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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Issue 92 Contents:

Bill Gates Changes the World
Melafind
FDA Drug Approvals
Biotech Graveyard of 2011
Top 15 Possible Blockbusters
Biomarkers
Patenting is Big Business
End Pay for Delay
Driving Medical Innovation
Cloud Computing
Pharma's Boom/Bust Cycle
Modified Rice Protein

Bill Gates Changes the World

Here's the truest definition of power: When you have the ability to not just solve a problem but also to create a sustainable market that addresses it. "There was nobody you could write a check to," remembers Gates, who stood ready a decade ago to buy billions of vaccine doses. In the 1980s Unicef had tripled the percentage of children who got basic vaccines for polio, diphtheria, tetanus and other diseases by corraling public funds, negotiating on price with other aid agencies and deploying thousands of aid workers to deliver them. But those efforts still fell woefully short of the need, and new medicines hitting

Issue 92	5113 <u>Kali Era</u> , <u>Khara</u> Year, Karthika month 2069 <u>Vikramarka Era</u> , <u>Khara</u> Year, Karthika month 1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Karthika month 2011 AD, November
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శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

the U.S. market faced an intolerable 15-to-20-year lag before reaching the kids of Tanzania or Nicaragua. “The chance of death from those diseases is 50 times greater in poor kids than in rich kids!” says Gates, his voice rising. The first critical step, he realized, was forging a lasting public-private partnership. The public half of that equation was solved quickly with his checkbook: Previous attempts had faltered due to lack of funds and infighting among aid organizations over scarce dollars. But the private component was trickier. Compared with manufacturing pills, making vaccines is difficult and expensive. Drug companies wanted to immunize kids in, say, Afghanistan, but couldn’t count on demand that would be large and predictable enough to cover their costs. They faced the unappetizing choice of being humane or profitable. So back in 1999 Gates traveled to Bellagio, Italy to hammer out a solution, along with Unicef, the World Bank, the UN, various pharmas and aid groups. The result was the Global Alliance for Vaccines & Immunisation, now called the GAVI Alliance, which Gates ultimately backed with a \$2.5 billion pledge and personal will, exhibiting the tough-guy tactics, when necessary, that earned [Microsoft](#) the fear of its rivals and enmity of U.S. antitrust regulators.

<http://www.forbes.com/sites/matthewherper/2011/11/02/the-second-coming-of-bill-gates/>

Melafind

Melanoma is nearly always cured when found early. But 85% of people with advanced melanoma die within 5 years. U.S. officials approved a new device U.S. officials approved a new device, which uses a special light to look below the surface, that may help doctors decide which moles to check for melanoma. It compares the mole with a database of 10,000 images. Then it recommends whether to biopsy the mole. In a biopsy, some or all of the mole is removed to examine it for cancer. The new device is called MelaFind. It is made by Mela Sciences Inc.

FDA Drug Approvals

Over the past 12 months, the U.S. Food and Drug Administration approved 35 new medicines. This is among the highest number of approvals in the past decade, surpassed only by 2009 (37). Many of the drugs are important advances for patients, including: two new treatments for hepatitis C; a drug for late-

Issue 92	5113 <i>Kali Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 2069 <i>Vikramarka Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 1933 <i>Salivahana Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

stage prostate cancer; the first new drug for Hodgkin's lymphoma in 30 years; and the first new drug for lupus in 50 years.

In a report released, FY 2011 Innovative Drug Approvals, the FDA provided details of how it used expedited approval authorities, flexibility in clinical trial requirements and resources collected under the Prescription Drug User Fee Act (PDUFA) to boost the number of innovative drug approvals to 35 for the fiscal year (FY) ending Sept. 30, 2011. The approvals come while drug safety standards have been maintained.

The report shows faster approval times in the United States when compared to the FDA's counterparts around the globe. Twenty-four of the 35 approvals occurred in the United States before any other country in the world and also before the European Union, continuing a trend of the United States leading the world in first approval of new medicines. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278383.htm>

Among the new drugs approved in FY 2011, a number are notable for their advances in patient care and for the efficiency with which they were approved:

- Two of the drugs – one for melanoma and one for lung cancer – are breakthroughs in personalized medicine. Each was approved with a diagnostic test that helps identify patients for whom the drug is most likely to bring benefits;
- Seven of the new medicines provide major advances in cancer treatment;
- Almost half of the drugs were judged to be significant therapeutic advances over existing therapies for heart attack, stroke and kidney transplant rejection;
- Ten are for rare or “orphan” diseases, which frequently lack any therapy because of the small number of patients with the condition, such as a treatment for hereditary angioedema;

Issue 92	5113 <i>Kali Era, Khara Year, Karthika month</i> 2069 <i>Vikramarka Era, Khara Year, Karthika month</i> 1933 <i>Salivahana Era, Khara Year, Karthika month</i> 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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- Almost half (16) were approved under “priority review,” in which the FDA has a six month goal to complete its review for safety and effectiveness;
 - Two-thirds of the new approvals were completed in a single review cycle, meaning sufficient evidence was provided by the manufacturer so that the FDA could move the application through the review process without requesting major new information;
 - Three were approved using “accelerated approval,” a program under which the FDA approves safe and effective medically important new drugs quickly, and relies on subsequent post-market studies to confirm clinical benefit. For example, Corifact, the first treatment approved for a rare blood clotting disorder, was approved under this program; and
 - Thirty-four of 35 were approved on or before the review time targets agreed to with industry under PDUFA, including three cancer drugs that FDA approved in less than six months.

The Prescription Drug User Fee Act was established by Congress in 1992 to ensure that the FDA had the necessary resources for the safe and timely review of new drugs and for increased drug safety efforts. The current legislative authority for PDUFA expires on Sept. 30, 2012.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278383.htm>

Biotech Graveyard of 2011

Many of the following dead companies are reminders of how difficult the biotech game is; one failure in the clinic nowadays can ruin a small drug developer, and limited supplies of capital have made some investors extremely conservative with their bets on teams that have faltered with previous R&D programs.

- [Advanced Life Sciences](#)
- [Altair Therapeutics](#)
- [Ambrilia Biopharma](#)
- [ARYx Therapeutics](#)
- [Peptimmune](#)

Issue 92	5113 <i>Kali Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 2069 <i>Vikramarka Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 1933 <i>Salivahana Era</i> , <i>Khara Year</i> , <i>Karthika month</i> 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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- [Phenomix Corporation](#)
 - [Tolerx](#)
 - [Transdel](#)

Read more: [The 2011 Biotech Graveyard - FierceBiotech](http://www.fiercebiotech.com/special-reports/2011-biotech-graveyard#ixzz1e1YiRq8h) <http://www.fiercebiotech.com/special-reports/2011-biotech-graveyard#ixzz1e1YiRq8h>

Top 15 Possible Blockbusters

The following 15 programs represent of the biggest blockbusters now in late-stage development:

- [Dalcetrapib](#)
- [Anacetrapib](#)
- [Bapineuzumab](#)
- [Solanezumab](#)
- [Eliquis](#)
- [Bardoxolone](#)
- [QVA149](#)
- [Xarelto](#)
- [Trastuzumab-DM1](#)
- [BG-12](#)
- [Tofacitinib](#)
- [AMR 101](#)
- [Bydureon](#)
- [Pertuzumab](#)
- [Quad](#)

Read more: [15 top blockbuster contenders - FierceBiotech](http://www.fiercebiotech.com/special-reports/top-15-blockbuster-contenders?utm_medium=nl&utm_source=internal#ixzz1ela6Dfyh) http://www.fiercebiotech.com/special-reports/top-15-blockbuster-contenders?utm_medium=nl&utm_source=internal#ixzz1ela6Dfyh

Issue 92	5113 Kali Era , Khara Year, Karthika month 2069 Vikramarka Era , Khara Year, Karthika month 1933 Salivahana Era , Khara Year, Karthika month 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Top R&D Budgets

1. [Pfizer: \\$9.4 billion](#)
 2. [Roche: \\$9.2 billion](#)
 3. [Merck: \\$8.12 billion](#)
 4. [Novartis: \\$8.08 billion](#)
 5. [Johnson & Johnson: \\$6.84 billion](#)
 6. [GlaxoSmithKline: \\$6.09 billion](#)
 7. [Sanofi-Aventis: \\$5.94 billion](#)
 8. [AstraZeneca: \\$5.3 billion](#)
 9. [Eli Lilly: \\$4.88 billion](#)
 10. [Bristol-Myers Squibb: \\$3.56 billion](#)
- Tied for 10th. [Takeda Pharmaceutical: \\$3.5 billion](#)

Read more: [The world's biggest R&D spenders - FierceBiotech](http://www.fiercebiotech.com/special-reports/worlds-biggest-rd-spenders?utm_medium=nl&utm_source=internal#ixzz1elaeEx7) http://www.fiercebiotech.com/special-reports/worlds-biggest-rd-spenders?utm_medium=nl&utm_source=internal#ixzz1elaeEx7

Biomarkers

Biomarkers, as defined by NIH, are "characteristics that are objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention." A biomarker has to be reliable, measurable, specific, and predicative. Understanding the

Issue 92	5113 Kali Era , Khara Year , Karthika month 2069 Vikramarka Era , Khara Year , Karthika month 1933 Salivahana Era , Khara Year , Karthika month 2011 AD, November
----------	--



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

multivariate nature of a disease and drug response depends on molecular profiling at epigenetic, genetic, and protein levels. SABiosciences' PCR Arrays, microRNA Arrays, Epigenetics ChIP Arrays, Methylation PCR Arrays, and Biology-on-Arrays can all be used to identify and validate biomarkers.

In clinical practice, biomarkers can be used to identify risk and susceptibility, diagnose a disease, assess disease severity or progression, classify patients, guide treatment, and predict prognosis. In drug development and the pharmaceutical industry, biomarkers can be used to predict toxicity, safety, or efficacy of a drug. Biomarkers can be categorized as target, mechanism and clinical to indicate if a drug hits its intended target, alters any mechanisms and if it is effective in vivo. Biomarkers can be also classified into three types: type 0 - natural history markers, type 1 - biological or drug activity markers, and type 2 - surrogate markers. Type 0 biomarkers measure the natural history of a disease and should correlate over time with known clinical indicators. They can be characterized in phase 0 clinical trials. Symptoms over the full range of a disease and most prognosis markers are type 0 biomarkers. In most cases, type 1 biomarkers are the markers that capture the effects of a therapeutic intervention in accordance with its mechanism of action. A type 2 biomarker (the NIH defines a type 2 biomarker or a surrogate marker as a biomarker intended to substitute for a clinical endpoint) is a measure of effect of a certain treatment that may correlate with a real clinical endpoint but does not necessarily have a guaranteed relationship. The most commonly used surrogate marker is blood cholesterol level.
<http://www.sabiosciences.com/ArrayList.php?application=BIOMARKER>

Patenting is Big Business

In the decade and a half since David Bowie bundled up his future music earnings into copyright-backed bonds to pay his taxes, RoyaltyPharma has securitized billions of dollars of drug patent royalty streams, countless "NPEs" have bought and enforced patents for cash settlements, and Ocean Tomo's patent auctions have become routine. Disney bought Marvel Comics for \$4 billion based mostly on its copyright-protected comics and movies, and trademarked cast of characters. An alliance of technology giants bought Nortel's patents for \$4.5 billion, and Google bought Motorola's patents for \$12.5 billion. Intellectual Ventures acquired 35000 patents for about \$ 5 b venture capitol.

Issue 92	5113 <i>Kali Era, Khara Year, Karthika month</i> 2069 <i>Vikramarka Era, Khara Year, Karthika month</i> 1933 <i>Salivahana Era, Khara Year, Karthika month</i> 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Monetizing Intellectual Property To Improve Financial Performance: http://www.mondaq.com/unitedstates/x/153908/Trademark/Monetizing+Intellectual+Property+To+Improve+Financial+Performance&email_access=on

When Patents Attack! <http://www.thisamericanlife.org/radio-archives/episode/441/when-patents-attack>

End Pay for Delay

According to Sen. Jeff Bingaman (D-NM), who introduced a bill in the Senate ([S. 1882](#))< “The legislation would prevent "parked exclusivities" from delaying full, fair, and early generic competition by modifying three key elements of existing law. First, the legislation would grant the right to share exclusivity to any generic filer who wins a patent challenge in the district court or is not sued for patent infringement by the brand company. The legislation also maximizes the incentive for all generic challengers to fight to bring products to market at the earliest possible time by holding generic settlers to the deferred entry date agreed to in their settlements. Finally, in order to create more clarity regarding litigation risk for pioneer drug companies and generic companies, the legislation requires pioneer companies to make a litigation decision within the 45 day window provided for in the Hatch-Waxman Act.”

The legislation, called the Fair and Immediate Release of Generic Drugs Act ([FAIR GENERxICS Act](#)) of 2011, fixes an unintended problem in the Hatch-Waxman Act – a law that provides the framework to incentivize name brand companies to develop new medications and generic manufacturers to bring medications to market. A provision in that law gives the first generic company to file for a patent the exclusive right to sell a generic version of the medication for 180 days after the original patent expires.

<http://bingaman.senate.gov/news/20111116-02.cfm>

Driving Medical Innovation

Issue 92	5113 Kali Era , Khara Year , Karthika month 2069 Vikramarka Era , Khara Year , Karthika month 1933 Salivahana Era , Khara Year , Karthika month 2011 AD, November
----------	--



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

FDA released a report containing immediate steps that can be taken to drive biomedical innovation, while improving the health of Americans. The report addresses concerns about the medical product development pipeline, one of the most pressing challenges facing the biomedical industries.

Release of the report, kicks off a new FDA-wide Innovation Initiative, which promises to redouble the agency's efforts to encourage innovations that will promote public health as well as strengthen the American economy.

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm>

Cloud Computing

Cloud computing is the delivery of software and data storage solutions via the internet with the associated hardware generally located in datacentres far from the cloud customers' main business premises.... While cloud computing is not new, the momentum behind it has never been so great: Apple's iCloud and Chromebook, Google's cloud-based laptop have raised the profile of cloud computing considerably by bringing it to the general public, while ever-increasing server capacity, network access and virtualisation of computer resources (which allows for the leveraging of IT hardware and software capabilities by virtue of economies of scale) are making cloud computing a viable and attractive IT solution to businesses of all sizes. There are broadly speaking two kinds of clouds: public and private. The private cloud, also known as the internal or proprietary cloud, provides dedicated network services to a single or limited number of users and is typically managed by the organisation it serves. The public cloud on the other hand is more open in nature (although still secure) and is based upon the true cloud computing model whereby the latest IT solutions are made available to the general public over the internet, bringing cost-savings and almost infinite scalability. Examples of public cloud providers include Window's Azure Services Platform and IBM's Blue Cloud. A third model, the hybrid cloud, blends characteristics of both the private and public cloud. <http://mop.newsweaver.ie/itgroup/9s25dh5ak15?a=1&p=18578715&t=16435914>

Pharma's Boom/Bust Cycle

Issue 92	5113 <u>Kali Era</u> , <u>Khara</u> Year, Karthika month 2069 <u>Vikramarka Era</u> , <u>Khara</u> Year, Karthika month 1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Karthika month 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Lipitor's U.S. patent expires on November 30, unleashing a wave of cheap generics and ending a fabled run that began in 1997. Of currently marketed drugs, Abbott Laboratories' rheumatoid arthritis drug Humira may have the best shot with annual sales of about \$8 billion, which the company sees growing by \$1 billion a year in the near future. But getting to Lipitor's peak annual sales of \$13 billion in a therapeutic area with several competitors is a lot to ask. According to Thomson Reuters Forecast, by 2016, the world's three top sellers will be rheumatoid arthritis treatments -- with Pfizer Inc's Enbrel and Johnson & Johnson's Remicade trailing Humira. The blood clot preventer Plavix from Bristol-Myers Squibb and Sanofi made a run at Lipitor, with sales of more than \$9 billion, but like Lipitor its heyday is coming to an end.

Pfizer obtained full ownership of Lipitor in 2000 through its \$114 billion acquisition of Warner-Lambert, with which it had co-marketed the fledgling drug. Former Pfizer Chief Executive William Steere, when asked at a press conference why he was making his hostile takeover bid for Warner-Lambert, broke into a Cheshire grin and replied with a single drawn-out word: "Lip-it-or." <http://www.reuters.com/article/2011/11/06/us-lipitor-idUSTRE7A51R520111106>

Modified Rice Protein

Yang and his colleagues inserted the gene encoding HSA into their rice plants in such a way that the gene was activated during seed production, and the resulting protein was stored in the rice grain along with nutrients normally used to help nurture a germinating embryo. The final product was a crop of rice seeds in which HSA made up more than 10% of the seeds' total soluble protein — one of the best yields of recombinant protein from plants to date. ...

The rice-derived protein was shown to be functionally equivalent to the version found in human blood plasma. Not only were the two chemically and physically identical, but they were also similar when tested for medical efficacy and immune reactivity. In rats with liver disease, both types of HSA proved equally effective in relieving symptoms associated with cirrhosis. And rats that were given rice-derived HSA showed no stronger immune reaction than animals that had been given the plasma-derived version.

Issue 92	5113 <u>Kali Era</u> , <u>Khara Year</u> , <u>Karthika month</u> 2069 <u>Vikramarka Era</u> , <u>Khara Year</u> , <u>Karthika month</u> 1933 <u>Salivahana Era</u> , <u>Khara Year</u> , <u>Karthika month</u> 2011 AD, November
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Read more: <http://healthland.time.com/2011/11/02/squeezing-blood-from-a-grain-of-rice/#ixzz1ey2jFO2R>

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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!)

Issue 92

5113 Kali Era, Khara Year, Karthika month
2069 Vikramarka Era, Khara Year, Karthika month
1933 Salivahana Era, Khara Year, Karthika month
2011 AD, November

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