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UC Legal - Office of the General Counsel

TO MEMBERS OF THE SPECIAL COMMITTEE ON INNOVATION TRANSFER AND ENTREPRENEURSHIP:

DISCUSSION ITEM

For Meeting of June 2, 2023

UPDATES: (1) AMGEN V. SANOFI AND (2) FEDERAL GRANT GUIDELINES – DEPARTMENT OF ENERGY-FUNDED TECHNOLOGIES

EXECUTIVE SUMMARY

The panel will provide the Regents Special Committee with an update on the recently decided United States Supreme Court case *Amgen v. Sanofi*.[1] Amgen's patents claimed an indefinite number of antibodies capable of a specific function. The patents described 26 exemplary antibodies and noted that others could be identified through known methods. The Court held the broad claims were invalid and violated the "patent bargain" in which inventors are granted exclusivity in exchange for describing the invention in "full, clear, concise and exact terms."[2]

The panel will also update the Special Committee on intellectual property provisions implemented in June 2021 by the U.S. Department of Energy (DOE) for the purpose of enhancing U.S. competitiveness. Through a Determination of Exceptional Circumstances (DEC), the DOE implemented enhanced U.S. competitiveness provisions requiring domestic manufacturing in patent rights clauses in its grants and cooperative agreements. There is concern that, because the DOE language deviates from the Bayh-Dole Act standard patent rights clauses in several meaningful ways, there may be downstream impacts, including possible chilling effects on licensing DOE-funded inventions. For such inventions that are licensed, UC will need to monitor licensees' compliance with DOE's substantial U.S. manufacturing requirements or risk significant penalties, including loss of invention ownership and the retained right to use the UC-generated invention for research and education purposes.

This panel will review DOE's patent rights language highlights, the potential effects on UC, and the potential for other federal agencies to adopt the same or a similar approach. The panelists are:

- Dr. Deborah Motton, Executive Director, Research Policy Analysis and Coordination, Research and Innovation, UCOP;
- Ms. Randi Jenkins, Principal Counsel, UC Legal, UCOP; and

[1] This case is unrelated to the Bayh-Dole Act.
[2] The court noted, "…if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain." 598 U.S. __ (2023), slip opinion.

- Ms. Kimberly Jones-Ross, Interim Executive Director, Innovation Transfer and Entrepreneurship, Research and Innovation, UCOP.

BACKGROUND

For over four decades, the Bayh-Dole Act has provided standard patent rights clauses to be included in federal awards.[3] The standard patent rights clauses justified the founding of technology transfer offices throughout the United States and are well known throughout the country's innovation pipeline from research institutes to industry. The following are selected key features of the standard patent rights clauses.

- Grantee's ownership of federally funded inventions is subject to the grantee's timely disclosure, election of title, and filing of one or more patent applications.
- Grantees must include in exclusive licenses for U.S. patent rights an obligation of the licensee to substantially manufacture in the U.S. for use or sale in the U.S. any products embodying the subject invention or produced using the subject invention.[4]
- Invention ownership will revert to the government if the grantee fails to timely disclose, elect title, file patent applications, or abandons patent applications or patents. In such cases, grantees retain a non-exclusive, royalty-free right (shop right) to practice the invention, revokable only to the extent necessary to achieve practical application of the invention through an exclusive license granted by the government to a third party.

Federal agencies may modify the standard patent rights clauses "in exceptional circumstances" when it is determined by a federal agency that eliminating a recipient's retention of title to subject inventions would better promote Congress' policy and objectives in utilizing inventions arising from federally supported research and development.[5]

In June 2021, through a Determination of Exceptional Circumstances (DEC), the DOE implemented enhanced U.S. competitiveness provisions requiring domestic manufacturing in patent rights clauses in its grants and cooperative agreements. DOE determined that despite funding many breakthrough technologies over the years, "too often the transition of these technologies has resulted in manufacture being offshored."[6]

Using the Determination of Exceptional Circumstances mechanism, the DOE implemented enhanced U.S. Competitiveness clauses in patent rights clauses for DOE-funded awards. The enhanced language expands U.S. manufacturing requirements to non-exclusive licenses and foreign patent rights, requiring substantial U.S. manufacture for all markets, not just for U.S.

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[3] 37 CFR §401.14
[4] "Substantially manufactured" is not defined in statute, regulation, or case law.
[5] 37 CFR §401.3 (a)(2)
[6] Frequently Asked Questions (FAQs) for Applicants and Awardees of DOE Financial Assistance and R&D Contracts regarding the Department's Determination of Exceptional Circumstances (DEC) for DOE Science and Energy Technologies issued in June of 2021.

products intended for the U.S. market. Under DOE's U.S. competitiveness requirements, the responsibility for compliance, and penalties for non-compliance, are shared between the grantee and the licensee. That is, the *grantee* must also accept the responsibility for ensuring that any products embodying any subject invention or produced through the use of any subject invention will be manufactured substantially in the U.S. Penalties for breach (as determined by DOE) may include: (i) reversion of invention ownership to DOE, (ii) nullification of existing license(s), and (iii) revocation of the grantee's shop rights.

DOE has published a detailed Frequently Asked Questions (FAQ) document and guidelines for requesting waivers or modifications to the U.S. Competitiveness requirement. Such waivers or modifications may be granted to grantees and licensees upon request when DOE determines: (1) the grantee demonstrates, with quantifiable data, that manufacturing in the United States is not commercially feasible, and (2) a waiver or modification would best serve the interests of the United States and the general public.[7]

UC campus technology transfer offices (TTOs) are beginning to receive invention disclosures subject to the DOE DEC. TTOs have expressed concern that DOE's right to impose the above-noted penalties may make such inventions less attractive to potential licensees and investors. For companies willing to engage in the waiver request process, it is not clear how many waivers or modifications to U.S. competitiveness provisions will be granted and what the timeline for the process will be. TTOs will need to build procedures into UC technology management for (i) requesting waivers when necessary, (ii) expanding license terms to include U.S. Competitiveness clause requirements, and (iii) monitoring and ensuring licensees manufacture subject products in the U.S. Further, the potential loss of shop rights warrants a spotlight in discussion. UC has historically relied upon its reserved right to practice UC-generated discoveries for research and education purposes. In the event that a DOE-determined breach results in the revocation of UC's shop rights, one option would be to pursue and negotiate a separate license with the DOE to allow for continued use of the technology for research and education purposes.

This is a significant sea change from standard operations under the Bayh-Dole Act. Other federal agencies may adopt the same or similar approach as DOE.

Key to Acronyms:

DEC	Determination of Exceptional Circumstances
DOE	U.S. Department of Energy
TTOs	Technology Transfer Offices

[7] DOE DEC Intellectual Property Provisions GNP-821-US, paragraph (n).1 Waivers