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Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered T Cell Therapies for the Treatment of Cancer to Moonlight Bio, Inc. (“Moonlight”), headquartered in Seattle, WA. [88 FR 66463](#)

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Introduction

[Moonlight Bio, Inc.](#) (“Moonlight”), headquartered in Seattle, WA. is an impressive entity to receive the license in terms of scientific qualifications and investor backing.

The technology is in the pre-clinical stage of development, and some exclusivity is merited. However, the license should (1) limit the scope of exclusive rights to that which is reasonably necessary, a requirement of 35 USC 209, (2) protect patients in the USA from pricing discrimination and/or excessive pricing, and (3) include measures to transfer technology to entities that will make treatments more affordable in developing countries.

International Reference Pricing cap

[Recently](#), HHS entered into a contract with HHS for reasonable pricing of a COVID 19 treatment. It’s not as if companies won’t agree to these conditions. In the past three years Pfizer, Sanofi, Merck, Lilly and other companies have included various versions of most favored nation or most favored customer pricing clauses in contracts, either from HHS or DOD.

The attached ANNEX on pricing clauses in U.S. government contracts for COVID-19 products provides several examples of conditions that companies, large and small, will sign, if asked.

I doubt that Sean Parker would take a hard line against a similar international reference pricing cap, one that protects US residents from paying more than residents in other high income countries.

The NIH could do much more than just cap prices at a high income country reference price ceiling. One approach is to progressively lower price or reduce the term of exclusivity after revenues exceed benchmarks. For a cell therapy, where the required trials are typically small, and the technology is licensed from the federal government, it would be reasonable to reduce the term of exclusivity by one year for every \$500 million after \$2 billion in sales, and the NIH could consider other numbers, but some limits on the scope of exclusive rights are required by 35 USC 209, and should be in place.

Access in Developing Countries

The United States Public Health Service Technology Transfer Policy Manual, [Chapter No. 300](#), PHS Licensing Policy¹ states “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.” This policy has clearly been ignored in past NIH licenses regarding treatments for cancer or rare diseases, and certainly when it comes to new cell or gene therapies.

The NIH can actually implement this policy in the Moonlight license by including specific measures that would do something, such as by limiting the exclusivity in countries with average incomes less than $\frac{1}{3}$ of the United States, or by requiring non-exclusive licensing through the Medicines Patent Pool of patent, data and know-how, or by other measures.

Granting worldwide rights on a patent application that can be brought into the national phase in any of the 157 PCT contracting states as well as in non-PCT member states will be a negative for access, unless the license includes some other measures such as pricing conditions or required sublicensing to the MPP to address access.

Transparency

The Federal Register notice concerns a patent application that is not public. The NIH should make a patent application public when asking the public to comment on a proposed license. If the invention, royalty rate, and other terms are all secret, it makes it difficult to comment on a license. We recognize the USPTO will not publish a patent application for 18 months. But if the NIH is the owner of the invention and the entity filing the application, it can certainly make the

¹ PHS Licensing Policy, 12/08/2010

application public whenever it wants, and certainly if there is a federal register notice asking for public comment on a license.

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: 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	Therapeutic Development	21	H.7. Fully redacted including the title

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
W911QY21C0031 June 7, 2021			
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>
Sanofi The Army W15QKN1691002; MCDC2011-005 July 30, 2020	Vaccine R&D and Production	28	<p>"5.1 Most Favored Nation Clause</p> <p>(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."</p>
Most Favored Customer Clauses			
ANP Technologies, Inc. The Army W911QY20D0019 May 29, 2020	Development and Production of a Diagnostic	11	<p>"MOST FAVORED CUSTOMER 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>

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
AstraZeneca The Army W911QY2190001 October 9, 2020	Monoclonal Antibody Treatment R&D and Production	32	<p>ARTICLE 9. Most Favored Customer</p> <p>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.</p> <p>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.</p>
Emergent BioSolutions Canada Inc. The Army W911QY2090013 June 24, 2020	Post-exposure Prophylaxis (PEP) Development	16	<p>“ARTICLE 9. Most Favored Customer</p> <p>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”</p>
Immunome, Inc. The Army W911QY2090019 July 3, 2020	“research and development of a standardizable and scalable [REDACTED] comprised of [REDACTED] antibodies [REDACTED]”	16	<p>“ARTICLE 9. Most Favored Customer</p> <p>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. . . .”</p>
Inovio Pharmaceuticals, Inc. The Army W911QY2090016 June 22, 2020	Vaccine Delivery Device Development	17	<p>“ARTICLE 9. Most Favored Customer</p> <p>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. . . .”</p>
Maxim Biomedical, Inc. The Army W911QY20D0018 May 11, 2020	Diagnostic Production	10	<p>“H.1 Most Favored Customer</p> <p>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. . . .”</p>

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
Murtech, Inc. The Army W911QY20D0017 May 11, 2020	Diagnostic Production	15	<p>“H.1 Most Favored Customer</p> <p>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.”</p>
Novavax The Army W911QY20C0077 P0002 June 4, 2020	Vaccine Development and Production	4	<p>“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.”</p>
Rigel Pharmaceuticals The Army W911QY2190018 January 29, 2021	Therapeutic Development	29	<p>ARTICLE 20. Most Favored Customer.</p> <p>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.</p> <p>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 OTA0 in writing, of which email is an acceptable form, within thirty (30) days of such offering.</p>
60 Degrees Pharmaceuticals The Army W911QY2190011 December 4, 2020	Therapeutic Development	16	<p>Article 9. Most Favored Customer</p> <p>A. [REDACTED] [REDACTED]</p> <p>C. This Article applies only to products sold in the [REDACTED] related to COVID-19.</p>
Government Preference Clauses			
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>

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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 October 13, 2020	Expanded Manufacturing and Production Capacity	8	9. Government Preference 9.1 [REDACTED] 9.2 [REDACTED] 9.3 [REDACTED]
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."