

**Written Testimony of
The Biotechnology Industry Organization (BIO)**

**Before the United States Senate
Committee on the Judiciary**

**Hearing Entitled
“Patent Reform in the 111th Congress: Legislation and
Recent Court Decisions”**

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The Biotechnology Industry Organization (BIO) is pleased to provide this written testimony on the critically important topic of patent reform. BIO thanks this Committee for its continuing leadership in strengthening the foundation of American innovation – intellectual property – and 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.

BIO's membership includes more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 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 that are revolutionizing patient treatment, greatly expanding our ability to feed a growing world population, and offering the promise of reducing our dependence on oil and other fossil fuels and leaving a cleaner environment for future generations.

While America has no monopoly on the generation of novel and inventive ideas, 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 BIO presents this testimony.

The biotechnology industry, fueled by the strength of the U.S. patent system, has spurred the creation of jobs for more than 7.5 million 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 more than 300 biotechnology drugs and diagnostics that are helping more than 325 million people worldwide; another 400 or so biotechnology products are in the pipeline. In the agricultural field, biotechnology innovations are growing the

economy worldwide by simultaneously increasing food supplies, reducing pesticide use, 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, diabetes, 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 strength 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.

This well-worn principle is even more relevant today, as this Committee holds the first Congressional hearing on patent reform since June 2007. During these past two years, both the legal and economic landscape relevant to patent reform has shifted dramatically. To the extent that proponents of patent reform argued two years ago that the judicial climate was overly protective of patents and patent owners (a view decidedly not embraced by BIO even back then), there can be no doubt that a series of landmark decisions by the U.S. Supreme Court and the United States Court of Appeals for the Federal Circuit has made it much harder to obtain and enforce valid patents, while making it easier to challenge them. And to the extent that concerns were raised in 2007 about the negative impact that some of the proposed patent reforms could have on U.S. economic growth at home and competitiveness abroad (a concern that BIO shared), there can be no doubt that such concerns are even more pronounced in light of the current economic situation in the U.S. today.

In light of the major changes that have taken place since many of these patent reform ideas were first suggested, BIO urges this Committee to undertake a careful and

comprehensive evaluation of the continuing need for, and potentially negative impact of, some of the more controversial provisions in the patent reform debate. We commend the Committee for beginning this process with this hearing, and believe the Committee should hold a series of hearings to examine these critical questions before moving forward with legislation.

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. Indeed, during the 10-15 years of investment in R&D prior to product approval, totaling on average \$1.2 billion for every successful new medicine, patents often are the main source of value of a biotech company. 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.

Decreasing investment in biotechnology will result in cessation or interruption of critical research projects, increasing layoffs, and in many cases the demise of start-up companies reliant on private capital, with an accompanying loss of high-paying U.S. jobs. Perceived weakness of patent rights will also impact collaborative research and development between small innovators and large manufacturers, which is often the only route to commercialization for small biotech companies. Further, collaborations between academic laboratories and biotechnology companies are likely to diminish, as companies worry about the strength and predictability of licensing rights based on weakened patents.

The result may well be a return to the 1970s, when our substantial Federal research investment yielded basic discoveries that simply languished on laboratory shelves.

President Obama has called for a renewed effort to cure cancer in our lifetime, and the Congress just granted the National Institutes of Health an additional \$10 billion as part of the economic stimulus package. Yet the wrong approach to patent reform could undermine these commendable efforts.

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 and in the translation of basic research into actual products. 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 giving the PTO more flexibility in setting its user fees, and by permanently ending fee diversion – 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 that incorporates an appropriate “grace period” so as to encourage both the prompt filing of patent applications and the early public dissemination of research results.
- 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 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 the Patent Reform Act of 2009

BIO welcomes efforts by this Committee to make improvements to the U.S. patent system. The Patent Reform Act of 2009, 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 the bill as currently drafted is so great that BIO must oppose the bill in its current form:

Expanded Post-Grant Reexamination: BIO opposes provisions in the bill that would broaden the grounds upon which a patent can be administratively challenged at any time during the life of the patent. This expansion of reexamination, on top of a new, time-limited post-grant opposition system, would be a dramatic departure from established norms, casting a cloud of uncertainty over issued patents and upsetting decades of settled, investment-backed expectations. Under this new system, virtually any competitor or customer of the patent holder – indeed, any person at all – can commence such a challenge at any time against any patent that is in force today. And, contrary to long-standing federal law, the patent could be challenged on the basis of unwritten prior art with no presumption of the patent's 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 such as

advanced biofuels. This expanded 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.

While BIO supported the creation of broader administrative challenges as contained in the Patent Reform Act passed by the U.S. House of Representatives in September 2007, the current bill goes too far by permitting any petitioner to attack a patent on the basis of unwritten prior art that was “in public use or on sale.” As interpreted by the courts, those bases for prior art attacks are simply too broad to provide any meaningful protection for patent owners against harassment and abuse of this new administrative process. Further, because of their subjective and fact-intensive nature, they would require the type of discovery and due process that the PTO is ill-suited to provide and manage efficiently, and that would undermine the very purpose of creating a streamlined, administrative alternative to the court system. And, most problematic, these types of challenges could occur long after the issuance of a patent, creating substantial prejudice to patent owners without the protections found in court.

Indeed, a system of administrative patent challenges that provides an early post-grant review proceeding *and* multiple later opportunities for expanded reexamination on the basis of unwritten prior art is highly prejudicial against patents specifically in technologies that operate under a long innovation cycle, such as biotechnology. In biotechnology, products often reach the marketplace only a decade or more after the patent was initially applied for. Thus, in biotechnology and other slow-developing technologies, the late reexamination challenge is likely to come many years after the patent was first applied for. Unwritten prior art in biotechnology is likely to involve the past use of research materials or past studies of biological material that become increasingly hard to document or disprove, especially as they recede in time. In other words, slow-developing technologies like biotechnology are likely to face more, and

bigger, evidentiary problems in such an expanded reexamination proceeding. These evidentiary problems are exacerbated by the patentee's inability to challenge the authentication, reliability, veracity and materiality of such evidence, because the reexamination provisions of the Patent Reform Act include neither a right to discovery nor any other protections that would account for the fundamental difference between traditional "patent and printed publication" evidence on the one hand, and "public use or on sale" on the other hand.

In BIO's view, in order to prevent abuse and misuse of any new post-grant reexamination system, any administrative alternative to patent validity litigation, especially if brought late in the life of the patent and on grounds that go beyond what is possible under current law, must account for the presumption of validity of patent claims that were examined and issued by the PTO. Further, any administrative post-grant review 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 broad-based 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 irreparable harm and inadequacy of remedies at law to obtain injunctive relief from continuing infringement.

Apportionment of Damages: BIO also opposes the provision in the bill 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 those 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, enforceable, and, absent a license, infringed.

The Patent Reform Act of 2009 would introduce a new default rule for determining and applying reasonable royalty damages, forcing the courts to use an entirely new and uncertain standard that would direct courts to “ensure that a reasonable royalty is applied only to that economic value properly attributable to the patent’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.

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. While proponents of this provision argue that they are only seeking to ensure that a royalty reflects the value of the patented component as opposed to the entire infringing product in which the invention is incorporated (which we note is one of the *Georgia Pacific* factors already in current law), the actual proposed bill text does something quite different – mandating apportionment *within* the patented invention itself, between prior art elements and what proponents claim are the "inventive features."

This approach makes infringement cheaper because it would assess royalties on something less than the full invention – thus devaluing patents, encouraging infringement and, more importantly, ultimately discouraging investment in the underlying technology. Further, the uncertainty that such a vague and ill-defined concept would breed would further cause a devaluing of patent assets generally, and the value of many existing and future licenses to such patents.

We emphasize that this devaluation of patents is more damaging in a multi-year, high-risk, capital-intensive industry such as biotechnology. Investors will be extremely reluctant to invest the hundreds of millions of dollars necessary to develop a biotech product if the patents that ultimately will protect that product have been devalued in this manner.

BIO also 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 such a 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.

BIO wants to emphasize that, with respect to its opposition to these two key provisions in this bill – damages and expanded reexamination – it stands in good company. There is broad consensus, among a variety of industries, universities, unions, and other stakeholders across the spectrum of American society, against these proposed changes. It is essential that the common interest prevail over the special interest of a highly-vocal but minority segment of American industry.

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 2009 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.

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 what is believed to be, at the time of filing, 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.

Recent Court Cases and Their Impact on Patent Reform Proposals

While any system will need to be modified over time, the legal system governing patents has proven to be largely self-correcting. Over the past several years, the U.S. Supreme Court and the Federal Circuit have issued (or are presently considering) a series of landmark patent decisions that resolve many of the key legal complaints that have been raised about the current patent system. For example:

- Business method patents: The Federal Circuit, in In Re Bilski, basically eliminated much-maligned patents on disembodied business methods.
- Venue abuses: The Federal Circuit in the TS Tech case, like the Fifth Circuit before it, recently compelled the Eastern District of Texas to start transferring more patent cases to other district courts in more appropriate locations.
- Willful infringement: Under the Federal Circuit's Seagate decision, willfulness is now a much more circumscribed doctrine that is harder to establish in litigation.

- Obviousness: In KSR, the Supreme Court made it easier for the PTO to reject applications on combination inventions, and for defendants to prevail on an obviousness defense against asserted patents.
- Licensor-licensee relationship: In MedImmune, the Supreme Court provided new avenues under which businesses which are on the receiving end of aggressive licensing invitations can go to court. In Quanta, the Supreme Court constrained a patent owner's ability to collect royalties from downstream users of its licensed invention.
- Infringement liability for exported software: In the Microsoft v. AT&T case, the Supreme Court limited the availability of extraterritorial infringement theories and eliminated infringement liability for exported software that is loaded on computers abroad.
- Permanent injunctions and “hold-ups” by “predatory” patent owners: In the eBay case, the Supreme Court made it harder for non-practicing patent holders to permanently enjoin infringers.
- Damages: Lucent v. Gateway is currently on appeal in the Court of Appeals for the Federal Circuit. It deals with the standards for calculating a reasonable royalty where the patented element is only a small part of the overall infringing product – the exact fact scenario that the proponents of damages reform believe needs clarification. The case will likely be decided by this summer and should clarify the law in this area.

Certainly, these major legal changes have dramatically shifted the patent landscape, generally weakening the rights of patent owners. This Committee should carefully consider the impact of these cases as a whole, in determining whether additional reforms that would further weaken patent rights would push the patent system too far in such a

direction, with potentially enormous negative consequences for America's engine of innovation.

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 its more than 1,200 members across the nation, BIO thanks you again for the opportunity to present these views on patent reform and urges your careful consideration of them.