Testimony of

Kathryn L. Biberstein

June 6, 2007

Written Testimony of Kathryn L. Biberstein
Senior Vice President
General Counsel and Secretary, Chief Compliance Officer
Alkermes, Inc.
Cambridge, MA
Testifying on Behalf of The Biotechnology Industry Organization (BIO) Before the United States Senate Committee on the Judiciary Hearing Entitled
"Patent Reform: The Future of American Innovation"
June 6, 2007

Chairman Leahy, Ranking Member Specter, and Members of the Committee, I am pleased to testify before you today on the critically important topic of patent reform. On behalf of the Biotechnology Industry Organization, of which my company Alkermes counts itself a proud member, I would like to thank this Committee for its continuing leadership in strengthening the foundation of American innovation: Intellectual Property. I also would like to thank the Committee for convening this hearing to discuss how we can, working together, develop a balanced and effective set of reforms to the U.S. patent system so that it continues to drive American innovation forward.

My name is Kathy Biberstein, and I am the Senior VP and General Counsel for Alkermes, Inc. Alkermes is exactly the sort of success story that the U.S patent system has fostered in this country. Alkermes was founded 20 years ago by leading academics in the Cambridge area on the basis of a proprietary patent estate. Last year, Alkermes leveraged its assets to become one of the few profitable, self-sustaining biotechnology companies in the sector. We reached this important milestone by developing innovative medicines based on our proprietary patent estate designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. Today Alkermes has developed two commercial products: RISPERDAL® CONSTA®, ((risperidone) long-acting injection), the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and marketed worldwide by Janssen-Cilag (Janssen), a wholly-owned division of Johnson & Johnson; and VIVITROL® (naltrexone for extended-release injectable suspension) the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the U.S. primarily by Cephalon, Inc. We are also working on several additional important product candidates in disease areas with large unmet medical need such as the treatment of diabetes, chronic obstructive pulmonary disease, and alcohol and opiate dependence. It is primarily through the strength of the patents covering our technologies that Alkermes has been successful in obtaining the venture capital and public market and other financing necessary to develop our pipeline of innovative products.

As I noted at the outset, I am here today representing the Biotechnology Industry Organization or BIO. BIO's membership includes more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. states. BIO

members - the vast majority of whom are small, emerging companies with little revenue and no marketed products - are involved in cutting-edge research and development of health care, agricultural, industrial, and environmental biotechnology products - products that are revolutionizing patient treatment and greatly expanding our ability to feed a growing world population, and offer the promise of reducing our dependence on oil and other fossil fuels and a cleaner environment for future generations.

I base my comments today on 15 years experience as a top executive in the biotechnology industry. I have perhaps a somewhat unique viewpoint on the issue of the contribution of intellectual property to innovation in America, as I spent eight years in the European biotechnology industry. While America has no monopoly on the generation of novel and inventive ideas for the treatment of serious disease, what it does have is a remarkable ability to fund the development of those ideas at early stages - frankly to the benefit of the entire world's population. It is mindful of this extremely important societal benefit that I present my testimony today.

The biotechnology industry, fueled by the strength of the U.S. patent system, has provided jobs for over 200,000 people in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and environmental products. In the healthcare sector alone, the industry has developed and commercialized over 300 biotechnology drugs and diagnostics that are helping more than 325 million people worldwide; another 370 biotechnology products are in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land water and nutrients, and increasing farm income. Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment.

Biotechnology innovation has the potential to provide cures and treatments for some of the world's most intractable diseases, such as cancer, Alzheimer's, Parkinson's, and HIV/AIDS, and to address some of the most pressing agricultural and environmental challenges facing our society today. All of this innovation is possible because of the certainty and predictability provided by the U.S. patent system. Therefore, when considering changes to this system, we urge the Committee to consider carefully the cautionary language embraced by the Hippocratic Oath - first, do no harm.

The Role of Patents in Biotechnology

Biotechnology product development often takes more than a decade and hundreds of millions of dollars of capital investment, a significant amount of which comes from private sources. Biotechnology product development is also fraught with high risk, and the vast majority of experimental biotech products fail to ever reach the marketplace. Investors will invest in capital-intensive, long-term, and high-risk research and development endeavours only if they believe there will be a return on their investment. Patents provide this assurance. Without strong and predictable patent protections, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky - without regard for whether they provide less societal value. Further, collaborative research and development between small innovators and large manufacturers, which is often the only route to

commercialization for small biotech companies, could be delayed or even undermined by attacks on patents over time.

Consequently, as Congress considers reforms to the patent system, it must be mindful of the critical role of patents in the growth and development of companies in the biotechnology sector. Different industries have different business models. For the biotechnology industry, effective patent protection is a necessity, not simply a business advantage or a luxury. We urge this Committee to take great care to ensure that any reforms it enacts support future innovation in all sectors of American society.

BIO's Views on Patent Reform

BIO members believe that, in the biotechnology arena, the patent system has done exactly what it was intended to do: stimulate innovation and R&D. By and large, biotechnology patents are of high quality. That is not to say that there is no room for improvement. As Congress crafts patent reform, BIO would urge the enactment of the following reforms:

? BIO supports full funding for the agency responsible for granting patents--the United States Patent and Trademark Office (PTO). This can be most effectively achieved by permanently ending fee diversion and thus ensuring that all fees collected by the PTO are used to improve the efficiency of the patent system.

? As means for enhancing patent quality, BIO supports expanded opportunities for members of the public to submit prior art during patent examination and repeal of the judicially-created inequitable conduct doctrine, which is chilling the exchange of information between patent applicants and PTO examiners.

? BIO supports a transition to a first inventor-to-file system.

? BIO supports willful infringement reforms that would specify that the litigants must first resolve the validity and infringement of the patent before turning to willfulness, as well as clarify the conditions under which courts can determine that willful infringement occurred.

? BIO supports, in principle, venue reforms that would discourage forum-shopping and encourage the choice of courts in districts where infringement occurred and where the parties actually conduct business, or where the evidence and witnesses are located.

? BIO supports reforms that would expand the prior user defense beyond methods of doing business to all statutory subject matter commercially used prior to the effective filing date of the claimed invention.

? BIO supports repeal of the Best Mode description requirement, which has no counterpart in foreign patent laws and serves largely as an often-abused defense in patent litigation to attack the subjective state of mind of the patent applicant.

? BIO supports restoring a rebuttable presumption of irreparable harm and inadequacy of remedies at law when evaluating a request for a permanent injunction following a finding of

patent infringement, so that the right to exclude - which is the essence of the patent right - is not undermined.

BIO's Position on S. 1145, the Patent Reform Act of 2007

BIO welcomes efforts by this Committee to make improvements to the U.S. patent system. S. 1145, the Patent Reform Act of 2007, which was introduced by Chairman Leahy and other members of this Committee, contains many - although not all - of the laudatory reforms outlined above. However, BIO is very concerned that other provisions in the bill would unintentionally promote uncertainty surrounding, and weaken the enforceability of, validly issued patents. The potential harm of the following provisions in S. 1145 is so great that BIO must oppose the bill in its current form:

Open-ended Post-Grant Opposition: BIO opposes provisions in S.1145 that would create an essentially limitless opportunity to broadly challenge a patent administratively at any time during the life of the patent. This post-grant review provision would be a dramatic departure from domestic and international norms, casting a cloud of uncertainty over issued patents. Under this new system, virtually any competitor or purchaser of the patent holder - indeed, any person that demonstrates "significant economic harm" from the patent - can commence such a challenge at any time. And, contrary to long-standing federal law, the patent would be given no presumption of validity.

If a patent can be easily challenged at any time under a low standard of proof - even years after the patentee and the public have come to rely on it, and years after biotech companies have invested hundreds of millions of dollars to bring a patented invention through clinical trials and regulatory approval - patents will have much less value, and investment predicated upon them will inevitably be diminished. This, in turn, will likely result in fewer cures for diseases and other breakthrough biotechnology products. This life-of-the-patent challenge opportunity also incentivizes dubious behavior by excusing poor due diligence by infringing companies, and by encouraging competitors to delay their validity challenge until they can maximize its impact.

BIO also shares the concerns expressed in the Department of Commerce's letter to House Judiciary Subcommittee Chairman Howard Berman, dated May 16, 2007, that the broad "second window," along with the substantial number of patents subject to the proposed review system, would undermine the ability of the PTO to effectively implement any new post-grant opposition system. As the expert agency charged with administering this new proceeding, we believe the PTO's views in this matter deserve careful consideration. We note that the PTO is actively engaging in the public discourse over a possible new post-grant review proceeding, and is suggesting alternatives aimed at providing post-grant patent review and an administrative alternative to patent validity litigation in a way that would mitigate the cloud of uncertainty fostered by the current bill.

In BIO's view, in order to prevent abuse and misuse of any new post-grant opposition system, any administrative alternative to patent validity litigation must maintain the presumption of validity of patent claims that were issued by the PTO. Further, any post-grant opposition system must include incentives to bring validity challenges early in patent life, and contain limits on the ability of challengers to harass patent owners. If we in the biotechnology industry - with long product lead times and a multitude of complex granted patents to evaluate - are comfortable with

limiting post-grant validity challenges to early in a patent's life, as currently exists in the European patent system, we think the bar is set quite high for industries with substantially shorter product development, and indeed product life, cycles to justify the necessity of longer periods during which such reviews should be permissible.

Last, creation of a new post-grant opposition system also must be accompanied by other critical reforms to the patent system - particularly, repeal of the inequitable conduct doctrine and Best Mode requirement, transition to a first-inventor-to-file system, and restoration of the presumption of injunctive relief to prevent continuing infringement.

Apportionment of Damages: BIO also opposes the provision in S. 1145 that would dramatically expand the situations in which a court would be forced into an "apportionment" process to determine what damages a patent owner should be awarded once a patent is found to be valid and infringed. Under current law, a guilty infringer of a patent currently has to pay the patentee damages adequate to compensate for the infringement, which may be the patentee's "lost profits," but are often limited to a "reasonable royalty." In determining a reasonable royalty, courts follow a flexible set of factors, including the 15 outlined in the landmark Georgia Pacific case, designed to ensure that the patent holder receives a fair royalty based on the value of his or her invention, but is not compensated excessively. The gist of these factors taken together is that a reasonable royalty is what a willing licensee under the patent would have agreed to pay and a willing licensor would have agreed to accept for a patent that both parties agreed was valid and infringed.

The Patent Reform Act of 2007 would introduce a new mandatory procedure for determining and applying reasonable royalty damages, forcing the courts to use an entirely new and uncertain standard that would directs courts to "ensure that a reasonable royalty is applied only to that economic value properly attributable to the patentee's specific contribution over the prior art." In other words, the court would be required to subtract from the infringed patent claim all elements that existed previously in the prior art, regardless of whether they ever existed in the claimed configuration or performed a similar function. Such an approach ignores the fundamental facts that virtually all inventions are, to some degree, premised on prior art, and that many patented components are essential to the intended functionality of the overall infringing product - two facts that are particularly applicable to biotech patents.

During testimony before a House Judiciary Subcommittee on this issue, Members were directed to the example of the Post-it® note, and asked to consider what value remains for that invention once the value of the paper and the adhesive are subtracted out. But let me provide you with what I believe is a more compelling question - whether, for instance, as the parent of a diabetic child faced with years of insulin injections, you would want to disincentivize a company such as Alkermes from its groundbreaking work on an inhaled form of insulin that can replace multiple daily injections, simply because the starting point for that research - begun many years ago - were two things that already existed as "prior art," insulin and small, hand-held inhalers?

Assuming that courts and juries could even apply a prior art subtraction standard in a reasonably accurate manner (which, as noted below, is highly doubtful), the resulting residual royalties would be lower than the reasonable royalties calculated under current law and would compensate

patent owners for only a portion of their invention, rather than its whole. This approach makes infringement cheaper - thus encouraging infringement and, more importantly, ultimately discouraging investment in the underlying technology.

On this issue, BIO urges Committee members to carefully consider the May 3, 2007 letter from Chief Judge Michel of the Court of Appeals for the Federal Circuit, which has been charged by the Congress with ensuring consistency in the application of patent law throughout the country. In his letter, the Chief Judge openly questions both the need for any changes to the law on apportionment and the ability of the judicial system to consistently and effectively implement the proposed new apportionment standard.

Clarity and predictability of patent rights, including the right to fair compensation for infringement, and the right to fairly stop infringers from future infringing acts, are of paramount importance to the biotechnology industry and must be part of any legislative debate on remedies for infringement.

Delegating to the PTO substantive rulemaking authority: S. 1145 would delegate, for the first time in the history of our patent laws, authority to the PTO to promulgate substantive rules interpreting the patent laws. BIO is unaware of any justification for this provision. Currently, the PTO has clear authority to promulgate regulations that govern the conduct of its proceedings. BIO is very concerned that granting broader, substantive patent law rulemaking powers could lead to agency "mission creep" and other unintended consequences at some point in the future. BIO is concerned that such unfettered rulemaking powers will permit the PTO to impose non-statutory restrictions on the ability of biotechnology companies and other innovative industries to obtain appropriate patent protection for their inventions. This is not unlike the concern the Commerce Department itself expressed in its recent letter, when it stated: "We have concerns about unbounded discretion, and therefore want to be certain that any grant [of rulemaking authority] is not overbroad."

BIO further believes that substantive rulemaking authority for the PTO would upset the carefully crafted balance in current patent law, in which Congress sets the rules on patentability, the U.S. Court of Appeals for the Federal Circuit interprets those rules to ensure nationwide consistency, and the PTO and the various district courts implement them. Under principles of administrative law, however, the now-proposed scheme would compel reviewing courts to a level of deference to PTO decision-making that could lead to divergent interpretations of patent law between the PTO and the federal courts - thus creating conflicts and inconsistencies that would upset settled norms of patent law and work to the detriment of all users of the patent system.

BIO wants to emphasize that, with respect to its opposition to these three key provisions in S. 1145, it stands in good company. There is broad consensus, among a variety of industries and stakeholders across the spectrum of American society, against these proposed changes. We note that America's universities and research institutions, the National Association of Manufacturers, the Innovation Alliance, the Coalition for 21st Century Patent Reform, medical device manufacturers, the American Bar Association, the American Intellectual Property Law Association, and the Intellectual Property Owners Association all are in general agreement that enactment of these three provisions as currently drafted would be detrimental to the future of

American innovation. It is essential that the common interest prevail over the special interest of a highly-vocal but minority segment of American industry.

This Committee also requested BIO's views with respect to the provision in the Patent Reform Act of 2007 that would create the right to appeal a district judge's claim construction order to the U.S. Court of Appeals for the Federal Circuit before the district court case could advance to core issues such as infringement or validity. BIO shares in the concerns noted by some that the Federal Circuit would not be able to quickly dispose of large numbers of claim construction appeals so that the underlying district court litigations could resume expediently. To the contrary, such appeals could clutter the Federal Circuit's docket with piecemeal appeals, bog down the appellate process, and hold up the underlying infringement suits for years. BIO is fully aware that many claim construction orders are reversed when patent cases are ultimately appealed from the district courts. But we believe that additional consideration must be given to how best this problem should be addressed before Congress undertakes any reform in this area.
Additionally, BIO strongly believes that the following elements must be included in any patent reform initiative, and notes with disappointment their absence from the Patent Reform Act of 2007 in its current form:

Inequitable Conduct Repeal: BIO supports the National Academy of Sciences' recommendation for reform of the inequitable conduct doctrine. Inequitable conduct is a frequently-abused defense in patent litigation by which infringers can allege that otherwise valid patents are "unenforceable" due to alleged misrepresentations or omissions during the patent application process. The threat of such accusations is chilling communications between patent applicants and examiners, and is negatively impacting the quality and efficiency of patent examination today. It also is a key driver in the cost and length of patent litigation, and has been described as a "plague" by the U.S. Court of Appeals for the Federal Circuit. BIO believes that this doctrine should be abolished. The regulation of applicant conduct should be committed to the expert agency, the PTO. Courts should address objective questions of patent validity, infringement, and anticompetitive behavior, and should no longer have authority to declare objectively valid patents unenforceable for reasons unrelated to actual invalidity.

The need to repeal or restrict this doctrine is supported by a broad range of stakeholders in the patent system, in addition to the National Academy of Sciences, including many of the groups and institutions referenced above, as well as the Department of Commerce and the PTO.

Best Mode Repeal: BIO supports repealing the Best Mode requirement. This requirement, which is unique to U.S. patent law, requires an inventor to describe the best mode of practicing her or his invention. BIO believes, as does the National Academy of Sciences, that this doctrine has outlived its usefulness as a requirement of patentability, and is instead used in modern patent litigation to attack the subjective state of mind of the inventor at the time the patent application was filed, in a belated attempt to invalidate an otherwise valid patent. Again, repeal of this requirement is supported by many stakeholders, with the goal of making the patent system more objective and less costly.

Conclusion

In conclusion, BIO urges this Committee to continue its consultation with affected industry sectors and to ensure that any new patent legislation strengthens, rather than weakens, the patent system that serves as the foundation of current and future American innovation. We stand ready to work with this Committee to ensure true improvements to the patent system that can be supported by all innovative industries.

On behalf of BIO and its more than 1,100 members across the nation, I thank you again for the opportunity to present these views on patent reform and urge your careful consideration of them.