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BIO Testifies on Patent Reform Act

By Jeff Joseph (Wednesday, August 08, 2007)

On June 6, the Senate Judiciary Committee held a hearing, entitled "Patent Reform: The Future of American Innovation," to hear testimony on the possible effects of the Patent Reform Act of 2007 (S. 1145). Appearing on behalf of BIO, Alkermes, Inc. Senior Vice President and General Counsel Kathryn Biberstein outlined the organization's views on patent reforms and its specific concerns with S. 1145.

Provisions in the legislation would unintentionally promote uncertainty surrounding-and weaken the enforceability of- validly issued patents, Biberstein explained to the committee.

"Biotechnology innovation has the potential to provide cures and treatments for some of the world's most intractable diseases, such as cancer, Alzheimer's, Parkinson's, and HIV/AIDS, and to address some of the most pressing agricultural and environmental challenges facing our society today," said Biberstein. "All of this innovation is possible because of the certainty and predictability provided by the U.S. patent system. Therefore, when considering changes to this system, we urge the Committee to consider carefully the cautionary language embraced by the Hippocratic Oath-first, do no harm.

"BIO welcomes efforts by this Committee to make improvements to the U.S. patent system," Biberstein continued. "While S.1145 contains many laudatory reforms, the potential harm of several of the provisions is so great that BIO must oppose the bill in its current form."

In her written and oral testimony, Biberstein detailed BIO's concerns regarding several provisions in the legislation including those that would establish a new open-ended post-grant opposition system, change how damages against patent infringers are calculated, and delegate substantive rulemaking authority to the U.S. Patent and Trademark Office.

Biberstein also urged the Committee to include in any patent reform initiative elements abolishing the inequitable conduct doctrine. Inequitable conduct is a frequently abused defense in patent litigation by which infringers can allege that otherwise valid patents are "unenforceable" due to alleged misrepresentations or omissions during the patent application process.

"The threat of such accusations is chilling communications between patent applicants and examiners and is negatively impacting the quality and efficiency of patent examination today," Biberstein testified.

She also called for repeal of the best mode requirement, unique to U.S. patent law, which requires an inventor to describe the best mode of practicing his or her invention.

"This doctrine has outlived its usefulness as a requirement of patentability and is instead used in modern litigation to attack the subjective state of mind of the inventor at the time the patent application was filed in a belated attempt to invalidate an otherwise valid patent," explained Biberstein.

"BIO urges this Committee to continue its consultation with affected industry sectors and to ensure that any new patent legislation strengthens, rather than weakens, the patent system that serves as the foundation of current and future American innovation," concluded Biberstein. "We stand ready to work with this Committee to ensure true improvements to

the patent system that can be supported by all innovative industries."

The complete testimony can be found at www.bio.org/ip/letters/.

Jeff Joseph is vice president of communications at BIO.

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