



Janet Napolitano
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Board of Regents of the University of California
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May 24, 2017

RE: UC Efforts to Patent Xtandi (enzalutamide) in India

Dear President Napolitano, Chairwoman Lozano, and Regents of the University of California:

We are writing to ask that you withdraw your efforts to obtain a patent on the prostate cancer drug enzalutamide (brand name Xtandi) in India. The grant of a patent on enzalutamide in India would prevent generic competitors from supplying the drug at an affordable price, both in India and in other countries where there is no patent, or where Astellas has abused its patent rights by charging prices that are excessive and create access barriers for this important drug.

Enzalutamide is a treatment for prostate cancer, developed by researchers at UCLA with the support of U.S. taxpayer dollars through grants from the National Cancer Institute at the National Institutes of Health and the U.S. Army Prostate Cancer Research Program. UCLA licensed enzalutamide in 2005 to a small San Francisco-based biopharmaceutical company called Medivation, which then entered into a collaboration agreement with the Japanese drug company Astellas Pharma. Astellas is responsible for the worldwide manufacture and distribution of enzalutamide.[1] On March 4, 2016, UCLA announced that it had sold its royalty interests in the patents on enzalutamide to Royalty Pharma for \$1.14 billion USD.[2] Pfizer then acquired Medivation for around \$14 billion USD on September 28, 2016.[3]

Trade publications reported that Xtandi global sales were \$1.87 billion USD in 2015, with projected annual global sales of \$4.78 billion USD by 2020.[4]

Astellas sells enzalutamide at a high price in India that is unaffordable to most cancer patients. The Times of India reported on November 10, 2016, that Astellas sold enzalutamide for an exorbitant Rs 3.35 lakh per 112 pills (a 28-day supply), which was estimated at the time amounted to \$5,014.60 USD — around \$44.77 USD per pill and \$179 USD per day. Astellas sells enzalutamide for \$26 USD per pill in its home country of Japan.

The World Bank estimated India's 2015 per capita income at \$1,590 USD per year[5], or \$4.36 USD per day, making the cost of the required four pill daily dose of enzalutamide more than forty times a person's daily income in India.

Recently, BDR Pharma and Fresenius Kabi, both Indian drug companies, and the Indian Pharmaceutical Alliance, challenged the University of California's attempt to obtain a patent on enzalutamide in pre-grant patent opposition proceedings. The Indian Patent Office denied the patent, leading attorneys for the Regents of the University of California to file a petition before the Delhi High Court.[6]

We request that the University of California withdraw its case and cease its efforts to obtain a patent on enzalutamide in India. The high price of Astellas branded Xtandi in India is shocking to anyone who thinks cancer drugs should be accessible and affordable, regardless of where you live.

Generic competition in India has historically driven down prices and significantly improved access to cancer drugs in India and other countries that are currently sourcing from India, and this will also apply to enzalutamide as it goes into production and registration.

California taxpayers should not foot the bill for or permit this patent litigation, which will benefit a Japanese drug manufacturer and a New York-based pharmaceutical corporation, but harm patients seeking affordable access to an important cancer medicine.

We also request that you direct your policy and legal teams to evaluate the University of California's intellectual property policies to ensure that the University does not aggressively pursue acquisition of intellectual property rights when such acquisition will harm affordable access in low-income countries.

We would like the opportunity to discuss this matter with you at your earliest convenience.

We look forward to your response.

Sincerely Yours,

Manon Anne Ress, Leena Menghaney and Judit Rius, for the Union for Affordable Cancer Treatment

Joined by:

1. AIDS Access Foundation, Thailand
2. All India Drug Action Network, India
3. All-Ukrainian Network of PLWH
4. amaBele Project Flamingo
5. Breast Health Foundation
6. Brian Citro, University of Chicago Law School International Human Rights Clinic
7. Campaign for Affordable Trastuzumab, India
8. Cancer for Care, South Africa
9. Chinu Srinivasan, Locost, India
10. Corporación Innovarte, Chile
11. Delhi Network of Positive People
12. Dr. B.Ekbal, Kerala Sastra Sahithya Parishadh, India
13. Dr. Gopal Dabade, Drug Action Forum - Karnataka, India
14. Dr. Mira Shiva, India
15. Ellen 't Hoen LLM, Medicines Law & Policy/ University Medical Center Groningen
16. Fundación IFARMA - Colombia,
17. Hannes Braberg, Staff Scientist at University of California, San Francisco
18. Health Action International
19. Health GAP (Global Access Project)
20. Hospice Palliative Care Association of South Africa
21. Housing Works
22. Igazi Foundation
23. Initiative for Health and Equity in society, India
24. International Treatment Preparedness Coalition (ITPC), South Asia
25. International Treatment Preparedness Coalition Latin American and Caribbean ITPC-LATCA
26. Just Treatment - A movement to defend the NHS and secure fair access to medicines
27. Jyotsna Singh, Health Writer, India
28. Kalyani Menon-Sen, Feminist Learning Partnerships, India
29. Knowledge Ecology International
30. La Alianza LAC - Global por el Acceso a Medicamentos
31. Look Good Feel Better
32. Lymphoedema Association of South Africa
33. Misión Salud
34. Other 98
35. Oxfam
36. Pancreatic Cancer Network South Africa
37. Pink Trees for Pauline
38. Pocket Cancer Support
39. Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
40. Professor Brook K. Baker
41. Public Citizen
42. Reach For Recovery
43. Reshma Ramachandran, MD, MPP, Co-Chair of the National Physicians Alliance and Assistant Scientist, IDEA (Innovation+Design Enabling Access) Initiative, Johns Hopkins Bloomberg School of Public Health
44. Salud por Derecho
45. SECTION27, South Africa
46. Social Security Works
47. South African Oncology Social Workers Forum

48. StopAIDS, UK
49. Suerie Moon, MPA, PhD, Director of Research, Global Health Centre and Visiting Lecturer, Graduate Institute of International and Development Studies, Geneva and Adjunct Lecturer, Department of Global Health and Population, Harvard T.H. Chan School of Public Health
50. The Cancer Association of South Africa
51. The Vrede Foundation
52. Third World Network
53. Treatment Action Campaign, South Africa
54. Universities Allied for Essential Medicine (UAEM)
55. Yale Global Health Justice Partnership
56. Young Professionals Chronic Disease Network (YP-CDN)

CC: Janna Tom, Associate Director, Research Policy Analysis and Coordination (janna.tom@ucop.edu); Amir Naiberg, Associate Vice Chancellor and CEO & President, UCLA Technology Development Corporation (amir.naiberg@tdg.ucla.edu); Charles F. Robinson, General Counsel & Vice President — Legal Affairs (charles.robinson@ucop.edu); Jenny Kao, Executive Director, Issues Management, Policy Analysis & Coordination (jenny.kao@ucop.edu); and John Stobo, MD, Executive Vice President, UC Health (john.stobo@ucop.edu).

Notes

[1] For additional details see, Knowledge Ecology International and Union for Affordable Cancer Treatment, letter to Sylvia Mathews Burwell, Francis Collins, and Ashton Carter (Jan. 14, 2016), <http://keionline.org/sites/default/files/Xtandi-March-In-Request-Letter-14Jan2016.pdf> (accessed May 10, 2017)

[2] Phil Hampton, *UCLA Sells Royalty Rights Connected With Cancer Drug to Royalty Pharma*, Mar. 4, 2016), <http://newsroom.ucla.edu/releases/ucla-sells-royalty-rights-connected-with-cancer-drug-to-royalty-pharma>.

[3] *Pfizer Completes Acquisition of Medivation* (Sept. 28, 2016), http://www.pfizer.com/news/press-release/press-release-detail/pfizer_completes_acquisition_of_medivation.

[4] Michael Gibney, *The Top 20 Drugs in 2020 — Worldwide Sales, 15. Xtandi*, FiercePharma, <http://www.fiercepharma.com/special-report/15-xtandi>.

[5] World Bank, World Development Indicators DataBank, GNI per capita, Atlas method (current US\$), accessed May 10, 2017.

[6] *The Regents of the University of California v. Union of India and Ors*, WP (Civil) No. 1163 of 2017. For additional information, see Don't Trade Our Lives Away, *Update from India on Xtandi (Enzalutamide) for Cancer Treatment*, May 3, 2017, <https://donttradeourlivesaway.wordpress.com/2017/05/03/update-from-india-on-xtandi-enzalutamide-for-cancer-treatment/>.