October 22, 2024

Suna Gulay French, Ph.D.
Technology Transfer Manager, NCI
Technology Transfer Center
Via email: suna.gulay@nih.gov

RE: Prospective Grant of an Exclusive Patent License: Anti-KK-LC-1 T Cell Receptors (89 FR 81089)

Dear Dr. Suna Gulay French:

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Introduction

Knowledge Ecology International (KEI) objects to the "Prospective Grant of an Exclusive Patent License: Anti-KK-LC-1 T Cell Receptors" (89 FR 81089) to T-Cure Biosciences, Inc. (T-Cure).

In summary, KEI suggests the NIH needs to be more forthcoming in the information it shares with the public when requesting comments on an exclusive license, and notes that in this case, it seems unlikely that an exclusive license is justified or that it would meet the legal standard set out in 35 U.S.C. § 209.

Background

KEI has previously commented on a proposed license to T-Cure in 2017, at which point the company had minimal web presence and very little information was available concerning the company.[1] The 2017 notice was concerning "T-Cells Transduced with HLA A11 Restricted CT-RCC HERV-E Reactive T-Cell Receptors for the Treatment of Renal Cell Carcinoma"; the license was executed and according to a 2020 press release, has since been amended, expanding to worldwide rights for the NCI-licensed inventions.[2] The same 2020 company press release described the company as having entered into a CRADA with the NIH regarding HERV-E targeting TCR therapy for renal cell cancer.

The current license involves patents and patent applications for anti-KK-LC-1 T Cell Receptors:

> "Disclosed is an isolated or purified T cell receptor (TCR) having antigenic specificity for Kita-Kyushu Lung Cancer Antigen 1.sub.52-60 (KK-LC-1.sub.52-60). Related polypeptides and proteins, as well as related nucleic acids, recombinant expression vectors, host cells, populations of cells, and pharmaceutical compositions are also provided. Also disclosed are methods of detecting the presence of cancer in a mammal and methods of treating or preventing cancer in a mammal."

The inventors are Sanja Stevanovic and Christian S. Hinrichs, two scientists that were working at the Experimental Transplantation and Immunology Branch of the National Cancer Institute, and who have since left the government.

[1] National Institutes of Health proposed exclusive license for kidney cancer patents to company without its own phone number. December 21, 2017. https://www.keionline.org/23739

[2] August 04, 2020 – T-Cure Bioscience Announces Expansion of Collaboration With the National Institutes of Health for T Cell Receptor (TCR) Therapy Targeting HERV-E for the Treatment of Kidney Cancer. https://t-cure.com/august-04-2020-t-cure-bioscience-announces-expansion-of-collaboration-with-the-national-institutes-of-health-for-t-cell-receptor-tcr-therapy-targeting-herv-e-for-the-treatment-of-kidney-cancer/

On March 17, 2021, T-Cure issued a press release stating it had acquired the KK-LC-1 TCR therapy under an exclusive, worldwide license with the National Cancer Institute (NCI) in 2020.[3]

> March 17, 2021 – T-Cure Bioscience Enters Into Agreement With Rutgers to Conduct Clinical Research of Novel T Cell Receptor Therapy for Treatment of Variety of Cancers
>
> Sherman Oaks, CA – March 17, 2021 – T-Cure Bioscience, Inc., a privately held company focused on developing T cell receptor (TCR) therapy products for the treatment of solid tumors, today announced that the Company has entered into a clinical research agreement with Rutgers, The State University of New Jersey, to fund a Phase I clinical study testing a TCR-based product candidate for the treatment of tumors expressing Kita-Kyushu lung cancer antigen 1 (KK-LC-1), such as gastric, cervical, lung, and triple negative breast cancers. T-Cure acquired the KK-LC-1 TCR therapy under an exclusive, worldwide license with the National Cancer Institute (NCI) in 2020. The Principal Investigator who will conduct the clinical research is Christian S. Hinrichs, M.D., Chief of the Section of Cancer Immunotherapy and Co-Director of the Cancer Immunology and Metabolism Center of Excellence at Rutgers Cancer Institute of New Jersey. Dr. Hinrichs is an expert in cancer immunology and immunotherapy and was recruited from the NCI where he served as Senior Investigator at the Genitourinary Malignancies Branch. T-Cure anticipates the KK-LC-1 TCR therapy will enter a multi-site Phase 1 clinical study in the second quarter of 2021 at the NCI, with the clinical study responsibilities to be transferred to Rutgers in the second half of 2021.
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> "I joined the Cancer Immunology and Metabolism Center of Excellence because I believe that Rutgers Cancer Institute can be a global leader in cancer and tumor immunology research and development. In support of that mission, I am excited to partner with T-Cure to launch the first cell therapy clinical trial targeting the KK-LC-1 antigen," stated Dr. Hinrichs. "I began collaborating with the T-Cure team on this T cell receptor therapy while at the NCI, and I am pleased to continue working with them to advance this therapy at Rutgers."
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> "We look forward to our partnership with Dr. Hinrichs at Rutgers as a continuation of the work we undertook with him and his team at the NCI to advance this novel TCR product candidate through preclinical and clinical development," stated Gang Zeng, Ph.D., Chief Executive Officer of T-Cure. "The TCR was isolated from the tumor-infiltrating lymphocytes of a patient who had a complete response to a safely administered immunotherapy. Accordingly, we believe it holds great promise for engineering patients' immune cells to effectively target and destroy cancer cells without being harmful to healthy tissue."

[3] March 17, 2021 – T-Cure Bioscience Enters Into Agreement With Rutgers to Conduct Clinical Research of Novel T Cell Receptor Therapy for Treatment of Variety of Cancers. https://t-cure.com/march-17-2021-t-cure-bioscience-enters-into-agreement-with-rutgers-to-conduct-clinical-research-of-novel-t-cell-receptor-therapy-for-treatment-of-variety-of-cancers/

Clinical Trials

On October 6, 2022, T-Cure Bioscience, Inc. issued a press release announcing that Phase 1 trials for the KK-LC-1 TCR-T therapy would be conducted at NCI and Rutgers sites.[4]

In KEI exchanges with NCI concerning this license (discussed further below), Dr. Suna Gulay French identified NCT05035407 and NCT05483491 as clinical trials involving this technology. Those same trials are hyperlinked in the T-Cure October 2022 press release.

> October 6, 2022 – NCI AND RUTGERS UNIVERSITY OPEN PHASE 1 CLINICAL TRIALS OF T CELL RECEPTOR THERAPY TARGETING KK-LC-1 FOR MULTIPLE SOLID TUMORS
> LOS ANGELES, CA – October 6, 2022 – T-Cure Bioscience, Inc., a privately held company focused on developing T cell receptor (TCR) therapy products for the treatment of solid tumors, today announced that the National Cancer Institute (NCI) and Rutgers University sites are open to recruit patients for the treatment of Kita-Kyushu lung cancer antigen 1 (KK-LC-1) expressing malignancies, including gastric, lung, cervical and triple negative breast cancers. The investigator-initiated phase 1 trials are intended to evaluate the safety and tolerability with dose escalation of the autologous TCR-T cells targeting KK-LC-1. The investigators are now actively recruiting participants who have failed first-line therapy for the above-referenced solid tumors.
>
> T-Cure licensed the commercial rights of the KK-LC-1 TCR-T therapy and entered into a Cooperative Research and Development Agreement (CRADA) with the NCI in 2020. The Company also initiated pre-clinical and clinical studies on KK-LC-1 TCR-T with Rutgers University in 2021.
>
> "We have been working with the principal investigator at Rutgers University, Dr. Christian Hinrichs, and the NCI, Drs. James Gulley and Scott Norberg for a couple of years. We are extremely excited to see both sites have received IND clearance from the FDA, and are now open for recruitment", stated Gang Zeng, Ph.D., Chief Executive Officer of T-Cure. "Our investigators are key opinion leaders of the cell therapy field. We are fortunate to work together to advance this novel TCR product candidate through the first ever clinical development in the world."

For the clinical trial NCT05483491, the sponsor is listed on ClinicalTrials.gov as Christian Hinrichs (affiliation is Rutgers University). In the first record posted of the trial in July 2022 until mid-April 2023, the collaborators listed included Rutgers, NCI and T-Cure, however, the company was then dropped from the list of collaborators on the record. Collaborators currently

[4] October 6, 2022 – NCI AND RUTGERS UNIVERSITY OPEN PHASE 1 CLINICAL TRIALS OF T CELL RECEPTOR THERAPY TARGETING KK-LC-1 FOR MULTIPLE SOLID TUMORS. https://t-cure.com/october-6-2022-nci-and-rutgers-university-open-phase-1-clinical-trials-of-t-cell-receptor-therapy-targeting-kk-lc-1-for-multiple-solid-tumors/

listed for the trial are NCI and Iovance Biotherapeutics, Inc. Additionally, according to the NIH RePORTER database, this clinical trial is supported by grant number P30CA072720, which has so far supported 75 projects for a total of $86,690,555 in funding.

For the clinical trial NCT05035407, the only sponsor listed is NCI with no other collaborators named.

Trial: NCT05035407

Trial Number:	NCT05035407
Trial Title:	T Cell Receptor Gene Therapy Targeting KK-LC-1 for Gastric, Breast, Cervical, Lung and Other KK-LC-1 Positive Epithelial Cancers
Projected Enrollment:	100 patients (recruiting)
Trial Sponsor:	NCI
Principal Investigator:	Scott M Norberg, D.O.,National Cancer Institute (NCI)
Trial Start Date:	March 8, 2022
Primary Completion (Estimated) :	April 7, 2025
Study Completion (Estimated):	April 5, 2026
Phase:	1
Sponsor:	National Cancer Institute (NCI)
Funding:	NIH

Trial: NCT05483491

Trial Number:	NCT05483491
Trial Title:	KK-LC-1 TCR-T Cell Therapy for Gastric, Breast, Cervical, and Lung Cancer
Projected Enrollment:	30
Trial Sponsor:	Christian Hinrichs (Rutgers, The State University of New Jersey)

Principal Investigator:	Christian S Hinrichs, MD, Rutgers Cancer Institute of New Jersey
Trial Start Date:	September 9, 2022
Primary Completion (Estimated):	September 1, 2026
Study Completion (Estimated):	December 31, 2028
Phase:	1
Sponsor:	Christian Hinrichs
Collaborators	National Cancer Institute (NCI), Iovance Biotherapeutics.
Funding:	NIH Grant P30CA072720

Issues with Trials

The two trials have a projected enrollment of 130 patients, which is larger than the enrollment for some of the trials for cell therapies previously approved by the FDA. Dr. Gulay French declined to answer our questions regarding the funding of the trials, but the NIH appears to be funding both.

Based upon the NIH ClinicalTrials.Gov registry, the larger trial is NCT05035407, which is currently being conducted at the NIH campus in Bethesda. Collectively, the data from the two trials can be used to obtain FDA approval. There are important non-patent intellectual property rights associated with the trial data. Orphan Drug exclusivity gives the company sponsoring the product for FDA marketing approval seven years of market exclusivity. The Biologics Price Competition and Innovation Act (BPCIA) gives the owner of the data 12 years of exclusive rights to rely on the data for a regulatory approval.

It is not clear from the T-Cure press releases or the NIH Federal Register notice if the federal government has given T-Cure or any other firm the rights to use the data from either of the two federally funded trials.

Today KEI learned of plans to merge the two trials, so that the Rutgers trial would be the legal entity listed as the sponsor, although the patients would still be treated at both the Rutgers and the NIH sites. Moreover, the manufacturing of the cells would be done separately, at Rutgers for the Rutgers site, and at the NIH for the Bethesda site. None of this is discussed in the Federal Register Notice, and Dr. Gulay French did not volunteer this information when queried about the trials.

The Section 209 Standard for Patent Exclusivity

Section 209(a) of the Bayh-Dole Act states that “a Federal agency may grant an exclusive or partially exclusive license on a federally owned invention . . . only if . .. granting the license is a reasonable and necessary incentive to (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public.”

It’s pretty hard to argue that the company needs exclusivity on this patent license, because:

1. The federal government appears to be funding the trials, vastly reducing the need for private investment in the development of treatment, and
2. The company registering the treatment seems likely to obtain 7 years of Orphan Drug regulatory exclusivity and 12 years of biologics test data exclusivity, and
3. The NIH apparently has already given T-Cure some other exclusive rights related to the product.

Even if the NIH does decide to use an exclusive license, it also is required by Section 209(a)(2) to limit the proposed scope of exclusivity, so it “is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;”

KEI’s Queries on the License

The information in the Federal Register notices for exclusive licenses are typically lacking basic information about the prospective license, and unnecessarily have a short 15-day notice period.

On October 5, KEI asked Dr. Gulay French the following questions:

> “1. What is the rationale for stating "The prospective exclusive license territory may be worldwide." Is a worldwide exclusive license a necessary incentive, or would it be sufficient for the exclusivity to apply in high income countries, for example countries with a per capita income at least 30 percent of the United States? Can the NCI share its market analysis with KEI?
>
> 2. Does the NCI have any data on how widely these types of treatments are available in developing [sic] countries, or given any thought to the type of access provisions in a license, such as those relating to transfers of manufacturing know-how or sharing of regulatory data would expand access?
>
> 3. What is the stage of development of this technology?

4. NCI conducts and funds trials on this type of technology. What is the per patient cost of such trials, and the enrollment requirement for FDA approval?"

On October 10th, Dr. Gulay French replied:

"1. As these are internal analyses, we do not share this information with outside parties. Further, the terms of the license remain to be negotiated. Accordingly, the scope of the licensed territory is not yet known.

2. I do not have this information and cannot comment on confidential negotiations. The terms of the license remain to be negotiated.

3. Clinical stage of development.

4. NIH has established the Research Portfolio Online Reporting Tools (RePORT) to provide access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research. This database allows users to search a repository of intramural and extramural NIH-funded research projects, including those that involve clinical trials."

KEI followed up on October 14th asking:

- "Can you share information on the clinical trials? What are the trial IDs, the trial enrollment, the trial costs and who is funding the trial or trials?" and,
- "For example, is this one of the trials, and are there others? https://clinicaltrials.gov/study/NCT05035407"

On October 16th, Dr. Gulay French stated that "I am aware of 2 clinical trials. The trial IDs are NCT05035407 and NCT05483491."

Eleven days after our 1st email inquiry the NCI provided us with known trials involving the technology to be licensed. Why not provide this information up front in the Federal Register notice or have some type of background document that people can get from an NIH website? Including information such as the stage of the development and any relevant clinical trials is always important for the public to evaluate if exclusivity is necessary or if the scope of rights are appropriate.

Sending us to the RePORT database is unhelpful, since it is often impossible to assign grants to specific trial outlays. The California Institute for Regenerative Medicine reports the grant amount for each trial it funds. The NIH should do the same thing.

T-Cure's Partners Appear to be Foreign-owned and Controlled Firms

T-Cure lists five partners on its "About" page.

- Genvira BioSciences is a firm headquartered in Ottawa, Ontario, Canada.
- Atlas Antibodies is a Swedish Life Science company.
- DiaCarta and Immunotech Biopharm are Chinese companies.
- BioNtech is a German firm.

Pricing and Access Issues

It's appalling that the NIH is not more forthcoming about the facts of a prospective license. The public has a statutory right to comment on prospective licenses, and that exercise is undermined by the NIH's typical refusal to provide relevant information about the proposed agreement.

In any event, if the NIH decides to give an exclusive patent license to this company:the following safeguards should be included in any agreement.

Data Rights

The government should also keep rights to the trial data (if they have not already been given away). Retained data rights would be important leverage should the licensee market the product at an excessive price.

Price Discrimination

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.

Technology Transfer

The NIH manufactures the treatment, and probably transferred that technology to Rutgers. The NIH needs to ensure that it is free to provide technology transfer to other firms that will serve patients in countries where T-Cure (or whoever buys the licenses from T-Cure) fails to serve adequately or at all.

Sincerely,

James Love
Clare Cassedy
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 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. . . .”
Merck Sharp & Dohme The Army W911QY21C0031 June 7, 2021	Therapeutic Development	21	H.7. Fully redacted including the title
Pfizer The Army W58P0522C0001 November 17, 2021	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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			(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.
Sanofi The Army W15QKN1691002; MCDC2011-005 July 30, 2020	Vaccine R&D 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."
Most Favored Customer Clauses			
ANP Technologies, Inc. The Army W911QY20D0019 May 29, 2020	Development and Production of a Diagnostic	11	"MOST FAVORED CUSTOMER H.1 Most Favored Customer 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 The Army W911QY2190001 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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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. The Army W911QY2090013 June 24, 2020	Post-exposure Prophylaxis (PEP) Development	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 . . . ."
Immunome, Inc. The Army W911QY2090019 July 3, 2020	"research and development of a standardizable and scalable [REDACTED] comprised of [REDACTED] antibodies [REDACTED] . . . ."	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	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. 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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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."
Rigel Pharmaceuticals The Army W911QY2190018 January 29, 2021	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 The Army W911QY2190011 December 4, 2020	Therapeutic Development	16	**Article 9. Most Favored Customer** A. [REDACTED] [REDACTED] C. This Article applies only to products sold in the [REDACTED] related to COVID-19.
Government Preference Clauses			
Becton, Dickson & Company The Army W911SR2030001 July 1, 2020	Needle Production	17	**"9. Government Preference** 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.
Global Life Sciences Solutions The Army W911NF2130001	Expanded Manufacturing and Production Capacity	8	**9. Government Preference** 9.1 [REDACTED] 9.2 [REDACTED] 9.3 [REDACTED]

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
October 13, 2020			
Retractable Technologies, Inc. HHS W911SR2030004 July 1, 2020	Expansion of Manufacturing Capacity of Needles/Syringes	23	**9. Government Preference** [REDACTED]
SIO2 Medical Products, Inc. The Army W911NF2030003 June 5, 2020	Vaccine Delivery Device R&D	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."