Patent Reform, March In, IPR Update

Policy Updates & Outlook Featuring Biotech Innovation Organization (BIO)

Please join us to discuss Patent Reform and Biopharma Policy on Friday Feb 11, 2022 at 10 am ET. Our 2022 thesis is that as congress halts policymaking the agencies are gearing up to enact policies, especially after the mid-term election if gridlock ensues with the House or House & Senate flipping to GOP control. We view legislating in 2022 as likely into the summer, given the trifecta's desire to shape policy before election season. However, a few policy issues related to patents and IP have been lurking in the background for a while. We have written about IPR reforms, as well as March In / TRIPS waiver for over a year. We will provide BIO's Patent expert to discuss the issues and areas they care about as well as positioning as we come out of a pandemic-turned-endemic, and the thorny issues that continue to present an overhang to the sector.

- **Capitol Street's 2022 Patent Reform Outlook Call: IPR, March-In Policy Update**.
    - DATE: Friday, February 11
    - TIME: 10:00 am EST (40 minutes)
    - GUEST SPEAKER: David Lachman, BIO (*biography below*)
    - FORMAT: Fireside chat (30 mins with 10 mins Q&A)
    - HOST: Capitol Street
    - RSVP**:** Please email Claire@capitol-street.com for Zoom webinar details.

- **IPR reforms and March in Rights are back in the spollight 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.

- **Will the government march-in, as a way to demonstrate a "win" on drug pricing as BBB stalls**? We will discuss the Xtandi patent bundle, petitioner, arguments (pro and anti-march in), as well as key policymakers and potential next steps on this high profile and potentially precedent-setting issue. We will also discuss Patent Reform policies being kicked around, e.g. IPR reform likelihood, details and timeline. David will discuss BIO's priority items, and the environment on Capitol Hill around the biotech & innovation agenda.

- **About our Guest Speaker. David Lachmann** is a Senior Director for Federal Government Relations at BIO. In addition to being BIO's dedicated IP lobbyist, he also focuses on international trade, privacy, antitrust, and immigration matters. He came to BIO in 2016 following a 25 year career on Capitol Hill, most recently as the Chief of Staff to the Subcommittee on the Constitution, Civil Rights, and Civil Liberties if the House Judiciary Committee. He was Representative Jerrold Nadler's first Legislative Director. Before starting his career on Capitol Hill, he was the Chief of Staff to a member of the New York State Assembly representing part of Brooklyn. He is a native of New York City.

- **Our take: We wrote a comprehensive March In analysis on Feb 8.** Please see for more details. Net/net 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 hearings 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

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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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