



Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
Frank Cullen, Executive Director

October 13, 2022

The Honorable Dick Durbin
Chairman, Senate Judiciary Committee
United States Senate
711 Hart Senate Building
Washington, D.C. 20510

The Honorable Chuck Grassley
Ranking Member, Senate Judiciary Committee
United States Senate
135 Hart Senate Building
Washington, D.C. 20510

The Honorable Patrick Leahy
Chairman, Subcommittee on Intellectual Property
United States Senate
437 Russell Senate Building
Washington, D.C. 20510

The Honorable Thom Tillis
Ranking Member, Subcommittee on Intellectual
Property
United States Senate
113 Dirksen Senate Building
Washington, D.C. 20510

The Honorable Jerrold Nadler
Chairman, House Judiciary Committee
U.S. House of Representatives
2132 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Jordan
Ranking Member, House Judiciary Committee
U.S. House of Representatives
2056 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry "Hank" Johnson
Chairman, Subcommittee on Courts, Intellectual
Property, and the Internet
U.S. House of Representatives
2240 Rayburn House Office Building
Washington, DC 20515

The Honorable Darrell Issa
Ranking Member, Subcommittee on Courts,
Intellectual Property, and the Internet
U.S. House of Representatives
2300 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Durbin, Ranking Member Grassley, Chairman Leahy, Ranking Member Tillis, Chairman Nadler, Ranking Member Jordan, Chairman Johnson, and Ranking Member Issa:

We are writing to provide information about the [Patent Eligibility Restoration Act, S.4734](#), introduced by Senator Thom Tillis (R-NC).

As former federal judges and Patent and Trademark Office leaders, we support this bill, while recognizing that certain provisions could still be modified during the legislative process. But we're gravely concerned to see misinformation circulating about the bill's content as it relates to the life sciences. With this letter, we hope to provide lawmakers with greater clarity.

First, some background.



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The Patent Eligibility Restoration Act aims to eliminate uncertainty caused by Supreme Court rulings in a series of cases: *Bilski v. Kappos* in 2010, *Mayo Collaborative Services v. Prometheus Laboratories* in 2012, *Association for Molecular Pathology v. Myriad Genetics* in 2013, and *Alice Corp. v. CLS Bank International* in 2014.

These cases introduced substantial confusion about what inventions are patent-eligible under [35 U.S.C. Section 101](#).

In [Bilski](#), the court found that a method for hedging risk in commodities markets could not be patented, but in doing so, created uncertainty about what processes are patent-eligible. In [Mayo](#), the court removed patent eligibility for most diagnostic tests and procedures, while in [Myriad](#), the court held that naturally occurring genetic sequences cannot be patented, rejecting the argument that isolated genes are chemically distinct from their natural state in the human body. In [Alice](#), the Court found certain "abstract ideas" not patentable, without defining exactly what qualifies as an abstract idea, thereby leaving whole swathes of artificial intelligence, cryptography, and other emerging technologies in a limbo of uncertainty.

Today, stakeholders almost unanimously agree that the precedents set by these cases threw America's innovation ecosystem into disarray.

The resulting [cloud of uncertainty](#) has decimated the U.S. diagnostics industry, for example, and stifled sectors in which our country faces stiff global competition -- among them biotechnology, artificial intelligence, 5G, and blockchain.

The Patent Eligibility Restoration Act would redress these negative effects.

Much of the hubbub surrounding the bill derives from opponents' assertion that it would permit patents on laws of nature, products of nature, and abstract ideas. Some critics have even claimed that the legislation would permit patents on human genes.

This is categorically untrue; the bill does neither of those things. Indeed, the [draft legislation](#) explicitly exempts unmodified human genes from patent eligibility. As it states, "a person may not obtain a patent for any of the following ... (C) An unmodified human gene, as that gene exists in the human body." (Emphasis added.)



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Any suggestion that this legislation would allow companies to patent anyone's DNA is simply false.

Moreover, the scaremongering claim that human genes have ever been patentable ignores the fact that the [entire human genome](#) has been published many times over. That is to say, knowledge of the DNA components of every human gene is available to scientists everywhere, unaffected by any patent, to use and study as they see fit.

On the other hand, innovative human-made technologies that treat or otherwise operate on human genes should indeed be patentable. An important example is immunotherapy, ground-breaking technology that treats certain types of cancer and saves countless lives. These types of inventions form the crux of the modern biotechnology industry, a critically important component of our economy that plays an outsized role in improving the human condition.

The Patent Eligibility Restoration Act clarifies that various important human inventions, such as groundbreaking medical diagnostic techniques, should be eligible for patent. It also brings our intellectual property system back in line with the rest of the developed world. In Europe, for example, [diagnostics research and development has thrived](#) over the last decade, whereas in the United States, Mayo alone caused investment in diagnostic technologies to fall by [\\$9.3 billion](#) in just four years.

Indeed, the pandemic showed that [European labs](#) were well ahead of the United States in terms of developing diagnostic tools for Covid-19 and supplying them to the rest of the world. In the post-pandemic world, there is even greater global demand for diagnostics of all kinds. The United States should be working to strengthen its diminished capabilities in this area.

Because patent eligibility touches all innovation-driven sectors, it's no exaggeration to say that American competitiveness is at stake as lawmakers weigh the proposed bill. There is room to debate its contours -- but misinformation should play no role in the discussion.

We at the Council for Innovation Promotion include former directors of the U.S. Patent and Trademark Office for both Republican and Democratic administrations,



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as well as federal judges appointed by presidents from both parties. Some of us have also worked in Congress. We have dedicated our careers to the patent system and understand its impact on innovation and our economy. We invite legislators to consider us a resource as they weigh these important issues.

Sincerely,

Andrei Iancu, Co-Chairman of the Board, Former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office (2018-2021)

David Kappos, Co-Chairman of the Board, Former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office (2009-2013)

Judge Paul Michel, Board Member, Former Judge of the U.S. Court of Appeals for the Federal Circuit (1988-2010)

Judge Kathleen O'Malley, Board Member, Former Judge of the U.S. Court of Appeals for the Federal Circuit (2010-2022)

Frank Cullen, Executive Director