

The Andhra Journal of Industrial News

IP and Industry News

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Issue 154 Dr. Sreenivasarao Vepachedu¹, JD, PhD, LLM

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TRUMP-PHARMA-LIAISON

If enacted, the Trump policies would result in up to 350,000 new jobs in the so-called Big Pharma over

A Decade In Drug Ir	A Decade In Drug Industry Layoffs					
Year	Number of jobs cut					
2000	2,453					
2001	4,736					
2002	11,488					
2003	28,519					
2004	15,640					
2005	26,300					
2006	15,638					
2007	31,732					
2008	43,014					
2009	61,109					
2010	53,636					
2011 (First three months)	3,385					
TOTAL	297,650					
Source: Challenger, Gray & Christmas, Inc. ©						

the next 10 years, according to PhRMA. This is a drop in the bucket because the employment in professional and business services added 522,000 jobs last year - in just one year. The US economy added 156,000 jobs in one month - December 2016, which was short of expected 175,000 jobs; In the past 8 years, from January 2009, the US economy has added 11,250,000 people to total nonfarm payrolls.

Almost a decade (2000-2009), the pharmaceutical industry has cut 297,650 jobs by 2009, as many people as the total employment at the three largest drug makers -- Pfizer, Merck, and GlaxoSmithKline -- combined, according to consulting firm Challenger, Gray & Christmas report "A Decade In Drug Industry Layoffs²".

During the Obama regime, the economy has added jobs for 75 straight months, the longest streak since 1939, although the overall rate of growth has been slower than in previous administrations. Between 2009 and 2013, US biopharma eliminated at least 156,000 American jobs, including scaling back R&D departments, slashing sales teams, and

eliminating redundancies in post-merger workforces. Since then, the industry has continued to slice and dice sections of its employment base, particularly in the wake of a record level of M&A activity in the sector (there were 182 biopharma deals totaling \$212 billion in 2014 alone). The US economy has consistently created at least 100,000 jobs per month for the last three years, According to outplacement firm Challenger, Gray & Christmas, employers have announced 493,431 planned layoffs so far this year—that's a 36% increase from the same period last year and 2% more than the total number of layoffs announced in 2014. The Wall Street Journal points out that Pfizer, for example, has a habit of snapping up big companies and then chopping up jobs as it realizes synergies from those deals.

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A Redistribution Of Talent And Resources: While company executives will always offer a good business

Mass layoffs in 2015, ranked by size

Chicago-based outplacement firm Challenger, Gray & Christmas, Inc. maintain a database of mass layoffs. The list below is current through Oct. 1, 2015. Target's June layoff announcement is not shown because it impacted the retailer's Canadian workforce.

be

RANK	DATE	COMPANY	SIZE
1	7/12/15	United States Army, troops	40,000
2	9/15/15	Hewlett-Packard	30,000
3	7/9/15	United States Army, civilian	17,000
4	4/18/15	Schlumberger Ltd	11,000
5	1/19/15	Schlumberger Ltd	9,000
6	8/25/15	Great Atlantic & Pacific Tea Co.	8,500
7	7/22/15	Microsoft	7,800
8	1/19/15	Baker Hughes	7,000
9	2/10/15	Haliburton Co.	6,400
10	4/26/15	Procter & Gamble	6,000
11	2/5/15	Radioshack	5,424
12	9/24/15	Caterpillar	5,000
13	5/30/15	JPMorgan Chase & Co.	5,000
14	7/24/15	Qualcomm Inc.	4,500
15	1/24/15	American Express	4,000
16	2/4/15	Weatherford International	4,000
17	7/26/15	Halliburton Co.	3,800
18	1/17/15	Wet Seal Inc.	3,700

rationale on the need for these consolidations, there is no doubt that biopharmaceutical researchers are aware that, on any given day, they could hear that their particular laboratory is going to shuttered³.

US-based employers announced 574,888 job cuts through November. That is 19 percent higher than the 2014 yearend total (483,171). At the current pace, 2015 was the biggest job cut year since 2009, when 1,272,030 job cuts were announced. Falling oil prices were blamed for 102,738 job cuts through November, which represents nearly one in every five job cuts announced in 2015.

Completing Pipeline Projects will certainly exacerbate the situation by contributing to the oil price fall, which is responsible for 0.1 million jobs lost. Once the pipelines are completed, additional construction and related workers will be laid off, further contributing to the job loss⁴.

Source: Challenger, Gray & Christmas, Inc.

FORTUNE

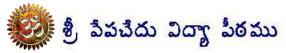
Since 2010, R&D investment in the industry has been relatively flat, rising less just about \$500 million over that timeframe (2010-2015). Pfizer, having absorbed 134,000 jobs through acquiring Warner-Lambert, Pharmacia, and Wyeth during the 1999-2009 period, saw its overall employment grow by roughly 27,000 by the end of 2013—in effect, disappearing over 100,000 jobs between 1999 and 2013.

Microsoft cut approximately 7,400 positions in 2014, 2,850 positions eliminated by January 2017, and about 700 jobs are expected to be cut in 2017.

While Trump was talking to the Congress boasting that he would bring back jobs to America and make America great again, on February 28, the University of California, San Francisco, laid off 49 information

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technology employees and outsourced their work to a company based in India. Anti-immigrant Trump criminalized immigrant community encouraging vigilante supremacists to attack Indian citizens and Indian Americans killing and terrorizing them⁵. Attacks on Indian Americans and Indian citizens were apparently collateral damage in the war against immigrants to make America great again⁶.

- In Drug Mergers, There's One Sure Bet: The Layoffs.
- Big Pharma Just Had a Terrible, Horrible, No Good, Very Bad Week of Job Cuts.
- <u>Counterfeit of medicines causes 37,000 job losses in EU Pharma Industry.</u> <u>New Case of Counterfeits Suspected at German Company.</u>

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Chinese Agro Espionage & Stealing Rice from US

The scale of international theft of American intellectual property (IP) has been unprecedented resulting in the loss of hundreds of billions of dollars per year and has been a drag on the American GDP growth, posing enormous challenges to national security and welfare. Unless current trends are reversed, there is a risk of stifling innovation, the consequences will be adverse for both developed and developing countries. The effects of this theft are twofold.

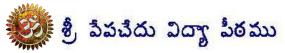
The first is the obvious loss of revenue as well as of the jobs associated with those losses to American companies of all sizes. The second effect is stifling of innovation slowing down the development of new inventions and industries that can further expand the world economy and continue to raise the prosperity and quality of life for everyone in the world.

Stolen IP represents a subsidy to foreign companies that do not have to bear the costs of developing or licensing it. China, Russia, India, and other countries constitute important actors in a worldwide challenge to American IP owners. Many issues are the same: poor legal environments for IPR, protectionist industrial policies, and a sense that IP theft is justified by a playing field that benefits developed countries. However, China stands out with a share of international IP theft estimated to be above 70%. A core component of China's successful growth strategy is acquiring science and technology by means of imports, foreign domestic investment, licensing, joint ventures, and IP theft, along with other policies to weaken IPR from mandating technology standards that favor domestic suppliers to leveraging access to the Chinese market for foreign companies' technologies. China's approach to IPR is evolving too slowly over the years without meaningful protection for American IP, while cyberattacks are increasing. Our innovative economy and security are at stake as US companies suffer losses and American workers lose jobs. Naturally, China has been the principal focus of the US intellectual property rights (IPR) policy.

An example of China's ways to achieve its goals is the Case of Yan and Zhang. A federal jury returned guilty verdicts on 16 February 2017 in this matter. Weiqiang Zhang⁷, a Chinese national residing in Manhattan, Kansas, was convicted on one count of conspiracy to steal trade secrets, one count of conspiracy to commit interstate transportation of stolen property and one count of interstate transportation of stolen property. Zhang acquired without authorization hundreds of rice seeds produced by Ventria and stored them at his residence in Manhattan.

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Wengui Yan, a geneticist at the US Agriculture Department, pleaded guilty to making false statements to the FBI when questioned about plans to send US rice samples to China. Yan admitted a group of Chinese tourists in 2013 told him of their plans to steal engineered US rice⁸.

The rice seeds have a wide variety of health research applications and were developed to express either human serum albumin, contained in blood, or lactoferrin, an iron-binding protein found, for example, in human milk. Ventria used locked doors with magnetic card readers to restrict access to the temperature-controlled environment where the seeds were stored and processed.

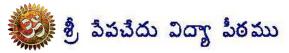
The FBI Field Offices in Little Rock, Arkansas and Kansas City, Missouri, the US Customs and Border Protection and the US Attorney's Office for the Eastern District of Arkansas investigated the case. The number of international economic espionage cases referred to the US Federal Bureau of Investigation is rising, up 15 percent each year from 2009 to 2014 and up 53 percent in 2015, according to the FBI.

China has long-term view on the agriculture sector: Weiqiang Zhang was an agricultural seed breeder at a Ventria Bioscience's facility in Junction City. Wengui Yan worked for the Department of Agriculture as a research geneticist at the Dale Bumpers National Rice Research Center in Arkansas. Yan has also been detained in Arkansas. Zhang is a lawful permanent resident of the US, Yan is a US citizen.

In 2013, the federal complaint accuses Zhang of collecting the seeds from his work for more than a year and storing them at his home in Manhattan, as well as handing at least some of them to a group of agriculture officials from China⁹.

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US- SWISS PRIVACY SHIELD10

Acting Under Secretary of Commerce for International Trade Ken Hyatt yesterday (January 11, 2017) announced the final approval of the US-Swiss Privacy Shield Framework. The Department of Commerce will begin accepting certifications on April 12, 2017.

The Swiss and EU laws on data protection are equivalent. Accordingly, the US- Swiss Privacy Shield Principles and Supplemental Principles are modeled on the Principles and Supplemental Principles developed for the US-EU Privacy Shield Framework. The US-Swiss Privacy Shield is intended for use solely by organizations in the United States receiving personal data from Switzerland for the purpose of qualifying for the Privacy Shield and thus benefitting from Switzerland's recognition of adequacy.

An organization must self-certify its adherence to the Principles to the Department of Commerce (or its designee) to rely on the US-SWISS Privacy Shield for transfer of personal data from Switzerland. Organizations that self-certify should publicly declare their commitment to adhere to the Privacy Shield Principles and must comply fully with the Principles.

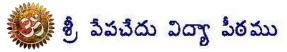
The US-SWISS Privacy Shield requires an organization to:

- (a) be subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC), the Department of Transportation or another statutory body that will effectively ensure compliance with the Principles (other US statutory bodies recognized by Switzerland may be included as an annex in the future);
- (b) publicly declare its commitment to comply with the Principles;
- (c) publicly disclose its privacy policies in line with these Principles; and
- (d) fully implement them. An organization's failure to comply is enforceable under Section 5 of the Federal Trade Commission Act prohibiting unfair and deceptive acts in or affecting commerce (15 USC § 45(a)) or other laws or regulations prohibiting such acts.

The US-SWISS Privacy Shield affects neither the application of national provisions implementing the Federal Act on Data Protection (FADP) that apply to the processing of personal data in Switzerland nor privacy obligations that apply under the US law.

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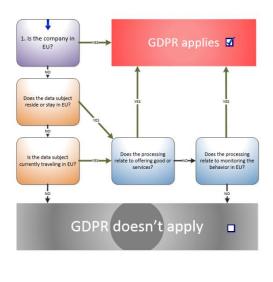
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The US-EU and US-Swiss Privacy Shield Frameworks were designed by the US Department of Commerce and the European Commission and Swiss Administration to provide companies on both sides of the Atlantic with a mechanism to comply with data protection requirements when transferring personal data from the European Union and Switzerland to the United States in support of transatlantic commerce¹¹.

Territorial scope of the GDPR (Flowchart)¹²

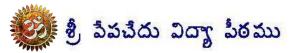


Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to the American public¹³.

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http://www.avvo.com/attorneys/60201-il-sreenivasarao-vepachedu-764535.html, and

http://www.crm-ip.com/vepachedu.html.

www.linkedin.com/in/vepachedu, and

http://www.crm-ip.com/vepachedu.html;





http://www.avvo.com/profile/dashboard

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² A Decade In Drug Industry Layoffs

http://www.forbes.com/forbes/welcome/?toURL=http://www.forbes.com/sites/matthewherper/2011/04/13/a-decade-in-drug-industry-layoffs/&refURL=https://www.linkedin.com/&referrer=https://www.linkedin.com/#6c898b015614

³ The Silver Lining In Big Pharma Layoffs And Site Closures? A Redistribution Of Talent And Resources:

http://www.forbes.com/sites/johnlamattina/2015/03/12/a-silver-lining-in-big-pharma-lay-offs-and-site-closures-a-redistribution-of-talent-and-resources/#49927eb8663f

Biopharma's new normal: Constant makeovers leave R&D jobs at permanent risk:

http://www.fiercebiotech.com/biotech/biopharma-s-new-normal-constant-makeovers-leave-r-d-jobs-at-permanent-risk

- ⁴ 2016 Employment Outlook.pdf
- ⁵ Solution for Job Problem in the US Get Rid of Those Who Don't Belong Here
- ⁶ The Undocumented and The Three– and Ten-Year Time Bars: https://www.linkedin.com/pulse/undocumented-three-ten-year-time-bars-rao-vepachedu; False Propaganda Against Victims of Human Trafficking Aliens:

https://www.linkedin.com/pulse/false-propaganda-against-victims-human-trafficking-aliens-rao; THE BLISSFUL IGNORANCE OF HUMAN RESOURCES & INTELLECTUAL PROPERTY: https://www.linkedin.com/pulse/prevent-erections-improve-performance-rao-vepachedu

- WEIQIANG ZHANG: https://academic.uthsc.edu/faculty/facepage.php?netID=wzhang16&personnel_id=248227
- ⁸ Arkansas Man Pleads Guilty to Making False Statements About Plan to Steal Rice Seeds:

https://www.justice.gov/opa/pr/arkansas-man-pleads-guilty-making-false-statements-about-plan-steal-rice-seeds

⁹ Arkansas Man Pleads Guilty to Making False Statements About Plan to Steal Rice Seeds:

https://www.justice.gov/opa/pr/arkansas-man-pleads-guilty-making-false-statements-about-plan-steal-rice-seeds

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Swiss-US Privacy Shield: better protection for data transferred to the USA:

https://www.admin.ch/gov/en/start/documentation/media-releases.msg-id-65210.html

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm

Shire Development LLC v. Watson Pharmaceuticals Inc. (Fed. Cir. 2017): https://www.linkedin.com/pulse/shire-development-llc-v-watson-pharmaceuticals-inc-fed-rao-vepachedu?trk=v-

feed&lipi=urn%3Ali%3Apage%3Ad flagship3 profile view base recent activity details shares%3B7ci9cQhTzRUT%2B%2B4z 7Euryg%3D%3D

New York Times, Washington Post, Mercury News, Bayarea.com, Deccan Chronicle, the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, The Guardian, Pravda, Spiegel, Connexion, etc.

<u>Disclaimer</u> All information is intended for your general knowledge only and is not a substitute for medical advice or treatment for special medical conditions or any specific health issues or starting a new fitness regimen.

"Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls." Rabindranath Tagore (1861-1941), Gitanjali, 1912.

One World One Family

AUM! SWASTI!

Om! Asatoma Sadqamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamqamaya, Om Shantih, Shantih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

SWASTI! AUM!

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¹⁰ See the US-SWISS Privacy Shield; US-Swiss Privacy Shield: better protection for data transferred to the USA; US-Swiss Privacy Shield: new framework for the transfer of data to the USA; PRIVACY SHIELD OVERVIEW https://www.edoeb.admin.ch/datenschutz/00626/00753/01405/01406/index.html?lang=en

¹¹ PRIVACY SHIELD OVERVIEW https://www.privacyshield.gov/Program-Overview

¹² Territorial scope of the GDPR (Flowchart): https://www.linkedin.com/pulse/territorial-scope-gdpr-flowchart-siarhei-varankevich

¹³ Abbreviated New Drug Application (ANDA): Generics:

¹⁴ In addition to the primary sources cited above, additional references include: