

IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

Issue 90 Contents:

Salient Features of Historic Patent Reforms in the US
FTC Report on Authorized Generics
Big Pharma Ventures
Clinical Trials In India
i6 Green Awards
President Obama Honors Nation's Top Scientists and Innovators

Salient Features of Historic Patent Reforms in the US

President Obama signed the America Invents Act - Leahy-Smith Patent Reform Act, the most significant change to US patent law in almost 60 years - on Friday, September 16, 2011, enacting it into law. Some provisions of the law take immediate effect, while remaining provisions become effective on different dates. The increased patent office fees will be effective on September 26, 2011. Other changes will not be implemented until 2012 and 2013, such as post-grant opposition procedures and the rules of novelty and nonobviousness.

A few changes are summarized below:

Fist to File: The first-to-file system will take effect 18 months from the date of enactment 9/16/2011. Any patent application which is filed within the next 18 months or can claim priority to an earlier patent

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

or application that was filed before the commencement date of the "first to file" system, will come under the old "first to invent" system.

Whoever files a patent application on a claimed subject matter first will be entitled to a patent over another inventor who later files an application on the same claimed subject matter, regardless of who first invented the claimed subject matter. Prior art will encompass any publication (including patents and published patent applications), public use, on sale or otherwise available to the public before the effective filing date of the claimed invention. A one-year grace period is being maintained to file an application after a disclosure of the invention by the inventor.

Adopting the first inventor to file system means that inventors will no longer be able to swear behind references to avoid certain invalidity challenges. Furthermore, interference proceedings will be replaced with derivation proceedings in the USPTO for first inventor to file applications and patents.

The adoption of a first-to-file system brings the U.S. in line with the rest of the world. However, there are still differences. For example, in the US the effective date is either the filing date of the application, or the priority date if priority is claimed to another application. This is in contrast to the one-year grace period available in Canada, which requires the Canadian application to have a filing date within one year of disclosure by the inventor. The same public disclosure by an inventor would not be citable as prior art on a subsequently filed U.S. application that claimed priority to a Canadian application, even though the U.S. application could be filed up to two years after the initial public disclosure by the inventor. In addition, an applicant wishing to file an application in both Canada and the U.S. must ensure that all data required to support utility, or its sound prediction, will be available within one year of an initial filing or inventor disclosure. In Canada, utility cannot be supported by the submission of post-filing data.

Scope of Prior Art (Effective upon expiration of 18 months beginning on September 16, 2011): The sections 35 U.S.C. § 102 and 35 USC § 103 are affected by the new law, which defines "effective filing

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada mont
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2011 AD, Septembe



IP and Industry News

date" as either the filing date of the earliest application to which the current application can claim a priority benefit, or the actual date of filing of the application.

The new section 102 is given below:

Sec. 102. Conditions for patentability; novelty

- (a) Novelty; Prior Art- A person shall be entitled to a patent unless—
- 1. the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- 2. the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.
 - (b) Exceptions-
- 1. DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION- A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
- A. the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- B. the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
- 2. DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS- A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if--
- A. the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
- B. the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)
- (2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

- C. the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.
 - (c) {CREATE ACT Save for later}
- (d) Patents and Published Applications Effective as Prior Art- For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application
- 1. if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
- 2. if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.'

Section 102 is changed to expand the scope and content of the prior art. Printed publications, public use and the on sale bar are still defined as prior art under the new § 102. In addition, § 102 is amended to include art "otherwise available to the public" before the effective filing date of the patent application. Prior art under § 102 also includes U.S. patent application publications of others having an effective filing date before the effective filing date of the patent application under prosecution.

Section 102(a)(2) provides that another inventor's issued patent or published application that was effectively filed before the filing date of the application in question but issued or published thereafter now constitutes prior art. Under § 102(a)(2), a foreign filing date may be used both as a priority date for an applicant's U.S. patent as well as a prior art date for defeating subsequent applications, thus overruling the *In re* Hilmer decision. (In the past, one could rely on a foreign filing date to establish an effective filing date under § 119 (i.e., the foreign filing date could be used for a patent-granting purpose and § 102(e)

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

(through its interpretation in *In re* Hilmer), the effective filing date based on the foreign filing date could not be used to predate a subsequent application for prior art purposes (i.e., the foreign filing date could not be used for a patent-defeating purpose)).

While the methodology for determining obviousness remains unchanged, the scope and content of the prior art available for use in the obviousness analysis have been expanded. All prior art having an effective filing date before the pending application is within the realm of prior art for determining obviousness.

Prior-User Rights and University Exception: The Act grants prior-user rights against any patented claim to a process or to a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, provided that the prior user commercially used the subject matter at least one year before the earlier of the effective filing date of the patent or the date on which the invention was disclosed to the public in a manner that qualifies for an exception under § 102(b). This may strengthen trade secret protection. An exception is "University Exception," wherein the defense may not be used against patents that, at the time the invention was made, were owned or subject to an obligation of assignment to institutions of higher education or technology transfer offices whose primary purposes are the commercialization of technologies developed by those institutions of higher education (§ 273(e)(5)).

Inventors and Assignees: Effective one year from the enactment of the Act, applications may be filed in the name of assignee (or a person/business to which an inventor has an obligation to assign). This provision eliminates the need to deal with inventors who are unable or unwilling to sign an oath or declaration required for prosecuting a patent application. Each inventor is still required to submit an oath or declaration. The Act details the statement that each inventor must make. An inventor's statement can now be made in an assignment document. A new declaration is not required in a continuation application, although a copy of the original may be required.

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

Prioritized Examination: Applicant can pay an additional \$4800 (\$2400 for a small entity) to file a request for prioritized examination of a nonprovisional application for an original utility or plant patent. Companies can take advantage of this prioritized examination ten days after the enactment of this Act.

Pre-grant Review: A third party may submit any publication of potential relevance to a patent application before the earlier of a notice of allowance or the later of (1) six months after the date of first publication or (2) the date of the first rejection. This new provision allows anyone to challenge another's filings, by bringing forward prior art during prosecution, which is a more cost effective approach to limit a competitor's patent rights compared to litigation or reexamination proceedings. This provision will be in effect one year from the date of enactment of the Act.

Post Grant Review Process: Within nine months after grant or reissue, a petitioner may request to cancel one or more claims of a patent on any ground except the best mode requirement. Filing a petition for post grant review of a patent will be more cost effective than challenging a patent in litigation or filing an *inter partes* review, which is replacing the current optional *inter partes* reexamination.

After the nine month window closes, third parties will be able to challenge a patent through an *inter* partes review to be conducted by Patent Trial and Appeal Board within one year. Basis for requesting an *inter partes* review is limited to prior art patents and printed publications. Changes the standard for initiating inter partes reexamination (now referred to as inter partes review) from "a new substantial question of patentability" to a reasonable likelihood that the petitioner will prevail with respect to at least one challenged claim.

The Office issued a notice in the Federal Register (76 Fed. Reg. 59055) that revises the standard for granting requests for *inter partes* reexamination. In the notice, the Office indicates that the rules of practice regarding *inter partes* reexamination have been revised to reflect the new standard for granting an *inter partes* reexamination provided in \S 6(c)(3)(A) of the AIA, as well as provide for the termination of *inter partes* reexamination on September 16, 2012 as provided in \S 6(c)(3) of the AIA.

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada mont
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2011 AD, Septembe



IP and Industry News

Ex Parte reexaminations may still be filed. In one year (on September 16, 2012), the USPTO will stop accepting inter partes reexamination requests and instead move to the new inter partes review procedure to be conducted before the new Patent Trial and Appeal Board rather than before an examiner. At the one-year anniversary, new post-grant review proceedings, transitional business method review proceedings, and supplemental examination proceedings will also be implemented.

Defense to Infringement Based on Prior Commercial Use: The Act expands the defense to infringement based on prior commercial use to affiliates and to all areas of technology with no restriction to business method patents. To use the defense, a party must show a reduction to practice and commercial use at least one year before the effective filing date of the subject patent. The Act prohibits deeming a patent invalid on novelty or non-obvious subject matter grounds solely because such prior commercial use defenses are raised or established.

Derivation Proceedings: The Act provides for derivation actions and proceedings that allow a first inventor with a later filing date to present evidence that an applicant with an earlier filing date derived the claimed invention from the first inventor. For situations involving two issued patents, the first inventor may bring a civil action against the earlier applicant (§ 291), and for situations involving two applications or involving an application and an issued patent, the first inventor may initiate a proceeding at the PTO (§ 135). However, a civil action may only be filed up to one year after the issuance of the first patent, and a proceeding initiated at the PTO may only be brought up to one year after the publication of the later filed application. With the focus now shifting to the filing date, a derivation action appears to be the only avenue for an inventor that lost the race to the Patent Office to receive priority.

Business Method Patents: According to the Act, an eight year transitional post-grant review proceeding will be established for reviewing the validity of covered business method patents, as defined in the Act. A Petitioner for review of a business method patent must have been sued for, or charged with, infringement of the patent before filing a petition for a transitional proceeding. The effective date of this

Issue 90	5113 <u>Kali Era, Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era, Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

transitional program for business method patents is one year after enactment of the Act and applies to patents issued before, on, or after that date. The petition is limited to prior art that is described in new § 102(a). If a party chooses to invoke its rights under this provision, it would be precluded from asserting an invalidity defense based on the same prior art during a civil trial. A business method is defined as "a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions."

False Marking: The Act prohibits anyone other than the United States from suing for applicable penalty under the false marking statute, and allows only a person who has suffered a competitive injury to file a civil action under the false marking statute for recovery of damages adequate to compensate for the injury. This portion of the Act shall apply to all cases that are pending on, or commenced on or after, the date of the enactment of this Act.

Marking: Patent holders can now "virtually" mark their products by fixing "patent" or "pat." together with a publicly accessible internet address. This change applies to any case existing on or filed after the date of enactment of the Act.

Human Organisms: The Act prohibits issuance of any patents with claims directed to or encompassing a human organism.

Best Mode: The Best Mode requirement remains a requirement, unchanged, for obtaining a patent under 35 U.S.C. § 112 Paragraph 1; however, under the new law, Best Mode can no longer be used as a defense in any action involving the validity or infringement of a patent. The Act eliminates the failure to disclose the best mode as a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable, even if it is later determined that the inventor unquestionably knew of a Best Mode and

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada mont
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2011 AD, Septembe



IP and Industry News

intentionally did not disclose it to the United States Patent and Trademark Office (USPTO) during examination.

Willful Infringement: The Act codifies current case law regarding no inference of willful infringement when an alleged infringer does not obtain an opinion of counsel. Codifying the Federal Circuit's *en banc* decision in Seagate, the Act provides that failure of a party to obtain an opinion of counsel when charged with infringement may not be used to prove willful infringement. However, the Act goes beyond the Federal Circuit jurisprudence by also providing that failure to obtain an opinion of counsel cannot be used to prove active inducement to infringe.

Micro Entity: The Act provides adds a class of "micro" entities to the current large and small entity classification (§ 123). Micro entities must meet additional requirements to those for small entity status, such as not being named as the inventor on more than four applications (§ 123(a)(2)), not having a gross income exceeding three times the reported median household income (§ 123(a)(3)), and not having assigned or agreed to assign the invention to an entity having a gross income exceeding three times the reported median household income (§ 123(a)(4)). Alternatively, inventors employed by and under agreement to assign inventive rights to institutions of higher education qualify as micro entities (§ 123 (d)). Micro entity status entitles the applicant to a 75% reduction of applicable fees effective immediately, and will likely help spur filings from individual inventors and small businesses for which the costs of procuring patent protection are particularly prohibitive.

Fees: For nearly 20 years, nearly \$1 billion of user fees had been diverted and misappropriated by Congress from the monies appropriated to the United States Patent and Trademark Office (USPTO). This has led to a huge backlog of patent applications waiting to be examined. While the Senate's original legislation gave the undiverted use of those funds to the USPTO, the House objected and it set up a separate account for the funds. If the USPTO needs the money, it has to come back to Congress to get it

Issue 90	5113 <u>Kali Era, Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era, Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

according to H.R. 1249, leaving the door open to an opportunity for Congress to continue the diversion of fees.

The Act provides the Director of the USPTO immediately with the authority to set and adjust the fees collected by the Office, but sunsets the fee setting authority seven years after enactment. The Act modifies the way in which fees are collected by the Patent Office are allocated, presumably allowing the Office to keep more of the fees collected for operation of the Office.

The United States Patent and Trademark Office (USPTO) announced its revised fee schedule on September 16, 2011 following the Leahy-Smith America Invents Act (Public Law 112-29) which was signed into law by President Barack Obama on September 16, 2011. The enactment of the legislation places a 15 percent surcharge on certain patent fees effective September 26, 2011. For a full list of fee changes, please go to http://www.uspto.gov/aia_implementation/15_Percent_Surcharge_Fee_Changes.pdf The fee due is the fee in effect on the date the document is timely filed. The USPTO postal mailing options are outlined below:

Certificate of Mailing or Transmission: Certain fees (e.g., issue and maintenance fees) may be paid through the postal mail using a certificate of mailing or transmission. See 37 C.F.R. 1.8. Correspondence will be considered as being timely filed on the date of transmission that appears on the certificate. Fees paid by postal mail with the properly filed certificates of mailing or transmission dated prior to September 26, 2011, will not be subject to the 15 percent surcharge.

Filing by Express Mail: Correspondences will be considered as being timely filed on the date the correspondence is deposited with a U.S. post office, if the express mail procedures described in 37 CFR 1.10 are followed. Therefore, fees paid by using the express mail will not be subject to the 15 percent fee increase when deposited with a U.S. post office, under the provisions of 37 CFR 1.10, prior to September 26, 2011.

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

USPTO accepts check, money order, credit card authorization, or deposit account authorization. Electronic payment methods are also available. Additional information on the currently accepted methods of payment is available at: http://www.uspto.gov/main/faq/index_feefaq_p.html.

At this time the USPTO may not offer the micro entity discount (75%) on any fees. As provided for in the Leahy-Smith America Invents Act (Public Law 112-29) these fees will be adjusted under the fee setting authority provided for in Section 10 of the AIA. The AIA continues to provide a small entity discount (50%) under 35 U.S. C. § 41(h)(1).

Once the USPTO sets these new fees, it is anticipated that the new fees will include a 50% reduction for small entities and a 75% reduction for micro entities for "filing, searching, examining, issuing, appealing, and maintaining patent applications and patents." Applicants qualifying for a small entity discount (50%) will be those who meet the current definition in 35 U.S. C. 41(h)(1) while applicants qualifying for a micro entity discount (75%) will be those who meet the definition outlined in AIA Section 11(g). For more frequently asked questions on AIA implementation please refer to http://www.uspto.gov/aia_implementation/faq.jsp

The revised USPTO fee schedule is available at: http://www.uspto.gov/about/offices/cfo/finance/fees.jsp. Satellite Offices: The PTO will establish three or more satellite offices within three years of the enactment of the Act. At least one satellite office will be in Detroit, Michigan.

The United States Patent and Trademark Office has created www.uspto.gov/AmericaInventsAct as an online guide dedicated to giving you the most current information on the agency's implementation of the AIA and how the law effects patent examination, post-issuance matters, and USPTO fee and budgetary issues. The AIA website also provides the opportunity to submit comment on the AIA and the agency's implementation of the law.

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

FTC Report on Authorized Generics

An authorized generic is a lower-cost, generic-label version of a brand-name drug that is already sold by the same manufacturer. The Hatch-Waxman Act is designed to ease the introduction of generic drugs by, in certain circumstances, granting a 180-day period of marketing exclusivity to the first generic competitor of a brand-name drug, known as a "first-filer." During that exclusivity period, no other generic company can receive FDA-approval to sell its product. However, this marketing exclusivity period does not prevent brand-name companies from introducing their own authorized generic versions. It has become increasingly common for brand-name drug makers to start marketing authorized generics at the same time a generic firm is beginning its 180-day marketing exclusivity period, leading to questions about the effects of authorized generics on pharmaceutical competition.

The <u>Federal Trade Commission</u> issued a final <u>report</u> on authorized generic drugs that concludes when pharmaceutical companies introduce an authorized generic version of their brand-name drug, it can reduce both retail and wholesale drug prices. The report also found that authorized generics have a substantial effect on the revenues of competing generic firms. Over the longer term, by lowering expected profits for generic competitors, the introduction of an authorized generic could affect a generic drug company's decision to challenge patents on branded drug products with low sales. However, the report concludes that in spite of this, patent challenges by generic competitors remain robust. Finally, the report finds that some brand companies may have used agreements not to launch an authorized generic as a way to compensate would-be generic competitors for delaying entry into the market.

The Final Report's main findings:

Competition from authorized generics during the 180-day marketing exclusivity period has led to lower retail and wholesale drug prices. During this time, competition by an authorized generic is associated

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada mont
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada mont
	2011 AD, Septembe



IP and Industry News

with retail prices that are four-to-eight percent lower, and wholesale prices that are 7 to 14 percent lower, than those without an authorized generic.

Authorized generics have a substantial effect on the revenues of competing generic firms. During the 180-day exclusivity period, the presence of an authorized generic competitor on average reduces the first-filing generic's revenues by 40 to 52 percent. In addition, revenues of the first-filing generic are between 53 and 62 percent lower during the first 30 months after the exclusivity period ends, if it is facing authorized generic competition. Introduction of an authorized generic can mean hundreds of millions of dollars in lost revenue for the first generic competitor to enter the market.

Lower expected profits could affect a generic company's decision to challenge patents on products with low sales. However, the reduced revenues resulting from authorized generic competition during the 180-day exclusivity period have not substantially reduced the number of challenges to branded drug patents by generic firms. Despite the presence of authorized generic competition, generic companies have continued to challenge patents, even on brand-name drugs in small markets.

There is strong evidence that agreements not to compete using authorized generics have become a way that some branded firms compensate generic firms for delaying entry to the market. http://www.ftc.gov/opa/2011/08/genericdrugs.shtm

Big Pharma Ventures

Major drugmakers such as Pfizer, Eli Lilly, Amgen, Novartis and GlaxoSmithKline have set up Venture funds to support R&D. Latest to join the club is Merck by setting up the Merck Research Venture Fund. Early-stage drug developers are hungry for cash as always, but traditional VC sources have showed a drop (9%) in venture dollars and 24% decline in the number of deals year-over-year for biotechs during the

Issue 90	5113 <u>Kali Era, Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era, Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

second quarter, according to data from Thomson Reuters in the PwC/National Venture Capital Association MoneyTree Report. http://invivoblog.blogspot.com/2011/09/mercks-500-million-venture-bet.html Even as it whittles down research operations in the U.S. and Europe, Pfizer is laying the groundwork for a new generation of Chinese scientists to advance its R&D. In another piece on Western drugmakers' research drives in the country, China Daily covers Pfizer pro Tan Lingshi's work to recruit Chinese scientists for his employer's growing research operations in the rising superpower. In 2000, China accounted for only 7.1 percent of the world's total GDP. In 2005, it was the world's fifth-largest economy. But what Tan Lingshi saw at that time was an immense opportunity to invest in research and development of Western drugs in China. http://www.chinadaily.com.cn/usa/weekly/2011-09/16/content_13712884.htm

Clinical Trials In India

For the first time since 2010 when six tribal girls from Gujarat and Andhra Pradesh involved in the clinical trials of anti-cervical cancer HPV vaccine died, the government has admitted that 1,725 persons have lost their lives to drug trials in the last four years.

The number of deaths has risen from 132 in 2007 and 288 in 2008 to 637 in 2009 and 668 last year, indicating the complete ineffectiveness of regulatory controls over the \$400 million sector. Last year, the government gave compensation in just 22 cases out of the 668 that resulted in deaths due to "serious adverse events" during drug trials, Health Minister Ghulam Nabi Azad told Parliament this week. Currently, 1,868 clinical trials are going on as per the Clinical Trial Registry of India maintained by the office of the Drug Controller General of India (DCGI). Many of the drugs being tested are not even of specific relevance to the country and could have been tested anywhere. Equally shocking is the fact that the rules, under the Drugs and Cosmetics Act, entirely trust the trial investigator with the reason attributed for the death of a subject. This is resulting in gross under-reporting of actual deaths during clinical trials. http://www.tribuneindia.com/2011/20110808/main1.htm

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

i6 Green Awards

This year, over \$12M was available for a challenge rewarding communities that utilize a Proof of Concept Center model, such as that championed by the Deshpande Center, to accelerate technology led economic development in pursuit of a vibrant, innovative clean economy. i6 Green solicited applications that strengthen the linkages between economic development and environmental quality. http://www.eda.gov/i6

On September 29, 2011, the Commerce Department's Economic Development Administration (EDA) awarded up to \$1 million to each of the six teams from around the country with the most innovative and competitive proposals. The U.S. Departments of Agriculture and Energy, the Environmental Protection Agency, and the National Science Foundation will award up to \$6 million in additional funding to i6 Green winners. They will also receive technical assistance from Commerce's United States Patent and Trademark Office and National Institute of Standards and Technology.

First announced at the White House launch of Startup America in January, the i6 Green Challenge follows last year's inaugural i6 Challenge focused on accelerating high-growth entrepreneurship in the United States.

Winners: U.S. Chief Technology Officer Aneesh Chopra, Acting U.S. Secretary of Commerce Rebecca Blank, U.S. Assistant Secretary of Commerce for Economic Development John Fernandez, U.S. Assistant Secretary of Energy for Policy and International Affairs David Sandalow, Deputy Assistant Director of the NSF Directorate for Engineering Kesh Narayanan, Chief Financial Officer of the U.S. Environmental Protection Agency Barbara Bennett. http://www.uspto.gov/news/pr/2011/irl_2011sep29.jsp

President Obama Honors Nation's Top Scientists and Innovators

"Each of these extraordinary scientists, engineers, and inventors is guided by a passion for innovation, a fearlessness even as they explore the very frontiers of human knowledge, and a desire to make the world a

Issue 90	5113 <u>Kali Era, Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era, Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

better place," **President Obama** said. "Their ingenuity inspires us all to reach higher and try harder, no matter how difficult the challenges we face."

President Obama named seven eminent researchers as recipients of the National Medal of Science and five inventors as recipients of the National Medal of Technology and Innovation, the highest honors bestowed by the United States government on scientists, engineers, and inventors. The recipients will receive their awards at a White House ceremony later this year.

The National Medal of Science was created by statute in 1959 and is administered for the White House by the National Science Foundation. Awarded annually, the Medal recognizes individuals who have made outstanding contributions to science and engineering. Nominees are selected by a committee of Presidential appointees based on their extraordinary knowledge in and contributions to chemistry, engineering, computing, mathematics, and the biological, behavioral/social, and physical sciences. The National Medal of Technology and Innovation was created by statute in 1980 and is administered for the White House by the U.S. Department of Commerce's Patent and Trademark Office. The award recognizes those who have made lasting contributions to America's competitiveness and quality of life and helped strengthen the Nation's technological workforce. Nominees are selected by a distinguished independent committee representing the private and public sectors.

Winners of National Medal of Science:

Jacqueline K. Barton, California Institute of Technology: For discovery of a new property of the DNA helix, long-range electron transfer, and for showing that electron transfer depends upon stacking of the base pairs and DNA dynamics. Her experiments reveal a strategy for how DNA repair proteins locate DNA lesions and demonstrate a biological role for DNA-mediated charge transfer.

Ralph L. Brinster, University of Pennsylvania: For his fundamental contributions to the development and use of transgenic mice. His research has provided experimental foundations and inspiration for

1	Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
		2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
		1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
		2011 AD, September



IP and Industry News

progress in germline genetic modification in a range of species, which has generated a revolution in biology, medicine, and agriculture.

Shu Chien, University of California, San Diego: For pioneering work in cardiovascular physiology and bioengineering, which has had tremendous impact in the fields of microcirculation, blood rheology and mechanotransduction in human health and disease.

Rudolf Jaenisch, Whitehead Institute for Biomedical Research and Massachusetts Institute of Technology: For improving our understanding of epigenetic regulation of gene expression: the biological mechanisms that affect how genetic information is variably expressed. His work has led to major advances in our understanding of mammalian cloning and embryonic stem cells.

Peter J. Stang, University of Utah: For his creative contributions to the development of organic supramolecular chemistry and for his outstanding and unique record of public service. **Richard A. Tapia**, Rice University: For his pioneering and fundamental contributions in optimization theory and numerical analysis and for his dedication and sustained efforts in fostering diversity and excellence in mathematics and science education.

Srinivasa S.R. Varadhan, New York University: For his work in probability theory, especially his work on large deviations from expected random behavior, which has revolutionized this field of study during the second half of the twentieth century and become a cornerstone of both pure and applied probability. The mathematical insights he developed have been applied in diverse fields including quantum field theory, population dynamics, finance, econometrics, and traffic engineering.

Winners of National Medal of Technology and Innovation:

Rakesh Agrawal, Purdue University: For an extraordinary record of innovations in improving the energy efficiency and reducing the cost of gas liquefaction and separation. These innovations have had significant

Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
	2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
	1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
	2011 AD, September



IP and Industry News

positive impacts on electronic device manufacturing, liquefied gas production, and the supply of industrial gases for diverse industries.

- **B. Jayant Baliga**, North Carolina State University: For development and commercialization of the Insulated Gate Bipolar Transistor and other power semiconductor devices that are extensively used in transportation, lighting, medicine, defense, and renewable energy generation systems.
- **C. Donald Bateman**, Honeywell: For developing and championing critical flight-safety sensors now used by aircraft worldwide, including ground proximity warning systems and wind-shear detection systems.

Yvonne C. Brill, RCA Astro Electronics (Retired): For innovation in rocket propulsion systems for geosynchronous and low earth orbit communication satellites, which greatly improved the effectiveness of space propulsion systems.

Michael F. Tompsett, TheraManager: For pioneering work in materials and electronic technologies including the design and development of the first charge-coupled device (CCD) imagers.

Notice: This material contains only general descriptions and is not a solicitation to sell any insurance product or security, nor is it intended as any financial, tax, medical or health care advice. For information about specific needs or situations, contact your financial, tax agent or physician.

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.

1	Issue 90	5113 <u>Kali Era</u> , <u>Khara</u> Year, Bhadrapada month
		2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month
		1933 <u>Salivahana Era</u> , <u>Khara</u> Year, Bhadrapada month
		2011 AD, September



IP and Industry News

Copyright ©1998-2011

<u>Vepachedu Educational Foundation, Inc</u>

Copyright Vepachedu Educational Foundation Inc., 1998-2010. All rights reserved.

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!)

Issue 90 5113 <u>Kali Era, Khara</u> Year, Bhadrapada month 2069 Vikramarka Era, <u>Khara</u> Year, Bhadrapada month 1933 <u>Salivahana Era, Khara</u> Year, Bhadrapada month 2011 AD, September