“March-In” Rights in the Era of COVID-19: An Unlikely Scenario for Remdesivir

As the total number of COVID-19 deaths in the U.S. is expected to climb to between 180,000 to 200,000 by September 5, 2020[1][2], there currently are no FDA-approved vaccines or drugs to prevent or treat COVID-19. However, the FDA has granted emergency use authorizations to some products for use in certain patients with COVID-19, including to Gilead for its investigational antiviral drug remdesivir[3].

On August 4, 2020, a bipartisan group of 34 state attorneys general (AGs) asked the U.S. government to exercise its march-in rights under the Bayh-Dole Act and license Gilead’s remdesivir to third-party manufacturers in order to scale up production and lower the price of the drug, or allow states to do so.[4] The AGs argued that the U.S. government should exercise its march-in-rights because the price of remdesivir is too high and because Gilead “has benefited from millions of dollars of public funding, including a $30-million NIH-funded clinical trial,” and “is unable to assure a supply of remdesivir sufficient to alleviate the health and safety needs of the country.”[5]

The AGs’ request that the U.S. government exercise its march-in rights under the Bayh-Dole Act, however, does not appear to be tethered to the law.

Under the Bayh-Dole Act, in specific circumstances, the U.S. government has the right to “march-in” and either grant licenses, or require the patent holder/licensee to grant licenses, to third parties under federally funded patents.[6] The U.S. government may exercise its march-in rights if it determines that action is necessary because the patent holder or licensee:

- has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;
- is not reasonably satisfying health or safety needs;
- is not reasonably satisfying regulatory requirements for public use; or
- has violated the U.S. industry preference provisions of 35 U.S.C § 204.[7]

If the U.S. government decides to exercise its march-in rights, the decision may be appealed to the U.S. Court of Federal Claims, and with respect to items (1) and (3) above, march-in rights may not be exercised until all appeals or petitions are exhausted.[8]

Despite having the authority, the U.S. government has never exercised its march-in rights. In its response to a 1997 petition requesting that the NIH exercise it march-in rights, the NIH noted its unwillingness “to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies,”[9] and, with respect to drug pricing,

in response to a 2004 petition, the NIH noted that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices."[10]

Given the fact that: (a) march-in rights are limited to federally funded patented inventions (and it is not clear to what extent federal funds contributed to the development or remdesivir[11]), (b) the Bayh-Dole Act is not triggered by high drug prices, (c) the NIH's unwillingness to exercise its march-in rights, particularly because it does not want to disincentivize innovation and does not believe that the Bayh-Dole Act should be used to control drug prices, and (d) the patent holder/licensee has the ability to appeal the U.S. government's decision to exercise its march-in rights, and some instances march-in rights may not be exercised until all appeals or petitions are exhausted, it seems unlikely that the Bayh-Dole Act will be invoked in response to the AGs' request that the U.S. government exercise its march-in rights.

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[1] According to the Centers for Disease Control and Prevention (CDC) COVID Data Tracker, as of August 21, COVID-19 has claimed 173,490 lives. **https://www.cdc.gov/covid-data-tracker/#cases**

[2] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html#anchor_1587397564229

[3] https://www.gilead.com/purpose/advancing-global-health/covid-19

[4] https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf

[5] https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf

[6] 35 U.S.C. §203(a).

[7] 35 U.S.C. §203(a).

[8] 35 U.S.C. §203(b).

[9] Harold Varmus, Director, NIH, Determination in the Case of Petition of CellPro,Inc., August 1, 1997,

http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[10] Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004,

http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[11]
https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/

President Trump Signs Four Executive Orders Designed To Reduce Drug Prices

President Trump recently announced four Executive Orders that direct the Secretary of the Department of Health and Human Services (HHS) to implement policy changes to reduce out-of-pocket costs and the price of prescription drugs. All but one of the Executive Orders has been issued with the remaining order on hold until August 24, 2020 pending discussions between the White House and leaders of the pharmaceutical industry. The Executive Orders include some prior policy proposals aimed at lower the cost of drugs and generating savings across the health care system. If implemented, many of these proposals will likely be challenged in court.

Most Favored Nations Policy

If issued, this Executive Order could tie the price that Medicare pays for certain drugs administered by doctors to prices negotiated by other economically comparable countries. This proposed Order is similar to a **2018 prior proposal** by the Center for Medicare and Medicaid Services ("CMS") to use its demonstration authority to test reimbursement changes for certain separately payable Part B drugs and biologicals using an international pricing index ("IPI"). The IPI model would result in lowering Medicare reimbursement for select drugs in certain geographies covered by the model to better match prices paid by similar economically situated countries. Health officials estimate this change would save Medicare $17 billion in the first five years. This order will be held until August 24, 2020 pending discussions with pharmaceutical industry leaders about alternative measures for lowering costs.

Increase Drug Importation

This **Executive Order** is designed to minimize international disparities in drug prices by increasing the trade of prescription drugs between nations with lower prices and those with persistently higher ones. The Administration argues that "reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs." The Administration aims to expand safe access to lower-cost importuned prescription drugs via three primary strategies.

First, the Order requests the Secretary of HHS to consider "facilitating grants to individuals of

waivers of the prohibition of importation of prescription drugs" provided that it "poses no additional risk to public safety and results in lower costs to the American People" under the Federal Food, Drug, and Cosmetic Act (FDCA).

Second, it addresses "authorizing the reimportation of insulin products" where the Secretary of HHS finds that it is "required for emergency medical care" under section 801(d) of the FDCA. Section 801(d) generally places limitations on the reimportation of U.S. manufactured insulin products unless an exception is met.

Third, it requires the Secretary of HHS to complete the rulemaking process regarding a **December 23, 2019** proposed rule to import prescription drugs from Canada. The proposed rule contemplates allowing states and certain other non-federal government entities to import certain prescription drugs from Canada if the certain requirements under the FDCA are met.

Access to Affordable Life-saving Medications

This **Executive Order** is designed to help low income American's without access to affordable insulin and injectable epinephrine through commercial insurance or Federal health care programs, such as Medicare and Medicaid, to purchase these products from a Federally Qualified Health Centers ("FQHC") at a price that aligns with the cost at which the FQHC acquired the medication. FQHCs are community-based health care providers that provide primary care services in underserved areas. FQHCs receive discounted prices through the 340B Prescription Drug Program on prescription drugs.

The Order directs the Secretary of HHS to condition future grants available to FQHCs on establishing practices to make insulin and injectable epinephrine available at the 340B discounted price paid by the FQHCs, plus a minimal administration fee, to individuals with low incomes. The Order specifies that low income individuals include those who (a) have a high cost-sharing requirement for either insulin or injectable epinephrine, (b) have a high unmet deductible, or (c) have no healthcare insurance.

Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

This **Executive Order** directs the Secretary of HHS to finalize a February 2019 **proposed rule** that would revise the discount safe harbor to the federal Anti-Kickback Statute ("AKS") with respect to pharmaceutical manufacturer rebates to health plans and pharmacy benefit managers ("PBMs"). Prior to finalizing the rule, the Order requires the Secretary of HHS to publicly confirm that the rule "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." Specifically, the Order directs the Secretary of HHS to "complete the rulemaking process he commenced seeking to:

> (a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a-7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs operating the Medicare Part D program; and
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> (b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees."

The Order makes it clear the Administration view rebates as the "functional equivalent of kickbacks" that "erode savings that could otherwise go to the Medicare patients taking those drugs. Yet

currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law." The policy objective of the order is to ensure that discounts offered on prescription drugs are passed on to patients. The Order states that, narrowing the safe harbor for discounts under the AKS will allow for billions in dollars of rebates in the Medicare Part D program to go patients at the point of sale.

The Administration's policy positions and proposals in the Order and the prior proposed rule have elicited strong reactions from various stakeholders who suggested they may challenge any changes implemented as a result of this Order.

Envisioning the New Normal in the Life Sciences Industry

The life sciences industry affects a substantial portion of the U.S. and European economies, in terms of both GDP and the number of individuals employed. And in the context of a global pandemic, the life sciences sector obviously plays an existential societal role. Accordingly, ensuring the safe and continuous functioning of life sciences companies is not only paramount for the industry itself, but for society as a whole. This post considers how laboratories and life sciences manufacturing facilities are adapting to the "new normal" in an effort to abide by governmental guidance and adopt operational best practices.

Laboratories

Unlike many other skilled industries, "work from home" is not a precautionary avenue available to laboratories to mitigate the risk of COVID-19. Given the need for on-site collaboration and nature of the work being performed, remote or virtual work is nearly impossible in the laboratory environment. Adding to the difficulty is that the highly-technical structure of laboratories can make space reconfiguration—for purposes of accommodating social distancing guidelines—challenging and expensive. And when one considers the high incidence of multiple-use items such as testing machines and apparatuses (not all of which can be easily washed down after each use), further health and safety obstacles emerge.

Despite some challenging realities that affect laboratories, the setting does possess certain intrinsic characteristics that provide advantages in a COVID-19 world. Widespread use of personal protective equipment (PPE), fastidious efforts to prevent contamination, use of fresh air, and systematic sanitization are fundamental aspects of the laboratory modus operandi and serve as effective tools to minimize the transmission of COVID-19.

In addition, some life sciences companies have redeployed the innovation endemic to the industry to create or utilize **proptech**-type preventative devices for their laboratories. For example, one Boston-based life sciences laboratory generated an app that maps out scheduling data to show the physical presence of employees in the laboratory, thus aiding social distancing efforts. Other laboratory operators are considering enhance safety measures such as thermometer screenings, contactless entry, and the establishment of designated spaces for various forms of decontamination and disinfection.

Life Sciences Manufacturing Facilities

Considering the production processes involved, like laboratories, a fully remote workforce is unrealistic for biomanufacturing and other life sciences manufacturing facilities. Consequently, such facilities need to address the risk of COVID-19 through on-site measures. Personal protective equipment, social distancing policies, and facility sanitization are essential. Moreover, as advances in artificial intelligence and robotics enable life sciences manufacturing facilities to further automate their production processes, companies should consider whether the inclusion of these technologies can eliminate workplace situations that lend themselves to the spread of COVID-19.

Looking Ahead

Given the likelihood of the continued presence of COVID-19, aging populations and myriad other factors, the life sciences sectors will continue to play a crucial role in the economies and societies of the U.S. and Europe. Accordingly, identifying and incorporating operational best practices that adapt to the "new normal" will be an ongoing, evolving and collaborative endeavor for companies and organizations in the life sciences realm.

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*For a longer discussion of return to work issues affecting both the life sciences and healthcare industries, please see **our recent article** or reach out to **PropSci@goodwinlaw.com** with any questions.*

Tranched Investments in Troubled Times

Investments in early stage life sciences companies often

provide that payments are tranched over time, subject to satisfying agreed milestones. This is normal, but in this abnormal market, stakeholders are approaching tranched investments with more caution.

As a starting point, where milestones and other completion conditions are met, the investor should be contractually obliged to invest the next tranche. To facilitate this, operational milestones should be objective tests and completion conditions should involve clear deliverables for the company. However, unforeseen events may challenge the tranched structure that was originally agreed when the initial investment was made.

In the current climate, R&D-focused business models of life sciences companies are under pressure. Specifically, as the effects of COVID-19 crystallise, there has been an impact the ability to carry out R&D, particularly where it involves third party contractors, laboratory testing and evaluating patients during clinical trials. Where R&D is able to continue, the pace at which it is moving is generally slower. This is particularly difficult for companies that rely on tranched funding from investors linked to satisfying specific milestones.

Consequently, where companies are mid-way through a tranched investment round, parties may consider adjusting them to allow for smaller and more frequent tranches or adjust the associated triggers. In circumstances where a milestone has not been met, an investor may be persuaded to waive the milestone to invest the next tranche earlier than planned. Where a milestone has been met, if the investor does not invest the agreed amount for whatever reason, the company may consider what the ramifications on the investor’s preferential rights should be.

Tranched investments are not an option to invest. However, in these times, flexibility may be needed and regular communication between companies and investors as to what is appropriate at the time is essential.