5-15-2024

Sanctions for Non Disclosure, as Set Out in Article 6 of the WIPO Basic Proposal on Intellectual Property, Genetic Resources and Traditional Knowledge, Should Include Possible Revocation of a Patent

James Love
Knowledge Ecology International (KEI)

Claire Cassedy
Knowledge Ecology International (KEI)

SANCTIONS FOR NON DISCLOSURE, AS SET OUT IN ARTICLE 6 OF THE WIPO BASIC PROPOSAL ON INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE, SHOULD INCLUDE POSSIBLE REVOCATION OF A PATENT

James Love and Claire Cassedy[1]

May 15, 2024

INTRODUCTION

The basic proposal for an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources prepared by the World Intellectual Property Organization (WIPO) Secretariat (GRATK/DC/3[2]) sets out in its Article 3 a narrow obligation to disclose (1) the country of origin of the genetic resource, or if not known, its source, and (2) the Indigenous Peoples or local community that provided traditional knowledge associated with the genetic resource, or the source of such knowledge.

Article 6 of the basic proposal sets out the sanctions and remedies for failures to make such disclosures. Among the controversies in the current diplomatic conference is Article 6.3, which states that "no Contracting Party

[1] James Love and Claire Cassedy, Knowledge Ecology International (KEI).

[2] World Intellectual Property Organization. BASIC PROPOSAL FOR AN INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES, prepared by the Secretariat. GRATK/DC/3, December 14, 2023. Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, Geneva, May 13 to 24, 2024. https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_3.pdf

shall revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3," unless there has been "fraudulent intent." (Article 6.4)

One lesson to learn from the U.S. experience under the Bayh-Dole Act is that required disclosures that are against the interest of the patent holder are often ignored when the enforcement of the obligation is weak.

In the case of the proposed treaty requiring the disclosure of the source of genetic materials and traditional knowledge, Article 6 in the Basic Proposal could be strengthened by eliminating the prohibition on revoking patent protections in Article 6.3, and also by creating a mechanism for third parties to file evidence of failures to disclose, perhaps within the PCT, and for some type of auditing process to evaluate if patent offices are enforcing the disclosure obligations.

THE EXPERIENCE IN THE UNITED STATES WITH THE OBLIGATION TO DISCLOSE FEDERAL FUNDING IN SUBJECT INVENTIONS

The obligation to disclose the source of genetic resources and associated traditional knowledge is similar to other obligations in intellectual property regimes, including, but not limited to, those associated with prior art for patents, the use of artificial intelligence for copyrights or patented inventions, and public funding of inventions, such as the disclosures required in the U.S. Bayh-Dole Act.

KEI has experience in monitoring the failures of US government research grant and contract recipients to disclose federal funding. We have found widespread failures to disclose funding for biomedical inventions funded by the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Defense Advanced Research Projects Agency (DARPA), and have asked all three of these agencies to correct the failures by taking possession of the inventions, which is one of the remedies set out in the statute.

In 2018, KEI's Andrew Goldman wrote a nine-page briefing note on the "Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions"[3] which provides a detailed overview of the legal and contractual obligations to disclose and the remedies and sanctions for non-disclosure, as well as a discussion of the reasons why such disclosures are important, and should be timely.

Goldman cited one U.S. court case Campbell Plastics Engineering & Mfg., Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004), where the U.S. government took title to a patented invention (U.S. Patent No. 5,895,537) as a remedy to a failure to disclose relevant research and development funding

[3] Andrew Goldman. Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions. KEI Briefing Note: 2018:1. Revised March 16, 2018. https://www.keionline.org/wp-content/uploads/2018/03/KEI-Briefing-Note-2018-1.pdf

from the U.S. Army Chemical Research, Development and Engineering Center.

Unlike the U.S. Army in the Campbell Plastics case, the NIH, BARDA and DARPA have repeatedly declined to take title to patents where there has been a well established failure to disclose in the case of biomedical inventions.

Since at least 1994 there have been a series of U.S. government reports and non-government commentary of the persistence of non-compliance with the Bayh-Dole Act requirements to disclose federal funding for a "subject invention," a term defined in 35 U.S.C. 201(e), as follows:

> (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: Provided, That in the case of a variety of plant, the date of determination (as defined in section 41(d) [1] of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

In 1994, the Inspector General of the Department of Health and Human Services sent a memorandum to Dr. Philip Lee, the Assistant Secretary of Health, titled "Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute."[4]

> "The attached report alerts you to weaknesses in procedures at the National Institutes of Health (NIH) for monitoring compliance with provisions of the Patent and Trademark Amendments Act (Act) of 1980 at the Scripps Research Institute (SRI) of La Jolla, California. The objectives of the Act are, in part, to promote utilization of inventions and technology arising from federally supported research and development, require manufacture of patented products in the United States, protect the public against nonuse or unreasonable use of new technologies, and ensure that the United States obtain sufficient rights in inventions."

In August 1999, the U.S. General Accounting Office (GAO) issued a report to the Chairman of the Senate Committee on the Judiciary titled "TECHNOLOGY TRANSFER: Reporting Requirements for Federally

[4] Memorandum from June Gibbs Brown, Inspector General of the Department of Health and Human Services to Dr. Philip Lee, the Assistant Secretary of Health. "Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute." June 15, 2004. https://www.keionline.org/wp-content/uploads/2018/03/oig-hhs-15june1994-scripps.pdf

Sponsored Inventions Need Revision".[5]

> Under the Patent and Trademark Laws Amendments of 1980, as amended (commonly known as the Bayh-Dole Act), small businesses, nonprofit organizations, and certain contractors operating government-owned laboratories may retain title to and profit from the inventions they create under federally funded research projects. Executive Order 12591, issued April 10, 1987, essentially extends these same privileges to large businesses. To gain these rights, a contractor or grantee must follow certain reporting and other requirements. Among these requirements are notifying the funding agency that an invention has been created, informing the agency that the contractor or grantee intends to retain title to the invention, filing a patent application, and submitting documentation that acknowledges the government's royalty-free license to use the invention. If the contractor or grantee fails to follow these requirements, the government may acquire title to the invention. . . . [page 1]
>
> Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General's draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government's royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights. [page 2]

From 2017 to 2021, KEI sent a series of letters and petitions concerning failures to disclose to three U.S. federal agencies, the NIH, BARDA, and DARPA. In none of these cases did the U.S. government take title to a patent. In some cases the funding agency was able to persuade a company or university to file a correction with the U.S. patent office disclosing federal funding of the invention, and in other cases the agency took no action at all.

The lax enforcement of the reporting requirement has created an environment where the grant recipients perceive almost no downside to ignoring the reporting requirements.

During the COVID-19 pandemic, KEI submitted a report to DARPA

[5] GAO/RCED-99-242, Available at: https://www.gao.gov/assets/rced-99-242.pdf

noting that as of August 28, 2020, Moderna had a "surprising practice of never declaring government funding in its 126 patents and 154 patent applications, despite having had funding from multiple federal agencies," and also submitted a follow up letter to BARDA. The 25-page report, titled "KEI Research Note 2020:3: Moderna failures to disclose DARPA funding in patented inventions" identified, as examples, eleven granted patents where there was evidence from published research that the inventions benefited from federal funding.[6]

All of the eleven patents in the letter to DARPA listed as the lead inventor Giuseppe Ciaramella, the Chief Scientific Office for Infectious Diseases at Moderna from October 2014 to February 2018, a period that included the priority date for all of the eleven patents. Eight of the eleven patents listed Moderna employee Sunny Himansu as one of the co-inventors. The patent applications were filed from April 2016 to July 2018, including seven applications filed in 2018.

A May 14, 2024 review of those patents found that only one of the eleven patents had since been corrected for a failure to disclose federal funding: patent number 10,653,767, which now cites support from DARPA Contract No. W911NF-13-1-0417. The date of the certification of correction was November 26, 2020, some three months after KEI asked DARPA to investigate Moderna. This disclosed grant had an award date of October 2013 and a completion date of September 2019, a time period that included the priority dates for all of the eleven of the granted patents.

The Moderna case is not dissimilar to several others, including cases when the disclosures are made much later or not made at all.

A letter to BARDA regarding Regeneron's failure to disclose federal funding for patent 10,787,501, for "Anti-SARS-CoV-2-spike Glycoprotein Antibodies And Antigen-binding Fragments," has resulted in no corrections to the patent.

Similarly, a letter to the NIH regarding the University of Pennsylvania failures to disclose federal funding for two patents for "Enhanced AAV-mediated Gene Transfer For Retinal Therapies," also resulted in no corrections to the patents.[7]

After KEI filed a complaint with the NIH over Cold Spring Harbor Laboratory's failure to disclose federal funding in two patents on a drug to treat spinal muscular atrophy (SMA),[8] the research institute corrected the

[6] Luis Gil Abinader. Moderna failures to disclose DARPA funding in patented inventions. KEI Research Note 2020:3. August 27, 2020. https://www.keionline.org/wp-content/uploads/RN-2020-3.pdf

[7] Luis Gil Abinader. Regeneron failed to disclose BARDA funding in their REGN-COV2 patent, October 20, 2020. KEI Research Note 2020:4. https://www.keionline.org/wp-content/uploads/rn-2020-4.pdf

[8] Letter to Daniel R. Levinson, Office of the Inspector General, HHS. Allegation of Isis Pharmaceuticals Failure to Satisfy Disclosure Requirements for a Subject Invention Under

disclosures in seven patents, although in only one of the SMA patents, despite the fact that the two patents share two inventors and the same subject matter. A review of the Cold Spring Harbor patent filings found that of 13 patents granted from 2012 to August 2017 that the NIH said benefited from federal funding, only 6 had disclosed the funding on the original patent.[9]

A 2017 review of patents granted to the Fred Hutchinson Cancer Center found that when Fred Hutchinson reported no federal funding on patent applications, it was wrong 45 percent of the time, according to corrections later filed with the USPTO.[10] [11]

I. LATE DISCLOSURE

In many important cases, the disclosure, when made at all, comes late. The Cold Spring Harbor certifications of correction were filed in some cases more than five years after the initial patent grant, and in one case 11 years and 11 days after the original patent application, and likely would have never been made had KEI not asked for an investigation into the failure to file.

In a case involving Novartis, the federal funding of a patent for the cancer drug Gleevec was disclosed on July 9, 2019, some 6,634 days (>18 years) after the drug was approved by the FDA and 6,829 days (18.7 years) after the original patent filing priority date.[12]

When the disclosures are late, persons checking for federal funding will not see the disclosure unless they check for the certificates of correction, which are only available as image files and not text searchable from the USPTO.

II. CHANGES IN POLICY IN 2018

Earlier regulations required the U.S. federal government just sixty days

---

the Bayh-Dole Act, 35 U.S.C. §§ 200 et seq., January 18, 2017. https://www.keionline.org/wp-content/uploads/18Jan2017-OIG-Investigation-Request-Nusinersen-Patents.pdf

[9] Kim Treanor. Following KEI request for investigation, Cold Spring Harbor Labs says 7 patents require correction to disclose federal funding. Knowledge Ecology International. October 20, 2017. https://www.keionline.org/23456

[10] James Love. Fred Hutchinson Cancer Center often fails to disclose federal funding of inventions on initial patent. Knowledge Ecology International. October 20, 2017. https://www.keionline.org/23457

[11] For several other cases, see: https://www.keionline.org/bayh-dole/failure-to-disclose

[12] James Love. Novartis, Dana Farber, Oregon Health & Science University Wait 18 Years to Disclose NIH Funding in Key Gleevec Patent, October 11, 2019. Bill of Health - The blog of the Petrie-Flom Center at Harvard. https://blog.petrieflom.law.harvard.edu/2019/10/11/novartis-dana-farber-oregon-health-science-university-wait-18-years-to-disclose-nih-funding-in-key-gleevec-patent/

after discovery of a failure to disclose to make an objection and request title to the patent. This was changed in 2018.

> "Of particular note, the 2018 update to Bayh Dole eliminated the previous sixty day objection period that allowed a fund recipient to retroactively correct defects in complying with disclosure and election of title obligations. Prior to this update, if a contractor failed to meet these disclosure or election obligations within the required time periods, the government had sixty days after discovery of the failure to object and request title. This allowed a contractor the opportunity to correct such a defect and if the government did not object within sixty days, the defect was cured. However, under the revised regulations, there is no longer an objection period. 37 C.F.R. § 404.14(d)(1). Instead, the government can object at any time and obtain title, presumably, even if an effort to correct the mistake was made. Thus, anyone receiving federal funding must timely notify the agency of any invention developed using the funding and timely elect to retain title to avoid a potential cloud over the invention title."[13]

CONCLUDING COMMENTS

The patent holders have several motivations to not disclose federal funding. If federal funding is acknowledged, agencies and the public are aware that the federal government has both a march-in right and a global royalty free right in the patent, points raised by the HHS Inspector General in the 1994 report cited above, as well as in the 1999 GAO report.

By hiding evidence that inventions benefited from federal funding, universities can seek more favorable licensing terms, and corporate patent holders can deflect criticism of high prices on drugs, vaccines, cell and gene therapies, diagnostic tests and other medical products and services.

One lesson to learn from the U.S. experience under the Bayh-Dole Act is that required disclosures that are against the interest of the patent holder are often ignored when the enforcement of the obligation is weak.

In 2018 the U.S. government revised its regulations to make it more risky for a patent holder to fail to make the required disclosures, in an effort to improve compliance.

In the case of the proposed treaty requiring the disclosure of the source of genetic materials and traditional knowledge, Article 6 in the Basic Proposal could be strengthened by the eliminating the prohibition on revoking patent protections in Article 6.3, and also by creating a mechanism for third parties

[13] Bonnie W. Nannenga-Combs, Ph.D. and John M. Covert, "Federally Funded Inventions and Compliance with the Bayh-Dole Act," SterneKessler.com, July 7, 2020. https://www.sternekessler.com/news-insights/publications/federally-funded-inventions-and-compliance-bayh-dole-act/

to file evidence of failures to disclose, perhaps within the PCT, and for some type of auditing process to evaluate if patent offices are enforcing the disclosure obligations.