A Proposed Path Forward for Legislatively Addressing Patent Eligibility Law

From the conference:

PATENTING GENES, NATURAL PRODUCTS AND DIAGNOSTICS: CURRENT STATUS AND FUTURE PROSPECTS

Held at The Banbury Center, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY

On November 9-11, 2016, a group of 22 IP professionals met at the Banbury Center to discuss the impact of United States Supreme Court decisions limiting available patent protection for natural products and diagnostics. Under these decisions, biopharma inventions that are readily patentable in other industrialized countries have been found to be ineligible for patenting in the United States, thereby erasing incentives to invest in developing such inventions.

Beginning with its 2010 decision in *Kappos v. Bilski*, the Supreme Court has progressively limited patent eligibility in the United States. Currently, it does so through a two-part test that has proven to be highly subjective and arbitrary in its application. The Court has justified its actions on the ground that the statutory limitations on patenting offer insufficient assurance that valid patents will not preempt access to the basic tools of science and technology, *e.g.*, natural laws, products, and phenomena, as well as other types of abstract concepts.

The participants in the Banbury Conference discussed in detail three measures that Congress could take to remedy the problems created by Supreme Court jurisprudence and restore the historic availability of patent protection for medicines and diagnostics based on the discovery of natural principles or products. These are:

1. Clarify that patent protection shall be available for inventions in all fields of *technology* and better conform U.S. patent law with internationally accepted norms of patentability. To this end, a number of participants recommended that Congress enact a substitute requirement limiting patent eligibility to technological inventions, *i.e.*, inventions contributing to the *technological arts*. Such a measure would codify the standard set out in the concurring opinion in *Kappos v. Bilski* and foster greater harmony between U.S. patent law and the patent law in Europe."
2. Enact a substitute, statutory eligibility standard that overrules the "implicit exception" and the two-part test used to implement it. The Court's rationale for imposing a judicial exception fails to take full account of the collective effect of the set of statutory requirements that limit the availability of conceptual patents—and that preclude the possibility that patents can either cover or preclude access to natural materials, laws, or phenomena. Maintaining a judicial exception is, therefore, unnecessary for any articulated constitutional or policy reason.
3. Exempt from patent infringement research uses of patented inventions where the exempted experimentation is limited to activities to better understand or improve the patented subject matter. Such an exemption should be limited and targeted in a manner that is consistent with the 2006 recommendation of the National Academies for doing so. This clarification that research performed on patented inventions is non-infringing would assure that no vestige remains of the Supreme Court's justification for imposing a judicial eligibility exception.

We, the undersigned, urge consideration be given to the measures outlined above.*

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