



GORMAN IP LAW

PROTECTING INNOVATION

Special Considerations for the Scientist Turned Entrepreneur

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Fall/Winter 2015



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Protecting Innovation: Special Considerations for Scientists Turned Entrepreneur

Scientists who launch start-ups to commercialize their work often find the already difficult challenge of obtaining patent protection even more difficult.

Like many entrepreneurs, scientist founders are at the pinnacle of their careers and are recognized experts. Many lack significant business management experience, having come from an academic environment or the R&D department of a large company where research is a primary part of what they do. They are comfortable being totally in charge of their projects and are not used to having their scientific decisions questioned.

Part 1: Understanding the Market Potential of Scientific Innovation

Over the last five years, the U.S. Supreme Court has decided more patent cases than it has in the previous two decades combined. The impact on those making innovative discoveries in the biotech and pharma fields is that it is far more difficult now than ever before to obtain legal protection for many types of scientific innovation.

Prior to 2012, the Supreme Court had decreed that “anything under the sun that is made by man” was patent eligible. Since then, the Supreme Court has started to focus on what is not patentable, including DNA, proteins and many isolated/purified natural products. This turn of events is particularly difficult for those of us in the biotech/pharma sector whose roots are in the natural world.

Frequently the founders are thinking only of the advance that the innovation provides for one area of science and either grossly overestimate its commercial potential or give no consideration to whether the invention can be sold at all.

For example, while many biotech start-ups begin with a particular compound for treatment of a particular disease, oftentimes this is not the case. Perhaps the start-up is founded around a platform technology or is targeting particular combinations of microorganisms, or their products, for application to environmental problems.

An objective view of the potential applications of the innovation not only helps the company to focus and increase its value potential, it can improve the likelihood of achieving patent protection.

As an example, perhaps the innovation allows one to generate novel, and unnatural proteins having new functions and the founders envision using the invention to create improved microorganisms for cultured dairy products.

Here, one of the first issues that must be addressed in developing a patent portfolio strategy is to identify the pertinent market(s) that will support commercialization of the invention. This may or may not be what the start-up founders considered as the target industry, despite the fact that the invention could be used in multiple fields of biotechnology, such as drug screening/development, pesticide improvement, or oil spill remediation.

Identifying viable markets requires consideration of how the purchaser will evaluate whether the costs of adopting the new technology are worth the investment. Perhaps manufacturers of cultured dairy products feel that the advantage afforded by a new microorganism pales in comparison to the costs of altering their procedures/equipment and re-training their workforce. If so, there is no sense in obtaining patent protection for products or methods with no true commercial value. On the other hand, oil companies may be particularly interested in products and procedures that produce *any* improvement in remediation.

Consequently, it may be that additional experimentation to identify novel proteins that would support the oil spill remediation market should be conducted before filing a patent application so that the protection is clearly apparent to the targeted industry and to increase the potential value of the patent.

Although it is more difficult to obtain broad protection of biotech/pharma innovations, a focused approach to application preparation and filing can ensure that an innovation can obtain solid protection without unduly compromising the scope of the protection.

Part 2: Prior Art Searches

Once a scientist turns entrepreneur decides to move forward with patenting, those with a strong research background often hesitate when it comes time to pay someone to research a topic when they are already intimately familiar with what is known, understood and speculated about in their area of expertise.

Yet conducting such a “prior art” search oftentimes better grounds the company and provides somewhat of an unbiased check on the ability of the science to be easily patented.

This is due, in part, to the fact that a professional searcher has no particular bias about the invention and uses pertinent, yet neutral, terms when conducting the prior art search in addition to the jargon commonly used in the laboratory and/or the literature of a particular field of study.

If the scientist’s invention is a new method of conducting PCR (polymerase chain reaction) to be used for identifying new organisms in deep ocean thermal vents, the scientists will not necessarily be aware of PCR methods associated with forensic applications used at crime scenes.

If there is no bias as to how PCR is used or what the ultimate point of using PCR is (*e.g.* identifying a new organism), then the publications searched could easily come up with a journal article about which the

scientists were unaware or which they had dismissed as unrelated because it was directed to something other than identifying new organisms.

Consequently, the searcher has a much higher probability of identifying prior art that an Examiner at the USPTO would consider relevant to the patent application – even if it does not immediately appear to be intimately related to the exact same end-product, approach, or implementation as that presented in the patent application.

Part 3: Application Drafting and Filing

Drafting a patent application is not a trivial task. Founders/inventors in the life sciences and biotech fields who try to short-cut the process by “do it yourself” patent drafting do so at their peril.

Too often, these highly educated leaders in their field believe that drafting a patent application is no different than writing a peer reviewed journal article or a grant proposal. But this is not the case because the patent application – even a provisional patent application – is a legal document. The Supreme Court recognized this as early as 1892 when it stated:

The specification and claims of a patent, particularly if the invention be at all complicated, constitute one of the most difficult legal instruments to draw with accuracy; and, in view of the fact that valuable inventions are often placed in the hands of inexperienced persons to prepare such specifications and claims, it is no matter of surprise that the latter frequently fail to describe with requisite certainty the exact invention of the patentee, and err either in claiming that which the patentee had not in fact invented, or in omitting some element which was a valuable or essential part of his actual invention. *Topliff v. Topliff*, 145 U.S. 156, 12 S.Ct. 825, 36 L.Ed. 658.

Legal terms and requirements that appear straight forward on their face require a comprehensive understanding of the current state of the law, past precedent and current court interpretation. Drafting a patent application without this understanding is often done to the peril of the inventor.

Among the common misconceptions of start-ups having little experience with the patenting process is the meaning of the legal terms “novelty” and “obviousness.” To most scientists and engineers – in fact most lay people – “novelty” means just what the Merriam-Webster dictionary says: “The quality or state of being new, different, and interesting; something that is new or unusual; something novel.”

But in patent law, novelty doesn’t mean exactly that. Instead, novelty means that when an Examiner searches the patent, scientific, and popular literature (“prior art”) that was published before the earliest filing date for the application, she or he cannot find *one single publication that has each and every element of the claim*.

Like novelty, the terms “non-obviousness” and “obvious” also have a special meaning in patent law. Once more, the focus is on the elements of the claim. But while novelty requires that each and every

element of the claim is present in a single publication, to destroy non-obviousness and show that an invention is obvious, an Examiner is allowed to *combine two or more references so that each and every element of the claim is represented.*

These legal definitions tend to flummox most start-ups, especially when the publications are directed to areas of biotechnology that do not seem at all related to the start-up's invention. Experienced patent drafters appreciate that while novelty may exist over two publications, the invention could be considered obvious even if the publications are focused on different aspects of biotechnology. This then allows the drafter to further define the invention by including aspects that are absent from the prior art, which in turn provides the best chance to move through the patenting process to granted patent with the minimal amount of argument and expense. Here, the benefits of conducting a prior art search before beginning to draft a patent application becomes apparent.

Another common error made by start-ups who draft their own applications is to inadequately present the innovation so that it is viewed as patent eligible subject matter. Prior to 2012, the Supreme Court had decreed that "anything under the sun that is made by man" was patent eligible. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1990). Since then, the Supreme Court has started to focus on what is not patentable, including DNA, proteins and many isolated/purified natural products. This turn of events is particularly difficult for those in the biotechnology sector whose roots are in the natural world.

Late last year, the United States Patent and Trademark Office (USPTO) issued revised Guidelines that provide good examples of patent eligible claims despite the fact that the underlying product or process is "natural." 79 Federal Register 241 (16 December 2014) pp 74618-74633. Thoughtful consideration of these examples allows the application drafter to identify the "significantly more" that the Supreme Court says is needed to jump the eligible subject matter hurdle. See *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 U.S. 1289 (2012); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 U.S. 2107 (2013); *CLS Bank v. Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 U.S. 2347 (2014).

But most start-ups are not familiar with the particulars of the Supreme Court cases, although they may have heard of them through the media, and are not aware of how these decisions have affected the ability to obtain patent protection for biotechnology innovations. As a result, an application drafted by a start-up frequently does not adequately differentiate the invention from the "natural" product or process.

In addition, the passage of the America Invents Act in September 2011 moved the United States from awarding patents on a First-To-Invent basis to a system rewarding the First-Inventor-To-File. The First-Inventor-To-File system encourages early filing of applications, but this approach can have drawbacks because if an application is filed too early, the description of the innovation may be incomplete. This can be particularly problematic if what is missing is needed to place the invention into the eligible subject matter realm. Also, while start-up companies may perform comparative tests of their new product or process to a known closely related one, the tests are frequently performed after a patent application has been filed, which may affect the ability to rely on those results. Consequently it is more

important than ever to consider timing when filing applications. Again, this can be a hard sell to start-ups who want to obtain patents as quickly as possible.

Working with biotechnology start-up companies can be extremely rewarding but does require a significant time and teaching investment on the part of the attorney. Generally the science that biotech start-ups are based on is outstanding; the high failure rate for the start-ups tends to be more a function of poor business decisions and the lack of business experience than failure to perform scientifically. Understanding the legal issues associated with biotechnology, whether they are related to intellectual property, regulatory, or environmental, increases the probability of a start-up's success in the marketplace.

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