



**News Updates: March 25, 2014**

**Patents/Compulsory Licensing/Intellectual Property**

**Publication: The Times of India**

**Edition: National**

**Date: March 25, 2014**

**Headline: [Plea against Gilead's patent bid](#)**

**Synopsis:** A patient group and a UK-based intellectual property law firm have together filed a patent opposition before the Delhi Patent Office to prevent US-based pharma company Gilead from gaining protection on a life-saving hepatitis-C drug in India. Gilead is expected to soon apply for an approval from Drug Controller General of India (DCGI) for sofosbuvir.

**Publication: The Financial Express**

**Edition: National**

**Date: March 25, 2014**

**Headline: [Indian generic drug firms court US off-patent market](#)**

**Synopsis:** With \$32 billion worth of drugs going off patent in the next two years, Indian pharma companies are going all out to launch generics in the US market, the world's largest; patent-related litigation for at least 18 drugs is pending in US courts. While the generics opportunity may not seem very large in the near term, the total sales of these drugs by innovators was \$29 billion in 2013. Eight of these are blockbusters — industry term for medicines that generate more than \$1 billion in sales. Moreover, all 18 are specialty drugs — commanding relatively high margins and generating double the return on investment compared with traditional therapies.

**Publication: Pharmabiz**

**Edition: Online**

**Date: March 24, 2014**

**Headline: [MultiCell files US & international patent applications for liver cancer treatment](#)**

**Synopsis:** MultiCell Technologies, Inc, a clinical-stage biopharmaceutical company, has filed additional US and international patent applications covering MCT-485 and its composition of matter, biological targets, mechanism of action, and methods and formulations for therapeutic use. MCT-485 is a very small noncoding double stranded RNA (dsRNA) molecule which has demonstrated a unique cytotoxic, oncolytic, and immune stimulating activity in in vitro models of hepatocellular carcinoma. MCT-485 is thought to target cancer by delivering a cytotoxic and oncolytic effect to only those cells having the highest tumour initiating capability that are part of the cancerous process such as cancer stem cells and tumour initiating cells.

**Publication: Jagran Post (similar story in Hindustan Times and Business Today)**

**Edition: Online**

**Date: March 24, 2014**

**Headline: [India ready to discuss IPR norms at WTO: Anand Sharma](#)**

**Synopsis:** Replying to a query over US charges that India's IPR norms discriminate against American companies, particularly in the pharmaceutical sector, Sharma said that if US wants a discussion over the matter at WTO then India is more than ready. India has expressed its concern over US Food and Drug Administration's audit inspections of Indian pharmaceutical companies and the disproportionate penalties imposed in some instances.

**Publication: Reuters**

**Edition: Online**

**Date: March 24, 2014**

**Headline: [U.S. top court takes no action in Teva MS drug case](#)**

**Synopsis:** The U.S. Supreme Court on Monday for the second time did not announce whether it would hear an appeal by Teva Pharmaceutical Industries Ltd in a patent fight with generic competitors over a top-selling multiple sclerosis drug. The case is closely watched because, if the court declines to take it, cheaper versions of the drug Copaxone could go on the market as soon as May.

#### Drug Pricing

**Publication: Business Standard**

**Edition: National**

**Date: March 25, 2014**

**Headline: [Essential medicine likely to get dearer as price revision looms](#)**

**Synopsis:** Soon, consumers might have to shell out more for essential medicines. The National Pharmaceutical Pricing Authority (NPPA) is seeking medicine cost details from individual companies, based on which current rates could be revised, according to an official. The move comes in the wake of complaints from leading pharmaceutical companies pointing out that the basis of price fixation by NPPA is not accurate. The companies had alleged while NPPA used IMS Health data, it does not represent the real prices. Following the complaints, department of pharmaceuticals (DoP) ordered NPPA to revalidate the data used for capping prices of essential medicines under the new policy.

**Publication: Pharmabiz**

**Edition: National**

**Date: March 25, 2014**

**Headline: [Maha FDA to approach NPPA for GSK's overpricing of paracetamol brands](#)**

**Synopsis:** Following Maharashtra Food and Drug Administration (FDA) stop sale order of Analgesic brand, Calpol, the state regulator is now planning to approach the National Pharmaceutical Pricing Authority (NPPA) to recover the excess amount earned as profit by GlaxoSmithKline at the revised overpriced rate. Thane unit of the State FDA recently issued stop sale order of Calpol 60 ml syrup manufactured by GSK under the brand name of Calpol till further notice. A combination of the narcotic hydrocodone and non-narcotic pain reliever acetaminophen, paracetamol oral suspension IC is prescribed for moderate to severe pain and fever.

#### Clinical Trials

**Publication: Mint**

**Edition: National**

**Date: March 25, 2014**

**Headline: [CSIR tuberculosis drug project enters Phase II clinical trials](#)**

**Synopsis:** The Council of Scientific and Industrial Research's (CSIR) open source drug discovery (OSDD) project on Monday handed over a new drug combination to the Lala Ram Sarup TB Hospital in New Delhi to take it forward for so-called Phase IIB clinical trials to study the efficacy of the drug that will target multi-drug resistant tuberculosis in Indian patients. The treatment PaMZ was originally developed by the Global Alliance for TB Drug Development, but the OSDD now has the rights for it.

#### Drug Regulation

**Publication: Business Standard**

**Edition: National**

**Date: March 25, 2014**

**Headline:** [Resistance and regulation](#)

**Synopsis:** The government's notification mandating the sale of antibiotics and certain other medicines strictly on a doctor's prescription came into force at the beginning of this month, after a year's transition period. However, most chemists continue to dispense these drugs for want of effective enforcement of the new norms. Few drugstores have begun asking for the doctor's prescription, and fewer still have begun keeping records of such sales with details such as the doctor's and the patient's names and the quantity of drugs supplied, as is required under the new measure.

### General Industry

**Publication:** The Times Of India

**Edition:** National

**Date:** March 25, 2014

**Headline:** [One in every 14 TB patients in Mumbai is a child](#)

**Synopsis:** One in 14 tuberculosis patients in the city is a child, and 5% among them suffer from the form which is resistant to multiple drugs, say civic statistics. What makes it worse is the fact that there is no clear medicine regimen for children or drugs to prevent TB. Of the 31,789 people diagnosed with TB in the city in 2013, around 2,398 were children. It was a marginal jump from 2,306 cases (out of total 30,828) that enrolled for the Revised National Tuberculosis Control Programme (RNTCP) the year before that. In the past two years, 227 children have been diagnosed with multi-drug resistant tuberculosis (MDR-TB), while another five were affected by the extensively drug-resistant form (XDR-TB). Experts say the challenge to diagnose TB in children gets magnified when it comes to screening them for the resistant forms. "A huge challenge lies in obtaining the right samples from kids," said an RNTCP official. It is apparently difficult to obtain sputum in children under five years of age and bacteriologic confirmation is tough to achieve in those under 10.

**Publication:** The Times Of India

**Edition:** National

**Date:** March 25, 2014

**Headline:** [Sick India seeks attention: Most states still struggle to provide basic healthcare](#)

**Synopsis:** State spending on health ranges from 4-6 % of the total expenditure for all larger states. Delhi, which allocates 12% of its expenditure on health is an exception, but is not strictly comparable. For one, Delhi has several large secondary and tertiary care hospitals which seem to eat up a lot of the funds while primary healthcare suffers, as is evident from the fact that Delhi has the highest IMR among all metro cities and its immunization coverage is barely 72%. Also, as Delhi does not have policing as part of its functions, it is spared a large chunk of spending that can be distributed across other heads.