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The Andhra Journal of Industrial News

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Issue 138

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COSTS OF INFRINGEMENT LITIGATION

For a claim that could be worth less than a \$1 million, median legal costs are \$650,000. When \$1 million to \$25 million is considered "at risk," total litigation costs can reach \$2.5 million or more. For a claim over \$25 million, median legal costs are \$5 million. For a small business, it is worthwhile to settle a case or agree to licensing terms for, say, \$100,000, rather than fight. It is typical to conduct a "freedom to operate" analysis before a company launches to make sure that the product destined to be marketed isn't infringing on known patents. A typical freedom to operate analysis costs about \$100,000.

PATENTSVIEW⁽²⁾

The USPTO has launched PatentsView, a new patent data visualization platform. The PatentsView beta search tool allows members of the public to interact with nearly 40 years of data on patenting activity in the United States.

PatentsView allows users to explore technological, regional, and individual-level patent trends via search filters with multiple viewing options. The database links inventors, their organizations, locations, and overall patenting activity using enhanced 1976-2014 data from public USPTO bulk data files.

LARGE TOXIN DATABASE⁽³⁾

Venomics, a European consortium funded by the European Commission, has created the world's largest database of toxins, which is the result of a large sampling and bioinformatic analysis program, is now set to be applied to the discovery of drugs against cardiovascular diseases, obesity and diabetes.

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Venomics took samples from 203 species of poisonous creatures for the database. Having extracted venom from species such as snakes, sea anemones and blue octopuses during expeditions to French Guiana, Mayotte, Polynesia and other locations, the team turned to technology to make the most of the samples.

The analysis has been a challenge because in the smallest species it was very hard to extract the venom. The main achievement has been to show that the use of these new omics technologies eliminates much of the complexity of the process and also the time, because using classic procedures would have taken us years.

BIOLOGICS⁽⁴⁾

Biological products (aka “biologics” or “biopharmaceuticals”) include products such as vaccines, blood, blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids, or combinations thereof, or may be living entities such as cells and tissues. Biologics are isolated from animals (including humans), microorganisms or plants. They can be produced by genetically modified organisms (GMOs) produced by biotechnology.

In 1901, diphtheria patients were routinely treated with a biologic antitoxin derived from the blood serum of horses. Recognizing the critical need for regulatory safeguards, Congress passed the Biologics Control Act in 1902, giving the Hygienic Laboratory of the Public Health and Marine Hospital Service the first control over the processes used to make biological products, or biologics, and the responsibility to ensure their safety for the American public. Today, the FDA's Center for Biologics Evaluation and Research (CBER) regulates biologics, such as vaccines, blood and blood components, allergenic patch tests and extracts, human immunodeficiency virus (HIV) and hepatitis tests, gene therapy products, cells and tissues for transplantation, and new treatments for cancers and other serious diseases.

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Sanofi Pasteur, the Bill & Melinda Gates Foundation and the Infectious Disease Research Institute (IDRI) partnered to create the Global Health Vaccine Center of Innovation (GHVCI)⁽⁶⁾, a joint effort aimed at making a new, cheaper model for vaccines development. It'll be based in IDRI's offices in Seattle with the focus of combining each party's expertise in an effort to accelerate the development of vaccines against a range of infectious diseases, while promoting the accessibility of such vaccines. An initial grant from the Gates Foundation will help to pay for the formation of the new entity, and, going forward, Sanofi Pasteur and Gates Foundation will fund its operation and growth.

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products⁽⁷⁾.

India's ability to make chemical-based generic drugs has been the foundation of the country's \$15 billion pharmaceuticals industry, but India faces a quality problem because while it can make "biosimilar"⁽⁸⁾ medicines that are close enough to the original product to satisfy regulators, Indian companies have been hit with dozens of bans by international regulators recently because of quality control problems at their plants. The global biosimilar market is predicted to have sales of \$25 billion by 2020, according to a 2014 Thomson Reuters report. Three companies Biocon, Dr Reddy's (\$RDY) and Intas are working with international partners for biosimilars destined for markets in the U.S. and Europe. Biocon has a venture with Mylan (\$MYL), while Dr. Reddy's is developing biosimilars with Germany's Merck KGaA and Intas is working with Canada's Apotex.

REFERENCES AND NOTES

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Additional Sources: The information published here is available from the primary sources cited above, and also from secondary sources such as: New York Times (NYT), Washington Post (WP), Mercury News, Bayarea.com, Chicago Tribune, USA Today, Intellihealthnews, Deccan Chronicle (DC), the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, womenfitness.net, about.com, mondaq.com, etc

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

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