

## <u>Resolution # 2212A</u> 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 Cal) and Tyler Lemon (IVP)

- WHEREAS Following a statement published as part of UC Berkeley's Light the Way Campaign, "Graduate students are at the fulcrum of Berkeley's public mission, they connect research to teaching, working alongside faculty to drive research excellence that shapes the world for the better"<sup>1</sup>; and
- WHEREAS UC Berkeley'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<sup>2</sup>; and
- WHEREAS Berkeley Intellectual Property and Industry Research Alliances (IPIRA), consisting of two peer divisions, The Industry Alliances Office and The Office of Technology Licensing, negotiates all research contracts with private companies and establishes relationships and contractual agreements that benefit the public<sup>3</sup>; and
- WHEREAS IPIRA implemented a Socially Responsible Licensing Program (SRLP) in 2003<sup>4</sup> with the goals of "promoting widespread availability of technology and healthcare, including in the developing world; sharing revenue and/or other benefits with those who collaborate with UC. Berkeley researchers; giving proper attribution to a research source or collaborator; **maximizing the societal benefit**

<sup>&</sup>lt;sup>1</sup> <u>https://light.berkeley.edu</u>

https://tdg.ucla.edu/ucla-considers-underserved-populations-when-licensing-medical-research-discoveries <sup>3</sup> https://ipira.berkeley.edu/about-us

<sup>&</sup>lt;sup>4</sup> https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1932328

**of technologies developed at UC Berkeley**; and stimulating additional investment by others to achieve these goals"<sup>5</sup>; and

- WHEREAS The SRLP has been an important step forward in establishing licensing policies at UC Berkeley which can be used to make medicines more accessible, particularly for its Reservation of Rights for Humanitarian Purposes which allows for the licensing of specific therapeutics to any nonprofit or other third party. But, insofar as information has been made accessible to the public, the SRLP has not been modified in over a decade and use of the SRLP is limited by the Humanitarian Purposes Clause to "use solely for protection from, treatment of, or diagnosis of Neglected Diseases in a Lower Middle-income country as that term is defined by the World Bank"<sup>6</sup>; and
- WHEREAS A lack of information exists regarding use of the SRLP beyond these examples 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<sup>7</sup> fulfills an equivalent role to IPIRA at UC Berkeley<sup>8</sup>; and
- WHEREAS the Affordable Access Plan which states, "We pledge to conduct our international affairs seeking the well-being and security of all, as responsible stewards of the investments and trust that our research sponsors, donors and citizens have placed in us, in compliance with the law, with appropriate controls, accountability and transparency". Such changes should improve and expand IPIRA's Socially Responsible Licensing Program 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 IPIRA's 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
- WHEREAS UCLA adopted an Affordable Access Plan (AAP) in 2020<sup>9</sup> <sup>10</sup> following a campaign by student advocacy group Universities Allied for Essential Medicines (UAEM)<sup>11</sup> and the UN-backed, global public health organization Medicines Patent Pool<sup>12</sup> protesting the cost of Xtandi, a prostate cancer drug also known as

<sup>7</sup> https://tdg.ucla.edu/

<u><sup>8</sup> https://ipira.berkeley.edu/</u>

- <sup>9</sup> https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf
- 10

<sup>&</sup>lt;sup>5</sup> <u>https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP\_Highlights\_100910.pdf</u>; emphasis added

https://ipira.berkeley.edu/sites/default/files/shared/docs/SAMPLE%20No%20EQUITY%20EXCL%20For%20Posting%207.17.18.pdf

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

<sup>&</sup>lt;sup>12</sup> <u>https://medicinespatentpool.org/news-publications-post/who-essential-medicines-committee-2021</u>

enzalutamide, in India; and

- 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"<sup>13</sup>. 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<sup>14</sup>; and
- 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<sup>15</sup>; therefore be it
- RESOLVED That the Graduate Assembly take the official position that the University of California Board of Regents should adopt the Affordable Access Plan in place at UCLA<sup>16</sup>on February 2, 2023 as a universal licensing mechanism across all University of California campuses as a leader amongst institutions prioritizing access to life-saving medicines; and be it further
- RESOLVED That the Graduate Assembly take the official position that UC Berkeley should pursue changes which will bring current licensing practices into alignment with the school's principles of global engagement<sup>17</sup>; be it further
- RESOLVED That the Graduate Assembly adopt the official position that UC Berkeley 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
- RESOLVED That the Graduate Assembly adopt the standing policy that UC Berkeley 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 at UCLA and other universities; and be it further
- RESOLVED That the Campus Affairs Vice President be directed to communicate the official

<sup>&</sup>lt;sup>13</sup> https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

<sup>14</sup> https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

<sup>&</sup>lt;sup>15</sup> https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

<sup>&</sup>lt;sup>16</sup> See pages 6-7 of https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

<sup>&</sup>lt;sup>17</sup> <u>https://globalengagement.berkeley.edu/about/uc-berkeleys-principles-international-engagement</u>

positions and standing policies contained in this resolution to Berkeley Intellectual Property and Industry Research Alliances (IPIRA); and be it finally

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