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OUTSIDE PERSPECTIVES

Overcoming Section 101 Challenges For Patent Holders

THE SUPREME COURT HAS TWICE RECENTLY reconsidered what types of inventions and discoveries are eligible

for patent protection. A unanimous Court in both decisions reaffirmed that U.S. patent law prohibits patent protection for abstract ideas, laws of nature, and natural phenomena. The Court also affirmed that applications of abstract ideas or natural ideas are patentable. Finding the line between unpatent-



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able ideas and patentable applications, however, can be difficult.

There are four basic requirements for acquiring a patent. The patented invention must be (1) useful, (2) novel, (3) non-obvious, and (4) the patent itself must sufficiently describe the invention and enable others to make the invention. Section 101 of the Patent Act relates to the first requirement—that an invention be useful. Section 101 states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor. ...” The Supreme Court has long held that Section 101 contains an implicit prohibition against patenting fundamental building blocks of science. The Court realizes that granting an exclusive monopoly for a natural law or mathematical algorithm, for example, could severely impede future research and innovation.

In the last 20 years or so, Section 101 was seldom used to invalidate a patent. The lower courts and the United States Patent & Trademark Office (USPTO) treated Section 101 as a coarse gate keeper rather than a robust filter to eliminate unpatentable subject matter. The prevailing legal standard for Section 101 was whether a claimed invention produced a “useful, concrete, and tangible result.”

A new class of inventions—business methods—became patentable under this broad standard. Methods of doing business historically had not been patented. Now that the floodgate had opened, a sizable number of business method patents were issued in the 1990s and 2000s. Critics argued that these newly patented business methods had in fact been traditionally practiced internally by firms and therefore were not novel. Further, these business methods were merely abstract ideas and not patentable under Section 101.

In 2008, the Court of Appeals for the Federal Circuit decided a case involving a business method. In that case, the inventor Bilski claimed a method of hedging risk in the field of commodities trading. The USPTO rejected the claims as unpatentable subject matter under Section 101. The Federal Circuit agreed that the Bilski claims were unpatentable but announced a “definitive” test for determining patent eligibility. A claimed process is patent-eligible under Section 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. This “machine-or-transformation” test was the sole test for patentability.

The Supreme Court also agreed that the Bilski claims were outside the scope of Section 101. However, the Supreme Court unanimously held that the machine or transformation test is an important clue for determining whether a claim is patentable under Section 101, but the machine or transformation test is *not* the exclusive test. The Court held that the claims at issue were unpatentable because they were an abstract idea for hedging risk. The Court stated that technology is in a constant state of flux. A rigid rule or categorical ban on patents for “inventions in areas not contemplated by Congress,” would frustrate the purpose of patent law.

In March 2012, the Supreme Court decided another Section 101 case, *Mayo Collaborative Services v. Prometheus Labs*. Prometheus owned a patent that claimed a method of “optimizing therapeutic efficacy” for treating Crohn’s disease comprising: (a) administering a drug; (b) determining the level of a metabolite; (c) wherein (i) a metabolite level $< X$ indicates a need to increase the drug; and (ii) a metabolite level $> X$ indicates a need to decrease the drug.

The district court found the patent invalid because the patent effectively claimed natural laws or natural phenomena: namely the correlation between metabolite levels and the toxicity and efficacy of drug dosages. The Federal Circuit reversed and held that the claimed method was patentable because the human body was transformed by the administering of the drug, and the blood was transformed when it was analyzed for metabolite levels. The Federal Circuit reasoned that satisfaction of the machine-or-transformation test confined “the patent monopoly within rather definite bounds.”

The Supreme Court reversed and found the claims covered natural phenomena coupled with routine, conventional steps. The law of nature was the relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a particular drug will prove ineffective or cause harm. This relation was a natural process of drug metabolism that existed apart from any human action.

The *Prometheus* Court stated that the issue was: “Do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?” The Court held that the claims simply described a natural law to doctors who were treating patients with this particular drug. Methods for determining metabolite levels were well-understood, routine, conventional activities previously engaged in by scientists who work in the field. This purely conventional or obvious activity was not sufficient to transform an unpatentable law of nature into a patent-eligible application of a law. The Court further found that the “transformations” discussed by the Federal Circuit were irrelevant. More importantly, the *Prometheus* Court stated that the machine-or-transformation test cannot trump the “law of nature” exclusion to patentable subject matter.

That the Supreme Court decided two Section 101 cases in two years, and given the unanimous nature of these two decisions, demonstrates that the Supreme Court views Section 101 as an important, and under-used limitation on patentable subject matter. We can draw several conclusions from the *Bilski* and *Prometheus* decisions. Section 101 challenges will become increasingly common at the

USPTO and in courts. The machine-or-transformation test is not a test at all because it neither includes nor excludes patentable subject matter. The Court is extremely concerned about granting monopolies on fundamental building blocks that should be available to all. Finally, applying unconventional (e.g., novel and nonobvious) steps to a process will likely help overcome Section 101 challenges.

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