American child of working-class, immigrant parents. I am also a human being, and the hurt inflicted and felt at Cure that night had a physical, palpable presence. A curtain had been momentarily lifted to

cians. But in private conversations with fellow students about the Cure event and the Stephanie Grace e-mail, there has been a recurring theme: What would it

about a racism that has become embedded, diffuse, and often subtle, unless we can describe it, know it, and speak about it?

This page is Page 6
--JJD

Debunking the "Evergreening" Patents Myth

By Jonathan J. Darrow

Much has been said lately about the difficulty of obtaining medicine at reasonable prices, and with ~~good reason~~: Important new drugs are often priced out of the reach of some consumers, and prices may rise over time until the drug's patent expires.

Blame for high prices is often placed on pharmaceutical companies that engage in "evergreening" practices, which industry critics define as manufacturers' practice of making minor variations to existing drugs to extend their patent coverage or, as one pundit put it, where "the patents never fall off the branches."

However, such characterizations of evergreening have little basis in U.S. patent law and perpetuate the myth that patents can be "extended" by minor modifications to existing products. The facts show otherwise: United States patents filed on or after June 8, 1995, last for 20 years, after which time the covered invention falls into the public domain and can be made, used, or sold by anyone. This 20-year patent term applies as much to patents in the pharmaceutical industry as to those in all other sectors, and product prices sometimes fall rapidly after patent expiration. (Extensions of up to five years may be granted for delays in obtaining the patent in the U.S. Patent & Trademark Office or time lost during the FDA approval process, but these extensions are generally not the object of critics' ire.)

In fact, critics are frequently surprised to discover that the effective life for drug patents is often far less than twenty years, owing in part to the lag between when a patent is filed (at which time the 20-year term begins to run) and when it is first sold on the market (after the long FDA approval process has been completed).

Those who fulminate against patent evergreening point out that drug companies employ a variety of tactics to maintain revenue streams for as long as possible. True enough. Companies do often patent minor modifications to existing drugs as well as new processes to make old drugs, new formulations of old drugs, new packaging of old drugs, and many other variations. Often these additional patents are sought shortly before the primary patent's expiration. But suggesting that these "extend" the effective patent term of the original product involves a bit of analytical slight of hand. This type of evergreening strategy only works if consumers and doctors can be persuaded to demand the new, patented, slightly modified – and often much more expensive – version of the old drug. The old drug, which is no longer subject to patent protection, is in the public domain. Although drug companies have obtained a new patent, the patent on the original drug product hasn't been extended at all.

While there are endless examples of this type of evergreening, one of the most cited is the patent obtained by AstraZeneca on Nexium (esomeprazole), a product introduced shortly before AstraZeneca's protection on Prilosec (omeprazole) was about to expire. The two drugs are nearly identical not only in chemical structure (their generic names hint at just how similar they are), but also in efficacy and side effects. Nevertheless, in 2009 doctors prescribed – and patients worldwide consumed – $7.8 billion worth of the evergreened Nexium rather than Prilosec, according to consultancy IMS Health. That year Nexium ranked as the world's third-highest revenue drug, far ahead of Prilosec, which did not even make the top 15. Never mind that cheap generic versions of Prilosec are available now that the original Prilosec patent has expired and even though the drug can now be obtained over-the-counter without a visit to the doctor. Pharmaceutical companies, it seems, have been very successful in convincing consumers and doctors that the newer version is worth the extra cost.

Clearly, there is room for improvement. Moreover, it is not clear that any patent system is appropriate when it comes to life-saving drugs that much of the world's population cannot afford. Nevertheless, we should be careful not to wrongly condemn the current patent system based on a misleading characterization of its provisions. When it comes to expensive evergreened drugs, one should look no further than the person in the mirror (and his or her doctor) to blame someone for paying a much higher price for essentially the same medicine.

Consumers, of course, are not well-positioned to know that Nexium is not meaningfully better than Prilosec. Likewise, consumers generally have little reason to know that a drug called Sarafem, used to treat severe PMS and exorbitantly priced at $9.00 per pill at one online drugstore, contains the identical active ingredient as Prozac, a depression medication with generic versions available for $0.83 per pill. Why doctors, insurance companies, and regulators such as the FDA are failing to guide consumers to the best drug products has been the subject of a growing number of books, journal articles, and news reports, but it generally boils down to substantial industry influence at every level.

Fortunately, consumers in the United States seeking to avoid gratuitous transfers of wealth to the pharmaceutical industry for newly patented versions of older drugs have a resource. Any consumer can examine the website of Consumer Reports Best Buy Drugs, launched in 2004, and learn that Prilosec and Nexium are "roughly equal in effectiveness and safety but differ in cost." And, Consumer Reports might have added, in patent protection.

The Independent Newspaper at Harvard Law School

Harvard Law Record

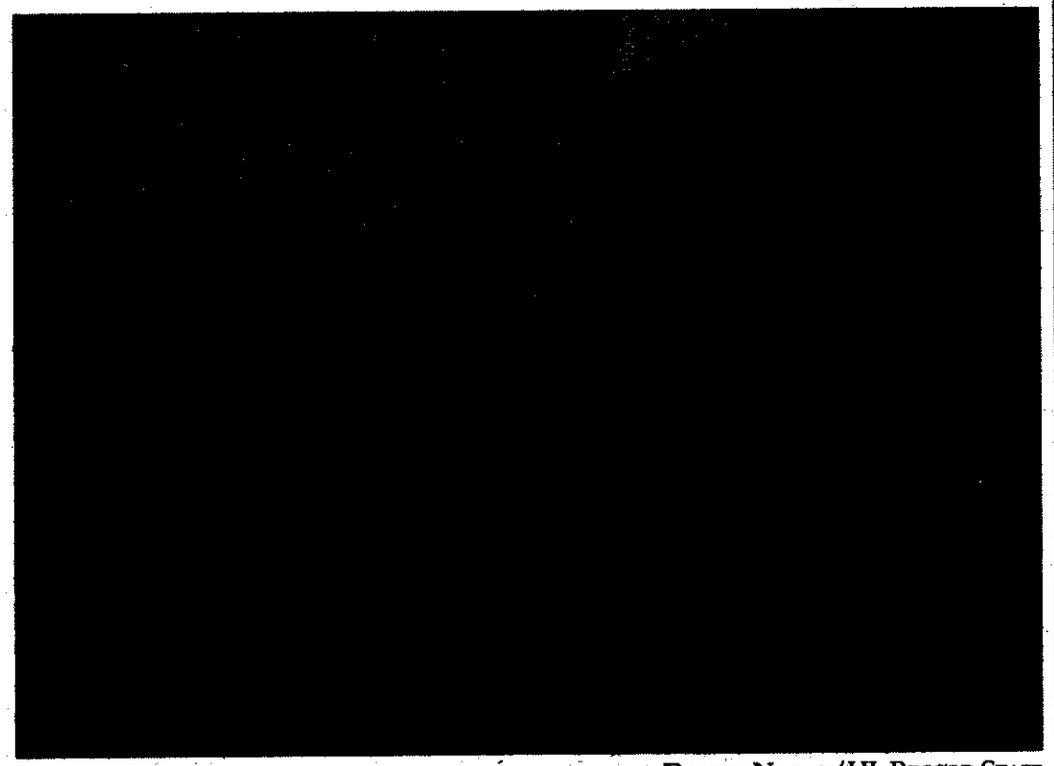
December 8, 2010 www.hlrecord.org — twitter @hlrecord Vol. CXXXI, No. 3

Leaders Celebrate EPA Founding

BY DANIEL NAZAR

Past and present Environmental Protection Agency leaders joined other government officials, leaders of non-profit organizations, and academic scholars to celebrate the 40 years since the EPA's founding on Friday, Dec. 3. The conference, held in the Ames Courtroom and Ropes-Gray Hall, featured panel discussions offering frank discussions of the EPA's history and mission, bipartisanship, and global warming.

Former Vice President and environmental advocate Al Gore spoke to a packed auditorium during lunch. There he remarked on the bipartisan spirit that had created the EPA in 1970 and congratulated William Ruckelshaus '60 for his successful bipartisan leadership as founding EPA Administrator. Gore advocated a return to that



DANIEL NAZAR/HL RECORD STAFF

Former Vice President Al Gore advocated a return to bipartisan leadership and decisionmaking during his remarks at a celebration of the EPA.

vative Republican doing that today?"

Speaking on the EPA's future, the former administra-

dom is not the absence of restraint, but a system of restraints," and that as the United States and its envi-

tion. "If you want to confront climate change, you first have to confront the discussion so we can have

HLS Students Sue TSA

BY JENNY PAUL AND JOEY SEILER

Two Harvard Law students have filed a federal lawsuit against the Transportation Security Administration that claims the use of "nude body scanners" and new enhanced pat-down techniques at airport security checkpoints are unconstitutional.

Jeffrey Redfern '12 and Anant Pradhan '12 filed the lawsuit Monday, Nov. 30 in the District Court of Massachusetts. The complaint names Secretary of Homeland Security Janet Napolitano and TSA Administrator John Pistole as defendants.

Beginning in March 2010, the TSA deployed 450 full-body scanners in airports throughout the country. Boston's Logan International Airport has 17 of the full-body scanners at issue in the lawsuit, according to the