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Issues & Perspectives

The America Invents Act for Academic Scientists

On 16 September 2011, President Barack Obama signed into law HR1249, the Leahy-Smith America Invents Act

(<http://www.govtrack.us/congress/bill.xpd?bill=h112-1249>), which has been described as the most important change in U.S. patent legislation since 1952, when the structure of modern patent law was established. Given the significance of the changes, we wondered: Are any of them important for scientists – academic scientists in particular – who may wish to commercialize the research arising from their labs or the technologies they develop?

We interviewed Erich E. Veitenheimer by e-mail to find out. He is a senior partner in the intellectual property (IP) law firm Cooley LLP. Veitenheimer earned a Ph.D. in plant breeding and genetics, with a minor in statistics, from the University of Wisconsin, Madison and, later, a law degree from Georgetown University in Washington, D.C. The Cooley firm represents Montana State University, New York University, Yale University, the University of Miami, Regents of the University of California, the Howard Hughes Medical Institute, and other academic and non-profit universities and institutions in IP matters. They also handle university intellectual property that has been in-licensed by a large number of small to mid-size companies, particularly in the life sciences, biotechnology, and pharmaceuticals space.

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Q: The Leahy-Smith America Invents Act (AIA) has been called the biggest change to U.S. patent law in 60 years. Please explain the changes most important to academic scientists who may wish to commercialize their science.

E.V.: The most important change the AIA makes is changing the U.S. patent system from a first-to-invent (FTI) system to a first-inventor-to-file (FITF) system. This aspect of the law affects all patent applications with a priority date on or after 16 March 2013 -- that is, to all patents filed on or after that date. The change to a FITF system brings the United States into alignment with the European Patent Office (EPO) and many other countries. However, the AIA has a grace period (discussed below) while the EPO doesn't. This is a major difference that has important implications for patenting strategy.

Next, the new law creates a "micro-entity" status that will result in lower patenting fees on qualifying individuals and academic institutions. While this provision was due to be effective upon enactment (16 September 2011), the U.S. Patent & Trademark Office has up to 18 months to develop the regulations to identify exactly which fees will be eligible for the reduction. The U.S. Patent & Trademark Office has issued a timetable that shows they expect to promulgate the regulations by February 2013.

In a third major change, the AIA provides for a new 9-month opening after a patent issues in which any third party may initiate a post-grant review of the patent. This review is somewhat similar to the patent-opposition procedures available in other countries, such as the EPO, and possibly allows for a less costly way of challenging patents than through an *inter partes* patent reexamination or a lawsuit. It has long been necessary to monitor published patent applications in order to timely file third-party submissions. Now it may also be necessary to monitor newly issued patents for the same purposes.

Under the AIA, academic scientists (and others) will now have 6 months from the publication of a patent application (by others) to submit prior art (e.g., disclosures, publications) that they believe the examiner should consider. Previously, this time period was 3 months. In addition, third parties can now provide comments on the relevance of the prior art they submit; no such comments were permitted prior to the AIA. Of course, taking advantage of this option will require becoming aware of the published application before the end of the 6-month window. So it's more important than ever to monitor the databases of published patent applications for patents on work that's similar to yours.

Q: It sounds like the most important change is the change from first-to-invent system to first-inventor-to-file system with a grace period. What are the implications of this change for how academic scientists and their institutions should think about issues such as disclosure?

E.V.: The AIA does away with the current 12-month grace period during which disclosures of the invention by others did not necessarily constitute novelty-defeating prior art. In other words, if someone else discloses the invention first -- in a scientific journal article, for example -- under the old law you might still be able to patent it, but under the new law, you can't.

However, the AIA still allows for such a grace period for disclosures by the inventor himself or herself, a joint inventor, or any third party who obtained the invention from them. So, if you disclose the invention yourself (in a journal article, for example), you then have 12 months to file your patent application, as long as you're the first to describe that invention in a publication.

Some have said that because of this grace period, the new law effectively creates a hybrid "first to file or publish" rule that encourages publication of inventions, particularly by academics. This conclusion appears to be substantiated by the following pre-passage legislative history:

An inventor who publishes his invention retains an absolute right to priority if he files an application within one year of his disclosure. No application effectively filed after his disclosure, and no prior art disclosed after his disclosure, can defeat his patent application. 157 Cong. Rec. 1348, 1365-66 (8 March 2011)



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Erich E. Veintenheimer

Historically, academic technology transfer offices (TTOs) have trained their academic scientists *not* to publish before filing a patent application, because under the previous system any disclosure by themselves or others, even one day prior to filing a patent application, could legally eliminate the possibility of patenting the invention in major non-U.S. countries. It remains true that whenever an academic and his or her tech-transfer office only plan to file a patent application in the United States (and other countries with an applicable grace period) -- or they want to prevent others from patenting their invention -- publishing their invention as soon as possible is probably a good idea.

Of course, as was also true before the AIA, publishing also eliminates the ability to maintain the invention as a trade secret or proceed in secrecy after filing a patent application and before it publishes as such 18 months later. Another potential problem with publishing first is that often publications are not as complete as a patent application filing would be, so it's not as effective in protecting your IP even in places where there is a grace period.

If there is interest in patenting the invention in countries without an applicable grace period, then an application should be filed prior to publishing it. Given the confusion being generated by the FITF system, it will be even harder for TTOs to reign in publication-hungry academic researchers.

Q: It sounds like international differences in patent law are important, even under the new law.

E.V.: Yes. About 40 other countries have some sort of a grace period, though usually they're more limited than the new grace period in the new U.S. law. For example, some countries only have a 6-month grace period for disclosures by the inventor, while others only allow a grace period for disclosures at government-sponsored forums.

But -- and this is the most important point -- the European Patent Office does NOT have a grace period. So, while U.S. law still provides an incentive to publish as a way of establishing an invention, under European patent law people who publish before they file a patent application aren't protected. Someone else could file the patent before you and gain priority in Europe. Publishing, then, can be a good strategy for United States patents but if you want to protect your

invention in Europe, you still should file your patent application before publishing.

Q: In practical terms, doesn't an inventor -- including an academic scientist -- always care about Europe, too, these days? Is there ever a case where an inventor only cares about patenting in the United States?

E.V.: Individual inventors generally believe their inventions are so useful, innovative, and commercially relevant that they would patent worldwide if they could and did not have to pay for it. The institutions are generally more practical, but also very aware that their potential licensees (many of which are international corporations) may only be interested if they can market it outside of the United States, too.

Individual inventors and their institutions reluctantly settle for patenting only in the United States where budgets dictate -- i.e., when there is no potential licensee in sight -- and/or where we are successful in convincing them that some disclosing activity they did within the past year (a poster session, public talk, etc.) precludes them from getting patents anywhere of economic usefulness except for the United States.

Q: So, to summarize, in most cases, in practical terms, the publishing-versus-patenting calculation of a U.S. scientist at an academic institution probably won't change as a result of the new law. They should still file first and publish later. Correct?

E.V.: In special cases, some described above, it might make sense to publish first. But in the majority of cases, it still makes sense to file a patent application first.

Q: Are there other important differences between United States and European patent law?

E.V.: Most notably, the EPO is more restrictive on what kinds of inventions in the life sciences are eligible for patenting. For example, plant varieties per se are not patentable in the EPO but remain patentable in the United States.

Q: Help us understand the timing. When do people need to start thinking about these changes?

E.V.: The new 12-month grace period of the AIA goes into effect on 15 March 2013. Patent applications filed on or after 15 March 2013 will be protected by the new grace period, so any article published after 15 March 2012 will establish your priority under U.S. law. Alternatively, whenever an inventor believes someone else has already filed or is about to file a patent application on an invention that they invented earlier, then they should consider filing an application for that invention before 15 March 2013 so that it will still fall under the old FTI system.

Q: One thing academic scientists hear a lot about is the importance of good record keeping for protecting intellectual property. In my experience, this is an area where academic laboratories often fall short. Does the new system change the way we should think about keeping records?

E.V.: Under the old system, TTOs encouraged their academic scientists to maintain good records of their conception and reduction-to-practice of an invention, in case a patent or patent application was pulled into a patent interference used to determine who invented it first.

Now, with the FITF system and elimination of the patent interference option, academics may falsely believe they no longer need to maintain such records. In fact, they need to maintain even more complete records under the AIA, since it provides procedures for them to allege that an invention claimed by another was actually derived from their own invention. "Substantial evidence" of such derivation is necessary under the AIA to prevail on such a claim, so it is now even more important to maintain a complete record of any correspondence with third parties regarding their research and findings.

Q: Is the new "micro-entity" status relevant to people working at universities or medical centers where research is done?

E.V.: Such people can qualify as a micro-entity and enjoy a 75% reduction on some patent-related government fees if they can certify: (1) that their employer, from whom the majority of his/her income is obtained, is an institution of higher education as defined in the Higher Education Act of 1965; or (2) the applicant has assigned, granted, or conveyed, or is under an obligation to assign, grant, or convey, an ownership interest in the application to such an institution of higher education.

Q: Any closing words?

E.V.: Although the AIA appears to favor early publication of an invention along with the filing of a patent application within 12 months of publication, in reality the more prudent practice would still be to file patent applications early, often, and completely. Given that others may publish and/or file on their inventions first, it is safest to file patent applications for each new invention or further improvement of an invention so as not to lose the ability to patent them for yourself. For example, the long-standing practice of filing a series of provisional patent applications that could later be combined into a single utility patent application appears to be even more favored under the FITF system. Such a process could, however, be a problem for TTOs without a licensee for the invention and facing somewhat more limited budgets

compared to large corporations.

Q: Thank you for taking the time to share your knowledge with us.

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