

Resolution 4/12/2023

Resolution in support of the Affordable Access Plan (AAP) for Intellectual Property Licensing

Authored by Megan Curtin, Diego De Nault, Allisun Wiltshire, (Universities Allied for Essential Medicines at Berkeley) and Neda Ashtari (UCLA)

- WHEREAS Following a statement published by UC Davis Health "We serve the public and our own students by focusing on improving lives, transforming care and sharing knowledge to advance health for all."; and ¹
- WHEREAS UC Davis's research into novel therapeutics has led to the discovery of new drugs which have the potential to benefit millions; however, many of these life-saving inventions are licensed to private companies that do not prioritize affordable access globally; and
- WHEREAS Licensing represents a key site of leverage in establishing policies and methods of enforcement which ensure that industry partners carry out the manufacture and distribution of therapeutics in a way that assures the most affordable outcome for members of the public who stand to benefit; and ²
- WHEREAS UC Innovation and Technology Commercialization (ITC), consisting of two units, UC Davis Innovation Access and UC Davis Venture Catalyst, negotiates all research contracts with private companies and establishes relationships and contractual agreements that benefit the public; 3 and
- WHEREAS The Public Intellectual Property for Agriculture (PIPRA), a not-for-profit organization that provides intellectual property rights analysis to support the commercialization of public sector innovations, was founded in 2004 by the UC Davis Associate Vice Chancellor for Research, Dr. Alan Bennett ⁴; and

¹https://www.ucdavis.edu/uc-davis-health-care

Tittps://www.ucuavis.euu/uc-uavis-neaitii-care

https://tdg.ucla.edu/ucla-considers-underserved-populations-when-licensing-medical-research-discoveries https://itc.ucdavis.edu/about/

⁴ https://bennettlab.ucdavis.edu/public-intellectual-property-resource-agriculture

- WHEREAS UC Davis Innovation Access collaboration with PIPRA has been an important step forward in establishing licensing policies at UC Davis which can be used to make agricultural products more accessible, particularly for its Reservation of Rights for Humanitarian Purposes which allows for the licensing of specific agricultural products to any nonprofit or other third party. But, insofar as information has been made accessible to the public, the use of the PIPRA Reservation of Rights for Humanitarian Purposes Clause is limited to use solely "for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country in a Lower Middle-income country as that term is defined by the World Bank" 5; and
- WHEREAS UC Davis crafted a reservation-of-rights clause intended for a commercial license of a health technology which is limited to use solely for "research and development purposes by any organization or other third party, anywhere in the world that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country" ⁵, and
- WHEREAS A lack of information exists on the ITC website regarding use of the Humanitarian Purposes Clause beyond examples of agricultural products and no apparent mechanisms of enforcement have been documented which would require the plan be enforced with all relevant therapeutics; and
- WHEREAS The Technology Development Group (TDG) at the University of California Los Angeles fulfills an equivalent role to UC Davis ITC: and ⁶ ⁷
- WHEREAS the Affordable Access Plan which states, "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." Such changes should improve and expand the UC Davis Innovation Access Reservation of Rights for Humanitarian Purposes to align it with UCLA's AAP so that therapeutics licensed to private companies are accessible to vulnerable communities in LMICs and Non-Commercialized Territories. Any amendments to the Innovation Access licensing policies should also include mechanisms which allow for third-party access to non-confidential versions of affordable licensing plans put forth by licensees; and be it further
- WHEREAS UCLA adopted an Affordable Access Plan (AAP) in 2020 following a ^{8 9} campaign by student advocacy group Universities Allied for Essential Medicines (UAEM) and the UN-backed, global public health organization Medicines Patent Pool protesting the cost of Xtandi, a prostate cancer drug also known as ¹⁰ enzalutamide, in India; and

_

⁵https://www.ipmall.info/sites/default/files/hosted_resources/IP_handbook/ch02/ipHandbook-Ch%2002%2 001%20Bennett%20Retention%20of%20Rights.pdf

- WHEREAS The AAP is included in all TDG-exclusive licenses which apply to low- and middle-income countries (LMICs) and countries set aside as part of "Non-Commercialized Territory". The AAP requires, upon therapeutic approval by the FDA or EMA, the delivery of a plan by the licensee to the UCLA Regents outlining how the licensee intends to support affordable access in LMICs and Non-Commercialized Territories. Should the licensee not provide a plan, they must present an argument in good faith to the University Regents as to why a plan is infeasible. Should the Regents decide that an affordable access plan is reasonable and desired, the licensee is required to present one within three months of meeting. Following the approval of a plan, Progress Meetings requested by The Regents must also be attended by the licensee where they report on the implementation status of their affordable access plan; and ¹¹
- WHEREAS The UCLA plan also requires that—to the extent that confidentiality allows—a version of affordable access plans be provided for the Regents to make available to third parties; therefore be it ¹¹
- RESOLVED That the UC Davis Graduate Student Association take the official position that the University of California Board of Regents should adopt the Affordable Access Plan in place at UCLA on April 12th, 2023 as a universal licensing mechanism across all ¹² University of California campuses as a leader amongst institutions prioritizing access to life-saving medicines; and be it further
- RESOLVED That the UC Davis Graduate Student Association take the official position that UC Davis should pursue changes which will bring current licensing practices into alignment with the school's principles of global engagement; be it further
- RESOLVED That the UC Davis Graduate Student Association adopt the official position that UC Davis should work with third-party, non-profit organizations, such as Medicines Patent Pool and UAEM, during the process of updating its policies as UCLA did in order to ensure transparency; and be it further at UCLA and other universities; and be it further
- RESOLVED That the UC Davis Graduate Student Association adopt the standing policy that UC Davis should take a leadership role in expanding access to therapeutics by working to establish novel methods of licensing which go beyond what has previously been attempted

⁶ https://tdg.ucla.edu/

⁷ https://itc.ucdavis.edu/

⁸ https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

⁹ https://tdg.ucla.edu/ucla-considers-underserved-populations-when-licensing-medical-research-discoverie

¹⁰ https://medicinespatentpool.org/news-publications-post/who-essential-medicines-committee-2021

RESOLVED That the Internal Vice President be directed to communicate the official positions and standing policies contained in this resolution to the UC Davis Innovation Access; and be it finally

RESOLVED That the External Vice President be directed to communicate the official positions and standing policies contained in this resolution to the University of California Board of Regents.

¹¹ https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

¹² See pages 6-7 of https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf