

The Andhra Journal of Industrial News

IP and Industry News

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Clean Technology Venture Capitol

The Clean Technology sector experienced a 12 percent increase in both dollars and deal volume in 2011, bringing the year's total to the highest level ever recorded at \$4.3 billion going into 323 deals, compared to \$3.8 billion going into 289 deals in 2010. Clean Technology investing accounted for 15 percent of all venture capital dollars in 2011 compared to 16 percent in 2010. In the fourth quarter, venture capitalists invested \$1.2 billion into 73 Clean Tech deals, up 34 percent in dollars but down 14 percent in deal volume from \$914 million going into 85 deals in the third quarter. For the full year 2011, three of the top ten deals were in the Clean Tech category; four of the top ten deals in Q4 fell into the Clean Tech category as well. Clean Technology crosses traditional MoneyTree industries and comprises alternative energy, pollution and recycling, power supplies and conservation.

Venture capitalists invested \$28.4 billion in 3,673 deals in 2011, an increase of 22 percent in dollars and a 4 percent rise in deals over the prior year, according to the MoneyTree Report by PricewaterhouseCoopers

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LLP and the National Venture Capital Association (NVCA), based on data from Thomson Reuters. http://www.pwc.com/us/en/press-releases/2012/annual-venture-investment-dollars.jhtml

India's Traditional Knowledge Digital Library

The Indian government has made available to the USPTO patent examiners India's Traditional Knowledge Digital Library (TKDL), a database of traditional knowledge. The USPTO plans to host several CSIR trainers at USPTO this spring to discuss the TKDL with examiners and other agency staff. http://www.uspto.gov/blog/director/entry/supporting_ip_a_global_challenge

New Jurists at the Board of Patent Appeals and Interferences

The USPTO's Board of Patent Appeals (BPAI) has an incredibly large backlog of *ex parte* appeals pending, more than 25,000. Recently, the Board gained 14 new administrative jurists. These new judges will help the office aggressively tackle the backlog of appeals waiting at the board. The board will be instrumental in shaping a new in-house post grant review process that is much faster and less expensive than litigation. Read the remarks from Director Kappos

Biosimilars

The U.S. Food and Drug Administration (FDA) published three draft guidance documents that describe the agency's interpretation of the biosimilar approval pathway created by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The draft guidance documents, "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009," "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," and "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," address a broad range of issues.

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President Obama unveiled his 2013 <u>budget proposal</u> that would impact drugmakers. The administration proposes to increase the availability of generic drugs and biologics by authorizing the Federal Trade Commission to stop companies from entering into anti-competitive deals, known also as "pay for delay" agreements, intended to block consumer access to safe and effective generics. The administration's proposal to accelerate access to affordable generic biologics involves modifying the length of exclusivity on brand name biologics. Beginning in 2013, this proposal would award brand biologic manufacturers seven years of exclusivity rather than 12 years under current law and prohibit additional periods of exclusivity for brand biologics due to minor changes in product formulations. Reducing the exclusivity period decreases the profits for the branded companies and investment into R&D for new break through drugs, resulting in \$4 billion in savings over 10 years to Federal health programs including Medicare and Medicaid.

Recently, *Forbes* reported that the development costs for an average drug (produced by a major pharmaceutical company) are as much as \$11 billion ("<u>The Truly Staggering Cost Of Inventing New Drugs</u>").

AIA Update

The USPTO announced the release of a proposed patent fee schedule issued under Section 10 of the AIA. To explain the proposed fee changes, USPTO prepared five documents: (i) a transmittal letter from the USPTO to PPAC explaining our fee setting philosophy; (ii) an executive summary of our proposed fee schedule; (iii) detailed information about our proposed fee schedule; (iv) a table of proposed fee changes; and (v) aggregate revenue calculations:

- USPTO Transmittal Letter to PPAC for Patent Fee Proposal
- Executive Summary: Patent Fee Proposal
- Detailed Appendices: Patent Fee Proposal
- Table of Patent Fee Changes

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<u>Aggregate Revenue Calculations</u>

Best in the Past 15 Years

Company	Number of Drugs
Novartis	21
Merck&Co	16
J&J	15
<u>Pfizer</u>	14
<u>Wyeth</u>	13
Bristol-Myers Squibb	11
Hoffmann-La Roche	11
Lilly	11
GlaxoSmithKline	10
Abbott	9
Amgen	9
Pharmacia & Upjohn	9

http://www.forbes.com/sites/matthewherper/2012/02/09/the-best-drug-companies-of-the-past-15-years/

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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!

(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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