

Laying the Proper IP Foundation for Your Life Science Venture: The Evolving Utility Requirement in the United States

Dana M. Gordon, Ph.D.
Foley Hoag LLP
Seaport World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2600

While they often disagree about which life science business plans and technologies will be the big successes of the first part of the Twenty-First Century, angel and venture-capital investors do agree that the two most important considerations in evaluating a prospect in the life sciences space are management and intellectual property (IP). Of course, individual investors also differ on which of the two considerations is paramount. However, speaking as an IP attorney, I believe the obstacles to success created by a poorly conceived or executed IP strategy are more difficult to overcome than those posed by the need to make changes in management personnel or strategy.

Many decisions relating to IP strategy are essentially irreversible. For example, if you elect not to file a patent application covering a novel and nonobvious compound and its therapeutic uses before making a public disclosure, no amount of business or legal acumen will be able to restore “absolute novelty” for the invention. Moreover, even if you timely file a patent application describing the compound and its uses, if the application fails to satisfy certain other legal requirements for patentability (e.g., utility), you may not be able to cure those shortcomings without losing the benefit of your filing date for some or all aspects of the invention. In the highly competitive life science space, loss of even as little as six months of priority for one of your core technologies can be devastating to your venture.

The Utility Requirement in the United States

U.S. federal law defines a number of requirements for patentability. Among them is the requirement that an invention be “useful.”¹ This requirement is known as “the utility requirement.” Until relatively recently, a concise definition of “utility” with respect to life science inventions (e.g., nucleic acid sequences) was somewhat elusive. However, the United States Patent and Trademark Office (“Patent Office”) issued in 2001 final guidelines clarifying how the utility requirement should be applied by patent examiners to life science inventions². Importantly, the guidelines established that the utility

¹ 35 U.S.C. § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

² United States Patent and Trademark Office “Utility Examination Guidelines” 66 Fed. Reg. 1092 (January 5, 2001).

requirement may only be satisfied by a showing of a “credible, specific, substantial and well-established” utility. For example, the guidelines made clear that patents should not be issued for mere strings of nucleotides.

When an inventor asserts a utility for a claimed invention, it is considered by the Patent Office to be “credible” unless the logic underlying the assertion is flawed or the facts presented are inconsistent with that logic. For example, a claim that a small molecule confers immortality would be deemed to lack credibility. However, uses of specific nucleic acid sequences as probes, markers or therapeutics are usually considered credible because they are well-established, generally. For example, because it is well known that siRNA may be used to investigate gene function and modulate gene expression, there should be little difficulty in establishing a credible utility for claims to methods using RNAi.

However, in order to persuade the Patent Office that the utility is “specific,” an inventor must do more than propose a generic utility for his or her invention. For example, if an inventor claims a natural or modified nucleic acid sequence as a gene probe, she must specify the target to which it hybridizes. Likewise, if an inventor claims a diagnostic utility for a siRNA, he must disclose the specific disease which may be diagnosed. In other words, to meet this prong of the utility requirement, the inventor must possess, at the time of filing the patent application, some knowledge as to the function of the targeted gene. Likewise, a probe function alone for a particular target will probably not be sufficient to establish a specific utility for the sequence. In other words, without knowledge of the target's function the invention will likely be deemed to lack a specific utility.

Moreover, the Patent Office must also conclude that the asserted utility is “substantial.” To a first approximation, if additional research is required to identify or confirm a "real world" use, then the invention lacks a substantial utility. Use of a small molecule to treat a known or newly discovered disease would be considered to be a substantial utility. However, claims to treating an unspecified disease or condition with the same molecule will likely be deemed to require additional research to establish a substantial utility. Likewise, the use of siRNA in basic research, such as for the investigation of a molecular biological mechanism, would also likely be deemed to lack a substantial utility. Lastly, the Patent Office specifically states that “throw away” utilities do not meet the tests for specific and substantial utility. For example, the use of a complex, modified nucleic acid sequence as molecular weight marker for a DNA digest gel is neither specific (because any sequence can function as a molecular weight marker) or substantial (because using a complex, modified nucleic acid sequence, which is both expensive and time-consuming to prepare, would not constitute a “real world” use).

Lastly, the utility must also be “well-established.” The Patent Office appears to mean that the utility must be well-known, immediately apparent, or implied by the inventor in his application (taking into account what is considered common knowledge in the art). For example, with respect to a small molecule demonstrated to have in vitro activity against a particular mammalian enzyme or receptor, the inference that modulating that activity in a mammal will lead to therapeutic results must stem from a well-established relationship between the targeted enzyme or receptor and the indication to be treated.

Recent Federal Appellate Decisions Interpreting the Utility Requirement

In *Rasmusson v. SmithKline*,³ the federal appellate court that hears patent appeals concluded that a claim to a method of treating a type of prostate cancer using a compound known as “finasteride” was not patentable because the applicants failed to satisfy the utility requirement. The court acknowledged that at the time the patent application was filed, one of ordinary skill in the art would have recognized that finasteride was a selective inhibitor of an enzyme known to convert the hormone testosterone to the structurally related hormone dihydrotestosterone. Further, the court agreed that one of ordinary skill would have known that elevated levels of dihydrotestosterone were associated with prostate cancer.

Notwithstanding these facts, the court concluded that one of ordinary skill in the art would not have accepted the mere assertion of efficacy as obviously true because contemporaneous scientific articles did not establish a clear connection between selective inhibition of the enzyme and anti-tumor effects. Moreover, the court ruled that because the application failed to provide substantiating evidence for the efficacy of finasteride in the treatment of prostate cancer the application would not have persuaded one of ordinary skill that finasteride would be efficacious in treating prostate cancer. Accordingly, the court ruled that the method was unpatentable because the application, even when supplemented by the contemporaneous knowledge of one of ordinary skill in the art, failed to satisfy the utility requirement.

In *In re Fisher*,⁴ the same court upheld the Patent Office's ruling that claims to a number of purified nucleic acid sequences were unpatentable because they lacked a specific and substantial utility. The sequences were expressed sequence tags (ESTs) taken from maize plants, each of which encodes a protein or protein fragment. The structures and functions of the corresponding genes and proteins were not known when the patent application was filed. However, the patent application did assert a variety of uses for the claimed ESTs, including their use as molecular markers, primers for polymerase chain reaction processes, and controlling protein expression.

The Patent Office concluded that the claims failed to satisfy the utility requirement because the patent application did not disclose a specific and substantial utility for the sequences. First, the asserted uses were deemed to be generic to any EST, not specific to the claimed sequences. The Patent Office also

³ *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005).

⁴ *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

concluded the claims lacked a substantial utility because the application did not disclose a use for any of the proteins associated with the ESTs.

The appellate court agreed that the asserted uses were not specific because any EST from the maize genome might be used. Likewise, the judges concluded that the claimed ESTs lacked substantial utility because the patent application would not have led one of ordinary skill in the art to conclude that any of them had a “real world” use. For example, no evidence was provided substantiating the use of any of the ESTs to modulate gene expression in maize or locate genes or fragments thereof in other plants or organisms. Further, no evidence was introduced to show that such information would have otherwise been available to one of ordinary skill in the art. Accordingly, the court held that claims did not satisfy the utility requirement.

Conclusion

In addition to a great management team, a life science venture seeking to commercialize a human therapeutic or diagnostic product or method must have a sophisticated IP strategy in order to succeed. While satisfaction of the utility requirement has often been viewed as a mere technicality, *Rasmusson* and *In re Fisher* make it crystal clear that a U.S. IP strategy that ignores the utility requirement can no longer be considered sufficient, let alone sophisticated. Therefore, the scientific and legal teams of a life science venture must give due consideration to striking the proper balance between developing more completely their inventions in the lab and clinic, and filing patent applications early and often. In the past, securing the earliest possible filing dates for inventions was the cornerstone of a strong IP foundation for a life science venture. Now, a life science venture that fails to consider carefully the utility requirement risks building on a shaky IP foundation in the United States.

About the Author

Dana Gordon, Ph.D. is a partner and registered patent attorney in the life sciences practice at Foley Hoag LLP. He regularly prepares and prosecutes U.S. and foreign patent applications in all areas pertaining to organic chemistry, including synthetic methods, small molecules, pharmaceutical formulations, polymers, polymorphs, RNAi, molecular diversity, radiological imaging and materials science. In addition, he advises companies of all sizes and leading universities on strategic aspects of patent-portfolio development, and he conducts non-infringement, validity and due-diligence assessments of U.S. and foreign patent-portfolios. Dr. Gordon received a B.S. in Chemistry, magna cum laude from UCLA with departmental highest honors; a Ph.D. in Chemistry from Yale University, where he was an NSF Predoctoral Fellow with Professor Samuel Danishefsky; and a J.D. from Boston College Law School. Additionally, Dana was a NIH Postdoctoral Fellow with Professor George Whitesides at Harvard University. Immediately prior to joining the firm in 1997, he was a tenure-track assistant professor in the chemistry department at Brandeis University.