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Cc: Abby Rives and Lyric Jorgenson

RE: Prospective Grant of Exclusive Patent Commercialization License: Human Monoclonal Antibodies That Broadly Target Coronaviruses to Leyden Laboratories B.V. in the Netherlands

Knowledge Ecology International (KEI) and Public Citizen (PC) offer the following comments regarding the grant of an exclusive patent commercialization license of human monoclonal antibodies that broadly target coronaviruses to Leyden Laboratories B.V. in the Netherlands, as noticed in the Federal Register 88 FR 72088 on October 19, 2023, 15 days ago.

Licensed Technology

The field of this license is limited to the "Prevention and treatment of coronavirus infection, illness, and transmission through mucosal delivery". The license may include the rights to develop and commercialize two types of products in the specified field of use, both preventative and therapeutic products.

The licensed inventions include U.S. provisional application (63/308,898), filed on February 19, 2022, and the PCT application (PCT/US2023/062324), filed on February 9, 2023, entitled "Human Monoclonal Antibodies that Broadly Target Coronaviruses" (HHS Reference No. E–047–2022). The Federal Register Notices on October 19, 2023, and on June 10, 2023 (87 FR 35559) describe the invention and the potential commercial applications.

See also the Annex on Questions to the NIH and the NIH responses.

Summary of Comments on the Proposed Exclusive License

1. Leyden appears to have the talent and resources to develop the licensed technology.
2. The geographic scope of the proposed exclusive license is worldwide and the PCT patent application geographic area is extremely broad, including in Africa, Asia, and Latin America. We object to the use of exclusive licenses in countries where per capita incomes are less than 30 percent of the United States.
3. There is a disconnect between the NIH's use of a worldwide exclusive license and the US government's promotion of voluntary licensing and technology transfer to increase access to medicines in developing countries.
4. The Bayh-Dole Act requires that government funded inventions are "available to the public on reasonable terms" and the NIH license needs to ensure this takes place.
5. We object to the grant of exclusivity in the U.S. market unless conditioned on an international high-income country reference pricing cap, similar to those used recently by both HHS and DOD for COVID-19 R&D and procurement contracts.
6. The License should require Lyden to ensure that products are registered and available in the US and all countries with an established need, if not directly from the licensee, from qualified third parties.
7. We ask that any exclusive license include either a mandate or an option to license inventions, regulatory test data and know-how to serve markets in countries with per capita incomes less than 30 percent of the United States.
8. Licenses should include to the extent possible terms to provide transparency that is consistent with the World Health Assembly Resolution 72.8.

Leyden Laboratories, B.V.

Leyden Laboratories is a company headquartered in the Netherlands that was founded by the scientists behind the AdVac and PER.C6 platforms which were acquired by Janssen (Johnson & Johnson) and formed the basis of the single-shot COVID-19 vaccine. The company has recently received Series B investor funding from Casdin Capital and GV (formerly Google Ventures) and SoftBank Vision Fund 2.[1]

Leyden Laboratories appears to have the expertise and resources to develop the licensed technology.

Geographic Scope of License and PCT Filings

The proposed geographic scope of the license is worldwide, and the PCT application for "Human Monoclonal Antibodies that Broadly Target Coronaviruses" provision for designated states (described in the ANNEX on WIPO PCT Designated States) is very extensive, including in developing countries in Asia, Africa and Latin America.

We oppose the use of exclusive licenses in developing countries where an exclusive license will predictably lead to unequal access and also proposes complementary measures regarding the registration of products and the licensing of know-how and regulatory data to implement Public Health Services licensing policy, 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."
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> United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, dated 12/08/2010.

Disconnect between global norms on voluntary licensing to address access in developing countries and NIH policies on worldwide licensing to for-profit companies

In countless discussions at the WTO TRIPS Council and the current negotiations at the WHO on a possible pandemic treaty, the United States, the European Union, other high-income countries and the global innovative pharmaceutical industry have extolled the benefits of voluntary licensing of biomedical inventions to developing country manufacturers as a means to expand access and affordability in developing countries. For example, in the current draft of a possible pandemic treaty (A/INB/7/3), Article 10(3)(c) requires Parties to promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products. While Article

[1] Leyden Labs Raises $200M in 2021 for a New Approach to Combat Viruses. Press Release. January 25, 022. https://leydenlabs.com/140m_seriesb_raise

10(3)(c) refers to “private rights holders,” it is odd that the NIH does not see its own licensing practices following the same guidance.

> **Article 10. Sustainable production**
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> . . .
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> (3) Each Party, in addition to the undertakings in paragraph 2 of this Article, shall:
>
> . . .
>
> (c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks.
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> *A/INB/7/3, Provisional agenda item 2, 30 October 2023*

Available to the Public on Reasonable Terms

The NIH should include license terms to protect US patients from paying excessive prices. The definition of practical application in the Bayh-Dole Act, 35 USC 201(f), requires licensees “to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.”

> 35 U.S.C.
> United States Code, 2011 Edition
> Title 35 - PATENTS
> PART II - PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS
> CHAPTER 18 - PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE
> Sec. 201 - Definitions
>
> §201. Definitions
> As used in this chapter—
>
> (f) The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

International High-Income Country Reference Pricing Cap

One measure to determine if a product is “available to the public on reasonable terms” is the relationship between the price in the United States and other high-income countries.

We note that since 2020, the United States has entered into many contracts for R&D and procurement which will provide the U.S. government with prices no higher than prices in

selected high-income reference countries. The most recent such agreement we are aware of concerns an HHS agreement with Regeneron[2], and earlier DOD agreements with international reference pricing commitments that were made with companies like Pfizer, Lilly, Sanofi, etc. (See the Annex on Reference Pricing Clauses in COVID-19 Contracts).

We propose that pricing for products developed under this license should not exceed the median prices charged in the seven countries with the largest GDP and at least 50% of the GNI per capita in the US, using the World Bank Atlas method. Alternatively, the NIH can consider a list of reference prices similar to those in the Annex on reference pricing agreements recently signed by companies with the US government.

However, we also ask that the reference pricing clause not only relate to prices for sales directly to the U.S. government. The Pfizer agreement on the pricing of Paxlovid is an example of an agreement where the reference pricing cap only applied to US government prices, and when Pfizer began to offer the products through retail channels outside of the DOD procurement agreement, the prices increased sharply in the U.S. This can be remedied by having the pricing cap apply to any sales in the United States, not only to sales to the federal government.

Global Registration and Affordability

The licenses should require the licensee to disclose the steps and actions to enable the timely registration and accessibility of the resulting medical technology at an affordable price in the United States and all countries identified as having an established need by the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO). This can be achieved through either direct supply to countries at publicly disclosed affordable rates with an adequate supply volume or by granting technology transfer and sufficient intellectual property rights to third parties, enabling them to meet these objectives.

Additional Measures Regarding Access to Medical Technology in Low- and Middle-Income Countries

The 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. The Medicines Patent Pool, known for its successful efforts in expanding access to vital medicines, should play a pivotal role in extending these benefits to those in need, especially in resource-constrained regions.

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[2] HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies: Agreement Promotes the Development and Access to COVID Therapies for Americans, Press Release, September 8, 2023. https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-monoclonal-antibodies.html

Transparency

The license should incorporate to the extent possible transparency norms that meet or exceed the standards outlined in Resolution WHA72.8, titled “Improving the transparency of markets for medicines, vaccines and other health products.” All we are asking here is for the United States government to live up to a global norm on transparency HHS negotiated and endorsed in 2019.

Conclusion

The NIH must ensure that the terms of this license promote the public interest and protect patients’ equitable access, should any preventative or therapeutic product come to market. In the event that the NIH grants the license, we ask that it incorporate the provisions listed above in order to achieve those goals.

Please notify us if and when a license is granted so that we may request a copy under the Freedom of Information Act.

James Love
Arianna Schouten
Knowledge Ecology International

Peter Maybarduk
Public Citizen

ANNEX 1: WIPO PCT Designated States

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW

European Patent Office (EPO) : AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR

African Intellectual Property Organization (OAPI) : BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG

African Regional Intellectual Property Organization (ARIPO) : BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW

Eurasian Patent Organization (EAPO : AM, AZ, BY, KG, KZ, RU, TJ, TM

ANNEX 2: Questions to the NIH and the NIH responses

1. What is the stage of development of the technology?

2. Does the license only concern a patent invention, or will it also involve any technology transfer from the NIH?

3. Has the NIH considered introducing international reference pricing into the license?

4. Can the NIH provide details regarding any grants or funding associated with the technology in the license?

All questions were sent on November 2, 2023, and did not receive a response.

ANNEX 3: Reference Pricing Clauses in COVID-19 Contracts

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 (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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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 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 . . . ."

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
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 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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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 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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government or an MCM Partner.”