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May 20, 2026

**Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of Cancer (91 FR 24551)**

Dear Dr. Burke:

Knowledge Ecology International (KEI) would like to offer the following comments regarding the "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of Cancer" (91 FR 24551) to OncoVanta Therapeutics, Inc., based in Hagerstown, Maryland.

The technology is to be licensed on a worldwide basis, and the field of use is broadly described as "T Cell Receptor (TCR)-engineered T cell therapy products for the treatment of cancer in humans."

While OncoVanta only announced their launch 8 months ago,[1] the company does have a web presence, which includes a website that lists the members of their leadership.

In the biographical description of Emmanuel O. Akala, who is listed as Vice President, Drug Delivery & Nanomedicine, OncoVanta's website includes this remark describing his role: "At OncoVanta Therapeutics, he advises on long-term delivery innovation strategies and future platform expansion opportunities that may strengthen therapeutic performance while remaining independent of NIH-licensed intellectual property."[2]

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[1] https://www.linkedin.com/posts/oncovanta-therapeutics_were-excited-to-announce-the-launch-of-oncovanta-activity-7365816462101348353-7Cqr

[2] https://oncovanta.com/leadership

Dr. Akala has been listed as Principal Investigator for over $2.5 million in federal grants, of that $700,000 since 2022.[3]

It is curious that while engaging with NCI to license this technology, the company explicitly states that they are being advised on "remaining independent of NIH-licensed intellectual property." It would not be a stretch to assume that a company seeking to be unencumbered by NIH-licensed IP would likely be seeking to negotiate an agreement that would include terms that would not obligate them to many public interest safeguards or access-ensuring terms.

In negotiating and agreeing to this (and any exclusive) license, the NIH is required to limit the scope of exclusive rights to that which is reasonably necessary (per 35 U.S.C. § 209), and should ensure the inclusion of safeguards to protect the public interest in access and affordability.

If the NIH proceeds with this license, KEI urges the NIH to include the following terms in the agreement:

**Access in Developing Countries**

The Federal Register notice states that the intended geographic scope is "worldwide." Taking that into account, 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 01/11/2024, "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."[4] 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.

**Price Gouging**

[3] NIH Reporter Database, search query: "Akala, Emmanuel" in the Principal Investigator field, for all FY.
[4] United States Public Health Service Technology Transfer Policy Manual. Chapter No. 300, PHS Licensing Policy. https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Chapter%20300%20-%20PHS%20Licensing%20Policy.pdf

Additionally, 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.

**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.

**Access Plan**

As the NIH Intramural Research Program Access Planning Policy came into force on October 1, 2025, KEI urges the NIH to ensure that the access plan as submitted by the company truly outlines how the company will facilitate access to any resultant product and does not merely tick a box to move the license forward.

The terms suggested by KEI in the preceding sections could be incorporated into the access plans as well as the main license agreement. Additionally, the access plan should disclose the steps that the company will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

KEI also urges the NIH to consider any requests for a waiver of the Access Planning Policy under the strictest of terms, and ensure that the granting of waivers is an exceptional occurrence rather than a regular practice. KEI asks that the NIH publish a list of licenses for which the submission of access plans have been waived.

**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

| Contractor, Agency, and Contract Number | Subject | Page Located | Reference Price Term Excerpt |
|---|---|---|---|
| **Most Favored Nation Clauses** | | | |
| Eli Lilly<br>The Army<br>W911QY21D0012<br>P0002<br>April 7, 2021 | Monoclonal Antibody Treatment Production | 7-8 | **"H. 7 Sales to Covered Nations**<br><br>(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<br>The Army<br>W911QY21C0016<br>October 26, 2020 | Monoclonal Antibody Treatment Production | 18 | "**H.7 Sales to Covered Nations**<br>(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<br>prices set forth in this contract. . . ." |
| Merck Sharp & Dohme<br>The Army<br>W911QY21C0031<br>June 7, 2021 | Therapeutic Development | 21 | H.7. Fully redacted including the title |
| Pfizer<br>The Army<br>W58P0522C0001 | Paxlovid Purchase Agreement | 33 | **H.7 Most Favored Nation Clause**<br><br>(a) If, at any time prior to, or during, the base term and any |

| Contractor, Agency, and Contract Number | Subject | Page Located | Reference Price Term Excerpt |
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| November 17, 2021 | | | exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase<br><br>(i) the same or a lesser volume of Product than the U.S. Government commits to purchase<br><br>(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. |
| Sanofi<br>The Army<br>W15QKN1691002; MCDC2011-005<br>July 30, 2020 | Vaccine R&D and Production | 28 | "**5.1 Most Favored Nation Clause**<br>(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." |
| **Most Favored Customer Clauses** | | | |
| ANP Technologies, Inc.<br>The Army<br>W911QY20D0019<br>May 29, 2020 | Development and Production of a Diagnostic | 11 | "MOST FAVORED CUSTOMER<br>H.1 Most Favored Customer<br><br>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." |
| AstraZeneca<br>The Army<br>W911QY2190001<br>October 9, 2020 | Monoclonal Antibody Treatment R&D and Production | 32 | **ARTICLE 9. Most Favored Customer**<br>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 |

| Contractor, Agency, and Contract Number | Subject | Page Located | Reference Price Term Excerpt |
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| | | | 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.<br>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 U.S. Government 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 [REDACTED] of such offering. |
| Emergent BioSolutions Canada Inc.<br>The Army<br>W911QY2090013<br>June 24, 2020 | Post-exposure Prophylaxis (PEP) Development | 16 | "**ARTICLE 9. Most Favored Customer**<br><br>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 . . . ." |
| Immunome, Inc.<br>The Army<br>W911QY2090019<br>July 3, 2020 | "research and development of a standardizable and scalable [REDACTED] comprised of [REDACTED] antibodies [REDACTED] . . . ." | 16 | "**ARTICLE 9. Most Favored Customer**<br><br>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.<br>The Army<br>W911QY2090016<br>June 22, 2020 | Vaccine Delivery Device Development | 17 | "**ARTICLE 9. Most Favored Customer**<br>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.<br>The Army<br>W911QY20D0018<br>May 11, 2020 | Diagnostic Production | 10 | **"H.1 Most Favored Customer**<br>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. . . ." |

| Contractor, Agency, and Contract Number | Subject | Page Located | Reference Price Term Excerpt |
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| Murtech, Inc.<br>The Army<br>W911QY20D0017<br>May 11, 2020 | Diagnostic Production | 15 | **"H.1 Most Favored Customer**<br>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<br>The Army<br>W911QY20C0077<br>P0002<br>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." |
| Rigel Pharmaceuticals<br>The Army<br>W911QY2190018<br>January 29, 2021 | Therapeutic Development | 29 | **ARTICLE 20. Most Favored Customer.**<br>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.<br>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<br>The Army<br>W911QY2190011<br>December 4, 2020 | Therapeutic Development | 16 | **Article 9. Most Favored Customer**<br>A. [REDACTED]<br>[REDACTED]<br>C. This Article applies only to products sold in the [REDACTED] related to COVID-19. |
| **Government Preference Clauses** | | | |
| Becton, Dickson & Company<br>The Army<br>W911SR2030001<br>July 1, 2020 | Needle Production | 17 | **"9. Government Preference**<br><br>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 |

| Contractor, Agency, and Contract Number | Subject | Page Located | Reference Price Term Excerpt |
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| | | | and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. . . . "<br><br>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. |
| Global Life Sciences Solutions<br>The Army<br>W911NF2130001<br>October 13, 2020 | Expanded Manufacturing and Production Capacity | 8 | **9. Government Preference**<br>9.1 [REDACTED]<br>9.2 [REDACTED]<br>9.3 [REDACTED] |
| Retractable Technologies, Inc.<br>HHS<br>W911SR2030004<br>July 1, 2020 | Expansion of Manufacturing Capacity of Needles/Syringes | 23 | **9. Government Preference**<br>[REDACTED] |
| SIO2 Medical Products, Inc.<br>The Army<br>W911NF2030003<br>June 5, 2020 | Vaccine Delivery Device R&D | 13 | "**9. Government Preference**<br>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." |