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IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

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Drugs to Raise High Density Lipoprotein (HDL)

The research, released in the [New England Journal of Medicine](#), may help explain earlier findings that increasing high density lipoprotein (HDL) doesn't always reduce cardiac risk. While people with naturally high levels of HDL have a lower risk of [heart disease](#), drugmakers haven't succeeded in developing medicines that mimic its effects. Patients with the most-efficient particles had a lower risk of heart disease, even after overall levels of HDL were taken into account, the study found. The results may benefit companies such as Merck & Co. in Whitehouse Station New Jersey, [Roche Holding AG](#) in Basel, [Switzerland](#), and Eli Lilly & Co. in Indianapolis, which are developing drugs that target HDL.

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New York-based [Pfizer Inc.](#)'s setback with the HDL-raising drug torcetrapib four years ago led Merck and Roche to reassess their HDL strategy. Torcetrapib, from Pfizer, unexpectedly increased death rates even as it raised levels of good cholesterol. Merck and Roche continued their HDL programs after concluding that their experimental products don't carry a similar risk. Studies of drugs known as fibrates that raise good cholesterol levels have failed to show lower heart disease risk, while Niaspan from [Abbott Laboratories](#) in [Abbott Park, Illinois](#), boosts HDL levels and reduces artery-clogging plaque.

In a second New England Journal study released, researchers from the Netherlands described a family with a mutation in the gene responsible for ferrying cholesterol to the liver. While family members with the mutation had higher levels of HDL, it was less effective at removing the fatty plaque and signs of clogged arteries were about the same.

Vicodin and Percocet Must Contain Less Acetaminophen

Makers of some narcotic pain relievers must cut back on a non-narcotic drug in the pills. The reason is safety, the U.S. Food and Drug Administration (FDA) said this month. The order affects Vicodin, Percocet and generic versions of these pills. All of them contain a narcotic. They also contain acetaminophen, which reduces pain and fever. By itself, acetaminophen is available without a prescription. Tylenol is the best known brand name. Regulators said the danger occurs when people take one of these narcotics along with over-the-counter products that also contain acetaminophen. An overdose of acetaminophen can cause liver damage. Some people die. Therefore, the FDA will require that Vicodin, Percocet and other narcotic-acetaminophen combination pills contain less of this drug. The limit of acetaminophen will be 325 milligrams. Now the pills contain up to 700.

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Industry Collaborations for New Drugs

A research agreement between [Florida Hospital](#), Sanford-Burnham and Japan's [Takeda Pharmaceutical Co. Ltd.](#), was signed in late December to form a collaboration aimed at discovering and evaluating new therapeutic approaches to obesity.

In January, [Sanford-Burnham Medical Research Institute](#) has entered into a collaboration with [Johnson & Johnson](#) subsidiary [Ortho-McNeil-Janssen Pharmaceuticals Inc.](#) (OMJPI) to discover compounds for Alzheimer's disease and major psychiatric disorders. Under the agreement, multi-disciplinary teams from Sanford-Burnham and OMJPI will collaborate to identify and validate new targets for drug discovery and will seek compounds suitable for lead optimization and further development by OMJPI. The deal grants OMJPI exclusive access for three years to a multi-disciplinary team of world-class scientists and a translational infrastructure dedicated to finding new approaches to treating patients with devastating neurological and psychiatric conditions.

[GE Healthcare](#) is joining forces with [Janssen Pharmaceutica NV](#) to research methods of detecting Alzheimer's in patients—even before they begin to exhibit symptoms of the devastating disease. The research effort is expected to combine the two companies' expertise in data integration, informatics, genomics and imaging. GE currently has Phase III trials underway for its amyloid PET imaging compound Flutemetamol. Beta amyloid—a protein that forms plaque in the brains of people with Alzheimer's—may begin to accumulate in the brain decades before Alzheimer's patients show symptoms. Having PET scanners identifying beta amyloid could be another weapon in early detection. Today, in the United States alone, 5.3 million people have Alzheimer's disease, and the annual cost of the disease is \$172 billion. It is the sixth leading cause of death, and its mortality rates are expected to rise as the baby boomer population ages. In the 2009 [World Alzheimer Report](#), [Alzheimer's Disease International](#) estimated that there are 35.6 million people living with dementia worldwide in 2010, increasing to 65.7 million by 2030 and 115.4 million by 2050.

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Jan. 13 saw the announcement that [sanofi-aventis](#) and the [University of California, San Francisco](#) (UCSF), the largest public biomedical research institution in America, have formed two research and development collaborations that bring together leaders from academia and industry to more rapidly advance groundbreaking innovation from the lab to the patient. The first is an oncology partnership that will focus on project-based collaboration to accelerate the progression of research through the clinical proof of concept stage. The second collaboration promotes innovative research in pharmacological science and in multiple therapeutic areas, such as oncology, aging, diabetes and inflammation. This marks the entry of Sanofi-Aventis as the first industry partner in UCSF's Program for Breakthrough Biomedical Research (PBBR). The PBBR program is described as awarding funds to projects of potentially high impact, greater creativity and with an innovative approach to scientific discovery. Currently entering its 14th year, PBBR provided \$42 million in these grants during its first decade alone, which now are credited with drawing more than \$300 million in external follow-up funding, as well as generating 900 scientific papers, 30 filed patents, licensed technologies and three startup companies. The partnership with UCSF reportedly enhances Sanofi-Aventis' approach of setting up a unique structure revolving around networks of creativity spread across regions, technologies and scientific areas of excellence.

Prediction for Branded Pharma

Independent research and market analysis firm [Datamonitor](#) predicts that it is going to be rough for the branded prescription pharmaceutical industry's leading companies, whose growth the firm predicts will slow to just 1.3 percent to the year 2015. Between 2003 and 2009, these same companies enjoyed robust sales growth at a compound annual growth rate (CAGR) of 7.1 percent, but sharp declines in branded sales following the loss of patent exclusivity will drive a rapid deterioration in growth. The difficulty and the inability of Big Pharma in developing new products, particularly those that can generate sufficient sales to compensate for blockbuster expiries, has compounded this problem, resulting in a shift away from blockbuster-centric growth strategies towards diversification into other areas of the market. [Bayer](#), [Novartis](#), [Roche](#) and [GlaxoSmithKline](#) will be the only Big Pharma companies to generate above-average growth over the period to 2015, Datamonitor predicts. Of 43 branded companies examined in detail by

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Datamonitor, 11 are expected to report a negative sales CAGR over the period to 2015. Of those expected to deliver a positive sales CAGR, only six will exceed the 7.1 percent average such companies experienced between 2003 and 2009.

Dr. David Horrobin noted that estimates of the ratios of compounds synthesized to marketed drugs at the time of peak success of Nobel Laureates Black, Bovet, Elion and Hitchings was about 100:1; most of the industry from about 1960 to about 1990 saw about 10,000:1 to 30,000:1; Big Pharma since the introduction of combinatorial chemistry and HTS, well over 1,000,000:1.

As new technologies such as high-content screening and time-resolved fluorescence, label-free and electrophysiology methods deliver more information per well and screened compound, data management and analysis become more complex. Mastering these challenges yields more precise information at the High-Throughput Screening (HTS) stage on compound mode-of-action and potential therapeutic window. Complete bioactivity profiles of compounds are compiled from sets of high-throughput primary and secondary screens, enabling optimized decisions on compound progression into the hit-to-lead phase.

HTS is defined as a method for scientific [experimentation](#) especially used in [drug discovery](#) and relevant to the fields of [biology](#) and [chemistry](#). Using [robotics](#), data processing and control software, liquid handling devices and sensitive detectors, HTS allows a researcher to *quickly conduct* millions of biochemical, genetic or pharmacological tests. HTS requires the miniaturization and automation of *in-vitro* bioassays so that millions of variables can be tested. Through this process, one can rapidly identify active compounds, antibodies or genes which modulate a particular bimolecular pathway. The results of these experiments provide starting points for drug design and for understanding the interaction or role of a particular biochemical process in biology. Yet after 25 years of HTS, we have little by way of NMEs that have contributed to the cure of disease or alleviation of debilitating symptoms.

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The drug discovery landscape is at a crossroads with profound changes looming in the horizon, and open innovation becoming the new mantra for reinvigorating the pharmaceutical R&D's lackluster drug candidate pipeline.

<http://www.drugdiscoverynews.com/index.php?newsarticle=4497>

<http://www.drugdiscoverynews.com/index.php?newsarticle=4496>

Antidepressants

Major depressive disorder (MDD), also called major depression, is a mental disorder characterized by an imbalance of chemicals in the brain, also called neurotransmitters, and is one of the most common mental disorders in the U.S. A person diagnosed with MDD exhibits a combination of symptoms, such as characterized by feelings of sadness, hopelessness, pessimism, guilt, and a general loss of interest in life, combined with a sense of reduced emotional well-being and low energy, that interfere with one's ability to work, sleep, study, eat, and enjoy once-pleasurable activities. Though an episode of depression may occur only once in a person's life, it more commonly recurs throughout a person's lifetime. The World Health Organization estimates that MDD affects approximately 18 million people in the U.S. More than 212 million prescriptions were written for antidepressants in 2009.

The U.S. Food and Drug Administration (FDA) has approved vilazodone HCl tablets, to be marketed under the brand name Viibryd™, for the treatment of adults with MDD. Viibryd is a new molecular entity (NME) and the first and only selective serotonin reuptake inhibitor (SSRI) and 5HT1A receptor partial agonist. The mechanism of the antidepressant effect of Viibryd is not fully understood. Clinical Data, Inc. plans to make Viibryd available in U.S. pharmacies in the second quarter of this year.

There are more than 20 antidepressant drugs currently available. Antidepressants correct the chemical imbalance in the brain. There are four (4) groups of antidepressant medications most commonly used to treat depression:

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- Tricyclic antidepressants (TCAs), which include: amitriptyline (Elavil), imipramine (Trofanil, Janimine), nortriptyline (Pamelor), and desipramine (Norpramin)
- TCAs work by slowing the rate at which neurotransmitters (chemical messengers) re-enter brain cells. This increases the concentration of the neurotransmitters in the central nervous system which relieves depression.
- Monoamine oxidase inhibitors (MAOIs) include phenelzine (Nardil) and tranylcypromine (Parnate). MAO is an enzyme responsible for breaking down certain neurotransmitters in the brain. MAOIs inhibit this enzyme and restore more normal mood states.
- Lithium carbonates, including Eskalith and Lithobid. Lithium reduces excessive nerve activity in the brain by altering the chemical balance within certain nerve cells. This drug has been used to improve the benefit of SSRIs and alone is effective in treating [bipolar disorder](#).
- Selective [serotonin](#) reuptake inhibitors (SSRIs) include: fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), citalopram (Celexa), and escitalopram oxalate (Lexapro).
- SSRIs act specifically on serotonin, making it more available for nerve cells, thus easing the transmission of messages without disrupting the chemistry of the brain.
- Two other antidepressants that affect two neurotransmitters, serotonin and norepinephrine, are venlafaxine (Effexor) and nefazodone (Serzone). Another of the newer antidepressants, bupropion (Wellbutrin), is chemically unrelated to the other antidepressants. It has more effect on norepinephrine and dopamine than on serotonin.

New Therapeutic from India

Hyderabad-based Bharat Biotech International Limited (BBIL) is all set to become the first Indian biotech company to come out with a new therapeutic vaccine, a cardiovascular thrombolytic agent (clot-bursting drug), called THR 100.

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The company has successfully completed Phase I and II trials of the new drug and Phase III clinical trials are currently in progress. adding the new vaccine will be commercialised in a span of six months. At present, doctors administer either Streptokinase or tPA (Tissue Plasmonigen Activator) to persons who suffer a heart attack. These will dissolve clots in the arteries of the heart wall. BBIL plans tie up with a big multinational company to market the product.

Big Pharma Faces Innovator Unfriendly Patent Regime in India

India has rejected an HIV drug patent application filed by US-based Abbott Laboratories, allegedly for lacking “novelty” under Indian laws. The denial of patent will help domestic drug-makers to profit at the cost of Abbott’s innovation and market low-cost versions of this drug in the developing world.

The rejection of Abbott’s patent application over a combination of lopinavir and ritonavir, sold under the brand name Aluvia, ended the four-year long intellectual property battle between the company and four pre-grant opponents. In its order on December 30, Mumbai patent office erroneously concluded that the drug lacked novelty and did not have any inventive steps to qualify for patent protection under domestic laws.

The Indian Patent Act permits patenting of innovations of new forms of known substances having extra efficacy. However, application of this law is very arbitrary. It is evident from the Indian generic industry’s interest that Abbott’s combination of lopinavir and ritonavir is considered to be the front line of defense for HIV positive patients who have failed to stay healthy with the first round of medicines available today. This in itself is a clear indication that the new combination is better than the existing medications and formulations today, an evidence for extra efficacy. New formulations of Kaletra (another brand name) have provided physicians and patients with real improvements in its use, dosing and convenience. The heat stable formulation solves specific convenience limitations of Abbott's earlier version, which required refrigeration. These challenges have been resolved with the new tablet, and there is significant benefit for

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patients in developing countries and resource limited settings. As a result of stability at higher temperatures, the new formulation has better efficacy in hot climates like Indian and African continents.

Abbott has become the largest pharmaceutical company in India after the acquisition of Piramal and Solvay. Abbott's current Indian businesses have a history dating back almost 100 years. Despite that, stand-alone sales for the year ended November 2009 were only Rs760 crore (~ \$165 million). Not a large figure, considering the Indian drug market size of Rs55,000-60,000 crore (~ \$ 15 billion). A year before that, Abbott's sales were only Rs665 crore (~ \$150 million). If other businesses are added, Abbott's sales in 2009 totaled Rs1,130 crore (~\$250 million), a majority of which came from pharmaceutical products. But with the acquisition of Piramal Healthcare's domestic formulation business worth Rs2,000 crore (by paying \$3.72 billion = Rs17,500 crore, almost nine times its worth), Abbott has emerged the largest drug maker in India in terms of marketshare. Piramal's domestic formulation business is the fourth largest in India, with 350 brands across various therapies, 5,500 employees and manufacturing units in the tax haven of Baddi in Himachal Pradesh. <http://www.business-standard.com/india/news/abbott-adds-local-expertise-to-its-global-resources/421420/>.

As a result of these acquisitions and in the wake of a series of disappointments in its drug development pipeline, setbacks in the court such as \$1.67 billion patent-infringement verdict, and recalls last year such as infant formula and strips, Abbott Laboratories cut 1,900 jobs triggering a restructuring of pharmaceutical commercial and manufacturing operations. Of the cuts, about 1,000 would be in manufacturing operations in Illinois where the largest concentration of Abbott's estimated 90,000 employees around the world are at its sprawling headquarters in the northern Lake County suburbs of Chicago; a trade of existing 5,500 Indian Piramal jobs and 9,000 Solvay Pharmaceuticals jobs worldwide for 1,000 US Abbott jobs - without adding any new jobs in India and Europe. This resulted in a net loss of 4,900 (3,000 Solvay jobs last year + 1,900 Abbott jobs this year) jobs worldwide and a net gain of about 10,000 ex-US employees for Abbott.

A round of consolidation has taken place throughout the pharmaceutical industry since Pfizer announced a \$68 billion takeover of Wyeth followed by U.S. giant Merck buying rival Schering-Plough for \$41.1

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billion, resulting in thousands of jobs cut in the US and worldwide. Abbott has no choice but to follow the industry trend and cut jobs in the US. The job cuts at Abbott come “in response to changes in the health-care industry, including U.S. health-care reform and the challenging regulatory environment,” Abbott said in a statement, indicating the overall pharmaceutical industry trend in the US, from where pharmaceutical industry jobs have been steadily moving overseas for quite some time; paving the way for the loss of innovation in the US - the innovation which has been responsible for the supremacy of the US in the world.

Soon there will be innovative new drugs from China and India, despite the unfriendly fledgling product patent regimes in these countries, as these countries emerge as the new leaders.

Bonus Cut

Reeling from product recalls that have sapped revenues and investor confidence, Johnson & Johnson, which employs about 114,000 people, told employees in a companywide e-mail that about half will receive 90 percent of what they would normally have received due to “mixed performance against our growth targets.” The move comes after layoffs and recalls involving hundreds of millions of products, such as Tylenol, Roloids, Sudafed, Benadryl, contact lenses and surgical devices.

EU Crackdown on Pharma

The EU regulator said it was pressing pharmaceutical companies for more information on their patent deals with generic companies to make sure there is no delay in cheaper drugs coming to market. The move is the latest in a series of EU crackdowns on possible anti-competitive practices in the

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pharmaceutical sector after a 2009 patents enquiry pointed to significant risks for European consumers, the Commission said.

It did not mention any company it requested information from, but Britain's AstraZeneca PLC and GlaxoSmithKline, France's Sanofi-Aventis and Novartis and Roche of Switzerland said last year the Commission had contacted them about drug patent settlements. The European Commission, the competition watchdog of the 27-nation EU bloc, said it had asked firms to submit copies of their patent settlement agreements concluded in the bloc last year.

Patent settlements are generally fees paid by pharmaceutical companies to generic drug makers to persuade them to delay selling the generic version of their medicines.

Innovators Switching to Copycats

Biosimilars, or follow-on biologics, are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. Unlike the more common small-molecule drugs, biologics generally exhibit high molecular complexity and micro-heterogeneity. Biologics are also very sensitive to manufacturing process changes, including the choice of the cell type, production process, purification process and formulation of the biologic into a drug. In view of the complexity and sensitivity of the biologics to manufacturing process, no two biotech medicines can be exactly the same, hence the term “biosimilar.” A number of biosimilar products are already in the market in Europe. Following enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), an abbreviated approval pathway for biosimilars has been created in United States. Spectrum Pharmaceuticals announced that it would develop a biosimilar version of the monoclonal antibody drug rituximab (marketed by Genentech/Roche). Worldwide sales of rituximab in 2009 in all indications, including non-Hodgkin’s lymphoma and chronic lymphocytic lymphoma, were approximately \$5.6 billion.

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More drugmakers are seeing potential in the business of producing copycat versions of expensive biotechnology drugs as U.S. guidelines take shape. Because of the complexity of biotech drugs, which are produced through biological processes that generally involve recombinant DNA technologies, they are often called "biosimilars" rather than generic copies. The prospect that companies that make brand-name biotechnology medicines would also try to produce generic versions would seem surprising in that they risk undermining their main business model. The new decade will be about access and cost. It's a low risk way to generate substantial revenue. Leading companies in this direction are Amgen, Merck, Biogen, Roche, etc. Innovation has lost its traditional high ground in the US, leaving innovation to copycats such as China and India, which traditionally have no respect for innovation. What would copycats do now without innovations?

See also Novartis' Winning Formula: http://www.boston.com/business/healthcare/articles/2011/01/04/fishman_novartis_posting_good_results/?page=1

The Ramanbhai Foundation's International Symposium

The Ramanbhai Foundation's International Symposium will be held February 1-4 in Ahmedabad, India and is hosted by the Zydus Research Center, the research arm of Indian pharmaceutical company Zydus Cadila. The symposium's speakers include world-leading scientists from academia and the pharmaceutical industry specializing in drug research and development for cancer, inflammation, and cardio-metabolic diseases, and early phase clinical research. <http://www.rbfsymposium.net/agenda.htm>

Best Mode

35 U.S.C. § 112, first paragraph, requires that a patent specification "set forth the best mode contemplated by the inventor of carrying out his invention." An inventor must disclose the preferred embodiment of the

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invention defined by the claims as well as preferences that materially affect the properties of the invention, to satisfy the best mode requirement. In a best mode inquiry, a court first defines the invention by construing the claims and then determines whether the inventor contemplated a best mode of practicing the claimed invention at the time of filing the application. If the inventor had a subjective preference for one mode over others, the court must then determine whether the specification's disclosure was sufficient to allow one of ordinary skill in the art to practice the best mode of the invention.

Although it is not necessary to label a preferred embodiment as the "best mode" within a patent specification, it is important to provide an enabling disclosure for a preferred embodiment, as contemplated by the inventors at the time of filing of an application. Practitioners should also note that in analyzing whether the specification discloses the best mode, courts will consider all of the limitations of the claimed invention, rather than just the "novel" features that distinguish the claim over the prior art.

Last year, the Federal Circuit affirmed in [Ajinomoto Co., Inc. v. International Trade Commission](#) a determination of invalidity by the U.S. International Trade Commission (ITC) for failing to disclose the preferred mode of practicing an invention. In this case, Ajinomoto filed a complaint with the ITC alleging that Global Bio-Chem Technology Group (GBT) violated 19 U.S.C. § 1337 by importing into the United States animal feed products containing an amino acid produced by a method which infringes various claims of U.S. Patent No. 5,827,698 (the '698 patent) and U.S. Patent No. 6,040,160 (the '160 patent). GBT argued that the asserted claims were invalid because Ajinomoto's specification failed to disclose the best mode of the invention as required by 35 U.S.C. § 112, first paragraph. GBT further argued that the patents at issue were unenforceable due to Ajinomoto's inequitable conduct for failing to disclose the best mode, the preferred bacterial strains, and carbon sources, and submitting fictitious data in support of the best mode. The ALJ agreed with GBT and found no violation of 19 U.S.C. § 1337 because the asserted claims were invalid and the '698 and '160 patents were unenforceable. Ajinomoto unsuccessfully petitioned the Commission for review of the ALJ's determination and subsequently appealed to the Federal Circuit. The Federal Circuit declined to review the ITC's determination.

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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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