A UNIFORM FRAMEWORK FOR PATENT ELIGIBILITY

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Patent doctrine has been plagued by a prolonged state of ambiguity. As recent cases and controversies reveal, there is an immediate need to clarify patent law so as to advance resolution of its most fundamental question – clear identification of the types of inventions that constitute patent-eligible subject matter. Coupled with the active role the Supreme Court has taken in examining this precise issue, individuals and non-profit organizations have galvanized a public discourse through constitutional challenges to the issuance of various biotechnology patents.

Despite a statutory framework that has remained constant since 1793, courts have been unable to create a comprehensive test for determining patent-eligible subject matter that veraciously embodies the legislative intent and constitutional mandate underlying the patent laws and is applicable across all technologies. Analysis of patent jurisprudence reveals a two-step method for determining eligible subject matter: an invention is patent-eligible if it (i) corresponds to a statutory category outlined in Section 101 of the Patent Act, which includes processes, machines, manufactures or compositions of matter and (ii) does not violate the product of nature doctrine, which precludes eligibility for laws of nature, natural phenomenon, mental processes and abstract ideas. Rather than establishing a framework that is grounded upon these principles, decisions have frequently been guided by intuition and analogy, and have often comingled analysis of subject matter eligibility with other statutory requirements. Though a plethora of eligibility tests has resulted, each test has produced inconsistent results when applied across a diverse range of technologies.

Much of the ambiguity surrounding patent-eligible subject matter may be traced to the failure of courts to adequately and appropriately define the categories that are encompassed by the product of nature doctrine. In turn, the absence of robust definitions has led to uncertainty as to the scope of subject matter that is ineligible for patent protection. This paper sets forth a new framework that addresses patent-eligible subject matter by accurately characterizing the statutory categories and creating a conceptual methodology that defines subject matter encompassed by the product of nature doctrine in technology-agnostic terms. For each product of nature category, a series of questions is proposed. The questions are structured so as to embody Supreme Court interpretation of the fundamental principles underlying the exclusion of products of nature from patent-eligible subject matter, and serve as a resource that courts and the Patent Office can use to delineate patentable subject matter. The advantages of this methodological approach are highlighted through the application of the new framework to traditional inventions and emerging biotechnologies.