



**BIOTECHNOLOGY AND THE PATENT SYSTEM:
BALANCING INNOVATION AND PROPERTY RIGHTS**

Claude Barfield and John E. Calfee

**Book Calls for Careful Reforms of Biotechnology Patent System,
Warn Against Drastic Changes**

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American patent law has reached an unprecedented crossroads, prodded by a landmark Supreme Court decision this spring and the prospect of sweeping new federal legislation this fall. At this critical time, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* (Claude Barfield and John E. Calfee, AEI Press, September 2007) provides a timely look at the complex issues involved in making patent law for cutting-edge high-tech industries such as the biotechnology and computer software sectors.

Barfield and Calfee clearly explain arcane issues of patent law and the tremendous effect that they can have on our economy, our technological progress, and our health. As Congress considers sweeping changes to the patent law, this book is a timely evaluation of the strengths and weaknesses of the current system and the risk of overly aggressive reform.

Biotechnology and the Patent System analyzes the role of intellectual property protection in biomedical research, one of America's leading growth industries. Barfield and Calfee explore ways in which patent law fosters future research and venture capital investment; they also evaluate whether the current system could potentially impede genomic research and the development of new treatment and diagnostic tools. With these competing concerns in mind, the authors evaluate proposals currently under discussion in Congress (S 1145 and HR 1908) and how they would affect biotechnological innovation and, in turn, the quality of our health care.

These proposals have created passionate disagreements among affected industries, with technology and software companies pressing for fundamental reforms that would shift the balance of power from patent holders to patent challengers. Biotechnology, pharmaceutical, and manufacturing firms, as well as large research universities and venture capital associations, contend that the reform proposals are too radical and would undercut U.S. international competitiveness and retard innovation.

In just a few decades, the U.S. biotechnology industry has gone from a handful of startups to a major industry with a market capitalization of \$400 billion and payroll of over 130,000 people. Yet the industry's growth can't mask a simple fact of life for most biotech companies: it is difficult

to make a profit because of the high costs, high risks, and extremely long development times in developing biotechnological therapies and devices. In 2006, the industry as a whole lost \$5 billion.

Potential changes to existing patent law would further complicate these issues; Barfield and Calfee show how some proposed changes to patent law would make it difficult to attract the venture capital that small biotech firms need to develop commercially viable products. They also show that the problems often cited by current critics of patent law are rendered moot by a series of self-correcting remedies and “working solutions” to allow for the responsible sharing of biomedical research.

Even so, Barfield and Calfee acknowledge the need for measured reforms of our current patent system that would allow people to challenge patent applications through administrative procedures without protracted and expensive litigation. They call for Congress to move cautiously and build upon consensus proposals, mindful of the unintended or negative consequences of previous reform efforts. Reform proposals that would garner widespread support include the implementation of a first-to-file patent system and the creation of a system to ensure all patent applications are published within eighteen months.

Claude Barfield and **John E. Calfee** are both resident scholars at the American Enterprise Institute.

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Advance Praise for *Biotechnology and the Patent System*

“Barfield and Calfee have produced a lucid, dispassionate and exceptionally thorough review of the issues, politics, and legislative aspects of patent reform. This up-to-date study reviews not just the shortcomings of the U.S. Patent Office and current patenting procedures but also the key issues in the patent reform legislation moving through the current Congress. Unlike advocacy tracts prepared by individual interest groups, their analysis shows how the interests of key groups, such as the biotechnology and software industries, as well as university researchers, differ.”

—Kenneth W. Dam, professor emeritus of American and foreign law and senior lecturer,
University of Chicago; senior fellow, The Brookings Institution

“Barfield and Calfee have written a little book with big implications. Their advice and guidance must be heeded as we move forward into the heated debate over patent law and real health care reform”

—Peter Pitts, president, Center for Medicines in the Public Interest; former associate
commissioner, Food and Drug Administration (2002–04)

“This study is an objective, unbiased, and well-reasoned examination of many of the difficult issues that must be addressed as we attempt to reform and modernize our nation’s patent laws. This is an excellent contribution to the dialogue on patent reform and to the ongoing congressional deliberations”

—Don Martens, Chair, Task Force on Patent Law Reform, Intellectual Property Law
Section of the American Bar Association