March 14, 2024

The Honorable Richard J. Durbin
Senate Judiciary Committee Chairman
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lindsey Graham
Senate Judiciary Committee Ranking Member
224 Dirksen Senate Office Building
Washington, D.C. 20510

To Chairman Durbin and Ranking Member Graham:

On behalf of the manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines, the Association for Accessible Medicines (AAM) writes to ***oppose S. 2140, the PERA Act***, introduced in the U.S. Senate on June 22, 2023. For several reasons, AAM is deeply concerned that the PERA Act would incentivize bad actors, deny patients access to lifesaving treatments, and reverse progress Congress has made to lower drug prices for America's patients.

Section 101 is critically important to AAM and its members. Because of two statutory schemes, the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), generic and biosimilar companies generally must address patent issues before launching a product through costly and protracted patent litigation. Eliminating invalid patents under § 101 enables generic and biosimilar companies to streamline pharmaceutical litigation. Because § 101 can be addressed at the outset of a case, § 101 is a useful tool for generic and biosimilar companies to avoid burdensome discovery and trim the number of asserted patents, which in some cases amounts to dozens.[1] This in turn can allow generic and biosimilar companies to launch their products sooner, providing patients with earlier access to more affordable medications.

The PERA Act would not only minimize these benefits of § 101, but it would make it easier for brand-name biologic companies to obtain less innovative patents, leading to higher drug prices. The *Myriad* case is a perfect example of the detrimental consequences that would follow from enacting the PERA Act.[2] In *Myriad*, Myriad Genetics obtained a broad patent on an isolated DNA sequence for two genes associated with breast cancer, BRCA1 and BRCA2. As a direct result of this patent, patients paid extremely high prices—to the tune of $3,000 per genetic test—and cease-and-desist letters led many researchers to stop studying the BRCA genes associated with breast cancer altogether.[3]

As summarized by AAM's specific concerns below, the PERA Act would abolish § 101's careful test for eligibility and would open the floodgates to non-innovative patents.

[1] *See, e.g.*, Complaint at ¶ 1, *AbbVie v. Boehringer Ingelheim Int'l GMBH*, No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017) (asserting 74 patents in patent litigation related to a biosimilar of Humira®).
[2] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579 (2013).
[3] Josh Dzieza, *Why the Supreme Court's DNA Decision Is A Big Deal*, *available at* https://www.thedailybeast.com/why-the-supreme-courts-dna-decision-is-a-big-deal?ref=scroll.

- Congress should not eliminate "[a]ll judicial exceptions to patent eligibility," which would effectively erase more than 150 years of carefully crafted Supreme Court precedent.[4] The Supreme Court has imposed sensible limitations on patentability, reserving patentability for applications of human ingenuity while explaining "the ancients secrets of nature" are not patentable.[5] Congress should move with deliberate caution when considering whether to take the drastic step of departing from the Supreme Court's significant body of law.

- The PERA Act's definition of "useful" lacks a meaningful filter for identifying patentable inventions.[6] The phrase "a specific and practical utility" is vague, ambiguous, and difficult to apply.[7] Moreover, as the Federal Circuit has repeatedly explained, the "threshold of utility is not high" and will be satisfied unless "the claimed device [is] totally incapable of achieving a useful result."[8]

- The PERA Act's amended definition of "process" is overly broad, encompassing "naturally-occurring process[es]" that are not "new."[9] Particularly when considered in connection with the other proposed provisions, this amendment would drastically expand patent eligibility to include naturally-occurring processes that a person merely "discovers."[10] Such a broad expansion would do little to promote innovation, as it has been observed that "patents on genetic discoveries do not appear to be necessary for either basic genetic research or the development of available genetic tests."[11]

- The PERA Act's reliance on "human activity" fails to meaningfully delineate between patentable and unpatentable subject matter.[12] By way of example, under the Act's framework, the patentee in the *Myriad* gene-patent case would be entitled to a patent merely because Myriad had snipped the gene out of the middle of a DNA molecule—a step lacking innovation but involving "human activity."[13] In fact, the PERA Act's related provisions make clear that ***any*** human activity is enough to render a natural material patent eligible, specifying that the mere step of "isolat[ing]" a gene is sufficient to deem the gene modified as opposed to how "that gene exists in the human body."[14]

For these reasons, AAM and its member companies strongly oppose S. 2140, the PERA Act.

---

[4] PERA Act, S. 2140, 118th Cong. § 2 (2023); *see also id.* § 3 (stating a patent eligibility determination should be made "without regard to . . .whether a claim element is known, conventional, routine, or natural occurring").
[5] *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).
[6] PERA Act, S. 2140, 118th Cong. § 3 (2023).
[7] *See id.*
[8] *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).
[9] PERA Act, S. 2140, 118th Cong. § 3 (2023).
[10] *Id.*
[11] National Institutions of Health, *Gene Patents and Licensing Practices and the Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society* (Apr. 2010) (introductory letter from Secretary's Advisory Committee on Genetics, Health, and Society).
[12] PERA Act, S. 2140, 118th Cong. § 3 (2023).
[13] *See. Myriad Genetics,* 569 U.S. at 579.
[14] PERA Act, S. 2140, 118th Cong. § 3 (2023).

Sincerely,

David Gaugh, R.Ph.
Interim President & CEO

cc: Sen. Thomas Tillis
Sen. Christopher Coons