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INDUSTRY
ORGANIZATION

November 5, 2001

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The Honorable J. Dennis Hastert
Speaker
H-232 US Capitol Building
Washington, DC 20515

Dear Speaker Hastert:

The Biotechnology Industry Organization (BIO) applauds your impending action on H.R. 2047, the Patent and Trademark Office Authorization Act of 2002. Our industry depends on strong, predictable patent protection, which can be assured only if the PTO is funded adequately to do its job.

Our industry has already produced more than 120 new medicines and vaccines, many of which were the first 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 PTO's ability to provide timely and high-quality intellectual property protection.

Bringing a biotechnology product to market can consume hundreds of millions of dollars and ten 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.

For biotechnology companies, patents are often the only assets to attract the capital necessary to develop life-saving products. Of the more than one thousand companies and research institutions in our membership, only five percent are profitable. The rest rely on patents to attract the investment capital that fuels drug discovery and product development.

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The provisions in H.R. 2047 lay the necessary groundwork for the PTO to issue quality, timely patents. This will in turn provide the essential mechanism for the biotechnology industry to continue to flourish.

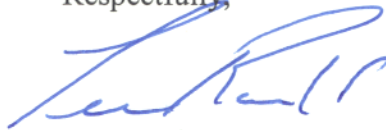
As part of a coalition, BIO has worked closely with the leaders of the House Judiciary Committee — particularly Chairman Sensenbrenner, Ranking Member Conyers, Courts and Intellectual Property Subcommittee Chairman Coble, and Ranking Member Berman — in developing a new approach to solving this problem. We urge you to support this important bill.

In recent years, PTO funding has not kept pace with the demands of the high-technology sector, including biotechnology. Patent fees have continued to be diverted to the general budget even as the PTO's caseload continues to soar. For FY 2002, the PTO projects a 12 percent increase in patent filings and an 84 percent increase in filings by FY 2006. Already, it takes three years for a biotech company to receive an initial response to a patent application. And the backlog will only get worse with 300 examiners available to review 38,000 to 40,000 biotechnology patent applications.

The House's action on H.R. 2047 can send an important signal to the Administration that within the next few months it must 1) develop a compelling five-year plan to get this agency back on track, and 2) request sufficient resources for the PTO in the President's Fiscal Year 2003 budget to begin aggressive implementation of that plan.

In conjunction with the confirmation of PTO Director nominee James Rogan, by passing H.R. 2047 Congress has an opportunity to make a resounding statement in support of intellectual property, thereby eliminating the patent application backlog that represents a threat to the nation's economy.

Respectfully,



Lee Rawls
Vice President, Government Relations
Biotechnology Industry Organization