



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

BOARD OF DIRECTORS

EXECUTIVE COMMITTEE

CHAIRMAN  
David E. Robinson  
Ligand Pharmaceuticals, Inc.

VICE CHAIRMAN  
FOOD AND AGRICULTURE  
Hendrik Verfaillie  
Monsanto Company

VICE CHAIRMAN  
HEALTH CARE  
Richard F. Pops  
Alkermes, Inc.

SECRETARY  
Thomas G. Wiggins  
Connetics Corporation

TREASURER  
Duane J. Roth  
Alliance Pharmaceutical Corp.

EX-OFFICIO  
Mark Skaletsky  
Essential Therapeutics

MEMBERS AT LARGE

David W. Anstice  
Merck & Company, Inc.

Wayne T. Hockmeyer  
MedImmune, Inc.

Vaughn M. Kailian  
COR Therapeutics, Inc.

John A. Ryals  
Paradigm Genetics

Frederick W. Telling  
Pfizer, Inc.

EMERGING COMPANIES  
SECTION

CHAIR  
H. Stewart Parker  
Targeted Genetics Corporation

VICE CHAIR  
Robert Chess  
Inhale Therapeutic Systems, Inc.

March 21, 2002

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

1225 EYE STREET, N.W., SUITE 400  
WASHINGTON, D.C. 20005-5958

202-962-9200  
FAX 202-962-9201  
<http://www.bio.org>

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.

The Honorable Lynn Rivers

March 21, 2002

Page Three

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,

A handwritten signature in cursive script that reads "Carl B. Feldbaum". The signature is written in black ink and extends across the width of the typed name below it.

Carl B. Feldbaum

President

Biotechnology Industry Organization