

Intellectual Property and Technology Law Update

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Supreme Court Rules Subject Matter That is *Effectively* a Natural Process is Unpatentable

The Supreme Court handed down a unanimous decision that a process that essentially defines how a law of nature works is unpatentable subject matter. The decision overruled a Federal Circuit holding that the claimed process was patent eligible due to significant physical limitations enumerated in the claims. The Justices noted that although laws of nature, natural phenomena and abstract ideas are not patentable subject matter, "an application of a law of nature ... to a known structure or process may [warrant] patent protection. ... But to transform an unpatentable law of nature into a patent eligible application of such a law, a patent must do more than simply state the law of nature while adding the words 'apply it.'"

The patent claims identified the relationship between concentrations of certain naturally occurring metabolites and efficacious dosages of a thiopurine drug used to treat autoimmune diseases. Each claim included: (1) an "administering" step, instructing a doctor to administer the drug to his patient; (2) a "determining" step, telling the doctor to measure the resulting metabolite levels in the patient's blood; and (3) a "wherein" step, describing the metabolite concentrations above where there is a likelihood of harmful side-effects and below where it is likely that the drug dosage is ineffective.

The Court reasoned that the laws of nature recited in the patent claims are not themselves patentable (i.e., the relationships between concentrations of metabolites and dosages). For the claimed processes to be patentable they must have additional features that provide practical assurance that the processes are genuine applications of those laws, rather than merely clever claim drafting. Lastly, the court noted additional arguments supporting the patentee's arguments — that the process is patent eligible because it passes the "machine or transformation test"; that, because the particular laws of nature that the claims embody are narrow and specific, the patents should be upheld; that the Court should not invalidate these patents under Section 101 because the Patent Act's other validity requirements will screen out overly broad patents; and, that a principle of law denying patent coverage here will discourage investment in discoveries of new diagnostic laws of nature — did not lead to a different conclusion.

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