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BLOOMBERG BNA STUDY ANALYZES THE IMPACT OF RECENT SUPREME COURT DECISIONS THAT LEAVE LIFE SCIENCES INDUSTRY UNDER CLOUD OF UNCERTAINTY Report Released at 2014 BIO International Convention Explores Important Changes to Patent Process

San Diego (June 25, 2014) – Bloomberg BNA and law firm Robins, Kaplan, Miller & Ciresi L.L.P., in conjunction with the Biotechnology Industry Organization, today published a study on the impact of recent U.S. Supreme Court decisions affecting the life sciences industry. The report, Stopped at the Threshold: The Practical Impact of the Supreme Court's Mayo and Myriad Decisions on Biotechnology Patent Practices, explores the impact of Supreme Court decisions handed down in 2012 and 2013 that have made it more difficult for companies in the multibillion dollar global life sciences industry to obtain patents.

The report surveys the impact of the Supreme Court decisions Mayo Collaborative Services v. Prometheus Laboratories ("Mayo") and Association for Molecular Pathology v. Myriad Genetics ("Myriad") – and the U.S. Patent and Trademark Office's (PTO) interpretation of those decisions – on companies that own or license patents across the life sciences industry. The authors interviewed 24 industry legal professionals representing the biotechnology industries, including corporate representatives affected by the changes and patent attorneys who deal regularly with the PTO, and gathered commentary from PTO officials. The study also analyzed approximately 350 patent applications recently rejected by the PTO that have been impacted by these decisions.

The report notes that recent interpretations of the law have "shaken the life sciences industry at its roots." Interviews with industry experts find that some of the affected companies believe the current environment "could force inventors and investors to abandon what could be life-saving projects or move to other countries where the laws facilitate innovation." The industry experts noted that the recent Supreme Court decisions, and the PTO's guidance on them, "have rewritten the playbook for biotechnology companies . . . [and] not only limit the scope of what discoveries remain patent eligible, they also transform the way the PTO's patent examiners will review life sciences applications."

"The decisions made by the Supreme Court and the resulting PTO guidance have far-reaching implications for the biotechnology industry," said Randy Kubetin, managing editor of Bloomberg BNA's *Life Sciences Law & Industry Report*. "The industry is still reverberating from the impact of these events and this report offers one-of-a-kind insight and analysis that makes it of great benefit to the entire life sciences industry."

"This study demonstrates that several recent Supreme Court decisions are increasingly impacting areas of biotechnology," said Hans Sauer, Deputy General Counsel for Intellectual Property, BIO. "The United States Patent and Trademark Office's interpretation of case law has led to the rejection of patent applications on industrial or medicinal biotech products."

"We were surprised to see how many claims the United States Patent and Trademark Office rejected on the basis of the Supreme Court's recent decisions," said Matthew McFarlane, co-author and Principal with the law firm Robins, Kaplan, Miller & Ciresi L.L.P. "It's important for inventors large and small to appreciate the wide variety of life sciences patent applications affected by relatively recent reinterpretations of the law."



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Tara Sharp, an associate with Robins Kaplan and co-author of the report, noted that, "The range of inventions impacted by the Supreme Court decisions and PTO guidelines is vast, and covers diverse technologies such as methods for diagnosing disease, biological products, including antibodies and proteins, and even plants and metallic compounds."

Bloomberg BNA Legal Editor John T. Aquino also served as a report co-author. An executive summary of the report is available at www.bna.com/BIO 2014 PR.

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About BIO

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the <u>BIO International Convention</u>, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. <u>BIOtechNOW</u> is BIO's blog chronicling "innovations transforming our world" and the BIO Newsletter is the organization's bi-weekly email newsletter. <u>Subscribe to the BIO Newsletter</u>.

About Robins, Kaplan, Miller & Ciresi L.L.P.

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