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FAQs: What Biotech Executives Need to Know About PERA

1. What is PERA and why does it matter to biotech?
The Patent Eligibility Restoration Act of 2025 (PERA) is a bipartisan bill introduced to reform Section 101 of the Patent Act, which governs what types of inventions are eligible for patent protection. For biotech companies, PERA could restore eligibility for diagnostic methods, gene-based therapies and other biologically rooted innovations that have been excluded under current judicial interpretations.

2. How does PERA change current patent eligibility standards?
PERA replaces the vague judicially created exceptions to Section 101 (laws of nature, abstract ideas, natural phenomena) with five defined statutory exclusions. It preserves the original statutory language of Section 101 but clarifies what is not eligible—while allowing broader eligibility for applied biotech innovations.

3. Will PERA allow companies to patent human genes?
PERA excludes unmodified human genes "as they exist in the human body" from patent eligibility. However, it lists broad exceptions to that exclusion to allow for patents on human genes that have been "purified, enriched, or otherwise altered by human activity." These exceptions are critical for gene therapy, diagnostics and personalized medicine. Interestingly, PERA does not limit the patenting of non-human genes, such as pathogens.

4. What types of biotech inventions would benefit from PERA?
- Diagnostic methods based on biomarkers
- Engineered cells and viral vectors used in gene therapy
- RNA-based therapies and antisense oligonucleotides
- AI-driven diagnostic platforms
- Novel compositions of matter derived from biological sources

5. Does PERA lower the bar for patent quality?
No. PERA only addresses eligibility. Inventions must still meet the rigorous standards of novelty (§102), non-obviousness (§103), and adequate disclosure (§112). Weak or overly broad patents will still be rejected under these provisions.

6. When could PERA become law?
In the Oct. 8 hearing on PERA, Sen. Thom Tillis (R-NC) said PERA was one of his top legislative priorities and expressed his hope that the full Senate Judiciary Committee would soon consider the bill. While that is not a certainty, holding a hearing on PERA is an important procedural step to get the bill considered by the full committee, after which it would go to the Senate floor to await a vote by the entire Senate. As it advances, Biotech stakeholders are encouraged to engage with congressional offices to ensure their concerns and priorities are reflected in the bill.

7. What should biotech companies do now?
- Consider meeting with bill sponsors to give feedback on the bill and establish monitoring for legislative developments

- Review your IP portfolio for inventions previously deemed ineligible
- Engage with legal counsel to prepare for potential eligibility expansion
- Evaluate investment strategies in diagnostics and gene-based platforms

8. How does PERA affect investment and commercialization?
Executives and investors testified that current eligibility uncertainty deters funding for diagnostics and frontier biotech. PERA seeks to provide a clearer legal framework, encouraging investment, partnerships and faster commercialization of innovative therapies.

9. What are the risks if PERA is not enacted?
Without reform, U.S. biotech companies may continue to:

- Struggle to get patent protection for critical innovations
- Shift toward trade secrets, reducing transparency
- Face reduced venture capital interest
- Fall behind China, the European Union (EU) and Japan in Intellectual Property (IP) competitiveness

10. Will PERA increase litigation risk from patent trolls?
Some retail and tech stakeholders raised concerns that PERA could revive vague business method patents. However, biotech inventions—especially those involving complex biological processes—are less likely to be targeted by such litigation. PERA also includes language to prevent rote computer-implemented or AI-generated claims from gaining eligibility.
