

January 30, 2024

Senator Richard Durbin  
711 Hart Senate Building  
Washington D.C., 20510

Senator Chris Coons  
218 Russell Senate Office Building  
Washington D.C., 20510

Senator Thom Tillis  
113 Dirksen Senate Office Building  
Washington D.C., 20510

Representative Darrell Issa  
2108 Rayburn House Office Building  
Washington D.C., 20515

Representative Zoe Lofgren  
1401 Longworth House Office Building  
Washington D.C., 20515

Dear Senators Durbin, Coons and Tillis, and Representatives Issa and Lofgren:

We, the undersigned public interest organizations, write to express our support for existing patent eligibility law and our opposition to S. 2140 - Patent Eligibility Restoration Act of 2023 (PERA).

### **Patent Eligibility Limits Are Vital to U.S. Innovation, Competition, and Economic Growth**

Today's patent eligibility law is critically important to American innovation, economic prosperity, and public health. The Supreme Court's decisions on patent eligibility have made the fields relating to genetics, diagnostic medicine, and software more advanced, competitive, and accessible.

For example, in its 2013 decision, *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)*,<sup>1</sup> the Supreme Court held that isolated genetic mutations, which are highly correlated with breast, ovarian, and prostate cancers, are ineligible for patenting, and therefore that Myriad Genetics' patent on those mutations was invalid. The decision benefited the diagnostics industry and patients almost immediately: the day the decision issued, five different laboratories announced they would provide tests for those mutations at significantly lower prices. The decrease in price—from \$4,000 to between \$1,000 and \$2,300—and availability of tests from different providers significantly improved both the accessibility and efficacy of testing.<sup>2</sup> These benefits have been

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<sup>1</sup> 569 U.S. 576 (2013).

<sup>2</sup> L. Cartwright-Smith, *Patenting genes: what does Association for Molecular Pathology v. Myriad Genetics mean for genetic testing and research?*, PUBLIC HEALTH REP, 129(3):289-92 (May 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3982540/> (citing R. Jaslow, *Supreme Court's gene patent ruling*

evident across the medical diagnostic industry. In the wake of the *Myriad* decision, investment exploded from \$6.21 billion in 2013 to over \$17 billion in 2018, and a wide range of new tests for genetic conditions became available.<sup>3</sup>

In 2014, the Supreme Court held in *Alice v. CLS Bank (Alice)*,<sup>4</sup> that a patent claiming the application of an abstract idea on a generic computer was ineligible for patenting because it added nothing to the idea that could be an actual invention. This decision has had similarly far-reaching benefits. In its “Saved By Alice” initiative, the Electronic Frontier Foundation collected numerous stories of creators and small businesses that thrived because of that decision.<sup>5</sup> For example, an army veteran named Justus Decher started a telehealth business that was saved from a patent assertion entity’s exorbitant demands after its patent was held invalid under *Alice*.<sup>6</sup> The telehealth industry has thrived under *Alice* with investment hitting an all-time high of \$4.2 billion in the first quarter of 2021.<sup>7</sup> Unfortunately, the *Alice* decision came too late to save some small businesses, including an online food delivery business that went bankrupt trying to defend itself against a patent that was invalidated under *Alice* a few years later.<sup>8</sup>

The Supreme Court’s decisions protect researchers, small and innovative companies, nonprofits, and individuals from low quality patents, enabling them to create, compete, and thrive. At the same time, these decisions ensure that inventors can obtain patents for their technological contributions, including to genetics, diagnostic medicine, and software. Existing patent eligibility law has given our country more innovation, economic growth, and accessible medical care.

## **PERA Would Harm Medical Research, Care, and Access**

If enacted, PERA would expand patent eligibility to an unprecedented scope by authorizing patents on natural phenomena, laws of nature, and abstract ideas for the first time in our country’s history. Aspects of nature and general concepts are not themselves inventions, but rather, the foundation of knowledge upon which inventions are constructed. For that reason, the Supreme Court has long recognized they belong to “the storehouse of knowledge of all men,” and must therefore be “free to all” and “reserved exclusively to none.”<sup>9</sup> Patent eligibility limits are necessary to ensure “that patent law not inhibit further discovery by improperly tying up the future use of these building

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*could boost patient care, experts say*, CBS NEWS (June 13, 2013), <https://www.cbsnews.com/news/supreme-courts-gene-patent-ruling-could-boost-patient-care-experts-say/>.

<sup>3</sup> *The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property*, 116th Cong. (2019) (statement of Sean George, CEO, Invitae Corp.), <https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf>.

<sup>4</sup> 573 U.S. 208 (2014).

<sup>5</sup> Electronic Frontier Foundation (EFF), *Saved by Alice*, <https://www.eff.org/alice> (last visited Jan. 28, 2024).

<sup>6</sup> EFF, *Alice Saves Medical Startup From Death By Telehealth Patent*, <https://www.eff.org/alice/alice-saves-medical-startup-death-telehealth-patent> (last visited Jan. 28, 2024).

<sup>7</sup> Heather Landi, *Global investment in telehealth, artificial intelligence hits a new high in Q1 2021*, FIERCE HEALTHCARE (Apr. 20, 2021, 3:45 PM), <https://www.fiercehealthcare.com/tech/global-investments-telehealth-ai-startups-reached-record-levels-q1-2021>. This trend also mirrors the increasing value of molecular diagnostic companies. See Letter from the Invitae on Request for Comment on Current Pat. Eligibility Juris. (Sept. 7, 2021), <https://www.regulations.gov/comment/PTO-P-2021-0032-0053>.

<sup>8</sup> EFF, *Alice Arrives Too Late to Save a Startup*, <https://www.eff.org/alice/alice-arrives-too-late-save-startup> (last visited Jan. 28, 2024).

<sup>9</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

blocks of human ingenuity.”<sup>10</sup> Removing these limits would allow companies to acquire exclusive rights to aspects of nature and information about our own bodies. Such a radical departure from historical and international norms would be a dangerous step into uncharted territory.

Of particular concern, PERA would authorize patents on isolated human genes, such as those associated with conditions like cancer, Alzheimer’s disease, and muscular dystrophy. The bill would similarly authorize patents on isolated genes from other biological organisms, including pathogens, such as COVID-19. And it would authorize patents on any use or transmission of the information these genes convey, allowing the Patent Office to grant corporations exclusive rights to the use of life-saving medical knowledge to diagnose and treat people who are currently suffering as well as to predict our risks of developing diseases in the future.

PERA’s supporters contend that the bill’s provision against patenting an “unmodified human gene” as it “exists in the human body” effectively mitigates the enormous harms that would result from a return to patenting human genes. Not so. Isolated genes fall outside that narrow provision because they are modified and do not exist as such in the human body. In fact, this exclusion would have no practical effect because it is impossible to use unmodified genes “as they exist in the human body,” including for medical diagnostics and other types of testing.

Patents on genetic information and uses thereof will not only limit the availability of current medical diagnostics and treatments, but also harm the availability of future health innovations. Because patents allow their owners to block competition, they would empower their owners to block competition from those who would otherwise offer more effective or affordable tests and treatments. This exclusionary power would, in turn, deter researchers from developing new tests and treatments for life-threatening and debilitating conditions, like cancer and Alzheimer’s disease. The result will be medical care that is more expensive, less innovative, and less accessible than it is today—just as it was in the days before the *Myriad* decision.

### **Existing Patent Eligibility Law Improves Pandemic Response and Preparedness**

The striking contrast between the response to COVID-19 and severe acute respiratory syndrome (SARS) highlights the importance of patent eligibility limits. During the 2003 outbreak of SARS, the Supreme Court had not yet clarified that naturally occurring gene sequences are ineligible for patenting. That led multiple companies to seek patents on the virus and its genetic sequence.<sup>10</sup> Concerned about the detrimental impact these patents would have on research needed to combat the SARS crisis, the U.S. Centers for Disease Control and Prevention (CDC) defensively filed its own patent applications, explaining this step was deemed necessary to “prevent folks from controlling the technology” and “give the industry and other researchers reasonable access to the samples.”<sup>11</sup>

Thanks to the Supreme Court’s clarification of patent eligibility law, patent races have not hampered the COVID-19 response. Scientists around the world are contributing information about the thousands of new strains of coronavirus they have sequenced, data that is vital to understanding

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<sup>10</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (internal quotation marks and citation omitted).

the virus (including its many variants) and developing testing and treatments.<sup>11</sup> While there have certainly been serious obstacles to providing sufficient access to testing and vaccines, this is not because longstanding patent eligibility limits undermined incentives to develop them. Dozens of laboratories have created and are offering diagnostic tests.<sup>12</sup> Numerous companies across the world have developed and are offering effective vaccines.

Had it been otherwise, if one company had been allowed to patent the viral genome, the rapid development of testing, treatment, and multiple vaccines that occurred would have been substantially complicated and delayed, because the patent holder would have had the power to block others from developing or offering competing treatments, tests, or vaccines.<sup>13</sup>

Indeed, Captain Kimberly J. Elenberg, Director for Force Modeling and Analytics for the Department of Defense Coronavirus 2019 Task Force, has credited current patent eligibility jurisprudence for playing a large role in allowing her team to coordinate the military's response to the pandemic.<sup>14</sup> For example, researchers discovered that a significant proportion of individuals infected with COVID-19 shed virus RNA in their stool, and therefore the level of virus RNA in wastewater can be measured to track community infection trends.<sup>15</sup> Under existing patent eligibility law, the correlation between the amount of virus RNA in stool samples and community infection levels was not eligible for patenting, even with the addition of a conventional wastewater test. Therefore, both the CDC and military could freely conduct wastewater tests and use the results to determine where to allocate testing resources.

Current patent eligibility law also plays a key role in protecting the public from *future* pandemics. Just like tracking new variants, detecting the emergence of new viruses requires unrestricted access to gene sequences, natural correlations, and conventional analytic methods implemented on generic computers. For example, Dr. Christopher Mason of Wiell Medical College has led a coordinated effort among researchers to sequence and characterize microbiota (bacteria, fungi, viruses, and other microbes) in cities across the world.<sup>16</sup> Thus far, their work has identified 10,928 viruses and 748 kinds of bacteria that had never before been documented.<sup>17</sup> Thanks to the ability to freely match genes associated with pathogenic viruses as well as antimicrobial resistance to newly identified strains, Dr. Mason's program is already helping us prepare for (and potentially mitigate) future health crises.<sup>18</sup>

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<sup>11</sup> Sandra Park, *The Dangers of Expanding What Can be Patented in the Age of COVID-19*, ACLU (Oct. 30, 2020), <https://www.aclu.org/news/privacy-technology/the-dangers-of-expanding-what-can-be-patented-in-the-age-of-covid-19/>.

<sup>12</sup> *Id.*

<sup>13</sup> Jorge L. Contreras, *COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible*, University of Utah College of Law Res. Paper No. 432 (Feb. 15, 2021), <https://ssrn.com/abstract=3808319>.

<sup>14</sup> Comments of Public Interest Patent Law Institute on Patent Eligibility Jurisprudence Study, Dkt. No. PTO-P-2021-0032 (Oct. 14, 2021) at 5, <https://www.regulations.gov/comment/PTO-P-2021-0032-0111> (citing telephone interview with Kimberly Elenberg, Dep't of Def. Covid Task Force Lead for Data Modeling & Analytics (conducted on Sept. 29, 2021)).

<sup>15</sup> Amy E. Kirby, et al., *Using Wastewater Surveillance Data to Support the COVID-19 Response — United States, 2020–2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 1242 (2021).

<sup>16</sup> Emily Anthes, *Subway Swabbers Find a Microbe Jungle and Thousands of New Species*, THE NEW YORK TIMES (May 26, 2021), <https://www.nytimes.com/2021/05/26/science/microbes-subway-metasub-mason.html>.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

## The Committee Should Make Decisions Based on the Public Interest Rather than Special Interests of Patent Owners

Nearly five years ago, the Senate invited a wide range of groups and individuals to testify about patent eligibility, including public interest organizations. Following that, the United States Patent & Trademark Office requested comments from the public on patent eligibility law. Numerous public interest organizations responded. Unfortunately, the recent hearing on PERA did not include a single organization representing the vast majority of Americans who seek to create, contribute to, or access technological advances, but do not own, assert, or profit off patents. To ensure the record represents the interests of the public beyond patent owners and private companies, attached hereto are a selection of statements from groups that participated in the 2019 hearing as well as the USPTO's report summarizing the comments it received.<sup>19</sup>

### Selected Responses to Witness Testimony at the Recent Hearing

We also wish to address directly a few of the inaccurate statements made at the most recent hearing.

- **Patent eligibility law is clear and works well.**

An ACLU study found that the Federal Circuit affirmed 89% of district court decisions finding patents ineligible in the five years following the 2014 *Alice* decision.<sup>20</sup> From 2013 through 2020, decisions applying § 101 had an affirmance rate of 65% when appealed to the Federal Circuit and decided in precedential opinions, higher than the circuit's overall affirmance rate of 56%.<sup>21</sup> From 2014 through 2020, district court and agency decisions addressing § 101 were affirmed at a higher rate than decisions under other sections of the Patent Act (§§ 102, 103 or 112).<sup>22</sup> Moreover, the Federal Circuit was asked to review nearly three times as many decisions relating to § 103 as decisions relating to § 101.<sup>23</sup> Section 101 cases constituted only 4% of all appeals.<sup>24</sup>

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<sup>19</sup>They are also available online: ACLU, <https://www.judiciary.senate.gov/imo/media/doc/Ruane%20Testimony.pdf>; R Street, <https://www.rstreet.org/wp-content/uploads/2019/06/testimony-101-hearing.pdf>; EFF, [https://www.eff.org/files/2019/06/03/eff\\_testimony\\_for\\_the\\_state\\_of\\_patent\\_eligibility\\_in\\_america\\_part\\_i\\_hearing.pdf](https://www.eff.org/files/2019/06/03/eff_testimony_for_the_state_of_patent_eligibility_in_america_part_i_hearing.pdf); and USPTO, *Report to Congress: Patent eligible subject matter: Public views on the current jurisprudence in the United States*, <https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf> (last visited Jan. 28, 2024).

<sup>20</sup> Comments of American Civil Liberties Union (ACLU) on Patent Eligibility Jurisprudence Study, Dkt. No. PTO-P-2021-0032 (Sept. 7, 2021), <https://www.regulations.gov/comment/PTO-P-2021-0032-0052> (citing Robert Sachs, *Alice: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since Alice v. CLS Bank: Part I*, IPWatchdog (Aug. 29, 2019), <https://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/>).

<sup>21</sup> *Id.* (citing Gibson Dunn, *Chart of Post-Alice Cases* (Mar. 1, 2019), <https://www.gibsondunn.com/wp-content/uploads/2019/03/Overview-of-Section-101-Patent-Cases-Decided-After-Alice-v-CLS-as-of-03-01-19.pdf> (last visited Jan. 28, 2024)).

<sup>22</sup> *Id.* (noting that the Federal Circuit heard appeals of 228 § 103 cases between 2014 and 2020, as compared to 80 § 101 cases).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* (noting that the Federal Circuit heard appeals of 489 cases relating to §§ 101, 102, 103 or 112 and 1437 appeals in total).

Federal Circuit judges have explicitly acknowledged that the test set forth by the Supreme Court for assessing subject matter eligibility is clear and the Federal Circuit’s application of the test to individual cases is consistent. Indeed, Federal Circuit Judge Alan D. Lourie emphasized in a concurring opinion accompanying the court’s *per curiam* Order in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, “our cases are consistent.”<sup>25</sup> He further recognized that in the context of diagnostic methods in particular, the distinction between eligible and ineligible subject matter is “a clear line.”<sup>26</sup> Despite dissenting in that case, Chief Judge Kimberly A. Moore acknowledged the clarity and certainty of current patent eligibility jurisprudence.<sup>27</sup>

Some Federal Circuit judges have expressed distaste for the Supreme Court’s patent eligibility jurisprudence, often appearing to be motivated by sympathy for concerns expressed by patent owners.<sup>28</sup> But these statements generally reflect the judges’ policy views rather than any confusion regarding the proper application of existing law. Such policy preferences have no bearing on the clarity of the current law or its ability to produce predictable outcomes.

Moreover, some judges have explicitly acknowledged the value of the Supreme Court’s clarification of patent eligibility law. For example, Judge Haldane Robert Mayer, whose tenure on the Federal Circuit spans 34 years, asserted that “[b]efore the Supreme Court stepped in to resuscitate section 101, a scourge of meritless infringement suits clogged the courtrooms and exacted a heavy tax on scientific innovation and technological change.”<sup>29</sup> Judge Mayer called the current § 101 framework “an expeditious tool for weeding out patents clearly lacking any ‘inventive concept.’”<sup>30</sup>

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<sup>25</sup> *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1336 (Fed. Cir. 2019) (Lourie, J., concurring).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 1363 (Moore, J., dissenting).

<sup>28</sup> *See, e.g., id.* at 1368-69 (Newman, J., dissenting) (“The major biotech industry organizations advise that our court’s application of *Mayo* ‘has caused great uncertainty to the industry, and . . . has called into doubt innumerable biotech patents.’”) (citation omitted); *id.* at 1358 (Moore, J., dissenting) (“Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline.”).

<sup>29</sup> *In re: Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1165 (Fed. Cir. 2018) (Mayer, J., concurring); *see also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 720 (Fed. Cir. 2014) (Mayer, J., concurring) (“The Supreme Court has taken up four subject matter eligibility challenges in as many years, endeavoring to right the ship and return the nation’s patent system to its constitutional moorings . . . the PTO has for many years applied an insufficiently rigorous subject matter eligibility standard . . .”). Judge Mayer has expressed similar views that patent eligibility should serve as a “threshold issue” to be resolved at the first opportunity. *See, e.g., OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1365 (Fed. Cir. 2015) (Mayer, J., concurring); *Ultramercial*, 772 F.3d at 717 (Mayer, J., concurring); *I/P Engine, Inc. v. AOL Inc.*, 576 F. App’x 982, 992 (Fed. Cir. 2014) (Mayer, J., concurring).

<sup>30</sup> *Id.*

- **PERA would allow the patenting of medical diagnostic methods, which patent laws in Europe and China prohibit.**

The European Patent Convention categorically prohibits patenting methods of surgery, therapy, or diagnosis performed on humans.<sup>31</sup> China’s patent law similarly prohibits patents on methods of diagnosing and treating medical conditions categorically.<sup>32</sup> While Europe allows the patenting of gene fragments, the available empirical evidence indicates that this has a *negative* effect on innovation and access. According to published, peer-reviewed academic studies, “results indicate that the proportion of European laboratories that have *refrained* from providing associated testing services owing to patent protection has increased over the last decade (up from 7% in 2008 to 15% in 2017), and that the non-profit sector was particularly strongly affected (up from 4% in 2008 to 14% in 2017).”<sup>33</sup>

- **Patent eligibility law does *not* systematically result in the rejection of patent applications in the U.S. that are granted in Europe and China.**

A 2017 essay by Kevin Madigan and Adam Mossoff,<sup>34</sup> which purported to report study results supporting this claim has been resoundingly debunked.

According to a detailed study of a random sample of Madigan and Mossoff’s data that was conducted by Abby Rives, nearly a quarter—24%—of the applications in their dataset had never received even a single eligibility-related rejection.<sup>35</sup> Another 61% had pending rejections under Sections 102, 103, or 112 at the time they were abandoned, making it inappropriate to attribute the abandonment solely to a rejection under Section 101.<sup>36</sup> Stunningly, only 15% of the applications identified by Madigan and Mossoff had received a sole eligibility-related rejection when they were abandoned.<sup>37</sup> Of those, almost a quarter (22%) are the basis for still-pending applications to the same invention disclosed in the abandoned application.<sup>38</sup> This means that, in many of these cases, the underlying applications were not rejected, and patents may well issue from those that remain pending.

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<sup>31</sup> European Patent Office, Guidelines for Examination, 4.2 Surgery, therapy and diagnostic methods, [https://www.epo.org/en/legal/guidelines-epc/2023/g\\_ii\\_4\\_2.html](https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_4_2.html) (“European patents are not to be granted in respect of ‘methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body’”).

<sup>32</sup> Qinghong Xu and Xiaoying Wu, *Diagnostic patenting: where does China stand?*, IAM, April 6, 2016, <https://www.iam-media.com/article/diagnostic-patenting-where-does-china-stand>.

<sup>33</sup> Liddicoat, J., Liddell, K., McCarthy, A.H. et al., *Continental drift? Do European clinical genetic testing laboratories have a patent problem?*, EUR. J. HUM. GENETICS 27, 997–1007 (2019), <https://doi.org/10.1038/s41431-019-0368-7>.

<sup>34</sup> Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

<sup>35</sup> Abby Rives, *A Brief Case Study in Policy-Relevant Empirical Assessments: The Shortcomings of Counting Patent Grants by Country to Inform Patent Eligibility in the U.S.* (Oct. 12, 2021), [https://static1.squarespace.com/static/571681753c44d835a440c8b5/t/6165c59179b6af76135e53cf/1634059665361/2021.10.12\\_Case+Study+on+Patent+Data.pdf](https://static1.squarespace.com/static/571681753c44d835a440c8b5/t/6165c59179b6af76135e53cf/1634059665361/2021.10.12_Case+Study+on+Patent+Data.pdf) (last visited Jan. 28, 2024).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

- **Patent eligibility law weeds out low quality foreign patent applications.**

In every year since 2008, the majority of granted U.S. patents have been issued to foreign entities for foreign inventions.<sup>39</sup> It is therefore not surprising that the Rives study found that 75% of the abandoned applications in the Madigan and Mossoff dataset were owned by foreign entities. For the 15% of applications that had only an eligibility rejection pending at the time of abandonment, the proportion of foreign-owned applications climbed to 85%. Notably, the assignee that owned more of these abandoned applications than any other was Huawei.

- **Only Section 101 can prevent the issuance of patents on gene sequences and other products of nature that PERA would make eligible.**

At the hearing, many references were made to sections of the Patent Act other than Section 101, such as Section 103, which requires patented inventions to be non-obvious when compared to prior work in the same field. These sections cannot do what Section 101 currently does: prevent patents from issuing on products and laws of nature that are new discoveries, but not human inventions.

For example, Section 101 currently prohibits a patent on the isolated gene sequence of a new COVID-19 variant with unexpected properties that developed through naturally occurring mutations. Because that variant is new and its properties are unexpected, it would not be disclosed or rendered obvious by prior work in the field. Nevertheless, the variant, and its genetic information, is a product of nature rather than a human invention.

In addition, Section 101 is unique because district courts can decide patent eligibility as a question of law without resort to expert testimony or evidence beyond the patent. As a result, meritless cases can be resolved at an early stage before huge sums of money are wasted on attorney’s fees and other litigation costs. By contrast, Section 103 requires specific factual determinations, and therefore typically requires expert evidence and can only be resolved at trial. In some cases, courts can and have decided Section 103 issues at summary judgment, but we are not aware of any rulings on the merits at the motion to dismiss stage, when many dispositive Section 101 motions are decided.<sup>40</sup> The difference for wrongly accused defendants is enormous: motions to dismiss are decided *before* discovery or trial, and thus before hundreds of thousands, and more often, millions, of dollars in litigation costs are accrued.<sup>41</sup>

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<sup>39</sup> USPTO, *U.S. Patent Statistics Chart Calendar Years 1963 – 2020*, [https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.htm](https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm) (last visited Jan. 28, 2024).

<sup>40</sup> Dr. Stefan O. Ochiana and Justin J. Hasford, *Alice Motions at the pleading stage in patent infringement litigations in the United States*, THE PATENT LAWYER, <https://patentlawyermagazine.com/alice-motions-at-the-pleading-stage-in-patent-infringement-litigations-in-the-us/> (last visited Jan. 29, 2024).

<sup>41</sup> Thomson Reuters, *Patent Litigation 101* (Oct. 27, 2022), <https://legal.thomsonreuters.com/blog/patent-litigation-101/#How-much-does-it-cost-to-litigate-a-patent?> (“[T]he cost of litigating a patent in the U.S. will average about \$3.5 million,” with “[r]oughly half of the costs . . . accrued by the end of discovery,” and “[t]he remainder . . . accrued in the trial process.”) (citing Gregory Day and Steven Udick, *Patent Law and the Emigration of Innovation*, 94 WASH. L. REV. 119 (2019), <https://digitalcommons.law.uw.edu/wlr/vol94/iss1/4>).



## **Conclusion**

PERA will wipe out 150 years of case law and set the stage for countless legal battles yet to be fought. Patients will risk losing access to genetic information that could save their lives. With no competition, patients, payers, and health care agencies will pay higher prices for less innovative testing and treatment. Big pharmaceutical companies may reap higher profits, but the American people would pay an incalculably heavy price.

We oppose PERA in the strongest possible terms. If you have questions, please contact Alex Moss at the Public Interest Patent Law Institute, [alex@piplus.org](mailto:alex@piplus.org).

Sincerely,

American Civil Liberties Union  
Electronic Frontier Foundation  
Generation Patient

Public Citizen  
Public Interest Patent Law Institute  
R Street Institute