May 28, 2024

RE: Prospective Grant of an Exclusive Patent License: Antibody-Drug Conjugates (ADCs) for Targeting CD56-Positive Tumors (89 FR 40495)

Dear Dr. Freel,

Knowledge Ecology International (KEI) offers the following comments regarding the “Prospective Grant of an Exclusive Patent License: Antibody-Drug Conjugates (ADCs) for Targeting CD56-Positive Tumors” (89 FR 40495) to McSAF Inside Oncology SAS (McSAF).

McSAF is based in Tours, France and per the Bayh-Dole Act, one of the requirements of granting an exclusive license is that licensees “substantially” manufacture the invention in the United States. Has McSAF requested a waiver of the domestic manufacturing requirement? The NIH should disclose in its notices whether the companies seeking exclusive licenses have requested waivers of this requirement. Furthermore, as McSAF is a foreign-based company, the NIH should particularly take care to include license terms that protect US patients from paying higher prices than other high income countries.

As the development of the technology was funded by US taxpayers, US patients should not pay more for the treatment than those in other high income countries. Any resultant treatment should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method.

Companies will enter into agreements with terms on this issue - recently HHS entered into an agreement with Regeneron for a COVID-19 treatment with a reasonable pricing clause, and similar international reference pricing clauses have been included in contracts with companies such as Sanofi, Moderna, and Pfizer. Attached is an ANNEX on Pricing Clauses in U.S. Government Contracts for COVID-19 Products citing examples of agreements.

Access in Developing Countries

Considering the proposed scope of the license is worldwide, we ask that the NIH include in this license terms that ensure affordable access to patients in developing countries.
As cited in the United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, dated 12/08/2010, “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.” NIH must include terms that implement this policy such as limiting the exclusivity in countries with average incomes less than one-third of the United States.

Additionally, NIH should retain a right to grant the WHO, the Medicines Patent Pool, or other governments the right to use the patent rights in procuring the medical technology from competitive suppliers, including technology transfer, in low- and middle-income countries (LMICs). This authority should be exercised when HHS or the WHO determines that people in these markets lack sufficient access to the required medical technology.

**Transparency**

In 2019, the United States endorsed the adoption of the World Health Assembly (WHA) Resolution 72.8, titled “Improving the transparency of markets for medicines, vaccines and other health products.” In this license, the NIH should incorporate, to the extent possible, transparency norms that meet or exceed the standards outlined in WHA72.8.

**Conclusion**

It is critical that the NIH ensures that the terms of this license promote the public interest in the invention and protect patients’ equitable access to the technology, should it come to market. KEI therefore requests that the license incorporates the provisions listed above in order to achieve those goals.

Sincerely,

Claire Cassedy
claire.cassedy@keionline.org
Knowledge Ecology International
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

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<tr>
<th>Contractor, Agency, and Contract Number</th>
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<tr>
<td><strong>Most Favored Nation Clauses</strong></td>
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| **Eli Lilly**                          | 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**                          | 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. . . .” |
| **Merck Sharp & Dohme**                | Therapeutic Development | 21 | H.7. Fully redacted including the title |
| **Pfizer**                             | Paxlovid Purchase Agreement | 33 | H.7 Most Favored Nation Clause
(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... |
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| **Sanofi**<br>The Army<br>W15QKN1691002; MCDC2011-005<br>July 30, 2020 | Vaccine R&D and Production | 28 | (i) the same or a lesser volume of Product than the U.S. Government commits to purchase
(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. |
| **ANP Technologies, Inc.**<br>The Army<br>W911QY20D00019<br>May 29, 2020 | Development and Production of a Diagnostic | 11 | “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.” |
| **AstraZeneca**<br>The Army<br>W911QY2190001<br>October 9, 2020 | Monoclonal Antibody Treatment R&D and Production | 32 | **ARTICLE 9. Most Favored Customer**
A. In the event that the Parties agree to a follow-on production pursuant to 10 U.S.C. § 2371b, Awardee agrees that it shall sell to the U.S. Government the first million doses of AZD7442 at a price of [REDACTED]. Any additional doses will be sold to the U.S. Government at a price to be negotiated and agreed by the Parties.
B. If Awardee develops a like product (commercialized version or derivative of the production model of the Prototype) with similar capability and intended application, but at a lower unit price (“Like Product”) regardless of |

**Most Favored Customer Clauses**

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.”
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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 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 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 . . . .” |
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 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.**       | Vaccine Delivery Device Development | 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.**             | 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.**                      | 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 . . .” |
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<td>Novavax</td>
<td>Vaccine Development and Production</td>
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<td>“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.”</td>
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| Rigel Pharmaceuticals                   | Therapeutic Development                    | 29           | ARTICLE 20. Most Favored Customer.  
A. In the event that the Parties agree to a follow-on production agreement pursuant to 10 U.S.C. 2371b, Awardee agrees that it shall sell to the U.S. Government up to [REDACTED] treatment courses of TAVALISSE at a price not greater than [REDACTED]. Any additional treatment course will be sold to the U.S. Government at a price to be negotiated and agreed by the Parties.  
B. If Awardee develops a like product (commercialized version or derivative of the production model of the Prototype) with similar capability and intended application, but at a lower unit price (“Like Product”) regardless of quantity, Awardee shall make the DoD aware of that similar product and the technical and price differences between that product and the Prototype. Such notification shall be made to the OTAO in writing, of which email is an acceptable form, within thirty (30) days of such offering. |
| 60 Degrees Pharmaceuticals              | Therapeutic Development                    | 16           | Article 9. Most Favored Customer  
A. [REDACTED]  
[B REDACTED]  
C. This Article applies only to products sold in the [REDACTED] related to COVID-19. |
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. . . .”  
For purposes of this section, “Covered Nation” shall mean a nation that is a member of the Group of Seven (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States) plus Switzerland. |
9.1 [REDACTED]  
9.2 [REDACTED]  
9.3 [REDACTED] |
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<td>The Army</td>
<td>Vaccine Delivery Device R&amp;D</td>
<td>13</td>
<td>“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.”</td>
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