When and How to Patent A Biotechnology Invention

by Jane Massey Licata and Kathleen A. Tyrrell

I. Legal Considerations

Determination Of Patentable Subject Matter

Determining and characterizing potentially patentable subject matter disclosed in an invention disclosure or a draft manuscript is a crucial first step in the process of deciding when and/or how to patent a biotechnology invention. Under the U.S. patent statute, any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, is patentable subject matter. According to case law, each type of invention is to be patented under the same legal standards and recent changes to the Manual of Patent Examination Procedure (MPEP) indicate an effort by the Patent Office to consistently apply these standards to biotechnology inventions. However, as a practical matter, obtaining a patent for a biotechnology invention presents unique challenges due to the nature and complexity of these types of inventions.

The 1997 amendment to the Patent Act has limited remedies for patent infringement against medical practitioners and related health care entities for performance of a medical activity. However, "medical activity" is defined narrowly so that creative claim drafting can significantly reduce the impact of this amendment. For example, medical activity does not include (1) the use of a patented machine, manufacture or composition of matter in violation of the patent; or (2) the practice of a patented use of a composition of matter in violation of the patent; or (3) the practice of a process in violation of a biotechnology patent. Rather, medical activities are intended to be limited to the performance of a medical or surgical procedure on a body. It is also important to note that the amendment merely represses the remedies available for infringement against a limited group, i.e. the doctor and his or her related health care entity. Medical device and pharmaceutical companies may still be held liable for active inducement or contributory infringement. Accordingly, medical methods patents should be crafted in light of these considerations.

Timing Issues

Publication or other public disclosure can impact on the patentability and scope of patent rights available for all types of inventions. For biotechnology inventions, however, a careful assessment from an enablement and novelty standpoint of just what is being disclosed with respect to the invention must be made. Often, there may be little or no impact from a disclosure of very preliminary data depending upon the disclosed hypotheses derived from the data. However, broad suggestions of utility of an invention based upon and published with preliminary data not necessarily enabling for the suggested utility prior to filing a patent application can affect patent rights to that invention dramatically. The type of data available, the prior art including the inventors, and the pace of the research should be important considerations in the timing of a patenting decision.

Use of the invention by a third party with no obligation to secrecy prior to filing of a patent application can also be deemed a statutory bar to obtaining a patent. In Baxter International v. COBE Inc., 88 F.3d 1054 (Fed. Cir. 1996), a research scientist at NIH had developed a centrifuge that anticipated the claims at issue before Baxter's critical date. The court held that NIH made no effort to conceal the centrifuge as a "confidential development" and had an antisecrecy policy. In fact, the court noted that the centrifuge was in a public building that could be observed by any number of people coming and going into the lab. Since there was no obligation of secrecy, this use was sufficient to for the Court to determine that the NIH centrifuge was in public use.

Statutory Requirements

While fairly extensive revisions were made to the July 1998 issue of the MPEP to incorporate changes necessitated by the final rules, AChanges to Patent Practice and Procedure@ which became effective as of December 1, 1997, few changes were made to Chapter 2100 entitled APatentability@. This chapter contains detailed guidelines for the Examiner to follow in the determination of:

1. statutory subject matter and utility of the invention under 35 U.S.C. '101
2. novelty of the invention under 35 U.S.C '102
3. obviousness of the invention under 35 U.S.C. '103; and
4. whether or not the specification meets the enablement, written description and best mode requirements set forth by 35 U.S.C. '112.

At one time, a major hurdle in obtaining a patent to a biotechnology invention was lack of utility under 35 U.S.C. '101. However, general principles governing utility are now provided in MPEP '2107. As a result of these guidelines and revisions to the MPEP, utility rejections are rare. Occasionally, however, a '101 rejection based upon non-statutory subject matter is made. Such rejections are often seen in computer-related cases but are also seen in biotechnology cases when the claims are inclusive of products of nature. Typically these rejections can be overcome by addition of language to the claims which illustrates the requisite human intervention. Of course the specification of a patent application to the invention must include support for such an amendment.

Novelty rejections, at least for biotechnology inventions, are also typically straightforward. This issue usually turns on whether or not a single prior art reference discloses the claimed invention. According to MPEP ' 2131, to anticipate a claim, the reference must teach every element of the claim. Accordingly, amendments to the claims to more particularly define the claimed invention will oftentimes overcome these rejections. However, discovery of a new property for a known composition will not render claims drawn to the composition novel over prior art teaching the composition even if the new property is included in the claims. Claims to using the composition in a method related to the new property may be patentable if it is determined that the new use is not inherent, i.e. does not follow by scientific reasoning from previously taught uses for the composition.

The major hurdles to obtaining a biotechnology related patent still reside in the more subjective areas of enablement and written description under 35 U.S.C. ' 112, first paragraph rejections and obviousness under 35 U.S.C. ' 103.

A primary focus of the prosecution of a patent application is generally the enablement and written description requirements under 35 U.S.C. '112, first paragraph. These are two separate and distinct requirements.

With respect to enablement, the focus is on whether a particular claim is supported by the disclosure in an application and requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims to enable one skilled in the pertinent art to make and use the claimed invention. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure in the patent coupled with information known in the art without undue experimentation.

MPEP ' 2164.01(b) entitled "How to Make the Claimed Invention" states that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of 35 U.S.C. ' 112 is satisfied. A key issue that arises for some biotechnology inventions is whether the starting materials necessary to make the invention are available. For example, claims to a product or process may require a particular strain of microorganism which is available only after extensive screening. Accordingly, deposit of the starting materials used to make the claimed invention in accordance with the Budapest Treaty may be required. For a regular U.S. application deposit is not required prior to filing of the patent application. However, many foreign countries require deposit prior to filing.

Requirements regarding how to use the claimed invention are outlined in MPEP ' 2164.01(c). If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. ' 112 is satisfied. As an example, MPEP ' 2164.018 states that "it is not necessary to specify dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based upon knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. ' 112." Differences in opinion between the Patent Office and inventors over what constitutes undue experimentation and predictability of a particular art field has kept this a challenging area of prosecution.

With respect to the Written Description requirement, it is likely that the MPEP will be revised in the near future as notice and request for public

comment on Interim Guidelines for Examination of Patent Applications under 35 U.S.C. ' 112, first paragraph AWritten Description@ Requirement was published in the Federal Register on December 21, 1999.

In general, these guidelines state that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. According to the guidelines, the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant=s disclosure a description of the invention defined by the claims. There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement and each claim is to be separately analyzed in its entirety including the preamble language and transitional phrase. Thus, for a claim drawn to @A structure comprising SEQ ID NO:1" there may be a written description problem if the unstated subject matter also encompassed by this claim is considered to be unpredictable. In contrast, a claim limited to AA structure consisting of SEQ ID NO:1" is unlikely to be rejected for this reason. Similarly, a preamble such as Agene@ implicitly recites structures such as promoters, enhancers, coding regions and other regulatory elements which must be sufficiently described in the specification so as to show applicant was in possession of the claimed invention. In contrast, less specific more generic preamble language such as nucleic acid, DNA or RNA does not typically present a written description problem.

At first glance, the criteria which must be met to render an invention obvious under 35 U.S.C. ' 103 appear straight forward. First, there must be some suggestion either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Further, MPEP ' 2144.08 contains detailed guidelines for determining obviousness of a species when the prior art teaches the genus. While these guidelines do not constitute substantive rulemaking, they are stated to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Cases cited in the guidelines as providing substantive law which are related to biotechnology inventions include In re Deuel, 51 F.3d 1552, 1558-59 (Fed. Cir. 1995). ("No particular one of these DNAs can be obvious unless there is something in the prior art to lead to a particular DNA and indicate that it should be prepared."); In re Baird, 16 F.3d 380, 382-83 (Fed. Cir. 1994) and In re Bell, 991 F.2d 781, 784 (Fed. Cir. 1993). ("Absent anything in the cited prior art suggesting which of the 1036 possible sequences suggested by Rinderknecht corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences."); In re Mayne, 104 F.3d 1339 (Fed. Cir. 1997) cited as holding that the known structural similarity of Ile and Leu meant that substitution of one for the other was obvious. These guidelines refer to general textbooks including the Dictionary of Biochemistry and Molecular Biology (John Wiley & Sons, 2d ed. 1989) and James Darnell et al. Molecular Cell Biology (2d ed. 1990) for guidance in the area of biotechnology and in determining the obviousness over exemplified species which may differ from a claimed species by a conservative substitution. Despite these guidelines and the recognition by the Patent Office that these cases outline the law of obviousness, obviousness rejections are still probably the most subjective portion of the prosecution and very often the most difficult to overcome.

II. Commercial Considerations

The process of obtaining patent protection for a biotechnology invention can be long and expensive. Accordingly, it is important to make a preliminary assessment of the commercial use and value of an invention. For example, what would the product be? Who are the players in the market? What is the time frame to bring a product to market? Are there significant practical and/or regulatory hurdles? Would other technologies be necessary to bring a product to market? If so, who controls these technologies? What are the competitive technologies that are either available or foreseeable? The type of patent protection is also a relevant consideration. The enforceability of a composition claim, as opposed to a product by process claim, or method claim, may be a significant commercial consideration.

III. Alternative Means of Protection

There are a variety of alternative means available which may adequately protect and be more suitable for a biotechnology invention. For example, in some cases, a materials transfer agreement may be a viable approach. Cross licensing is also a frequent means of doing business in the biotechnology industry. Occasionally, trade secret protection may be useful; although, in the academic environment, it may be difficult to enforce or deemed to be at odds with the mission of the institution.

IV. Cost and Time Frame

Since patenting of a biotechnology invention can be expensive and time consuming, it is important to consider whether a technology can be licensed within certain time frames, i.e., before or shortly after the priority application is filed or before the foreign filing deadline. For a patent application filed after the effective date of GATT, the term of a patent is now measured from the earliest effective filing date. This may have significant implications for some types of biotechnology inventions.

V. Protection Afforded

When a patent attorney determines that an invention is patentable, it does not necessarily mean that the protection obtained will provide commercial value. In some cases, however, a patent can provide leverage to obtain research funding or access to other technologies. Accordingly, before embarking on the challenging process of obtaining patent protection for a biotechnology invention, the nature, scope and value of the claims that may issue should be carefully considered.