Biotechnology 2012

Biotechnology played a pivotal role in the development of more targeted drugs in 2012 as the science continues to elucidate the molecular mechanisms of diseases. The volatile biopharmaceutical industry historically comprised of venture-backed start-ups produced some whopping news in 2012, from the first new obesity drug in 13 years to a heated race to develop the first all-oral, side-effect-free treatment for hepatitis C. Nothing, however, was bigger than the arrival of the pharmaceutical industry at the long-dreaded patent cliff. "Big Wins, a Cliff, a Race and a Red Face: A 2012 Recap" at http://bioworld.blogs.bioworld.com/

Corruption: Brazil, China, Poland and Russia
Eli Lilly and Company announced that it has reached an agreement with the U.S. Securities and Exchange Commission (SEC) to settle issues regarding compliance with the U.S. Foreign Corrupt Practices Act (FCPA). The settlement relates to an investigation by the SEC of certain activities of four Lilly affiliates Brazil, China, Poland and Russia from 1994 through 2009. Lilly was first notified of the investigation in August 2003. Without admitting or denying the allegations, Lilly has consented to pay a civil settlement amount of $29.4 million and agreed to have an independent compliance consultant conduct a 60-day review of the company's internal controls and compliance program related to the FCPA. The company believes that this civil settlement brings resolution to issues from the past and is in the best interest of the company.

Succinic Acid from Soy
New microbes are engineered to metabolize a variety of sugars found in soybean meal, based on production of succinic acid from glucose. The theoretical ideal is a 1:1 ratio of feedstock (the extracted sugars) to product, which is achievable by industry. Soy may become an inexpensive new source of a widely used chemical for plastics, textiles, drugs, solvents and as a food additive. Succinic acid is traditionally produced from petroleum.

Forbes’ Top 30 Rising Stars in Science and Health, 2012

- Josh Sommer, raised $2.5 million that has been used to fund 11 labs.
- Paige Cramer, found that a drug, Bexarotene, stimulated the bodies of mice to get rid of a protein thought to be involved in causing Alzheimer’s in humans.
- Christina Fan, developed a technique that allows scientists to test a baby for Down syndrome with a simple blood test that counts fetal DNA in the mother’s bloodstream.
- Halle Tecco, the first incubator for digital health start-ups right out of Harvard biz school.
- Mitchell Guttman, found a lincRNA, a stretch of genetic material that doesn’t code for a protein but instead acts as a genetic regulator, controlling how embryos develop and playing a role in human disease.
- Jillian Shapiro figured out away to get another new type of genetic material, called microRNA, into cells using viruses. That could lead to new types of medicines.
• Suhasa Kodandaramaiah created robots that can measure electrical potentials and genetic changes in brain cells more efficiently than a human scientist, and started a company to commercialize them.

• Adrian Cheng invented a powerful non-invasive, high-speed microscope technology for imaging the activity of thousands of cells in the brain simultaneously, in real time, offering a view of neural circuits at work.

• Vipul Goyal works on “position-based cryptography”—using someone’s geographic position as a decryption key so that no eavesdropper at a different location could unscramble a secret message

Prepare for the First-Inventor-to-File Regime
The new First-Inventor-to-File Regime created by the America Invents Act of 2011 begins on March 16, 2013. Applications filed on March 16, 2013 or after will no longer be able to claim invention-date priority, but may be able to use it in a derivation proceeding, which replaces the interference proceeding. Thus, a secret prior invention or reduction to practice by a third party will no longer be relevant to patentability. However, these applications will continue to have the one-year pre-filing grace period, and will be subject to prior user rights and post-grant review, and can be invalidated by public uses and sales of similar inventions in foreign countries. Prepare for and take advantage of this new regime:

Importance of IP
Innovation—the process, through which new inventions are generated and successfully introduced in the marketplace—is a primary driver of U.S. economic growth and national competitiveness. Intellectual property is used everywhere in the economy, and IP rights support innovation and creativity in virtually every U.S. industry. A recent Department of Commerce report titled “Intellectual Property and the U.S.
Economy: Industries in Focus” [http://www.esa.doc.gov/Reports/intellectual-property-and-us-economy-industries-focus](http://www.esa.doc.gov/Reports/intellectual-property-and-us-economy-industries-focus) found that IP-intensive industries support at least 40 million jobs and contribute more than $5 trillion dollars to, or 35 percent of, U.S. gross domestic product (GDP). As stated by the Commerce Department’s Acting Secretary Blank, “Strong intellectual property protections encourage our businesses to pursue the next great idea, which is vital to maintaining America’s competitive edge and driving our overall prosperity.” Without IP protection, the inventor who had invested time and money in developing the new product or service (sunk costs) would always be at a disadvantage to the new firm that could just copy and market the product without having to recoup any sunk costs or pay the higher salaries required by those with the creative talents and skills. As a result, the benefits associated with American ingenuity would tend to more easily flow outside of the United States. [http://www.cardinal-ip.com/ip-news-strategy/importance-of-ip/](http://www.cardinal-ip.com/ip-news-strategy/importance-of-ip/)

**2012 FDA Approvals**
The Food and Drug Administration has approved 40 new drugs and vaccines in 2012, one of the most impressive totals ever, according to data from Pharmaceutical Approvals Monthly and FDA press releases.

**Malaria**
The structure of Chang Shan, a Chinese herbal medicine, used for thousands of years to treat fevers associated with malaria, uncovered by a high-resolution structure solved at The Scripps Research Institute (TSRI), described in the journal Nature this week, the structure shows in atomic detail how a two-headed compound derived from the active ingredient in Chang Shan works. Scientists have known that this compound, called halofuginone (a derivative of the febrifugine), can suppress parts of the immune system. Halofuginone jams the gears of a molecular machine that carries out “aminoacylation,” a crucial biological process that allows organisms to synthesize the proteins they need to live. Chang Shan, also known as Dichroa febrifuga Lour, probably helps with malarial fevers because traces of a halofuginone-like chemical in the herb interfere with this same process in malaria parasites, killing them in an infected person’s bloodstream. [http://www.scripps.edu/news/press/2012/20121223schimmel.html](http://www.scripps.edu/news/press/2012/20121223schimmel.html)

Calpain, a calcium-regulated enzyme, is essential to a host of cellular processes, but can cause severe problems in its overactivated state. It has been implicated as a factor in muscular dystrophy, AIDS, Alzheimer's disease, multiple sclerosis, and cancer. As such, finding and exploiting calpain inhibitors is
an important area of research. One of calpain's functions is that it eases the ability for cellular invaders such as the Plasmodium falciparum parasite, which is responsible for malaria, to exit their hosts and infect other cell, which may be used in the treatment of malaria, according to research published in the latest issue of the Journal of the American Chemical Society.

http://www.sciencedaily.com/releases/2012/12/121227142953.htm

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritagamaya, 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!)