



News Updates: January 22, 2014

Compulsory License/Patents

Publication: Mint (Supplement-Bloomberg TV)

Edition: National

Date: January 22, 2014

Headline: Cancer drugs which can be produced legally will be offered at affordable prices (No link available)

Synopsis: Yusuf Hamied, Chairman Cipla Ltd. talks to Mini Menon on tough patent regulations which have made it difficult for Indian generic pharmaceutical companies to make cheaper versions of established drugs.

Attached is the scan of the report.

Publication: Mint

Edition: Online

Date: January 21, 2014

Headline: [Biocon's copy of Roche breast cancer drug still expensive for India](#)

Synopsis: In India, where a vial of Roche Holding AG's breast cancer medicine Herceptin costs more than 15 times the per capita monthly income, the first homegrown copy may still leave the price out of reach for most people. Roche's eight-year-old drug will face competition starting next month from a cheaper version made by Bangalore-based Biocon Ltd with a US partner, Mylan Inc. The copy will be priced 25% lower than Herceptin, Biocon said on 18 January.

Website: Business Week

Edition: Online

Date: January 21, 2014

Headline: [Merck to Bristol-Myers Face More Threats on India Drug Patents](#)

Synopsis: Pharmaceutical companies from Merck & Co. (MRK:US) to Bristol-Myers Squibb Co. (BMY:US) face fresh threats to protecting their patents in India as a government-appointed panel prepares to evaluate more drugs for local makers to copy.

The panel is looking beyond the cancer treatments it studied last year to areas such as HIV and diabetes, according to two people with knowledge of the matter, who asked not to be identified because the discussions are private. It plans to study more than 20 drugs and recommend the government assign about three so-called compulsory licenses to allow local firms to make low-priced copies in India, they said.

Publication: Mail Today

Edition: Delhi

Date: January 22, 2014

Headline: [Time to get moving on cancer drugs](#)

Synopsis: THE changing environment for drug patents in India has finally begun to pay dividends. Within weeks of removal of patent barrier on a crucial breast cancer drug, Bangalore-based Biocon has announced availability of a cheaper variant. It is indeed good news for cancer patients. It also shows how a robust patent regime can balance

protection of innovation with patient welfare. The Indian patent law respects and upholds genuine innovation – even when it is incremental- but does not favour granting of patents on flimsy grounds. Using this provision in the law, patent authorities as well as courts set aside patents of multinational pharma companies, particularly for costly cancer drugs, during 2013. Breast cancer drug trastuzumab – marketed as Herceptin by Roche – is the most recent example of this. Herceptin was not patentable under Indian law since it was developed prior to 1995, so Roche filed for secondary patents on an Indian patent it had for a combination of HER2+ antibody with ‘acidic variants’. This was challenged because it was just another derivative of a known substance.

Website: MoneyControl

Edition: Online

Date: January 21, 2014

Headline: [Bayer's plea against compulsory licensing hits hurdle](#)

Synopsis: Bayer’s plea allowing Natco a compulsory license to manufacture a drug discovered by it hit a fresh hurdle in the Bombay HC. Bayer had filed this plea against the Intellectual Property Appellate Board (IPAB) in 2013. A division bench of the Bombay HC, headed by Justice Oka, refused Bayer’s plea to place the matter before the court for urgent hearing. In a brief order passed today, the division bench cited several pending cases and disregarded the urgency cited by Bayer.

Website: Bloomberg News

Edition: Online

Date: January 21, 2014

Headline: [Roche Herceptin Copy's Price Still Out of Reach in India](#)

Synopsis: In India, where a vial of Roche Holding AG (ROG)’s breast cancer medicine Herceptin costs more than 15 times the per capita monthly income, the first homegrown copy may still leave the price out of reach for most people.

Roche’s eight-year-old drug will face competition starting next month from a cheaper version made by Bangalore, India-based Biocon Ltd. (BIOS) with a U.S. partner, Mylan Inc. (MYL) The copy will be priced 25 percent less than Herceptin, Biocon said Jan. 18.

Publication: The Times of India

Edition: Online

Date: January 21, 2014

Headline: [Breast cancer drug copy cheaper, yet unaffordable for 75% of patients](#)

Synopsis: Good quality copies of expensive branded drugs are almost always good news for patients. However, the biosimilar of the breast cancer drug trastuzumab, recently brought to the market by Biocon, though cheaper than the originator drug, is going to be out of reach for 75% of those who need them in India.

The Campaign for Affordable Trastuzumab while welcoming Biocon's biosimilar named CANMAb, pointed out that at the price of Rs 19,500 per vial of 150 mg and Rs 57,500 for a 440 mg vial, it would be inaccessible to a large number of patients.

Publication: Business Standard

Edition: National

Date: January 22, 2014

Headline: [IPAB refers opposition to anti-cancer drug to patent office](#)

Synopsis: The Intellectual Property Appellate Board (IPAB) has asked the patent office to consider afresh a matter related to the patent application of US-based Abraxis BioScience for its anti-cancer drug Abraxane, following pre-

grant opposition by Hyderabad-based Natco Pharma.

Natco has developed a generic version of the drug under the brand name Albupax. Emails sent to Celgene, which acquired Abraxis BioScience in 2010, and Natco Pharma for comment on the order didn't elicit a response till the time of going to press.

Drug Pricing/Pricing Policy

Publication: Business World

Edition: National

Date: January 21, 2014

Headline: [Getting The Dose Right](#)

Synopsis: Leading Domestic drug maker Lupin has been cherry-picking research scientists from the labs of its global competitors such as Teva and Sandoz for its yet-to-be-set-up drug research laboratory in the US, the world's largest medicine market. Back home, Cipla, the Indian company that took the global drug industry by storm by slashing the cost of anti-AIDS medicines to a thirtieth of the innovators' price a decade ago, is creating a Tech Discovery Engine to nurture innovation through collaborations with small innovation clusters in San Diego, Boston and Cambridge. Dr Reddy's Laboratories, yet another Indian drug major, has entered into a long-term partnership with Germany's Merck to develop a portfolio of biosimilars (low-cost versions of a biotech drug), with a cancer focus.

Publication: Pharmabiz

Edition: Online

Date: January 22, 2014

Headline: [Lowering of paracetamol to 325mg applicable to FDC with other analgesic/anti-inflammatory drugs only: DCGI](#)

Synopsis: The drugs controller general of India (DCGI) has once again clarified that lowering of the paracetamol content to 325 mg is applicable to the combination of the paracetamol with other analgesic/anti-inflammatory drugs only.

The issue of permitting FDC formulations of paracetamol containing 500mg per tablets, which are being sold as OTC products for indication which are other than pain medication prescription based products, was discussed in the 46th meeting of the Drugs Consultative Committee (DCC) held on November 12-13, 2013.

USFDA

Publication: Business Standard

Edition: National

Date: January 22, 2014

Headline: [Zydus Cadila gets USFDA nod for anti-depressant drug](#)

Synopsis: Drug major Zydus Cadila has received approval from the US health regulator to market Bupropion Hydrochloride extended-release tablets, an anti-depressant medicine, in the American market.

Zydus Cadila has received the final approval from the US Food and Drug Administration (USFDA) to market Bupropion Hydrochloride Extended-release Tablets USP (XL) in the strength of 300 mg, the company said in a statement.

Publication: Pharmabiz

Edition: Online

Date: January 22, 2014

Headline: [Indian pharma companies secure 154 ANDAs approval from US FDA during 2013](#)

Synopsis: The Indian pharmaceutical companies and their subsidiaries have established strong presence in the United States and other regulated markets with higher investment in research and development (R&D) during the last couple of years. Indian companies received final approval for 154 ANDAs during the year 2013 from US FDA and 38 tentative ANDAs approval during 2013.

The US FDA has approved a total 400 final ANDAs during the year 2013 as against 476 in the previous year and it approved total 86 tentative ANDAs during 2013 as against 94 during 2012. Out of the total approvals, Indian companies grabbed 38.5 per cent final approval during 2013 as against 37.4 per cent in the previous year. Similarly, Indian companies received 44.2 per cent of total tentative approvals as compared to 42 per cent in the previous year.

General Industry

Publication: The Hindu Business Line

Edition: National

Date: January 22, 2014

Headline: [Torrent Pharma Q3 standalone net up 36%](#)

Synopsis: Ahmedabad-based Torrent Pharmaceuticals Ltd has registered standalone net profit of Rs 114 crore for the quarter ended December 2013, higher by 36% from Rs 84 crore reported in the corresponding period last year. The company declared an interim dividend of 100 % or Rs 5 per equity share of Rs 5 each.

Publication: Business Standard

Edition: Mumbai, Delhi

Date: 22 Jan 2014

Headline: [Indian drug makers gasp with relief as US regulator relaxes inhaler norms](#)

Synopsis: Indian drug makers are eager to enter the generic inhaler combination business in the US after the drug regulator there eased guidelines for cheaper alternatives to GlaxoSmithKline (GSK)'s blockbuster respiratory drug, Advair.

Even as pharmaceutical giants Lupin, Sun Pharma and Cipla are preparing plans to launch their generics in the US, Glenmark has already launched its Advair generic in emerging markets.

Publication: The Hindu Business Line

Edition: National

Date: January 22, 2014

Headline: [Eli Lilly launches reusable insulin pen](#)

Synopsis: Eli Lilly and Company India aims to be in the top-20 list of pharmaceutical companies in the nation by 2020, Eli Lilly India MD Edgard A. Olaizola told Business Line here on Tuesday. The company will be bringing in all its diabetes products to the country, Olaizola said. It has launched a new reusable insulin pen, the HumaPen Savvio.