

The Regents of the University of California

SPECIAL COMMITTEE ON INNOVATION TRANSFER AND ENTREPRENEURSHIP

July 18, 2023

The Special Committee on Innovation Transfer and Entrepreneurship met on the above date at the UCSF-Mission Bay Conference Center, San Francisco campus.

Members present: Regents Hernandez, Leib, Matosantos, Park, and Reilly; Chancellors Christ, Hawgood, Khosla, and Muñoz; and Advisory members Green, Ku, Pouchot, and Timmons

In attendance: Regents Anguiano, Ellis, Robinson, and Tesfai; Faculty Representatives Cochran and Steintrager; Staff Advisor Mackness and Staff Advisor-designate Emiru; Secretary and Chief of Staff Lyall, Deputy General Counsel Wright, Provost Newman, Chief Compliance and Audit Officer Bustamante, and Regents Analyst Sheridan

The meeting convened at 2:05 p.m. with Special Committee Chair Park presiding.

1. PUBLIC COMMENT

Special Committee Chair Park thanked Chancellor Hawgood for hosting and announced that Regents Emeritae Pouchot and Timmons agreed to serve as advisors to the Special Committee. She invited the public to provide comment on University-related matters. The following person addressed the Special Committee.

A. Raquel Lopez, an undocumented student at UC Berkeley, thanked the Regents for their support of equitable student employment opportunities.

2. UPDATE ON ROYALTY AUDIT IDENTIFICATION APPROACH

[Background material was provided to the Special Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Senior Vice President and Chief Compliance and Audit Officer Bustamante recalled that Ethics, Compliance and Audit Services (ECAS) developed an approach to identifying royalty audits in response to Recommendation 12 in the report of the Regents Working Group on Innovation Transfer and Entrepreneurship to probe the strengths and weaknesses of the University's efforts to protect its intellectual property rights. At the Special Committee's October 2022 meeting, ECAS recommended a hybrid approach for monitoring licensing in which ECAS and the campuses would share this responsibility. The Special Committee supported this recommendation. He reported that since then, ECAS staff met with each campus' technology transfer office to gain insight into their monitoring activities and discuss the allocation of responsibilities. ECAS also met with UC Legal to draft license agreement terms. Based on this information, ECAS refined the proposal found

in the background materials, including monitoring activities to be performed by ECAS given sufficient resources, updates to the license risk factors to be used as criteria for monitoring, and projections of productivity.

Systemwide Deputy Audit Officer Matthew Hicks summarized the main points of agreement from discussions with the campus technology transfer offices. They agreed that the University should commit more resources to monitoring licensees but stated that the campuses do not have the capacity to do so. They expressed strong support for centralized monitoring performed by ECAS, with the caveat that any interactions with licenses should be done in collaboration with the campuses so that they can manage those relationships.

Mr. Hicks outlined additions to the proposal discussed at the October meeting. ECAS will perform the following monitoring functions: review self-audit results, develop customized licensee questionnaires that identify the licensee's obligations, monitor industry news, and monitor aging reports to identify unpaid licensee invoices. ECAS learned that much of the information it would need to perform these functions is available in the Patent Tracking System (PTS). The proposal also includes estimates of what could be accomplished with a central team of employees and the associated required funding.

Principal Counsel Rita Hao stated that one of ECAS's recommendations was that license template agreements should include a "self-audit" provision that requires licensees to perform internal audits of their agreements with the University. UC Legal developed this language and encouraged the campuses to include it in new agreements.

Mr. Hicks displayed active license agreements by revenue and noted that it would not be difficult to review all license agreements above \$1 million next year.

UCLA Technology Development Group Associate Vice Chancellor Amir Naiberg commented on the advantages of audits being performed by an organization such as ECAS that is arms' length from the campus as it allows the campuses to maintain their relationships with the licensees while receiving unbiased opinions on the fulfillment of the negotiated license terms. He added that a modern PTS system and assistance from ECAS will help ease the campus workload in preparing for an audit. He also stated that UCLA fully supports ECAS' proposal, but reserved judgment on whether the self-audit provision will achieve its goals.

UCLA Technology Development Group (TDG) Chief Financial Officer and Chief Operations Officer Tim Grauerholz reminded the Regents that TDG began implementing a customized licensee questionnaire to ensure that licensees are complying with financial and reporting obligations. They found that the majority of licensees were out of compliance for issues such as failure to report sublicensee income, pay milestone fees and earned royalties, and provide timely reports. The questionnaire also helped the campus identify ten candidates for full audits which it aims to complete in this fiscal year with the help of ECAS.

Mr. Hicks said that ECAS will request budget approval to support centralized licensee

monitoring and auditing services, develop information sharing protocols with the campuses, and pilot some centralized monitoring activities.

Regent Hernandez asked how much income ECAS expects to recover above the cost of auditing. Mr. Hicks replied that in the past 14 years, ECAS performed nearly 50 audits, identified \$6.6 million in underpayments, and recovered \$2.6 million with a net audit cost of \$583,000. The return on investment for recovered funds was 4.5 times, and 11 times for all identified underpayments. He opined that there is tremendous opportunity to recover funds, particularly by using a disciplined, risk-based approach to identifying high-risk audit candidates. Mr. Bustamante added that UCLA has been very successful in recovering funds by taking a systematic approach to auditing and therefore he expects that more revenue will be generated by applying this approach systemwide.

Regent Hernandez asked whether licensee non-compliance was a result of misinterpretation of agreement terms or was intentional. Mr. Hicks replied that non-compliance could be a result of inadequate controls or complex royalty calculations, or there could be a disagreement regarding the contract terms. Information sharing among the campuses will include learning from each other about typical reasons for initiating an audit.

Regent Hernandez asked if the University could make contract terms clearer. Ms. Hao replied that UC Legal recently initiated regular meetings among licensing officers to share information and close loopholes in contract terms.

Regent Robinson remarked that the targeted companies represented a very small proportion of all licensees. Mr. Bustamante explained that ECAS plans to focus on companies that generate more than \$1 million in revenue so as not to undermine relationships with small companies and would work closely with the campuses to identify which ones to audit. Additionally, once it becomes known that UC has a robust royalty audit process, this will create a deterrent effect. Regent Robinson agreed with this approach but observed that the number of potential targets and the revenue it will produce may not support the additional resources to investigate them. Mr. Bustamante said ECAS will take a measured, thoughtful approach and will increase auditing activity only if it generates a return on investment and the campus technology transfer officers determine it is needed.

Regent Leib asked the Chancellors for their perspective. Chancellor Hawgood reinforced the need for a nuanced, balanced approach. Chancellor Khosla expressed reservations about auditing for the sake of compliance, which could create undue burdens on smaller companies, and argued that the University should only pursue flagrant cases.

Advisor Ku opined that it is good for licensees to know that the University will audit them and is a best practice that will produce “good hygiene.” However, since there are only approximately 25 companies producing royalties of over \$1 million, there is not a great need for additional staff to perform this function.

Regent Reilly asked why only \$2.6 million was recovered from the \$6.6 million of identified underpayments over the past 14 years. Ms. Hao responded that she did not know

the reason but would report back to the Special Committee.

Regent Tesfai asked Mr. Naiberg to elaborate on his hesitancy about the self-auditing provision of the proposal. Mr. Naiberg replied that it may be an unnecessary hurdle and that the consultant that proposed it did not provide data showing that this requirement would result in reporting discrepancies. He felt it would be more productive for the University's own auditors to focus on the top revenue-producing companies rather than requiring self-reporting by all companies. This would provide more reliable information. Ms. Hao clarified that the self-auditing provision is an optional tool; the campuses will decide whether to include it in their agreements. She observed that some technology transfer officers believe it makes sense in certain circumstances.

Regent Ellis expressed hesitation about the audits and observed that the targets of audits are the University's own students and faculty. He opined that there are better ways to allocate those resources.

Special Committee Chair Park expressed appreciation for ECAS' thoughtful and methodical approach. She noted that ECAS worked with the campuses to refine the plan so that the oversight is strategic and would continually be revisited.

Regent Matosantos asked about the request for additional resources to support this project. Mr. Bustamante responded that ECAS currently did not have a line item in its budget for this type of activity and it had no ability to fund the effort without decreasing other activities. In addition, ECAS had no internal expertise in this area. In the past, at the request of the campuses it paid an outside vendor to investigate using ECAS' general operating funds. A sustained approach would need a dedicated employee.

3. **INNOVATION AND ENTREPRENEURSHIP AT UC SAN FRANCISCO**

[Background material was provided to the Special Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chancellor Hawgood observed that innovation and entrepreneurship (I&E) have been part of UCSF's mission from its founding in 1963. UCSF was seminal in the development of the biotechnology industry when its professors, in collaboration with others, first demonstrated gene cloning and filed a patent application for recombinant DNA, leading to the formation of Genentech, the world's first biotechnology company.

Chancellor Hawgood remarked that before 2017, UCSF's I&E efforts were fragmented and not easy to navigate. In 2017, UCSF organized this work under a single vice chancellor and office now called Innovation Ventures. It has four departments: the Office of Technology Management and Advancement, which manages intellectual property (IP) licensing; an office of funding, which manages two seed funding programs – the Catalyst Program and the InVent Fund; an education entrepreneurship program that teaches entrepreneurship to both UCSF students and faculty and external parties; and the Office of Strategic Alliances which interacts with external companies that want to work with UCSF.

Chancellor Hawgood described the approach of the Office of Technology Management and Advancement. It first asks if a technology is useful and would have a commercial market. This informs UCSF's decision whether to support a discovery and leads to more successful projects. The office also established market metrics that explain why UCSF prioritizes certain inventions and it developed an internal database to manage the workflow from disclosure to licensing and equity, as well as dashboards that report that work.

Chancellor Hawgood stated that UCSF is ready to accept delegated authority to manage equity in its licenses. He noted that UCSF currently holds equity in 77 companies, with a portfolio of approximately \$260 million. The campus aims to increase this to a \$1 billion portfolio by 2030.

Chancellor Hawgood described two funds that provide proof-of-concept funding. The Catalyst Award program provides about 20 awards between \$50,000 and \$100,000 each year, as well as access to over 100 pro-bono advisors with expertise specific to the project, and an entrepreneur in residence program to help faculty advance their projects. The newly established InVent Fund supports the most promising product opportunities from proof-of-concept to company creation with a target of providing \$100,000 to \$1.5 million per project. It is a philanthropic fund, with no expected return to donors, and UCSF has committed that it will reinvest half of any returns into the fund so that it can be an "evergreen" fund. UCSF has raised \$13 million for the fund to date with a target of \$50 million to \$100 million and has committed nearly all of the funds raised to 18 projects. He noted that it was too early to predict its success.

Finally, Chancellor Hawgood provided an overview of UCSF's entrepreneurship education program. In addition to teaching UCSF faculty and students how to build companies, during the pandemic, UCSF created an online class in biotechnology entrepreneurship offered globally. In the past three years it has enrolled over 300 students from 27 countries.

Chancellor Hawgood introduced Interim Vice Chancellor of Business Development, Innovation and Partnerships Peter Kotsonis. Mr. Kotsonis described the strategy of the Office of Strategic Alliances. It focuses on fewer, more meaningful partnerships with industry that take advantage of UCSF's strengths, and also partners with other UC campuses with complementary expertise to leverage the University's intellectual property. UCSF also has entered into relationships with venture-funded startup accelerators.

An example of one such partnership is the Laboratory for Genomics Research, a partnership between UCSF, UC Berkeley, and GlaxoSmithKline (GSK), which is a five-year \$67 million investment in an incubator for the development of breakthrough functional genomics technologies targeting new medicines. UC researchers work side by side with GSK scientists in a dedicated, state-of-the-art laboratory. This is a unique approach and requires structures to manage risk.

Regent Leib asked Chancellor Hawgood to provide his view of the delegation of authority for equity management. Chancellor Hawgood replied that the biggest step occurred several

years ago when the University began to allow campuses to take equity in companies. He believed that the ability for campuses to manage these relationships would be beneficial and anticipated that substantial resources would be returned to the campus. He offered an example of a cell design technology developed at UCSF that was sold to Gilead for \$577 million. He noted that the campus was creating structures to manage potential conflicts of interest.

Regent Leib asked if there is anything the University can do to enhance its equity holdings. Executive Director of Technology Management and Advancement Anthony Francis responded that UCSF's strategy is to take a longer-term view than the University usually does to maximize value and to position UCSF as a shareholder. This goes beyond a compliance-based approach to an investment-based approach to help the companies grow. He stated that UCSF aims to exert more control in the startup process so that projects have a better outcome. Currently, University policy does not allow campuses to hold a large percentage of equity in a company, as this poses challenges in terms of conflicts of interest.

4. **SPEAKER SERIES: A JOURNEY FROM BASIC IMMUNOGENETICS TO A COMPANY PRODUCING CANCER IMMUNOTHERAPY**

[Background material was provided to the Special Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chancellor Hawgood introduced Professor Alex Marson, UC San Francisco School of Medicine Professor and founding Director of the UCSF Institute of Genomic Immunology, among other titles. He is also a founder of Arsenal Biosciences (Arsenal), a company that creates therapeutics for common forms of cancer. His research is on understanding how genetics control cells in the immune system.

Professor Marson described how scientists built a new company based on discoveries in several laboratories. He emphasized that UCSF's discovery of recombinant DNA fundamentally changed how medicine is delivered – from pills to biologics that are treatments for cancer, growth hormone, insulin, etc. He believed that one was now witnessing another expansion of medicine in which human beings' own cells become medicine. Arsenal's research aims to engineer DNA code inside cells to attack pathologies and treat common forms of cancer.

He stated that in 2012 two major scientific advances occurred – the ability to engineer cells to treat blood cancer at the University of Pennsylvania and the invention of CRISPR DNA editing by UC Berkeley's Jennifer Doudna in collaboration with the University of Vienna's Emmanuelle Charpentier. This provided a precise tool to change genes and use these cells to deliver medicine. Professor Marson's laboratory's mission is to combine these two technologies and to deploy CRISPR in human immune cells. He described the work of Theo Roth, a student in his laboratory, who dyed T-Cells green so that he could count the number of cells that were developed following gene editing at clinical scale. This became the basis for Arsenal.

Professor Marson explained that in addition to developing CRISPR-based delivery systems, Arsenal is also pursuing ways to create a DNA code to make immune cells recognize cancer and is developing screening capability to see which DNA sequences are most effective in conferring a property into immunotherapies to make them effective against different types of cancer. He remarked that since UCSF licensed the technology developed in his laboratory, Arsenal dramatically increased the size of the DNA sequences that can be delivered. This could not have been done in an academic setting; it required industrial engineering.

Professor Marson elaborated on the process of changing how DNA code recognizes cancer cells. CAR-T cells are artificial sensor receptors on the surface of T-cells that enable T-cells to sense where the cancer is. Arsenal is now working on DNA codes that can sense a variety of ways to recognize when cancerous cells are different from healthy cells. Arsenal has also built a robot that can run tens of thousands of experiments in parallel using advanced computational power and machine learning to discover which immunotherapies will be the most effective in the future. Arsenal now has one drug to treat ovarian cancer in Phase 1 clinical trials and a second drug treating kidney cancer is ready to be submitted to the Food and Drug Administration for approval. He conveyed his enthusiasm for the possibilities that scientific research, combined with the power of industry expertise and scale, can lead to the development of new treatments.

Regent Reilly asked Chancellor Hawgood which of the recommendations of the Regents Working Group will be most helpful to UCSF. Chancellor Hawgood replied that the fact that the Regents are validating innovation and entrepreneurship is most significant. It helps attract faculty to UCSF as an attractive place to pursue a career that incorporates I&E. In addition to campus equity management, the potential for faculty to take a leave of absence for entrepreneurial activity is promising, if used judiciously.

Special Committee Chair Park thanked Professor Marson for his presentation and noted that Provost Newman intended to continue to highlight research, innovation, and entrepreneurship at Regents meetings after the work of the Special Committee concludes.

The meeting adjourned at 4:00 p.m.

Attest:

Secretary and Chief of Staff