

David J. Kappos and David C. Hoffman: Patent legislation would slow biotechnology innovation

**By David J. Kappos and
David C. Hoffman**

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Congress once again has introduced legislation aimed at curbing abusive patent litigation. While there is wide agreement on the desirability of curtailing frivolous threats and suits, there is another critical issue with our nation's patent system that seems overlooked, perhaps even lost, in the debate: how to provide incentives for investment in biotechnology innovation in an era when research and development spending by both government and industry is falling.

The investment in a strong patent system as a means to provide incentives for R&D is one that Americans have made willingly for generations, driving innovations in biotechnology that have revolutionized the prevention and treatment of many life-threatening diseases. Unfortunately, our national mindset has shifted. Public funding for research in the life sciences is decreasing, and incentives for innovation are being degraded.

The patent system, the primary incentive that encourages investment in life sciences innovation, has been declared inapplicable to major sectors of life science by the U.S. Supreme Court. Meanwhile, the new legislation pending in Congress, however well-meaning, could further diminish the strength of our nation's patent system.

Indeed, these reforms could quickly make the United States a laggard in life sciences innovation.

The exclusivity provided by a patent enables those taking on enormous risks by investing in R&D the opportunity to recoup their investment. Studies have shown that an exclusivity period of at least 12.9 years is required just to recoup the development costs of the average biotech drug. Furthermore, the patent system provides a built-in mechanism for encouraging follow-on innovation – disclosure. A key feature of patents is that they are published; no inventor is granted exclusivity over his or her invention without first teaching the world how it works. This is particularly critical in biotechnology, where innovation occurs mainly by accretion, with each succeeding breakthrough building on the previous one.

Advances in diagnostic testing may hold the keys to effective treatment for devastating afflictions such as cancer. Pancreatic cancer, today primarily diagnosed at an advanced stage, is practically a death sentence. Ovarian cancer has effective treatment options, but pivotal to effectiveness is diagnosis at an early stage. Advances in the life sciences promise to unlock these genetic mysteries, but at significant expense. From identifying a manageable set of genes as predictors of clinical pathology to validation studies and data analysis to commercial launch, this years-long development process is

fraught with technical and regulatory hurdles. With costs in the tens of millions or higher, a strong patent system is vital to provide incentives for investment in this important industry.

When we step back to look at the investments required to create new diagnostics in biotechnology, patents are a critically necessary driver. Tomorrow's innovations in the life sciences promise to be equally, if not more impressive than past accomplishments – but no less risky or expensive.

If the world is ever to overcome today's confounding afflictions, and if the United States is to lead that charge, we must double down on our investment in innovation. That means doubling down on the strong patent protections that positioned America as the world leader in biotechnology innovation in the first place.

While the pleas for more patent reform dominate the headlines and congressional attention, policymakers should not be drawn into reform that degrades our patent system for the vast majority of innovators for whom patents represent a hugely positive incentive to invest in innovation.

David J. Kappos, former director of the U.S. Patent and Trademark Office, is an intellectual property lawyer for Cravath, Swaine & Moore. David Hoffman is senior corporate counsel of IP & Transactions at Genomic Health, based in Redwood City. They wrote this article for this newspaper.

CRAVATH, SWAINE & MOORE LLP