SEPTEMBER 2024

DEVOTED TO LEADERS IN THE INTELLECTUAL PROPERTY AND ENTERTAINMENT COMMUNITY

VOLUME 44 • NUMBER 8

THE Licensing Journal®

Edited by Gregory J. Battersby and Charles W. Grimes

Wolters Kluwer

Patent Licensing

Jennifer Chheda, Colleen Heisey, Robert Latta, and Tyler Loveall

On May 22, 2024, the NIH announced that it is seeking public input on the development and implementation of a new policy to promote patient access to products stemming from NIH-owned inventions.[1] This request for comments is part of ongoing efforts to improve patient access to vaccines, drugs, biologics, and medical devices to patients in the United States and abroad, who may otherwise lack access to such products due to a number of factors, including high costs.

The new policy would apply to commercial patent licenses relating to NIH-owned inventions made by investigators in the Intramural Research Program (IRP), the NIH's internal research program. Covered licenses include those that authorize the commercialization of drugs, biologics, vaccines, or devices developed by the NIH for preventing, diagnosing, or treating human diseases. The NIH notes that the policy would not apply to third-party IP but that the application of the policy to IP jointly owned by the NIH and a third party (or parties) will be considered at a later time.

The NIH proposes new language to be added to its IRP model license agreements that requires a licensee to provide an "Access Plan" to the NIH within three months of a Licensed Product entering a first pivotal clinical trial (i.e., a Phase III trial or equivalent), unless the licensee obtains in advance a written waiver or modification, requests for which the NIH must consider in good faith. 89 Fed. Reg. 45003, 45005 (May 22, 2024). The proposed provisions would also require a licensee to confer with the NIH regarding a licensee's progress toward patient access to the applicable product and to consider in good faith any NIH-suggested modifications to the Access Plan within 30 days of the NIH's request. *Id.* The request may occur only once annually.

The term "Access Plan" would be defined as a licensee's plan, including the plan(s) of any sublicensee(s), that describes the licensee's strategy for supporting broad access to a Licensed Product for the population of the United States and: (i) certain underserved communities such as those described in the proposal; and/or (ii) populations in countries defined by the World Bank classification system as lower- and middle-income countries. *Id.* Under the proposed provisions, the Access Plan must include at minimum "a brief description of the Licensed Product(s)," "the anticipated patient population(s)," "other products, tools, facilities, or unique resources necessary for use of the Licensed Product," and at least one strategy for mitigating access challenges, such as affordability, availability, acceptability, and sustainability. *Id.* The NIH intends to develop further guidance about acceptable plans, but a key requirement of the proposal would allow the NIH to request, publish, and publicly disclose to third parties nonconfidential versions of any Access Plans.

The announcement highlights potential strategies that licensees might consider including in their Access Plans, such as, for example, "committing to keep prices in the [United States] equal to those in other developed countries" and "not raising costs above inflation." *Id.* With respect to intellectual property, the NIH notes other strategies may include sublicensing to manufacturers in non-U.S. countries on voluntary and mutually agreeable terms, "committing to license all intellectual property and know-how needed to make a product if the licensee exits a market," or "agreeing to sublicense relevant intellectual property on a low- or no-royalty basis." *Id.*

The NIH is seeking input from the public regarding, among others: (i) activities and "strategies to mitigate access challenges and expand the reach, and benefit, of drugs, biologics, vaccines, and devices stemming from NIH[-owned] inventions"; (ii) "how access plans could incorporate transparent cost accounting measures"; and (iii) how to maintain the flexibility needed to enable licensees to develop and commercialize products while promoting certainty and transparency on access efforts and enforcement. *Id.* at 45004.

The period for submission of comments ended on July 22, 2024.

Three Key Takeaways

1. The proposed policy may have a chilling effect on the

licensing of NIH-owned inventions conceived by IRP investigators and may reduce the desirability of IRP collaboration.
2. Public disclosure of Access Plans could potentially reveal a licensee's strategic or commercially sensitive information relating to the development and commercialization of medical products.
3. By requiring the development of Access Plans aimed to reduce the price and increase the availability of medical products, the proposal may result in increased competition to drive prices down, but it is yet to be seen how burdensome these obligations might be on licensees, as well as any chilling effect this proposed policy may have on the pharmaceutical industry.

Dr. Jennifer Chheda (Ph.D.) is a partner in Jones Day's New York office in the Intellectual Property Practice. She has more than 25 years of experience in procuring and enforcing patents relating to biologics and small molecules, such as gene therapy, RNA (ribonucleic acid) therapeutics, antibodies, antibody-drug conjugates, cell-based therapies (e.g., CAR-T cells), vaccines, and enzyme replacement therapy. She has developed, implemented, and managed worldwide patent portfolios covering commercial biologics and pharmaceuticals. In addition, Jennifer has drafted and negotiated intellectual property agreements, including license, sponsored research, and development agreements. She has also provided IP advice in the context of M&A transactions and IP-related transactions.

Colleen Heisey is a partner in the Jones Day Washington office in the Health & Life Sciences practice. With more than 20 years of experience focused on Food and Drug Administration (FDA) regulated products, she has a strong understanding of the legal, regulatory, and compliance issues facing drug, biologics, medical device/diagnostic, and food/dietary supplement clients. Her practice involves strategic counsel to clients navigating near-market and post-market opportunities and obligations, including matters related to product jurisdiction, pathways to market, regulatory exclusivities, accelerated approvals, orphan drug status, adverse event reporting, recalls, and managing federal agency inquiries and enforcement actions.

Robert (Rob) Latta is a partner in Jones Day's San Diego office in the Intellectual Property practice. His practice focuses on transactions in life sciences and environmental sustainability matters. He advises clients on a range of life science, agrifood, and technology transactions, including licensing, strategic alliances, joint ventures, confidentiality, manufacturing, supply, and distribution agreements. His technical background coupled with extensive experience working within the life sciences allows him to bridge the gap between life sciences and computer sciences industries, particularly in matters related to computational biology and bioinformatics matters.

Tyler Loveall is an associate in Jones Day's Detroit office in the Health Care & Life Sciences practice. He represents hospitals, health systems, digital health care companies, and other health care entities on regulatory and transactional matters.

The views set forth herein are the personal views of the authors and do not necessarily reflect those of the Firm. The contents should not be construed as legal advice on any specific facts or circumstances and are intended for general information purposes only.

1. *See https://www.federalregister.gov/documents/2024/05/22/2024-11188/national-institutes-of-health-nih-office-of-science-policy-osp-request-for-information-on-draft-nih.*