February 20, 2019

Walter G. Copan Under Secretary of Commerce for Standards and Technology and NIST Director 100 Bureau Drive Gaithersburg, MD 20899

Via email: walter.copan@nist.gov

Dear Walter G. Copan:

On December 6, 2018, the Department of Commerce National Institute of Standards (NIST) published a draft green paper (NIST Special Publication 1234) titled, "Return on Investment Initiative for Unleashing American Innovation." The draft green paper is 135 pages long, with 313 footnotes, and 8 pages of references. Some of the proposals in this document are designed to narrow and even eliminate important safeguards in the Bayh-Dole Act, and in particular, to protect companies that sell expensive drugs, vaccines, diagnostic tests and gene- and cell-treatments like CAR T from obligations to ensure products are affordable and accessible.

According to an initial press release, the deadline to file feedback or comments on the draft green paper was January 9, 2019. NIST did not provide a notice in the Federal Register, but only on its web page.

Between the publication of the draft green paper and this original deadline to file comments were 22 work days, and two public holidays: Christmas and New Year's Day. This gave the public a very limited window to study and comment on a long and technical draft green paper that proposes to eliminate key safeguards provided under the Bayh-Dole Act.

Furthermore, NIST was affected by the lapse in federal appropriations that occurred between December 22, 2018 and January 25, 2019, and during that period the draft green paper was not available at the NIST website.

Knowledge Ecology International (KEI) requested an extension of the deadline to file comments on the green paper due to the lapse in federal appropriations. KEI did not receive a response from NIST regarding this request for a deadline extension.

On February 19, 2019, KEI wrote an additional email to several co-authors of the paper asking whether the deadline to file comments had been extended. Chuck Na from the NIST Technology Partnerships Office replied on the same day stating that the deadline to file comments had been extended to February 5, 2019, and that this extension was announced on the following website: <u>nist.gov/tpo/return-investment-roi-initiative</u> That website currently says

that it was "updated February 06, 2019," and as of today the deadline extension notice does not seem to be available. This deadline extension was not directly communicated to KEI nor presumably to other organizations, and added merely 7 more work days to the comment period.

The timing of the original notice, the lack of information during the government shutdown period, and the lack of information about the deadline extension severely limited the public's ability to file comments on the draft green paper.

We request the NIST publish a notice in the Federal Register to invite comments on the draft green paper, with an extended deadline for comment.

Sincerely,

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Luis Gil Abinader Knowledge Ecology International