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March 21, 2002

The Honorable Howard Berman
Ranking Member, House Judiciary Subcommittee on Courts,
The Internet and Intellectual Property

Dear Representative Berman:

The Biotechnology Industry Organization (BIO) opposes H.R. 3967, the Genomic Research and Diagnostic Accessibility Act of 2002, introduced by Rep. Lynn Rivers (D-Mich.) on March 14. Our industry depends on strong, predictable patent protection to attract investments for development of innovative lifesaving products. H.R. 3967 is a solution looking for a problem that does not exist. Based on the erroneous assumption that researchers are not now free to do research on patented genetic materials, the bill would 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 the 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.

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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, 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.

Throughout your tenure, the House Judiciary Subcommittee on Courts, the Internet and Intellectual Property has been a consistent advocate of strong intellectual property protections because you know the value of a strong patent system to emerging industries. We urge you to continue on this farsighted path and oppose H.R. 3967.

Respectfully,



Carl B. Feldbaum

Biotechnology Industry Organization