

Text from AUTM, the Association of University Technology Managers

*AUTM is a global network of more than 3,200 technology transfer professionals who work in academic, research, government, legal and commercial settings. AUTM is dedicated to promoting and supporting technology transfer through education, advocacy, networking and communication.*

## **Introduction**

We in the university community find ourselves perhaps uniquely challenged among all clients of the USPTO given the mandate of our investigators both to create and disseminate knowledge; a proposition and practice that has been supported - at least in the US pre-AIA - by the grace period for scientific publications. The university community was supportive in the course of negotiations toward implementation and harmonization, but now that the US has moved to First Inventor to File, an expectation of reciprocal moves on the part of others is not an unreasonable request. However, given our current understanding of the grace period under the AIA, it is not clear whether any such request will or should be considered. As interpreted by USPTO, disclosures during the grace period must be essentially identical for the grace period to apply. Presumably even a minor modification in a subsequent disclosure would be disqualifying "prior art." Such a narrow grace period does not serve the interests of many U.S. stakeholders, and particularly disadvantages U.S. universities.

As mentioned above, a fundamental goal of higher education is to publish scientific papers advancing human knowledge. However, expectations from state and federal governments place increasingly high expectations on the academic research enterprise to contribute to technology based economic development - which is increasingly combined with a need to protect intellectual property arising from

publicly financed R&D. This expectation, along with an increasingly globalized economy, means that uncertainty in interpretation of, or, outside of the US, an absence of a grace period, likely means that scientists will either hesitate to publish, or will lose their ability to pursue patenting. Having to make such a choice is not in the interest of science or economic development, and undermines the intent of intellectual property law in promoting innovation. Academic community norms tend to place a higher priority on publishing than patenting.

The combined effect also appears disadvantageous to U.S. universities and their ability to play a catalytic role in driving economic growth by leveraging their intellectual property assets.

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## **Background**

U.S. research universities play an important role both in educating people from around the world driving forward the frontiers of knowledge, and as a source of new technologies driving the economy. This dual role makes it very important that research results be promptly published while at the same time universities and other non-profit organizations must be cognizant of protecting patent rights arising from federal funding entrusted to them to manage under the Bayh-Dole Act. This creates a unique pressure for the university research community typically not felt by industrial organizations. In order to achieve the social expectations for creating knowledge and for partnering with industry to create new products, jobs and companies, having a grace period for filing patents is very important both in the U.S. and around the world. As such, harmonization of international patent laws is a critical goal in today's global economy.

To realize the scope of what is at stake, academic research institutions

spent \$54.9 billion on science and engineering in 2009, of which \$32.6 billion was federally funded. This investment represents 36% of all U.S. research and 53% of U.S. basic research - precisely where new industries such as biotechnology are created provided adequate patent protection is available. Indeed, because 60% of academic research is spent on the life sciences, the ability to secure strong patents is vital for commercial development and economic growth. It is estimated that for every dollar spent on academic research, companies must spend \$10 of their own funds for development. In the development of new drugs, this industry investment averages between \$1.3 billion to \$4 billion per drug -- and may even reach as much as \$11 billion per drug according to Forbes magazine: (<http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>). Even after such investments are made, commercial success is not guaranteed.

The pharmaceutical industry has eliminated many tens of thousands of basic research and discovery scientist positions from pay rolls in the last decade, fundamentally changing the profile of the industry and the outlook for the introduction of new medicines to the market.

In partial response to the changed global business environment for the industry, companies are increasingly relying on universities as essential partners able to provide new products for their drug development pipelines in an effort to find new therapies to alleviate human suffering. However, without the certainty afforded by strong patents, such efforts and major investments will likely not be made. If the results of academic research are published before patents are filed under the new first inventor to file system, the chances of the public benefiting from new treatments in the marketplace are reduced significantly.

According to a recent study in the **New England Journal of Medicine**, 153 new drugs, vaccines or new applications of existing drugs are protecting health around the globe because of federally funded

research that produced inventions -- primarily from universities-- patented and licensed under the Bayh-Dole Act (*The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, Stevens, Rohrbaugh, et al., *The New England Journal of Medicine*, February 10, 2011, pp. 536- 541. Before enactment of Bayh-Dole, no drugs had been developed when patents had been taken away from the inventing universities, thus denying taxpayers the benefits of research they are funding.

The development of new medicines is not the only area in which university technologies play an important role in shaping society; the energy sector, clean fuels and bio-agriculture industries all benefit from advances originating in our universities.

U.S. academic inventions are important drivers of the economy: between 1996 and 2010, university patent licensing contributed approximately \$836 billion to U.S. gross domestic output, \$388 billion to gross domestic product, while supporting 3 million good paying jobs (*The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2010*

(<http://www.bio.org/articles/economic-contribution-universitynonprofit-inventions-united-states-1996-2010>). According to the 2011 survey of the Association of University Technology Managers, university patented inventions spurred the creation of 591 new products and 670 startup companies across the U.S. Currently 3,927 university spinoff companies are in operation, creating new jobs and benefits for American taxpayers. Without provision for an adequate grace period, these benefits are all in jeopardy.

The U.S. is not alone in facing this challenge, as countries around the world are looking to integrate their own research universities into their economic systems. Without strong patent protection, accomplishing this is made much less likely.

AUTM welcomes the opportunity to address this group and remains ready to provide input into the important discussion on patent harmonization. In particular, we reference the impact of changes on the ability of society to reap the full benefit of innovations created in universities around the world by use of well-crafted patent law.