



Client Alert



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Patent Reform Revitalized

While healthcare legislation has dominated the attention of congress, patent issues are still percolating. Patent reform has been a topic on Capital Hill for the past five years, in which most of the battles have pitted the industries of big pharma and biotech against computers and semiconductors. These industries find themselves on the opposite sides of many issues, such as how and whether patents should be opposed, a first-to-inventor versus a first-to-file system and the damages provisions of patent infringement. In general, the pharma/biotech industries desire strong, broad and enforceable patents in which there are no statutory limitations on damages. In contrast, the computer and semiconductor industries desire patents that are less enforceable and have limitations on damages. This arises because, in the pharmaceutical industry, large blockbuster drugs are covered by, on average five to 10 patents, while in the computer industry, the biggest products may be covered by up to 1,000 patents. Using an oversimplified approach to illustrate the point, for "equal" \$1 billion products, each patent on the pharma/biotech side is "worth" \$100-200 million, while each patent in the computer world is "worth" \$1 million. One can readily see why the computer industry may place less value on any given piece of intellectual property, while in the pharma/biotech industry, each patent represents a large piece of the value pie.

On March 4, 2010, the leaders of the Senate Judiciary Committee issued a press release announcing amendments, known as the Managers' Amendment, to the current Patent Reform Bill. A review of the amendments indicates that the new legislation has become more favorable to the positions generally taken by the pharma and biotech industries. In a press release regarding the new legislation, the international Biotechnology Industry Organization (BIO), stated:

The new managers' amendment contains many positive changes to the underlying patent reform legislation reported out of the Senate Judiciary Committee last April, which BIO supported. While we continue to review the proposal in full detail with the Judiciary Committee and our members, the latest amendment makes several important and well-crafted improvements to the overall bill. The proposal represents a significant step forward towards meaningful patent reform that will help sustain America's global leadership in innovation and spur the creation of high-wage, high-value jobs in our nation's innovation economy.

The new bill decreases the strength of the post-grant opposition period by shortening the time period for opposition, as well as increasing the standard for being able to oppose an issued patent. This position favors the pharma/biotech position because it makes it harder to invalidate a patent through opposition in the patent office. In addition, the amendment changes the damages provision to a “gatekeeper” standard, wherein the courts or juries are only allowed to consider substantial, legally sufficient evidence when deciding what damages to award. This amendment is in contradiction to the previous version of the Patent Reform Bill that limited damages to adequate compensation or, in the very least, a reasonable royalty for the invention that was used.

The Managers’ Amendment regarding the determination of damages will be, in large part, at the sole discretion of the judge. Many believe it will allow for patentees to be fairly compensated for unauthorized use of their inventions, while at the same time preventing what many believe to be outrageous sums awarded in past damages suits. The current amendment states:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court. In determining damages, the court will direct the jury to consider any relevant factors or methodologies, under applicable law, based on the evidence presented.

Some believe that the damages amendment helps infringers more than the patentee, while others believe it provides a more even playing field. If anything, it is agreed that the amendment could lead to the possibility of more appeals.

Furthermore, the amendment reduces the sting of an inequitable conduct charge, by allowing a “supplemental examination” of material possibly related to patentability. There is still much debate on whether the amendment to the “Inequitable Conduct” provision of the bill helps or hurts the patent system. It certainly favors the patentee, but many believe decreasing the penalty for inequitable conduct is harmful, as it may lead to intentional deceit. The United States Patent and Trademark Office (USPTO) can still rule in favor of inequitable conduct if there was intent to mislead or deceive the patent office during patent prosecution. The current amendment states:

A patent owner may request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent. Within 3 months of the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conclude the supplemental examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.

[...] A patent shall not be held unenforceable under section 282 on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior

examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

While the pharma/biotech industry wanted a complete repeal of inequitable conduct, the current amendment appears to allow patentees to rectify many instances of conduct that, while lacking a fraudulent standard, were caught up in the previous standard of inequitable conduct. This new standard should eliminate many unnecessary claims of inequitable conduct within lawsuits.

While patent reform has its backers in Congress, it remains to be seen whether Congress will be able to devote the necessary time and resources to arriving at a new legislation. What seems clear is that the pharma/biotech industries have won the most recent battle in the lobbying leading up to the hoped for legislation. It is likely, however, that many more battles remain to be fought.

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