

The NIH does not enforce the statutory requirement to restrict the scope of exclusive rights in a patent license as set out in 35 USC § 209(a)(1-2).

August 18, 2023

James Love

Knowledge Ecology International

Submitted to: SciencePolicy@od.nih.gov

The NIH does not enforce the statutory requirement to restrict the scope of exclusive rights in a patent license as set out in 35 USC § 209(a)(1-2).

Any reform of NIH licensing policy should address this failure.

Introduction	2
NIH Practice	2
The covered inventions	2
The field of use	3
The geographic territory	3
Concerns over developing country access	3
Unnecessary exclusivity in United States	5
The period of time exclusivity applies (the term)	5
Conditions on pricing	7
The NIH Reasonable Pricing Clause experience	7
Taxol	7
ddl	8
The 1995 elimination of the NIH reasonable pricing clause	8
The misrepresentation of the data on NIH CRADAs	10
Figure 1: NIH Standard and Materials CRADAs, Reported by OTT as executive, by fiscal year	11
Table 1: Average number of standard CRADAS and NIH Budget per CRADA for different time periods	12
The NIH licenses of patents and data to Ridgeback for the Ebola Drug Ebanga	12
ANNEX Pricing Clauses in U.S. Government Contracts for COVID-19 Products	14
Table A-1, U.S. Government COVID-19 Contracts Containing Reference Price Constraints on Resultant Products	14
ANNEX: examples of NIH redactions regarding agreements with Ridgeback	19

Introduction

There are two aspects of the NIH's failure to enforce the 35 USC § 209 restrictions.

First, 35 USC § 209(a)(1) only allows the grant of an exclusive license on a federally-owned invention when, "granting the license is a **reasonable and necessary incentive** to call forth the investment capital and expenditures needed to (A) bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public." (emphasis added).

Second, 35 USC 209(a)(2) requires that for an exclusive license, "the proposed scope of exclusivity 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." (emphasis added).

The two conditions on the grant of an exclusive license on patents owned by the federal government are designed to protect the public from a private party obtaining a legally enforced monopoly on an invention owned by the federal government, except when the terms of the exclusive right are both reasonable and necessary to achieve commercialization, and the exclusive rights are limited to what is reasonably necessary.

The scope of rights that should be limited under § 209 may involve many issues, including most importantly these five issues:

1. The specific inventions,
2. The field of use,
3. The geographic territory,
4. The amount of time the exclusivity applies (the term), and
5. Conditions on pricing.

NIH Practice

The covered inventions

The specific inventions are often listed in the public notice for a license and are not limited to inventions with granted patents. The covered inventions may be inventions where applications for patents have been submitted, but not yet granted, and even inventions where applications may be filed in the future. For example, in the current prospective exclusive license to the mystery company EnZeta, the licensed inventions will include, in addition to four specific and named patent applications, "any and all other U.S. and ex-U.S. patents and patent applications

claiming priority to any one of the foregoing, now or in the future.” Among the four named patent applications in the EnZeta license, two were filed 2023 and the most recent application was filed May 9, 2023, less than four months ago.

The field of use

In some cases, the NIH limits the field of use in a license, to some degree, and in others, the field of use is “commensurate in scope with the patent rights,” or unlimited by the license itself.

The degree that a field of use is limiting can be important and varies by license. These are a few examples:

- EnZeta Immunotherapies, Inc. August 2023. “manufacture, distribution, sale and use of T-cell-based immunotherapies for solid tumors.”
- Elgia Therapeutics, Inc., July 2023. “Development, manufacture, use and commercialization of Caspase Inhibitors disclosed and claimed in the prospective licensed patent rights, for the treatment of inflammatory diseases, such as hidradenitis suppurativa (HS) in humans and animals.”
- Affini-T Therapeutics, Inc., December 2022. “Development, manufacture and commercialization of T or Natural Killer cell therapy products genetically engineered to express the P53 R175H-reactive T cell receptor claimed in the Licensed Patent Rights for the treatment of cancer in humans.”
- Australian National University, May 2023. “commensurate in scope with the patent rights.”
- University College London Business, Ltd. (“UCLB”), incorporated in England and Wales, May 2023. “commensurate in scope with the patent rights.”
- The Progeria Research Foundation (“PRF”), July 2021. “commensurate in scope with the patent rights.”

The geographic territory

The NIH most commonly grants worldwide rights to its patented inventions.

Concerns over developing country access

KEI often asks the NIH to exclude exclusivity in developing countries, or more generally, to not grant exclusive rights in countries with a per capita income of less than 30 percent of the United

States. As far as we know, the NIH has always rejected KEI's proposals to limit the exclusive rights in lower-income countries, even when the license covers treatments for HIV or other illnesses that often benefit from voluntary open licenses from big drug companies to the Medicines Patent Pool (MPP).

Just one of many examples of exclusive licenses in developing countries concerns the 2020 license to RNAceuticals, a firm without a web page. The technology is for N6, which is a "Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains." Eleven health and patient NGOs and nine individuals wrote to Dr. Fauci on July 20, 2020 objecting to the territory of the license, stating:

"For existing HIV drugs, most companies that currently hold patents on useful antiretroviral drugs have demonstrated a willingness to license on a non-exclusive basis in roughly 115 lower and middle income countries, including South Africa and India, via the Medicines Patent Pool. Instead this proposed license would extend exclusivity to this mystery firm to HIV antibodies already in clinical trials to Brazil, China, India, South Africa, and Russia, and apparently Serbia.

The USAID is aware that most persons living with HIV reside in countries with lower incomes and scarce resources to purchase medicines, and that the role of donors in supporting such areas is constantly at risk and is declining relative to the number of persons needing treatments. While only a handful of developing countries are included in the proposed license, several have large populations of persons living with HIV, and five countries (India, China, Brazil, Russia and South Africa) can play an important role in manufacturing generic versions of products covered by the license. The exclusive license would allow the licensee to prevent that manufacture."

The United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy, 12/08/2010, includes this often ignored statement:

"PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

As the NIH is fully aware, there is massive evidence of disparities in access to new drugs by geography, and while the United States has repeatedly endorsed the norm "to promote access to medicines for all" in regard to intellectual property rights, the NIH routinely grants worldwide rights to licensed patents, knowing full well that in most cases this will lead to unequal access globally. Of particular concern are the licenses that include exclusivity in India and other countries with the capacity to manufacture and sell generic or biosimilar versions of treatments.

KEI has often asked HHS and the NIH to include, in licenses, a provision that permits the NIH to enable more competitive licensing in developing countries, either through the Medicines Patent

Pool or other arrangements. These requests are generally ignored by HHS and the NIH, and most NIH-issued exclusive licenses, with few exceptions, have provided for worldwide rights.

We have asked the NIH to take into account the fact that the inclusion of India and other developing countries in the geographic territory of the exclusive rights has almost no impact on the business decisions of the companies developing the products. Nearly all of the business decisions for most licensed inventions concern potential markets in Europe, North America, Japan, Korea and Australia, or more generally, markets where the per capita incomes are greater than 30 percent of the United States, and where either public or private health insurance can pay for the products.

In cases where a technology will have significant use for persons living in lower-income countries, it will sometimes be the case that the U.S. government is among the countries providing donor funds, and in these cases, high prices will be a burden on US taxpayers, or limit the effectiveness of the US donor efforts.

Unnecessary exclusivity in United States

For some products that are already in clinical development, and even for some pre-clinical technologies, the exclusivity in other high-income countries is a sufficient incentive to bring products to the market. KEI has in the past asked the NIH to limit the exclusivity to other high-income countries, while permitting generic or biosimilar competition in the United States. To our knowledge, the NIH almost never (and perhaps never) considers this as an option, even though it is a very simple way to benefit U.S. residents while providing the incentive necessary to bring the products to market.

The period of time exclusivity applies (the term)

One of the more frustrating aspects of the NIH licensing practice concerns the period of time the exclusivity applies. In previous years, the licenses for NIH-owned patents sometimes limited the number of years of exclusivity, but more recently, apparently ALL of the NIH exclusive licenses run for the entire term of the patent.

One example of the earlier policy concerns the HIV drug didanosine (ddI), the subject of an NIH Office of Technology Transfer [case study](#).

“The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could become non-exclusive early, prior to the expiration of the NIH patents. Several companies competed for the license. Criteria for selecting the licensee included the

company's technical ability to develop this compound into a drug and manufacture it in large quantities, its willingness to work cooperatively with the NIH, and its willingness to make development of this compound a priority. The BristolMyers Squibb plan was judged superior by the selection panel, and the license was signed in January 1988. NIH exercised its prerogative to have the license become nonexclusive in October 2001."

Videx® Expanding Possibilities: A Case Study, NIH, National Institutes of Health Office of Technology Transfer, September 2003,

When asked recently about the NIH policy regarding the term of exclusivity, Mark Rohrbaugh said that the NTIS had negotiated licenses, including the ddl license, with shorter terms of exclusivity, but once the NIH took over responsibility for negotiations of licenses to the patents it owned, the agency has a policy of granting the life of the patent exclusivity in every license. This clearly runs counter to the requirements in § 209 to ensure that the "scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

KEI has made a number of proposals to the NIH regarding the term of exclusivity in license. One is to limit the exclusivity to a specific number of years, similar to the ddl license. In determining the number of years for exclusivity, KEI has asked the NIH to estimate the amount of money needed to bring a product through FDA approval, the anticipated market for the product, and to take into account other federal subsidies and incentives including but not limited to:

- Federal grants or contracts,
- Advance purchase agreements,
- Priority Review Vouchers,
- Orphan Drug Tax Credits,
- Orphan Drug Exclusivity,
- FDA test data exclusivity for both small molecules and biologic drugs, and
- Regulatory exclusivities and subsidies in Europe and other markets.

For some products, the existence of grants from the NIH or other federal agencies such as BARDA, DoD, etc, the eligibility for the FDA priority review voucher (worth around \$100 million recently), and various regulatory exclusivities make the incentive of exclusivity in a patent license unnecessary once a product is approved by the FDA, therefore a much shorter patent exclusivity is appropriate. The NIH, however, makes no such distinction and grants life-of-patent exclusivity in all cases.

Another alternative to a specific shorter term for the license is to tie the term of exclusivity to the revenue generated by a product. For example, KEI has asked the NIH to set a benchmark revenue milestone, for example at \$1 billion in global sales for a product, and then reduce the term of exclusivity by one year for every \$500 million in additional global sales, or to consider different milestone targets. There are many advantages to tying the exclusivity to revenue

milestones, since the real world actual cash flow eliminates the need to guess about the size of the potential market.

The NIH has also rejected all of these proposals, and without any analysis of the feasibility.

Conditions on pricing

In the past, the NIH placed some conditions on product pricing. Both Taxol, a drug for cancer, and ddI, a drug for the treatment of HIV, are examples of products with such conditions.

More recently, during the COVID-19 pandemic, the US government has negotiated a number of contracts with pricing conditions, including in several cases, reference pricing clauses, such as most favored nation pricing conditions, or most favored customer clauses. The Annex on Pricing Clauses in U.S. Government Contracts for COVID-19 Products illustrated that companies, including large ones, will agree to restrictions on pricing, including for products in development.

KEI has asked the NIH over a hundred times to include in its licenses a requirement that U.S. residents pay no more than the median price paid by residents in the seven countries with the largest GDP and at least 50 percent of US per capita income. The NIH has rejected every one of these requests, regardless of the stage of development of the technology.

The NIH Reasonable Pricing Clause experience

Following a controversy over the high price of the HIV drug zidovudine (AZT), President George Herbert Walker Bush (GHWB) put into practice the use of a reasonable pricing clause in NIH CRADA and patent license agreements. The first products to reach the market with the pricing clause were the unpatented cancer drug Taxol (approved by the FDA in 1992) and the HIV drug ddI (approved by the FDA in 1991).

Taxol

Taxol was an unpatented product for which the US government held the rights to all of the Phase 1, 2 and 3 clinical trials used for the FDA approval. The NIH entered into a CRADA agreement with Bristol Myers Squibb (BMS) to register the drug with the FDA and commercialize the drug. The CRADA gave BMS the exclusive rights to use the data from the NIH-funded and -conducted clinical trials for FDA approval, giving BMS what was effectively a five year monopoly. The language in the CRADA agreement with BMS was vague as regards the implementation of the obligation, but the NIH negotiated a 15-product reference pricing formula with BMS. The agreement allowed BMS to charge \$4.87 a milligram for Taxol, a substantial increase over the \$0.25 per milligram the NIH was paying a contractor to make the drug for clinical trials. This led to a controversy that is well documented in a Congressional hearing: US House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, *Exclusive Agreements between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development*. Serial No. 102-35. July 29.

(<https://babel.hathitrust.org/cgi/pt?id=pst.000019275802&seq=1>), as well as other Congressional Hearings and GAO reports.

ddl

In addition to the shorter patent term, the NIH negotiated a reasonable pricing clause in its patent license with BMS for the HIV drug ddl, marked by BMS as Videx. BMS agreed to sell ddl at a price roughly 30 percent lower than the price that GSK was charging for AZT, a similar HIV drug.

The 1995 elimination of the NIH reasonable pricing clause

From 1991 to 1993, both Houses of Congress held hearings on the pricing of drugs developed with federal assistance, generating a number of news stories and commentary. Members of Congress also proposed additional measures to deal with high drug prices, including new concerns over the high prices for drugs for rare diseases, many of which had benefited from significant federal R&D subsidies. One supporter (at least publicly) of the reasonable pricing clause on NIH-funded drugs was Dr. Bernadine Healy, the Director of the NIH from April 9, 1991 to June 30, 1993.

From 1992 to 1994 the industry hardened its opposition to the reasonable pricing clause, and the NIH changed its policies following the election of President Bill Clinton and the appointment of Donna Shalala as Secretary of HHS in January 1993 and the appointment of Harold Varmus as NIH Director in November of 1993.

The biotech industry experienced a series of pricing swings from 1991 to 1995 which influenced the debate on the NIH reasonable pricing clause, even though the clause was rarely relevant to products approved by the FDA during that period.

In 1991, news reports about biotech share prices used terms like “soaring” or titles like “Biotech Firms’ Stocks Dazzle Wall Street,”¹ By 1993 the tone had cooled, particularly for the venture market for biomedical stocks.

The NASDAQ Biotechnology (NBI) index was trading at 210 in early 1994, but fell below 145 in July. The NYSE Arca Biotechnology index (BTK) was started at 200 in October 1991 and peaked at 223.92 in January 1992, fell to 82 by 1994 and was as low as 78 in March 1995.

The declines in the biotech share prices were driven by various factors including concerns over possible Congressional imposed price controls, high profile failures of drugs in clinical trials and

1

<https://www.washingtonpost.com/archive/business/1991/04/15/biotech-firms-stocks-dazzle-wall-street/2459b873-cf27-4b58-8df7-f30fa21c029b/>

court decisions in patent disputes. The NIH reasonable pricing clause became an accessible target of panicked biotech investors and drug company lobbyists.

In 1994, the NIH held two forums on the CRADA reasonable pricing clause. The first forum, held July 21, 1994, had panel members representing Pfizer, BMS, Upjohn and Eli Lilly, as well as the smaller firms Genetic Therapy Inc. and Mitotix, and Allan Fox, a lawyer for rights holders, as well as Brigham and Women's Hospital (a large recipient of NIH funding), and several government officials. At this meeting Lisa Raines, Vice President of Government Relations for Genzyme, the company created to commercialize Ceredase, made a motion to eliminate the reasonable pricing clause. Ceredase was a drug developed at Tufts University on NIH grants, and at the time of the forum, it was at the time the most expensive drug in the world.

There was significant criticism of the first forum for its industry heavy representation, and the NIH was forced to hold a second forum on September 8, 1994. The published report on the CRADA forums is available [here](#). I attended both forums, and spoke at the second. Among the arguments against the use of the reasonable pricing clause was that it had not been used effectively to benefit consumers, and was intensely disliked by investors and drug companies, so the net benefits of eliminating something that had no benefits favored its removal, an argument used today against the march-in rights clause in the Bayh-Dole Act.

In the 1994 midterm elections, the Republican Party captured unified control of Congress for the first time since 1952, elevating Representative Newt Gingrich as Speaker of the House and Senator Robert Dole as Senate President.

On April 11, 1995, the NIH published a [Notice](#) rescinding the reasonable pricing clause, including its enforcement in existing contracts. Dr. Varmus stated, "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public." I criticized the action as follows.

James Love, an economist with the Center for Study of Responsive Law, a group founded by the consumer advocate Ralph Nader, said the decision abandoned efforts to protect consumers and taxpayers, and opened the door to high prices for pharmaceuticals developed through substantial Government investment. "Under today's actions, a drug company will be able to charge any conceivable price for any drug, no matter how small the private sector's role in the development of the drug," Mr. Love said, "and no matter how comprehensive and complete the Government's role in the drug's development."

Warren E. Leary, U.S. Gives Up Right to Control Drug Prices, *New York Times*, April 12, 1995.

The misrepresentation of the data on NIH CRADAs

Following the elimination of the reasonable pricing clause in CRADAs, the NIH created a new type of CRADA for materials transfers. The original CRADA was then called a “Standard CRADA” and the new one a “Materials CRADA,” sometimes referred to later as a MCRADA. The new materials CRADA was initially widely used by the NIH, although over time much less so. But by combining the numbers of both the standard and the materials CRADAs, the critics of the reasonable pricing clause misleadingly claimed that the elimination of the clause led to a dramatic increase in industry engagement, and this became a standard talking point for critics of the reasonable pricing clause, particularly by the NIH OTT, AUTM members and drug companies.

Figure 1 illustrates how misleading it was to lump the numbers from the CRADAs and MCRADAs together. The average number of Standard CRADAs from 1989 to 1994 was 34. When the standard and materials CRADA numbers were added together, it appeared as if there were 87 agreements in 1996, and 153 in 1997, a huge increase. However, when standard CRADAs amounts are compared to each other, a different picture emerges. The 1996 number of standard CRADAs was 44, while the 1997 number of standard CRADAs was 32, the same or lower than four of the years when the reasonable pricing clause was in effect. By 2006, the number of standard CRADAs fell to 22, and was only 23 the following year, both amounts lower than any year when the reasonable pricing clause was in effect. From 1997 to 2010, the average number of standard CRADAs was slightly higher at 36, but only by 2, and during a period when the NIH budget per CRADA was far larger (see Table 1).

Figure 1: NIH Standard and Materials CRADAs, Reported by OTT as executive, by fiscal year

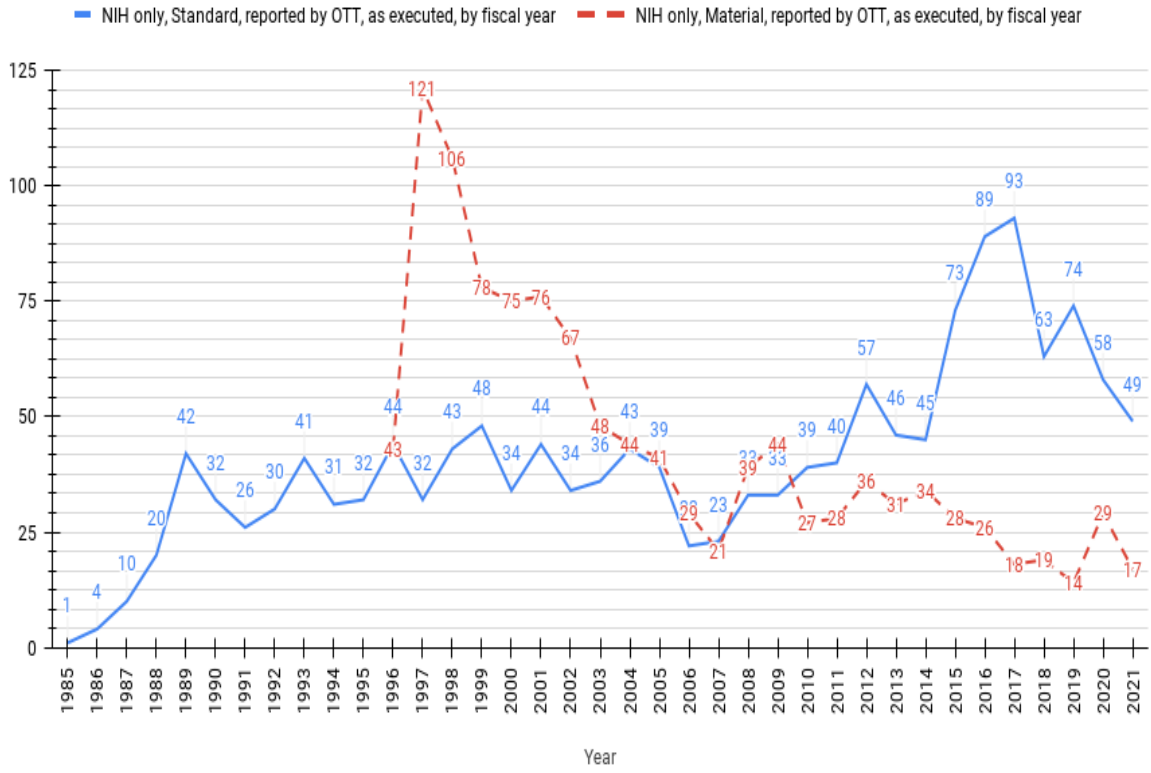


Table 1: Average number of standard CRADAS and NIH Budget per CRADA for different time periods

Period	Average number of standard CRADAs executed by fiscal year	Number of CRADAS	NIH Budget	NIH Budget / CRADA
1986 to 1988	11	34	\$18,111,814,000	\$532,700,412
1989 to 1994	34	202	\$53,211,311,000	\$263,422,332
1989 to 1995	33	234	\$64,510,833,000	\$275,687,321
1996 to 2002	40	279	\$115,592,929,000	\$414,311,573
2003 to 2009	33	229	\$201,688,788,000	\$880,737,066
2011 to 2020	64	638	\$336,420,349,000	\$527,304,622
1996 to 2010	36	547	\$348,519,717,000	\$637,147,563

Looking at the CRADA data over time, including the massive decline in the use of the materials CRADAs, it appears as though the number of CRADAs is driven by factors largely unrelated to the reasonable pricing clause, the national or global market for therapeutics or the NIH budget.

The data have been misused to mislead the general public and policymakers, not only by the rights holder lobby, including persons representing universities that have a putative mission to educate, but also frequently by NIH OTT officials to advance their anti-reasonable pricing agenda.

The NIH licenses of patents and data to Ridgeback for the Ebola Drug Ebanga

The NIH grants of an exclusive patent license and an exclusive license to US NIH clinical trial data for the Ebola drug Ebanga (ansuvimab-zykl, formerly referred to as mAb114) illustrates how the NIH can ignore the restrictions on exclusive license set out in § 209.

The research to develop mAb114 was carried out and supported by the NIH, BARDA, DARPA, and the clinical trials to support the registration of the drug were undertaken by the NIH in collaboration with public health authorities in Africa and MSF. According to one NIH release:

“The National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center (VRC), part of NIH, developed the investigational treatment and conducted and sponsored the clinical trial. . . VRC scientists developed mAb114 in collaboration with scientists at the National Institute of Biomedical Research (INRB) in the DRC; the Institute for Research in Biomedicine and Vir Biotechnology, Inc.'s subsidiary Humabs BioMed, both based in Bellinzona, Switzerland; and the U.S. Army Medical Research

Institute of Infectious Diseases at Fort Detrick, Maryland. The Defense Advanced Research Projects Agency funded the production of mAb114 for clinical testing.”
<https://www.niaid.nih.gov/news-events/investigational-monoclonal-antibody-treat-ebola-safe-adults>

Ridgeback Biotherapeutics, a firm headed by Wendy Holman, received two large grants from BARDA related to the drug, including Contract No. 75A50120C00009, wherein Ridgeback can be reimbursed up to \$153,663,387.24 for “CMC efforts for mAB114 for the Development and Treatment of Ebola”, and 75A50119C00059, wherein Ridgeback was awarded \$13,988,547 for “Additional in-scope work for CMC efforts for mAB114 development for the treatment of Ebola”

The NIH initially provided a non-exclusive license to mAB144 inventions, but later would provide Ridgeback with exclusive rights to data from an NIH run clinical trial for purposes of drug registration. In September of 2020, NIAID told KEI the following regarding mAb114 clinical trial data via email:

“NIAID filed two INDs related to mAb114 – one for the Phase 1 clinical trial of mAb114 and one for the PALM clinical trial in which the efficacy of mAb114, ZMapp, Remdesivir, and REGN-EB3 was evaluated. To enable expedited review of the BLA for mAb114 by the FDA, NIAID transferred the Phase 1 IND to Ridgeback Biotherapeutics. NIAID received no consideration for this transfer, and it was not conveyed under a license agreement. The transfer will accelerate access to this important therapeutic, enabling effective responses to ongoing Ebola outbreaks in Africa. NIAID remains the sponsor of the PALM clinical trial, and the data from this clinical trial has been shared with all of companies that supplied study products for this clinical trial.”

By transferring the Phase 1 clinical data to Ridgeback, Ridgeback obtained a 12 year FDA regulatory monopoly on the test data.

The NIH could have retained the rights in the data, allowing the government to obtain generic or biosimilar versions of the drug from third parties. One consequence of the transfer of the data rights to Ridgeback is that for now, the US government now has to buy the drug from Ridgeback. Another consequence is that Ridgeback was able to claim a material threat medical countermeasure priority review voucher (PRV), as provided under section 565A of the Federal Food, Drug and Cosmetic Act (FDCA), which is currently worth about \$100 million.

Ridgeback received FDA approval for Ebanga (mAb114) on December 21, 2020. But on March 15, 2021, the NIH apparently proposed making its patent license for the mAb114 inventions exclusive, despite the fact that Ridgeback had received significant funding from BARDA, had 12 years of exclusive FDA test data rights, has Orphan Drug marketing exclusivity through December 21, 2027 and received a priority review voucher worth about \$100 million.

KEI’s comments on the 2021 exclusive license notice is [here](#). As usual, the NIH has not provided information to KEI on the final outcome of the proposed exclusive 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 A-1, U.S. Government COVID-19 Contracts Containing Reference Price Constraints on Resultant Products

Contractor, Agency, and Contract Number	Subject	Page	Reference Price Term Excerpt
Pfizer DOD/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>

<p>ANP Technologies, Inc. DOD/Army W911QY20D0019 May 29, 2020</p>	<p>Development and Production of a Diagnostic</p>	<p>11</p>	<p><u>"MOST FAVORED CUSTOMER"</u> 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>
<p>Becton, Dickson & Company DOD/Army W911SR2030001 July 1, 2020</p>	<p>Needle Production</p>	<p>17</p>	<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> <p>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.</p>
<p>Eli Lilly, DOD/Army W911QY21D0012 P0002 April 7, 2021</p>	<p>Monoclonal Antibody Treatment Production</p>	<p>7-8</p>	<p>"H. 7 Sales to Covered Nations"</p> <p>(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. . . . "</p>

<p>Eli Lilly DOD/Army W911QY21C0016 October 26, 2020</p>	<p>Monoclonal Antibody Treatment Production</p>	<p>18</p>	<p>“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. . . .”</p>
<p>Emergent BioSolutions Canada Inc. DOD/Army W911QY2090013 June 24, 2020</p>	<p>“the research and development of an advanced human immune globulin manufactured from human plasma with antibodies to SARS-CoV-2 (COVID-HIG) for post-exposure prophylaxis (PEP) of Coronavirus Disease (COVID-19)”</p>	<p>16</p>	<p>“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”</p>
<p>Immunome Inc DOD/Army W911QY2090019 July 3, 2020</p>	<p>“research and development of a standardizable and scalable [redacted] compromise of [redacted] antibodies”</p>	<p>16</p>	<p>“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. . . .”</p>
<p>Inovio Pharmaceuticals, Inc. DOD/Army W911QY2090016 June 22, 2020</p>	<p>“the development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery of INO-4800 against COVID-19, with demonstrated capability to be produced at a large scale, as well as full automation for production of the device arrays, (hereinafter referred to as the ‘Prototype Project’).”</p>	<p>17</p>	<p>“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. . . .”</p>

<p>Maxim Biomedical, Inc. DOD/Army W911QY20D0018 May 11, 2020</p>	<p>Diagnostic Production</p>	<p>10</p>	<p>“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. . . .”</p>
<p>Murtech, Inc. DOD/Army W911QY20D0017 May 11, 2020</p>	<p>Diagnostic Production</p>	<p>15</p>	<p>“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.”</p>
<p>Novavax DOD/Army W911QY20C0077 P0002 June 4, 2020</p>	<p>“Vaccine Development and Production”</p>	<p>4</p>	<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>
<p>Sanofi DOD/Army W15QKN1691002; MCDC2011-005 July 30, 2020</p>	<p>Vaccine Research and Development (including Clinical Trials) and Production</p>	<p>28</p>	<p>“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.”</p>
<p>SIO2 Medical Products, Inc. DOD/Army W911NF2030003 June 5, 2020</p>	<p>Vaccine Delivery Device Research and Development</p>	<p>13</p>	<p>“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.”</p>

Merck Sharp & Dohme Contract DOD/Army W911QY21C0031 June 7, 2021	COVID 19 Therapeutic	21	H.7. Fully redacted including the title
Rigel Pharmaceuticals DOD/Army W911QY-21-9-0018 January 29, 2021	COVID-19 Therapeutic	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 °TAO in writing, of which email is an acceptable form, within thirty (30) days of such offering.”</p>

ANNEX: examples of NIH redactions regarding research collaboration agreement with Ridgeback

RESEARCH COLLABORATION AGREEMENT

This Agreement is between the National Institute of Allergy and Infectious Diseases (“NIAID”), which is a component of the National Institutes of Health (“NIH”), an agency of the U.S. Department of Health and Human Services, having offices located at 5601 Fishers Lane, Rockville, MD 20852, and Ridgeback Biotherapeutics (“Ridgeback”) (“Collaborator”), having a principal place of business at [REDACTED] (b)(6) [REDACTED] (collectively, the “Parties”). This Agreement is neither a funding agreement as defined in 35 U.S.C. § 201(b) nor a cooperative research and development agreement authorized under the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. §§ 3710a *et seq.*, and Executive Order 12591 of April 10, 1987. NIAID enters into this Agreement pursuant to the authority of the Public Health Services Act of 1944, as amended (42 U.S.C. § 241).

BACKGROUND

1. [REDACTED] (b)(4)
2. [REDACTED]
2. NIAID and Collaborator want to transfer between the laboratories of their investigators, during the term of this Agreement, proprietary research materials [REDACTED] (b)(4) required to conduct the research project [REDACTED] (b)(4)

APPENDIX A

Research Project

- I. **Abstract of the Research Project – for Public Release**
EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS ABSTRACT TO THE PUBLIC.

Ridgeback Biotherapeutics and the Vaccine Research Center (VRC), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) will collaborate to advance development of monoclonal antibodies against Ebola virus toward licensure for therapeutic and prophylactic use in control of outbreaks and prevention of epidemics.

- II. **Goal(s) of Project**

[REDACTED] (b)(4)

IV. Respective Contributions of the Parties

Ridgeback

[Redacted] (b) (4)

VRC/NIAID

[Redacted] (b) (4)

V. Material Contributed by VRC/NIAID

[Redacted] (b) (4)

VI. Material Contributed by Collaborator

[Redacted] (b) (4)