UCLA Health

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September 7, 2017

Dr. Manon Anne Ress, Union for Affordable Cancer Treatment
Ms. Leena Manghaney, Union for Affordable Cancer Treatment
Ms. Judit Rius, Union for Affordable Cancer Treatment
Mr. James Love, Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

SUBJECT: Letters re: UC Patents on Xtandi in India

Dear Dr. Ress, Ms. Manghaney, Ms. Rius, and Mr. Love:

Thank you for your letters of May 24, 2017 and July 28, 2017 expressing concern about the patent protection being sought in India for enzalutamide. After consulting with the various arms of the University involved in this activity, I am writing to provide you with some information on this case.

The University of California maintains a longstanding commitment to achieving the broadest public benefit by licensing University-created technology for development into products that can be accessed by the public. Without a license to industry and the company's pledge to invest the time and significant resources into development of the product and securing FDA approval to ensure safety and efficacy of the product, it is unlikely that the public would reap the clinical benefits of therapeutic technology at all. The process of licensing University-created technology is an arduous effort that requires identification of willing industrial partner(s), then seeks to balance the requirements of the company's legitimate business concerns with the University's need to ensure diligent development of the drug. The discussions surrounding the license are complex and take into account various internal and external factors that the company must grapple with before achieving success with any healthcare product. Without this commitment on behalf of the licensee company and its partners, making new healthcare products available to the public would likely be impossible.

The University is committed to addressing global health issues and its research has done much to address health issues of developing countries. In addition to research done on all ten campuses, we have a Global Health Institute dedicated to the training of future global health leaders and accelerating the discovery of global health solutions. In the realm of technology licensing, we have specifically addressed global health and other unmet needs in the University's Licensing Guidelines. In addition, UC worked closely with other research institutions to draft and endorse the Nine Points to Consider in Licensing University Technology, which specifically raises the issue of unmet needs, particularly in developing countries. These considerations are not prescriptive however, since it is widely known that a variety of complex and potentially contradictory issues must be taken into account to weigh and balance the needs of the licensee company with the University's desire to ensure a product is diligently developed into a usable product.

Each UC campus has the delegated authority to negotiate and execute licenses under the umbrella of system-wide policy considerations. Every licensing situation is necessarily handled on a case-by-case basis taking into account the nuanced details of the technology and the market and unique set of circumstances surrounding each technology. In exclusive licenses, the licensee usually has a significant role in the prosecution of patent applications in the United States and other countries. Not only do they pay for the costs, but they want to ensure the claims are crafted in such a way that the products they are developing are protected. Because the licensee pays the costs of patenting, they are also typically allowed by contract to choose the countries in which to file.

Similarly, in the case of enzalutamide, an exclusive license agreement for the development of the product was signed between the Regents of the University of California (UCLA) and Medivation Inc. (then a U.S. start-up company), the only company that was willing to take on the risk of developing the underlying technology. Under the terms of our license agreement Medivation agreed to diligently develop the technology and bring it to the marketplace, and to bear all the costs of doing so. Pursuant to said agreement, while the patents are held in the name of The Regents, the licensee has substantial input and control on their prosecution and maintenance. The Regents are obligated to use their best efforts to keep the patents licensed to Medivation from lapsing. The appeal in India was filed and is being controlled and managed by and at the request of Medivation and its commercial partner Astelles, the Regents are a named party in accordance with these contractual obligations. Nevertheless, UC has brought to Medivation's attention the concerns that UACT has raised.

Importantly, this life-saving drug would not currently be available for patients *at all* were it not for Medivation's significant investment and diligent efforts.

Sincerely,

John C. Mazziotta, M.D., Ph.D.
Vice Chancellor, UCLA Health Sciences
CEO, UCLA Health System

Cc: File
Regent Chairman Kieffer
President Napolitano
Regent Sherry Lansing
Regent Richard Sherman
General Counsel Robinson
Chancellor Gene D. Block