Tentative TRIPS Waiver Granted COVID-19

Mach In Slow Trot: Xtandi's Reinvigorates Government IP Rights Debate

- **Four countries negotiators have come to a tentative agreement on a COVID-19 patent waiver that has not been WTO-approved**. The agreement between the EU, India, South Africa and the United States allows some developing countries to use powers they already have under TRIPS to use patents on COVID-19 vaccines to address the public health emergency without the consent of the patent owners, according to *Biocentury* (here).

- **The deal has been narrowed significantly, and is not a done deal**. The agreement is limited to developing countries that exported less than 10% of COVID-19 vaccines in 2021, a threshold that excludes China from using COVID-19 vaccine patents without authorization. The deal has been substantially narrowed from South Africa's original proposal, including by excluding COVID-19 therapies and tests and by deleting any mention of trade secrets, clinical trial data or other non-patent IP.

- **If ratified, is unlikely to accomplish anything other than allowing the negotiators to claim victory.** Biopharma companies (PFE, MRNA, AZN, JNJ others) argue that it sets a precedent for diluting IP rights and fails to address barriers that prevent people in poor countries from accessing vaccines, while global health advocates say the original proposal has been narrowed into insignificance.

- **The WHO is sponsoring an attempt to create a COVID-19 mRNA vaccine patterned after the Spikevax vaccine from Moderna**. MRNA's commitment that it will not enforce its patent rights in 92 low- and middle-income countries (LMIC) was helpful, WHO officials said at a Feb. 23 press event. Moderna's refusal to provide technical assistance is adding six to eight months to the development timeline, WHO Director-General Tedros Adhanom Ghebreyesus said.

- **TRIPS waiver for COVID was not granted in 2020/21.** We have written about march in extensively as the Biden administration has 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 has not come to fruition given that the WTO is a deliberative body that takes months for consensus policy.

MARCH-IN

- **Recall, separately, that 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.

- **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

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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 – and he is now back at the White House.** 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. (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**: TRIPS is not a done deal, and this is a diluted & narrow agreement, but still worth watching for precedent-setting purposes. 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). 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 march in 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.

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