

**LEGAL UPDATES**

“Restoring Gold Standard Science” Executive Order – Potential Impacts for Patent Applicants and Owners

06/09/2025 | 3 minute read

In response to concerns about eroded public confidence in scientists and the alleged misuse of scientific information by federal agencies to justify political ends, President Trump’s “[Restoring Gold Standard Science](#)” Executive Order, issued May 23, aims to rebuild public trust in science and ensure federal agency decisions are informed by credible, reliable and impartial scientific evidence. The White House touts “gold standard science” as another step toward spurring innovation and translating discovery to success. As such, the order has direct implications for the agency tasked with driving U.S. innovation – the United States Patent and Trademark Office (USPTO).

“Gold standard science,” as defined by the new Executive Order, is science conducted in a manner that is reproducible, transparent, communicative of error and uncertainty, collaborative and interdisciplinary, skeptical of its findings and assumptions, structured for falsifiability of hypotheses, subject to unbiased peer review, accepting of negative results as positive outcomes and without conflicts of interest. These foundational principles are consistent with the scientific community’s own ongoing efforts to enhance research quality.

Changes Directed by the Executive Order

The order reestablishes the scientific integrity policies of the first Trump administration, as they existed on January 19, 2021. To ensure alignment with its “gold standard science” principles, the order specifically mandates agencies to review and, where necessary, revise or rescind scientific integrity policies issued between January 20, 2021, and January 20, 2025. The situation is rapidly evolving: the Trump administration formally rescinded the [National Institutes of Health \(NIH\) Scientific Integrity Policy](#) on March 28, 2025.

Further, to the extent practicable, the Executive Order requires agency heads to make “influential scientific information” publicly available. “Influential scientific information” refers to scientific and technological information (data, analyses and conclusions) produced or used by an agency, which can be reasonably assessed to substantially impact important public policies or private sector

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decisions. The policies and rules of this order apply to all employees involved in the use, interpretation or communication of scientific information and to all agency decision making.

The order requires the director of the Office of Science and Technology Policy (OSTP) to issue guidance for agencies on implementing "gold standard science" by early July 2025. Agency heads and employees must then adhere to the order's guidelines. Within 60 days of the OSTP guidance publication (by early September 2025), agency heads must report to the OSTP director on actions taken to implement "gold standard science" at their agency.

The Trump administration encourages American research organizations across academia, industry and philanthropy to align their activities to "gold standard science," as defined by the White House.

Practical Considerations for IP Owners

The USPTO is not one of the over 20 federal departments and agencies that have implemented scientific integrity policies. Still, examiners and administrative patent judges use scientific information to inform legal determinations of patentability. Therefore, to mitigate risks and maximize opportunities, we assessed areas potentially impacted by application of the "gold standard" to scientific information relied upon by the agency during examination of patent applications.

For Applicants

Applicant-generated data could face heightened scrutiny after implementation of this Executive Order. In areas like biotechnology or pharmaceuticals, experimental data can be crucial for demonstrating written description, enablement and non-obviousness, but applicants frequently rely on prophetic examples to make this showing. Although sanctioned by the courts, prophetic examples, by their nature, lack actual, transparent and reproducible data. If the agency were to limit the use of prophetic examples, patent filings may be delayed until applicants gather sufficient empirical data.

The order provides a "weight of scientific evidence" approach to scientific evaluation. Under this approach, each piece of information is considered based on its quality and relevance, and then integrated, transparently, with other relevant information to inform scientific evaluation. If the USPTO implements this approach, applicants could argue that a prior art reference fails to meet the "gold standard" due to its poor quality such that the weight of scientific evidence requires allowance. Even so, we would recommend caution before making statements disparaging prior art.

The order's demand for transparency directly conflicts with the protection of trade secrets. Applicants may find it necessary or desirable, however, to submit trade secret or proprietary materials during prosecution (e.g., under *37 CFR 1.105* or MPEP § 724). If so, applicants should fully consider whether such materials (data, analyses, models, source code) meet the order's definition of "influential scientific information" before submitting to the USPTO.

For Patentees

This Executive Order may provide a stronger framework for an alleged infringer to assert misconduct. Under the "inequitable conduct" defense, misrepresentation to the USPTO can render a patent unenforceable. As such, patent holders should analyze whether scientific evidence submitted to or relied upon during examination meets the order's definition of "scientific misconduct" (fabrication, falsification or plagiarism).



We will continue to monitor the implementation of the “Restoring Gold Standard Science” Executive Order and its impact on IP rights. If you have questions about how this order may impact your research, patent strategies and existing IP portfolio, please contact [Lisbeth Robinson, Ph.D.](#), or your regular Lathrop GPM attorney.