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A. *Title*

Innovation as a Policy Lever

B. *Abstract*

The legal test of whether a patent claim is inventive impacts the effectiveness of the system as a whole. The decision to protect certain types of information, or alternatively to maintain such information in the public domain, has the potential to impact industries, the process of knowledge creation, the potential to create, and the public's ability to access emerging innovations. It is inevitable that the decision to determine whether a claim is inventive implicates the law's purpose.

There is universal agreement that the patent system is intended to operate for the public benefit. From that point forward, the picture becomes unclear. Some sources identify that the system's purpose as facilitating the creation of new knowledge; others emphasize innovation. Most recently, the U.S. Supreme Court has focused on creating "open space" around the patent system to ensure that the creation of new ideas is not precluded by claims to abstract subject matter, obvious inventions, or the automatic injunction. At the same time, stakeholders assert the necessity for a strong patent system in order to ensure funding to sustain a workable scientific infrastructure.

A review of international decisions reflects some highly deliberate approaches. As one example, Australia's *D'Arcy v. Myriad* found that an isolated DNA segment was artificial, and therefore patentable. Setting this comparatively low creative bar, the *D'Arcy* decision rested on the social good produced by the subject matter of the claim—that is, "the treatment of breast and ovarian cancers." India's rigorous patentability criteria under section 3(d) of its Patent Act demands significant improvements to meet health needs before the burden of patent protection will be imposed on its population. These (and other) examples demonstrate that nations can, and do, use patentability to effectuate economic or social policy.

This essay examines the extent to which the U.S. can likewise consider the legal tests of patentability as express policy levers. Specifically, this piece questions whether the tools used to reach the invention determination are likely to lead to results that mesh with the U.S. patent system's goals. The U.S. Supreme Court's recent pronouncements in the patentability determination largely look backward for precedential support. Establishing standards based on fragments assembled from *Flook*, *Chakrabarty*, *Graham*, and the like befits a common law system for a property-based regime, where stability is important and sudden shifts in the law may interfere with stakeholder expectations. Nonetheless, these standards miss opportunities to promulgate principles that address some of the most challenging questions in the field and may be necessary to sustain its relevance in the long term.

As one example, the *Alice/Bilski* test for the abstract subject matter exclusion draws on proximity to pre-existing concepts and concerns about preclusion. Although it can be expected that this indistinct test will develop into more crystalized concepts through progeny in the Federal Circuit, the Court's framework requires additional policy articulation to ensure that the space created around patentable subject matter furthers the system's goals in fact. Similarly, *Myriad*'s bright-line acceptance of CNDA as patentable subject matter fails to contend with the nuanced policy concerns inherent in separating the artificial from matter existent in nature.

Consistent with the patent system's fixation on invention as a human act, the nonobviousness analysis conceptually ties "invention" to the presumed mental acts of those engaged in a problem-solving task. Yet the explanatory language, which rests on the hypothetical thought processes of a hypothetical person, uses language freighted with perhaps unfounded assumptions about the nature of scientific creativity. More recently, the Federal Circuit has resorted to determining nonobvious using the language of presumptions. Moreover, any concern about funding for the scientific infrastructure is notably absent from any of these authorities.

This piece will provide alternative approaches that can allow decision makers to fulfill particular policy objectives in the context of making patentability determinations. In some, these can be undertaken under the existing legal standards. In others, the present standards must be changed to accommodate more meaningful engagement with the system's goals.