Big battles in IP – where is Congress?

There are possible reforms that could better adapt the US patent system to the realities of present day entrepreneurship. Lin J Hymel explains.

Recent times have seen major IP battles fought in the courts, with revolutionary impact on diagnostics, biotechnology, and software. Several cases have created high levels of uncertainty in business, investment, and future technology development. They call for legal reform by US Congress, because the alternative is decades of unpredictable case law and hamstrung economic development.

Dramatic expansion of patent ineligible subject matter

Prior to 2012, the US relied on a handful of cases that excluded certain limited subject matter from patent eligibility, such as abstract ideas, laws of nature, and mental steps. There was some uncertainty, but generally the exceptions were limited to fundamental concepts that, if patented, threatened to put large swaths of technology off-limits to further development. However, in the Mayo v Prometheus case the Supreme Court of the US (SCOTUS) surprisingly held that a correlation between a specific level of a metabolite of a man-made drug in the blood of a patient and the likelihood of side effects from the man-made drug is a fundamental law of nature that cannot be patented. Faced with this decision, the US Patent and Trademark Office (USPTO) then concluded that the same logic must apply to all “natural correlations” used in medical diagnosis and other fields. In Myriad Genetics, SCOTUS held that an isolated and functionally identified genomic DNA sequence does not amount to a patentable invention. Again, the USPTO extended the court’s logic to its fullest, rendering patent ineligible all isolated natural products. More recently, the Alice Corp v CLS Bank decision held that computer software that merely implements an abstract idea is not patent eligible, overturning the established rule that a programmed computer is a special purpose machine.

Each of these decisions immediately invalidated thousands of existing patents and rejected thousands of pending applications, leaving ongoing R&D efforts with no prospect of patent protection despite disclosure of the invention. A great deal of uncertainty resulted from failure of SCOTUS to provide definitions of prohibited laws of nature, natural products, and abstract ideas. Outside the narrow facts of each case, the standard remains essentially, “I know it when I see it”. Further, uncertainty has resulted from the sanctioned dissection of claims and ambiguity in dealing with the leftover claim elements. The USPTO has struggled valiantly to fill the void with its guidance, but the gap is too great to be bridged by imaginative examples.

The courts have shown that they are ill prepared to distinguish between fundamental laws of nature or abstract ideas that should be barred from patent protection and applications thereof that should be patent eligible. For example, Mayo v Prometheus put Einstein’s mass-energy equivalence on a par with an individual patient’s metabolism of a specific drug. The courts’ failure to limit their holdings to truly fundamental concepts, and the USPTO’s broad application of those holdings, has led to slippery slopes and uncertainty. Every process in the universe operates by the laws of nature. Mathematics and software break any phenomenon into abstract ideas. But which laws and abstract ideas are so fundamental that they should be excluded from patent protection? The present approach assumes that no natural phenomenon or abstract concept is too small or too specific to be excluded from the court’s proscribed analysis.

Moreover, basing subject matter eligibility on strength of inventive concept, analysed by claim dissection, is misleading and too subjective. Extracting natural laws and abstract ideas from a patent claim can leave nothing seemingly novel, particularly when the novelty lies in the combination, and it strips away the features that cause the claim to read not on the law or abstract idea itself but on its application. For example, in Sequenom v Ariosa, the Court of Appeals for the Federal Circuit’s (CAFC) analysis dissected out the presence of cfDNA in maternal blood as a natural phenomenon, leaving the remainder of the claim (detecting the DNA) as routine, without acknowledging that the claim as a whole (detecting cfDNA in maternal blood for analysis of paternity) was novel. The present approach of dissecting out all natural laws, natural products, and abstract ideas is flawed; it has left large swaths of technology deprived of patent protection, has put the US out of step with the rest of the world, and will negatively impact the US economy.

Many of those driving the litigation leading to the SCOTUS decisions that have shrunk the realm of patent eligible subject matter are interested in weakening the patent system overall. Some have even expressed the opinion that patents are unnecessary, because there is a drive to discover and invent, that does not need the right to exclude or the financial return assured by a patent. Even if true to some extent for very early stage research, particularly in academics, patents provide vital security for the extensive investment of capital and time required to develop a new technology to commercial feasibility. Thus, the absence of patent protection, even if limited to certain areas of technology, will...
inevitably reduce investment and realisation of the economic benefit of new inventions.

What is needed to set the system right again is for Congress to overrule these cases by statutorily defining patent eligible subject matter in far greater detail than in the current 35 USC 101 provision. A revised statute should not only define both included and excluded subject matter, but it should also provide positive examples of patent eligible subject matter so as to limit the exclusions and judicial tinkering. Isolated and purified natural products should be explicitly made patent eligible, before there is a public health crisis for lack of new antibiotics and other drugs derived from natural sources. Genomic DNA sequences can be rendered patent ineligible in the statute as a matter of policy. Dissection of patent claims to determine subject matter eligibility should be prohibited by statute, and only review of the claim as a whole should be allowed. These matters are better dealt with by Congress with the help of experts and input from all stakeholders than by a handful of judges with little or no training in technology.

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Lessons from the CRISPR invention dispute
CRISPR/Cas9 technology offers the promise of highly precise gene editing and is ripe for commercial development. However, the dispute over priority of invention has clouded the promise of this technology. Two groups of inventors, together with their academic institutions and corporate partners, are fighting an epic patent interference (Interference No 106048) to determine who was first to invent and to a business. When much value is at stake, legal battles always will be heated and more complex. Dissection of patent claims to determine subject matter eligibility should be prohibited by statute, and only review of the claim as a whole should be allowed. These matters are better dealt with by Congress with the help of experts and input from all stakeholders than by a handful of judges with little or no training in technology.

Summary
Nonetheless, there are possible reforms that could better adapt the US patent system to the realities of present day entrepreneurship, with its fast paced development, highly competitive investment paradigms, and often short product lifecycles. The goals should be to enhance early patent procurement to secure investment and offer a buffer from competitors while maintaining an environment that still fosters both competition and collaboration. These goals would be best served not by weakening or eliminating patents, but by increasing them while limiting their ability to exclude others, and while opening the door to licensing opportunities. For example, Congress might consider limiting the right to exclude others from practising a patented invention to the first five years of patent term, coupled with a compulsory licensing scheme that takes effect once the period of exclusivity expires. This would provide a head start over competition for a pioneering invention, and yet open the door to competition later in the technology lifecycle, while still rewarding the originator with royalty income. Other alternatives could be to allow an assignee to designate one patent per technology for full retention of exclusivity, while reducing or eliminating exclusivity for other patents (any loss of exclusivity would have to be coupled with compulsory licensing), or simply reducing patent term overall. Such creative solutions could better promote technology development than weakening or eliminating patents.

Footnotes
6. Clustered regularly interspaced short palindromic repeats. The tool enables scientists to alter genomes.
7. The Broad Institute Inc et al v The Regents of the University of California et al, Interference Number 106,048. An interference assists the USPTO director in determining priority.

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