June 6, 2017

Dr. Thomas E. Price
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
via email: Thomas.Price@hhs.gov

Dear Secretary Price:

Beginning in 2013, researchers — working on grants from the National Institutes of Health (NIH) — filed for a number of patents on **Clustered regularly interspaced short palindromic repeats** (**CRISPR).** The past two years there have been a number of patent applications filed and granted on CRISPR technologies, and also concerns about patents obstructing the advancement of science and about the development and pricing of new products including drugs and vaccines.

We are writing to ask the Department to develop a policy on the licensing of federally-funded CRISPR patented inventions.

In part 1, we review the importance of the CRISPR technology. Part 2 discusses the public interest in non-discriminatory licensing of CRISPR patent. In part 3, we make suggestions regarding the policies that would advance the public interest, and ensure that those inventions are "available to the public on reasonable terms"[1] and that the licenses are designed to achieve the purposes and objectives of the Bayh-Dole Act[2] and to maximize the benefits to taxpayers and patients.

[1] 35 USC § 201(f).
[2] 35 U.S.C. §§ 200 *et seq*.

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Part 1. The CRISPR technology has important research and medical applications.

Our genes have been called the instruction manual to life. They determine everything from one's eye color to one's susceptibility to developing certain diseases. By being able to manipulate genes we could potentially correct the faulty ones that give rise to orphan diseases, such as spinal muscular atrophy, turn off genes that cause cancer, or even instruct our immune cells to destroy tumors.

Before CRISPR, editing genes was a very time consuming process that required complex systems, such as zinc fingers. When it came to whole organisms like mice, editing genes would take numerous rounds of breeding, many years, and a lot of luck. Even stably silencing genes in single cells could take several months using very common shRNA protocols.

What makes the CRISPR system superior is its simplicity, versatility, and precision. CRISPR is made of two components: the enzyme that cuts the gene, and the RNA template that instructs CRISPR where exactly to cut. Furthermore, this system can be used and adapted for any organism.

Gene editing is so essential to biomolecular research that the ramification of the CRISPR technology will touch every field of biology and medicine. Gene editing is used in virtually every biomedical lab and is among the first thing researchers teach their trainees to master (*i.e.*, using restriction enzymes, bacterial transformation, transfection, and site directed mutagenesis). Designing physiologically relevant organisms that model human diseases is a bedrock of medical research and drug discovery. Without these cellular and animal disease models, we cannot study disease mechanisms, nor could we screen vast libraries of molecules for potential medicines. There are already many gene-editing CRISPR tools and protocols demonstrating how to generate lentiviral CRISPR libraries or produce 'knock-out' animal models, such as in mice and fruit flies.[3, 4, 5, 6, 7]

The CRISPR-cas9 system is 4 years old and already we are seeing new innovations.[8, 9]

CRISPR technology has already been widely adopted by researchers, and "[a]pplications … are appearing at a furious pace, and gathering momentum toward therapeutic use in human cells."[10] CRISPR is also "[f]aster, cheaper, and easier to use"[11] than older gene editing methods.

Scientists have also used the CRISPR technology to engineer mosquitoes to become resistant to malaria. This resistance is even passed to subsequent generations when the engineered mosquitoes mate with 'normal' (wild type) mosquitoes. This elegant solution not only prevents mosquitoes from spreading malaria, but also avoids exterminating an important food source for birds and other insectivores.[12]

HIV/AIDS could also be eradicated using CRISPR. HIV integrates into our genes, forcing people living with the virus to stay under treatment their whole lives. Currently, resources are directed towards eliminating HIV cellular reservoirs in the human body using, for example, HDAC inhibitors. However, with CRISPR, we could simply cut out pieces of the embedded viral

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[3] Addgene CRISPR/Cas9 Guide. https://www.addgene.org/crispr/guide/
[4] Genetic Editing with CRISPR. https://research.cornell.edu/news-features/genetic-editing-crispr
[5] CRISPR-Cas: A Laboratory Manual. http://www.cshlpress.org/pdf/sample/2016/crispr-cas/CRISPR-CasFM.pdf
[6] CRISPR Genome Engineering Resources. http://www.genome-engineering.org/crispr/
[7] E-CRISP Design of CRISPR constructs. http://www.e-crisp.org/E-CRISP/
[8] Cong L et al. Multiplex genome engineering using CRISPR/Cas systems. Science. 2013 Feb 15;339(6121):819-23.
[9] Mali P et al. RNA-guided human genome engineering via Cas9.Science. 2013 Feb 15;339(6121):823-6.
[10] Caitlin Smith, "Editing the Editor: Genome Editing Gets a Makeover with CRISPR 2.0," *Science Magazine*, Jan. 13, 2017, http://www.sciencemag.org/custom-publishing/technology-features/editing-editor-genome-editing-gets-makeover-crispr-20.
[11] Id.
[12] Gantz VM et al. Highly efficient Cas9-mediated gene drive for population modification of the malaria vector mosquito Anopheles stephensi.Proc Natl Acad Sci U S A. 2015 Dec 8;112(49):E6736-43.

genome, forever silencing the virus.[13] Of course, this technology can be extended to other human viruses such as hepatitis B virus, human papillomavirus, and herpes virus.[14, 15, 16]

CRISPR had been used to knockout porcine endogenous retroviruses, making future transplants with porcine organs much safer, and thus addressing the shortage of organs for transplantation.[17] Proof of concept in animal models have already been published where CRISPR is used to remove genetic diseases such as Duchenne muscular dystrophy from germline DNA (sperm/egg).[18]

The CRISPR system is maturing quickly and its impact is stretching beyond biomedical research and into drug discovery and manufacturing. It promises to become as fundamental a molecular tool in drug development as the hammer is to building a house. When CRISPR is combined with current molecular tools such as high throughput functional screens, for example, CRISPR-cas9 can be adapted to comprehensively identify new cancer drug targets.[19] CRISPR based genomic screens (CRISPRi, CRISPRa) are also important in identifying disease mechanisms and epidemiological trends (polymorphisms).[20, 21]

Pharmaceutical giants such as Novartis, Bayer, and AstraZeneca have already adopted CRISPR technology into their drug discovery platforms for everything from cancer to blood disorders to blindness, and the technology is behind many new start ups.[22, 23, 24, 25, 26]

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[13] Hu W. RNA-directed gene editing specifically eradicates latent and prevents new HIV-1 infection. Proc Natl Acad Sci U S A. 2014 Aug 5;111(31):11461-6.
[14] Wang J, Quake SR. RNA-guided endonuclease provides a therapeutic strategy to cure latent herpes viridae infection.Proc Natl Acad Sci U S A. 2014 Sep 9;111(36):13157-62.
[15] Kennedy EM et al. Inactivation of the human papillomavirus E6 or E7 gene in cervical carcinoma cells by using a bacterial CRISPR/Cas RNA-guided endonuclease. J Virol. 2014 Oct;88(20):11965-72.
[16] Kennedy EM et al. Suppression of hepatitis B virus DNA accumulation in chronically infected cells using a bacterial CRISPR/Cas RNA-guided DNA endonuclease.Virology. 2015 Feb;476:196-205.
[17] Yang L et al. Genome-wide inactivation of porcine endogenous retroviruses (PERVs).Science. 2015 Nov 27;350(6264):1101-4
[18] Long C et al. Prevention of muscular dystrophy in mice by CRISPR/Cas9-mediated editing of germline DNA. Science. 2014 Sep 5;345(6201):1184-8.
[19] Shi J et al. Discovery of cancer drug targets by CRISPR-Cas9 screening of protein domains. Nat Biotechnol. 2015 Jun;33(6):661-7
[20] Gilbert LA. Genome-Scale CRISPR-Mediated Control of Gene Repression and Activation. Cell. 2014 Oct 23;159(3):647-61.
[21] Shalem O, Sanjana NE, Zhang F. High-throughput functional genomics using CRISPR-Cas9. Nat Rev Genet. 2015 May;16(5):299-311.
[22] Novartis, CRISPR genome editing fuels cancer drug discovery. https://www.nibr.com/stories/nerd-blog/crispr-genome-editing-fuels-cancer-drug-discovery
[23]Megget K. Crispr goes commercial. Royal Society of Chemistry, Chemistry World. 2016https://www.chemistryworld.com/business/crispr-goes-commercial/9359.article
[24]Orcutt M. Big Pharma Doubles Down on CRISPR for New Drugs. MIT Technology Review. 2016. https://www.technologyreview.com/s/545366/big-pharma-doubles-down-on-crispr-for-new-drugs/)
[25] Swaminathan N. CRISPR-based startups are rushing to IPO and don't seem to care that we don't know who officially owns CRISPR, Quartz, 2016. https://qz.com/813552/crispr-therapeutics-ipo-raised-56-million-but-the-companys-future-is-in-jeopardy-because-of-the-crispr-patent-war/

Industries that rely on bacterial systems, such as in food processing (yogurt, cheese, etc.) or pharmaceutical and biofuel production (ethanol) may use CRISPR to make their bacterial stocks more resistant to contamination and increase productivity. [27]

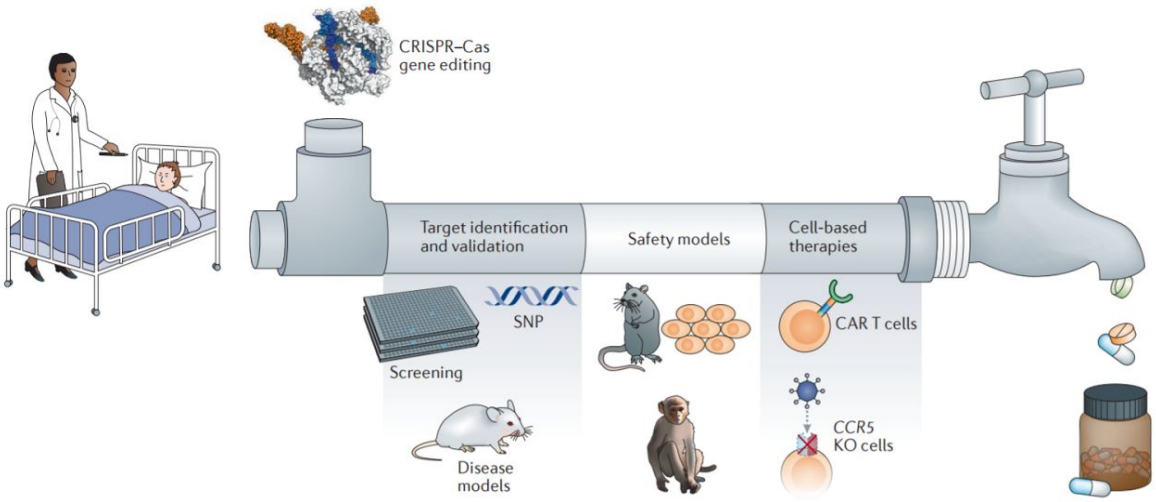
Several clinical trials using CRISPR are set to begin in 2017 in the area of cancer immunotherapy.[28] Specifically, scientists in the United States and China are using CRISPR to engineer immune cells to fight cancer.[29]

Some have argued that CRISPR is spurring the kind of fruitful competition in R&D that has not been seen since the genome project, or even since Sputnik and the moon landing.[30]

CRISPR is a striking example of how allowing a broad or non-exclusive access to an essential technology can spur innovation at an incredible rate. Scientists, doctors and drug developers everywhere are already using and improving the CRISPR technology. Since 2013, over 4800 scientific articles related to CRISPR have appeared on pubmed. The impact of this technology parallels the sequencing of the human genome and engineering taq polymerase in PCR. Applying monopoly rights to such a fundamental tool will stifle innovation and slow down the progress to new and better medicines.

[26] Editas Medicine http://www.editasmedicine.com/, Intellia Therapeutics http://www.intelliatx.com/, Eligo Bioscience http://eligo-bioscience.com/, Autum https://www.atum.bio/ etc.
[27] Pak E. CRISPR: A game-changing genetic engineering technique. Harvard, Science in the News. 2014. http://sitn.hms.harvard.edu/flash/2014/crispr-a-game-changing-genetic-engineering-technique/
[28] First CRISPR clinical trial gets green light from US panel. http://www.nature.com/news/first-crispr-clinical-trial-gets-green-light-from-us-panel-1.20137
[29] CRISPR gene-editing tested in a person for the first time. http://www.nature.com/news/crispr-gene-editing-tested-in-a-person-for-the-first-time-1.20988?WT.mc_id=TWT_NatureNews
[30] China Has Launched the First-Ever CRISPR Gene-Editing Trial in Humans. http://fortune.com/2016/11/15/first-crispr-trial-humans-china/

Figure 1: Pipeline of CRISPR–Cas- assisted drug discovery (From Fellmann C *et al.*)[31]



Part 2. There is a public interest in open, non-discriminatory licensing of CRISPR patents on reasonable terms.

Patents on CRISPR cover the editing of over 20,000 genes in a variety of fields, from basic research to new cancer therapies. The use of exclusive licenses on the certain CRISPR technologies runs contrary to previous federal guidance, and aggressive licensing practices will harm the public by restricting research and development of new CRISPR technologies, hindering the development of products that use the inventions, and by increasing their prices.

1. The CRISPR patent landscape and licensing arrangements.

Key CRISPR patents are held by five universities, one hospital, and one researcher: Massachusetts General Hospital, Duke University, the Broad Institute (joint Harvard and Massachusetts Institute of Technology entity), the University of California, Berkeley, the University of Vienna, and Emmanuelle Charpentier (a French biologist, geneticist, and chemist), all of whom benefited from U.S. government research funding.

The Broad Institute, a joint venture between the Massachusetts Institute of Technology (MIT) and Harvard University, holds the following patents, invented by Feng Zhang in his Broad Institute laboratory:[32]

[31] Fellmann C, Gowen BG, Lin PC, Doudna JA, Corn JE.Cornerstones of CRISPR-Cas in drug discovery and therapy. Nat Rev Drug Discov. 2017 Feb;16(2):89-100.
[32] See here for additional information: http://keionline.org/node/2723.

Table 1: CRISPR patent landscape

Patent No.	Inventors	Assignees	Title	Filing Date
8697359	Feng Zhang	The Broad Institute; MIT	CRISPR-Cas systems and methods for altering expression of gene products	10/15/2013
8771945	Feng Zhang	The Broad Institute; MIT	CRISPR-Cas systems and methods for altering expression of gene products	2/18/2014
8795965	Feng Zhang	The Broad Institute; MIT	CRISPR-Cas component systems, methods and compositions for sequence manipulation	2/18/2014
8865406	Feng Zhang; Fei RAN	The Broad Institute; MIT	Engineering and optimization of improved systems, methods and enzyme compositions for sequence manipulation	3/24/2014
8871445	Le Cong; Feng Zhang	The Broad Institute; MIT; President and Fellows of Harvard College	CRISPR-Cas component systems, methods and compositions for sequence manipulation	4/23/2014
8889356	Feng Zhang	The Broad Institute; MIT	CRISPR-Cas nickase systems, methods and compositions for sequence manipulation in eukaryotes	2/18/2014
8895308	Feng Zhang; Fei RAN	The Broad Institute; MIT	Engineering and optimization of improved systems, methods and enzyme compositions for sequence manipulation	6/2/2014
8906616	Feng Zhang; Le Cong; Patrick Hsu; Fei RAN	The Broad Institute; MIT; President and Fellows of Harvard College	Engineering of systems, methods and optimized guide compositions for sequence manipulation	5/29/2014
8932814	Le Cong; Feng Zhang	The Broad Institute; MIT; President and Fellows of Harvard College	CRISPR-Cas nickase systems, methods and compositions for sequence manipulation in eukaryotes	4/22/2014
8945839	Feng Zhang	The Broad Institute; MIT	CRISPR-Cas systems and methods for altering expression of gene products	4/18/2014

8993233	Feng Zhang; Le Cong; Randall Jeffrey Platt; Neville Espi Sanjana; Fei RAN	The Broad Institute; MIT; President and Fellows of Harvard College	Engineering and optimization of systems, methods and compositions for sequence manipulation with functional domains	12/12/2013
8999641	Feng Zhang; Le Cong; Randall Jeffrey Platt; Neville Espi Sanjana	The Broad Institute; MIT; President and Fellows of Harvard College	Engineering and optimization of systems, methods and compositions for sequence manipulation with functional domains	3/26/2014

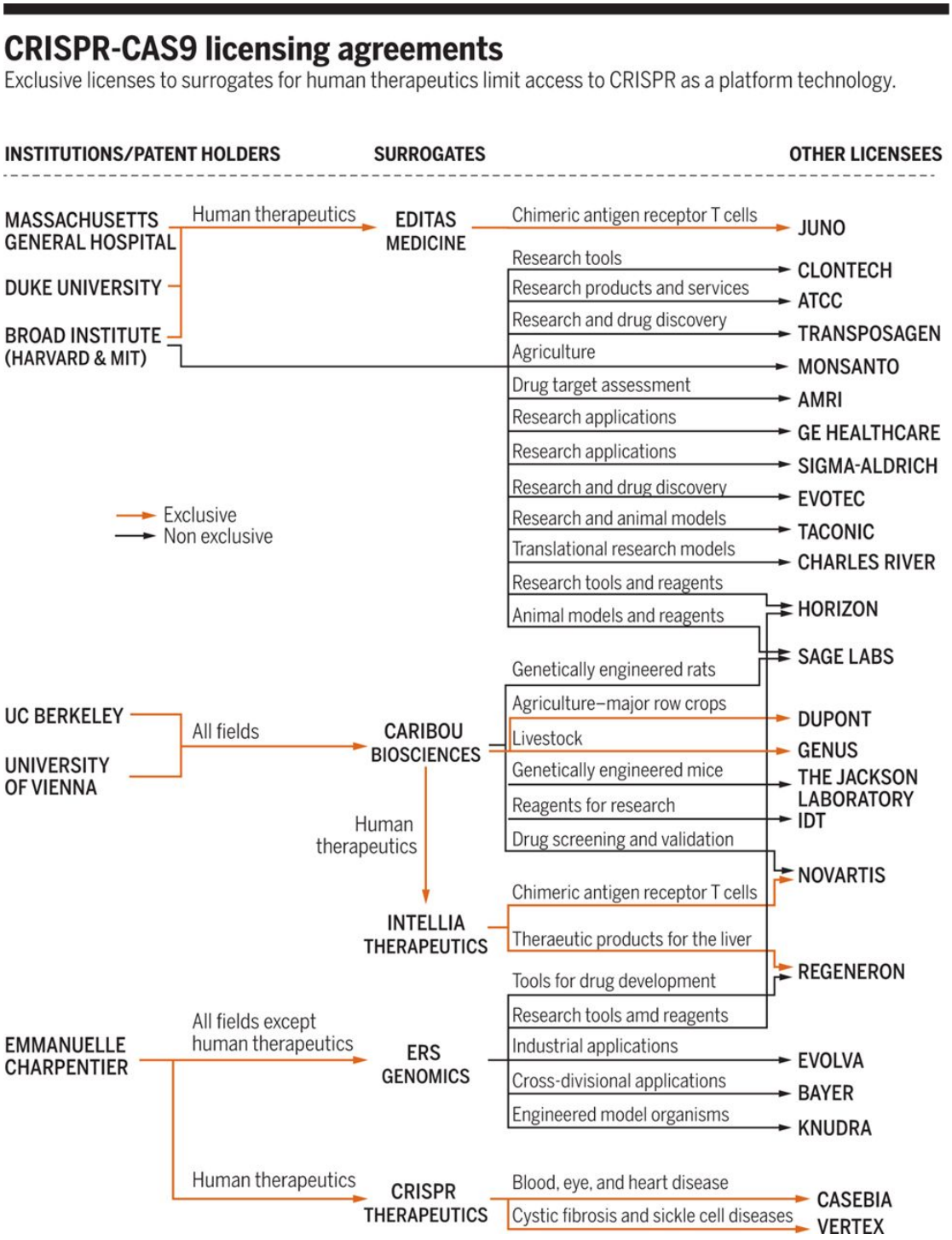
All of the Broad Institute patents declare government rights and funding in the inventions.

UC Berkeley has granted the rights in PCT/US2013/032589 (filed March 15, 2013) — claiming priority in the U.S. provisional applications 61/652,086 (filed May 25, 2012), 61/716,256 (filed Oct. 19, 2012), and 61/765,576 (filed Feb. 15, 2013) — and all following and related patent applications to Caribou Biosciences.[33] The recent interference proceedings at the Patent Trial and Appeals Board covered patent application 13/842,859 (filed March 15, 2013), which claims priority in all of the above U.S. patent applications.[34]

The CRISPR patents and patent applications are licensed for use in human therapeutics through three independent "surrogate" companies: Editas Medicine, Intellia Therapeutics, and CRISPR Therapeutics. Some of the universities directly license CRISPR technologies on nonexclusive terms for non-therapeutic use directly to researchers, while others have additional arrangements involving surrogates. The following figure from a recent article in *Science* by Jorge Contreras and Jacob Sherkow displays the relationships between patent holders, surrogates, and licensees, as well as the types of licenses:[35]

[33] Caribou Biosciences Exclusive License, https://dataverse.harvard.edu/file.xhtml?fileId=2970182&version=1.0.
[34] *Broad Inst. v. U.C. Regents*, Patent Interference No. 106,048 (P.T.A.B. Feb. 15, 2017) (per curiam), https://www.washingtonpost.com/news/speaking-of-science/wp-content/uploads/sites/36/2017/02/DecisionsOnMotions.pdf.
[35] Jorge L. Contreras and Jacob S. Sherkow, "CRISPR, Surrogate Licensing, and Scientific Discovery: Have Research Universities Abandoned Their Public Focus?," *Science* 355, no. 6326 (2017): 698-700.

Figure 2: CRISPR-CAS9 licensing agreements



2. Exclusive licenses on CRISPR are contrary to federal guidance

The National Institutes of Health (NIH) issued a set of principles and practical guidance in 1999 for the recipients of NIH grants and contracts on the dissemination of "biomedical research resources,"[36] particularly research tools. Those principles contextualize the development of federally-funded biomedical research tools within the policy goals and obligations contained within the Bayh-Dole Act.

In interpreting the obligations of contractors under the Bayh-Dole Act, the NIH explained the obligation of federally-funded researchers to ensure broad access to research tools:

> "Generally, recipients are expected to maximize the use of their research findings by making them available to the research community and the public, and through their timely transfer to industry for commercialization."[37]

Moreover, they noted that the right of federal contractors to retain title to federally-funded obligations entailed "corresponding obligations to promote utilization, commercialization, and public availability of these inventions."[38]

However, the NIH warned against the use of exclusive licenses as the primary means for promoting utilization, commercialization, and public availability in the context of research tools:

> "Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention."[39]

CRISPR is a "broadly applicable 'platform' technology — like stem cells or the internet — that could enable innumerable specific applications."[40] The patents on CRISPR held by the universities, as noted above, cover the editing of 20,000-plus genes in the human genome, and are not directed to specific fields of use. The grant of exclusive licenses on the use of CRISPR technologies for use in broad fields of research — such as cancer therapeutics, liver diseases, and agricultural uses — runs contrary to the NIH guidance on the appropriate use of licenses to advance biomedical research and development.

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[36] National Institutes of Health, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72090 (Dec. 23, 1999).
[37] Id. at 72092.
[38] Id. at 72092.
[39] Id. at 72092-93.
[40] Contreras and Sherkow, 700.

3. Exclusive licenses are an unnecessary and inappropriate means to incentivize research using the CRISPR platform.

The widespread use of CRISPR on nonexclusive terms provides ample evidence that exclusive licenses on the gene editing tools are unnecessary to incentivize use, or research using the editing tools.

Of the licensing agreements identified by Sherkow and Contreras, three quarters (21 out of 28) have been on nonexclusive terms, with two companies receiving both exclusive and nonexclusive licenses.

An HHS advisory committee comprised of top public health officials and clinical researchers has also recognized that scientists have independent incentives — apart from patents and exclusive licenses — to conduct biomedical research, particularly in the area of genetic research, including the "desire to advance understanding, help their patients by developing treatments for disease, advance their careers, and enhance their reputations."[41]

Exclusive licenses are inappropriate in promoting the development of CRISPR technologies because they "could rapidly bottleneck the use of CRISPR technology to discover and develop useful human therapeutics,"[42] as well as technologies in other fields. Sherkow and Contreras argued that broad licensing agreements — for example, in the field of Chimeric Antigen Receptor T cell (CAR-T) cancer immunotherapy, which Juno Therapeutics has an exclusive license on from Editas Medicine — could prevent the use of CRISPR for research in areas where the exclusive licensee does not have the bandwidth to develop the technology, particularly in the field of rare disease drugs.[43]

4. Exclusive licenses on CRISPR patents will limit patient access.

The HHS advisory committee found that monopoly conditions on genetic test technologies have resulted in higher prices and limited patient access. For example, exclusivities on the BRCA cancer test and the Canavan disease genetic test resulted in higher prices above a competitive market rate. In the case of the BRCA test, the high prices have created barriers to the use of the test, or the timely use of the test, even for high risk patients. The Canavan patent holder "used

[41] Secertary's Advisory Committee on Genetics, Health, and Society, Department of Health and Human Services, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (2010), 20, http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf (hereinafter "Secretary's Advisory Committee Report").
[42] Contreras and Sherkow, 698.
[43] Contreras and Sherkow, 700.

their patent monopoly to establish restrictive license conditions and sought license fees that exceeded what laboratories offering similar tests for Tay-Sachs disease were willing to pay."[44]

Clinical access was also limited by the licensing practices of patent holders on genetic tests,[45] and, in cases where "an exclusive-rights holder narrowed or cleared the market of competing tests through patent enforcement,"[46] patients also faced limited access. For example, the patent holders for tests for the hearing loss gene *GJB2* and for familial LQTS have used their monopoly rights to force competitors out of the market.[47]

CRISPR has application both in genetic testing and in therapeutics. Exclusive licenses on fundamental CRISPR patents coupled with aggressive licensing practices will create problems.

Part 3. DHHS policy on the licensing of CRISPR patents.

As noted in Annex 1, DHHS has adopted at least 20 statements on sharing policies and related guidance for NIH-funded research resources.

There is a pressing need for a U.S. government policy statement regarding the licensing of government-funded CRISPR inventions.

The following comments are offered to assist the DHHS in developing such a policy statement:

1. In 2001 and in subsequent agreements with the WiCell Research Institute, Inc., the NIH intervened to ensure access to non-commercial research institutions to patented inventions involving stem cells.[48] The WiCell/NIH agreement can be seen as implementing a 1999 NIH policy statement on "Sharing Biomedical Research Resources,"[49] and focused primarily on ensuring non-profit entities would be able to use stem cells for research purposes.[50]

[44] Secretary's Advisory Committee Report, 38.
[45] Id., 39-42.
[46] Id., 42.
[47] Id., 42-45.
[48] WiCell Agreement No. 02-W012B, 09042012 NIH, Amended and Restated Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service U.S. Department of Health and Human Services. November 2012. https://www.ott.nih.gov/sites/default/files/documents/pdfs/wicell-rev.pdf.
[49] National Institutes of Health. Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. Federal Register Vol. 64, No. 246, page 72090-6. December 23, 1999.
[50] Debra Roberton, NIH sacrifices commercial rights in WiCell deal, *Nature Biotechnology* 19, 1001 (1 November 2001), doi:10.1038/nbt1101-1001.

2. The policy statement for CRISPR patents should ensure non-exclusive licensing in all fields of technology. The CRISPR technology is not a product, but a tool that can be used to create products and advance our understanding of human diseases. It is in the public interest to ensure non-discriminatory freedom to use the technology, in some cases royalty-free, and in other cases with fair and reasonable remuneration.

3. A related area concerns patents that are essential to implement standards. For many technologies, including but not limited to those involving networked information technologies or green energy technologies, so-called standards essential patents (SEPs) can impose costs on society and limit innovation, if licensed on unreasonable or discriminatory terms. Often these disputes are resolved through contracts between patent holders and Standards Developing Organizations (SDOs), with a commitment that the patent holders agree to license patents on fair, reasonable, and non-discriminatory terms, referred to as FRAND terms. The US Patent and Trademark Office (USPTO) and the U.S. Department of Justice (USDOJ) have addressed this issue in a nuanced January 8, 2013 policy statement.[51]

4. In the case of the CRISPR patents, the policy should be to ensure open and non-discriminatory licensing of the patents to both nonprofit and for-profit entities.

5. The licensing of CRISPR patents to non-commercial entities for research purposes should be royalty-free, a condition met by earlier CRISPR patent holders.

6. The licensing of CRISPR patents to commercial entities may require payment of royalties, but only on FRAND terms.

7. The licensing of CRISPR patents to any entity should not have reach-through rights to subsequent patents, unless the reach-through clause is designed to benefit an entity that is creating a research commons.

8. The funding agency should require the patent holders to disclose license agreements and royalty payments, as well as the rationale for royalties charged.

9. The NIH should reserve the right to require that royalty payments be based upon only the use as a research tool, or only on final products.

[51] United States Department Of Justice And United States Patent & Trademark Office Policy Statement On Remedies For Standards-essential Patents Subject To Voluntary F/rand Commitments January 8, 2013

Conclusion

We thank you for your attention to this important issue, and request a meeting to discuss this matter further at your convenience.

Sincerely,

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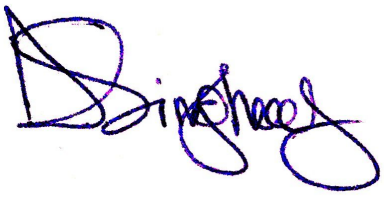

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Annex 1: NIH Sharing Policies and Related Guidance

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and funding recipient institutions are expected to make the results and accomplishments of their activities available to the research community and to the public at large. The following links highlight selected NIH policies and related guidance on sharing of research resources developed with NIH funding.

1. Policy on Dissemination of NIH-Funded Clinical Trial Information (8/2016)
2. NIH Intramural Human Data Sharing Policy (8/2016)
3. NIH Public Access Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research (02/2015) (PDF - 474 KB) – This document describes NIH's plans to build upon and enhance its longstanding efforts to increase access to scholarly publications and digital data resulting from NIH-funded research.
4. Genomic Data Sharing (GDS) (8/2014) Final Genomic Data Sharing (GDS) Policy that provides for the sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. Effective for grant applications and contract proposals submitted for January 25, 2015 due date and thereafter.
5. NIH Grants Policy Statement (Availability of Research Results) (11/2015) - Section of the NIH Grants Policy Statement discussing the availability of research results developed with NIH funding, including publications, data, unique research resources, and intellectual property (inventions and patents).
6. Common Data Element (CDE) Resource Portal (03/2013) - The Common Data Element (CDE) Resource Portal provides access to NIH-supported CDE initiatives and other tools and resources which can help researchers use common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records.
7. Table of NIH Data Sharing Policies (03/2013) - This table lists additional data sharing policies in effect at NIH at the NIH, IC, division, and program levels that apply to broad sets of investigators and data.
8. Table of NIH Data Sharing Repositories (03/2013) - This table lists various NIH-supported data repositories that accept submissions of appropriate data from NIH-funded investigators and others, as well as including resources that aggregate information about biomedical data and information sharing systems.
9. Data Repositories Resource Guide (09/2012) - (MS Word - 30 KB) - This resource guide document is designed to assist the NIH extramural community by identifying examples of data repositories which may be used for sharing data developed under NIH funding programs, consistent with NIH sharing policies.

10. Data Standards and Common Data Elements Resource Guide (09/2011) - (MS Word - 29 KB) - This resource guide document is designed to assist the NIH extramural community in identifying and utilizing certain data standards and common data elements in NIH programs.
11. Example Plan addressing Key Elements for a Data Sharing Plan under NIH Extramural Support (08/2010) - (MS Word - 55 KB) - This resource document is designed to assist the NIH extramural applicant community in preparing data sharing plans by providing an example that shows how a sharing plan addresses the key elements for a data sharing plan.
12. Key Elements to Consider in Preparing a Data Sharing Plan under NIH Extramural Support (12/2009) – (PDF - 32 KB) - This resource document is designed to assist the NIH extramural applicant community in preparing data sharing plans by identifying key elements that should be addressed in the plan.
13. NIH Genome-Wide Association Studies (GWAS) Policy (Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)) (08/2007) - Policy concerning sharing of GWAS data obtained in NIH supported or conducted research. (Please refer to Genomic Data Sharing (GDS) Policy webpage.)
14. Data Sharing Regulations/Policy/Guidance Chart for NIH Awards (08/30/2006) - (MS Word - 62 KB) - This chart is designed as a quick guide only for the purpose of identifying various data sharing regulation/policy/guidance documents applicable to NIH funding.
15. NIH Public Access Policy (02/2005) - Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research.
16. NIH Model Organism Sharing Policy (NIH Policy on Sharing of Model Organisms for Biomedical Research) (05/2004) - Policy concerning the sharing and distributing of model organisms and related research resources generated using NIH funding.
17. NIH Data Sharing Policy (Final NIH Statement on Sharing Research Data) (02/2003) - Policy concerning the sharing of research data for funding applications seeking $500,000 or more in direct costs in any year of the project period.
18. NIH Research Tools Policy (Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources) (12/1999) - (PDF – 150 KB) - Policy designed to provide NIH funding recipients with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds, and intended to assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy.
19. Biological Materials Policy (NIH Procedures for Handling Non-Election of Title to Patentable Biological Materials) (05/1996) - NIH policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued.
20. Developing Sponsored Research Agreements (Considerations for Recipients of NIH Research Grants and Contracts) (11/1994) - Issues and points to consider in developing sponsored research agreements with commercial entities, where such agreements may include research activities which are fully or partially funded by NIH, in

order to assist funding recipients ensure such agreements comply with the requirements of the Bayh-Dole Act and NIH funding agreements while upholding basic principles of academic freedom.