

April 5, 2021

Re: “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions,” NIST-2021-0001-0001, <https://www.regulations.gov/document/NIST-2021-0001-0001>

We submit these brief comments in connection with the above-referenced docket number and NIST’s January 4, 2021, announcement that it is soliciting comments “on proposed revisions to regulations that would further the Return on Investment (ROI) Initiative for Unleashing American Innovation” (the “notice of proposed rulemaking” (NPRM)).¹

In general, we oppose NIST’s proposed rulemaking. We generally share the concerns raised in the following comments:

- Comments of Jamie Love (Knowledge Ecology International),²
- Comments of Kathryn Ardizzone (Knowledge Ecology International),³
- Comments of Luis Gil Abinader (Knowledge Ecology International),⁴
- Comments of Claire Cassidy (Knowledge Ecology International),⁵
- Comments of Peter Arno (University of Massachusetts-Amherst) and Dana Neacsu (Columbia University),⁶ and
- Comments of Reshma Ramachandran (Yale), Ravi Gupta (University of Pennsylvania), and Joseph Ross (Yale).⁷

Rather than reiterate those concerns, we write to raise a separate concern. In its NPRM, NIST contends that its proposed rulemaking “is not an ‘economically significant’ regulatory action under section 3(f)(1) of [Executive Order 12866], as it does not have an effect on the economy of \$100 million or more in any one year, and it does not have a material adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.”⁸ This contention is likely wrong.

NIST’s proposed revisions to existing rules are substantial. As NIST’s NPRM itself announces, NIST’s proposed revisions would affect “march-in rights, filing of provisional patent applications, electronic filing, the purpose of royalties on government licenses, and the processes for granting exclusive, co-exclusive and partially exclusive licenses and for appeals.”⁹ The

¹ 86 FR 35, <https://www.govinfo.gov/content/pkg/FR-2021-01-04/pdf/2020-27581.pdf>

² <https://www.keionline.org/wp-content/uploads/KEI-Overview-NIST-Proposed-Changes-2021.pdf>

³ <https://www.keionline.org/wp-content/uploads/KA-KEI-NIST-Standing-26March2021.pdf>

⁴ <https://www.keionline.org/wp-content/uploads/LGA-NIST-Subject-Invention-definition-26March2021.pdf>

⁵ <https://www.keionline.org/wp-content/uploads/KEI NIST BayhDole Comments Zika Letter 25Feb2021.pdf>

⁶ <https://www.keionline.org/wp-content/uploads/Arno Neacsu Public-Comment-NIST-3 30 21.pdf>

⁷ <https://www.keionline.org/wp-content/uploads/Ramachandran-Gupta-Ross-NIST-5April2021.pdf>

⁸ 86 FR 35, 38.

⁹ *Id.* at 35.

NPRM would, among other changes, make substantial amendments to 37 C.F.R. § 404.7, which governs the issuance of exclusive, co-exclusive, and partially exclusive licenses to federally owned patents by federal agencies to private parties.¹⁰ The NPRM would also, it seems, change the considerations a federal agency is supposed to weigh when setting the royalty rates it charges patent licensee, by adding new language to 37 C.F.R. § 404.1: “Royalties collected pursuant to this part are not intended as an alternative to appropriated funding or as an alternative funding mechanism.”¹¹ And these revisions would “apply to all Federal agencies.”¹² As such, NIST’s revisions would change how the U.S. government licenses, asserts, and derives revenue from its portfolio of patents.

These changes matter because they would affect a huge number of patents, some of which are economically important. We focus here on just one subset of the patents affected by the proposed revisions—those patents that are federally owned.¹³ Federal agencies own thousands of patents, and many are of major economic importance. For example, in 2020, the Government Accountability Office (GAO) surveyed patents owned by just one federal Department—the Department of Health & Human Services (HHS)—and determined that HHS obtained over 4,000 patents between 1980 and 2019.¹⁴ At least 93 of these HHS-owned patents are of obvious economic importance, as they cover 34 distinct drugs approved by the Food & Drug Administration (FDA) and brought to market by pharmaceutical companies, including vaccines and treatments for cancer.¹⁵ The National Institutes of Health (NIH), one of HHS’s constituent agencies, has, according to GAO, licensed these 93 patents to pharmaceutical companies and collected “up to \$2 billion in royalty revenue” from 1991 through February 2020.¹⁶ Indeed, GAO reported that three patent licenses from NIH to pharmaceutical companies were so economically significant that each individual license generated more than \$100 million for NIH and HHS.¹⁷ GAO also reported (based on data generated by NIST itself) that HHS’s total revenues from patent licensing in one single year, 2016—the most recent year for which data is available—exceeded \$130 million.¹⁸

The economic significance of licensure of federally owned patents by just one federal Department—HHS—belies NIST’s contention that its proposed changes to the rules for licensing federally owned patents are not “economically significant.” NIST’s proposed rulemaking would revise the rules for the licensing activities of not just HHS but every other

¹⁰ *Id.* at 43-44.

¹¹ *Id.* at 43.

¹² *Id.* at 35.

¹³ Patents that are not federally owned but are obtained and held by nonprofit organizations and small business firms pursuant to government grants, contracts, and cooperative agreements (the focus of 37 C.F.R. Part 401) are likely equally or even more economically significant, as other commenters have observed.

¹⁴ <https://www.gao.gov/assets/gao-21-52.pdf> at Highlights.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at 41.

federal Department and agency. As such, it seems likely that NIST’s proposed rulemaking is, in fact, “economically significant” for purposes of Executive Order 12866. As a consequence, the proposed rulemaking likely merits the scrutiny from the Office of Management and Budget (OMB) and the Office of Information and Regulatory Affairs (OIRA) that “economically significant” regulatory action typically receives.

We thank the agency for its consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Morten', with a stylized flourish at the end.

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