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Office of the President

TO MEMBERS OF THE HEALTH SERVICES COMMITTEE:

DISCUSSION ITEM

For Meeting of December 15, 2020

MEDICINES PATENT POOL – CONSIDERING UNDERSERVED POPULATIONS WHEN LICENSING INTELLECTUAL PROPERTY

EXECUTIVE SUMMARY

The University of California, Los Angeles' Technology Development Group (UCLA TDG) recently implemented a practice of including in its patent license agreements to UCLA's biopharmaceutical innovations a provision requiring its licensee to provide and implement an "Affordable Access Plan" (AAP). A copy of the AAP provision is attached as Appendix A. The intent of the AAP provision is to encourage UCLA's licensee, if and when it receives U.S. Food and Drug Administration (FDA) approval, to develop and implement plans for supporting affordable access to the UCLA patented drug in low- and middle-income countries (LMICs), which plans may include collaborating with governments and non-profit organizations.

The AAP provision arose out of efforts among UCLA leadership regarding whether and how UCLA can play a role in ensuring that underserved communities in LMICs have affordable access to technologies originating from UCLA. In early 2020, Dr. John C. Mazziotta, Vice Chancellor of UCLA Health Sciences and CEO of UCLA Health, had several conversations with the Medicines Patent Pool (MPP), a World Health Organization (WHO)-backed international organization. MPP has a reputation for successfully collaborating with governments, industry (including Pfizer, Gilead, and AbbVie), patient groups, and other stakeholders to prioritize and license needed medicines and pool intellectual property to encourage affordable access to drugs within underserved communities. Dr. Mazziotta recommended that MPP work with UCLA TDG to see whether any effort could be made at the licensing stage to influence UCLA's licensees to provide affordable access to its drugs in underserved communities.

UCLA TDG and MPP had several collaborative conversations regarding the challenges university technology transfer offices have had in identifying contract language of substance which would influence its licensees' behavior but not deter pharmaceutical partners from taking a license. Ultimately, it was concluded that the AAP provision was ideal as it provided UCLA an opportunity to participate in and facilitate dialogue among UCLA, its licensee, and key stakeholders such as MPP, so that LMICs are considered sufficiently early in the commercialization stage to have a positive impact on affordable access.

The AAP provision has also been vetted with, and received encouraging feedback from, numerous UCLA constituents, industry representatives, and attorneys who regularly represent UCLA licensees. To date, UCLA TDG has been successful in incorporating such a provision in its biopharmaceutical license agreements and has received minimal pushback from its licensees. Dr. Mazziotta will provide an overview of the AAP provision and UCLA's discussions with MPP. UCLA seeks the Committee's feedback about promoting the use of provisions such as AAP and collaborations with organizations such as MPP across UC.

BACKGROUND

Numerous universities throughout the nation have faced pressure from advocacy groups when pharmaceutical innovations arising from their campuses have been successfully translated into effective, but relatively high-priced drugs. UCLA experienced such scrutiny in recent years in relation to a prostate cancer innovation, which was patented by UCLA and further developed into a prostate cancer treatment by Pfizer (XTANDI®). Even though the University's patents are typically a portion of the licensee's relevant intellectual property portfolio and it plays no role in the complicated pricing and marketing strategies implemented by its licensee, which was the case with UCLA and XTANDI®, the University nonetheless is often pressured to take action.

In response to the concerns raised by advocacy groups regarding Pfizer's pricing of XTANDI®, UCLA formed a Task Force in early 2018 to identify and vet solutions that may address the costs of drugs originating from UCLA in developing countries. The Task Force reviewed and discussed a number of relevant documents, including the "Nine Points to Consider in Licensing University Technology[1], UCOP's Licensing Guidelines[2], and articles published by APLU[3], AAU[4], and the National Academies of Sciences, Engineering, and Medicine[5]. The Task Force concluded that:

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[1] See "In the Public Interest: Nine Points to Consider in Licensing University Technology" published by the Association of University Technology Managers dated March 6, 2007 at: https://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf

[2] See "University Licensing Guidelines" issued by UCOP dated February 1, 2012 at: https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf

[3] See "Statement to APLU Members of Recommendations on Managing University Intellectual Property" published by the Association of Public and Land-Grant Universities (APLU) dated March 2015 at: https://www.aplu.org/projects-and-initiatives/research-science-and-technology/task-force-intellectual-property/March2015TaskForceManagingUniversityIntellectualProperty.pdf

[4] See "Statement to the AAU Membership on University Technology Transfer and Managing Intellectual Property in the Public Interest" published by the Association of American Universities (AAU) dated March 2015 at: https://www.autm.net/AUTMMain/media/Advocacy/Documents/AAU_Working_Group_Managing_University_IP_MAR2015.pdf

[5] See "Managing University Intellectual Property in the Public Interest -- Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue" published by The National Academies of Sciences, Engineering, Medicine (2011) at https://www.nap.edu/read/13001/chapter/1

> *All of these reports stress that the primary goal of patent and licensing policies and practices is to maximize the further development, use, and beneficial social impact of these products. Revenue and profit should not be the primary motivation. The UCOP Guidelines correctly note that 'developing successful practices is an evolving process, for an issue as complex as balancing access by developing countries to biomedical products with ensuring timely and appropriate development and commercialization of the product.' If the approach is too prescriptive, licensees may be discouraged because of a perceived need to overcome too many obstacles in product development.*

The Task Force ultimately recommended that one of the following two provisions be incorporated into UCLA TDG's patent license agreements:

> Task Force Provision #1: *As part of its public mission to bring products to the marketplace, UCLA strives to enable underserved populations, which have limited access to adequate quantities of medical innovations arising from UCLA's laboratories, to have access to these innovative products. Licensees are encouraged to consider these populations' interests when marketing and selling Licensed Products.*
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> Task Force Provision #2: *UCLA intends to dedicate a certain portion of its licensing proceeds to address the needs of underserved populations. Licensee is encouraged to match UCLA's contributions to this fund.*

Ultimately UCLA TDG incorporated Provision #1, as it was determined that Provision #2 raised issues in view of certain restrictions imposed by the Bayh-Dole Act regarding the purposes for which revenues derived from licensing federally funded inventions may be used.[6] However, while the language of Provision #1 was well received by licensees during negotiations, UCLA leadership explored ways to improve it and to enable UCLA to have a material impact on the issues the Task Force was aiming to address.

MEDICINES PATENT POOL AND UC

Over the two-year period since implementation of the Task Force, UCLA leadership has met with students, faculty, the pharmaceutical industry, and UC intellectual property stakeholders to continue to seek improved means for addressing its goals of ensuring affordable access to drugs originating from its campus. With the assistance of the Task Force, Dr. Mazziotta identified MPP, which licenses commercially available medications and makes them available in underserved countries.[7]

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[6] Specifically, the Bayh-Dole Act provides that after payment of expenses, nonprofit organizations may use "the balance of any royalties or income earned by the contractor with respect to subject inventions . . . for the support of scientific research or education."

[7] See https://medicinespatentpool.org.

About the Medicines Patent Pool

MPP was established in 2010 by Unitaid,[8] an international organization that invests in innovations to prevent, diagnose, and treat the human immunodeficiency virus (HIV)/AIDS, tuberculosis, and malaria. Unitaid is a hosted partnership of the World Health Organization. The goal of MPP is to increase access to, and facilitate the development of, life-saving medicines for LMICs through voluntary licensing and patent pooling. MPP works with international organizations, industry, patient groups, and governments to prioritize and license new and existing medicines for people in LMICs.

MPP started its work addressing the HIV, where there were gaps in access to novel antiretroviral medications. For example, MPP enabled the generic manufacture of dolutegravir (DTG) and similar HIV treatments at a lowered price, providing access to the life-saving drug to individuals in need. In 2014, the patent holder to DTG, ViiV Healthcare, entered into a license agreement with MPP, giving MPP the rights to license the generic manufacture of DTG for adults and children. The licenses permit generic pharmaceutical companies based anywhere in the world to manufacture and combine DTG with other drugs. MPP has sublicensed the generic manufacture of DTG to several companies, allowing sale of generic DTG and the combination tenofovir/lamivudine/dolutegravir in more than 130 countries.

MPP's licenses and sublicenses are negotiated on a case-by-case basis and are geared to improve treatment options for the broadest number of people living in developing countries.

To date, MPP has signed agreements with patent holders for HIV antiretrovirals and an HIV technology platform, hepatitis C direct-acting antivirals, and a tuberculosis treatment. It has agreements with ten patent holders, including leading pharmaceutical companies, such as AbbVie, BMS, Gilead, ViiV/GSK and Pfizer, and with 21 generic manufacturers, mostly located in LMICs. Since its establishment in 2010, its manufacturing partners have distributed 14.6 billion doses of treatments in LMICs. MPP's work has been endorsed by the G7, G20, and the United Nations as a collaborative mechanism to facilitate access to medicines in LMICs.

UCLA's Collaboration with MPP

Following a set of meetings between Dr. Mazziotta and MPP, and subsequent collaborative conversations among MPP and UCLA TDG, UCLA TDG recently implemented a practice of including in its patent license agreements to UCLA's biopharmaceutical innovations a provision requiring its licensee to provide and implement an "Affordable Access Plan" (AAP). The AAP provision requires the licensee to identify shortly after receiving FDA approval:

- *A specified set of low- and middle-income countries ("**LMICs**") in which the Licensee does not intend to commercialize the Licensed Products (the "**Non-Commercialized Territory**"); and*

[8] See more information regarding Unitaid at: https://unitaid.org/#en.

- *Licensee's and/or its Sublicensees' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations.*

The AAP provision also provides UCLA the ability to initiate discussions among its licensees and key stakeholders, such as MPP, who have the experience necessary to effectively enable affordable access to LMICs. The hope is that by encouraging discussion and shining a light on these issues early in the licensee's marketing and commercialization plans, UCLA's licensees will be more apt to take steps to more effectively address affordable access issues.

The AAP provision has been vetted with, and received encouraging feedback from, numerous UCLA constituents, including an advocacy group that has been active on UCLA's campus, industry representatives, and attorneys who regularly represent UCLA licensees. To date, UCLA TDG has been successful in incorporating such a provision in its biopharmaceutical license agreements and has received minimal pushback from its licensees. Given this positive reaction and progress, UCLA TDG is inclined to move beyond piloting the AAP provision and to incorporate it more formally as part of its licensing practices going forward.

The AAP provision, and collaborations with organizations such as MPP, address a vital component of UC's public mission to make its innovations available to communities throughout the world. The University, as a public institution and an academic medical center, can use this opportunity to act as a role model for other institutions across the world to ensure that innovations are accessible to LMICs and those most in need. Therefore, UCLA seeks the Committee's feedback about pursuing such activities on a systemwide level.

Appendix A

Affordable Access Plan Provision: Language incorporated by UCLA TDG into its exclusive license agreements to biopharma innovations:

- Insert the following in the whereas clauses:

WHEREAS, as part of its public mission to bring products to the marketplace, The Regents uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from UCLA's laboratories, to have affordable access to these innovative products;

- Insert the following as a Diligence/Development Milestone:

Affordable Access Plan. Within __ (X) months of receiving FDA or EMA approval of a Licensed Product, Licensee will provide The Regents with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), Licensee agrees to discuss such reasoning with The Regents in good faith within one (1) month thereafter ("**Initial Discussion**") and, if following such Initial Discussion The Regents concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to The Regents within three (3) months of such Initial Discussion. The "**Affordable Access Plan**" shall include the following -- to the extent such Plan includes confidential information, Licensee will also provide a non-confidential version or statement of such Plan that The Regents can make available to third parties:

A. A specified set of low- and middle-income countries ("**LMICs**") in which the Licensee does not intend to commercialize the Licensed Products (the "**Non-Commercialized Territory**"); and

B. Licensee's and/or its Sublicensees' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations.

Within thirty (30) days of The Regents' request (but no more often than once annually), Licensee agrees to confer with The Regents to review Licensee's progress, and to consider in good faith any reasonable modifications suggested by The Regents, with respect to its Affordable Access Plan ("**Progress Discussions**"). For clarity, while The Regents may invite a designated entity to join either the Initial and/or Progress Discussions under this Section 5.3, such discussions will at all times be made subject to the confidentiality obligations set forth in Section 19 (Confidentiality).

- Incorporate subpart (f) bolded below into the Progress Reports requirements section:

Progress Reports. . . . Each report will contain at least the following information: . . . **(f) status of implementation of the Affordable Access Plan.**