Comments responsive to National Institutes of Health Notice No. 2024-11188 (89 F.R. 45003)

Attention: Abby Rives, Director, Office of Technology Transfer and Innovation Policy

Dear Abby,

My comments are respectfully submitted in response to the NIH request for public comment on its proposal to institute a new policy requiring licensees of patent rights arising from its intramural research program to submit "access plans" for products based on the licensed patent rights. The new policy would be applicable to all commercialization licenses (non-exclusive, exclusive, co-exclusive, or field limited) for "drugs, biologics, vaccines, or devices." The aim of the new policy would be to promote patient access to the licensed products, where access is defined to "include product affordability, availability, acceptability, and sustainability."

I am a biopharma innovation counsel, with experience in negotiating agreements at the interface between the private sector and universities, research institutions, and government. Much of my career has been as in-house counsel to leading biopharma companies, including GSK, Emergent Biosolutions, and Biogen. I served as president of the Licensing Executives Society, USA and Canada, in 2020-2021. I am familiar with the legal framework created by 35 U.S.C. 207 and 37 C.F.R. part 404. I also participated in the NIH workshop convened in July 2023 to discuss practices and policy initiatives for NIH to consider in enhancing innovation and public access to NIH-funded discoveries.

I join in the comments submitted by the Bayh-Dole Coalition and in addition, I write separately to express my concern about the proposed access plan policy for the following reasons:

- NIH has not identified any factors that make it more difficult for the public to access and benefit from NIH patent rights than general barriers to access in the biopharmaceutical field. Imposing the access plan requirement may therefore be unjustified, and selectively impair the market for NIH patent rights, driving potential licensees to seek alternatives. Before finalizing the access plan policy, it would seem prudent for NIH to assess whether its current policies are creating access barriers that exceed those in the market generally. I would support conduct of a survey or other type of study by NIH to answer this question.

- NIH has not provided any discussion of how the newly required access plans would be integrated into its commercial license templates or individually negotiated licenses, other than that they will be required shortly after commencement of the first pivotal trial (I note that drugs can still fail in pivotal trials, so this timepoint will inevitably mean that some access plans will be needlessly required for failed drugs). Would the access plan be required of all licensees regardless of technology or the potential for a licensed product to be used in resource poor environments? Would there be a penalty for failure to produce an access plan or to adhere to a proffered plan? Would that be grounds for NIH to terminate a license? To exercise march-in rights? In the absence of detailed information on these aspects of the policy it is impossible to truly assess the impact of NIH's plan. I also note that use of an access plan to introduce new penalties into a license agreement would be inequitable unless NIH also intends to make new concessions in favor of the licensee,

perhaps in the form of a lower royalty rate for commercialization in resource-poor environments.

- How long would the access plan requirement be imposed? For the term of the licensed NIH patent rights? Or for the lifetime of the licensed product? Would the requirement survive the license agreement? Would it be binding on successors of the licensee? What would be the mechanism for amending an access plan – would NIH see this as an opportunity to impose an "amendment royalty"? NIH has not provided information necessary to address such questions, and as noted above, the use of an access plan to introduce a penalty appears to be an unjustified overreach.

- How will the licensee subject to an NIH access plan resolve conflicting requirements by other funders? NIH has not provided any information on whether its action is coordinated with other funding agencies such as the Bill & Melinda Gates Foundation or the Wellcome Trust. Being subject to the differing requirements of multiple funders significantly raises compliance risks for drug developers.

- There are many aspects of access to medicines that are not under the control or influence of the licensee. For example, the licensee has no impact on the decisions of health insurers or pharmacy benefit managers when those entities set co-pay amounts. There have been instances where co-pay requirements cannot be reconciled with the medical value of a drug. If the licensee is supposed to limit the financial burden on end-users it would have to negotiate with a multitude of different insurers leading to chaos in pricing practices.

- The concept of sustainability must be understood from the perspective of the manufacturer: is it financially sustainable to enter a marginal market? Is it financially sustainable to continue to serve a dwindling market? In the case of a licensee that is a for-profit company (most are), the access plan policy must acknowledge the legal obligations of the company to its shareholders. The access plan requirement should not place any company in jeopardy of incurring shareholder lawsuits.

- Access plans should not impose any requirement to disclose pricing or policies and procedures for determining pricing, that place licensees in jeopardy of violating antitrust or competition law requirements. Also, it is unreasonable to hold licensees to any obligation that the initial US market price be on par with international pricing. The US is the wellspring of new biomedical innovation for the world, and developers must have a means to pay back the considerable costs of pursuing that innovation. NIH has not proposed any viable alternative to drug pricing to accomplish that societally beneficial objective.

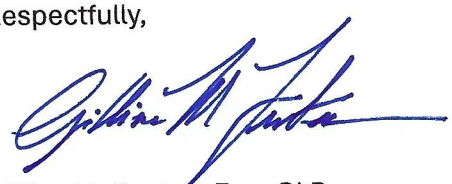
- Many of the proposed strategies for licensees to consider would, if published, impair the licensee's ability to negotiate favorable terms of an alliance with sublicensees or other types of partners. Indeed, some of the listed strategies would potentially operate as an implied obligation for the licensee to enter into downstream agreements covering its own know-how and privately developed IP rights, a clear and inequitable overreach.

- Some portions of the proposed policy could operate to disincentivize development of pioneering but expensive products such as cell and gene therapies. NIH should not

discourage the advancement of such therapies since their success will stimulate further research into cheaper and more robust interventions for the same diseases, which in many cases are orphan or ultra-orphan diseases where patients have no other currently available options.

If strictly limited in applicability only to those agreements where it is foreseeable that a product would be used in resource-poor settings (e.g., in low income or lower middle-income countries), and for technologies that are specifically addressed to well-recognized health needs of underserved populations, an access plan could be a useful instrument for assuring that a product developer achieves goals with clear societal benefit. Indeed, this is how access plans are currently used by special-purpose funders such as the Gates Foundation, Wellcome Trust, CARB-X and CEPI. However, there is no precedent for imposing access plan requirements outside of agreements to provide purpose-directed non-dilutive funding. Certainly there are no prior examples of such requirements in licenses of intellectual property where the licensor is not providing any other resources to support the licensee's development efforts. For these reasons, I question whether the proposed NIH policy is appropriate for licenses to commercialize NIH patent rights. It would seem to be more appropriate for NIH to deploy its access plan policy only in the context of government contracts where funding is provided to private sector entities developing products on the basis of NIH patent rights.

Respectfully,



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