KEI Comments on NIH Proposal to Require License Holders to Provide Access Plans

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Table of Contents

Introduction

The NIH is proposing obligations on companies to make products and services affordable and accessible.[1] There will be considerable opposition to this, as there has been in the past. This note provides some historical context for the negotiations, and makes several recommendations for the implementation.

Access and affordability measures from 1980 to 1995

The 1980 restrictions on the term of exclusivity

Prior to the Bayh-Dole Act, the federal government had broader discretion to determine the ownership of federally-funded inventions and also to deny or limit the term of exclusivity for both intramural- and extramural-funded inventions.

When the Bayh-Dole Act was passed in 1980[2] universities, non-profit organizations and small businesses were generally able to obtain titles to patents on federally-funded inventions, but the federal government still retained an important oversight on the use of exclusive licenses. Specifically, unless a firm qualified as a small business, the term of exclusivity was limited to the earlier of five years of commercial sales or eight years from signing a license, unless the patent holder obtained permission to extend the exclusivity from the federal government.

35 USC § 202. Disposition of rights (of the 1980 Act)

[1] National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning. 89 FR 45003.
[2] 94 STAT. 3022 Public Law 96-517, DEC. 12, 1980.

> (c)(7)(B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance unless, on a case-by-case basis, the Federal agency approves a longer exclusive license.

The 1982-1983 cisplatin case

The cancer drug cisplatin was invented at Michigan State University on a grant from the NIH, and subsequently licensed by Research Corporation, a patent corporation, to Bristol-Myers. The original license, based upon a patent application, was issued in 1977 and limited the exclusivity to three years from the first initial sale. In May 1978, Bristol and the Research Corporation successfully petitioned to extend the term of exclusivity to five years from the first commercial sale. The drug was approved by the FDA on December 19, 1978, and exclusivity was set to end on December 26, 1983.

On September 8, 1982, HHS received another request from Research Corporation, this time to extend the exclusive license to Bristol-Myers for an additional seven years. BMS claimed that it needed the extended monopoly to justify funding research to determine which other cancers could be successfully treated with cisplatin.

HHS published a notice of the request for the exclusive license extension in the Federal Register on February 4, 1983, asking for comments.[3]

A few days later, on February 18, 1983, President Reagan issued a “Memorandum on Government Patent Policy.”[4]

> To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38 of Title 35 of the United States Code.
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> In awards not subject to Chapter 38 of Title 35 of the United States Code, any of the rights of the Government or obligations of the performer described in 35 U.S.C. 202 - 204 may be waived or omitted if the agency determines (1) that the interests of the United States and the general public will be better served thereby as, for example, where this is necessary to obtain a uniquely or highly qualified performer; or (2) that the award involves co-sponsored, cost sharing, or joint venture research and development, and the

[3] 48 FR 5313.
[4] https://www.reaganlibrary.gov/archives/speech/memorandum-government-patent-policy

performer, cosponsor or joint venturer is making substantial contribution of funds, facilities or equipment to the work performed under the award.

In addition, agencies should protect the confidentiality of invention disclosure, patent applications and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws.

HHS received responses from five generic manufacturers objecting to the extension of the exclusivity, each expressing an interest in obtaining non-exclusive licenses to make and sell cisplatin in the United Sames. At least one of the companies was already selling a generic version in Europe. In response to the BMS rationale, all generics companies offered to undertake research relating to new uses of cisplatin.

Several members of Congress wrote to HHS. Senators Orrin Hatch (R-UT), Charles Mathias (R-MD), and Strom Thurmond (R-SC) supported the Bristol-Myers request. Senator Joseph Biden (D-DE) and Representative Thomas Carper (D-DE) opposed the extension of exclusivity.

Lawyers for Andrulis Research Corporation sent an 18 page letter to the NIH on June 15, 1983, setting out the legal and policy basis for providing non-exclusive licensing, with provisions for generic manufacturers to fund research on the drug. The Andrulis memorandum proposed that the funding could be managed by each company, or provided to a research foundation, or managed directly by the government. Andrulis argued that under its counter proposal, the public would benefit from much lower prices on the government-funded invention, and that granting a legal monopoly was not necessary to fund the additional research on additional uses of cisplatin.

On November 25, 1983, Bristol-Myers was granted an extension of the exclusivity on the license for five years, two less than requested. But Bristol-Myers was also required to reduce prices by 30 percent during the period of the extended exclusivity (48 FR 53177), and to provide $35 million for independent research, directed by Dr. Robert Wittes, an NIH employee.

The 1984 amendments to the Bayh-Dole Act eliminated the restrictions on the term of exclusivity

The pharmaceutical industry subsequently lobbied Congress to eliminate any restrictions on the term of exclusivity for extramural-funded inventions. In 1984, a year in which President Reagan obtained a landslide electoral victory, the restrictions on the term of exclusivity for extramural-funded inventions were eliminated in P.L. 98-620.

The reasonable pricing clause from 1987 to 1995

Concerns over the pricing of government-funded drugs later arose, stimulated by outrage over the high prices for the HIV drug AZT, a drug developed with considerable support from the NIH and at one point described as "the most expensive prescription drug in history."[5]

Beginning late 1987[6] the NIH engaged companies on including a "reasonable pricing clause" in CRADAs and patent licenses agreements. In 1989 the NIH adopted a policy of including reasonable pricing clauses in both CRADA and patent licenses.[7],[8]

Standard templates were developed for patent licenses and CRADA terms, from which negotiated agreements sometimes deviated. One of the standard templates for CRADAs reads as follows:

> DHHS has responsibility for funding basic biomedical research, for funding medical treatment through programs such as Medicare and Medicaid, for providing direct medical care and, more generally, for protecting the health and safety of the public. Because of these responsibilities, and the public investment in the research that culminated in the Licensed Patents Rights, PHS may require LICENSEE to submit documentation in confidence showing a reasonable relationship between the pricing of a Licensed Product, the public investment in that product and the health and safety needs of the public. This paragraph shall not restrict the right of LICENSEE to price a Licensed Product or Licensed Process so as to obtain a reasonable profit for its sales or use. This Paragraph 5.03 does not permit PHS or any other government agency to set or dictate prices for Licensed Products or Licensed Processes.

The combination of an obligation to show a reasonable relationship between the price and the public investment and the prohibition on the government agencies to "set or dictate prices" raised obvious questions regarding the nature of the obligation.

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[5] AIDS Drugs, Need and Greed. September 29, 1989. New York Times. https://www.nytimes.com/1989/09/29/opinion/aids-drugs-need-and-greed.htm.

[6] U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, Pricing of Drugs Codeveloped by Federal Laboratories and Private Companies, Serial No. 103-2. January 25, 1993. Page 95.

[7] Reports on the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. July 21, 1994 and September 8, 1994. National Institutes of Health. https://www.keionline.org/wp-content/uploads/2018/03/NIH-CRADA-Report-on-Reasonable-Pricing-Clause-1994.pdf

[8] "Burroughs' pricing so upset government officials that they began inserting "reasonable price" clauses in licensing agreements for other drugs developed with government assistance, including the promising AIDS antiviral agents DDC and DDI." Marlene Cimons and Victor F. Zonana, New York Times, September 19, 1989. https://www.latimes.com/archives/la-xpm-1989-09-19-mn-111-story.html; Reports on the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. July 21, 1994 and September 8, 1994. National Institutes of Health. https://www.keionline.org/wp-content/uploads/2018/03/NIH-CRADA-Report-on-Reasonable-Pricing-Clause-1994.pdf

In 1991, two products reached the market with the reasonable pricing clause, both involving Bristol-Myers Squibb (BMS).

The BMS/ddI/Videx reasonable price negotiation

In the 1980s, the NIH had developed the HIV drug ddI and sought a company to commercialize the drug. On May 8, 1987, the PHS published a "Request for Establishment of Collaborative Agreement for the Preclinical and Clinical Development of Dideoxyadenosine/Dideoxyinosine as an Anti-Viral Agent Useful in the Treatment of Acquired Immunodeficiency Syndrome (AIDS)."[9] Six companies responded. On October 29, 1987, PHS announced its intention to grant an exclusive license to the patents on ddI to Bristol-Myers.[10]

A September 10, 1991 letter to Congressman Ron Wyden by Dr. Samuel Broder, then the Director of the National Cancer Institute, described the provision in the ddI license agreement as follows:

> The license agreement does not expressly limit the price that Bristol can charge for ddI. Bristol agrees in Article 3.2 of the license agreement that the National Technical Information Service (NTIS) in the Department of Commerce has the right to grant sublicenses to other companies if Bristol fails to provide evidence that there is a reasonable relationship between its pricing of ddI; and the health and safety needs of the public.[11]

The enforcement mechanism in the ddI license was the threat to grant additional patent licenses. The negotiations between the NIH and BMS led to a price for ddI that was lower than the price of AZT, the first HIV drug in the same class,[12] and to a limited period of exclusivity.

The license allowed for a possible 15 years of exclusivity, but gave the NIH the possibility of making the license non-exclusive after 10 years, which it did in 2001.[13] The NIH described negotiation over the term of the license as follows:

> "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.

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[9] 52 FR 17478
[10] 52 FR 41612.
[11] U.S. 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, 1991, page 361. https://babel.hathitrust.org/cgi/pt?id=pst.000019275802&seq=3
[12] Philip Crawford, AIDS Brings Financial Opportunities, Moral Dilemmas, November 30, 1991, New York Times. https://www.nytimes.com/1991/11/30/your-money/IHT-aids-brings-financial-opportunities-moral-dilemmas.html
[13] Videx® Expanding Possibilities: A Case Study, National Institutes of Health Office of Technology Transfer, September 2003. https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf

> 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 Bristol Myers 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.

In a 1993 Congressional hearing, Zola Horovitz, PhD., the Vice President for Business Development and Planning at BMS, described the price negotiations with the NIH as follows:

> The Standard NIH Pricing Clause
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> Because the "reasonable pricing clause" has no statutory basis, and because a number of potential collaborators have been reluctant to agree to pricing restrictions of any kind, the precise language of the clause has varied from time to time. Typically, however, the standard "reasonable pricing clause" includes two elements: (1) a declaration of the government's "concern that there be a reasonable relationship between the pricing of a licensed product , the public investment in that product, and the health and safety needs of the public;" and (2) a statement to the effect that the government "may require that this relationship be supported by reasonable evidence." .
>
> Bristol - Myers Squibb agreed to include an early version of this standard clause in the exclusive commercialization license to Videx (ddI), a patented AIDS drug discovered by the NCI , and subsequently developed by Bristol - Myers Squibb. In fact , Videx is the only product that has come to market under an agreement containing the standard NIH pricing clause.
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> When Videx was introduced in October of 1991 , Bristol-Myers Squibb established a price considerably lower than that of the only other comparable product then on the market . The Videx price was almost universally viewed as reasonable, and Bristol-Myers Squibb was publicly commended for the manner in which it honored its reasonable pricing obligations .

The Taxol reasonable price determination

The cancer drug paclitaxel was developed at the NIH without patents on the compound for use in treating cancer. The NIH entered into a CRADA agreement with BMS, which included a modified version of the reasonable pricing clause.

The negotiations over the price included the NIH presenting BMS with a list of 15 reference prices. BMS subsequently announced a price that was just less than the median of the group.

In a 1993 Congressional hearing, Zola Horovitz, PhD., the Vice President for Business Development and Planning at BMS, described the price negotiations with the NIH as follows:[14]

> The Taxol project also provides a valuable model with respect to the fair the reasonable pricing of products developed under CRADAs. In fact, it should become the standard against which the pricing of other products developed under CRADAs will be judged, not only because the process struck a fair balance between the interests of both CRADA partners, but also because it worked exceptionally well. . . .
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> . . . at the time Taxol was approved, Bristol- Myers Squibb provided the NCI with a second document describing the details of the Taxol pricing structure, including rebates and discounts provided to various government agencies and Bristol-Myers Squibb's own patient access and reimbursement assistance programs. On the basis of information contained in that document, NCI concluded that the projected cost per cycle of Taxol therapy is well below that of many other recently-approved anticancer agents and is in the mid-range of other agents currently used in the treatment of refractory ovarian cancer, and that Bristol-Myers Squibb had taken appropriate steps to assure that no patient would be denied the drug because of inability to pay facts that both Bristol-Myers Squibb and the NCI view as strong evidence that the price of Taxol is fair and responsible.

The Taxpayer Assets Project of the Center for Study of Responsive Law criticized the NIH methodology for a reasonable price, including in a January 1993 Congressional testimony.[15]

> The "fair pricing" clause in the Taxol CRADA was a decidedly abbreviated version of the standard clause. It reads :
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> > NCI has a concern that there be a reasonable relationship between the pricing of taxol, the public investment in taxol research and development, and the health and safety needs of the public. Bristol-Myers Squibb acknowledges that concern, and agrees that these factors will be taken into account in establishing a fair price for taxol.
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> . . .
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> How did NCI evaluate the Taxol price? Rather than focus on BMS's actual costs, NCI officials told the firm that it expected the drug to be priced in the range of other cancer drugs. NCI submitted to BMS a list of 15 drugs and their estimated "monthly wholesale cost." BMS was asked to set the price so that a month of Taxol would cost no more than

[14] U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, Pricing of Drugs Codeveloped by Federal Laboratories and Private Companies, Serial No. 103-2. January 25, 1993. Page 94.

[15] "Private Sector Pricing of Taxol and Other Pharmaceutical Inventions Developed with Federal Funding," included in U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, Pricing of Drugs Codeveloped by Federal Laboratories and Private Companies, Serial No. 103-2. January 25, 1993.

> the median price for the group. NCI was, in essence, telling BMS that it could price Taxol, a government-funded drug invention, the same as other cancer drugs were priced, regardless of where the funding came from, and regardless of how "fair" those prices were.

The main line of criticism directed at the NIH was that it had taken a new cancer drug from discovery through phase III trials, and right before FDA approval had handed off the intellectual property rights (the rights in the regulatory data) to BMS with a contract that allowed the company to charge $4.87 a milligram for a drug the government was manufacturing for $0.25 per milligram, despite the fact that BMS had played a minimal role and invested very little in the development of Taxol.

While the NIH was pressed by consumer groups and members of Congress to have more concrete and effective pricing conditions,[16] investors and rights holders mobilized in opposition to the obligation, and presented their views in two NIH sponsored panels.[17] In 1995, the Clinton administration responded by eliminating the provision altogether, on the grounds that the benefits were small relative to the costs in terms of barriers to industry collaboration with the federal government. NIH Director Harold Varmus also said that “The vast majority of CRADAs result in new scientific knowledge, not new products.”[18]

The New York Times reported the decision with the headline, “U.S. Gives Up Right to Control Drug Prices.”[19]

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[16] United States Senate, Committee on Governmental Affairs, Drug Pricing: Poor Prescription for Consumers and Taxpayers? : hearing before the Committee on Governmental Affairs, United States Senate, One Hundred Third Congress, second session, July 27, 1994. S. Hrg. 103-1045; U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities and Technology, Underreporting Federal Involvement in New Technologies Developed At Scripps Research Institute, Serial No. 103-93. July 11, 1994; The federal government’s investment in new drug research and development : are we getting our money’s worth?, Hearing before the Special Committee on Aging, United States Senate, One Hundred Third Congress, first session, Washington, DC, February 24, 1992. Serial 103-1 Washington: U.S. G.P.O. : U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, Pricing of Drugs Codeveloped by Federal Laboratories and Private Companies, Serial No. 103-2. January 25, 1993; U.S. 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, 1991.

[17] Reports on the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. July 21, 1994 and September 8, 1994. National Institutes of Health. https://www.keionline.org/wp-content/uploads/2018/03/NIH-CRADA-Report-on-Reasonable-Pricing-Clause-1994.pdf

[18] Press Release. NIH News. April 11, 1995. https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[19] Warren E. Leary, U.S. Gives Up Right to Control Drug Prices, *New York TImes*, April 12, 1995. https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html

Dr. Harold Varmus, director of the institutes, said the research agency would give up the option to review the introductory price of products developed from basic research sponsored by the Government. The policy was adopted in 1989 in response to criticism that drugs developed with substantial Government help were being marketed at excessive prices.

Dr. Varmus said reviews of the policy indicated that the pricing clause had driven industry away from many collaborations with N.I.H. scientists that could have benefited the public. "Eliminating the clause will promote research that can enhance the health of the American people," he said.

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."

Legislative efforts to restore the reasonable pricing clause from 1996 to 1999

Bernie Sanders, when serving in the House of Representatives, offered a series of amendments and bills to restore the reasonable pricing clause, including one combined with the reasonable pricing obligation with measures on transparency, research mandates and other topics.

H.R. 4270, the 104th Congress. 'Health Care Research and Development and Consumer Protection Act'

On September 27, 1996, Sanders introduced H. R. 4270, which addressed several different new obligations and authorities for HHS.

- Section 3: **Report on Research Of The Federal Government.** Extensive reporting on the federal government role in the development of new products.
- Section 4: **Reasonable Price Agreement.** A requirement for reasonable pricing agreements for patents or other intellectual property rights of federally funded research and development.
- Section 5: **Purchase Of Drugs Developed With Taxpayer Support.** A review to determine a reasonable price for federal reimbursements under the government grams, when the product "was developed with significant Federal support."

- Section 6: **Material Transfer Agreement.** A mechanism to induce the sharing of biological materials for research purposes,
- Section 7: **Promotion Of Research And Development.** Authority for the Secretary of Health and Human Services to establish the minimum amount a drug manufacturer would be required to make available for research and development of its new health care technologies.
- Section 8. **Report on Sales**. A report on sales would include the total number of each drug sold and the total revenue received from such sales, including sales made outside the United States.
- Section 9: **Government Expenditure On Prescription Drugs.** Annual reports on the amount of money the federal government expends, directly or through reimbursement, for the purchase of prescription drugs, and the amount of money expended each year on drugs which were developed with significant Federal support.

This bill merits discussion for its more holistic approach, dealing with pricing, the enhancement of R&D, and transparency.

The reasonable pricing waiver

The reasonable pricing obligation was subject to a waiver. The rationale for including the waiver is that there would be situations, including those referred to by Dr. Varmus in his 1995 decision to eliminate the reasonable pricing obligation in NIH license and CRADA agreements, when the reasonable pricing clause would discourage collaborations. In short, the government would have more leverage on pricing in some cases, and less leverage in others. The waiver was designed to eliminate any objection to the reasonable pricing clause that the NIH would describe by giving HHS the authority to waive the clause, whenever doing so was in the public interest.

The process for granting the waiver included a requirement that the Secretary of HHS provide for public comment on the requested waiver, and provide a finding that the waiver is in the public interest.

> SEC. 4. REASONABLE PRICE AGREEMENT.
> (a) IN GENERAL.—If any Federal agency or any non5 profit entity undertakes federally funded health care research and development and is to convey or provide a patent or other exclusive right to use such research and development for a drug or other health care technology, such agency or entity shall not make such conveyance or provide such patent or other right until the person who will receive such patent or other right first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (b).

Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (b).

(b) WAIVER.—No waiver shall take effect under sub18 section (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

Transparency

Several provisions in the bill requiring reporting on the role of federal R&D in the development of product, the revenue generated and units sold, and the impact on government budgets of products were designed to provide policy makers and the public with better information to inform policy making.

New authority to review prices on products that benefited from federal funding

The bill would provide a broader authority to review the prices of products that benefited from federal R&D programs, even when a license or CRADA did not include a reasonable pricing agreement, when there was no license or CRADA, or when the funding was extramural in nature.

Two provisions to enhance R&D

The Material Transfer Agreement (MTA) provision gave the Secretary the authority to compel the sharing of materials including cell lines and other biologic resources for research purposes. The R&D mandates in Section 7 allowed the federal government to set floors on the percent of sales invested in R&D, for different types of products, based upon patient protection, orphan drug status, or the magnitude of sales. This provision was motivated by the earlier decision in the cisplatin case, designed both to ensure that measures to lower prices would not be automatically seen as resulting in lower amounts of R&D spending, and giving the government a new instrument to enhance innovation.

H. R. 626, 106th Congress, Consideration of Competitive Bidding

Another Sanders bill, H.R. 626, introduced February 8, 1999, in the 106th Congress, would also have required persons who undertake federally-funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human

Services. The obligation for a reasonable pricing agreement extended to both intramural- and extramural-funded research.

For agreements where the federal government conveys or licenses exclusive rights to federally-funded research, the bill would have required a consideration of competitive bidding for the rights.

> (b) CONSIDERATION OF COMPETITIVE BIDDING.—In cases where the Federal Government conveys or licenses exclusive rights to federally funded research under subsection (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—
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> > (1) qualified bidders compete on the basis of the lowest prices that will be charged to consumers;
> >
> > (2) qualified bidders compete on the basis of the least sales revenues before prices are adjusted in accordance with a cost based reasonable pricing formula;
> >
> > (3) qualified bidders compete on the basis of the least period of time before prices are adjusted in accordance with a cost based reasonable pricing formula;
> >
> > (4) qualified bidders compete on the basis of the shortest period of exclusivity; or
> >
> > (5) qualified bidders compete under other com10 petitive bidding systems.
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> Such a competitive bidding process may incorporate requirements for minimum levels of expenditures on research, marketing, maximum price, or other factors.

Like the earlier bill, the reasonable pricing obligation was subject to a possible waiver, with the same procedure.

> (c) WAIVER.—No waiver shall take effect under sub15 section (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

1999 requests to expand global access to federally-funded inventions

On February 16, 1999, Access to Treatment (a Thai NGO) wrote a letter to HHS Secretary Donna Shalala asking for a review of the pricing of ddI, a treatment for HIV that was invented by NIH researchers and licensed to BMS. Access to Treatment wanted HHS to grant Thailand the

right to manufacture generic versions of the drug. On April 20, 1999, Dana Delman, a Policy Analyst for the US FDA Executive Secretariat, sent a letter rejecting the Thai NGO request.

On September 3, 1999, Ralph Nader, James Love, and Robert Weissman wrote to NIH Director Harold Varmus asking that the NIH enter into an agreement with the World Health Organization (WHO), providing a pathway to share access to US government-funded patents on medical inventions. Dr. Harold Varmus rejected the request in a letter sent on October 19, 1999.

The 2000 amendments to the Bayh-Dole Act

On July 31, 2000, Public Citizen filed a lawsuit against the NIH asking for information relating to two previous FOIA requests. Johnson & Johnson joined the litigation as an Intervenor-Defendant. Public Citizen was seeking (1) NIH revenues from royalties based on NIH inventions for both intramural and Cooperative Research and Development Agreement ("CRADA") research, and (2) records concerning the percentage of sales that NIH received as royalties. On October 26, 2000, while the lawsuit was pending, Maria Freire, representing the NIH, denied the Public Citizen Health Research group FOIA request.[20]

On November 1, 2000, Congress passed the Technology Transfer and Commercialization Act of 2000.[21] Among other things, the Act included an extensive rewrite of 35 USC § 209, requiring federal agencies to treat license development plans and reports on the utilization of inventions as confidential business information.

> such [plan/report] shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

Requests to address global access to NIH-funded inventions, 2000 to 2006

On March 17, 2000, the last year of President Bill Clinton's second term in office, Secretary Donna Shalala wrote to Representative Janice Schakowsky, regarding an earlier request from Schakowsky to President Clinton, that the U.S. government "provide the World Health Organization (WHO) with royalty-free rights to health care products for which the United States holds rights to such inventions."[22] Shalala acknowledged there was a legal basis to share rights in inventions, but declined to do so.

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[20] The case was decided in 2002. *Public Citizen Health v. National Institutes of Health*, 209 F. Supp. 2d 37 (D.D.C. 2002). https://casetext.com/case/public-citizen-health-v-national-institutes-of-health
[21] PL Public Law 106-404
[22] https://www.keionline.org/wp-content/uploads/donnashalala2janschakowsky.pdf

In a March 28, 2001 letter, Ralph Nader, James Love, and Robert Weissman wrote to US Secretary of Health and Human Services Tommy Thompson, requesting that HHS enter into an agreement that would enable the World Health Organization, UNICEF and other public health organizations to use US government rights in patents on medicines and other health care inventions. Thompson rejected the request on July 6, 2001, providing this rationale:[23]

> Our experience demonstrates that licensing conditions like the one you suggest will reduce the commercial feasibility of developing new pharmaceutical products and related technologies from federally funded research. If HHS were to impose such terms, especially after a product has been developed, we would eliminate the incentive of the private sector to partner with us. Whether imposed prospectively or retroactively, conditions on patent licenses as you suggest would materially impair the value of such licenses and would deter the private sector from attempting to commercialize inventions underwritten by HHS research or grants. Such a course of action would lead to fewer innovative medicines and therapies reaching patients around the world.

On September 29, 2006, in the 109th Congress, Senator Patrick Leahy (D-VT), introduced S.4040, titled the Public Research in the Public Interest Act.[24] The purpose of this Act was "to promote global public health and America's national security by ensuring that innovations developed at federally-funded institutions are available in eligible developing countries at the lowest possible cost." The Act defined eligible countries as "any country of which the economy is classified by the World Bank as ''low-income'', or ''lower-middle-income''. The mandate was to provide open non-exclusive licenses to federally-funded inventions. The bill proposed a royalty of 2 percent for low income countries and 5 percent for lower-middle-income countries. Senator Leahy's remarks on the bill were entered into the Congressional Record on September 29, 2006.[25]

WHO resolution WHA72.8 on transparency

In 2019, the World Health Assembly (WHA) of the World Health Organization (WHO) adopted resolution WHA72.8, titled "Improving the transparency of markets for medicines, vaccines, and other health products.[26] The United States government was a strong supporter of the resolution throughout the negotiations.

> Noting the importance of both public- and private-sector funding for research and development of health products, and seeking to improve the transparency of such funding across the value chain;

[23] https://www.keionline.org/27500
[24] https://www.congress.gov/bill/109th-congress/senate-bill/4040
[25] https://www.congress.gov/congressional-record/volume-152/issue-125/senate-section/article/S10682-1
[26] https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/a72_r8-en.pdf

. . .

Agreeing that policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there are reliable, comparable, transparent and sufficiently detailed data/1/ across the value chain,

. . .

/1/ Including but not limited to data on: availability, especially in small markets; units sold and patients reached in different markets; and the medical benefits and added therapeutic value of these products.

. . .

1. URGES Member States in accordance with their national and regional legal frameworks and contexts:

(1) to take appropriate measures to publicly share information on the net prices/2/ of health products;
(2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, **costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval**, while ensuring patient
confidentiality;
(3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as **reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives**;
(4) to facilitate improved public reporting of patent status information and the marketing approval status of health products;
(5) to improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management;

/2/ For the purposes of this resolution, “net price,” “effective price,” “net transaction price” or “manufacturer selling price” are the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives.

The misleading use of CRADA statistics to discredit reasonable pricing clauses

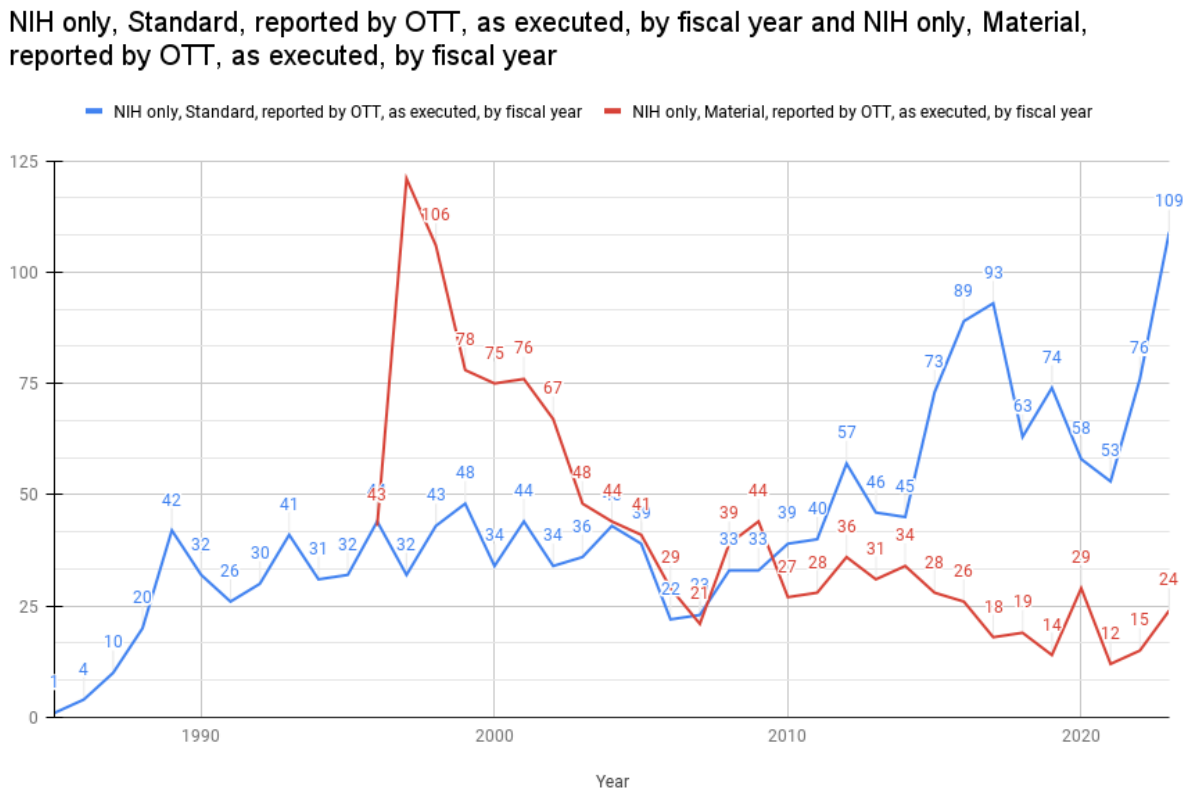
When Congress or the Administration has been asked to consider restoring the reasonable pricing clauses, or using march-in rights to address concerns over pricing, some NIH officials and dozens of persons associated with rights holders have made misleading claims about the impact of the reasonable pricing clause on the number of CRADAs, suggesting that the use of CRADAs exploded when the reasonable pricing clause was eliminated in April 1995. This was done by combining numbers for standard CRADA agreements, with a new category for materials CRADAs, which did not exist until 1996, to show a sharp increase in CRADAs issued for 1996 through 1998. KEI has offered several critiques of this practice, as have Ameet Sarpatwari, Alison K. LaPidus and Aaron S. Kesselheim.

- Jamie Love Responds to Criticism of Knowledge Ecology International Letter, IP Watchdog blog, May 15, 2019.

- James Love, The number of standard and material CRADAs executed by the NIH from 1985 to 2020 and the relationship to NIH reasonable pricing clause. KEI Briefing Note 2021:3, April 5, 2021.

- Ameet Sarpatwari, Alison K. LaPidus, Aaron S. Kesselheim. Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support. Ann Intern Med.2020;172:348-350. [Epub 28 January 2020]. doi:10.7326/M19-2576

The figure below presents the data on NIH-only CRADAs executed, by fiscal year, for both the Standard and the Materials CRADAs, through the end of 2023, the last three years undoubtedly influenced by the COVID-19 pandemic years.



It is useful to note that not all CRADA agreements involve the development of products. It is also worth noting that the reasonable pricing clause in the years 1989 to 1995 was also inserted in patent licenses. Industry lobbyist Joe Allen and then-NIH official Mark Rohrbaugh discussed this in a 2016 email exchange, which unfortunately is quite hard to read in the way the NIH formatted the documents in response to a FOIA request. KEI has some historical data on the granting of exclusive licenses on NIH-owned patents at https://drugdatabase.info/nih-exclusive-licenses/, and a review of that data does not support the claim that the reasonable clause had discouraged industry engagement. But KEI would welcome further clarification of this topic from the NIH, given the challenges of constructing useful statistics from NIH FOIA responses.

KEI comments on proposed exclusive licenses, from 2015 to 2024

From 2015 to the present, KEI, by itself or joined by others, has provided comments on 114 proposed exclusive licenses. On July 22, 2024, Claire Cassedy provided the NIH links to each set of comments, and a summary describing several measures that KEI has asked be included in licenses[27] which is also included here:

[27] Claire Cassedy, KEI Submission to the NIH, regarding previous proposals for terms in exclusive licenses on federally owned inventions, July 22, 2024. https://www.keionline.org/40130

Pricing and Access In USA

1. **Price discrimination/International High Income Country Reference pricing.** (used for most of the comments). The license should place restrictions on charging US residents higher prices than the median prices charged in countries with the seven largest GDP and per capita incomes of 50 percent or more than the United States per capita income.

2. **Pricing cap**. (used for some but not all licenses). In any case, and in addition to any other considerations of what constitutes a reasonable price, the license holder is expected to limit the cost of the products or services to U.S. residents to no more than the lesser of either (a) the average annual per capita income in the United States, or (b) the amount of the average annual per capita income in the United States, per quality adjusted life year (QALY) benefit of the product.

3. **Years of exclusivity.** (used in several licenses). We propose the license include terms that reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the terms stipulate that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the sublicense could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

4. **Alternative years of exclusivity**. (Used in at least one case). The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

5. **Exclusivity outside the US (in high income countries).** We ask that if exclusive rights are granted, that this only be in high income countries, but not in the United States. Or at a minimum, have the U.S. exclusivity shorter than the exclusivity in other high income countries, perhaps after global revenue targets are reached.

Global Access

6. **Global registration and affordability.** The license should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

7. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

8. **Non-exclusivity in low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide some mechanism giving effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

9. **Option for license to WHO.** The license should provide that under 35 USC 202(c)(4), the World Health Organization (WHO) may request from the NIH a license to practice or have practiced on its behalf, the patented invention, subject to the following procedures:
    a. The WHO can identify an important public health concern that is not being met by the holder of the license to the NIH owned invention, including but not limited to the goal of access to medicine for all;
    b. The WHO can explain the steps it has taken to address the issues, including attempts to negotiate voluntary licenses from the holder of the license to the NIH owned invention; and
    c. The WHO can explain how its proposed use and licensing of the invention will address the unmet health need, without unreasonably prejudicing the legitimate interests of the license holder, taking into account the legitimate interests of third parties and the goal of access to medicine for all.

10. **Technology Transfer.** The NIH should include a provision to provide for technology transfer, including licenses to inventions and data, manufacturing know-how, and access to biologic resources, to companies or other entities that could provide access to the technology in developing countries, in the event that licensees do not serve these markets, or if the prices it charges are not reasonably affordable in developing countries.

Transparency

11. **Transparency of R&D outlays.** The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward companies be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

12. **Sales and Access Transparency. (**Units sold by country are the best evidence of access, and tracking sales is important for judging adequacy of incentive). With regard to sales we request an annual report that provides data on the following variables:
    a. Units of sales, by country
    b. Revenue for sales, by country.

13. **Transparency of government subsidies.** With regard to government subsidies for research, we request a report that provides data for the following, by year:
    a. Grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
    b. Tax credits associated with R&D for the product, including the U.S. orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
    c. Other government R&D subsidies.

14. **Acknowledgement of federal funding - publication and publicity. (Stevens Amendment obligation).** The licensee should be required to include, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and the total and proportionate contribution of federal funding to the research and development performed to bring the inventions to market.

15. **WHO Transparency Resolution.** 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.

Suggestions for the implementation of access plans

The range of activities and strategies to mitigate access challenges and expand the reach, and benefit, of drugs, biologics, vaccines, and devices stemming from NIH inventions is pretty broad, limited by one's imagination as much as legal constraints. KEI has proposed dozens of different measures in the 114 comments we have provided to previous requests for comments on proposed exclusive licenses, and typically we are doing so in a very short 15 day period to comment.

In the United States, finding ways to lower prices is important, and it should be a consideration when licensing federally-owned inventions. There are many different ways a license can deal with pricing issues, some dealing with the price itself, and others dealing with the period of exclusivity. None of the rights holders are likely to encourage the NIH to control or lower their prices in any way, but the NIH has a greater responsibility to the public.

The consequences of an aging population

The United States has an aging population. In 2000, 12.4 percent of the population was 65 or older. The US Census estimated that 17.5 percent of the US population was 65 or older in 2023, including 16.1 percent of men and 18.9 percent of women. In six years, 1 of 5 US residents are expected to be 65 or older, and the percentages are expected to increase.

The United States is not alone in facing an aging population. The burdens of providing health care to a growing number of persons out of the labor force requires policy makers to rethink the methods of financing innovation, and the structure of incentives.

Incentives need to be more efficient

The granting of temporary monopolies, through patents in inventions and a proliferation of *sui generis* regulatory monopolies does work, but at a high cost, and often with appalling inequality of access. Governments need to structure incentives to induce the most useful innovation and to do so in cost effective ways, while addressing concerns over equity of access.

When governments fund R&D and seek commercial partners to commercialize inventions, it makes no sense to ignore the role of the government in derisking the development of products, and it is also irresponsible to enforce extensive secrecy regarding everything from licensing terms to the costs of relevant R&D.

Transparency throughout the value chain is important for a variety of obvious reasons. Policy makers need to have access to facts rather than corporate public relations narratives in order to design and evaluate licensing policies and the many incentives available to companies.

Triggers for price reductions or shorter periods of exclusivity

Reference price cap. Within the United States, prices for products based upon a government funded invention should normally be no more than the median price for other high income countries with large economies. There could be exceptions, but if so, a manufacturer would need to present a compelling rationale.

Excessive revenues. The funding agency should have a model for when revenues from a product are excessive, which would trigger price reductions or reductions in the term of exclusivity. Such a model would ideally be somewhat nuanced, and informed by data and realistic assumptions regarding the risks and costs of development, based upon the type of product, the stage of development at the time of licensing, and some assessments of the therapeutic relative value of the Intervention. In the past, KEI has proposed for some products that after the first $1 billion in global sales, the term of exclusivity be reduced one year for each additional $0.5 million in revenue, but also suggested that the NIH could use different parameters. Whatever parameters are used, they should be informed by some data on development costs. The NIH itself funds and conducts trials, and can require reports on utilization of inventions, and should be in the business of collecting and publishing data on development costs, to inform whatever policies it embraces. Focusing more on revenues and less on prices is particularly important for products where the prices per QALY or similar metrics are not helpful, such as for treatments with either very large or very small patient populations, or products that treat chronic conditions rather than provide cures. For example, for drugs to treat cancer using familiar mechanisms, the NIH could assign different benchmarks for revenues for products that were in pre-clinical, Phase I, II or III stages of development, with the earlier stages of development having higher revenue thresholds.

Unfavorable placement on formularies. For products where health insurance is the primary payer in the United States, there should be a trigger if products end up with access restricted by formularies, because of high prices.

Failure to provide for access for persons without insurance. For some products, manufacturers should be required to have access programs for persons who are without adequate insurance.

Affordability in developing countries. In developing countries, the funding agency could give manufactures the flexibility to set prices, but only if the manufacturer could demonstrate the products are reasonably affordable in the countries. Here having data on the units sold in countries will often be the best evidence of access.

Emergencies/exceptional circumstances. The NIH should have the authority to invoke exceptional obligations on license holders in exceptional circumstances, such as in an emergency.

These are tests that can be evaluated objectively, and the public should have the opportunity to comment on the need to invoke a government action.

Regulating the term of exclusivity

Section 209 of the Bayh-Dole Act requires agencies to limit the scope of rights to that which is reasonably necessary to induce investments. In the past, the NIH and other federal agencies typically negotiated the years of exclusivity.

The ANNEX on the term of exclusivity for exclusive licenses includes 129 notices in the Federal Register from 1979 to 1991 where the published notice either provides the number of years of exclusivity (57 notices), or describes the term as limited in duration as a “limited number of” years or a “limited period of time” (72 notices). Other notices are silent on the term of the license, even though some are also for a limited duration of exclusivity. For example, the Federal Register notice for the Bristol-Myers ddI exclusive patent license (54 FR 26071) is silent on the term of exclusivity, while, as discussed above, the actual term of exclusivity was limited. For the Federal Register notices that give a term, the most common is five years, and the longest term mentioned is 10 years.

In recent years the NIH apparently routinely grants life of patent licenses, even when it is obvious that the long period of exclusivity is an unnecessary and excessive grant of monopoly rights. For example, when the NIH licensed the rights to Yescarta to Gilead, or when the NIH proposed providing exclusive rights to the drug Ebanga (for the treatment of Ebola) to Ridgeback, after the drug had already obtained FDA approval.[28]

If the NIH feels confident that a company will have made sufficient profits to justify its investments in the development of a licensed product before the patent expiration, and if a loss of exclusivity is sufficient to enable generic competition, limiting the number years of exclusivity is often easier than calculating a price. In some other cases, such as a product that has a challenging regulatory pathway and a small client population, it may be necessary to address the price itself.

Regulatory pathways, manufacturing know-how and access to biologic resources

For products with challenging regulatory pathways, complex manufacturing or proprietary cell lines, the NIH should have the authority to compel ancillary measures that may be necessary to enable the supply of a generic product. One useful and recent model for this is the European

[28] Assuming the proposed exclusive license was executed by the NIH following comments opposing the license modification.

Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))[29]. These are recitals 32a and 32b from the current version of the regulation.

> (32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration. It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee's interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. While this Regulation requires the disclosure of trade secrets only when they are strictly necessary in order to achieve the purpose of the Union compulsory licence, it should be interpreted in such a manner as to preserve the protection afforded to trade secrets under Directive (EU) 2016/943. The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure. Those appropriate measures may consist of model contractual terms, confidentiality agreements, strict access protocols, technical standards and the application of codes of conduct. Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory license should be considered to be unlawful within the meaning of that Directive.
>
> (32b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing.

[29] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0143_EN.html

While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.

Standard templates of access plans

The NIH should publish standard templates of access plans that the NIH would consider acceptable, to apply in different situations. For example, a template for a small molecule HIV drug may be different from one for a new cell or gene therapy, and the template for a platform technology, like CRISPR editing tools or mRNA manufacturing technologies. The template for a diagnostic test might be different from the template for a drug or a vaccine.

The NIH should allow all licensees to propose alternative plans, but only if the NIH agrees they are adequate substitutes. To the extent possible, both the standard templates and the negotiated alternatives should be public. This is important in evaluating the initiative, but also in enabling the public to benefit from any rights that the public has in the agreement. In the COVID-19 Other Transactions Authority (OTA) contracts, some march-in provisions were redacted and kept secret by the funding agencies, making it impossible for the public to know when, if or how they might benefit from the provisions.

Waiver of access plans obligations

KEI encourages the NIH to provide the possibility of waiving the obligation for an access plan, when appropriate and in the public interest, and there will be instances where a compelling case will be made to do so. Rather than make the access plans very weak so that universal mandates are acceptable, be more ambitious for the access plans, but balance this with the possibility of a waiver, when needed. However, like the earlier legislative proposals on the reasonable pricing clause, require that any waiver only be granted after public notice, setting out the rationale for the waiver, and allowing the public to comment on the waiver.

Increase royalties for licenses that do not have access plans

The NIH has been licensing its technologies on concessionary terms, often at 1.5 percent royalties for start-up licenses or 4 percent for other licenses. The NIH should have significantly higher royalties for any license that does not have an acceptable access plan, and in particular, royalties should scale upwards for products that have very large global revenues.

Require standardized reporting on utilization

The reporting on utilization should be standardized in topics such as units sold, prices, and revenues, and in particular on the reporting on investments in R&D related to the product using the patented invention. Standards for reporting R&D outlays are particularly important given the

historical confusion over how these numbers are reported. For example, out-of-pocket costs should be reported without adjustments for risks or capital costs, and overheads should follow standard conventions. The costs of acquiring intellectual property rights should be listed separately, as should stock options to senior management. The NIH should use this data to publish statistics on the costs of developing products, and use the same standards for R&D investments funded both intramural and extramural by the NIH, and other federal agencies should be encouraged to participate.

Propose amendments to statutes on confidentiality

The 2000 amendments to Section 209 of the Bayh-Dole Act create a zone of secrecy over the licensing of federally-patented inventions that is appalling. The NIH needs to propose amendments to restore the more flexible approach taken in the 1980 Act, and ensure that the agency can publish at least portions of the development plans, the access plan and the annual utilization reports, including by providing information consistent with WHO norms set out in WHA72.8.

Make the pledges enforceable (through careful drafting)

The access plan will be seen as a pledge. Professor Jorge L. Contreras is a professor at the University of Utah with expertise in patent pledges. Professor Conteras has recently shared a paper examining the challenges of enforcing such pledges. A review of his paper by Arianna Schouten is included in ANNEX 1 below.

Consider expanding the obligations for access plans to extramural-funded projects

Clearly most of the NIH-funded research is undertaken by non-federal researchers and organizations. The intramural initiative can be an important test of how such access plans can be implemented, but the longer term goal should be to extend the obligations to the extramural programs.

Concluding comments

The NIH is to be commended for proposing to reintroduce access obligations on NIH-licensed inventions. If history is a guide, there will be considerable resistance from rights holders and investors, many of whom have profited enormously from obtaining exclusive rights to NIH-funded and developed technologies.

To make a policy sustainable, the NIH should ensure that the access plans provide significant health benefits for patients, and that the implementation is transparent.

ANNEX 1: Chapter Review: Patent Pledges As Portfolio Management Tools: Benefits, Obligations And Enforcement

Arianna Schouten
Knowledge Ecology International (KEI)
July 22, 2024

Jorge L. Contreras is a legal scholar and professor at the University of Utah. He is a recognized legal scholar with expertise in patent pledges. His interest in patent pledges is connected to the role of how patent pledges have increasingly been used to make voluntary public commitments to limit the enforcement and other exploitation of patents.

He has recently shared a chapter on patent pledges that explores the impact of patent pledges on the organizations that make them. In his chapter, he distinguishes three types of patent pledges based on their legal structure.[30]

- **Type A - Unilateral Covenants**: These are one-sided commitments by the pledgor without requiring any return commitment. Enforcement is typically based on promissory estoppel. For this, he cites Moderna's 2020 pledge as an example ("while the pandemic continues, Moderna will note enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic").
- **Type B - Bilateral Commitments**: These involve contractual arrangements with specific entities like SDOs (Standards Development Organizations) and are enforceable under contract law.
- **Type C - Public Licenses**: These are grants of license interests to the public, enforceable under license theory.

Type A pledges are made directly to the public generally and all members of the public are entitled to benefit. Type B pledges are made to a specific contractual counterparty or

[30] Contreras, J.L., 2023. Patent Pledges as Portfolio Management Tools: Benefits, Obligations and Enforcement. A Modern Guide to Patenting. Challenges of Patenting in the 21st Century (K. Blind, N. Thumm, eds., Edward Elgar: 2024, Forthcoming), University of Utah College of Law Research Paper, (562). Accessible at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4473807

organization.

Table 1

Patent Pledge Taxonomy Based on Legal Structure

Pledge Type	Examples	Legal/Enforcement Basis
A. Unilateral Covenant	Tesla, IBM, Google, Moderna IETF licensing commitments	Promissory estoppel
B. Bilateral Commitment	SDO membership agreements IEEE, ETSI licensing commitments	Contract
C. Public License	Open COVID Pledge	License

Table source: Contreras, J.L., 2023. Patent Pledges as Portfolio Management Tools: Benefits, Obligations and Enforcement. In A Modern Guide to Patenting. Challenges of Patenting in the 21st Century (K. Blind, N. Thumm, eds., Edward Elgar: 2024, Forthcoming), University of Utah College of Law Research Paper, (562)

Enforceability

Drawing on his taxonomy, Contreras distinguishes the conditions (if any) under which a pledge beneficiary may enforce the pledge obligation.

- **Type A - Unilateral Covenants:** Type A pledges can have legal effect with common law promissory estoppel, which requires the demonstration of a detrimental reliance on the pledge, although this can be difficult to prove.
- **Type B - Bilateral Commitments:** Type B enforcement is relatively clear under ordinary principles of contract law, at least in common law jurisdictions. However, issues can arise with third-party beneficiaries who may not have direct contractual relationships but are the intended beneficiaries from the pledge.
- **Type C - Public Licenses:** Type C pledges, which involve public licenses, are enforceable as they grant an interest in property akin to open-source software licenses, which have been validated and enforced by courts.

Challenges of Enforcement of Pledges

There are a number of reasons why the different types of pledges, their enforceability, and the general use of pledges are important. One reason that patent pledges require further examination is due to the legal challenges associated with the enforceability of such pledges.

Some of the legal challenges are as follows:

- The legally binding nature of unilateral covenants (Type A pledges); and
- The lack of direct contractual privity for third parties that seek to enforce commitments (such as seen in Type B pledges); and

- As seen in Moderna's legal dispute, the vague language of their pledges has led to significant legal disputes.

Another important topic worthy of further scrutiny is the enforcement mechanism and remedies. While remedies can vary, the specific performance of the pledge is often more aligned with the purposes of the pledge. However, courts may opt to grant monetary damages instead of enforcing specific performance. It is crucial that the NIH's plan also recognizes the types of damages and the enforcement body.

Why is this important?

Moderna's case during the COVID-19 pandemic, involving its pledges and subsequent attempt to revoke them, highlights how pledge-like legal obligations are often not taken seriously, as Contreras points out. It is important that any pledge-like access model that the NIH develops considers this challenge and ensures that it is appropriately addressed. Some important aspects which would be important to include are:

- **Clear and specific language**: Terms of access plans need to be unambiguous and precisely defined to avoid the pitfalls seen in Moderna's legal case.
- **Structured commitments**: Categorization of access plans in the form of bilateral commitments can allow the NIH to draw on contract law and allow for legal certainty and predictable enforcement.

Finally, we recommend that the NIH, when developing their access plan, review Contreras' paper, thereby the NIH can make an informed decision on how to craft their access plans and ensure they are grounded in an unambiguous, enforceable, and predictable way.

ANNEX 2: Exclusive Licenses on federally owned inventions for which the Federal Register notice indicates a limited number of years of exclusivity

Agency	FR Cite	Year	Term of license
Air Force	47 FR 40463	1979	10 years
DOE	46 FR 29495	1979	10 years
DOE	46 FR 37545	1979	10 years
Navy	46 FR 32062	1979	10 years
Navy	48 FR 5588	1979	10 years
Navy	49 FR 18350	1979	10 years
Navy	49 FR 46580	1979	10 years

PHS	48 FR 35172	1979	10 years
NTIS	47 FR 31717	1979	10 years from the effective date of the license agreement
HHS	47 FR 14223	1979	5 years
NAVY	44 FR 18724	1979	5 years
NAVY	44 FR 28036	1979	5 years
NAVY	44 FR 28036	1979	5 years
NAVY	44 FR 37329	1979	5 years
NAVY	44 FR 41285	1979	5 years
NAVY	44 FR 54538	1979	5 years
NAVY	44 FR 59583	1979	5 years
NAVY	44 FR 59583	1979	5 years
NTIS	46 FR 22782	1979	5 years from the date of New Drug Approval by the FDA of the products embodied in the invention
NTIS	46 FR 24223	1981	5 years after the invention is put into practice on a commercial scale
NTIS	46 FR 25336	1981	5 years from the date of New Drug Approval by the FDA but not more than eight years from the effective date of the license agreement
NTIS	46 FR 26674	1981	5 years from the effective date of the license agreement
NTIS	46 FR 26674	1981	5 years from the effective date of the license agreement
NTIS	46 FR 28892	1981	5 years from the date of the license agreement
NTIS	46 FR 31042	1981	5 years from the date of the first commercial sale
NTIS	46 FR 31916	1981	5 years from the date of the first commercial sale
NTIS	46 FR 35952	1981	5 years from the date of regulatory approval or first commerical sale but not to exceed eight years from the date of license agreement
NTIS	46 FR 37305	1981	5 years from the date of the first commercial sale
NTIS	46 FR 37305	1981	5 years from the date of the first commercial sale
NTIS	46 FR 39638	1981	5 years from the date of the first commercial sale
NTIS	46 FR 39639	1981	revocable after five years if the products embodied in the invention have not been made commercially available to the public
NTIS	46 FR 40916	1981	5 years from the date of the first commercial sale
NTIS	46 FR 56858	1981	5 years from the date of the first commercial sale
NTIS	46 FR 8073	1981	5 years from the date of Government regulatory approval for sale in the United States and five years from first commercial sale in each licensed foreign territory, but not exceeding eight years from the effective date of the license agreement
PHS	46 FR 14972	1981	5 years from the date of first commercial sale in the United States of America, or eight (8) years from the date of the license, whichever occurs first,
PHS	46 FR 32509	1981	5 years
PHS	46 FR 55564	1981	5 years

PHS	49 FR 30799	1981	5 years
PHS	50 FR 42228	1981	5 years
PHS	50 FR 42228	1981	5 years
PHS	52 FR 6393	1981	5 years
PHS	53 FR 11562	1981	5 years
PHS	48 FR 53177	1981	5 years (in addition to existing 5 year period that came from an extension of original 3 year period)
HHS	47 FR 8408	1981	5 years from date of first commercial sale
NTIS	47 FR 21911	1981	5 years from date of first commercial sale
PHS	50 FR 36676	1981	5 years from date of first commercial sale or 8 years from the date of the license, whichever comes first.
HHS	47 FR 40488	1982	5 years from first sale, or 8 years from date of license
NTIS	47 FR 7720	1982	5 years from grant of license
PHS	48 FR 1114	1982	5 years from the date of first commercial sale in the United States of America, or 8 years from the date of the license, whichever occurs first
PHS	48 FR 22640	1982	5 years from the date of first commercial sale of the product or 10 years from the date of the license, whichever comes first
NAVY	44 FR 22504	1982	6 years
Navy	46 FR 46986	1982	7 years
PHS	48 FR 5313	1982	7 years (requested; in addition to existing exclusivity of 5 years from date of first commercial sale that came from extension of original 3 year period)
NTIS	47 FR 30805	1982	7 years from date of issue of a value claim, and no more than 14 years from date of license
DOE	46 FR 35141	1982	Duration of the remaining term of the patent, but less than 10 years
NTIS	44 FR 52857	1982	5 years from first commercial sale in any licensed foreign country, no longer than eight years from the effective date of the license agree as to any country
NTIS	46 FR 10522	1982	5 years from the date of New Drug Approval by the Food and Drug Administration of the products embodied in the invention (but not more than eight years from the effective date of the license agreement).
DOE	51 FR 44941	1982	limited duration
NASA	44 FR 2042	1982	limited number of years
NASA	44 FR 2043	1982	limited number of years
NASA	44 FR 2043	1982	limited number of years
NASA	44 FR 2043	1982	limited number of years
NASA	44 FR 52385	1982	limited number of years
NASA	44 FR 52386	1982	limited number of years
NASA	44 FR 64923	1982	limited number of years

NASA	44 FR 68539	1983	limited number of years
NASA	46 FR 20336	1983	limited number of years
NASA	46 FR 20336	1983	limited number of years
NASA	47 FR 12000	1983	limited number of years
NASA	47 FR 12001	1983	limited number of years
NASA	47 FR 12001	1983	limited number of years
NASA	47 FR 15670	1983	limited number of years
NASA	47 FR 15671	1983	limited number of years
NASA	47 FR 24670	1983	limited number of years
NASA	47 FR 24670	1983	limited number of years
NASA	47 FR 32667	1983	limited number of years
NASA	47 FR 41675	1983	limited number of years
NASA	47 FR 4779	1983	limited number of years
NASA	47 FR 4779	1983	limited number of years
NASA	47 FR 7553	1983	limited number of years
NASA	48 FR 19497	1983	limited number of years
NASA	48 FR 19497	1983	limited number of years
NASA	48 FR 24230	1983	limited number of years
NASA	48 FR 30493	1983	limited number of years
NASA	48 FR 31926	1983	limited number of years
NASA	48 FR 34821	1983	limited number of years
NASA	48 FR 34821	1983	limited number of years
NASA	48 FR 34821	1984	limited number of years
NASA	48 FR 39708	1984	limited number of years
NASA	48 FR 46455	1984	limited number of years
NASA	48 FR 54548	1984	limited number of years
NASA	48 FR 54549	1984	limited number of years
NASA	48 FR 9093	1984	limited number of years
NASA	48 FR 9094	1984	limited number of years
NASA	48 FR 9094	1984	limited number of years
NASA	48 FR 9094	1984	limited number of years
NASA	49 FR 18054	1984	limited number of years
NASA	49 FR 18054	1984	limited number of years
NASA	49 FR 31513	1984	limited number of years
NASA	49 FR 31513	1984	limited number of years

NASA	49 FR 31514	1984	limited number of years
NASA	49 FR 31514	1985	limited number of years
NASA	49 FR 3703	1985	limited number of years
NASA	49 FR 37678	1985	limited number of years
NASA	49 FR 37679	1985	limited number of years
NASA	49 FR 5703	1985	limited number of years
NASA	50 FR 21672	1985	limited number of years
NASA	50 FR 21672	1985	limited number of years
NASA	50 FR 24967	1985	limited number of years
NASA	50 FR 24967	1985	limited number of years
NASA	50 FR 41430	1985	limited number of years
NASA	50 FR 7016	1986	limited number of years
NASA	51 FR 12946	1986	limited number of years
NASA	51 FR 13301	1986	limited number of years
NASA	51 FR 19426	1986	limited number of years
NASA	51 FR 19427	1986	limited number of years
NASA	51 FR 28145	1986	limited number of years
NASA	51 FR 30451	1986	limited number of years
NASA	52 FR 30981	1986	limited number of years
NASA	52 FR 33669	1987	limited number of years
NASA	53 FR 17519	1987	limited number of years
NASA	54 FR 21140	1987	limited number of years
NASA	56 FR 10286	1987	limited number of years
NASA	56 FR 58405	1987	limited number of years
NASA	44 FR 2043	1988	limited number of years
NASA	52 FR 21632	1988	limited number of years
NASA	49 FR 48836	1989	limited period of time
NASA	51 FR 41034	1991	limited period of time
NASA	52 FR 7047	1991	limited period of time