Upcoming Patent Law Changes Will Put Pressure on Patents

Jack Griem
Partner, Loeb & Loeb Patent Litigation Department

This article reflects the personal views of the author, not his firm or any client.

Patent law is changing rapidly. The changes are putting even greater pressure on patents as a tool for protecting a pharmaceutical or biotechnology company's hard-won inventions. The Leahy-Smith America Invents Act (the "AIA") has made it harder than ever to get a patent, and has also created new ways to challenge patents in the Patent Office before they can be asserted in court. The changes created by the AIA have started to go into effect, with major changes becoming effective in March 2013, and so now is the time to rethink how your company obtains and asserts patents to protect the products and services it has in development and on the shelves.

The AIA switched the United States from a "first to invent" system, to a "first inventor to file" system, to harmonize U.S. law with laws in other countries. As part of that change, the definition of "prior art" (i.e, all existing knowledge that is used to determine whether an invention is sufficiently new and non-obvious to merit a patent) was expanded to include all public uses or sales by third parties, anywhere in the world, that are accessible by the public at any time up until the day the patent application is filed. One example of these potential public uses is a clinical trial that uses the invention and provides information about it to patients and physicians without confidentiality restrictions. Under current law, a one-year grace period applies, so that only third party uses and sales occurring at least one year before the patent application is filed are considered prior art. In addition, under current law, only uses and sales in the United States could be considered prior art. These changes become effective March 16, 2013, for all patent applications filed on or after that date. Patent applications claiming inventions disclosed in an application filed before March 16, 2013, will continue to be judged based on the existing, more narrow definition of prior art.

In addition, starting in March 2013, a new "post-grant review proceeding" will give a third party nine months to challenge the validity of any newly-issued AIA patents by filing a petition with the Patent Office. This new post-grant review proceeding will allow any third party to raise any ground for invalidity and require the Patent Office to reconsider the validity of the newly-issued patent. A party challenging a patent in a post-grant review proceeding need only show invalidity by a more-likely-than-not "preponderance of the evidence" standard, rather than the standard "clear and convincing evidence" standard used when the validity of a patent is challenged in court. This post-grant review proceeding will include a limited amount of discovery into the documents and testimony of the patent owner, and create an estoppel against raising the same arguments in a later court proceeding. Under current law, the only way for a third party to challenge the validity of a patent in the patent office is to file a request for "reexamination", in which the evidence of invalidity is limited to publications and earlier patents, without any discovery. Because it will cost significantly less than a regular court proceeding, and apply a lower standard, the post-grant review proceeding may become a popular method of challenging the validity of patents.

In this new environment, (even though obtaining and defending patents is going to be more difficult than ever), health care, pharma and biotech companies should not lose focus on why they are getting patents in the first place. Patents create value for a pharmaceutical or medical device company by giving the company the right to exclude competitors from the market. In this industry, quality counts much more than quantity. So holding strong patents that form a solid basis for a lawsuit against a generic competitor or other infringer remains very important.

These changes will mean that companies will likely have to put greater resources into obtaining and defending their key patents; however, the patents they obtain and defend should be considered very strong because they have survived this more rigorous process. Because of the new broader scope of prior art, it may take longer to look for potential prior art, and take more time for patent counsel to obtain a strong patent after disclosing that prior art to the Patent Office. In addition, companies will have to spend more time monitoring the pending patent applications of competitors, in order to be prepared to make post-grant challenges where appropriate. This is the procedure in Europe, where post-grant oppositions to recently issued European patents are common, particularly in the pharmaceutical area. Moreover, companies should anticipate a greater volume of early challenges to their most valuable patents, soon after they issue, because of the potential financial and practical advantages of the new post-grant review process.

The key to preparing for this new patent environment is good preparation and planning. Best practices will include budgeting for a few potential post-grant oppositions, which will hopefully take the place of more expensive patent litigation matters. In addition, in-house patent counsel will need to work more closely with their colleagues who conduct clinical trials to make sure they understand the worldwide picture on potential prior art clinical trials and sales. Companies may also want to consider consulting with experienced litigation counsel as a regular part of the process of obtaining patents, given the greater number of potential challenges and threats to their patents once they issue. Litigation counsel can then provide insight into what aspects of a patent are likely to be challenged, and provide tactical advice on how to prepare.

John (Jack) Griem is a partner in the New York office of Loeb & Loeb LLP, where he concentrates his practice primarily on intellectual property litigation, particularly pharmaceutical and biotech patent litigation. He is also experienced in analyzing and negotiating license and technology development agreements, strategic portfolio development, and addressing intellectual property issues arising in corporate and finance transactions. Griem can be reached on jgriem@loeb.com.