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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Biomarkers

Biomarkers may help determine among patients at risk for disease, who is likely to respond to treatment and what course a disease might take. As biomarker findings are cited by other researchers in their papers, the information gets widely disseminated, even if untested in larger studies. An analysis of 35 of the most widely cited medical papers on [biomarker](#) discovery showed that most of the findings didn't hold up in larger studies, according to a review in [Journal of the American Medical Association](#). Findings not supported in larger analyses included those linking the [BRCA1](#) breast tumor gene to colon cancer, and a measure of inflammation called [c-reactive protein](#) to heart disease. <http://www.bloomberg.com/news/2011-05-31/linking-disease-markers-to-medical-condition-often-exaggerated-study-says.html>

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Clear and Convincing Evidence

A unanimous United States Supreme Court confirmed the heightened "clear and convincing evidence" standard of proof for questions of fact regarding the validity of a patent. (*Microsoft Corp. v. i4i Limited Partnership et al.*, Supreme Court No. 10-290, June 9, 2011 (*i4i*)).

The decision reaffirms more than a century of settled law. In 2007, the Supreme Court stated that the rationale underlying the need for the clear and convincing evidence standard "seems much diminished" when a validity challenge is based on evidence that had not been presented to the PTO during a patent's examination. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426. The Supreme Court rejected Microsoft's proposal that the presumption of validity be weakened for validity challenges that were not considered by the USPTO during prosecution of the application. The Court clarified in *i4i* that the clear and convincing evidence standard applies regardless of whether evidence of invalidity has been previously considered by the PTO. The *i4i* Court also suggested that juries should be instructed that the presentation of evidence not before the PTO makes the burden of demonstrating invalidity by clear and convincing evidence "easier to sustain: "Simply put, if the PTO did not have all material facts before it, its considered judgment may lose significant force. And, concomitantly, the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain.... When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent."

Justice Sotomayor delivered the opinion for seven of the justices. Justice Breyer wrote a concurring opinion that was signed by Justices Scalia and Alito. Justice Thomas concurred. Chief Justice Roberts recused himself.

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Indo-US Business

“The incredible growth of India’s economy has resulted in positive spillover effects for the United States. A quick look at the data reveals a trade relationship that is accelerating, mutually beneficial, and relatively balanced. Between 2002 and 2009, U.S. goods exports to India quadrupled, growing from \$4.1 billion in 2002 to more than \$16.4 billion in 2009, and U.S. services exports to India more than tripled, increasing from \$3.2 billion in 2002 to more than \$9.9 billion in 2009. U.S. exports to India have grown faster than exports to practically all other countries in the world.

2010 broke records for U.S.-India trade in goods with U.S. exports to India up 17% and U.S. imports from India up 40%. This surge of nearly 30% to a high of \$48.8 billion in goods trade moved India up two notches to become our 12th largest goods trading partner. This positive trend continues, with two-way goods trade up 19% in the first quarter of 2011 over the same time period last year....

India is also a growing source of foreign direct investment into the United States. The total stock of FDI from India to the United States stood at almost \$5.5 billion at the end of 2009. It has grown at a compound annual growth rate of 35 percent during the 2004 to 2009 time period, making India the 7th fastest-growing source of investment in the United States. Indian companies invest heavily in many U.S. industries such as energy and information technology, and we expect their investments to increase.”

Robert O. Blake, Jr. Assistant Secretary, Bureau of South and Central Asian Affairs, Kolkata, India
<http://www.state.gov/p/sca/rls/rmks/2011/166496.htm>

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Biotech and Pharma Industry

A report by consulting firm Ernst & Young that detailed the strains weighing on the industry said companies face a funding squeeze, a less predictable regulatory environment, and tougher scrutiny on drug reimbursements as public and private payers react to complaints about rising health care costs. The report showed that the capital-driven biotechnology industry has seen a decline in innovation investments — money used to discover new drugs — as larger companies tap the debt markets to buy back shares and pay dividends to investors. While overall funding for biotechs increased by about 15 percent last year, innovation capital outlays dropped by about 20 percent, according to the report. At the same time, it said, many smaller companies are finding it hard to get any financing from venture capitalists. And if they do, the funding rounds increasingly limit upfront payments — offering additional money only if clinical milestones are met. http://www.boston.com/business/healthcare/articles/2011/06/29/biotechs_see_future_of_partnerships_more_selectivity/

Big Pharma has increasingly turned to doing deals with smaller players to compensate for failures and patent expirations, which in the end may not be working as envisioned. The pharmaceutical industry spent an estimated \$68 million less on drug R&D in 2010, a 3 percent drop from spending during the previous two years, according to data compiled by CMR International. Meanwhile, there were 55 Phase III terminations from 2008 to 2010, which was more than double the number between 2005 and 2007. At the same time, the number of drugs entering Phase III clinical trials fell by 55 percent in 2010, and those entering Phase I and Phase II trials fell 47 percent and 53 percent, respectively. It gets worse. There were 21 new molecular entities (NMEs) launched on the global market in 2010, compared with 26 in the previous year, which was the lowest number of NMEs launched by Big Pharma over the past decade. Of

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course, some may argue the number of launches reflects tougher regulatory scrutiny, as opposed to R&D struggles. "The strategy of Big Pharma to in-license more drugs for development does not appear to be paying off at present," Phil Miller of Thomson Reuters, which owns CMR. <http://seekingalpha.com/article/277074-biotech-deals-fail-to-yield-results>

Eli Lilly will lose the most revenue from its pharmaceuticals during the "patent cliff," waving goodbye to more than 50 percent of its sales through 2020 as its brand name drugs lose their market exclusivity, according to estimates by Bernstein Research analyst Tim Anderson. AstraZeneca and Pfizer will fare almost as badly. The industry as a whole faces \$100 billion in losses as brand names face competition from cheap generic alternatives through 2015. <http://www.bnet.com/blog/drug-business/patent-cliff-losses-mean-eli-lilly-must-acquire-or-be-acquired/8778>

Another byproduct of Big Pharma's appetite for acquisitions is job destruction, while the job creation in the US is at its lowest point since 1980s. By the end of 2010, the number of people working part-time because they couldn't find full-time work had nearly quadrupled since the 1950s. *Fortune*, July 4, 2011.

The folks at [Scientific American](http://www.scientificamerican.com) have launched "1,000 Scientists in 1,000 Days" -- a program to bring together scientists, teachers and students to improve America's "dismal" showing among wealthy countries (27th out of 29) in graduating college students with degrees in science or engineering. I'm sure they mean well -- but, at least as it applies to the field of chemistry, "1,000 Unemployed Scientists Living With Their Parents at Age 35 While Working at the Gap" would be a better name, says John Bloom. Read more: http://www.nypost.com/p/news/opinion/opedcolumnists/america_vanishing_science_jobs_V3TzWwPRZsmTh1sGmtVr8L#ixzz1QmPWzn2e

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Last year, the pharmaceutical industry spent about \$2 billion on assorted R&D activities in India, but that figure is expected to reach a whopping \$25 billion by 2025. The reasons are varied, but can be traced to expanding activities by Indian companies, additional government investment and a growing pool of qualified researchers, according to a new report by the Boston Consulting Group. The optimistic forecast for India reflects declining R&D productivity in regions where such work has traditionally been conducted, notably the US and Western Europe. In 2002, pharma spent \$25.3 billion in the US, which accounted for 83 percent of the worldwide total. By 2009, that grew to \$35.4 million, but represented 76 percent of the total. There were also percentage declines in Western Europe and Japan. <http://www.pharmalot.com/2011/06/rd-spending-in-india-is-projected-to-mushroom/>

Pedigree in the US

The US is a so-called meritocratic society. In a meritocratic society, as the phrase indicates, merit is the sole criterion. Nonetheless, like in India, where pedigree is an important factor, it is very much a factor in the US.

However, unlike in India where casteism was and is a fact of life and is determined by birth, the pedigree plays an important role in a different way in the US, despite the fact that there are examples of CEOs starting in the mail room or as janitors and working their way up or college dropouts making to the top of the richest people's list - those are exceptions. The reality for a majority is that you are better off attending an Ivy League school and rubbing shoulders with elite by playing certain games, especially if you are vying for a job on the Wall Street or at a Fortune 500 company. Bill Clinton and Barak Obama are exceptionally intelligent, but they went to Ivy League schools.

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Lauren Rivera, a sociologist at Northwestern University, who studied and wrote about the academic pedigree in the US in the journal *Research in Social Stratification and Mobility*, says, “elite professional service employers rely more on academic pedigree than any other factor.” For these recruiters prestige counts more than anything else, because if you are from a “super-elite” school you must be smart and polished. Efficiency in hiring dictates that selection from run-of-the-mill from a top tier school is preferred over a high achiever from even a second tier school.

By the way, once you are at an elite school, don’t forget to play a game like lacrosse, squash etc. If you don’t play any of the elite games, you will be branded a “nerd” - not good for job prospects in elite companies, even if you are a graduate from an Ivy League school.

See also, “Its True: We’re All Snobs,” *Fortune*, June 13, 2011.

Fungal Evolution

Modern living comes with an increasing need for electrical household equipment such as dishwashers, washing machines and coffee machines. A characteristic of these appliances is a moist and hot environment. In the case of dishwashers, high temperatures between 60° to 80°C are intermittently produced and aggressive detergents and high concentrations of salt are used in each washing cycle, which apparently became habitats for certain fungi.

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A potentially pathogenic fungus has found a home in dishwashers, researchers have found in a paper published in the British Mycological Society journal, Fungal Biology. 62% of the dishwashers contained fungi on the rubber band in door, 56% of which accommodated the polyextremotolerant black yeasts *Exophiala dermatitidis* and *E. phaeomuriformis*.

Exophiala dermatitidis is rarely isolated from nature, but is frequently encountered as an agent of human disease, both in compromised and healthy people. It is also known to be involved in pulmonary colonization of patients with cystic fibrosis, and also occasionally causes fatal infections in healthy humans. The invasion of black yeasts into our homes represents a potential health risk. <http://www.biospace.com/News/my-dishwasher-is-trying-to-kill-me-new-research-in/224714>

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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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