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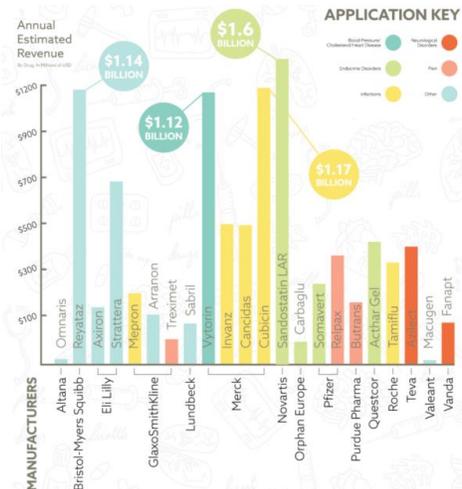
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Issue 156

Dr. Sreenivasarao Vepachedu¹, JD, PhD, LLM

PATENT CLIFF²

AstraZeneca, Eli Lilly, GlaxoSmithKline, Pfizer, Roche, etc. are at risk of losing about \$ 26.5 billion this year due to patent expiration for about 18 branded drugs. Patents expiring include Roche's Rituxan, GSK's Advair, Eli Lilly's Humalog and Cialis, AstraZeneca's Byetta, Pfizer's Viagra and Merck's Vytroin³.



According to an annual analysis of the US drug market by the IMS Institute for Healthcare Informatics, nominal drug spending dropped by 1% in 2012 to \$325.8 billion. It was the first-ever decline in that measure⁴. It was reported that \$55 billion in total drug sales lost patent protection that year⁵. This year, about 45% of the sales at risk looking forward are for biologics⁶. Eli Lilly, Pfizer, Takeda, Bristol-Myers Squibb and Gilead, which brought in more than \$10 billion last year in the US covering multiple sclerosis, HIV, erectile dysfunction and cancer, among others, are each set to hit the patent cliff this year (see Dickson Data graphic, on the left).



Last year, manufacturing issues have pushed the expected approval of Roche's experimental drug for multiple sclerosis to next year, bringing to six the number of drugs whose approvals by the FDA have been delayed because of questions over production⁷.

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
[Swasti](#) Sri HEVILAMBI Year, VISAKHA Month
ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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[Home](#)

[The Foundation](#)

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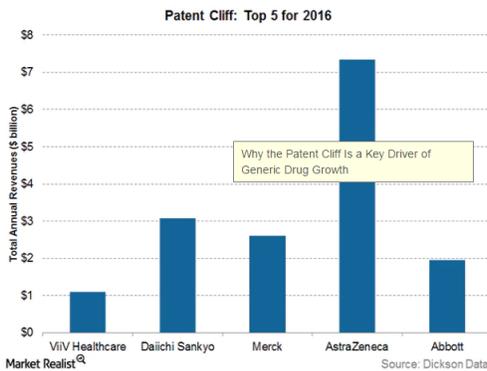
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[VPC](#)

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Patent cliffs have led to steep revenue losses for innovator pharmaceutical companies creating an opportunity for generic and smaller companies to come to market with copies⁸. In 2011 Pfizer lost exclusivity for its anti-cholesterol drug, Lipitor. Generic versions quickly emerged and, by 2014, sales of generic copies handily surpassed Lipitor sales. Novartis and Merck had similar experiences after the expiration of patents for Diovan (high blood pressure medication) and Singulair (asthma medication), respectively, in 2012.

Pharmaceutical companies undergo an expensive and time consuming process to develop new drugs, which entails many years and billions of dollars in research and development, as well as an arduous approval process by the US Food and Drug Administration (FDA). In exchange, the FDA generally provides drug companies with 5 years for small molecules and 12 years for biologics of exclusivity and protection and patent protection for 20 years from the filing of a patent application. Patents are a property right granted by the United States Patent and Trademark Office anytime during the development of a drug and can encompass a wide range of claims. Exclusivity refers to certain delays and prohibitions on approval of competitor drugs available under the statute that attach upon approval of a drug or of certain supplements.

Patents and exclusivity apply to drugs in different ways. Patents can be issued or expire at any time regardless of the drug's approval status. Exclusivity attaches upon approval of a drug product if the statutory requirements are met. Some drugs have both patent and exclusivity protection while others have just one or neither. Patents and exclusivity may or may not run concurrently and may or may not cover the same aspects of the drug product. Patents and exclusivities that have expired are removed from the Orange Book. The holder of marketing approval of the Approved Product from FDA can apply for certification of the extended time for a patent to the USPTO⁹ which provides the patent term extension for maximum period of 5 years¹⁰.

Exclusivity depends on the type of exclusivity is at issue.

- Orphan Drug Exclusivity (ODE) – 7 years
- New Chemical Entity Exclusivity (NCE) – 5 years
- Generating Antibiotic Incentives Now (GAIN) Exclusivity– 5 years added to certain exclusivities
- New Clinical Investigation Exclusivity – 3 years

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

[Swasti](#) Sri HEVILAMBI Year, VISAKHA Month

ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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The Andhra Journal of Industrial News

IP and Industry News

[Home](#)[The Foundation](#)[Management](#)[The Andhra Journal of
Industrial News](#)[The Telangana
Science Journal](#)[Mana Sanskriti
\(Our Culture\)](#)[Vegetarian Links](#)[Disclaimer](#)[Solicitation](#)[Contact](#)[VPC](#)[Vedah-Net](#)

- Pediatric Exclusivity (PED) – 6 months added to existing Patents/Exclusivity
- Patent Challenge (PC) – 180 days (this exclusivity is for ANDAs only)

The Hatch-Waxman Act (HWA) is the informal name given to the Drug Price Competition and Patent Term Restoration Act of 1984¹¹. One of the main provisions of the Act is that it allows for an expedited FDA approval process for generic drugs while also granting certain market and patent exclusivity for both branded and generic drug companies.

Similarly, biosimilars are generic versions of biologic drugs under the Biologics Price Competition and Innovation Act (BPCIA) of the Affordable Care Act (ACA), 2011¹². A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Zarxio (filgrastim-sndz) is the first biosimilar product approved in the United States in 2015. Sandoz, Inc.'s Zarxio is biosimilar to Amgen Inc.'s Neupogen (filgrastim), which was originally licensed in 1991. Zarxio is approved for the same indications as Neupogen¹³.

The FDA typically balances innovation in the pharmaceutical industry with affordable and equitable access to medications by controlling the marketing of brand and generic products, and in the past 3 decades, most disputes around patent and regulatory exclusivities proceed with a high level of transparency around relevant patents as required under both the HWA and BPCIA, through a patent dance between the branded drug maker and the copy maker. The first biosimilar is no exception. However, Snadoz did not comply with one of the provisions of ACA that requires the biosimilar applicant to provide the reference product sponsor a copy of its application and manufacturing information so that the patent dance can begin. Amgen sued Sandoz for refusing to participate in the the patent dance¹⁴.

Congress intended the HWA to encourage generic firms to challenge drug patents in the midst of their terms, in addition to expediting the market entry of generic drugs after patent expiration. As a result, now there is a wasteful litigation involving the so-called patent dance increasing the costs for both branded and generic companies, which would be borne by the patient ultimately¹⁵. Both brand and generic companies typically deduct their litigation costs associated with paragraph IV litigation as ordinary and necessary costs of prosecuting or defending patent infringement¹⁶. The brand firms value deterring entry, on average, is at \$4.6 billion. In contrast, generic firms value the right to enter at \$236.8 million dollars (all values in 2010 dollars). Therefore, the settlements strongly reduce the (per-case) average consumer surplus delivered by Paragraph (iv) litigation¹⁷. Additionally, as IPRs are relatively much less expensive

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
[Swasti](#) Sri HEVILAMBI Year, **VISAKHA** Month
ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



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IP and Industry News

[Home](#)

[The Foundation](#)

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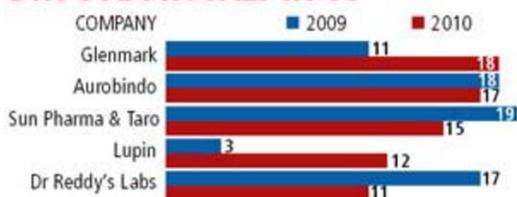
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than litigation and, thus, provide a more cost effective means of invalidating a patent, challengers may choose to make use of IPR proceedings¹⁸. In patent litigation, parallel proceedings before federal courts and the PTO are seemingly routine nowadays¹⁹. The impact of Hatch-Waxman on incentives to innovate has received somewhat less attention. A 1998 report by the Congressional Budget Office estimated that generic competition reduces by 12% the net present value of the total stream of future profits expected from the average brand-name drug. In particular, the Congressional Budget Office found that, for brand-name drugs, the negative effects on returns from generic competition probably outweighed the positive effects of patent term restoration²⁰.

The use of generics has increased substantially since the mid-1990s, in part because of increases in the mechanisms available to promote generic use, including incentives in commercial insurance plans and public coverage, such as tiered formularies with lower patient co-payments for generic than for brand-name drugs, and restricting formulary coverage to generics in certain therapeutic categories. As a result, generic products' share of total prescriptions in the US increased from 36% in 1994 to 84% in 2012²¹. It is estimated that the generics will continue to dominate prescription drug usage in the United States, rising from 88% to 91% to 92% of all prescriptions dispensed by 2020²². The reduction in the number of blockbuster products and shortened market exclusivity periods over time are consistent with the results of other recent studies²³.

The Food and Drug Administration is cracking down on drug makers selling products in the US (mostly generic drugs) that were made at certain plants in India. Generic pharmaceutical industry in India and Israel has benefitted due to the HWA. A 2012 report by visiongain lists 11 Indian companies among the top 50 generic drug manufacturers worldwide. Five Indian companies (Ranbaxy, Cipla, Dr. Reddy's, Sun Pharma and Lupin) are in the top 20, the joint-highest representation for any country. While Teva remains the largest player in the industry, with revenues of over \$10 bn for its generics portfolio in 2011, the competition is growing ever more intense²⁴.

DRUG APPROVALS IN US



As a result of worldwide competition the American jobs have moved out of the US which traditionally depended on the innovative drugs. The FDA has sent warning letters about manufacturing or packaging violations not only to companies with plants in India, but also to companies operating plants in Australia, Austria, Canada, China, Germany, Japan, Ireland, and Spain²⁵. Common issues include inadequate testing and quality checks, inconsistencies in data collection, and contaminated products.

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

[Swasti](#) Sri HEVILAMBI Year, VISAKHA Month

ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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The Andhra Journal of Industrial News

IP and Industry News

[Home](#)[The Foundation](#)[Management](#)[The Andhra Journal of
Industrial News](#)[The Telangana
Science Journal](#)[Mana Sanskriti
\(Our Culture\)](#)[Vegetarian Links](#)[Disclaimer](#)[Solicitation](#)[Contact](#)[VPC](#)[Vedah-Net](#)

When India joined the WTO in 1995, its pharmaceutical exports were valued at less than \$600 Million. Over the last 20 years, India's pharmaceutical industry has evolved from almost nonexistent to a world leader in the production of high quality generic drugs. India has garnered a worldwide reputation for producing high quality, low cost generic drugs. India's pharmaceutical industry is one of the fastest growing segments of the Indian economy with an average annual growth rate of 14 percent during 2002-2005. Overall, the Indian market for pharmaceuticals is projected to grow at an average annual rate of between 15 and 20 percent during 2005-2010. The surge in production has been driven by legislative reforms, the growth in contract manufacturing and outsourcing, value added foreign acquisitions and joint ventures, India's mastery of reverse engineering of patented drug molecules, and India's efforts to comply with its World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPs) obligations²⁶. India has been making inroads into biosimilars also. Many of the Indian companies such as Biocon, Dr Reddy's, Zydus Cadila, Wockhardt, Intas, etc are already active in biosimilar markets in India and other emerging markets. Dr Reddy's Laboratories Ltd, the first Indian firm to rollout a biosimilar, has seen its biologics business grow multiple-fold since the launch of Reditux (rituximab) in 2007 and its products are currently being sold in over 10 emerging markets²⁷. The Generics and Biosimilars Initiative lists more than 60 approved biosimilars in India²⁸. Biosimilars presents a \$240 billion global opportunity for Indian pharmaceuticals industry, while the domestic market is expected to reach \$40 billion by 2030, according to a report²⁹. The market for biosimilars is an attractive one for Indian companies, with Japan being the third-largest market after the US and the European Union (EU), according to a recent report by IMS Institute for Healthcare Informatics³⁰.

A letter from Sandoz to Amgen sparked the original lawsuit. Sandoz told Amgen in 2014, when the FDA accepted its application for Zarxio, that it would not participate in the patent dance and that the letter served as the start of its 180-notice. Amgen then filed a suit, alleging patent infringement. The Federal Circuit Court ruled last year that BPCIA's 180-day provision is mandatory, and that effective notice can only be given after FDA approval. Sandoz petitioned the Supreme Court to hear the case. The Supreme Court held a 70-minute oral argument in Sandoz v. Amgen. The decision will be issued by the end of June, and irrespective of which side the SCOTUS favors, the biosimilars from the rest of the world will be pouring into the US providing cheaper alternatives for Americans³¹.

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
[Swasti](#) Sri HEVILAMBI Year, **VISAKHA** Month
ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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IP and Industry News

[Home](#)

[The Foundation](#)

[Management](#)

[The Andhra Journal of
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[The Telangana
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[Mana Sanskriti
\(Our Culture\)](#)

[Vegetarian Links](#)

[Disclaimer](#)

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[Contact](#)

[VPC](#)

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² A patent cliff refers to a situation when one or more of a company's products' patent protections expire resulting in revenue loss for the company and lay off of scientists and sales personnel, as a result of the expiration that exposes the company's product to generic competition. The generic is then typically granted a 180-day exclusivity period. Generally sold at steep discounts to their branded counterparts, generics often gain large portions of market share from branded drugs in a short amount of time following patent expirations.

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Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

Swasti Sri HEVILAMBI Year, VISAKHA Month

ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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IP and Industry News

[Home](#)

[The Foundation](#)

[Management](#)

[The Andhra Journal of
Industrial News](#)

[The Telangana
Science Journal](#)

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Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

Swasti Sri HEVILAMBI Year, VISAKHA Month

ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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The Andhra Journal of Industrial News

IP and Industry News

[Home](#)[The Foundation](#)[Management](#)[The Andhra Journal of
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Science Journal](#)[Mana Sanskriti
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Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

Swasti Sri HEVILAMBI Year, VISAKHA Month

ISSUE OF APRIL, 2017 AD (Published online MAY 1, 2017)



శ్రీ వేపచేదు విద్యా పీఠము

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IP and Industry News

[Home](#)

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³⁰ The biosimilar opportunity for Indian healthcare companies:

<http://www.livemint.com/Money/3uiuNrRaQ02df5ThEXyCM/The-biosimilar-opportunity-for-Indian-healthcare-companies.html>

Special Report: The Battle For Biosimilars In India: <https://www.ip-watch.org/2016/05/02/special-report-the-battle-for-biosimilars-in-india/>

³¹ SUPREME COURT ORAL ARGUMENT IN SANDOZ V. AMGEN: <http://www.bigmoleculewatch.com/2017/04/26/supreme-court-oral-argument-in-sandoz-v-amgen/>; https://www.supremecourt.gov/oral_arguments/argument_transcripts/2016/15-1039_bqm1.pdf

Patent watch: Have the biosimilar floodgates been opened in the United States? Nature Reviews Drug Discovery 14, 303–304 (2015) <http://www.nature.com/nrd/journal/v14/n5/full/nrd4622.html>

³² In addition to the primary sources cited above, additional references include:

[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.

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“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 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!)

SWASTI! AUM!

Issue 156

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era

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