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## The Andhra Journal of Industrial News

IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

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Venture Capital in 2010

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2. [Reata Pharmaceuticals](#) - \$78M
3. [Relypsa](#) - \$70M
4. [Pearl Therapeutics](#) - \$69M
5. [NanoInk](#) - \$65M
6. [TetraLogic Pharmaceuticals](#) - \$59.83
7. [Achaogen](#) - \$56.31M
8. [Otonomy](#) - \$49.07M
9. [Tetraphase Pharmaceuticals](#) - \$45M
10. [Agile Therapeutics](#) - \$45M\*
11. [Incline Therapeutics](#) - \$43M
12. [Cellular Dynamics International](#) - \$40.6M
13. [Calistoga Pharmaceuticals](#) - \$40.22M
14. [Sagent Pharmaceuticals](#) - \$40M
15. [Complete Genomics](#) - \$39M
16. [Intrexon](#) - \$37.51M

Read more: [Top 15 Biotech Venture Capital Deals of 2010 - FierceBiotech](http://www.fiercebiotech.com/special-reports/top-15-biotech-venture-capital-deals-2010?utm_medium=nl&utm_source=internal#ixzz1FjopQdPW) [http://www.fiercebiotech.com/special-reports/top-15-biotech-venture-capital-deals-2010?utm\\_medium=nl&utm\\_source=internal#ixzz1FjopQdPW](http://www.fiercebiotech.com/special-reports/top-15-biotech-venture-capital-deals-2010?utm_medium=nl&utm_source=internal#ixzz1FjopQdPW)

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#### Neuroscience Research

GlaxoSmithKline has decided to end all neuroscience research, and has canceled its \$1.5 billion dollar deal with Targacept, which covered a group of experimental NNR-targeted therapies for development of treatments for pain, smoking cessation, addiction, obesity and Parkinson's disease. Targacept gained \$35 million up front and made a total of \$45 million over the course of the deal. Targacept regains full rights to its programs subject to the alliance, including compounds discovered or advanced as part of the alliance. Targacept recently received a \$200 million milestone payment from AstraZeneca for progress on TC-5214, a drug for major depressive disorder.

Former Eli Lilly neuroscience chief David Bredt moved to the neuroscience research group at Johnson & Johnson, which is looking to advance its own pipeline of drugs for Alzheimer's and other neurological diseases, where he will oversee development of new drugs and ways for measuring their worth, such as biomarkers and animal models for testing the molecules.

Alzheimer's disease experts say research into biomarkers is making it increasingly possible to determine whether a person might develop Alzheimer's disease--perhaps even decades in advance. The earlier it is detected, the better the chances are of being able to delay its symptoms or at least prepare for them.

In Alzheimer's Disease, current biomarkers include a cerebrospinal fluid (CSF) tap and positron emission tomography (PET) scans. However, the CSF tap is an invasive procedure, while the accessibility of PET scans is limited making both options not particularly tenable in the long term. Studies are currently underway looking at blood plasma proteins, which could act as biomarkers, as well as MRI brain scans to analyze different brain areas.

Alzheimer's Disease has a long incubation period making it difficult from a drug development perspective. A clinically useful biomarker would predict the progression from mild cognitive impairment to Alzheimer's Disease. An ideal biomarker is that links the causal path between the underlying

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pathology and clinical presentation. [http://www.pharmatimes.com/Article/11-03-08/Biomarkers\\_the\\_way\\_forward\\_for\\_pharma.aspx](http://www.pharmatimes.com/Article/11-03-08/Biomarkers_the_way_forward_for_pharma.aspx)

Creutzfeldt-Jakob disease (sCJD), or the human form of mad cow disease, is a degenerative brain disease that's always fatal within a year of onset and has no cure. There is currently no way to even diagnose the disease until after brain tissue is obtained by biopsy after death. The ability to accurately diagnose patients while they are still living is necessary to prevent accidental spread of sCJD and reduce misdiagnosis of treatable causes of dementia.

Most neurodegenerative diseases are thought to be caused by the toxic accumulation of insoluble protein aggregates in the brain, which is toxic to cells. Additionally, defects in the pathway regulating apoptosis (programmed cell death) have been proposed as a mechanism of neurodegeneration. Defects in mitochondria, for example, have been shown to increase apoptosis in neurons, resulting in neurodegeneration. Hyperactive immune cells that engulf dying and injured cells before they have a chance to recover may contribute to neurodegeneration characteristic of some diseases, posing a previously unreported mechanism for dementia, a [paper](#) from the *Proceedings of the National Academy of Sciences* reports.

<http://www.the-scientist.com/news/display/58031/>

### **Alzheimer's Disease Drugs On the Market**

#### **Galantamine (Razadyne, Nivalin)**

This medication is among a class of Alzheimer's drugs called cholinesterase inhibitors, which are prescribed for mild to moderate symptoms. Razadyne is marketed by Ortho-McNeil Janssen Pharmaceuticals. Sopharma, based in Bulgaria, markets Nivalin primarily in Eastern Europe. The Indian pharmaceutical company Sun Pharmaceutical Industries recently received the FDA OK to sell a generic

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version of galantamine in the United States. The drug helps delay symptoms, or prevents them from becoming worse, for a limited time.

#### **Rivastigmine (Exelon)**

Exelon is marketed by Novartis, although there are generic equivalents, including those marketed by Sandoz and Sun Pharmaceuticals. It is used to treat mild to moderate dementia due to Alzheimer's. Rivastigmine, too, is a cholinesterase inhibitor. One of many things Alzheimer's does to the brain is decrease the levels of acetylcholine, which is a chemical messenger tied to memory. Cholinesterase inhibitors improve the effectiveness of acetylcholine. Unfortunately, since the brain produces less acetylcholine as Alzheimer's progresses, medications like rivastigmine can lose their effectiveness over a period of time.

#### **Donepezil (Aricept)**

According to the Mayo Clinic, Donepezil is among the most prescribed of the cholinesterase inhibitors and was the first to offer once-a-day dosing. It is also the least likely to produce serious side effects, the Mayo Clinic says, and appears to temporarily postpone the development of Alzheimer's in people with mild cognitive impairment (MCI), a memory-related condition that may precede Alzheimer's. Donepezil is marketed under the name Aricept Japanese drugmaker Eisai and partner Pfizer. The FDA is now taking a look at a patch form of Aricept by Teikoku Pharma USA. Aricept is among [2010's biggest patent expirations](#), and Roxane, Apotex and Aurobindo all have submitted ANDAs for multiple strengths of the drug.

#### **Memantine (Namenda)**

Memantine, marketed under the brand name Namenda, helps delay the progression of some symptoms associated with moderate to severe Alzheimer's, allowing patients to maintain some functions--like using the bathroom independently--a little longer. Namenda works by regulating glutamate, a brain chemical that can kill brain cells if an excessive amount builds up. Because it works differently than cholinesterase inhibitors, the two types of drugs can be prescribed in combination. Generally, Namenda is prescribed in

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later stages of Alzheimer's. The drug is marketed in the United States by Forest Laboratories and Merz Pharmaceuticals. A [generic version of Namenda](#) is marketed in the United States by Sun Pharmaceuticals.

Much of the current Alzheimer's disease research is devoted to finding biomarkers for early detection. Figure out the underlying pathologies associated with Alzheimer's disease, like formation of amyloid plaques, and maybe you can get as much of a decade-long jump on the disease before it begins affecting memory. <http://www.fiercebiotechresearch.com/special-reports/making-sense-alzheimers-drug-pipeline/making-sense-alzheimers-drug-pipeline>

#### **Fight Against Tuberculosis**

AstraZeneca became the newest member of a €16 million multi-member partnership to find new therapies for tuberculosis. The current remedies for the disease have been in use for over 50 years, and require several months or years of treatment. But with the expertise and help of companies like AZ and Sanofi-Aventis, as well as the University of Cambridge and other institutions in Pavia, Italy and Uppsala, Sweden, the group hopes to shave months off of treatment time. Research will be conducted in London and Norwich, UK, Russia, India and South Africa to find 10 to 20 TB treatment candidates that will be narrowed down to two to three final drugs for TB patients. A much larger 2002 TB partnership, the Global Fund, is launching an exchange-traded fund that will charge investors a 2.5 percent annual fee, with most of the proceeds going towards the Global Fund and its research.

#### **Patent Cliff For BigPharma**

**Pfizer's** Lipitor (atorvastatin) was released in 1998, and by 2006 it had reached peak sales of \$12.9 billion, accounting for 27% of the total revenue. In 2010, with \$10.8 billion in sales, Lipitor accounted for 15.8% of total revenue. In 2008, Pfizer reached an agreement with Indian generics manufacturer Ranbaxy Laboratories. Ranbaxy will have a license to sell atorvastatin in the U.S. effective Nov. 30, 2011,

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and have exclusivity for 180 days before other drugmakers can enter the market. Watson Pharmaceuticals will also introduce a generic for Lipitor. Between 2010 and 2012, drugs that make up 42% of Pfizer's pharmaceutical revenue will lose patent protection, among them the antacid Protonix. The loss of exclusivity on so many drugs -- among them antipsychotic Geodon, with \$890 million in U.S. sales in 2010; erectile dysfunction drug Viagra with \$1.015 billion; overactive bladder drug Detrol/LA with \$693 million; and eye pressure lowering medicine Xalatan with \$616 million to name some -- will deeply impact Pfizer, which has already destroyed pharmaceutical research in the US by laying off thousands of scientists. The pharma giant says that its oral JAK inhibitor tofacitinib--which recently underwent a name change from tasocitinib--hit its primary endpoint for statistical significance among patients with rheumatoid arthritis. The experimental therapy, probably one of Pfizer's biggest late-stage blockbuster prospects, hit its marks for reducing symptoms of RA. The therapy has passed a key Phase III hurdle and has now been tested in more than 4,000 patients. That's a big step forward for Pfizer.

**Eli Lilly** introduced the antipsychotic Zyprexa in 1996. In 2010, Zyprexa's worldwide revenues were just over \$5 billion, or nearly 22% of Lilly's full year sales. In 2009, Lilly agreed to pay \$1.415 billion to settle criminal and civil allegations for the off-label promotion of Zyprexa to treat dementia. Also in 2005 and 2007 (\$700 million and \$500 million, respectively), Lilly settled lawsuits with patients over claims that Lilly withheld information about the drug's link to high blood sugar level and diabetes. Zyprexa's [patent](#) is set to expire in October 2011, and Lilly is one of the worst positioned companies to compete after the patent cliff.

**Johnson & Johnson** saw patents expire for antipsychotic Risperdal in 2008 and seizure med Topamax in 2009, and now it's set to lose [patent protection](#) on heavy-duty antibiotic Levaquin and ADHD treatment Concerta, a sustained-release version of Ritalin. J&J is more diversified than most pharmas, with large consumer products and medical devices segments. Nonetheless, in 2010, Levaquin (levofloxacin) and Concerta (methylphenidate) had sales of \$1.4 billion and \$1.3 billion worldwide, comprising together

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12% of the \$22.4 billion in pharmaceutical revenues and 4% of the company's total \$61.6 billion in revenues.

**Bristol-Myers Squibb** is facing 2012 [patent](#) expirations for two of its three top sellers, Plavix and high blood pressure med Avapro, with global sales in 2010 of \$1.2 billion, and its deal to market Abilify is also due to expire in 2012 (\$2.6 billion in worldwide 2010 sales).

**Sanofi** already lost [patent protection](#) in the U.S. on its top seller, Lovenox (enoxaparin), a blood thinner. In 2010, the company said generic competition caused loss of more than 2 billion euros in sales. Sandoz, the generic pharmaceutical division of **Novartis**, is already marketing generic enoxaparin.

**AstraZeneca's** antipsychotic Seroquel was introduced in 1997, and has been approved for a variety of conditions from depression to bipolar disorder to schizophrenia. Worldwide sales amounted to \$5.3 billion in 2010, or nearly 16% of Astra's revenues. Seroquel was originally going to expire in September 2011 but received a six-month extension from the FDA through a pediatric exclusivity.

**Merck's** oral asthma and allergy treatment Singulair was first cleared by the FDA in 1998. Its growth has been consistent despite the FDA adding warnings to its label about side effects including depression and increased suicidal thoughts. In 2010, worldwide sales for Singulair were \$5 billion, a 7% increase, and nearly 11% of Merck's total revenue. Merck is already reeling from the loss of exclusivity for its blood pressure drugs Cozaar/Hyzaar. The two have seen sales slump by 41% in 2010 to \$2.1 billion. Merck has already overcome lost revenue from several major products due to patent expiry or product withdrawal, including Vioxx (withdrawn in 2004), Proscar (2005), Zocor (2006), Fosamax (2008) and Cozaar (2010).

**Takeda's** [patent](#) on the type 2 diabetes medication Actos which was launched in 1999, already expired in January. Takeda came to an agreement with generic drugmakers Ranbaxy, Watson and Mylan under which they won't start marketing Actos until August 2012. Sandoz, **Teva Pharmaceutical Industries** and a few others will enter the market 180 days later. Over the first nine months ending in December of its fiscal 2010, Actos recorded sales of 293 billion yen (\$3.58 billion), or 27% of its total revenue. Sales were also affected by a sharp decrease in Prevacid sales due to the loss of exclusivity in the U.S.

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**Amgen's** arthritis and psoriasis treatment Enbrel is a large-molecule biologic. As such, it will be much harder to duplicate. Even with the FDA trying to put in place procedures to ease the entry of generic biologics, or biosimilars, into the market, the process is just beginning. Hence the attraction of biotech to Big Pharma: It's the reason Roche bought Genentech, and Sanofi-Aventis acquired **Genzyme**. With Enbrel's total sales in 2010 coming to \$3.5 billion -- 23% of Amgen's total revenue -- it, too, would have felt the vulnerability of the patent cliff. And **Pfizer** would take yet another hit, as it markets Enbrel outside the U.S., Canada and Japan. Pfizer's 2010 sales of Enbrel were \$3.2 billion.

The imminent arrival of the dreaded "patent cliff" has been haunting the pharmaceutical industry for years, and it's finally here. With patents on many blockbuster drugs about to expire, an estimated \$250 billion in sales are at risk between now and 2015, according to data from EvaluatePharma. <http://www.thestreet.com/story/11027354/1/10-popular-drugs-set-to-lose-their-patents.html>

### **The Story of Temozolomide**

An application for the patent in the USPTO was filed on August 23, 1982, by a British pharmaceutical company. The specification identified and characterized 13 tetrazine compounds, including one named temozolomide. The specification stated that these derivatives possessed anticarcinogenic activity in several animal models. On November 18, 1983, in the first substantive office action, the examiner rejected claims to a method of treating leukemia through administration of a tetrazine compound for lack of utility. The examiner suggested that utility could be established through clinical reports and data, FDA acceptance, or other methods. Rather than respond to the office action, the applicant initiated a cycle of filing continuation applications and then abandoning them 12 times over the next nine years. Only in the 12th cycle did the applicant file a substantive response to the non utility rejection, arguing that the animal data disclosed in the *original specification* established the claimed utility in humans. After two more office actions, the patent office allowed the claims and the patent issued on November 9, 1993.

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In the meantime, drug development of temozolomide had progressed. Phase I testing of temozolomide began in 1987. By 1989, reports showed that temozolomide was safe and had some anticancer activity. In 1999, the FDA approved temozolomide for treatment of a particular form of cancer. On March 19, 2007, Barr Laboratories filed an ANDA with a paragraph 4 certification challenging the validity of the patent and seeking FDA approval for a generic version. Cancer Research filed suit in Delaware on July 20, 2007. The district court held Cancer Research's patent unenforceable in part due to prosecution laches. Cancer Research appealed to the Federal Circuit.

Reversing the finding of prosecution laches, Federal Circuit held that prosecution laches requires a finding of prejudice during the period of delay. Thus, an accused infringer must show that it or others invested in, worked on, or used the technology during the period of delay. The majority emphasized that material prejudice is a requirement of any laches defense. In so doing, the Federal Circuit rejected its own totality of the circumstances test, recently enunciated in *Symbol Technologies, Inc. v. Lemelson Medical, Education, & Research Foundation* (422 F.3d 1378 (Fed. Cir. 2008)).

In *Woodbridge v. United States* (263 U.S. 50 (1923)), the Court held that Woodbridge had forfeited his right to a patent where he delayed the issuance of his patent for eight and a half years longer than he was entitled, because he delayed to increase his commercial profit and cover products released during the delay. In *Webster Electric Co. v. Splittorf Electrical Co.* (264 U.S. 462 (1924)), the Court held a patent unenforceable because of (1) an eight year delay in prosecuting broad claims and (2) the intervening rights of others. In *Crown Cork & Seal Co. v. Ferdinand Gutmann Co* (304 U.S. 159 (1938)) and *General Talking Pictures Corp. v. Western Electric Co* (304 U.S. 175 (1938)), the Court held that no excuse is necessary for a delay in presenting new claims in a continuation or division application in the absence of intervening rights.

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On February 28, 2011, the Federal Circuit denied Barr's petition for rehearing. Judge Prost, joined by Judges Gajarsa, Moore, and O'Malley, dissented that the majority opinion encourages applicants "to keep prosecution open and reshape their claims to capture later technological and business developments, all to the public's injury," and arguing that the proper test is the "totality of the circumstances test." The doctrine of prosecution laches aimed in large part to prevent improper prosecution from harming the public, when the patent term was 17 years from the grant date, as in this case.

The [patent term](#) in the United States was changed in 1995 to bring U.S. patent law into conformity with the [World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights](#) (TRIPs) as negotiated in the [Uruguay Round](#). It is no longer possible to maintain such [submarine patents](#) in the US. However, the time and cost for the development of a new drug have gone up considerably.

#### **GSK in Sri Lanka**

GlaxoSmithKline (GSK) has invested in a new manufacturing plant in Sri Lanka for the production of its over-the-counter (OTC) painkiller Panadol. The INR200m (\$4m) facility in south western city of Moratuwa will house both laboratory space and production lines and, when operational early next year, will manufacture almost 2bn tablets a year. UK-based drug maker GSK, which sells around 70m packs of Panadol in Sri Lanka every year, told the *Ceylon Daily News* that the investment would roughly double production capacity. Last year the company moved into Panadol liquid manufacturing.

#### **Need for Diagnostics**

There is a great need for better prostate cancer diagnostics. In the U.S. alone, there were an estimated 217,730 new cases of prostate cancer last year, making it the most common form of cancer among men in the country. Yet the research continues to make it clear that a one-size-fits all approach to treating prostate cancer is ludicrous, as many men have slow-growing tumors and don't require the same level of

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response as those with aggressive cancer. Active in this area are companies like [Genomic Health](#), [Oxford Gene Technology](#), [Quanterix](#), [Metamark Genetics](#), [Myriad Genetics](#) etc.

#### **Nanodiamonds**

According to a report by the Northwestern University in *Science Translational Medicine*, enhancing chemotherapeutic efficiency through improved drug delivery would facilitate treatment of chemoresistant cancers, such as recurrent mammary tumors and liver cancer. One way to improve drug delivery is through the use of nanodiamond (ND) therapies, which are both scalable and biocompatible. Here, we examined the efficacy of an ND-conjugated chemotherapeutic in mouse models of liver and mammary cancer. A complex (NDX) of ND and doxorubicin (Dox) overcame drug efflux and significantly increased apoptosis and tumor growth inhibition beyond conventional Dox treatment in both murine liver tumor and mammary carcinoma models. Unmodified Dox treatment represents the clinical standard for most cancer treatment regimens, and NDX had significantly decreased toxicity in vivo compared to standard Dox treatment. Thus, ND-conjugated chemotherapy represents a promising, biocompatible strategy for overcoming chemoresistance and enhancing chemotherapy efficacy and safety.

#### **Fungus Fights Malaria**

Researchers have engineered transgenic fungi that drill into mosquitoes and kill the malaria parasite inside -- the first tool of its kind -- a February 25, 2011 study in *Science* reported. Used in conjunction with traditional insecticide methods against mosquitoes, experts say this bioinsecticide has the potential to greatly improve malaria eradication efforts. Notably, the fungus has no effect on humans, meaning it could be safely released in large-scale malaria control efforts.

Malaria is responsible for the deaths of nearly 1 million people each year, most of them children living in sub-Saharan Africa. Because the parasite that causes the disease, *Plasmodium falciparum*, is transmitted

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by a mosquito vector, scientists have historically tried to control the infection by killing the mosquitoes with insecticides. This approach has caused the rapid evolution of insecticide-resistant mosquitoes, lessening the effects of current control tactics. Because the fungus is slow-acting, the mosquitoes may not quickly evolve resistance against its attack. <http://www.the-scientist.com/news/display/58028/>

#### **Daiichi Sankyo's Problems in India**

Daiichi Sankyo, the Tokyo-based pharmaceutical company, acquired Gurgaon-based Ranbaxy, Daiichi bought a mature firm that would help it access the American and Indian markets. Contrary to what Mr. Shoda promised at the time of acquisition, Ranbaxy CEO Mr. Singh left the company in 2009, while Mr. Shoda has moved up to become chairman of Daiichi Sankyo.

In its eagerness to tap the expertise of a generic drug maker, Daiichi took the risk of buying Ranbaxy for top dollar, without proper due diligence. Three weeks later, the US Food and Drug Administration banned imports of 30 of Ranbaxy's generic drugs, and later determined that the company was selling adulterated or misbranded medicine. It blacklisted two of the company's manufacturing units, limiting the company's ability to sell drugs made in those facilities. Ranbaxy then reported currency-exchange losses of nine billion rupees in 2008. The Indian company has also been through a series of top-level management changes, including the recent exit of its CFO Omesh Sethi in January. [http://online.wsj.com/article/SB10001424052748704662604576201741223441376.html?ru=yahoo&mod=yahoo\\_hs](http://online.wsj.com/article/SB10001424052748704662604576201741223441376.html?ru=yahoo&mod=yahoo_hs)

#### **Carbidopa-Levodopa**

Impax Laboratories, the Hayward, CA-based developer announced that the Parkinson's drug it in-licensed from GlaxoSmithKline last year--its second attempt at an extended release version of carbidopa-levodopa--handily beat out the standard of care for controlling a key symptom of the disease in a late-stage study. The primary endpoint of the IPX066 trial was the percentage of "off time"--when patients' medication effect has worn off and there is a return of Parkinson's symptoms--during waking hours.

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IPX066 demonstrated a 37 percent improvement from baseline compared to a 17 percent improvement from baseline for the standard treatment.

Parkinson disease affects both men and women in almost equal numbers. It shows no social, ethnic, economic or geographic boundaries. Of all the neurodegenerative disorders it is second to Alzheimer's disease in numbers of cases, with more than 1.3 million patients suffering from it in major countries.

#### **Gene Therapy for Parkinson's**

Parkinson's disease is a degenerative brain illness that causes problems including tremors, rigidity and slow movements. It affects about one in every 500 people. There is no cure, but some drugs help control symptoms. In patients with Parkinson's disease, their brains get overactive after losing the normal supply of a chemical called GABA. The new treatment, gene therapy, works by inserting billions of copies of a gene into patients' brains that helps them produce more GABA.

Doctors drilled a hole into patients' brains and slipped in a virus engineered to bring in billions of copies of a gene to help the brain pump out more GABA. After six months, those who got the gene therapy scored 23 percent better on a standard test to measure motor skills while those who did not get the gene therapy did about 13 percent better. The study was published online in the journal, *Lancet Neurology*. Neurologix Inc. is the biotechnology company that devised the therapy and study.

#### **Patent Reforms in the US - America Invents**

The United States Senate voted to approve <http://react.bracewellgiuliani.com/reaction/web/BILLS112s23es.pdf> (titled the "America Invents Act"). The Senate Bill S. 23 includes the following measures:

Transition from a first-to-invent system to a first-to-file system for determining priority of multiple inventors to the same or similar inventions (Section 2);

Prioritization of reviews for certain patents deemed critical to U.S. economic development (Section 23);

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Establishment of a transitional program to review granted business-method patents in light of the Supreme Court's recent decision in *Bilski v. Kappos* (Section 18);  
Formation of a new "first-window" post-grant, patent-opposition system with a shorter timeframe but broader jurisdiction than the current reexamination procedure (Section 5);  
Establishment of procedures for third parties to submit for consideration and inclusion in the record of a patent application, any patent, published patent, or other printed publication of potential relevance to the examination of the application (Section 7);  
Creation of a small-business ombudsman at the USPTO (Section 22);  
Modification of current bans on tax patents to allow patents for certain types of tax-return filing software (Section 14);  
Amendments to 35 U.S.C. § 292 restricting the availability of false-marking damages to the federal government and those persons who have suffered a competitive injury as a result of false patent marking (Section 2);  
Requirement that the USPTO disclose the amount of time it takes to conduct *inter partes* and post-grant reviews (Section 5);  
Provision allowing the USPTO to set its own fees (Section 9);  
Elimination of fee diversion from the USPTO to the U.S. general treasury (Section 20);  
Set new fees for applicants that select not to use electronic filing methods (Section 9); and  
Establishment of three or more USPTO satellite offices (Section 21).

Europe is seeking to improve its patents system, too. On March 9th finance ministers from 25 of the 27 European Union countries agreed to the creation of a single European patent which would not need separate validation at national level—which has been a glaring gap in the single European market. <http://www.economist.com/node/18389167>

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Despite the new laws and the attention to patent reform on both sides of the Atlantic, new inventions will soon be coming from Asia and Indian continents as a result of the industry moving to that region.

#### **Medtronic Goes to China**

Medtronic, the US-based medical technology firm, has officially opened its new regional headquarters building in Shanghai, China. The Minneapolis company has maintained smaller offices in Shanghai since 1996, but the new purpose-built facility represents its first permanent home in the region. Medtronic said the building symbolized its commitment to further its localized product development and manufacturing operations in China.

Medtronic said that establishing a base of operations in China marked an important stage in the process of expanding its services across the country. Simon Li explained: "In the next five years, while continuing to strengthen service to customers and patients, Medtronic will also invest in R&D, clinical studies and manufacturing and will establish a modern service and manufacturing network, with Shanghai as the centre but with branches all over China."

#### **Pfizer Moves to China**

Pfizer plans to move its antibacterial research group from Groton, CT to Shanghai, China. Some research scientists may stay on at the Groton site for up to two years as they complete advanced projects; newer programs will move to China as soon as the site is ready. Pfizer's antibacterial research includes drugs for the treatment of MRSA and other antibiotic-resistant superbugs. The paper notes that given the relatively small return on investments pharma companies reap from the generics-packed antibiotics market, the cheaper China digs could be a way for Pfizer to increase its profit margins.

#### **Bill Gates and Drug Discovery**

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Bill Gates has invested a small part of his personal fortune and professional reputation in a Cambridge, MA-based startup that is promising to use cutting-edge computational technology to identify new drugs for difficult targets. Gates and Dr. Richard Friesner, the co-founder of Schrödinger and a chemistry professor at Columbia University, co-led the seed round with assistance from Atlas Venture, the founding investor in Nimbus.

The funds are being earmarked to advance Nimbus' lead programs in diffuse large B-cell lymphoma, inflammatory disorders and metabolic disease. The fledgling biotech is targeting key proteins like IRAK4, a signaling kinase that becomes inappropriately activated in lymphoma and inflammation, and ACC, a metabolic enzyme that controls the synthesis and burning of fat. "While traditional chemistry approaches have failed to develop medicines for these targets, the Nimbus team has generated selective, potent and differentiated compounds within its first year," states the company release. "Over the next 12-18 months, Nimbus will refine clinical candidates for these targets and will expand its pipeline to include a new series of important targets." Nimbus is partnered with Schrödinger. [http://www.fiercebiotech.com/press-releases/nimbus-discovery-unveils-first-its-kind-drug-discovery-paradigm-announces-s?utm\\_medium=nl&utm\\_source=internal](http://www.fiercebiotech.com/press-releases/nimbus-discovery-unveils-first-its-kind-drug-discovery-paradigm-announces-s?utm_medium=nl&utm_source=internal)

### Generics in the US

Generic drugs account for more than 70% of pharmaceutical prescriptions written in the United States, and larger percentages of prescriptions overseas and throughout the world. The FDA's Office of Generic Drugs has for many years lacked adequate government funding and staffing to process ANDAs and to conduct required inspections of generic manufacturing facilities both in the U.S. and around the world supplying the American market. The FDA is currently working to develop a system in which manufacturers of generic drugs will pay fees to the FDA when seeking approval to sell generic versions of prescription drugs. Charging generic manufacturers "user fees" will assist in providing the FDA the resources it needs to inspect generic drug manufacturing facilities in a timely manner, promptly conduct

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scientific evaluations of applications to sell generic drugs, and to establish periodic surveillance inspections of generic drug manufacturing facilities. In short, the FDA believes that user fees would go far in speeding up the approval process for Abbreviated New Drug Applications (CANDAs) to make new generic medicines available to the public more quickly than current procedures allow. User fees paid by ANDA sponsors would reduce the backlog of unapproved ANDAs and shorten the time from submission to market approval by furnishing the agency with resources to hire much needed additional staffing necessary for the review and approval process. Several blockbuster drugs are scheduled to lose patent protection in the next few years, providing an unprecedented opportunity for generics to compete in the marketplace and get their equivalent medicines to the public soon after these patents expire.

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*Source: The primary sources cited above, 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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