March-In Rights Likely A Slow Trot at Best

Xtandi's High US Price Reinvigorates Government IP Rights Debate

- **March in Rights are back for debate with Xtandi (Pfizer, Astellas) petition front and center.** Knowledge Ecology International (KEI) is leading the charge by filing a March in petition against Xtandi. KEI is a non-government organization (NGO) focused on the effects of intellectual property on public health, cyberlaw, e-commerce, and competition. Recall march-in rights are a government mechanism that enables federal authorities to grant patent licenses to third parties or to declare patent ownership on federally funded products or research.

- **TRIPS waiver for COVID therapies & vaccines was not granted in 2020/21.** We wrote about march in extensively as the Biden administration pursued a TRIPS waiver with the COVID vaccine. In October 2020, the governments of India and South Africa, with the support of 62 WTO member states, proposed a TRIPS agreement waiver proposal that would temporarily waive intellectual property rights protections for technologies needed to prevent, contain, or treat COVID-19, including vaccines. White House officials supported the notion (USTR Katherine Tai) but the waiver never came to fruition given that the WTO is a deliberative body that takes months for consensus policy.

- **The KEI march in rights premise is that U.S. residents should not pay more than other high income countries for U.S. government funded products.** According to KEI, Xtandi costs ~$114 per capsule in the US. The per capsule Xtandi price is ~$22, outside of the US. KEI has unsuccessfully approached various pharmaceutical manufacturers including ABBV, BIIB, and MRNA alleging that they have not complied with various aspects of Bayh-Dole, the legislation authorizing march in rights.

- **To date, march in rights have not been successfully deployed: we believe that KEI's petition faces several hurdles.** We believe that there is no IP on the actual active molecule comprising Xtandi. A further clarification delineates that the patents cover the inventions products are predicated on, and NOT the actual products. Furthermore, The National Institute of Standards and Technology (NIST) issued a comprehensive report outlining the use of march in rights to rein in drug prices. The report details several requests to the NIH to exercise march in rights. The NIH stated, "the use of march-in to control drug prices was not within the scope and intent of its authority." See NIST report here.

- **We currently have no NIH leadership -- former NIH director Dr. Francis Collins was a vocal critic of march In rights.** Known for sequencing the human genome, Collins described march in rights as a mechanism that compromises innovation. His permanent successor will have a key role in determining march in rights' future traction. Notably the key names under consideration for the NIH Director role all have significant industry ties. Lawrence Tabak is the acting interim NIH director. The list of contenders includes:

    - **Jennifer Doudna**, biochemist Nobel Prize CRISPR inventor, founder of Mammoth Biosciences, Caribou and Scribe Therapeutics
    - **Levi Garraway**, oncologist and CMO of Roche, Broad Institute
    - **Sue Desmond-Hellman**, former head of Bill and Melinda Gates Foundation, board member at Pfizer, and former president of product development at Genentech
    - **Laurie Glimcher**, immunologist, President and CEO of Dana Farber Cancer Institute and board member at GlaxoSmithKline

- **In the unlikely event NIH opts to march in on Xtandi, a litigious (and lengthy) process will ensue, and the US would have to find a manufacturer to obtain ANDA and manufacture product.** (1) The NIH would very likely face legal challenges from ALMPY over the government's actual authority to march in. Several entities including UCLA, Pfizer and Royalty Pharma have a stake in Xtandi's multiple patents.

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(2) There may be dosing /method of use patents that are not touched by march in therefore the full march in scenario may not play out in one fell swoop with march in granted. (3) Even upon successful litigation which could take years, the NIH would still have to go through extensive regulatory hurdles at the FDA. The US government would have to contract with a manufacturer to obtain an ANDA at FDA and then produce its version of Xtandi, which again will take months and years versus weeks into months.

- **Key policymakers and administration officials to watch**. There are several new and acting key US government officials to watch as the march in rights debate ensues. Key folks to observe include Ron Klain (Biden's Chief of Staff), Tim Wu (Biden's special assistant for technology and competition policy), Gina Raimondo (US Secretary for Commerce), and Cathy Vidal (USPTO Director Nominee).

- **NEXT STEPS**: We view march in as unlikely at this time, as the administration simultaneously is pursuing ARPA-H, Cancer Moonshot, Cures 2.0, and FDA Use Fee legislation that involve public-private partnerships[s) and heavily rely on industry. We could see NIH hold a hearing to vet the issue. Press reports of last week note that NIH will make a decision in the next month or so. If the government were to exercise march in, we note that there would be multiple steps AFTER that, such as contracting with a biopharma manufacturer to produce the product after receiving an ANDA approval from FDA. The Senate is currently 50/50 and the illness of only one Senator (Ben Ray Luján, D-NM) throws the upper chamber's slim majority into uncertainty, which is important as this is not a bipartisan initiative in our view. Recall the TRIPS waiver involving COVID vaccines was largely White House driven and could be revived to include COVID-19 therapies that received government support (molnupiravir, MRK). However the WTO has not moved on TRIPS, and with the pandemic becoming endemic, we do not necessarily see the waiver materializing.

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