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This U.S. court decision just quashed innovation in health care

The Federal Circuit court's decision against Sequenom health care company has ripple effects over patents.

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Imagine you ask your physician to check your cholesterol levels and she warns you that even though this is a routine need, the procedure is dangerous and inexact—and has not been improved in decades. With apologies, she explains that because medical diagnostic techniques were ruled unpatentable, innovation in this area has dried up. Even investments into much-need advancements just no longer made financial sense for the American scientific community.

Well, the Federal Circuit's decision in June that declared a wide swath of healthcare innovation unpatentable threatens to impose just this sort of stagnation. The ruling in Ariosa Diagnostics v. Sequenom, Inc. is unlikely to make waves at your local pharmacy or prompt a raucous reaction such as we saw recently when a prescription drug's price increased by 5900% overnight. But ironically, Sequenom poses an even more dire threat. By discouraging critical investment in healthcare innovation, this bad decision ordains that the next wave of medical breakthroughs will not be available at any price—because they will not be funded in the first place.

And perhaps most alarming is that this case is part of a larger trend in the court system.

The Sequenom decision puts a dismal twist on the old adage, "bad facts make bad law." Sequenom shows that recent cases have produced laws so bad that even patents supported by good facts are now falling prey. At the center of the case is a patent for an improved method of prenatal diagnostic testing—a non-invasive technique that can identify certain genetic conditions, such as neural defects, for which early notice can make a real difference for soon-to-be parents. Previously, similar testing required inserting a hollow needle into the uterus, which was not only unreliable but also dangerous. Sequenom's test provides the same information from a sample of the mother's blood, in a safer and more dependable procedure.

This case presented a prime opportunity for the courts to conduct a much-needed recalibration of the patent eligibility debate by thoughtfully scrutinizing a game-changing life sciences patent. The Federal Circuit declined to course-correct, instead declaring this discovery as categorically ineligible for patent protection, even after lauding it as a "significant human contribution" that "revolutionized prenatal care." The very best of what the patent system strives to incentivize.

This decision highlights the chasm that has formed between the Constitutional mandate to incentivize innovation and the real-world patent judgments handed down by courts in recent years. At the root of this troubling gulf is a decision by the U.S. Supreme Court hinging patentability determinations on whether the invention falls into one of three categories: a law of nature, a natural phenomenon or an abstract idea — and if so whether what remains amounts to a separately "inventive concept."

Requiring courts to determine what is "directed to" a law of nature, natural phenomenon or abstract idea is, simply, an unworkable standard — no invention exists that does not rely to some degree on one of these categories. Appraising "inventiveness" is equally challenging, needlessly encroaching on far more mature patent doctrines. This test, with its compounded arbitrariness, is the legal equivalent of a mood ring.

The Sequenom case takes an already precarious test to dangerous new depths—essentially attempting to value inventions by summing their parts. After finding that each step of the company's patented method was previously known in the field, the Federal Circuit leapt to the conclusion that those steps, taken together, were therefore not sufficiently "inventive" to "transform" a natural phenomenon (the correlation between fetal genetics and specific markers in maternal blood) into a patentable invention (the method to harness that correlation for the first time).

As such, the case expands the problematic test it inherited in a manner that projects a bias against scientific advancement, artificially separating discovery from invention, with the former deemed patentable only if described in terms of the latter.

Neither the patent clause of the Constitution (which secures inventors' exclusive rights to their inventions), nor the Patent Act (which defines the requirements of patentability) offer support for this capricious distinction. It is unsettling to think what celebrated inventions throughout history would have been rejected as unpatentable when viewed through the problematic lens of the Sequenom case—from Morse's reliance on the natural law of electromagnetism for the telegraph to Edison's discovery of materials naturally suited as filaments for his iconic light bulb.

Applying routine techniques to the natural world in order to achieve a desirable result in a new and better way is the cornerstone of the scientific method. The history of innovation is a dynamic reapplication and reordering of that which is known in light of what is newly discovered.

Instead of embracing and reinforcing this innovative tradition, questionable court rulings on patentable subject matter are now threatening to "swallow all of patent law"—the precise consequence against which the Supreme Court warned in a 2014 decision, Alice Corp. v. CLS Bank—a narrowly-tailored software ruling that has been so misconstrued by lower courts that it has imperiled continuing investment in a field rife with innovation potential. The warning seems to have fallen on deaf ears—lower courts have taken the Alice case and its progeny as license to short-circuit robust analysis in favor of an unpredictable and ill-advised 'I-know-it-when-I-see-it' patent law jurisprudence.

There are remorseful undertones in the Sequenom case's majority's deference to Supreme Court precedent, which come out most overtly in the concurring opinion when it concludes that but for the "sweeping language of the [higher court's] test," there is "no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."

When bad facts make law so bad that not even good facts can survive it—when courts are all but apologizing for their decisions—the need for urgent course correction is clear. Courts and policymakers cannot stand idly by while vital innovation sectors are sapped of investment incentive. The judicial branch must quickly take action by erasing those lines, or Congress must intercede by swiftly passing corrective legislation. When it comes to American innovation, the stakes are too high to allow the current anti-innovation climate to irreparably damage our future.

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