The Honorable Lynn Rivers  
United States House of Representatives  
Washington, DC 20515

Dear Representative Rivers:

I am writing on behalf of the Biotechnology Industry Organization (BIO) to express our concerns regarding the Genomic Research and Diagnostic Accessibility Act of 2002 (H.R. 3967), which you introduced on March 14. This measure could have a chilling effect on biotech research and development in this country because it would put intellectual property protection of biotech inventions on shaky ground.

Our industry depends on strong, predictable patent protection to attract investment for development of innovative lifesaving products. H.R. 3967 would exempt from patent infringement those individuals who use patented genetic sequence information for noncommercial research purposes. This bill assumes that under the current system, researchers are not free to do research on patented genetic materials and therefore proposes to exempt individuals or entities involved in performing genetic diagnostic, prognostic and predictive tests for research purposes from infringement action. The fact of the matter is that academic researchers who are not engaged in research for commercial use are not affected by the existence of a patent. Biotech companies do not sue researchers who are conducting research for purely academic purposes.

Our industry has already produced more than 120 new medicines and vaccines, many of which were major breakthroughs for previously intractable diseases. These products have helped more than 270
million people worldwide, and millions more stand to benefit from the 350 additional drugs and vaccines now in late-stage development. The viability of the companies developing these products is directly related to the strength and quality of intellectual property protection provided.

Bringing a biotechnology product to market can consume hundreds of millions of dollars and 10 or more years of painstaking research and clinical trials, often accompanied by numerous setbacks. Investors and researchers simply will not take on that kind of risk if the intellectual property behind those products is unprotected, or poorly protected, from infringement. Indeed, one of the three fundamental pillars of a thriving biotechnology industry is strong intellectual property protection. Weaken this pillar—as would your bill—and the effects on investment are immediately destructive.

Patents are often the only assets biotechnology companies have to attract the capital needed to develop lifesaving products. Of the nearly 1,100 companies and research institutions in our membership, only 5 percent are profitable. The rest rely on patents to attract the investment capital that fuels drug discovery and product development.

Any attempt to undermine patent protection on genetic materials will be detrimental to our companies’ survival. H.R. 3967 would diminish the incentives patent laws provide to conduct genomics research and develop genetic tests. Without the assurance of strong protection of intellectual property rights, and the ability to enforce them, commercial entities will be discouraged from expending the resources it takes to bring research discoveries into clinical practice and widespread use. Many of the recent discoveries that could be used as the basis for genetic tests are for extremely rare diseases. Commercial development would assuredly not take place without the protections built into the patent system.
I urge you to reconsider your position on H.R. 3967. The industry faces formidable new challenges ahead that demand additional investments in R&D. Undermining our country’s intellectual property system would be detrimental to the biotech sector in these challenging times.

Respectfully,

[Signature]

Carl B. Feldbaum
President
Biotechnology Industry Organization