



**The Statement of the
The Biotechnology Industry Organization
On
H.R. 1908, The Patent Reform Act of 2007
The United States House of Representatives
Committee on the Judiciary
Subcommittee on Courts, the Internet, and Intellectual Property**

April 26, 2007

The Biotechnology Industry Organization (BIO), the trade association for more than 1,100 biotechnology companies, academic and research institutions and related organizations commends the House Judiciary Subcommittee on Courts, the Internet and Intellectual Property for its continued leadership on issues related to the foundation of American innovation: Intellectual Property. We are grateful for the opportunity to comment on H.R. 1908, The Patent Reform Act of 2007.

BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. 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 which have helped more than three hundred and twenty-five million people worldwide; roughly 400 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. All of this is possible because of the certainty and predictability provided by the U.S. patent system. Biotechnology innovation, if allowed to progress, has the potential to provide treatments for some of the worlds most intractable diseases and address some of the most pressing challenges facing our society today.

Patents are the life-blood of the biotechnology industry. The majority of biotechnology companies are small business start-ups that have been created based solely on the promise of their patent estate. These companies do not have products on the market, but have patents that protect their inventions and entice investment in their R&D projects. Through these patents our members are able to translate their inventions in the areas of healthcare, agriculture, and the environment into novel biotechnology products and applications. Today, the United States leads the world in biotechnology research and development primarily because of the strength of its patent system.

The Role of Patents in Biotechnology

The United States patent system is designed to spur innovation and encourage research and development of new products and services for the benefit of society. Particularly in the biotechnology sector, innovation protected by strong, predictable patents catalyzes investment and growth. Jobs are created and society benefits from both the availability of new products, services or treatments and the economic opportunities surrounding these new discoveries. Biotechnology product development can take decades 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 only invest in capital-intensive, high-risk research and development endeavours 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 in less risky projects.

Consequently, the critical role of patents in the growth and development of companies in the biotechnology sector makes it essential for Congress to carefully consider the impact of various patent reform proposals. In considering patent reform, we urge this Subcommittee to take great care to ensure that the reforms enacted serve all sectors of society and do not disproportionately benefit or harm one segment of the users of the PTO.

The Biotechnology Industry Organization's Position on Patent Reform

BIO members believe that, in the biotechnology arena, the patent system has done exactly as 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, but rather to urge that changes be considered carefully and not tip the balance of quid pro quo too heavily in favor of some segments of the U.S. economy at the expense of others. First and foremost, BIO supports adequate funding for the agency responsible for granting patents—the United States Patent and Trademark Office. This can be most effectively achieved by permanently ending fee diversion at the PTO. With adequate funding, the PTO can take steps to improve patent quality through hiring and training of examiners and developing the tools necessary for searching and examining patent applications. As a means for enhancing patent quality, BIO also supports expanded opportunities for third party submissions of prior art during the patent examination process.

BIO supports reforms that would harmonize global patent standards which will make obtaining and enforcing patents efficient and predictable throughout the world. As an example, BIO supports the transition to a first inventor-to-file system. A well-crafted first inventor to file system would ideally contain incentives for inventors to seek patent protection quickly and would encourage scientific publication, collaboration, technology transfer, and public discourse. A first inventor to file system should also simplify the definition of prior art - the legal inquiry into the kinds of preexisting information that make an invention “not new -” to no longer encompass information that would have been unavailable or inaccessible to members of the interested public.

BIO also supports certain proposals that would eliminate subjectivity in patent litigation and therefore reduce the cost of patent litigation. Every dollar spent on litigation takes a dollar away from money spent on research and development of innovative biotech products. BIO urges Congress to eliminate legal doctrines that have no direct bearing on patent validity, and are useful only as tools in aggressive patent litigation, such as Best Mode and unenforceability.

For biotech companies, patent rights are valuable only if they can be enforced. Investors will not finance the lengthy and expensive development of biotech products only to have them copied by a competitor. U.S. patent laws currently deter infringement activity through fair compensation to the patent owner after a finding of infringement. Another deterrence to infringement is the right of patent owners to fairly stop infringers from future infringing acts. Weakening the right of the patent owner to enforce his/her patents will discourage investment in the research and development of biotechnology products.

BIO's Position on H.R. 1908

While BIO welcomes efforts by Congressmen Berman and Smith to make improvements to the U.S. patent system, we are concerned that H.R. 1908 as introduced, contains provisions BIO opposes that will create uncertainty surrounding, and weaken the enforceability of, validly issued patents. The bill also fails to include certain critical reforms called for by the National Academies of Science. The following outlines BIO's position on H.R. 1908.

Provisions BIO Supports

Willful infringement reform: BIO supports H.R. 1908's provision that specifies that the litigants must first resolve the validity and infringement of the patent before turning to willfulness. Additionally BIO supports H.R. 1908's clarification of the conditions under which courts can determine that willful infringement occurred.

Venue reform: BIO supports, in principle, 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. H.R. 1908 takes important first steps in this direction.

Pre-grant submissions of prior art: BIO supports H.R. 1908's provision that would allow members of the public to provide the Patent Office prior art publications for a limited period during the examination of a patent application.

The prior use defense: BIO supports the provision in H.R. 1908 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.

First-Inventor-to-File: H.R. 1908 moves in the right direction by including language transitioning the U.S. to a first-inventor-to-file system, but the actual language of the bill needs further clarification.

Provisions BIO Opposes

BIO, however, strongly opposes provisions in the bill that would weaken patent rights and create uncertainty for patent owners. These provisions include, but are not limited to, the following:

Open-ended Post Grant Opposition: Specifically, BIO opposes provisions in H.R. 1908 that would create an opportunity to broadly challenge a patent administratively. The post-grant review provision in the bill would be a dramatic departure from domestic and international norms, casting a cloud of uncertainty over issued patents. The legislation would create a new post-grant opposition system, under which a patent is given no presumption of validity and could be broadly challenged administratively throughout its term. Under the legislation, any challenger who can demonstrate to the PTO that the challenged patent is likely to cause the challenger "significant economic harm" will be able to challenge the patent at any time. In addition, the challenger can request a post grant proceeding after receiving a notice of infringement from the

patent owner. The proceeding may commence under a low threshold. If a patent can be challenged at any time under a low threshold—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 likely be diminished. 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 it is worth their effort. Further, BIO believes that a post-grant system would not be effective or acceptable without first implementing the reforms described below relating to the Inequitable Conduct defense and the Best Mode requirement, among other matters.

Apportionment of Damages: BIO also opposes the provision in H.R. 1908 that would change the law governing apportionment of damages. Under current law, a guilty infringer of a patent currently has to pay the patentee damages based on lost sales, or a reasonable royalty. Presently, judges have great flexibility in determining a reasonable royalty based on the 15 factors set forth in the landmark *Georgia Pacific* case. The Patent Act of 2007 introduces a new mandatory procedure for determining and applying reasonable royalty damages. The legislation requires courts to conduct an analysis “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”, not the entire value of the product. If royalties are based upon the value of a component, not the value of the product as a whole, this result would make infringement cheaper, thus encouraging infringement, making it just another business decision. 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 apportionment of damages.

Delegating to the PTO substantive rulemaking authority: H.R. 1908 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 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. As an example, the PTO is currently proposing rules that would, contrary to the intent of the Patent Act, limit the ability of biotechnology companies and other patent applicants to obtain the full scope of patent protection for their inventions, in a misguided attempt to reduce the bureaucracy’s workload. The rules also would require applicants to submit statements into the application record that may make the patent examiner’s job somewhat easier, but may well be used at a later time in litigation against the patent owner, particularly in the absence of meaningful Inequitable Conduct reform. There is no indication of why such powers are now needed for the PTO.

Additional Necessary Reforms

BIO also seeks inclusion of the following provisions, as recommended by the National Academies of Science:

Inequitable Conduct reform: Since the early 109th Congress, the main patent reform bills have all contained proposals to implement the National Academies' recommendation for reform of the Inequitable Conduct doctrine. H.R. 1908 fails to address this important concern entirely. "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 absence of Inequitable Conduct repeal is now of even greater concern due to the bill's inclusion of a new post-grant cancellation proceeding and substantive PTO rulemaking authority. Creating a new post-grant system without repealing this antiquated doctrine will open up a new vein of inequitable conduct accusations, with post-grant proceedings being used to "mine" the record for possible instances of Inequitable Conduct, and with patent owners' statements in defense of their patents being used against them in later district court litigation.

Best Mode repeal: H.R. 1908 also fails to repeal the Best Mode requirement. Best Mode is an old requirement under U.S. patent law that has no counterpart in foreign law, according to which the inventor must describe the best mode of practicing her or his invention. BIO believes that this doctrine has outlived its usefulness as a requirement of patentability, and is instead used in modern patent litigation to attack the state of mind of the inventor at the time the patent application was filed. In order to enhance objectivity in the patent application and litigation context, BIO believes that the Best Mode requirement should be repealed.

Conclusion

In conclusion, BIO urges this Committee to continue its consultation with affected industry sectors. As noted, intellectual property protection is a critical element of biotechnology product development and job growth, and while BIO supports efforts to strengthen this system, we look forward to working with the Congress to improve the patent system in ways that can be supported by all innovative industries.