**INFORMATION PAPER**

MCMR-JA 21 July 2016

SUBJECT: exercise of Government march-in rights RE: XTANDI®

1. Purpose: This information paper is provided in support of the response to USAMRMC Tasker 1602042 concerning a request to the Secretary of Health and Human Services (DHHS) and the Secretary of Defense (DoD) to exercise the Federal government’s march-in rights with respect to a cancer treatment developed with funding from the National Institutes of Health (NIH) and the Congressionally Directed Medical Research Program (CDMRP), a subordinate organization of the U.S. Army Medical Research and Materiel Command. To our knowledge, this request to exercise march-in rights is the first ever directed to an agency of the DoD.
2. BLUF: We recommend that DoD decline to exercise its march-in rights. This action would accord with the denial of the request to exercise march-in rights already communicated by DHHS and NIH to the Requestor via letter on April 13, 2016.
3. The Federal government has never exercised the march-in rights available to it. There have, however, been several petitions directed to the NIH requesting such action. Several of the NIH requests have similar fact patterns to and make similar arguments as those currently presented to the DoD. All such requests have been denied by DHHS.
4. DoD’s exercise of the march-in authority could have a chilling effect on the willingness of contractors and others to partner with the DoD and jeopardize the ability of Federal technology transfer laws to drive innovation, product development and job creation in the U.S. In the biomedical realm, government partnering with private industry is imperative to take new drugs and vaccine through the FDA approval process. Uncertainty and concerns about government exercise of march-in rights could reduce the number of potential investors willing to support the development of needed medicines, equipment and treatments for the Warfighter.
5. Facts:
   1. The Request to exercise march-in rights, dated January 14, 2016, was addressed to the DHHS, NIH, and the DoD. The Requestors are Knowledge Ecology International (KEI) and The Union for Affordable Cancer Treatment (UACT), both non-profit organizations, hereinafter referred to as “KEI.” KEI has requested that DoD exercise its government purpose license or its march-in rights under the Bayh-Dole Act with regard to the drug enzalutamide.
   2. Invention and development of enzalutamide was funded in part by NIH and DoD awards to the University of California at Los Angeles. Several patents were obtained and assigned to the Regents of The University of California (Regents). Enzalutamide is FDA approved and marketed under the brand name “Xtandi®” by Astellas Pharma, a licensee of Regents. Xtandi® is used to treat metastatic prostate cancer.
   3. KEI states that the price of Xtandi® in the United States is far higher than the price of the drug in other countries, including high income countries. KEI asks the DHHS, NIH and DoD to use its march-in authority to address the disparity in price of Xtandi.® KEI proposes that the Federal government exercise its march-in rights by granting an open patent license to any generic drug manufacturer to make enzalutamide.
   4. March-in rights may be exercised by the government if any of the four following conditions exist: (1) the contractor or assignee has not taken or is not expected to take effective steps in a reasonable period of time to achieve practical application of the invention; (2) health or safety needs are not reasonably satisfied by the contractor, assignee or licensees; (3) public use requirements are not reasonably satisfied by the contractor, assignee or licensees; or (4) the preference for manufacture of the invention in the U.S. has not been satisfied and has not been waived by the government.
   5. KEI relies upon 35 U.S.C. 203(a)(1) as support for its request to exercise march-in rights. Section 203(a)(1) would permit the government to require Regents, its assignee or exclusive licensee to grant a license to a responsible applicant if Regents or its assignee have not taken, or are not expected to take with a reasonable time, effective steps to achieve practical application of the invention. KEI argues that the definition of “practical application” in 35 U.S.C. 201(f) includes a condition that the benefits of the invention be available to the public on reasonable terms and that Xtandi’s excessively high price does not constitute “reasonable terms.” KEI also argues that Xtandi® is so expensive that the price effectively limits public access to the drug.
   6. The drafters of the law eventually codified in 35 U.S.C. 203 have stated that the march-in rights provision was never designed to address price. Instead, it was designed to address failure to develop and exploit federally funded inventions, lack of manufacturing capacity or physical shortages, use during public health emergencies and the like.
   7. Investigation by CDMRP indicates that Xtandi® is FDA approved, available to medical providers for the normal 8-month course of treatment, and that its price is comparable to that of other drugs used to treat advanced prostate cancer. Furthermore, there are several access programs that provide financial assistance to patients needing the drug, including plans sponsored by the manufacturer, Astellas.

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Approved by:

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