



News Updates: June 19, 2014

Patents/ Compulsory licensing/ Intellectual property rights

Publication: The Hindu Business Line

Edition: National

Date: June 19, 2014

Headline: [Health Ministry's new bid for cancer drug copy nixed](#)

Synopsis: In what should come as relief for US drug major Bristol-Myers Squibb, the Ministry of Commerce has rejected a fresh proposal by the Health Ministry seeking a compulsory licence for production of a copy of its patented blood cancer drug, Dasatinib. In its response, the Department of Industrial Policy and Promotion (DIPP), which is a part of the Commerce Ministry and responsible for such approvals, said the Health Ministry's arguments did not conclusively prove that a generic version of the medicine was needed.

"We have written back saying that we could not support their proposal as more justification was required," a DIPP official told BusinessLine. The Health Ministry had proposed that a compulsory licence be given for a generic version of Dasatinib in January this year and then again in May after the DIPP asked it to specify why it wanted the Centre to step in. In the second proposal, it said the licence should be granted for 'public non-commercial use' and the cost of producing the blood-cancer medicine be met through Government schemes.

Publication: Business Standard

Edition: National

Date: June 19, 2014

Opinion piece: T S Vishwanath, Principal Adviser at APJ-SLG Law Offices

Headline: [Who will bite the IPR bullet?](#)

Synopsis: The flexibilities available to developing countries under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) regime of the World Trade Organisation (WTO) came up for discussion at the TRIPS Council meeting in Geneva recently. The divide between developed and developing countries on the protection of intellectual property will take long to be completely sorted out since the approach to intellectual property rights (IPR) remains different given the socio-economic reasons in both these worlds. However, while there has been a growing tendency to protect IPR of individuals, there is a feeling that the small and medium sized industry in developing countries needs help to understand and respect this important area of work in WTO. Countries like India are taking steps to understand the best possible way forward that would make sense to the Indian government and industry.

Clinical trials

Publication: The Economic Times

Edition: National

Date: June 19, 2014

Headline: [EMA nod to publishing clinical trials data of okayed drugs a welcome move](#)

Synopsis: Late last week, the European Medicines Agency (EMA) agreed on a policy to publish clinical trials data of the drugs it approves. The new policy is expected to be finalised soon and to become effective on October 1 this year. It is a major victory for pressure groups that have been fighting for increased transparency in clinical trials. The rules may still not go far enough, but it is a beginning that will make a difference to clinical trials all over the world. For all those who participate in clinical trials, it may come as a shock that the data about their trials may never be published. There is a business reason for it. Companies who sponsor the trials fear that it might help their competition.

Drug regulation

Website: Pharmabiz

Edition: Online

Date: June 19, 2014

Headline: [AIDCOC expresses concern over CDSCO's move to centralise drug licencing](#)

Synopsis: To enhance drug regulatory and monitoring mechanism in the country, the All India Drugs Control Officers' Confederation (AIDCOC) recently sent a representation to union health ministry expressing concern over centralisation of the power at the Centre and urged the government to continue following federal structure and legislative scheme under the Drugs and Cosmetics Act, 1940. The confederation strongly feels that since India is a federal country with clear division of responsibility between the Central government and State government, with defined division of responsibilities, it should not be changed or tinkered with. AIDCOC stressed that bringing any changes to the present structure will create chaos and confusion in the industry, that will further complicate effective and smooth implementation of the Act.

Universal Health Coverage

Publication: The Financial Chronicle

Edition: National

Date: June 19, 2014

Opinion piece: Sushil Sharma, chairman, Arthritis Foundation of India

Headline: [Why health investment is productive](#)

Synopsis: With a BJP government in place with a comfortable majority, it is time to implement right to health, which effectively means free treatment facilities to millions of below poverty line (BPL) and above poverty line (ABL) families across the country in the event of accident and illness. The new government must launch this ambitious new scheme and christen it the Mahatma Gandhi national insurance scheme for health (MGNISH). It should be a joint enterprise of the centre and the state and both private and public hospitals across the country should be made stakeholders.

Cancer

Publication: The New Indian Express

Edition: National

Date: June 19, 2014

Headline: [Defeated by high costs, cancer patients give up on treatment](#)

Synopsis: The government is talking of capping the prices of essential drugs for cancer. That should come as welcome news to patients in Bangalore, many of whom give up after a few months of treatment. A significant number of patients (some put the number at over 50 per cent) stop visiting hospitals after two or three cycles of chemotherapy. They also drop out from regular follow-up visits, say doctors. Oncologists say cancer patients are diagnosed mostly in the advanced stages, calling for a longer duration of treatment involving surgery, chemotherapy and radiotherapy, besides medication and check-ups.

Publication: Daily News & Analysis

Edition: National

Date: June 19, 2014

Headline: [Honour for Tata Memorial for ethical practices in clinical research](#)

Synopsis: At 64,000 new cancer patients every year, the Tata Memorial Hospital probably sees the highest load in the world. But that has not dented the commitment of the Parel-based hospital towards its patients a bit. In fact, the centre just lifted it a few notches. TMC has become the only government-run hospital in the country to be maintaining the highest ethical standards to protect taking part in clinical research. The comprehensive cancer-care institute is autonomously run under the Department of Atomic Energy. "In the US, the largest institutes cater to close to 30,000 patients in a year," said Dr

Rajendra Badwe, director, TMC, reacting to the accolade that came after 18 months of rigorous screening.

CSR

Publication: The Hindu Business Line

Edition: National

Date: June 19, 2014

Opinion piece: Tulsi Jayakumar, professor of economics, SP Jain Institute of Management and Research, Mumbai

Headline: [A flaw in the CSR design](#)

Synopsis: Section 135 of the Companies Act 2013 and the resultant Corporate Social Responsibility (CSR) rules 2014, issued by the ministry of corporate affairs came into effect in April 2014. The activities listed which may be included by companies in their CSR policies appear 'confusing'. They include eradicating hunger and poverty, promoting education, promoting gender equality and empowering women, reducing child mortality and improving maternal health, and combating HIV virus, AIDS, malaria and other diseases. For one, these activities are traditionally supposed to be undertaken by a welfare state. Is this then an admission of the Government's abrogation of responsibility? It has been argued by some economists that such CSR spends are a drop in the ocean of overall government spending on the social sector. The question is: Can this make a difference to the provision of essentially public goods that the Government has so far not delivered? A more disturbing aspect of Section 135 relates to the linking of a company's profit-making with the development of local areas. Companies are required to spend 2 per cent of their average net profits in the preceding three years and focus on local areas, around which they operate. This is an absurd proposition.

General Industry

Publication: The Economic Times

Edition: National

Date: June 19, 2014

Headline: [Novartis India vice-chairman & managing director, Ranjit Shahani says company now focuses on new products, business growth](#)

Synopsis: Just a year after Swiss drugmaker Novartis lost the patent battle for its anti-cancer drug Glivec, the company has said it has "moved on" with a focus on new product launches and growing its India business, a strategy that reinforces the importance of Indian market for multinational drug makers despite regulatory challenges. Novartis India has over the past year launched three successful patented drugs and over 12 generic drugs that have helped it expand its presence in the country. "Glivec is behind us. Strategically all products which are in Novartis pipeline and also make commercial case will be launched in India," said Ranjit Shahani, vice chairman and managing director of Novartis India.

Publication: Business Standard

Edition: National

Date: June 19, 2014

Headline: [Cipla's drug pipeline turns it into \\$10-bn target](#)

Synopsis: Indian drugmaker Cipla may be the industry's next target in a record run of takeovers. Cipla, a maker of generic HIV, cancer and respiratory medications, has almost doubled the number of treatments under development in the past year and analysts projects its revenue will surge 60 per cent by 2017. Drawn by demand for the \$5.7billion company's medicines internationally and factories across India, Teva Pharmaceutical Industries or Mylan may be suitors, said IIFL Holdings. After Mumbai-based Cipla bought its South African distributor and raised its stake in a Ugandan manufacturer to gain more control of exports, buyers may have to offer at least \$9.7 billion to convince the founders to sell, said Angel Broking Ltd. Any deal would follow about \$190 billion of global drug and medical-products takeovers this quarter, according to data compiled by Bloomberg.

Publication: The Telegraph

Edition: National

Date: June 19, 2014

Headline: [Doctors' British 'junket' in MCI glare](#)

Synopsis: India's apex regulator for medics has started hearings on a complaint that a drug company financed a pleasure trip to Britain for several doctors and their families. A non-government organisation, the Swasthya Adhikar Manch, filed the complaint two years ago against a group of doctors based in Madhya Pradesh but the state regulator did not act on it. The Medical Council of India (MCI) last Thursday heard presentations by the Manch, which claimed a drug company named Intas had paid for the May 25 to 30, 2012, trip to England and Scotland. In June 2012, the Manch had complained to the MCI, which regulates licensing and practice by doctors in India, that the doctors had breached the ethical regulations imposed on them by the MCI by accepting the drug company's hospitality.

Publication: Mint

Edition: National

Date: June 18, 2014

Headline: [NHRC concerned over rise in leprosy cases, seeks report](#)

Synopsis: The National Human Rights Commission (NHRC) on Tuesday expressed concern over rise in cases of leprosy in the country and issued a notice to the Union health ministry seeking a report within four weeks. The Commission took suo moto cognisance of a media report which said though the government has declared that leprosy is under control, official data shows the incidence of the crippling disease has been on increase with 1,26,800 new cases in 2010-11, 1,27,295 in 2011-12 and 1,34,752 in 2012-13, NHRC said in a statement here.

Similar report in-

The New Indian Express- [Leprosy: NHRC Issues Notice to Health Ministry](#)

Publication: Business Insider

Edition: Online

Date: June 18, 2014

Headline: [New Report Ranks US Healthcare Dead Last Among Wealthy Nations](#)

Synopsis: The United States has the most expensive healthcare system in the world. And, according to a new report released by the Commonwealth Fund, it is also one of the worst performing systems when compared with other wealthy countries. The United Kingdom took the top spot, followed by Switzerland. Countries were judged based on quality, access, efficiency, equity, performance and healthy lives. The data were drawn from three international surveys of patients and primary care physicians conducted by the Commonwealth Fund from 2011-2013, and also used data from the World Health Organization and the Organization for Economic Cooperation and Development.