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September 3, 2024

RE: Prospective Grant of an Exclusive Patent License: Dimethyl Synaptamide for the Treatment of Autoimmune Disorders and Inflammatory Diseases (89 FR 66730)

Dear Dr. Varonin,

Knowledge Ecology International (KEI) offers the following comments regarding the “Prospective Grant of an Exclusive Patent License: Dimethyl Synaptamide for the Treatment of Autoimmune Disorders and Inflammatory Diseases” (89 FR 66730) to Autala Bio Inc., A Civala Company (“Autala”). The notice states that Autala is incorporated in Delaware, but does not provide the location of the company’s headquarters or any other information regarding the firm.

There appears to be no internet presence for Autala outside of results related to the instant Federal Register notice, nor for the Civala Company. A search of the Delaware business registry returns no results for Autala, and a search for Civala returns entries for “Civala, Inc.” and “Civala Services, LLC” whose listed registered agents are “Corporation Service Company” and “Capitol Services, Inc.”, respectively.

How can the public be expected to provide comments on the appropriateness of an exclusive license when there is so little information about the company that will receive exclusive rights to a taxpayer-funded invention? We call on the NIH to provide in the Federal Register notices greater information on both the technologies to be licensed (for example, stage of development, any clinical trials underway, amount of NIH funding expended) and on the company to receive the license (for example headquarters location, names of principals, website, whether any previous NIH employees are involved with the company).

Particularly considering the dearth of information available to the public regarding Autala, the NIH must ensure that the terms of the exclusive license to Autala include safeguards to guarantee that any resultant treatment is affordable and accessible to the public.

KEI urges the NIH to include terms concerning the following, in order to protect patients’ access to treatments related to the technology to be licensed.

Price Gouging

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

The notice states that the scope of the license may be worldwide, we therefore ask that the NIH include in this license terms that ensure affordable access to patients in developing countries.

KEI recently submitted a letter to the NIH noting that:

“NIH licensing policy frequently favors a worldwide monopoly on NIH-owned inventions, despite ample evidence that such monopolies are associated with morally repugnant disparities in access, and that the extension of the monopoly to lower income countries provides little, if any, consequential incentives for the commercialization of inventions.”¹

KEI’s August 28, 2024 letter also provides data concerning both the enormous disparities in access to products and also the small quantitative impact on incentives if the NIH takes concrete steps to limit the geographic scope of monopolies for products in developing country markets.

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

¹ James Love. Letter to Abby Rives and Vladimir Knezevic of the NIH. August 28, 2024. <https://www.keionline.org/wp-content/uploads/KEI-NIH-28Aug2028.pdf>

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

Conclusion

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

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

ANNEX Pricing Clauses in U.S. Government Contracts for COVID-19 Products

In 2020 and 2021, several U.S. government contracts for the development of COVID 19 vaccines, therapeutics, diagnostic tests and other related products included provisions on pricing. Some contracts include a most favored nation pricing clause that specifically requires the company to provide the U.S. government with “a price lower” than the price offered to any centralized federal authority that is “a member of the Group of Seven plus Switzerland.” The non-US members of the G7 are Canada, France, Germany, Italy, Japan, the United Kingdom.

Table A1, U.S. Government COVID-19 Contracts Containing Reference Price Constraints on Resultant Products

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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			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	<p><u>5.1 Most Favored Nation Clause</u></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."
Most Favored Customer Clauses			
ANP Technologies, Inc. The Army W911QY20D0019 May 29, 2020	Development and Production of a Diagnostic	11	<p><u>MOST FAVORED CUSTOMER</u></p> H.1 Most Favored Customer <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>
AstraZeneca The Army W911QY2190001 October 9, 2020	Monoclonal Antibody Treatment R&D and Production	32	<p>ARTICLE 9. Most Favored Customer</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. 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

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
			offering.
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>
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	Vaccine Development and Production	4	“The Contractor shall maintain a most favored customer provision for the product once authorized or licensed by the

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
W911QY20C0077 P0002 June 4, 2020			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 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	Expansion of Manufacturing Capacity of Needles/Syringes	23	9. Government Preference [REDACTED]

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
W911SR2030004 July 1, 2020			
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."