BOSTON WOMEN'S BUSINESS
Covering Massachusetts, New Hampshire and Rhode Island

October 2007 THE PROFESSIONAL AND BUSINESS WOMAN'S JOURNAL

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Patent Reform/Repercussions to Be Watched

The U.S. patent system is undergoing major changes that may have a large impact on the biotechnology and pharmaceutical industries.

The U.S. Patent and Trademark Office (USPTO) recently passed new and controversial regulations regarding patent prosecution.

In addition to the USPTO's new regulations, various pieces of legislation, including the "Patent Reform Act of 2007," have been introduced or discussed in Congress in the past few years. S. 1145 is the proposed Senate bill and H.R. 1908, passed in September, is the House of Representatives bill.

Research-intensive industries such as pharmaceuticals and biotechnology, which rely on strong patent rights, are very concerned about the USPTO's recent changes as well as certain provisions of patent reform.

Understanding these changes and proposals as well as their repercussions will be vital to these industries.

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USPTO's New Regulations on Continuations and Claims. On Aug. 21, the USPTO published new rules which included controversial changes to patent prosecution.

Two key changes to the revised rules involve limitations on the number of continuation applications and a limitation on the number of claims that may be filed.

Specifically, the revised rules provide that for an applicant to file more than two continuation applications or more than one Request for Continuing Examination, the applicant make a showing as to why the amendment, argument or evidence being filed therewith could not have been previously submitted.

Biotech and pharmaceutical industries have come to rely on continuation applications to ensure patent protection for important commercial products. Because the commercial relevance of a pharmaceutical invention may not be clear until well into the drug development phase, the ability to file later continuations is extremely important.

By limiting this practice, the new rules restricting continuations will significantly hinder the patent prosecution practices of pharmaceutical and biotechnology companies.

The new rules also require an applicant to file an extensive examination support document if an application contains more than five independent claims or 25 total claims. These rules negatively impact biotech and pharmaceutical companies, which often rely on the use of multiple claims to ensure that different embodiments of a drug product are covered.

The USPTO's rules, which take effect Nov. 1, have already been challenged.

In Tafas v. Dudas, E.D. Va., filed Aug. 22, an inventor has sued the USPTO, asserting that the agency has exceeded its congressional rulemaking authority in issuing the new regulations. Other challenges are expected and should be closely followed.

Post-Grant Review. Bills introduced by Congress would also drastically change the patent system. One proposed reform involves the institution of a post-grant review proceeding.

Under the current law, an issued patent may only be challenged via litigation or a reexamination. Based on the

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perception of low patent quality, Congress has proposed an administrative post-grant review proceeding to challenge the validity of issued patents.

Such proceedings would require a lower burden of proof to show invalidity than in patent litigation where a patent is presumed valid.

The current Senate bill establishes two separate time periods for filing such a post-grant request. It would provide a so-called "first window" of 12 months from the issue date of a patent to initiate a proceeding and a "second window" allowing a request to be filed at any time during the life of the patent by a requester who has received notice alleging infringement.

The institution of a second window in such post-grant proceedings would arguably diminish the value of patents and cause uncertainty in patent rights.

The House bill only allows post-grant review petitions to be filed during the first 12 months after issuance. By not including a second window, the bill favors greater certainty in patent rights.

This is particularly important for pharmaceutical and biotechnology companies, where significant investment in research is made and a product will be released, if ever, years after the patent has been issued.

Inequitable Conduct. Congress also proposes to change standards for inequitable conduct. Currently, defendants often assert that the patent at issue should be held unenforceable based upon alleged "inequitable conduct" by the patentee in obtaining the patent.

A defense of inequitable conduct requires proof that the patent holder intentionally misrepresented or concealed material information from the USPTO. Because of the uncertainty and wide use of the defense, some judges have called the defense a "plague" on the patent system.

The amended Senate bill includes a provision providing that the party alleging inequitable conduct must prove, by clear and convincing evidence, that material information was misrepresented or omitted from the patent application with the intent to deceive.

The standard of materiality (not cumulative and important to a reasonable patent examiner) is similar to current legal precedent.

A concern with this standard for pharmaceutical companies and other patent holders, however, is it could lead to a patent being held unenforceable even if not a single claim in the patent is found invalid.

The House bill codifies the judicially made doctrine of inequitable conduct and incorporates the USPTO standard of materiality. Intent to deceive the Office must be proven separate from materiality.

Where inequitable conduct is found, a judge may impose sanctions ranging from denial of equitable relief and lost profits to holding the patent or related patents unenforceable.

It is unclear whether such a reform will successfully reduce the number of inequitable conduct allegations.

Conclusion. Research-intensive industries, such as biotechnology, must keep a close watch on the imminent changes, which may weaken their patent rights.

The final rules issued by the USPTO will significantly change how biotech and pharmaceutical patents are prosecuted. These rules will dictate much narrower and quicker prosecution. In Congress, the House has approved a bill and consideration by the Senate will now resume.

For the pharmaceutical and biotechnology industries, patent reform supporting strong patent rights would be favored. This would include legislation that provides limited opportunities to challenge patents and reduces the impact of inequitable conduct assertions.

Patent reform should be closely followed to see how the debates progress.

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