs) were recorded in trials carried out by drug companies between 2005 and 2012. The ministry's dubious contention that only 89 deaths and 506 SAEs out of those were attributable to the trials notwithstanding, those are not figures to be disregarded. But the manner in which the regulations have been tightened — with the usual attendant problems of lack of transparency and infrastructure — has caused a massive slump in the number of clinical trials being carried out in the country and, consequently, delayed the launch of new drugs.

Similar report in-

Pharmabiz- [Only 89 out of 3458 deaths could be attributed to clinical trials during 2005-13: Health ministry](#)

Medical Council of India

Publication: The Times Of India

Edition: Online

Date: March 11, 2014

Headline: [MCI misleading health ministry or ministry misinforming parliament?](#)

Synopsis: There seems to be a communication gap between the Medical Council of India (MCI) and the Health ministry. MCI claimed on February 18 they had no jurisdiction on doctors' associations and hence all its decisions against officer bearers of doctors' associations were void. However, just two days later, on February 21, health minister Ghulam Nabi Azad told Parliament that MCI was taking action against office bearers of the Indian Medical Association for endorsing food products.

Publication: Daily News & Analysis

Edition: Online

Date: March 12, 2014

Headline: [Pathology doctors registered with MCI can run labs, sign reports](#)

Synopsis: Doctors across sectors are furious that lab technicians are running shop even as high courts of up to four states have passed interim orders stating that only a qualified pathologist can sign diagnostic reports. Maharashtra Association of Practicing Pathologists and Microbiologists (MAPPM) has written to state authorities stating that even as interim orders of various high courts including Maharashtra, Madhya Pradesh, Gujarat and Andhra Pradesh clearly state that only a pathologist possessing a M.D. degree in Pathology can run a lab and sign reports, lab technicians are openly flouting court orders.

Drug Regulation

Publication: The Times Of India

Edition: National

Date: March 12, 2014

Headline: [No ACs in pharmacies, drugs prove ineffective](#)

Synopsis: 'Store in a cool, dry place' is a standard prescription for storage of most medicines. At many pharmacies in the city, this often translates into tossing them onto racks that are exposed to dust and heat. Recently, when a team from the Directorate of Drugs Control undertook a routine inspection in the city, they found a carton of anti-tetanus shots with a wholesale dealer stored without refrigeration. "This is shocking," said Dr Jacob John, a former virologist of the Christian Medical College, Vellore. "What officials were looking at was a box that carried potentially ineffective vaccines," he said.

General Industry

Publication: Daily News & Analysis

Edition: National

Date: March 12, 2014

Headline: [Right to jobs, health, homes in Congress manifesto](#)

Synopsis: After delivering the right to information, right to food, to education and to employment in rural areas, the Congress is now hoping to lure voters by extending rights to water, housing, sanitation, health, and job reservations for members of scheduled caste (SC) and scheduled tribes (ST). The Congress is expected to enumerate these rights-based legislations in its manifesto. The manifesto team, which includes Union minister Jairam Ramesh and Congress vice president Rahul Gandhi's confidante Mohan Gopal, an academic, is busy giving finishing touches to the manifesto to ensure that the party does not violate the Election Commission's guideline of not including "populist" or "unrealistic" promises.

Publication: The Hindu

Edition: National

Date: March 12, 2014

Headline: [Regulating stem cell therapy](#)

Synopsis: A revised set of guidelines on stem cell research was recently released by the Indian Council of Medical Research and the Department of Biotechnology, seven years after an earlier one was issued. Despite claiming that the revision was necessitated by a need to "reflect new scientific and clinical findings" that have changed the landscape of stem cell research being undertaken in the country and its possible translation, there is a glaring omission that reflects a lack of application of the mind. The guidelines make it abundantly clear that any use of stem cells in patients except to treat various haematological, immunological and metabolic disorders using haematopoietic stem cells should, by default, be considered as clinical trials. The exemption is on the grounds that the use of haematopoietic stem cells to treat the said disorders has been "established as a standard of medical care."

Publication: Mint

Edition: National

Date: March 12, 2014

Headline: [Ranbaxy scrambles for ingredients to make generic Nexium](#)

Synopsis: Drugmaker Ranbaxy Laboratories Ltd is in talks with at least two companies on sourcing ingredients for a generic version of AstraZeneca Plc's heartburn drug Nexium, a source said, to ensure the pills can be sold in the United States. Washington in January prohibited Ranbaxy, India's top drugmaker by revenue, from selling drugs in the United States using ingredients from one of its plants in northern India due to poor manufacturing practices.

Similar reports in-

The Financial Express- [Ranbaxy scrambles for ingredients to make generic Nexium](#)

The Hindu Business Line- [US ban on Toansa unit: Ranbaxy may source APIs from external sites](#)

The Hindu- [Pharma exports face stricter scrutiny](#)

Reuters- [Ranbaxy scrambles for ingredients to make generic Nexium](#)

Publication: The Financial Express

Edition: National

Date: March 12, 2014

Headline: [Centralised system under discussion](#)

Synopsis: In order to ensure that the profitable central public sector enterprises (CPSEs) allocate and exhaust their funds for the corporate social responsibility (CSR) work, the government is considering a proposal for creating a special purpose vehicle (SPV). But experts feel that CPSEs are well-equipped to spend CSR money on their own and meet the objective of inclusive growth and that there is no need for a separate agency for this purpose.

The proposal, mooted by the ministry of heavy industries and public enterprises in consultation with the corporate affairs ministry, entails the creation of a SPV or a similar financial entity, which will be independent of the individual CPSEs.