

FROM: Clare M. Love, Eric L. Sawyer, Robert Sachs, Universities Allied for Essential Medicines
TO: The Hon. Xavier Becerra, Secretary, the Department of Health and Human Services
The Hon. Lawrence A. Tabak, Acting Director, the National Institutes of Health
RE: Xtandi March-in Petition and Most Favored Nation Clause in Pfizer Contract
DATE: February 3, 2022

Dear Secretary Becerra and Acting Director Tabak:

We are the petitioners in the march-in request before the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) asking the government to exercise march-in and other rights on the patents for the prostate cancer drug Xtandi, on the grounds that it is not reasonable to charge dramatically higher prices in the United States than in other high income countries.

In our petition, we argue that this price discrimination against U.S. prostate cancer patients makes the cost of Xtandi in the United States unreasonable, and that HHS can, and should, exercise march-in rights to remedy the abuse. We write to bring to your attention new information that lends direct support to the reasonable pricing standard advanced in the petition.

A contract between the Army and Pfizer to purchase the Covid-19 treatment Paxlovid contains a most favored nation clause dictating that if Pfizer charges a “Covered Nation” a lower price than it charged the United States for Paxlovid, then Pfizer must offer that lower price to the United States. The clause, located at section H.7 of the contract, states that if the government accepts the lower price, the contract is thereby amended to reflect the lesser cost. A “Covered Nation” is Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, or Switzerland.

Similarly, in the Xtandi march-in request, petitioners argue that the price of Xtandi is unreasonable because it exceeds “the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.” These countries, as of the date of the original 2019 petition, were Canada, France, Germany, Italy, Japan, the United Kingdom and South Korea.

If the price for Xtandi was based upon the most favored nation pricing clause in the Paxlovid contract, the country with the lowest price today would be Japan. In 2021, the price for a 40 mg capsule of Xtandi in Japan was 2,354.10 yen (a small decrease from the price of 2,397.70 yen in 2020). At the February 2, 2022 exchange rate of 114.44 yen to the U.S. dollar, this is equal to \$20.57 per 40 milligram capsule. The January 2022 Redbook Average Wholesale Price (AWP) for Xtandi is \$130, or 532 percent higher. On an annual basis, the pricing difference is enormous: \$30,032 compared to \$189,800. In other words, the U.S. price is *higher* by \$159,768 per year.

Pfizer is a licensee of the Xtandi patents. If Pfizer participates in the march-in proceedings and argues that an international reference pricing standard should be rejected because it would chill innovation, then that claim should be judged against the fact that Pfizer freely entered into a contract that included a most favored nation clause that would have set a lower standard than the petitioners proposal, because it requires the lowest price rather than the median price among the reference countries.

Pfizer represents in the Paxlovid contract that U.S. taxpayer funding did not contribute to the development of the Covid-19 treatment. In contrast, all three Orange Book patents for Xtandi state that federal grants funded the research underlying the patented technology. When, as was the case with the Xtandi patents, the federal government subsidized the cost of developing a new drug or other health product, the government has more a compelling reason to insist on a most favored nation price, or the weaker international pricing standards that we have proposed (the *median* price from the countries with the largest GDP and at least half of U.S. per capita income).

A copy of the Pfizer Paxlovid agreement is enclosed. We are also enclosing a table of reference price clauses included in other research and development and purchase agreements executed by the U.S. government related to Covid-19 vaccines, diagnostics, treatments, and other products.

Sincerely,

Clare M. Love

Eric L. Sawyer

Robert Sachs

Universities Allied for Essential Medicines

ANNEX Pricing Clauses in U.S. Government Contracts for COVID-19 Products

In 2020 and 2021, several U.S. government contracts for the development of COVID 19 vaccines, therapeutics, diagnostic tests and other related products included provisions on pricing. Some contracts include a most favored nation pricing clause that specifically requires the company to provide the U.S. government with “a price lower” than the price offered to any centralized federal authority that is “a member of the Group of Seven plus Switzerland.” The non-US members of the G7 are Canada, France, Germany, Italy, Japan, the United Kingdom.

Table A1, U.S. Government Covid-19 Contracts Containing Reference Price Constraints on Resultant Products

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
Pfizer The Army W58P0522C0001 November 17, 2021	Paxlovid Purchase Agreement	33	<p>H.7 Most Favored Nation Clause</p> <p>(a) If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase</p> <p>(i) the same or a lesser volume of Product than the U.S. Government commits to purchase</p> <p>(ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.</p>
ANP Technologies, Inc. The Army W911QY20D0019 May 29, 2020	Development and Production of a Diagnostic	11	<p><u>“MOST FAVORED CUSTOMER</u> H.1 Most Favored Customer</p> <p>Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within thirty days (30) of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the Parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD.”</p>
Becton, Dickson & Company The Army W911SR2030001 July 1, 2020	Needle Production	17	<p>“9. Government Preference</p> <p>9.1 Pricing. During the term of the Agreement, the Recipient agrees that, in the event that it enters into a Group Purchasing Organization (GPO) contract with a Qualifying Third Party (as defined below) with respect to a Qualifying Product (as defined below) with a per unit GPO price lower than that offered for the same Qualifying Product to the Government, the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. . . .”</p>

Eli Lilly The Army W911QY21D0012 P0002 April 7, 2021	Monoclonal Antibody Treatment Production	7-8	"H. 7 Sales to Covered Nations (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 September 2021 sell any COVID-19 bamlanivimab/etesevimab combination therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . ."
Eli Lilly The Army W911QY21C0016 October 26, 2020	Monoclonal Antibody Treatment Production	18	"H.7 Sales to Covered Nations (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . ."
Emergent BioSolutions Canada Inc. The Army W911QY2090013 June 24, 2020	"the research and development of an advanced human immune globulin manufactured from human plasma with antibodies to SARS-CoV-2 (COVID-HIG) for post-exposure prophylaxis (PEP) of Coronavirus Disease (COVID-19)"	16	"ARTICLE 9. Most Favored Customer A. Awardee agrees that it shall not offer, sell, or otherwise provide the production model of the Prototype to any entity at a price lower than it offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer (S) and the price sold to the DoD multiplied by the number of items sold"
Immunoome Inc The Army W911QY2090019 July 3, 2020	"research and development of a standardizable and scalable [redacted] compromise of [redacted] antibodies"	16	"ARTICLE 9. Most Favored Customer A. Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a lower price than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."
Inovio Pharmaceuticals, Inc. The Army W911QY2090016 June 22, 2020	"the development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery of INO-4800 against COVID-19, with demonstrated capability to be produced at a large scale, as well as full automation for production of the device arrays, (hereinafter referred to as the 'Prototype Project')."	17	"ARTICLE 9. Most Favored Customer A. For a period of six (6) years from the Effective Date, Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."
Maxim Biomedical, Inc. The Army W911QY20D0018 May 11, 2020	Diagnostic Production	10	"H.1 Most Favored Customer A. Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to

			the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. . . .”
Murtech, Inc. The Army W911QY20D0017 May 11, 2020	Diagnostic Production	15	“H.1 Most Favored Customer A. Awardee agrees that during the term of this contract and for a period of 2 years thereafter, it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (herein the ‘Items’) (for the avoidance of doubt, CLIN 0001 production model end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products) to any entity at a price lower than that offered to the DoD.”
Novavax The Army W911QY20C0077 P0002 June 4, 2020	“Vaccine Development and Production”	4	“The Contractor shall maintain a most favored customer provision for the product once authorized or licensed by the FDA, such that the Contractor shall not give any entity a better price than the DoD for a period of five (5) years from the award of this contract, limited to customers in the U.S. and purchases made in the U.S to include sale prices as compared to commercial clients with respect to quantity, location of delivery, fundamental differences in deliverable formulation, and material differences in terms and conditions for commercial contracts.”
Sanofi The Army W15QKN1691002; MCDC2011-005 July 30, 2020	Vaccine Research and Development (including Clinical Trials) and Production	28	“ 5.1 Most Favored Nation Clause (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health and in recognition of the long historical partnership between the U.S. Government and Sanofi Pasteur working on global pandemic solutions, as well as the investments made towards the development of a safe and effective vaccine against COVID-19, Sanofi Pasteur agrees that it will not sell any COVID-19 vaccine licensed under this Agreement to any nation that is a member of the Group of Seven plus Switzerland (‘Covered Nation’) at a price that is more favorable than those set forth in this Project Agreement.”
SlO2 Medical Products, Inc. The Army W911NF2030003 June 5, 2020	Vaccine Delivery Device Research and Development	13	“ 9. Government Preference 9.1 Pricing. During the period of performance and the exercised optional availability periods, the Recipient agrees that, in the event that it offers, sells or otherwise provides a Qualifying Product (as defined below) to any Qualifying Third Party (as defined below) at a per unit price lower than that offered for the same Qualifying Product to the Government or a third party purchasing Qualifying Product pursuant to a designation by the Government pursuant to Section 9.2 or 9.3 (an ‘MCM Partner’), the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government or an MCM Partner.”