

## **I. Introduction**

A series of extensive patent reform proposals are currently pending before Congress and the United States Patent and Trademark Office (USPTO). Those proposals represent some of the most sweeping changes to patent law in decades. In general, the proposals would make patents more difficult to obtain, easier to invalidate, and easier to infringe. The computer and telecom industries have favored most of the pending legislation and rule changes. By contrast, the biotech industry (meaning both the biotechnology and pharmaceutical industries) opposes most of the proposed changes. The opposing views of these two groups reflect important differences in the way products are brought to market in the computer/telecom and biotech industries. In the computer and telecom industries, products are released relatively quickly following discovery. By contrast, products in the biotech industry are brought to market only after the investment of hundreds of millions of dollars and after significant delay due to regulatory review. Because of the expense and delay involved in bringing such products to market, biotech faces considerable risks even under the current system. Those risks are certain to increase if the proposed reforms are adopted.

## **II. Proposed Patent Reform Legislation**

The Patent Reform Act of 2007 is currently before Congress and represents the most dramatic change in patent law in decades. Multiple attempts at patent reform have recently been made, and the current legislation is similar to patent reform legislation that came before Congress in 2005 and 2006. Some of the major motivations for patent reform include: harmonizing the U.S. patent system with other countries, improving the quality of issued patents, diminishing the uncertainties associated with litigation, and streamlining the examination process. Identical versions of the Patent Reform Act were introduced in the House and Senate and were subsequently modified in the House and Senate Judiciary Committees. In general, the two versions seek to implement a first-to-file system, redefine what is considered prior art, establish post-grant opposition procedures, codify the grounds for willful infringement, expand the prior use defense, modify the manner in which damages are apportioned in litigation, modify the bases for venue, provide for interlocutory review of Markman rulings, and expand the rulemaking authority of the PTO.

While several of the House and Senate bills' provisions are the same or similar, there are a few important differences between the two. First, the Senate version permits first and second window post-grant review, while the House version permits only first window review. Second, the Senate version repeals inter partes reexamination while the House version expands the scope of inter partes reexamination in lieu of second window post-grant opposition. The House version requires that administrative judges hear petitions and allows for oral hearings. Third, the Senate version expands PTO rulemaking authority only with respect to fee-setting, whereas the House version expands regulatory authority for continuation applications.

While some of the modifications proposed in the House and Senate bills make the bills more favorable to biotech, several provisions remain problematic. Specifically, post-grant review, and in particular second window review, of patents would weaken biotech patents by making them easier to invalidate. Provisions limiting damage awards and modifying the bases for willful infringement would make it less expensive for competing companies to infringe biotech patents, thus putting biotech patent holders at greater risk. Lastly, increasing the PTO's rulemaking authority would be problematic for biotech since this would likely mean limitations on continuing application practice and enhanced burdens on applicants.

Because of bi-partisan support for the Patent Reform Act of 2007, the bill is likely to pass. Passage may, however, depend upon which industries have greater influence, the computer and telecom industries or the biotech industry.

### **III. USPTO Proposed Rule Changes**

Several rule changes are currently pending before the USPTO. Those proposals, if adopted, will have a dramatic effect on patent prosecution, particularly in the area of continuing applications. In general, the proposed rules would add complexity to patent prosecution and increase the burden on patent applicants. The PTO's motivation for the proposed rule changes is to improve patent quality and to reduce the large number of backlogged patent cases. The proposed changes include limitations on the numbers of continuing applications and RCEs permitted, limitations on the numbers of claims permitted, limitations on the use of alternative claim language, modification of ex parte appeal procedures, changes to information disclosure statements, and modification of accelerated examination procedures.

Some of the most dramatic rule changes before the PTO are in the area of continuing applications. The PTO introduced the final rules for continuing applications on August 21, 2007, and those rules will be effective November 1, 2007. After that time, applicants will be limited to two continuations or CIPs and one RCE as a matter of right. Additional continuations, CIPs, or RCEs may be obtained only through a petition and showing. Although an earlier version of the rules proposed otherwise, the PTO has permitted applicants to file divisionals either in series or in parallel, so long as 35 U.S.C. § 120 is satisfied for priority claims. The final rules also limit applicants to 25 total and 5 independent claims as a matter of right. Additional claims are permitted with the submission of an examination support document (ESD). An ESD essentially lays out for the examiner all relevant prior art, indicates where the elements of the claimed invention are found in the prior art, and explains why the claimed invention is patentable over the prior art. The patent office thus requires applicants to perform a significant proportion of the examination in exchange for additional claims.

The PTO continues to receive comments for a series of other proposed rule changes. Under a current proposal, Markush group practice is limited. Because it is time-consuming to search the large numbers of alternatives arising out of Markush groups, the PTO proposes to limit the use of alternative claim language to those alternatives that are related and not overlapping. Moreover, the proposed changes permit intraclaim restriction requirements. The PTO anticipates a large number of appeals in the wake of profound rule changes, and thus the PTO has proposed modifications to the ex parte appeal procedures. Under the new rules, applicants would be required to submit more information at appeal, the format of all appeal briefs would be modified, and page limits would be imposed for briefs. The proposed rules also permit sanctions for misconduct. In an additional proposal, the PTO has increased the burden on applicants when filing information disclosure statements by requiring applicants to include more information regarding the IDS citations.

While the final continuing application and claims rules are more favorable to biotech than the earlier proposed versions, the final rules and the other proposed rules still present several problems for biotech. For biotech, decreases in the number of continuing applications would be problematic. Such a change will likely result in weaker and narrower patents. Moreover, many applicants will choose to submit an ESD rather than limit their claim numbers to the proposed 25 total and 5 independent claims. Applicants will thus likely face problems with prosecution

history estoppel. Because Markush claims are used prevalently in biotech applications, limitations on alternative claim language are likely to have a significant negative impact on biotech applicants. Under the proposed rules, patent prosecution will become more complex and the resulting patents will be narrower in scope and easier to invalidate.

The final continuing application and claim rules have been released and will become effective in November. It remains to be seen, however, which, and to what extent the other proposed rule changes will be adopted.

#### **IV. Conclusions**

The proposed patent reform legislation and PTO rule changes are likely to make patents more difficult to obtain, narrower in scope, easier to invalidate, and less costly to infringe. In such an environment, investors are likely to invest more conservatively, and thus a chilling effect on biotech innovation and investment can be expected.