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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Issue 121

Cost of Developing New Drugs and the “Quid Pro Quo”

“ Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not. As a member of the patent board for several years, while the law authorized a board to grant or refuse patents, I saw with what slow progress a system of general rules could be matured.” Thomas Jefferson to Isaac McPherson, Document 12, 13 Aug. 1813, Writings 13:333-35¹.

The Congress shall have Power to ... promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . .”The US Constitution, Article I, Section 8, Clause 8²

The USPTO registers trademarks based on the commerce clause of the Constitution (Article I, Section 8, Clause 3). Under this system of protection, American industry has flourished. New products have been invented, new uses for old ones discovered, and employment opportunities created for millions of

¹ **The Founders' Constitution**, Volume 3, Article 1, Section 8, Clause 8, Document 12

http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html, The University of Chicago Press

² The United States Patent and Trademark Office (USPTO) is the federal agency for granting U.S. patents and registering trademarks. In doing this, the USPTO fulfills the mandate of Article I, Section 8, Clause 8, of the Constitution, http://www.uspto.gov/about/index.jsp?utm_source=www.domtail.com

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Americans. The strength and vitality of the U.S. economy depends directly on effective mechanisms that protect new ideas and investments in innovation and creativity. The continued demand for patents and trademarks underscores the ingenuity of American inventors and entrepreneurs³.

What price is the modern society willing to pay for innovation⁴? Even when a major breakthrough occurs providing overall savings, payers don't want to pay for it because it is expensive. Again, what is the price that the modern society willing to pay for innovation that extends the life by a few months?

Hepatitis C is a largely asymptomatic disease. It is estimated that three million Americans are infected with this virus, but most don't know they have it and only 20% seek treatment. However, the virus, which resides in the liver, causes scarring, leads to cirrhosis and patients can then develop liver failure and liver cancer.

³ http://www.uspto.gov/about/index.jsp?utm_source=www.domtail.com, accessed on May 31, 2014.

⁴ The costs of pharmaceutical R&D have been studied using several conceptual models and measurement methods.

<http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/>, accessed on May 31, 2014;

How Much does it cost to develop a new drug, <http://www.cptech.org/ip/health/econ/howmuch.html>, accessed on May 31, 2014.

There are three key elements of investment decisions in early stage drug development programs: (1) the nature of the risks at different stages; (2) the probabilities associated with those risks; and (3) the associated discount rates or opportunity costs of capital appropriate for those risks, **Some Simple Economics for Early Stage Drug Development**, <https://aaas.confex.com/aaas/2014/webprogram/Paper12032.html>, accessed on May 31, 2014.

Baras et al., Drug development risk and the cost of capital, *Nature Reviews Drug Discovery* **11**, 347-348 (May 2012); Effects of development phase, market capitalization and industry on CAPM β ; http://www.nature.com/nrd/journal/v11/n5/fig_tab/nrd3722_T1.html, accessed on May 31, 2014.

Cockburn et al., The Cost of Capital for Early- Stage Biotechnology Ventures,

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=3&ved=0CEwQFjAC&url=http%3A%2F%2Fwww.nvca.org%2Findex.php%3Foption%3Dcom_docman%26task%3Ddoc_download%26gid%3D465%26ItemId%3D93&ei=YoKMU9-XNoOOyAS68oCoCw&usq=AFOjCNGE9BGJCpcznNmJxiTp3ttOjKSwg&sig2=mQBE9iNAXY3rCac7I2MILg, accessed on May 31, 2014.

Is the \$1.3 billion new drug a myth? New drugs could be hitting, or even exceeding this mark – it depends on what your assumptions are:

<http://www.sciencebasedmedicine.org/what-does-a-new-drug-cost/> and <http://www.sciencebasedmedicine.org/what-does-a-new-drug-cost-part-ii-the-productivity-problem/>, accessed on May 31, 2014.

Kessel et al., A better prescription for drug-development financing, *Nature Biotechnology* **25**, 859 - 866 (2007).

The Truly Staggering Cost Of Inventing New Drugs, *Forbes*, February 10, 2012; <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>, accessed on May 31, 2014.

On average, it costs \$1.3 billion to bring a new drug to market; <https://lillypad.lilly.com/entry.php?e=1424>, accessed on May 31, 2014.

The US\$ 1 billion drug. A fairytale. http://www.avance.ch/newsletter/docs/avance_on_dimasi.pdf, accessed on May 31, 2014.

Many bioentrepreneurs incorrectly estimate the value of their technology by failing to account adequately for the cost, risk, and time inherent in product development, *Stewart et al.*, Putting a price on biotechnology, http://www.recourts.nl/index_bestanden/MCBB/Pricing_Biotechnology.pdf, accessed on May 31, 2014.

Research and development costs vary widely from one new drug to the next. Those costs depend on the type of drug being developed, the likelihood of failure, and whether the drug is based on a molecule not used before in any pharmaceutical product (a new molecular entity, or NME) or instead is an incremental modification of an existing drug... The federal government spent more than \$25 billion on health-related R&D in 2005. Only some of that spending is explicitly related to the development of new pharmaceuticals. Congressional Budget Office, Research and Development in the Pharmaceutical Industry, October 2006; <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf>, accessed on May 31, 2014.

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Patients were given a cocktail of drugs plus injections of interferon for 24-48 weeks and cure rates range from 40 – 80%, depending on the severity of the disease. However, these drugs are poorly tolerated, particularly the interferon component which causes flu-like symptoms in patients. As a result, many with hepatitis C often avoid treatment.

A breakthrough drug Sovaldi⁵, from Gilead, is a pill that cures hepatitis C in more than 90% of patients in just 12 weeks. It is safer than the older regimens and is roughly 20% cheaper than the older treatments. Gilead is changing \$84,000 per patient for Sovaldi, \$1,000/pill⁶. The costs are hitting Medicaid programs extraordinarily hard because the population of patients in need of Sovaldi tend to have low incomes and wouldn't be able to afford it without the government insurance⁷.

New data from Bristol-Myers Squibb's ongoing Phase III clinical program studying the DCV Dual Regimen is anticipated to be presented at an upcoming scientific forum. Data from a separate daclatasvir and asunaprevir Phase III trial in Japanese patients with HCV genotype 1b who were either interferon-ineligible/intolerant or non-responders (null and partial) to interferon-based therapies served as the basis for a regulatory filing in Japan in October 2013⁸.

Bristol-Myers Squibb also recently announced that the European Medicines Agency (EMA) validated the company's marketing authorization application (MAA) for the use of daclatasvir for the treatment of

⁵ SOVALDI is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf, accessed on May 31, 2014.

⁶ <http://www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/>, accessed on May 31, 2014.

⁷ <http://www.forbes.com/sites/brucejapsen/2014/04/28/pricely-hepatitis-pill-sovaldi-rattles-medicaid-programs/>, accessed on May 31, 2014.

⁸ Approximately 170 million people worldwide are infected with hepatitis C, with an estimated 2.7–3.9 million chronically infected in the United States.

<http://news.bms.com/press-release/bristol-myers-squibb-submits-ndas-daclatasvir-and-asunaprevir-us-fda-treatment-hepatit>, accessed on May 31, 2014. The all-oral combination of Gilead Sciences' Sovaldi (sofosbuvir) and Bristol-Myers Squibb's daclatasvir was associated with high rates of sustained virologic response (SVR) among patients infected with hepatitis C virus (HCV) genotypes 1, 2 and 3.

<http://www.firstwordpharma.com/node/1179624?tsid=33#axzz33UQKtCEV>, accessed on May 31, 2014.

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adults with HCV with compensated liver disease, including genotypes 1, 2, 3, and 4. The application seeks the approval of daclatasvir for use in combination with other agents for the treatment of chronic hepatitis C and will be reviewed under an accelerated regulatory review.

Physicians and insurers are inclined to agree that there no benefit in extending life for a few months with an expensive new drug that costs tens of thousands of dollars⁹. The ethical debates about the value of life vs. the cost to society as a whole is a moot point, because the constitution and the patent laws were enacted only after a thorough debate on such “ethical” issues. However, these motivated debates continue because certain parties do not want to honor the “quid pro quo” agreement that societies have signed off on for the greater good of the society.

When a law is enacted, it must be upheld by all citizens, failure to do so would be breaking the law. The intellectual property laws and the laws under which various federal agencies such as FDA operate and grant monopolies to innovators, and the granted monopolies for a short period of time for the greater good of the society must be upheld, except under national emergencies as agreed under WTO regime. It would be unethical to dishonor the monopolies granted because the cost of a new innovative drug is out of common man’s reach. If there is a compelling reason, other than a national emergency, various interested parties may subsidize the cost approved for a drug by the government and honor the patent monopoly granted by the government, There should not be any ethical concern in paying \$84,000 per patient for Sovaldi, \$1,000/pill, which is 20% cheaper than the older treatments, provided the doctors and patient decide to undergo the treatment to extend the life of the patient by few months. Obviously, this few months of extension of life is affordable to only rich. While the poor may get the same life extension provided charitable institutions pitch in to defray the cost, without squeezing the insurance providers or the tax payers. We have non-profit organizations that are encouraged by the IRS to contribute to the welfare of the poor, e.g., AIDS Drug Assistance Programs (ADAPs) provide HIV-related prescription drugs to low-income people with HIV/AIDS who have limited or no prescription drug coverage¹⁰.

There is no reason to break any legitimate monopolies granted by the USPTO or FDA, our commitment to innovation, and our ethical obligations to extend the life of a poor dying homeless person with HCV

⁹ What Price Innovation? The Sovaldi Saga, Forbes, May 29, 2014, <http://www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/>, accessed on May 31, 2014.

¹⁰ AIDS Drug Assistance Programs (ADAPs), April 08, 2014; <http://kff.org/hiv/aids/fact-sheet/aids-drug-assistance-programs/>, accessed on May 31, 2014.

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infection or other disease, or to impose an additional burden on the insurance provider or the tax payer. The constitutionally mandated “Quid pro Quo”¹¹ must be honored, until the Constitution is amended¹² and the related laws are changed.

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.

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!)

¹¹ Written Description: Protecting the Quid Pro Quo Since 1793, <http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1278&context=iplj> , accessed on May 31, 2014.

¹² The authority to amend the Constitution of the United States is derived from Article V of the Constitution. The Constitution provides that an amendment may be proposed either by the Congress with a two-thirds majority vote in both the House of Representatives and the Senate or by a constitutional convention called for by two-thirds of the State legislatures. <http://www.archives.gov/federal-register/constitution/>, accessed on May 31, 2014.

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