Centre for CIPROM intellectual property management

NEWSLETTER

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Intellectual Property advocacy in the fields of:

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ENZALUTAMIDE (XTANDI) OF UCLA (UNIVERSITY OF CALIFORNIA) – UNFAIR MONOPOLISTIC PRICING AND INADEQUATE ACCESSLEADING TO SUFFERING FOR PATIENTS. CANCER UNION AND 56 OTHERS URGE UCLA TO BACK DOWN.

(Courtesy – SpicyIP - Ritvik Kulkarni)

XTANDI Updates: Cancer Union and 56 others request UCLA to back down from Delhi HC review of IPO's patent rejection order; Delhi HC refuses to hear the matter on priority

In a positive development, the Union for Affordable Cancer Treatment (**UACT**), along with 56 other organizations, has requested the University of California (**UCLA**) to withdraw from its proceedings before the Delhi High Court against the IPO's rejection of its patent[1] in XTANDI. In its letter dated 24th May 2017, UACT reminds UCLA that its research for the blockbuster drug for prostate cancer was supported by US taxpayer dollars through the National Cancer Institute at the National Institutes of Health and the US Army Prostate Cancer Research Program. UACT lays emphasis on the seminal role played by generic competition to achieve lower drug pricing in India and laments Astellas' high pricing of XTANDI for the Indian market.

The letter concludes as follows:

"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."

Ides of March

It is pertinent to note that the US Federal Government is empowered by the Bayh-Dole Act to grant third-party patent licenses through the government agency which funded the research towards the invention. These rights can be exercised *inter alia* if the current licensee has not taken effective steps towards the practical application of the invention or if such action is *necessary to alleviate health or safety needs* which are *not reasonably satisfied* by the current licensee. Writing for IP Watch, Steve Seidenberg posits that march-in rights are a powerful method in driving down the prices of egregiously overpriced patented drugs whose research was funded by federal institutions.

Alas, in an 'exasperating farrago' of federal inaction, the US Government has never exercised its march-in rights in 37 years of the history of the Bayh-Dole Act. This is because the US Government does not believe that these rights can be used to affect drug prices as long as public access is ensured. It also reckons that exercising these rights might discourage private investment in technology.

That said, it is equally pertinent to note that federal funding in the US for drug research is often limited to the initial stages of research. The latter, more expensive stages are funded more often by private investment than by government agencies.

Proceedings in India

Our readers will recall that Pfizer's patent for the prostate cancer drug 'Enzalutamide' (XTANDI) was rejected by the Indian Patent Office (IPO) in a well-reasoned order passed in November 2016. This blockbuster drug is currently sold by Pfizer at Rs. 3,35,000/- for a packet of 112 capsules which suffice only for 28 days of dosage. (*See* Rahul's post on the patent rejection order). Subsequently, UCLA through its Regents challenged the rejection order in a writ petition before the Delhi High Court and sought the patent application to be reheard by the IPO. (Read Inika's post on *The Regents of the University of California v. Union of India).*

Recently, the Delhi HC in its order refused to hear the matter in May and has instead listed it for hearing on July 20, 2017. The Petitioner had reportedly requested the Court to list the matter in May itself since only 10 years of the patent term were remaining, 50 other countries had already granted the same patent and because it has simply sought that the pre-grant opposition proceedings be remanded back to the IPO. The Union of India firmly disagreed with the remedy of remand since such an act would completely defeat the purpose of the Indian Patents Act, 1970.

Refusing the Petitioner's request, the Court is reported to have orally observed that it cannot afford such preferential treatment to the protection of private commercial interest and consequently listed it for hearing in July instead. Furthermore, the Court in its order has also directed the Petitioner to file a rejoinder to the counter-affidavits by early June.

Appointment Delayed is Patent Granted

Despite this positive development, there's a good chance that the Delhi HC will remand this matter back to the IPO if the Indian Government does not make requisite appointments to the Intellectual Property Appellate Board (**IPAB**); which happens to be the forum where the Petitioner's grievances should actually ideally lie. Instead, the Petitioner has clearly taken advantage of governmental inaction and proceeded to bypass the procedure to earn a review of the IPO decision.

In a hard-hitting post, Prashant has succinctly explained as to how the Indian Government's actions and stance are marred by statutory, administrative, and constitutional infirmities. In particular, the Finance Act 2017 has effectively repealed Chapter XI of the Trademarks Act, 1999. On the one hand, the Government is hell bent on usurping control of the IPAB and diluting its independence. On the other hand, it's nevertheless causing an unpardonable delay in making the necessary appointments to the tribunal. Prashant has also launched a fervid attack against the constitutionality of Section 184 of the Finance Act, which allows the government to determine qualification and other criteria for the IPAB through rules. He argues that Section 184 is blatantly unconstitutional because it amounts to the delegation of Parliament's essential functions to the Executive and consequently dilutes the judicial independence of the IPAB.

While most Indians are immune and even apathetic to delays caused by each organ of Indian democracy, these very delays have previously had far-reaching, serious and very direct ramifications for them. A UNCITRAL arbitral tribunal in 2011 directed the Indian government to shell out millions from Indian taxpayers' money as damages to White Industries Australia, mainly on grounds of India's excruciatingly slow judiciary.

This time around, if the Xtandi application is resurrected by remand, numerous patients in India are likely to lose their life and wealth on account of XTANDI's high pricing. If that's not impetus enough for the Government to make haste in making the requisite IPAB appointments, I'm not sure what will.

CL the Deal

What happens if the patent application is eventually granted, whether by the IPO in remand or by means of a functioning IPAB granting the Regents' appeal? There is always the chance that XTANDI patent holder Pfizer may follow Gilead's practice with Sofosbuvir and enter into Voluntary Licensing Agreements (**VLAs**) with generic companies in order to make its drug more accessible and effectively avoid any further patent validity challenges. However, VLAs have their own dose of deceit and pitfalls. In particular, Gilead's VLAs invited heavy criticism and aversion on account of its 'anti-diversion' measures. (*See* Rupali's post on the Gilead VLAs here)

If Pfizer refuses to grant voluntary licenses, the aforementioned generic drug manufacturers (and others) will still have a chance of applying for a compulsory license in Xtandi on grounds of its steep pricing and consequent lack of accessibility. If a CL is indeed granted, generic versions of Xtandi can be sold in India for as less as $0.50 per pill or $2 a day; making it one of the best discount offers of all time.

[1] 9668/DELNP/2007 = PCT/US2006/011417

[1]https://spicyip.com/2017/05/xtandi-updates-cancer-union-and-56-others-request-ucla-to-back-down-from-delhi-hc-review-of-ipos-patent-rejection-order-delhi-hc-refuses-to-hear-the-matter-on-priority.html

[2]http://cancerunion.org/wp-content/uploads/2017/05/UACT-U-Cal-Xtandi-Patent-India-2017May24.pdf

Contd from pg1.. (…letter)

ANNEXURES

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University of California, Office of the President
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via email: president@ucop.edu

Board of Regents of the University of California
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1111 Franklin St., 12th floor, Oakland, CA 94607
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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 annualglobal 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 JuditRius, 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. CorporaciónInnovarte, Chile
11. Delhi Network of Positive People
12. Dr.B.Ekbal, Kerala Sastra SahithyaParishadh, India
13. Dr. Gopal Dabade, Drug Action Forum - Karnataka, India
14. Dr. Mira Shiva, India
15. Ellen 'tHoen 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. MisiónSalud
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. SaludporDerecho
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, U CLA 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] P fizer 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, T he 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] T he 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) forCancerTreatment , May 3, 2017, https://donttradeourlivesaway.wordpress.com/2017/05/03/update-from-india-on-xtandi-enzalutamide-for-cancer-treatment/