

Despite the best efforts of the courts and the US Patent and Trademark Office (USPTO), the current test for identifying patent-eligible subject matter under §101 has proved unworkable. Court decisions and USPTO guidelines have raised more questions than they have answered. As a result, stakeholders at every level are left with uncertainty about when patents and patent applications satisfy the requirements of §101. This uncertainty threatens to deprive society and consumers of the benefits of a patent system having clearly defined requirements for obtaining patent protection.

Stakeholders are under pressure to help decision-makers recognise all the innovations and ensuing benefits that will go undeveloped, undisclosed, and unrealised as a result of the current ill-defined test for subject matter eligibility.

The need for guidance

The uncertainty surrounding patent-eligible subject matter stems from the trio of Supreme Court cases starting with *Bilski v Kappos*, continuing through *Mayo v Prometheus*, and culminating with *Alice v CLS Bank*. The inconsistency with which the examining corps and courts apply Mayo's two-part test for subject matter eligibility is proof enough of its failure as an effective tool.

This uncertainty has affected all entities with a stake in the patent system: practitioners, patent owners and applicants, and examiners and judges. Practitioners in certain fields are now uncertain of how to draft claims that clearly satisfy §101. Potential applicants in certain technical fields are left wondering whether it is worth pursuing patent protection for their innovations given the potential costs associated with overcoming rejections for alleged lack of statutory subject matter. Patent owners must now question the value of their patent portfolios given the uncertainty surrounding monetising and enforcing their patents. And examiners and judges struggle to apply the test for subject matter eligibility in a consistent and disciplined manner.

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Following *Alice*, the rates of rejection at the USPTO and the rates of invalidation in the courts on §101 grounds have skyrocketed. The irony is that industries providing much of the current innovation in our society have been hardest hit, namely the biotechnology and software industries.

Some might argue that the current test for patent-eligible subject matter is properly rejecting applications that should not be issued and rightly invalidating patents that should never have been issued. Others might argue that certain classes of inventions—eg,

software-implemented inventions—should be excluded from patent protection. Regardless of the merits of these positions, guidance that clarifies the standards under §101 should nevertheless be solicited, if only to ensure that resources used to obtain and enforce patent rights are put to their most productive uses.

Since *Bilski*, *Mayo*, and *Alice* have not provided the clarity hoped for, stakeholders must turn to those authorised to make patent law and who are in the best position to evaluate the effects of that law—in other words, US Congress.

Guiding principles

When petitioning for guidance about patent-eligible subject matter, stakeholders should remind decision-makers of the purposes of a patent system. At its core, a patent system serves to promote innovation and the disclosure of that innovation beyond what would naturally occur in its absence. The mechanism by which a patent system does this is simply through the possibility—not the guarantee—of patent protection.

Stakeholders should also remind decision-makers that the ultimate beneficiaries of a patent system are not the patent owners themselves, but society and consumers. The limited monopoly granted to patent owners is simply what society has chosen to tolerate in exchange for the heightened development and disclosure of innovations, as well as the benefits derived from them.

Therefore, stakeholders should help decision-makers understand what society and consumers risk losing if there exists an ill-defined test for subject matter eligibility, which fosters a perception that the possibility of obtaining patent protection is diminished.

What's at stake

'Unseen innovations' refer to those innovations that go undeveloped or undisclosed as a result of the perception that obtaining patent protection would be impossible or too costly. Society and consumers are deprived of a host of benefits if potential innovations are not developed, or, if developed, are not disclosed. Decision-makers should be made aware that these potential benefits are at risk if the current unworkable test for subject matter eligibility is left in place.

From the perspective of the individual consumer, unseen innovations include those that would provide better, cheaper, and a greater variety of, goods and services. Consumers risk losing innovations that would improve the quality, efficiency, and overall value of goods and services beyond those currently available. Consumers also risk losing competitive prices for goods and services made possible by innovations in providing them.

The competitive activities unleashed by protecting innovations that consumers value are also at risk. Unseen innovations include those that would be developed either as alternatives to

patented inventions or as design-arounds. Unseen innovations diminish consumers' freedom to choose between competing goods and services, including those that compete along the dimensions of innovation and price. Consumers also risk losing the value-enhancing and pricereducing effects of competitors entering the marketplace who are supported by investments made because of the possibility of patent protection.

From a broader societal perspective, unseen innovations include those that would improve individuals' wellbeing. Perhaps the clearest examples are innovative drug treatments and diagnostic methods that could be developed to alleviate ailments, treat diseases, and save lives. In addition, however, society also risks losing the benefits that follow from the economic activities set loose by providing those goods and services to consumers, eg, losing the employment needed to manufacture, deliver, and sell those goods and services either by the patent owners themselves or licensees of those patents.

Recognising the existence of unseen innovations is not to suggest that innovations would never occur or that their ensuing benefits would never materialise. Rather, the key consideration is how we can use effective incentives to maximise the benefits that flow from innovation. A clear standard for subject matter eligibility is a critical factor in providing those incentives.

A modest proposal

Many solutions have been proposed to improve Mayo's two-part test. Whatever solution is ultimately adopted, that solution should clearly inform all stakeholders when a claim recites patent-eligible subject matter.

One way to achieve this is through an objective test for subject matter eligibility—in other words criteria which, if satisfied, demonstrate that a claim meets the requirements of §101. An objective test need not specify what is necessary to recite patent-eligible subject matter, but simply what is sufficient.

An objective test would allow patent applicants and practitioners to evaluate the trade-offs associated with claims that clearly recite patent-eligible subject matter but might be more limited in scope, and those that might be broader in scope but risk not meeting the requirements of §101. In addition, an objective test would allow examiners and judges to make quick assessments of whether a claim satisfies §101.

As a result, efforts to examine and evaluate claims could focus on the more challenging questions of whether a claimed invention is novel and non-obvious. Furthermore, an objective test would allow patent owners to easily assess the value of their patent portfolios by identifying which patents are at risk of being invalidated on §101 grounds, should those patents be enforced.

In short, an objective test would ensure that the limited resources available to secure, enforce, and monetise patents are put to their most productive uses.

Different objective tests could be defined for different fields of technology and designed to accommodate the unique aspects of those fields.

For example, in the context of computer and software-implemented innovations, one potential objective test might clarify (i) that any machine programmed to carry out computerised functions recites patent-eligible subject matter under §101; and (ii) that a claim reciting such a machine is entitled to patent protection when those functions are novel and non-obvious. To ensure objectivity, clarification should be provided that this threshold inquiry is to proceed without any consideration of whether the recited functions are basic functions or were previously known.

This type of objective test would return the initial inquiry of patent-eligible subject matter to its proper place as a threshold test that accommodates innovations in new and presently unknown fields of technology. It would also return any inquiries of what may be wellunderstood, routine, or conventional to their proper place under the evidence-based standards of §102 and §103.

Regardless of the solution, whether it's an objective test or otherwise, those able to provide clarification should recognise all the unseen innovations that will surely be lost from further delay.

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