

How to avoid filing catastrophes under the America Invents Act

Jeremy Cubert and **Eric Silverman** introduce readers to Pharmville, USA, a futuristic community of inventors operating after full implementation of the America Invents Act

Welcome to United States patent practice under the Leahy-Smith America Invents Act (AIA) of 2011! The year is 2014, and all provisions of the AIA are in full effect. Let's have a look around at a typical day in a place called Pharmville, USA, where drugs and small molecules are nurtured and developed.

First to publish and perish?

The residents of Pharmville are attending a drug development conference and all participants have signed a confidentiality agreement. Today's topic is WonderDrug, and Phil from PharmCo gives a presentation on the difficulties associated with making stable liquid formulations of the drug.

Doris, from DrugCo, approaches Phil after his talk and asks how PharmCo plans to solve the stability problem. Phil replies that PharmCo is working on making stable formulations. In fact, says Phil, "our paper on stable, liquid WonderDrug formulations is coming out next week in Pharmville Formulation".

Doris smiles, excuses herself, and enters an empty room. She calls DrugCo's patent attorney and reminds him that she had also been working on stable formulations of WonderDrug. She asks the patent attorney to immediately draft and file a patent application on stable formulations of WonderDrug based on the laboratory notebooks that she will have couriered to him documenting DrugCo's work. By the end of the day, DrugCo has filed a provisional patent application on stable WonderDrug formulations.

A week later, Phil's paper is published. He realizes he neglected to ask PharmCo's patent counsel to file a patent application and calls him right away. PharmCo's patent application is filed four weeks later. Phil is relieved to find out that under the AIA, his own publication is not prior art against his patent application. But should Phil relax at all? (See figure 1.)

While Phil's article will not be prior art against his patent application, Doris's patent application will. Under new 35 USC § 102(a)(2), a patent cannot issue if the invention was described in a US patent or published US patent application effectively filed by another before the applicant's effective filing date. The exception of 35 USC § 102(b)(1)(A) applies only to disclosures by the inventor or someone who derived the subject matter from the inventor. Doris is not the inventor of the PharmCo application, and her laboratory notebooks are strong evidence that she developed the WonderDrug formulation on her own, and did not derive it from Phil. Thus, even though Phil published before Doris filed her application, due to Phil's delay in filing,

One-minute read



Under the America Invents Act, patent filing is meant to be a more straightforward process. Rather than inviting complicated interference proceedings over inventorship, AIA encourages a true inventor to get to the patent office quickly in order to secure his or her invention. But, as the residents of Pharmville, USA find out in these hypothetical scenarios, the first-to-file system that will take effect March of 2013 under the America Invents Act includes its own complexities. Inventors and assignees must be more diligent than ever in these early years of the new law in order to avoid losing crucial patent priority rights.

Welcome to Pharmville



Figure 1

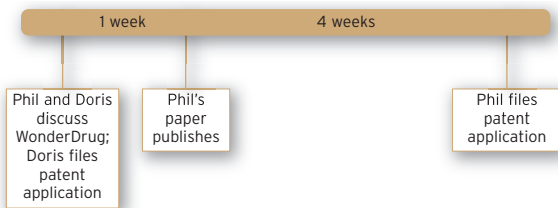
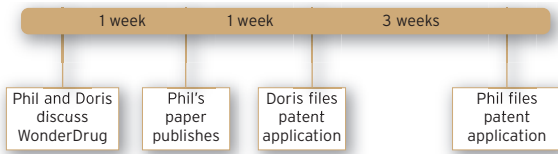


Figure 2



he is not protected from her earlier patent priority date. Since Doris has laboratory notebooks supporting her work before she even attended the conference, Phil will not be able to show that Doris derived the invention from Phil.

Now what if Doris's package with the laboratory notebooks fell out of the back of the delivery truck and didn't arrive at the patent attorney's office for two weeks? In this scenario, Phil's article was published before Doris's application was filed and Phil's application was filed after Doris's application. (See figure 2).

Who gets priority under the AIA? No one. While Phil's article is not prior art to Phil's application, it is prior art to Doris's application. Doris's application will be prior art to Phil's application.

Under the AIA, being first to publish might appear to be a good idea and may still be valuable in preventing others from obtaining a patent on the disclosed subject matter. However, tipping off competitors regarding your publishing and patenting activities may be harmful even if you are careful not to disclose the content of your invention. You may spur a competitor to race you to the patent office and you may not win the race. In the good old days before the AIA, a patent interference may have given Phil a chance to show he conceived the invention before Doris. But in 2014, under the AIA, the foot race to the patent office is the controlling factor unless Doris derived the invention from Phil.

Preserve and prevent

How could Phil have preserved PharmCo's priority right? Phil should have filed, at a minimum, a provisional patent application disclosing the contents of his paper before the conference. Ideally, a patent application should have been filed before his article was even submitted to the journal for review. Under the

Disclose and file with care

- File patent applications as early as possible (this tip applies both before and after AIA).
- Develop procedures to file provisional applications rapidly when needed.
- Be careful not to spur the competition into filing or publishing by disclosing enough information to give away your development plans or progress even if you do not disclose the invention.
- Note that the one year grace period does not apply to publications by others.
- Strategic publications designed to prevent competitors from obtaining a patent are more important under the AIA because of the more limited grace period.
- Preserve, witness, and sign laboratory notebooks as before for possible use in derivation proceedings.

AIA, the best practice is to file patent applications prior to any public disclosures – especially where the disclosures are planned and under the control of PharmCo.

Inventors should develop procedures for filing quick provisional patent applications for emergency situations. For example, provisional patent application form cover sheets should be available for rapid filing of presentations, posters and abstracts as provisional patent applications before a public disclosure. Although rushed filing of a provisional is not ideal, it may protect against the harsh impact of a first inventor to file system where the one year grace period is not available for public disclosures by others.

The new grace period

Although a one year grace period to file a patent application is still available under the AIA, the grace period protection is not available for most publications of others. Under the AIA, the grace period is personal to the inventor, and offers only limited protection from third-party publications. Prior to 2014, if Doris had published a paper disclosing the invention prior to the conference, Phil could swear behind the publication if he filed his application within a year of Doris's publication. But under the AIA, if Phil does not file his application before Doris publishes, Phil loses priority. Even if Phil publishes before Doris, Doris's publication defeats Phil's patent application if Doris's publication comes out before Phil files his patent application. The AIA's limited grace period does not protect Phil from Doris's prior publication. Phil's patent rights can perish even if he publishes before Doris.

The narrowing of the one year grace period offers new opportunities for so-called defensive publications to prevent



Figure 3

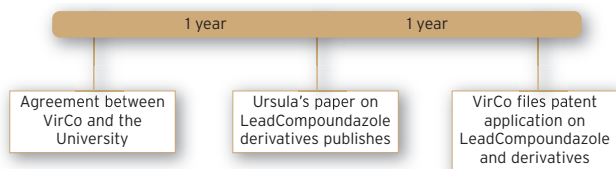
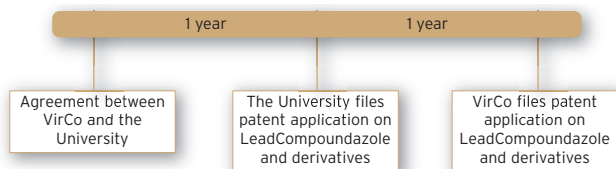


Figure 4



others from obtaining patent protection. Assume that Doris calls her patent attorney in front of Phil and says: "File my patent application on stable WonderDrug formulations tomorrow!" Phil, in shock, calls the journal planning to publish his article and has his article published on the internet the same day. In this case, Phil did not derive the invention from Doris and published his paper before Doris could file her patent application. Since no grace period applies to Doris's application with respect to Phil's publication, she is precluded from obtaining her patent because of Phil's publication. Likewise, because Doris filed her patent application before Phil, her earlier filing date precludes Phil from obtaining a patent. Phil's defensive publication precluded Doris from obtaining a patent.

Derive and conquer

Victor, a vice president of VirCo, oversees research into new anti-viral drugs. A VirCo scientist has just isolated LeadCompound-azole from the warts of an exotic frog. LeadCompound-azole shows excellent activity against pox viruses in animal studies, but its cytotoxicity is too high for humans. Victor would like to synthesise and test derivatives of LeadCompound-azole, but VirCo does not have staff or funding for the job. Instead, Victor contacts a well-known chemist, Professor Ursula, at the University of Pharmville and proposes a collaboration. Ursula puts Victor in touch with the University technology transfer office and a collaborative agreement is signed.

Under the agreement, VirCo will provide samples of LeadCompound-azole, and

Dodge derivation problems

- The scope of the one-year grace period under the AIA's first-inventor-to-file scheme is much narrower than under the old laws, so inventors must take extra care to safeguard proprietary subject matter until a patent application is filed in the United States.
- Maintaining records of inventions, such as laboratory notebooks, is still important despite the first-inventor-to-file provisions of the AIA. These records could be important evidence in derivation proceedings before the USPTO or in civil derivation proceedings.
- Derivation proceedings before the USPTO or in civil court offer only limited protection because of narrow time frame for filing.
- Because of the narrow grace period under first-inventor-to-file provisions and the limited protection of derivation proceedings, monitoring the activities of both collaborators and competitors is even more important under the AIA than it was under the pre-AIA patent laws.

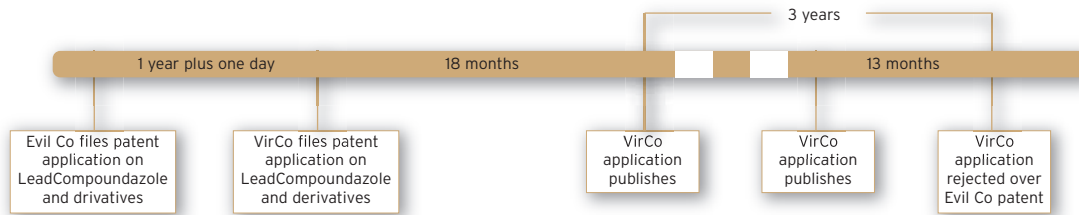
Ursula's laboratory will synthesise a library of LeadCompound-azole derivatives – drugs with similar chemical structures, but hopefully having lower toxicity. The agreement also specifies that VirCo will own all intellectual property rights in the derivatives and specific methods of making them, but the University retains the rights to any generally applicable synthetic methods that Ursula may develop. The University agrees to give VirCo royalty-free non-exclusive licences to synthesise LeadDrug-azole derivatives using any methods developed during the collaboration.

Two years later, Victor asks Ursula for an update. "Oh," says Ursula. "We've synthesised a dozen LeadCompound-azole derivatives already! Didn't you see our paper in the Pharmville Organic Chemistry Journal? It was published almost one year ago." Victor looks up the journal, and finds Ursula's paper, which depicts not only the chemical structure of LeadCompound-azole, but also the structure of a dozen derivatives. Victor asks VirCo's patent attorney to file a patent application immediately. VirCo's attorney files the application exactly one year to the day after Ursula's manuscript was published. But Victor is still worried. He knows that, under the AIA a paper by the VirCo scientists is not prior art against the VirCo's patent application if the application is filed within one year, but what about Ursula's publication? (See figure 3).

Ursula's publication will not be prior art against VirCo's patent application if VirCo can show that Ursula's work was obtained from VirCo under new 35 USC § 102(b)(1)(B). If VirCo scientists maintained proper laboratory notebooks that were signed and witnessed each week, then they should be



Figure 5



able to show that VirCo invented LeadCompound-azole. But in order to show that they also invented the derivatives, VirCo will likely need evidence that they came up with the idea to synthesize the derivatives. If Victor can show that Ursula’s publication was obtained from VirCo, then the publication will not be prior art against VirCo’s application. Note that under the AIA, an assignee can file an application and is deemed to be the applicant. Thus, even though Ursula is an inventor, VirCo can file without her and correct the inventorship later.

Victor then learns that the University filed a patent application on the LeadDrug-azole derivatives. VirCo claims all rights to that application under the research agreement, but due to a defect, the agreement is held invalid. Does VirCo have any recourse? (See figure 4).

Yes, VirCo can petition to institute a derivation proceeding before the USPTO under new 35 USC § 135(a), alleging that the University and Ursula derived the invention from VirCo. While the legal standard for showing derivation has not yet been promulgated by the USPTO or by the courts, it will likely involve a showing of prior invention by someone, along with some evidence of intent. In addition to the evidence that Ursula obtained the invention from VirCo, counsel for VirCo will have to show intent. A copy of the collaboration agreement between VirCo and the University, even if invalid, may be evidence of Ursula’s intent to derive. Victor cannot delay in filing the petition, because VirCo has only one year after publication of their application to institute the derivation proceeding.

Like most US patent applications, VirCo’s application publishes 18 months after filing – nothing has changed under the AIA in that respect. Three years after its publication, the VirCo application is rejected over a patent assigned to Evil Co. The Evil Co patent, which issued 13 months before the rejection, is based on an application published just over a year prior to the filing of the VirCo application. After some investigation, Victor learns that Evil Co’s chief scientific officer, Evelyn, was a reviewer for Ursula’s paper on LeadCompound-azole derivatives. It turns out that Evelyn requested significant revisions to Ursula’s manuscript, delaying its publication so that Evil Co could file their patent application before Ursula’s manuscript

published. Since Evil Co beat VirCo in the foot race to the USPTO, who gets the patent? (See figure 5).

Under the AIA, the Evil Co patent is prior art against VirCo. Even though Evil Co derived their work from VirCo, the one-year period for eliminating prior art that was obtained from VirCo expired before VirCo’s application was filed. It is also too late for VirCo to petition the USPTO to open a derivation proceeding, because more than one year has passed since VirCo’s patent published. Finally, it is also too late for VirCo to sue for derivation in civil court under new 35 USCA § 291(b), because the timeline to sue for derivation expired one year after Evil Co’s patent issued. Thus, VirCo has no mechanism to obtain a patent. The only thing that VirCo can do is suggest that the USPTO refer the matter to the Attorney General to investigate whether Evil Co committed fraud on the USPTO by claiming to be the inventor of the patented subject matter.

How could VirCo have protected itself from the apparently unfair consequences of its collaboration? First, VirCo should have been sure that the University and Ursula were legally obligated to share any proposed public disclosures or submission to a journal or meeting of any kind regarding the project to VirCo for review at least 60 days in advance. Second, VirCo could have insisted that VirCo approve any distribution of VirCo’s confidential information to a third-party in advance and that the third-party be placed under the same confidentiality obligation that applies to the University.

The best protection for VirCo would have been to closely monitor Ursula’s progress. Better monitoring and communication may have permitted VirCo to file a patent application before any paper was submitted to the journal and the negative consequences could have been avoided entirely.



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