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May 12, 2005

The Honorable Lamar Smith
Chairman
Subcommittee on Courts, the Internet,
and Intellectual Property
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Howard Berman
Ranking Member
Subcommittee on Courts, the Internet,
and Intellectual Property
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Smith and Ranking Member Berman:

The biotechnology industry has developed and marketed more than 350 medicines that have treated or cured hundreds of millions of patients. As the most research intensive industry in the world, and one in which the United States is dominant, we are completely dependent on a strong and vital patent system. As the Congress begins a process of reforming the United States patent system, we strongly urge you to ensure that your reforms preserve those features of our patent system that have proven essential to a commercial environment that stimulates the development of new life saving products for millions of Americans. That environment is one where an innovator can obtain comprehensive patent protection for its innovations, and can rely on guaranteed patent exclusivity to prevent the unauthorized use of that technology.

While BIO supports many elements of the current patent reform agenda which have substantial merit, several measures in the current reform agenda before Congress are inimical to our long-term viability as an industry. The harm that would be caused by these measures far outweighs any possible positive benefits of other patent reform proposals. These measures, if enacted, would (1) require patent owners to justify entitlement to injunctions after the patent was proven to be valid and infringed, (2) allow infringers to challenge patents under a weaker evidentiary showing, and (3) limit the ability of patent applicants to obtain certain patent claims based how much time it has taken to present the claim. We respectfully urge you to oppose these measures.

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Challenging a Patent

Public confidence in the validity of patents issued by the PTO is essential to securing the capital needed for research and development. Under current law, once granted, a patent is presumed valid unless a challenger proves by "clear and convincing evidence" that the patent fails to meet one or more statutory requirements for patentability. This higher burden of proof is a key component of our patent system and is based on the presumption that the PTO has done its job in examining patent applications.

Proposals have been made to lower the standard courts use to evaluate challenges to issued patents. In particular, some proposals would allow a court to invalidate a patent using a "preponderance of the evidence" standard. Adopting this standard would turn determinations of patent validity into a virtual coin toss, thereby dramatically reducing the value of patents to inventors and investors and making it much harder to secure investment capital. It is appropriate to require a party that wishes to challenge a patent to meet the higher burden of proof because patents are property rights that should not be easily displaced. These property rights anchor and protect significant investments made by industry in new technology. Moreover, the practical challenges of requiring courts to administer two different standards for proving invalidity – turning on whether evidence was fully considered by the patent examiner or not – will undermine efforts to reduce the complexity and uncertainty of patent litigation.

Enforcing a Patent

Patent rights are valuable only if they can be enforced; the House proposal would undermine the ability of owners of valid patents to stop others from infringing their rights. Injunctions are the primary mechanism through which patent owners enforce their rights against infringers. Under current law, if a court finds a patent to be valid and infringed, the court presumes the patent owner will suffer "irreparable harm" unless the infringer stops the infringing activity. The burden thus is appropriately placed on the proven infringer to rebut this presumption.

The House Committee print would radically alter this equation. It would place the burden on the patent owner to justify entitlement to its exclusive rights by

requiring the patent owner to prove irreparable harm in each case from the infringement of the court-determined valid patent. Under the proposed standard, a patent owner would not be able to obtain a permanent injunction if it could not prove "irreparable harm." Importantly, the draft requires the determination of irreparable harm to take into account "the extent to which the patentee makes use of the invention." Many small biotech companies do not yet have products on the market, so requiring "use" of the patent does not fit into the business model of an industry with such a long road to FDA approval before a company is able to "use" or "work" their invention.

Under the House proposal, the fact-finder could simply require the infringer to pay compensatory damages (determined by the fact finder to be a fair rate) and continue his infringing activity. This is tantamount to compulsory licensing which will eviscerate the value of patent rights, and their effect in inducing companies in the biotechnology sector to undertake high-risk and expensive research and development activities. Simply put, a patent system that guarantees only some level of compensation, instead of exclusivity, will provide inadequate rewards for meaningful inventions and inadequate incentive to spur innovation and product development. Indeed, for decades, the United States has criticized developing countries for processes that amount to compulsory licensing as a means for these governments to take away private property rights in technology. These countries do not have the necessary incentives to develop technology on their own and so they just take it from us. It is inconceivable that we would be considering changes in our own laws that would lead us in that same misguided direction.

Obtaining a Patent

Finally, flexibility in the patent application process is essential for complex inventions; proposals that limit flexibility will ultimately undermine the quality of patent applications and extend the time it takes to approve a patent. Inventors must have the flexibility to respond to inquiries by the PTO and clarify claims through continuation applications. Tying the patent owner to the scope of the broadest claim in the initial application, as proposed in the House Committee Print, ignores the reality of biotechnology innovation and encourages applicants to make overly broad claims, which would undermine the quality of patent applications. Since it takes 12 to 15 years of patent life for a biotech product to make it through the FDA approval

process, the inventor's understanding of the invention increases during that time and the patent application should be modified to reflect the new knowledge through a continuation application.

We appreciate the complexity of this debate. However, we note that the harm that would be caused by these proposals far outweighs any possible positive benefits of other patent reform proposals. While other industries have offered examples of the ways in which the patent system fails their needs, the diverse biotech industry respectfully urges you to consider the detrimental effects that these proposed changes would have on the many industries that are founded upon a strong and predictable patent system. At a time when we are urging other countries to adopt strong patent protection, it would be counter-productive to undermine the world's most respected patent system.

Thank you for considering our concerns and giving us the opportunity to comment. For questions, please contact Brent Del Monte, Vice President of Federal Government Relations at (202) 962-9200.

Sincerely,

A. Scott Whitaker
Chief Operating Officer
Biotechnology Industry Organization