RECENT CHANGES TO THE US PATENT LAWS: THEIR EFFECT ON INVENTIONS IN BIOTECHNOLOGY

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On November 29, 2000, the American Inventor's Protection Act (AIPA) became law. While the Act contains many diverse provisions, two of the most significant provisions for companies working in the biotechnology area are publication of U.S. patent applications and provisional patent rights.

Publication of U.S. Patent Applications

Amended statute 35 U.S.C. §122(b) now provides for publication of U.S. patent applications 18 months from the earliest priority filing date. Publication will affect all new applications, including divisionals, continuations, CIPs, but not requests for continued examination (RCEs). Applications that will not be published include applications that are abandoned prior to the 18 month publication date, applications under secrecy order, design applications, and applications filed with a request not to be published. A request that the application not be published may be submitted only if the application has not been and will not be filed abroad in a country that requires 18-month publication. The statute also provides that a redacted copy of a U.S. application may be submitted for publication if a corresponding foreign application contained less subject matter than the corresponding filed U.S. application. The published U.S. patent applications are made available only via the USPTO electronic database.

One major difference between the conventional publication of foreign patent applications and new publication of U.S. patent applications is that publication of U.S. patent applications makes the contents of the file maintained at the U.S. Patent Office available to the public. Under new 37 CFR §1.14(c)(2), anyone can request a copy of a published pending patent application file upon written request. Thus, it is now possible to monitor the filing and prosecution of published patent applications of competitors in both the U.S. and Europe, arguably the two largest markets in the world. Based on this new accessibility, as a practical matter, it may be desirable for you or your attorney to periodically search the USPTO database for newly published patent applications of competitors in your field or market. The search may be conducted at http://www.uspto.gov/patft/index.html using conventional boolean search terms.

The 18-month publication will likely have a positive effect on competitors who try to "design around" the newly published invention. In general, the later in the patenting process that a competitor becomes aware of a patented product, the more difficult and expensive it becomes for him to design a noninfringing product. With the 18-month publication, a competitor can become aware of a product for which patent protection is sought much earlier, and begin the design around process earlier and less expensively. On the other hand, the 18-month publication will publicly disclose a claimed invention that may cover an infringing activity of a competitor. The publication could alert the infringer to cease its infringing activity well in advance of patent issuance, and thus prevent the applicant from recovering potentially significant damages.

Provisional Patent Rights

Prior to enactment of the AIPA, the applicant for patent had no rights until the patent actually issued. However, under new 35 U.S.C. §154(d)(1), an applicant has the right to obtain a "reasonable royalty" from any person who infringes the invention claimed in a published patent application. These new rights become effective upon publication of the application and continue until the patent issues.

Certain criteria must be met before a claim to a reasonable royalty may be made against an infringer. For the infringer to be liable, he must have actual notice of the published patent application, and the invention claimed in the issued patent must be substantially the same as the invention claimed in the published application. Thus, for an applicant to successfully recover a reasonable royalty for the activity of an infringer post-publication, but pre- patent grant, an issued claim covering the infringer's activity must have been published. As a practical matter, it may be desirable to send potential competitors copies of published patent applications by Registered Mail to effectively put them on notice of the claimed invention.

The provisional patent rights will likely be particularly useful for biotechnology companies which patent research tools, such as receptors useful in drug screening. Prior to enactment of the AIPA, competitors would have access to the foreign patent files of the research tool, and could practice the invention in secret in the U.S. without fear of

any legal penalty. By the time the U.S. patent issued, the competitor would cease using the tool, and the applicant would have no recourse. However, under the new provisional rights provisions of the U.S. patent laws, applicants will now have an early legal remedy, providing all the criteria are met.

For more information on the American Inventor's Protection Act, please contact Todd E. Garabedian, Ph.D., at 203-498-4483.