Congress and Courts Need to Look in the Mirror When Asking Why Medical Innovation is Declining

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It's easy to talk about innovation. But true innovation is groundbreaking, disruptive and transformative. And that type of innovation, which is the kind that we say we most desperately need and want, doesn't happen in a vacuum.

Real innovation is a function of risk and reward in a very mathematical sense. The more risk, the greater the reward. But the converse is also true—the less reward, the less one will be willing to risk. And in the United States today, that innovation equation is broken and it has been for some time.

Today, the number one complaint from innovators—whether in biotech, AI, fintech, or medical diagnostics—is the sheer unpredictability of what subject matter is considered patent-eligible under 35 U.S.C. 101. And while it may be possible to get some limited protection for biotech, AI and fintech companies, there is a *de facto* bright line prohibition against the patenting of medical diagnostics thanks to the Supreme Court's decision in *Mayo* and an obstinate refusal by Congress to do anything to fix the situation.

Senate Inaction Speaks for Itself

Ironically, Senator Durbin (D-IL) is unhappy with the Trump Administration proposed National Institutes of Health (NIH) budget. On Tuesday, June 10, during the testimony of NIH Director Dr. Jay Bhattacharyabefore the Senate Appropriations Committee, Durbin incredulously said: "To think that this nation would walk away from medical research. For god sake, we lead the world in medical research. Why would we give up on it?"

Sadly, Senator Durbin was obviously just grandstanding and is not fundamentally concerned by an erosion in medical research in the United States. If he were truly as concerned as he pretends to be now, he would have at some point over the past decade passionately advocated in favor of patent eligibility reform. Durbin has not been a champion for patent eligibility reform, but in his defense, the overwhelming majority of Senators haven't either. Sure, Senators Thom Tillis (R-NC) and Chris Coons (D-DE) have introduced a patent

bill and for the past several years that has included attempts to reform patent eligibility, but the bill has been percolating behind the scenes for more than a decade and still hasn't been acted upon in Committee. So, to say the Senate is not interested in the issue is simply factual. Likewise, it is purely factual to say that one of the main consequences of failed patent eligibility policy is much less medical research, with fewer diagnostics than otherwise possible and fewer medical devices and treatments.

The Courts are Even Worse

The United States chose to largely walk away from medical research—at least privately funded medical research—13 years ago when the Supreme Court issued its ruling in *Mayo*. And the United States has continued to repeatedly turn its back on privately funded medical research since then, as the Federal Circuit has time and time again ruled that medical diagnostics are not patent eligible. Neither the Supreme Court nor Congress has done anything to fix this inexplicable forfeiture of private funding of medical research. Notwithstanding, Senator Durbin now gets up on his soapbox to lecture the Trump Administration because he doesn't like the level of federal spending on medical research. The irony couldn't be more nauseating.

The magnitude of the problem created by the Supreme Court killing medical innovation was most apparent in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* The Supreme Court had the opportunity to rectify its grievous mistake, but instead denied *certiorari* to Sequenom, Inc., letting stand a decision of the United States Court of Appeals for the Federal Circuit, which had ruled that a truly revolutionary medical test was patent ineligible.

The discovery at the heart of the innovation in question resulted in a test for detecting fetal genetic conditions in early pregnancy that avoided dangerous, invasive techniques that are potentially harmful—even deadly—to both the mother and the unborn child. The Federal Circuit concluded that the discovery was "a significant contribution to the medical field," but that did not matter insofar as patent eligibility is concerned.

The invention, which became embodied in U.S. Patent No. 6,258,540, claimed certain methods of using cffDNA. The patent teaches technicians to take a maternal blood sample, keep the non-cellular portion (which was "previously discarded as medical waste"), amplify the genetic material that only they had discovered was present, and identify paternally inherited sequences as a means of distinguishing fetal and maternal DNA.

Federal Circuit Judge Richard Linn, who wrote a separate concurring opinion, explained that given the unnecessarily sweeping language of the Supreme Court's decision in *Mayo* he was constrained to agree that the patent claims at issue were ineligible even though he concluded "Sequenom's invention is truly meritorious."

We're Seeing the 'Unforeseeable Consequences'

Of course, the obvious negative consequences of making medical diagnostics unpatentable is not limited to medical diagnostics themselves. As Medtronic explained in an *amicus* brief filed in *Bilski*, "the development of a diagnostic test almost always precedes the ability to treat the disease and is often a distinct research enterprise separated by years, if not decades." And the Medtronic brief went on to conclude that an erosion of patent eligibility to define what innovation will be acceptable will have "unforeseeable consequences, including the unfortunate chilling of future innovation."

Not surprisingly, the conclusion is that when you take away incentives you will get less innovation—and not limited to the targeted category of innovation. It should be obvious to everyone that Medtronic is precisely correct; if there are fewer medical diagnostics there will be fewer medical devices and treatments. After all, you can't possibly figure out how to treat something if you can't diagnose the condition in the first place.

The entire Congress, the Supreme Court, and all the judges on the Federal Circuit need to look in the mirror to see who is responsible for decreased medical research and fewer medical breakthroughs. This legal uncertainty has become a silent killer of innovation—particularly medical innovation.