

**MERRY CHRISTMAS & HAPPY NEW YEAR
2015**

HASAN AND SINGH

Intellectuals @ Law

Patents, Trademarks, Designs, Copyright & Protection of Plant Varieties

Newsletter January 2015

1. Bayer loses bid to overturn India's first compulsory licence.

German drug major Bayer has lost its long-running battle to get India's first-ever compulsory licence – for its liver and kidney cancer drug Nexavar (sorafenib tosylate) – overturned. In the order granting the compulsory licence in 2012, the Patent Controller had noted that, while in 2011 8,842 patients were eligible for the drug, Bayer had supplied Nexavar to fewer than 200 patients after the patent began in 2008. Critics also point out that Bayer only set up a patient access programme for Nexavar once the compulsory licence proceedings had been initiated.

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2. Novartis-Cipla battle shakes up Indian pharma industry.

The Indian pharmaceutical industry has been rocked by yet another high-profile patent battle between a local drug maker and a global giant. Swiss drug manufacturer Novartis has sued Cipla for infringing on its patent for respiratory drug Onbrez. Hearings on the case have been completed in the Delhi High Court, which is expected to announce its judgment on January 9.

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3. TM Registry Ordered to Examine Plea.

The Intellectual Property Appellate Board (IPAB) has directed the Trade Marks Registry to consider the petition of a US based multi-national company, E I Du Pont De Nemours and Company, that has challenged the trademark 'Nomex', registered by a pharmaceutical firm in Mumbai.

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4. India-led BRICS opposes UN move on model drug law.

India has spearheaded a move by BRICS countries to oppose a United Nations agency's move to float without consultations with member states a model law on fraudulent drugs that has raised fears of genuine generic drugs trade getting disrupted.

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5. US concludes OCR of India's intellectual property policies.

Citing positive steps taken by the new Indian government in addressing America's concerns on intellectual property (IP) rights, the US has concluded its Out-of-Cycle Review of India's intellectual property.

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6. AstraZeneca sues Aurobindo over blood sugar drug patent.

London-based pharma major AstraZeneca has dragged Aurobindo Pharma to the court for allegedly trying to make a generic version of its branded sugar control drug Onglyza before patent expiry. This is the second suit the Indian drugmaker has been facing from AstraZeneca this year, after a fight over heartburn drug Nexium earlier.

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7. DU team develops portable blood substitute.

A team of researchers from Delhi University has claimed to have developed a safe and portable blood substitute, which can be used irrespective of blood groups. The blood substitute can prove to be a boon for many patients who face the problem of unavailability of blood in emergency situations.

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8. India's Cadila launches first cheaper copy of world's top-selling drug.

Indian drugmaker Cadila Healthcare Ltd said on December 09, that it launched in India the first biosimilar version of the anti-inflammatory medicine adalimumab, the world's top-selling drug, at a fifth of its U.S. price.

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9. Europe, Israel, Sign Historic Patent Prosecution Highway Agreement.

The European Patent Office has signed a Patent Prosecution Highway (PPH) pilot program with the Israel Patent Office which will enable the accelerated treatment of patent applications starting January 2015. The heads of the two offices had signed the agreement in Brussels. The pilot program will leverage fast-track patent examination procedures in order to enable innovators from Europe and Israel to obtain patents more quickly and efficiently. The EPO recently signed similar agreements with the patent offices of Canada, Mexico and Singapore. All four pilot programs will begin on 6 January 2015.

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10. Claris Lifesciences confirms patent challenge for its generic version of PROPOFOL in USA.

Claris Lifesciences has filed an Abbreviated New Drug Application (ANDA) for Propofol for Injection, 10 mg/ml with the US Food and Drug Administration (USFDA) with a Paragraph IV certification. The company's ANDA is a generic version of DIPRIVAN, which is indicated for general anaesthesia for surgery or other medical procedures.

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11. 215 products registered as geographical indication.

As many as 215 products were

registered as geographical indication (GI) till December 15, 2014, according to Indian government. Geographical Indication identifies a product whose quality, reputation and other characteristics are attributable to its geographic origin

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12. IPAB asks UK-based bed maker and Indian firm to explore settlement.

The Intellectual Property Appellate Board (IPAB) has asked UK-based luxury bedding and upholstery firm Hypnos Ltd, and Hosur Coir Foam Pvt Ltd to explore possibilities of amicable settlement in a dispute on trade mark Hypnos for their beds and mattress products.

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13. With Opdivo approval, Bristol-Myers arms for PD-1 battle against Merck's Keytruda.

The Bristol-Myers Squibb-vs.-Merck match in melanoma is on. Bristol-Myers (\$BMY) scored FDA approval for its cancer immunotherapy Opdivo (nivolumab) three months ahead of schedule, setting it up for a head-to-head contest against Merck's (\$MRK) recent debut in the same class, Keytruda.

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14. India's NPPA extends pricing policy on drugs, adding fuel to price cap fire.

Amid escalating tension between drugmakers and India's National

Pharmaceutical Pricing Authority over price caps on "essential drugs," the NPPA has extended its pricing policies to cover 52 additional meds, including commonly used painkillers and antibiotics and drugs for cancer and skin disease treatment

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15. Ranbaxy now faces product bans in Europe.

Six years after the FDA banned products from a Ranbaxy Laboratories plant in Dewas, India, the European Commission and Germany have restricted imports of sterile drugs from the facility. Regulators have banned Ranbaxy's injectable versions of its cephalosporin antibiotics following an inspection earlier this year of the company's plant in central India.

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16. OAPI & Zimbabwe Joins Madrid Protocol.

OAPI & Zimbabwe are the latest in a flurry of countries to declare that they will be joining the Madrid Protocol in the new year. The accession took place earlier this month, on 5th & 11th December respectively. OAPI & Zimbabwe are the 93rd & 94th member of the Madrid Protocol system.