KNOWLEDGE ECOLOGY INTERNATIONAL

March 13, 2020

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Via Email: Secretary@HHS.gov

Re: Three areas in Section 202 of the Bayh-Dole Act that require action to ensure sufficient rights in patents on coronavirus relevant inventions

Dear Secretary Azar,

Knowledge Ecology International (KEI) writes to ask that the United States government take effective and timely measures to ensure there are sufficient rights in patented inventions funded by the federal government related to the development and acquisition of diagnostic tests, drugs, vaccines, or other technologies used to surveil, diagnose, prevent or treat coronavirus or other health threats.

Specifically, we address three often overlooked areas in the Bayh-Dole Act where the federal government can and should take actions now to protect the public's health.

1. The United States should enter into agreements with the World Health Organization and other appropriate entities to enable assignments of patent rights under 35 U.S.C. § 202(c)(4);

2. The United States should create the mechanisms to ensure appropriate licensing of non-federally funded contractor patents under 35 U.S.C. § 202(f); and

3. The United States should restrict or eliminate a contractor's ability to retain title to certain federally funded inventions under the "exceptional circumstances" provision in 35 U.S.C. § 202(a).

We note that the NIH RePORT[1] database already identifies more than $1 billion in federally funded projects that have the key word "coronavirus,"[2] and Congress has just approved and the President has signed the "Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020," which provides $836,000,000 in additional funding for NIAID, $3,100,000,000 for a "Public Health and Social Services Emergency Fund," $435,000,000 for "Global Health Programs," and other funds dealing with the coronavirus.[3] We also expect Congress to enact additional funding bills.

In treating and controlling the coronavirus pandemic, there is a public interest in innovation and access to and the affordability of diagnostic tests, drugs, vaccines, or other technologies. Patents on new technologies provide an incentive for private investors, but also create a barrier to competition and, left unsupervised, can lead to unaffordable prices. When public sector funding is involved, it is the government's duty to ensure that the benefits of inventions are available to the public on reasonable terms, and are licensed in such a way as to ensure further innovation, and when appropriate, competition among suppliers.

As you are aware (and have addressed previously, during the George W. Bush Administration),[4] the U.S. government has stand-by authority, under 28 U.S.C. § 1498(a), to have any patented invention "used or manufactured by or for the United States without license of the owner," subject to the payment of reasonable compensation. Further, when federal funds are used in the development of any invention, the U.S. government has "a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world" (35 U.S.C. § 202(c)(4)).

The royalty-free right in federally funded inventions can make 28 U.S.C. § 1498(a) a more useful tool, when one or more of the patents are federally funded, as is now the case for several important biomedical inventions, and may well be the case for inventions funded in connection with the coronavirus pandemic response.

That said, there are additional provisions in the Bayh-Dole Act which are potentially quite important, that have not received enough attention. These involve provisions in 35 U.S.C. § 202 that permit the U.S. government to include additional public interest, and in this case, public health, safeguards in federally funded research.

1. **35 U.S.C. § 202(c)(4) -- Entering into Agreements to Enable Assignments in Patent Rights**

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[1] The RePORT (Research Portfolio Online Reporting Tools) website provides access to a variety of reporting tools, reports, data, and analyses of NIH research activities. One of the tools available on the RePORT site is the RePORTER (RePORT Expenditures and Results) module.
[2] NIH RePORT Query, Text Search: coronavirus (and), Search in: Projects Admin IC: All, Fiscal Year: All Fiscal Years.
[3] https://www.congress.gov/bill/116th-congress/house-bill/6074/.
[4] Alex M. Azar II, Letter to the Editor, ''The Cipro Dilemma,'' *American Lawyer*, January 31, 2002.

Under 35 U.S.C. § 202(c)(4), in addition to the federal government's royalty-free right, a funding agreement may include "the right to assign or have assigned foreign patent rights in the subject invention" to third parties, and other "additional rights . . . as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement."

In the case of the coronavirus, the U.S. should include such a provision in every funding agreement that permits these assignments, pursuant to an agreement with the World Health Organization (WHO).

The United States should also reach out to other countries, ask that they make similar provisions in any funding agreements, and consider bilateral reciprocal agreements that would permit the U.S. to obtain rights to patents funded by foreign governments.

For this to happen, the U.S. government must first enter into one or more agreements, to satisfy the requirements of 35 U.S.C. § 202(c)(4).

To be as clear as possible, the U.S. may allow the WHO or other UN agencies, governments or even nongovernmental organizations like the Red Cross or Doctors without Border, to use inventions funded by the U.S. government, under conditions or limitations the U.S. determines are in the national interest. But this provision of the Bayh-Dole Act is conditioned on the existence of such an agreement AT THE TIME OF FUNDING.

An agreement between the U.S. and the WHO would be a logical first step and could be very simple. Even a one paragraph agreement, endorsed by both parties, via email, would be sufficient. It could be as minimal as this:

> The United States of America agrees to consider requests by the World Health Organization to obtain a limited assignment of rights in U.S. funded patent rights for biomedical inventions related to the detection, prevention or treatment of coronavirus related illnesses. The terms and conditions associated with such an assignment, if so granted, will be determinated by the U.S. Department of Health and Human Services (HHS). The WHO agrees the United States of America is under no obligation to grant any such requests, but only to consider them.

2. 35 U.S.C. § 202(f) -- Setting Out Additional Licensing Obligations

In addition to provisions that would permit the WHO, foreign countries or other entities to benefit from U.S. rights in federally funded patents, there is an opportunity, in the Bayh-Dole Act, to set out additional licensing obligations on entities receiving federal funding.

35 U.S.C. § 202(f) sets out the conditions under which a "funding agreement with a small business firm or nonprofit organization" can "contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions."[5] Put simply, this means that the U.S. government can leverage its substantial, multi-billion dollar funding towards providing competitive access to inventions that the government has not funded, including, but not limited to, existing patent rights. This is a narrow authority, and requires "the head of the agency"[6] to determine that "the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object."[7] Note that in that instance "practical application" is defined by the Bayh-Dole Act, in Section 201(f), to include an obligation "to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." [8] This is separate from the march-in rights in 35 U.S.C. § 203, and as noted, extends to patents owned by the contractor that are not subject inventions. (The term subject inventions refers to federal funding of the invention.)[9]

We ask that your office undertake the appropriate analysis to develop the proper legal basis to exercise the rights set out in 35 U.S.C. § 202(f), when it is necessary to achieve public health objectives related to the coronavirus pandemic.

3. 35 U.S.C. § 202(a) -- Restricting or Eliminating Title in Exceptional Circumstances

There is an additional area of flexibility in the Bayh-Dole Act that is highly relevant to the coronavirus pandemic. Under 35 U.S.C. § 202(a), the federal government may limit or eliminate a contractor's ability to retain title to a federally funded invention, "in exceptional circumstances, when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter[.]"

The policy objectives of the Bayh-Dole Act are set forth in 35 U.S.C. § 200. They include "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area."

The federal government has the authority in 35 U.S.C. § 202(a) to retain title to inventions by contractors relating to the coronavirus pandemic, and to manage such rights in the public interest directly, rather than depending upon the normal, more modest safeguards for contractor inventions, such as the more problematic provisions for federal march-in rights set out in 35

[5] 202(f)(1).
[6] 202(f)(1).
[7] 35 U.S.C. § 202(f)(2).
[8] 35 U.S.C. § 201(f)(Emphasis added).
[9] 35 U.S.C. § 201(e). The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement:

U.S.C. § 203. A major drawback of relying on march-in authority—particularly in the case of a public health emergency—is the stipulation, under Section 203(b), that the exercise of the authority is subject to an automatic stay if the contractor or other adversely affected party files an appeal.

The coronavirus pandemic certainly qualifies as “exceptional circumstances.” Indeed, on March 13, 2020, President Trump declared that it is a national emergency to combat the coronavirus pandemic.

Conclusion

Discussions of federal rights in government funded inventions often focus on the march-in rights set out in 35 USC § 203, and occasionally on the federal government’s worldwide royalty free right in inventions it funded. This letter addresses three additional areas for action, all of which require foresight and planning. These involve (1) the negotiation of agreements with the WHO or other entities for assignments of patent rights, (2) measures necessary to condition funding on the licensing of inventions not funded by the federal government, and (3) the invocation of exceptional circumstances to prevent contractors from taking title to federally funded inventions.

Ensuring the development and affordability of, and access to, diagnostic tests, drugs, vaccines, or other technologies related to the coronavirus pandemic is of the utmost importance, and these measures will enhance your ability to meet this unprecedented public health challenge.

Sincerely,

James Packard Love
Director
Knowledge Ecology International
http://keionline.org
james.love@keionline.org

ANNEX

35 U.S.C. §200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area. [emphasis added]

35 U.S.C. §202. Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: Provided, however, That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or, (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

35 U.S.C. § 202(d)(4)

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production. [emphasis added]

35 U.S.C. § 202(f)

(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.