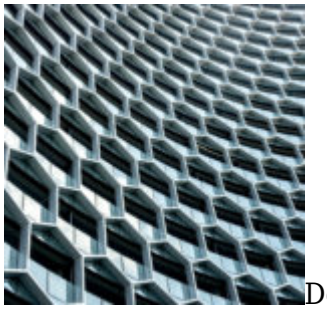
Goodwin's Annual Rare Disease Symposium

Goodwin's Life Sciences team will be hosting an upcoming event in our Boston office on March 13, 2024 to spotlight the critical work being done to address the 7,000+ rare diseases that impact more than 300 million people globally.

Join us **in person** in our Boston office or attend **virtually** for our Annual Rare Disease Symposium on March 13, 2024. Look forward to an afternoon of engaging fireside chats, inspirational presentations, and networking with your peers in the rare disease community. This year's program will include speakers covering the patient, advocacy, policy, research, and CEO's perspectives.

Antitrust & Competition Life Sciences Year in Review 2023



Despite increasingly aggressive rhetoric from the agencies, 2022 was largely characterized as "business as usual" in the antitrust world. In contrast, 2023 featured a significant step up in enforcement activity, including multiple challenged transactions and lengthy investigations in the life sciences space. As notable, many of these enforcement activities involved more "novel" theories of harm — such as bundling, potential competition, and harm to research, development, and innovation — displaying a willingness by the Federal Trade Commission (FTC) to put its rhetoric into action. At the same time, the novel theories pursued by both the FTC and Department of Justice (DOJ) have generally (though not uniformly) been met by skepticism in federal court.

Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Elliot Silver**, and **Charlie Stewart** discuss transaction developments and predictions in the **Antitrust & Competition Life Sciences Year in Review 2023**.

Recent Bayh-Dole Act News: Comments on the Draft Framework; HHS Refuses to March-In on Xtandi; and Delayed Contracting Doesn't Avoid Bayh-Dole

U.S. universities and academic institutions rely heavily on federal grants to fund their research and generate innovations in life sciences. Universities often out-license patents protecting inventions created using federal funding to private companies including many startups. Hundreds of drugs have been developed by collaboration between universities and private industry. The Bayh-Dole Act of 1980 governs the use of federal grants and ownership of inventions and intellectual property generated from the sponsored research. In exchange for federal support, recipients agree to grant the federal government a non-exclusive license to resulting patents covering any inventions supported by the grant. Further, the government retains the right to "march-in" and grant third parties licenses under certain circumstances.

Proposed Updates to Exercise of March-In Rights

On December 7, 2023, the National Institute of Standards and Technology (NIST) released a **draft framework** attempting to clarify the circumstances under which the U.S. federal government can "march-in" and grant licenses to third parties for inventions supported by federal grants. We originally wrote about the proposed guidance on "march-in" rights and provided Q & A **here**. To date, the government has never exercised such "march-in" rights.

Public comments to the draft framework were due by February 6, 2024. Evidencing the potential impact on the dynamics in the U.S. life sciences startup ecosystem, 51,873 public comments were submitted by the deadline. As of February 12, 2024, there were **672 posted comments**. Of these, those in opposition of the proposed framework expressed concerns that it would disincentivize entrepreneurship and innovations, countering the original purpose of the Bayh-dole Act.

- Howard Dean, former governor of Vermont, stated that "the framework put forward on December 8 will have little – if any – impact on the prices consumers pay for medicines, but will negatively impact the private sector's willingness to commercialize federally supported technologies, across all industries. … even if marching in on the basis of price were authorized by the law, which is not, the NIH's long-held contention that prices would not be impacted is correct. The truth is that most medicines are protected by a number of different patents, very few of which are Bayh-Dole subject inventions."

- Biotechnology Industry Organization (BIO) commented that "[t]he suggestions in the draft framework that agencies use the march-in authority to regulate the pricing of successfully commercialized products, particularly complex products like biopharmaceutical products, is not only inconsistent with the statute, it is unrealistic. In the biopharmaceutical sector, for

example, patents on inventions supported by federal funding only infrequently have a connection to a finished, marketed biopharmaceutical product, and when they do, that connection is usually attenuated. … One study estimates that 'biotechnology companies invest $100 in development for every $1 the government invests in research that leads to an innovation.'"

- The National Venture Capital Association (NVCA) commented that "NIST's guidance would unavoidably deter VCs from investing in inventions arising from federally funded research—directly contrary to the innovation environment the Act meant to foster. The increased risk directly disrupts existing investors' reliance interests. And it further makes any future technologies backed by federal funds potentially toxic for VC investment. This outcome 'frustrate[s] the policy that Congress sought to implement' through the Bayh-Dole Act—that is, to encourage private investment in government-funded inventions."

- Multiple universities submitted comments, some noting that Bayh-Dole works well in its current form. The **University of North Carolina – Chapel Hill** commented that "[t]he Bayh-Dole Act is legislation that works extremely well, and no changes to the Act are necessary. In fact, the use of march-in rights as described in the Draft Guidelines would represent a huge step backwards and threaten to undermine the positive effects of the Act." **Ann Arbor SPARK** commented that "[t]he framework changes you are proposing are unnecessary. They increase uncertainty and undermine a proven policy framework. They will have a detrimental and destabilizing effect on university research commercialization and startup company formation." Several universities raised concerns regarding negative effects on their ability to commercialize university research. **Cornell University** noted that "[t]he risk of price-based march-in rights will discourage potential licensees, disincentivize the commercialization of federally funded inventions, and decrease the likelihood of university technology adoption. This will likely lead to the scenario where new products, particularly new drugs, will no longer be based on the technologies of federally funded intellectual property to the detriment of the U.S. economy, consumers, and U.S. global competitiveness. This would have a negative impact on Cornell's technology transfer enterprise, …" **Yale University** likewise commented that "[t]he shift of final control of licensing away from universities would have significant adverse effects on universities' efforts in knowledge transfer. Exercising march-in rights to issue a non-exclusive license is tantamount to breaking a patent, and the knowledge that an agency could take such action would erode investors' confidence in the value of the intellectual property embodied in the patent. Entrepreneurs and investors would be reluctant to make the considerable investment required to bring university inventions to market if they knew that federal agencies could issue non-exclusive licenses to competitors at any time. No private entity would expect to attract investors on such terms, and it is unrealistic to expect that the proposed march-in framework could be adopted without undermining the efficacy of the Bayh-Dole Act." The **University of Texas System** commented on the potential effects on faculty: "[i]f this proposal is enacted, there is substantial concern that faculty will become less interested in the commercial process overall, adversely impacting businesses and start-ups across the state that seek to partner with their local institutions. … Faculty who want to see their research developed and translated into public benefit will be incentivized to leave our universities for industry, depriving our students of important learning and research opportunities."

Many of the comments were from individuals in support of the proposed framework. The Federal Trade Commission also submitted comments in support, arguing amongst other things that "price may be an appropriate basis for marching in." Knowledge Ecology International (a filer of multiple

petitions for march-in) was likewise pleased to see price as a basis for march-in, but commented that "on the issue of standards for unreasonable pricing, the draft guidance gets a failing grade."

Xtandi® Decision

On February 5, 2024, the U.S. Department of Health and Human Services (HHS) **affirmed** the National Health Institute's (NIH) decision not to exercise march-in rights with respect to Xtandi® (enzalutamide). The NIH's original decision was issued in **March 2023** in response to a petition by several cancer patients. NIH stated that Xtandi was widely available to the public. Further, NIH noted that the remaining patent life and the lengthy administrative process involved for a march-in proceeding weighed against any attempt to exercise its march-in rights.

University of South Florida Board of Trustees v. U.S.

The Federal Circuit recently upheld the government's royalty-free license to a patent resulting from government sponsored research. The ***University of South Florida Board of Trustees v. United States***, decided on February 9, 2024, involved the issue of whether the government held a royalty-free patent license over certain Alzheimer's disease research funded by a NIH grant if the inventions were created prior to a sub-contractor funding agreement. In this case, the grant covered experiments to reduce the claimed invention to practice (i.e., production of transgenic mice and recognition that the mice worked for their intended purpose). Mayo, the grantee, agreed to cover the cost of certain research conducted at UCSF (the subcontractor). The Mayo/UCSF contract was actually executed after UCSF's work was begun. The Federal Circuit ruled that the license to the government can be retroactively applied because the statutory language broadly covers work done before the contract if the work was eventually paid for by the federal funding. Per the Federal Circuit, "what occurred here is not an uncommon fact pattern in government funding of research conducted in part by non-grantee members of a consortium called for in a government grant. Specifically, the record makes clear that subcontracts are commonly not executed until sometime after the grant is awarded, yet the grant-covered work proceeds without waiting for the inking of a subcontract."

This case is a good reminder that (1) Bayh-Dole kicks in even when the funds are only supporting reducing a prior-made invention to practice, and (2) it does not matter when the contract is executed; if federal monies are used, Bayh-Dole kicks in.

Life Sciences Companies Make Up a Small Portion of the Companies Opting-In to the Unitary Patent; Ireland Announces Referendum Date

 Life sciences companies continue to make up a small portion of the companies registering for Unitary Patents. Per the European Patent Office's **statistics** portal, as of January 30, 2024 there have been 18,721 registered Unitary Patents. The Uptake Rate is 17.5%. Of this, Medical Technology companies account for 2,266 (or, 11.8%) of the registrations. This is the largest of the 35 technology fields that the portal is tracking. Pharmaceuticals account for 717 (or, 3.7%) of the registrations. Biotechnology accounts for 444 (or, 2.3%) of the registrations.

Notably, Johnson & Johnson has the largest share of registrations at 267. This is followed by Siemens, with 261 registrations. Other life sciences companies cracking the top 25 include: Hoffman-La Roche (82 registrations), Align Technology (46 registrations) and Becton, Dickinson & Company (105 registrations).

In related news, Ireland has also **announced** that its referendum on whether to ratify the Agreement on a Unified Patent Court (UPCA) will occur in June 2024. If Ireland votes yes, it will become the 18th country to actively join the UPC. All 27 members of the EU are eligible to join the UPC, though only 24 have signed the UPCA. Non-EU countries, such as England, cannot join the UPC. Notably, Poland and Spain have not signed the UPCA.