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# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

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#### **Historic Patent Reforms in the US: An Update**

President Obama signed the Leahy-Smith America Invents Act (AIA) -the most significant change to US patent law in almost 60 years - last year, on September 16, 2011. Some provisions of the law, such as the increased patent office fees took immediate effect (on September 26, 2011), while remaining provisions will become effective on different dates in 2012 and 2013, such as post-grant opposition procedures and the rules of novelty and nonobviousness, and first inventor to file provisions.

The USPTO already implemented eight provisions of this huge federal legislation and in the process of getting draft rules out for ten more. The USPTO began publishing notices of proposed rulemaking in January, 2012 relating to provisions that will take effect on or after September 16, 2012. The notices will include rules that will implement changes for the inventor declarations, the post-grant review procedures - such as new post-grant review, **inter partes** proceedings, supplemental examination - the derivation proceeding, and a number of other items. The USPTO has planned a series of cross-country roadshows to discuss the proposed rules implementing various provisions of the AIA. The proposed rules to be covered include: (i) the OED statute of limitations, (ii) inventor's oath and declaration, (iii) third party submission of prior art in a patent application, (iv) citation of prior art in a patent file, (v) supplemental examination,

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(vi) post-grant review, (vii) *inter partes* review, (viii) the transitional program for covered business methods, and (ix) derivation. The proposed rules for (i) to (iv) published in the Federal Register on January 5 and 6, 2012, and the proposed rules for (v) to (ix) are expected to publish in the Federal Register in mid- to late January 2012. The final rules are expected to be published in July, 2012. Please visit for more information: [http://www.uspto.gov/aia\\_implementation/index.jsp](http://www.uspto.gov/aia_implementation/index.jsp)

A few changes are summarized below.

### Changes Already in Effect

**Defense to Infringement Based on Prior Commercial Use:** Effective from 9/16/2011, 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.

**False Marking and Virtual Marking:** Effective from September 16, 2011, the new law delivered a one-two punch to false marking cases. 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. Previously the suits had *qui tam* provisions meaning plaintiffs would split the proceeds with Uncle Sam. Further, expired patent labels don't constitute false marking. This portion of the Act applies to all cases that are pending on, or commenced on or after September 16, 2011, the date of the enactment of this Act.

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.

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Since September 16, several courts have rejected false marking claims because of the claimants' failures to show a direct competitive injury. See, e.g., *Fisher-Price, Inc. v. Kids II, Inc.*, No. 10-cv-00988 A(F), 2011 WL 6409665 (W.D.N.Y. Dec. 21, 2011); *Advanced Cartridge Techs., LLC v. Lexmark Int'l, Inc.*, No. 8:10-cv-486-T-23TGW, 2011 WL 6719725 (M.D. Fla. Dec. 21, 2011). The Court acknowledged that the claimant had demonstrated competitive injury, but dismissed the false marking claim to the extent it depended on false marking with an expired patent number in Fasteners for *Retail, Inc. v. Andersen*, No. 11 C 2164, 2011 WL 5130445 (N.D. Ill. Oct. 28, 2011). The Court has ruled that enactment of the AIA does not preclude claimants from continuing to assert that false patent marking violates state consumer protection laws, such as state laws of false advertising and unfair competition in *Sukumar v. Nautilus, Inc.*, No. 7:11-cv-00218, 2011 WL 6325854 (W.D. Va. Dec. 19, 2011). A challenge to the constitutionality of the new false marking provision has been rejected in *Seirus Innovative Accessories, Inc. v. Cabela's Inc.*, No. 09-cv-102 H(WMC), 2011 WL 6400630 (S.D. Cal. Oct. 19, 2011).

**Joinder:** Effective September 16, 2011, the AIA imposed a new requirement that, in order to name multiple defendants, a plaintiff must show not only that the defendants infringed the same patent, and that the defendants were involved in some common infringing conduct. In a multiple-defendant lawsuit brought in Illinois, the court cited the AIA in support of its decision to grant a motion to sever the claims against one of the defendants and transfer them to Maine. *Pinpoint Inc. v. Groupon, Inc.*, No. 11 C 5597, 2011 WL 6097738 (N.D. Ill. Dec. 5, 2011).

**Human Organisms:** Effective from September 16, 2011, the Act prohibits issuance of any patents with claims directed to or encompassing a human organism.

**Best Mode:** Effective from September 16, 2011, 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. However, the best mode requirement remains as an examination issue.

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**Micro Entity:** Effective from September 16, 2011, the Act 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. But the discount is not available per the AIA until the USPTO sets or adjusts fees for "filing, searching, examining, issuing, appealing, and maintaining patent applications and patents" using the fee setting authority provided for in Section 10 of the AIA.

**Inter Partes Reexamination:** Effective from September 16, 2011, the Act changes the standard for initiating *inter partes* reexamination from "a new substantial question of patentability (SNQ)" to "a reasonable likelihood that the petitioner will prevail" with respect to at least one challenged claim. 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. *Ex Parte* reexaminations may still be filed.

**Fee Increase:** The Act provides the Director of the USPTO immediately with the authority to set and adjust the fees collected by the Office, but automatically terminates the fee setting authority seven years from the 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 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](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.

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

**Prioritized Examination:** Effective from September 26, 2011, an applicant can pay an additional \$4800 (\$2400 for a small entity) to file a request (Track I Petition) for prioritized examination of a nonprovisional application for an original utility or plant patent. Only applies to nonprovisional applications (including continuing applications) filed via EFS-Web after September 26 that are complete and which are accompanied by request for prioritized examination. Filing an RCE, extension of time, suspension of action, or amendment exceeding claims to 4 independent claims or 30 total claims terminates prioritized examination.

The required petition is very simple, and as of January 3, 2012, 1,694 Track I petitions have been submitted to the USPTO. On average it is taking 40.8 days to move Track I cases from receipt of petition to completion of pre-examination processing (which includes deciding on the petition). The longest it has taken is 95 days. On average only 10 of those 40.8 days are consumed in handling the Track I petitions, and 40.8 days in pre-exam for Track I compared to the USPTO normal (Track II) pre-exam processing time of 69.6 days.

**Prioritized Examination after RCE:** Effective from December 19, 2011, prioritized examination may be requested in an application where an RCE has been filed.

“Prioritized examination” under section 11 of AIA for a fee should not be confused with “priority examination” under section 25 discussed below.

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#### Future Changes

**Priority Examination:** Effective from September 16, 2012, a procedure for priority examination for technologies important to U.S. competitiveness (Sec. 25; § 2(b)(2)) is available. Priority examination under section 25 is for products, processes, or technologies that are *important to the national economy or national competitiveness without* recovering the aggregate extra cost of providing such prioritization. This is in addition to the existing opportunity for “advancement of examination” under 37 CFR 1.102 through a “petition to make special” (MPEP 708.02).

**Inventors/Applicants:** Effective from September 16, 2012, 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. Also, a new declaration is not required in a continuation application, although a copy of the original may be required.

**Pre-grant Review:** Effective from September 16, 2012, 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 of the application or (2) the date of the first rejection of any claim. 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. Provision will apply to all applications filed before, on, or after effective date.

**Post Grant Review (PGR):** Effective from September 16, 2012, within nine months after grant or reissue of a patent, a petitioner may request to cancel one or more claims of the patent on any ground except the best mode requirement. The standard of review is “more likely than not that at least one of the claims challenged is unpatentable.” After a written decision, petitioners may not assert issues that they “raised or reasonably could have raised.” Some features of PGR are given below:

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- While the regulations will be in place from September 16, 2012, PGR is applicable to business method patents (from September 16, 2012) and all patents subject to the first-inventor-to-file system (from March 16, 2013)
- Grounds include § 112: “any ground that could be raised under Paragraphs 2 or 3 of section 282(b) (§ 321(b)) (§282(b)(2) Invalidity of the patent or any claim in suit on any ground specified in part II of 35 USC as a condition for patentability, (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of [35 USC §§112](#) or [251](#))
- Standard: “more likely than not that at least one of the claims challenged is unpatentable” (§ 324(a))
- PGR to be filed within 9 months after patent grant (§ 321(c))
- No review, if PGR request is filed after challenger files a civil action challenging validity of the patent (§ 325(a))
- Automatic stay of civil action if the challenger files a civil action after PGR request (§ 325 (a)(2))
- No stay of consideration of motion for preliminary injunction if infringement action is filed within 3 months of patent grant, even if PGR has been filed (§ 325(b))
- Patent owner may file 1 motion to amend the patent (§ 326(d)) during a PGR
- Can be terminated by settlement prior to decision on merits (§ 327)
- Estoppel: after a written decision, petitioners may not assert issues that they “raised or reasonably could have raised”

A DJ action is typically initiated by a potential patent infringement defendant to secure a more desirable venue (*e.g.*, a venue other than the patentee friendly Eastern District of Texas). However, under 35 U.S.C. § 325 and 35 U.S.C. § 315, respectively, a potential defendant seeking to utilize a DJ action to secure venue will foreclose a later filed post-grant review or inter partes review.

Further, if a potential defendant (or real party in interest) files a DJ action on or after the potential defendant files a petition for post-grant review or inter partes review, the DJ action is automatically stayed until:

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- the patent owner moves the court to lift the stay;
- the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or
- the petitioner or real party in interest moves the court to dismiss the civil action. (35 U.S.C. § 325 (a)(2) and 35 U.S.C. § 315 (a)(2)).

The new patent review proceedings may be a true blessing for businesses who may be accused of patent infringement but who are too small to fund a defense to an infringement lawsuit.

**Inter Partes Review:** Effective from September 16, 2012, third parties will be able to challenge a patent, after 9 months from grant of a patent or after a PGR, through an *inter partes* review to be conducted by Patent Trial and Appeal Board and completed within one year, after the nine month window closes for post grant review. Basis for requesting an *inter partes* review is limited to prior art patents and printed publications and only novelty and obviousness may be raised. Changes the standard for initiating *inter partes* reexamination (and *inter partes* review) from "a new substantial question of patentability (SNQ)" to "a reasonable likelihood that the petitioner will prevail" with respect to at least one challenged claim. 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.

**Business Method Patents and Post-grant Review:** Effective from September 16, 2012, 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 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." The transitional post-grant review proceeding applies to business method patents issued before, on, or after September 16, 2012.

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**Supplemental Examination:** Effective from September 16, 2012, supplemental examination proceedings will also be implemented. Supplemental examination is intended to allow patent owners to clean the record of situations that could give rise to a claim of "inequitable conduct." If the PTO determines that the new or corrected information raises a substantial new question of patentability, it may order an *ex parte* reexamination. Under new Subsection (c) of §257, a patent cannot be held unenforceable on the basis of conduct relating to information considered, reconsidered or corrected during the supplemental examination.

**Willful Infringement:** Effective from September 16, 2012, 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.

**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 U.S. Patent and Trademark Office announced that it had entered into a five-year lease agreement on a 31,000 square foot space at 300 River Place Drive in Detroit, where the Elijah J. McCoy USPTO will be located. According to the announcement, the Office intends to open the Detroit satellite office by July 2012. The Office asks prospective employees to send e-mail inquiries to [detroitiring@uspto.gov](mailto:detroitiring@uspto.gov) for more information.

January 30, 2012 was the deadline for comments for future locations. A lengthy list of other cities including Austin, Texas, Denver, Boston and Honolulu as well as the Silicon Valley have joined the competition. Promoters have said the branch office would come with jobs for 500 examiners and engineers, although the Detroit office will employ only about 120. In addition, patent attorneys note, many examiners work out of their homes and commute to the main office to meet with applicants. The patent office, in soliciting proposals, listed five areas that would play a large role in the selection. Those areas included improved recruiting and retention of

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examiners that would hinge on factors such as cost of living and number of attorneys in the field, contributions toward speeding and improving the process, and access to innovators as judged by measures such as the number of patents already held by residents in the area. The patent office did not disclose how Detroit ranked in those areas, beyond the engineering base associated with the auto industry.

**Fist to File:** The first inventor to file, the most significant change, will only be effective from March 16, 2013. Under the new law, 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.

**Scope of Prior Art:** Effective from March 16, 2013, the sections 35 U.S.C. § 102 and 35 USC § 103 are affected by the first inventor to file system, which defines "effective filing 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.

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

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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) (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.

**Derivation Proceedings:** Effective from March 16, 2013, 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.

For more frequently asked questions on AIA implementation please refer to [http://www.uspto.gov/aia\\_implementation/faq.jsp](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>.

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**Genetic Diagnostic Testing:** USPTO Schedules Hearings and Seeks Comments on Genetic Diagnostic Testing In a press release and corresponding notice in Wednesday's Federal Register (77 Fed. Reg. 3748), the U.S. Patent and Trademark Office announced that it would begin gathering information on independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests. The Office is collecting such information in order to prepare a report to the Committee of the Judiciary for both the Senate and House pursuant to § 27 of the Leahy-Smith America Invents Act.

#### **Fair Use of NPL by the USPTO and Applicants**

The USPTO memo on the fair use of NPL can be found at <http://patentdocs.typepad.com/files/memo-on-use-of-npl.pdf>, which addresses the following questions:

Q. Whether it is fair use for the USPTO to make copies of copyrighted non-patent literature (NPL) and provide such copies to an applicant in the course of patent examination?

USPTO: the Office's copying and providing of copyrighted NPL to applicants constitutes fair use.

Q. Whether it is fair use for the USPTO to provide certified copies of entire file histories, including copyrighted NPL, to members of the public, for a fee?

USPTO: ...the incidental inclusion of copies of copyrighted NPL in a copy of a certified file wrapper offered to the public for a fee is protected by the doctrine of fair use.

Q. Whether it is fair use for an applicant to make a copy of a piece of copyrighted NPL and submit it to the USPTO?

USPTO: ... it is fair use for an applicant to make copies of NPL and submit those copies to the USPTO during examination in an IDS.

#### **Big Pharma in the US**

The evolution of pharmaceutical competition since Congress passed the Hatch-Waxman Act in 1984 jeopardized the continued pharmaceutical innovation in the US. Substituting generic medicines for their brand-name counterparts resulted in \$ 824 billion loss to the branded market over the decade 2000 to 2009. In 2009 alone the use of FDA-approved generic pharmaceuticals robbed the innovator companies \$ 139.6 billion.

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The data, compiled by IMS Health and based on 332 branded drugs (200 new drugs/132 new formulations) experiencing first generic entry between 1995 and 2008, including such drugs as Prozac, Imitrex, Zocor, Neurontin, and Ambien, showed that the average number of generic entrants within one year of the first generic drug to enter the marketplace has risen for all drugs (for drugs having greater than \$100 million in annual sales, increasing from 6 in 1995 to 10.1 in 2008), and the average period of data exclusivity fell from 13.5 years in 1995 to 12.4 years in 2008 (translating into a revenue loss of greater than \$100 million for drugs with greater than \$100 million in annual sales). The study also noted that 95% of generic drug entrants were for drugs with greater than \$100 million in annual sales. Hatch-Waxman, Paragraph IV challenges also rose during the period, with 9% of all drugs (and 17% of drugs with greater than \$100 million in annual sales) being challenged in 1995 and 64% of all drugs (75% of drugs with greater than \$100 million in annual sales) being challenged under Paragraph IV in 2008. The time between initial launch of a branded drug and the first challenge under Hatch-Waxman has also greatly reduced, going from 18.7 years in 1995 to 8.7 years in 2008. It was estimated that the average revenue garnered by a generic during the 180-day generic exclusivity period is \$60 million, which is 12 times the average cost of ANDA litigation (\$5 million).

The success of the Hatch-Waxman regime for small molecule drugs is the root cause of Branded Pharma's troubles today in the US, combined with higher standards of FDA scrutiny and the Big Pharma's inability to develop novel and better drugs.

The global generics market is likely to witness strong growth driven by the patent expiry of several major blockbuster drugs worth \$150 billion between 2010 and 2017. That is the view of researchers at Frost & Sullivan which claims that the market earned revenues of \$123.85 billion in 2010. This will rise almost 9.3% to reach \$231.00 billion in 2017, according to the the analysis which covers the USA, Germany, the UK, France, Spain, Italy, India and China. The report notes that generic firms "have been proactive in forging strategic alliances" with branded drugmakers to bag marketing rights and exclusivity in producing copycat versions of blockbusters, notably Pfizer's Lipitor (atorvastatin). The big names in the sector,

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notably Teva, Sandoz and Mylan, “are increasingly focused on biosimilars, as this segment provides a competitive edge and presents huge profit margins.”

See for more:

[Savings Achieved Through the Use of Generic Pharmaceuticals \(http://www.prescriptionaccess.org/2010\\_Report\\_Generic\\_Savings\\_GPhA.pdf\)](http://www.prescriptionaccess.org/2010_Report_Generic_Savings_GPhA.pdf).

The effect of Paragraph IV decisions and generic entry before patent expiration on brand pharmaceutical firms," *J. Health Econ.* 30: 126–45 (<http://www.ncbi.nlm.nih.gov/pubmed/21074873>).

Goldman *et al.*, 2011, "The benefits from giving makers of conventional "small-molecule" drugs longer exclusivity over clinical trial data," *Health Affairs* 30: 84–90 (<http://content.healthaffairs.org/content/30/1/84.abstract>)

*Science* 326: 370–71.

[Maybe Hatch-Waxman Data Exclusivity Isn't So Good For Traditional Drugs After All -http://www.patentdocs.org/2009/10/maybe-hatchwaxman-data-exclusivity-isnt-so-good-for-traditional-drugs-after-all.html](http://www.patentdocs.org/2009/10/maybe-hatchwaxman-data-exclusivity-isnt-so-good-for-traditional-drugs-after-all.html).

Grabowski *et al.*, 2011, "[Evolving Brand-Name and generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act](http://content.healthaffairs.org/content/30/11/2157)," *Health Affairs* 30: 2157-66 (<http://content.healthaffairs.org/content/30/11/2157>).

### **Wall Street Responsible for Loss of Jobs in Pharma**

Last year when Pfizer announced plans to slash R&D by 1/3rd, its shares rose by 5%. Two days after, Merck announced that it would maintain its R&D, only to see its shares plunged by 3%. Investors had sent Big Pharma a very clear message: Stop spending so much money to create new drugs, even if you're losing exclusivity on your older drugs through the so-called patent cliff. It's cheaper to just buy developed molecules from private startups. Big Pharma is succumbing to Wall Street's worst instincts rather than demonstrating corporate and civic responsibility. America will look back and rue the day that short-term

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financial considerations were given priority over long-term planning or simply blame it on the inevitable rise of China and India. <http://www.wallstreetstockshare.com/2011/11/28/no-new-drugs-blame-wall-street>. More layoffs are ahead.

Abbott laid of 700 jobs this year already. Possible layoffs at various other companies and they buy/merge. Amgen is buying Micromet for \$1.16 billion at a 33 percent premium to its market price. Celgene announced the acquisition of a privately-held biotech company, Avila Therapeutics for \$925 million.

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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, 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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