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Federal Agency Return on Investment in Foreign Patenting

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Preface

This report documents the U.S. federal agencies' use of foreign patents and provides evidence about the costs and benefits of acquiring foreign as well as U.S. patents to protect the intellectual property for inventions created in their laboratories. In the six months following the completion of this report, we assembled additional data. The new data about the patent portfolios of the U.S. federal agencies extends back in time four decades from the present. With the additional data, we estimated two new models to complement the work in this report. First, we estimated a distributed lag function showing the effects on license revenue of an agency's history of patent applications for inventions granted U.S. patents. The estimation shows that those effects depend on whether the agency also obtained foreign patent protection for its inventions. Second, with the additional data, we were able to re-estimate the dynamic panel data model presented in this report by using a far simpler instrumental variables regression estimator. The results are essentially the same as those obtained with the more sophisticated Arellano-Bond model as reported in this report. The results for the distributed lag model and for the dynamic panel data model tell the same story. When an agency protects its inventions with foreign patents in addition to its U.S. patents, the agency's invention-license revenues are far greater than if the agency does not obtain the foreign patent protection. The two new estimated models are available in our paper, David P. Leech and John T. Scott, "Foreign Patents for the Technology Transfer from Laboratories of U.S. Federal Agencies," *Journal of Technology Transfer*, forthcoming. The results using the new models in the forthcoming paper complement those in this report. For the eight agencies with sufficient foreign patents to estimate their impact, adding a U.S.-patented invention increases a federal agency's annual invention-license revenue if the invention is also protected with foreign patents. If the invention does not have foreign patent protection, the change in the agency's annual license revenue is considerably less for the eight agencies, and it is significantly negative for three of them. The forthcoming paper also provides a formal explanation of the observed instances of negative marginal revenue—namely, without foreign patent protection, potential licensees' demand for invention licenses is inelastic because commercialized products using the inventions will be less profitable.

For this report we wish to acknowledge, first and foremost, the help and advice provided by Karen Rogers and Steven Ferguson of the NIH Office of Technology Transfer. They provided comprehensive licensing cost information without which constructing the statistical models at the heart of this report would have been exceedingly more difficult and perhaps less reliable. They also provided deep insights into the mechanics and challenges of the federal laboratory licensing process. To the extent that the findings and analysis of this report are helpful to the federal laboratory technology transfer community, considerable thanks is due to them. Geert Boedt of the European Patent Office provided essential guidance for the work with the worldwide patent database PATSTAT. The insights gained from the two case studies included in the report would not have been possible without the assistance of Robert Danziger (Professor of Medicine, Pharmacology, Physiology and Biophysics, University of Illinois at Chicago), Mark Miller (CEO, Biosynthetic Technologies), and Trevor Gauntlett (Trevor Gauntlett Consulting). Finally, we acknowledge the guidance provided by our NIST project manager, Nicole Gingrich, and the comments of readers at NIST.

Abstract

This report documents the U.S. federal agencies' use of foreign patents, in addition to U.S. patents, to protect the intellectual property for inventions created in their laboratories. The report describes the extent of U.S. and foreign patents in the patent portfolios of the U.S. federal agencies, and it describes the process of licensing of the agencies' patented inventions. A dynamic panel data model is estimated for each agency's invention-license revenues as a function of the history of its applications and granted patents. The evidence supports the view that an agency that obtains U.S. patents for its inventions but does not obtain foreign patent protection may reduce the value of licenses to use the technologies. Value for the licensee may be reduced because the corporations that license the agency's technologies may face international competition from firms that copy those technologies and compete with lower costs because they do not incur full development costs or pay royalties for licensing the technologies. The report estimates the agencies' benefits, in terms of licensing revenues, and costs for obtaining foreign-patent protection for their U.S.-patented inventions. The report provides detailed case studies of the licensing and commercialization of two federal-agency technologies.

Key words

Commercialization; Domestic patents; Federal laboratories; Federal agencies; Foreign patents; Invention licenses; Invention valuation; Lab-to-Market; Patents; PATSTAT Worldwide Patent Database; Technology transfer.

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1. Study Objective and Introduction

1.1. Study Objective

The central question explored in this report concerns the return on investment (ROI) to the foreign patent filing expenses of federal agencies. Acquiring patent protection in foreign countries can be complex and costly. These costs and complexities create barriers to securing global intellectual property protection, especially for cost-conscience organizations such as start-up businesses and federal agencies managing their federal R&D laboratories. Determining the answer to the following kinds of questions was the objective of the study reported here:

- When federal agencies receive patent protection on their inventions inside the United States, but choose not to file for international patent protections, are the total benefits of these inventions potentially reduced? In other words, is the economic impact of the taxpayer dollars contributing to those inventions reduced because of underestimating the additional benefits from foreign patent protection?
- When agencies do not seek foreign patent protection on inventions that have strong potential for commercialization, do companies that license federal agency-created technology, and incur the development costs necessary for commercialization, face a reduced ability to be globally competitive when the technology can be imitated by foreign companies in foreign markets at a lower cost because foreign competitors do not bear licensing and development costs?
- Are the costs and complexities of acquiring patent protection in foreign countries worth it for federal agencies?

1.2. Introduction

This report summarizes the findings of a study conducted in three parts (each of which is included in Appendices A-C).

In the following summary sections, Section 2 (Patenting and Licensing) sets the stage by describing the federal government's goals in patenting and licensing federally-developed

technology, and by characterizing the processes involved. It also looks at some of the challenges faced by the Offices of Technology Transfer (OTTs) within federal agencies. Observations from in-depth case studies conducted as part of the overall study conclude the section.

Section 3 (Federal Agencies' Patent Portfolios) quantifies the extent of domestic and foreign patenting among 11 federal agencies based on their patent applications to the USPTO for fiscal years 2003 through 2018.

In Section 4 (Benefits and Costs of Foreign Patent Protection for U.S. Federal Agencies' Technologies) a statistical model of the benefits and costs of domestic and foreign patents is described that is based on historical licensing revenue data compiled by NIST in its annual *Federal Laboratory Technology Transfer* reports; the history of agencies' patent portfolios compiled by the authors from the European Patent Office's worldwide patent database PATSTAT; and comprehensive patenting cost data provided by the agency with one of the largest patent portfolios, and the most internationally diversified, among the 11 agencies studied. The model accounts for differences between agencies with relatively large and small patent portfolios, identifies statistically significant impacts for the agencies' histories of U.S. and foreign patent applications and granted patents, and predicts with stated accuracies the licensing revenues as a function of the patent histories of agencies with significant patent portfolios.

2. Patenting & Licensing

Asked to compare the preference for software *patents* or software *copyrights* if government-operated laboratories were permitted to acquire copyrights, Daniel Lockney, of NASA's OTT stated succinctly, "patents cost a lot of money, and we're all strapped for cash."[1]

Federal agency's OTTs face many challenges beyond the budget constraints. The job that OTTs are required to perform requires reconciling and balancing multiple legislated goals for

[1] Daniel Lockney, personal communication, December 4, 2019.

the dissemination of government-funded and government-developed technologies; the OTTs must deal with the technical complexities, risks, and prospects of transitioning a technology from the laboratory to the marketplace (commercialization); they must, as we shall explain, work with predictions of the future in often global, technology-driven, churning markets.

Federal agencies use their authority (to obtain patents and license technology) to support the policy and objectives of Congress:

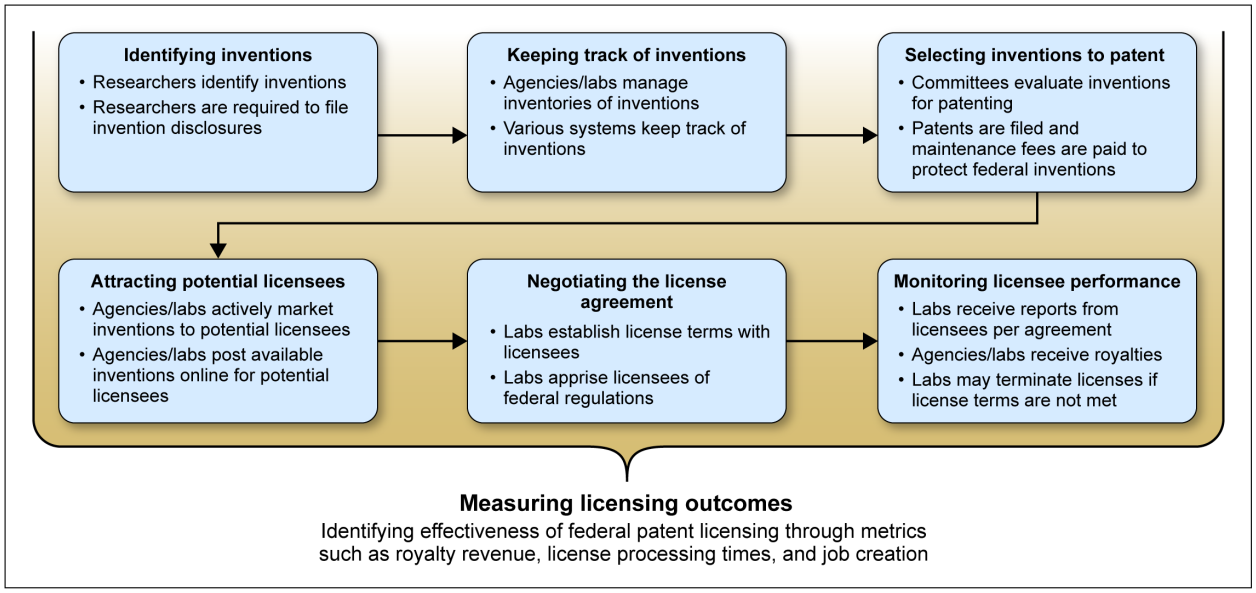
> "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; … to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government …."[2]

Accordingly, federal agencies have authority to acquire, maintain, and manage portfolios of U.S. and foreign patents for the technologies generated by them, and grant licenses and collect royalties for patented technologies.[3] The relevant laws and regulations encourage maximum participation of small business firms and promote collaboration between commercial concerns and nonprofit organizations. They also seek to ensure that government agencies obtain sufficient rights in federally supported inventions, while seeking to minimize the costs of administering policies pertaining to patent rights in inventions made with federal assistance.[4] All these objectives occur on a background of achieving an agency's first-order mission goals and, therefore, its technology mix. Some agencies are focused more on biotechnology, pharmaceuticals, and medical devices while others are focused more on computer technology, machinery, and semiconductors.[5]

[2] U.S. Code, Title 35, Section 200, https://www.law.cornell.edu/uscode/text/35/200.
[3] U.S. Code, Title 35, Section 207, https://www.law.cornell.edu/uscode/text/35/207.
[4] U.S. Code, Title 35, Section 200, https://www.law.cornell.edu/uscode/text/35/200. See also U.S. Code, Title 35, Section 209, https://www.law.cornell.edu/uscode/text/35/209.
[5] National Institute of Standards and Technology (NIST), *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, U.S. Department of Commerce, April 2018, available at https://www.nist.gov/tpo/reports-and-publications.

Figure 1 presents an overview of the federal patenting and licensing process within which those involved in the invention patenting and licensing stages face important constraints. In addition to technologies originating entirely in the agencies' laboratories, there will be those that evolve from cooperative work with partners – CRADA partners or Bayh-Dole contractors for inventions with co-inventors employed by the federal agencies. In those cases, industrial partners will be especially likely to manage the acquisition and maintenance of patents, with the federal agencies among the assignees, for jointly developed technologies.[6]

Figure 1. Federal Patenting and Licensing Process.[7]



Source: GAO analysis based on review of regulations and agency documentation. | GAO-18-327

Among the challenges and constraints of patenting an invention, the cost of the patenting process stands out among practitioners.[8] But behind that concern are some difficult, if taken-for-granted, analytical issues concerned with predicting "high-value" inventions. First, what is a high-value invention? Some have expressed the view that the goal of technology transfer

[6] There are three parts of the U.S. Code under which inventions created in whole or in part by Federal employees may occur, 15 USC 3710a, 35 USC 202, 35 USC 207.
[7] United States Government Accountability Office (GAO), *Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions* (GAO-18-327), Washington, D.C., June 2018, p. 11. (https://www.gao.gov/products/GAO-18-327)
[8] Ibid., p. 43.

programs is primarily the transfer itself, not the associated licensing revenue.[9] Thus, an invention that may generate great social value if the technology is transferred, but that will be very costly to develop and commercialize and for which it will be difficult to appropriate sufficient returns to cover the development costs, would appropriately be licensed without the requirement of substantial royalty payments. That said, technologies for which companies anticipate sufficient profits to support commercialization, economic logic suggests that between two inventions being placed into the marketplace, from the licensee's commercialization perspective the "higher value" project will be the one anticipated to make a greater addition to the licensee's economic profit stream (the addition measured as a present discounted value). Thus, an agency's invention-licensing revenues, *negotiated and received*, typically reflect market forces and the market values of the commercialized technologies. According to the GAO, the financial compensations arranged in the licenses, "… typically establish financial terms on a case-by-case basis that are tailored to the specifics of the technology, licensee, and market conditions."[10] Since market value underlies and enables commercialization, the licensing revenues received measure not only the financial benefit received by the agency, but also the lower bound on the social value of the technology which includes the addition to the economic profits generated by the licensee's use of the technology, as well as the additional social value that spills over to other companies and to consumers. Such additional value, captured by others, for a licensee's commercialized technologies is expected because no licensee will be a perfectly price discriminating monopoly of textbook lore.

It should be emphasized that 35 USC 207 states that a Federally owned invention may be licensed "royalty-free or for royalties or other consideration." The statement above, that license revenues *that are negotiated and received* typically reflect market values does not

[9] See, Kelly Day Rubenstein, "Transferring Public Research: the Patent Licensing Mechanism in Agriculture," *Journal of Technology Transfer*, Vol. 28, pp. 111-130, 2003. The GAO, too, has reported that "DOD, DOE, NASA, and NIH officials … stated that getting the technology *into the marketplace* is their primary goal in licensing (GAO, op. cit., p. 28). [Emphasis added.] Also, Ferguson and Kaundinya, op cit., pp. 191-192, observe: "Compared to biomedical licensing from corporations, the federal laboratories and universities bring a different focus and perspective to the table when negotiating the technology transfer agreements. Because these agreements are used to further overall institutional missions, representatives from such nonprofit institutions consider the public consequences of such licenses as their first priority, not the financial terms that may be involved."

[10] GAO, op. cit., p. 14, and limited exceptions noted there, and then see more generally pp. 12-16.

then imply the law must be anticipating that the Government would be licensing inventions with no market value because the licenses can be "royalty-free." Rather, the licensing revenues that are collected are grounded in and reflect market value. This statement does not contradict the law, nor does it contradict what technology transfer professionals say when they explain why royalty free licenses are made. Nor does it imply that Congress wants federal agencies to maximize licensing revenues. Indeed, the range of B/C ratios estimated in this report regarding narrowly financial returns of licensing revenues to the agencies, and the examples provided, confirm exactly what the technology professionals report. In other words, the royalties that are paid would not be paid unless the licensee saw market value as justifying the payment. If an agency decides in support of its mission to give away a technology it certainly can, but if it does charge a royalty, the licensee is paying it because it thinks the market value justifies the payment. For that reason, for the royalties that are paid, we can learn something about the economic value of obtaining foreign patents.

Given that the technology transfer process entails licensing and market valuation, the initial decision to apply for patent protection typically involves evaluation committees comprised of inventors, technology transfer professionals, and patent attorneys. Among the factors considered are: whether the invention meets patentable criteria (useful, novel, and non-obvious[11]); how the invention relates to the laboratory's mission; and if patenting will likely bring the invention to commercial use and practical application.[12]

The question of whether the invention will result in commercial use depends on the ability to project the technology's use in a future market. The projection typically must be made long before the technology would be commercialized. It is widely recognized that the timespan from patent application to licensed production (not the licenses themselves) can be quite long for inventions from the federal laboratories alone and also for some of the inventions developed in cooperation with others, as shown in the case studies reported here. In the intervening years domestic and global market and technology dynamics are quite likely to change in ways that are often hard to forecast, reducing the likelihood of picking inventions

[11] https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-4
[12] GAO, op. cit., p. 12.

that will eventually be successfully commercialized. For example, the analysis of federal agency patent portfolios presented in Appendix A found that for the 11 agencies studied, the lag time from the successful application for a patent until the patent was granted varies greatly over the sample for fiscal years 2003 through 2018. Across the 11 agencies, the lag time from application to patent publication is approximately 3 years for domestic patents and almost 5 years (4.85 years) for foreign patents. Licenses are often granted before the patent applications have resulted in granted patents, but then the lag from the granting of a license until the invention is developed and commercialized will typically be much longer than the lag from the patent application to the patent grant. The case studies in Appendix C illustrate the lags.

In part because each federal agency designs its own program to meet technology transfer objectives consistent with its other mission responsibilities, it is difficult to generalize about patent licensing beyond describing the stages of the process. Still, it seems clear that the closer one moves in the direction of the problems facing the license negotiators, about a particular license or group of licenses, the more difficult generalization becomes. Nevertheless, predicting the high-value inventions is a necessary part of the invention-selection process and agencies have developed strategies for lowering the inherent risks.[13]

This brings the discussion back to the question of cost and the comment at the beginning of this section that, "patents cost a lot of money, and we're all strapped for cash." With all the analytical complexities involved, the cost of patenting is still generally considered a significant issue. GAO reports that federal agency laboratory officials cite the costs of patenting as a major challenge of selecting high-value patents.[14] So, the bottom line of the analysis reported in the next section—more emphasis should be placed on acquiring foreign patents when agencies anticipate that licensees will be selling products in international markets using the licensed technologies—is problematic because, despite the benefits in

[13] Steven M. Ferguson and Uma S. Kaundinya, "Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs," chapter 14, pp. 185-206, in *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies*, Edited by Craig Shimasaki (Oxford, UK, and Waltham, MA U.S.A.: Academic Press, Elsevier, 2014), pp., 189-90.
[14] GAO, op. cit., p. 43.

terms of ROI to patenting expenses, acquiring foreign patenting costs more than acquiring U.S. patents alone.

The analysis presented here does not consider the extent to which all federal agency license agreements have resulted in commercialization. That question was beyond the scope of the investigation. The focus, instead, is on the return on investment in the cost of obtaining foreign patents. Two case studies of patenting and licensing process outcomes are presented in Appendix C. Both cased studies tell complementary stories about the success of the patenting and licensing process, despite the long time for commercialization to be realized. The two cases in Appendix C complement each other, and they also complement this report's analysis of the agencies' patenting and licensing process and the agencies' ROI on acquiring foreign patents.

Before turning to what can be learned from these two successful cases, some reflections on a case study that could not be completed are worth considering. As will be detailed in the following section (Federal Agencies' Patent Portfolios), federal agencies vary widely in the extent to which they acquire foreign patent protection. For example, the foreign proportion of all distinct Health and Human Services (HHS) patents is approximately 50 percent. For the Environmental protection Agency (EPA) the foreign proportion is 25 percent. And the agencies' approaches to foreign patenting are also very different. While NIH (within HHS) routinely files for foreign patent protection, EPA routinely does not do so currently. According to a representative, "EPA stopped filing foreign patents many years ago because we never saw a good return on investment."[15] If the types of technologies developed by EPA and its technology partners do not have prospects for sales in international markets, of course, the decision not to file applications for them would be a good one. The benefit-to-cost ratios developed in Section 4 below (for the financial return to the investment in foreign patents) confirm what the EPA representative said about the poor return for their foreign patent applications.

[15] Anonymous personal communication, March 11, 2020.

In one case, on the basis of a 2008 collaborative agreement, a CRADA in this case, with a company that will be referred to as Alpha Company, the company, rather than the EPA, applied for the U.S. patent in 2009, and foreign patents thereafter.[16,17] Had the EPA applied for the patents and decided to license the technology to their technology development collaborator, Alpha Company, EPA's experience of "poor ROI" would likely have been affirmed.

According to EPO records, Alpha Company filed European Patent Office and World Intellectual Property Organization applications as well as follow-on applications to Brazil (BR), China (CN), Costa Rica (CR), Canada (CA), and Australia (AU). The applications to Brazil, China, and Costa Rica, however, were discontinued, and the application to EP was "withdrawn." Patents *were* eventually granted by both USPTO (2011) and by Canada (2018, subsequent to the application in 2009), and both remain "active" (they expire in 2029). A patent was also granted by Australia in 2015 (subsequent to the application in 2009) but its legal status is now "ceased." This pattern of "application" and "withdrawal," and the various gaps between application and patent grant, illustrate one of the challenges of the patenting and licensing process. That is, whether the applicant is a federal agency or a company, after a patent application is filed the expected market demand may not materialize soon enough to warrant continued investment in patent prosecution. When the patent was granted, in 2011, it was assigned to both the EPA and Alpha Company.

Alpha specialized in environmental remediation of complex environmental problems using green (plant-based) technology *in situ*. (Conventional remediation at the time involved the costly removal of soil contaminants and off-site treatment.) In 2008, the Alpha Company had 19 employees. In 2014 Beta Company, also small, bought the rights to all Alpha Company's intellectual property. The CEO of Beta Company explained that Alpha's demise had nothing to do with the patented technology. It was a minor part of both Alpha's and Beta's service

[16] From the patent in question: "This invention was made with the support of the United States Government as indicated in a Cooperative Research and Development Agreement (CRADA) with the Environmental Protection Agency (EPA) (EPA Case No. 755-09). The Government has certain rights in the invention."
[17] "Alpha Company" was subsequently purchased by "Beta Company," and the CEO of Beta discussed some details of the jointly assigned EPA patent on the condition that the true identities of Alpha and Beta not be divulged.

offerings. However, after the financial crisis of 2009, Alpha, as a small publicly held company, was unable to deal with the new regulatory burdens placed on public companies. Alpha's Board of Directors determined that it could not continue on its current path and sold its intellectual property to Beta Company.

Even though the patented technology itself played no part in Alpha Company's undoing, its approach to technology was very different than that of Beta Company's and relatively costly. Alpha and Beta have complementary patents in the sense that they are both focused on non-conventional plant-based remediation. But Alpha routinely filed domestic and international patents whereas the Beta Company's approach was "more pragmatic concerning investment in patent filings and prosecution."[18]

Regarding the specific technology that grew out of the 2008 EPA-Alpha collaboration, continued experimentation with the technology did not indicate the ability to generate the expected chemical result. The catalyst expected to be superior to competing chemicals turned out to be merely comparable to low cost commodity products already on the market. In other words, according to the Beta Company CEO, "the original vision for the technologies held by the inventors did not align with the true commercial prospects of the intellectual property in the marketplace" — an example of something that happens quite often in technology companies. This was the cause of the pattern of "application" and "withdrawal" and the various time gaps between application and patent grant that can be read in the patent records.

The Beta Company CEO explained that from a company point of view there is a limited time window under patent laws for market-testing a product prior to filing. But there is a risk in waiting to file since someone could file problematic prior art. So, it is not unusual to trim the number of jurisdictions in which patents are prosecuted as market potential is more fully assessed. Given these limitations of the patented technology in the market, it was decided that the Alpha Company's IP did not warrant much additional investment in patenting or

[18] Anonymous personal communication, April 9, 2020.

marketing. Yet, at the time of the evaluation there was interest from resellers in the U.S. and Canada, which is why those patents were continued:

> "While sales volume in U.S. and Canada had been very low, with most of the investment in the patent process having been made, we continue to keep those patents active for the time being. Our decision to keep this patent active in the U.S. was based on market interest and timing and the fact that most of the costs were incurred before the decisions were made to trim investment in patents."[19]

Turning to a pair of patenting and licensing case studies that exhibit remarkable success, first a word about their "selection" as case studies. The requirement was to develop "up to three case studies" based, in part, on recommendations from federal agencies. Developing a case study requires some cooperation from the licensor and the licensee. For the most part, that cooperation proved very hard to secure. As discussed at length in the USDA estolide oil case study (Appendix C), the willingness of license participants to discuss details of a particular license arrangement is quite limited and very uneven among federal agency licensors and among their licensees. An initial 12 case study candidates (8 of which were suggested by just 4 of the 11 federal agencies that were asked for suggestions) was quickly reduced to just one (USDA's estolide oil) because the licensee, Biosynthetic Technologies (a privately held company), was willing to answer detailed questions that other parties to license agreements—federal agencies and companies alike—were not, taking the approach that since some of the information was proprietary, it would be best not to provide any information. The second completed case study is focused on NIH's drug-eluting coronary stent license and was the result of extraordinary cooperation with experts, the availability of Security and Exchange Commission filings typical of publicly traded companies, and fortuitous access to court records concerning related patent litigation. (The full NIH drug-eluting coronary stent license case study is contained in Appendix C.)

[19] Anonymous personal communication, April 9, 2020.

As the reader will see, both case studies focus on licenses and patents that have been very successful both in terms of commercialization and in terms of generating revenue that pays back patenting and licensing costs by many multiples. And while the overall conclusion of this report is that more investments should be made in support of foreign patenting by federal agencies (based on the subsequent analysis of the ROI for foreign patents for technologies that also have domestic patents compared with the return on domestic patenting alone; the basic message from the estimated relationship holds across all the agencies with foreign patenting activity), these case studies are in no way representative of all federal agency licenses involving patent protection in foreign jurisdictions. Nor are the cases comparable in all respects. They involve very different technologies, industries, and historical circumstances; and yet, they both illustrate the uncertainties in the agencies' patenting and licensing process and the lags from invention in the federal laboratories to successful commercialization of the developed technology. Note that the statistical model designed for this research project develops information about the value of foreign patent protection, as compared with U.S. patent protection alone, for the agencies. That is the research question addressed for which new knowledge is developed.

After applying for USPTO patents and also filing EP and PCT applications, thereby protecting the intellectual property, when a license is finalized, the license may be royalty free (and in some cases the licensee may take over further prosecution of the patents). Since the overarching goal is technology transfer, and getting the patents supports the successful acquisition of licensees and the transfer of the technologies, even if an agency spent more of its budget acquiring patents than it got in return in licensing revenues, the goal of Congress for technology transfer is supported.

The NIH stent technology transfer involved a fairly large, well-financed, publicly-traded licensee while the USDA's estolide oil technology licensee originated in a regional farmers cooperative, and struggled for years to evolve into a corporate organization that could sustain the interest of large equity investors. In the case of the stent technology, a series of European patent litigation battles successfully defended the NIH's licensee's intellectual property claims in foreign markets. For the USDA licensee the mere existence of U.S. and foreign

patents was sufficient to ward off competitors. Still, some common features are worthy of notice.

Both clearly succeeded in commercializing the U.S. government's patented technology and both earned millions of dollars in royalties for their licensor agencies. While estolide technology earned several multiples of the USDA's investment in its patenting and licensing process for all of the domestic and foreign patents obtained in the family of patents for the technology, NIH's drug-eluting coronary stent technology was nothing short of a blockbuster in terms of license revenue, earning tens of millions of dollars in royalties for the NIH, more than the cost of the underlying research effort and the patenting and licensing expenses combined. Revenues aside, the NIH technology has been hailed as a "medical marvel" that improves lives of hundreds of thousands of patients every year in the U.S. alone. USDA's estolide oil technology claims are more modest but it could well be that with global concerns about environmental sustainability, the commercialization horizon will expand much further into the future.

What is also very clear from both case studies is the considerable time span between invention and commercialization. These time spans make it clear why filing the foreign patent applications, without yet having an agreement with a licensee, is a good idea. If the agency's OTT believes that the commercial potential is strong, it can file the applications and protect the IP while it looks for the right licensee. With the IP protected, it will not be offering what one of the agency's technology transfer experts called "damaged goods." Moreover, once the right licensee is found, it may be able to take over the further prosecution of the patents, for example filing new applications in additional countries cooperating with the European Patent Office where an EP patent was originally obtained, and also may take over the payment of the annuity fees for the patents applied for at the outset by the agency. These long time spans mean that a large measure of uncertainty is close to the foreground of most decisions to patent scientific inventions and to license the promise of their commercialization. In the case of the drug-eluting coronary stent technology, the long process from lab-to-market was driven by the regulatory approval processes for medical devices in Europe, Japan, and the U.S. and by litigation in European markets. In the case of

the coronary stent technology effective demand was strong. In the case of estolide oils technology effective demand was nascent but has been growing as the U.S. and other economies slowly come to terms with demands of environmental sustainability.

In the case of the coronary stent technology, the exclusive licensee (Angiotech Pharmaceuticals) had already developed a patent portfolio (the so-called Hunter patent and the family of patents that were based upon it) that complemented various aspects of the technology that would be incorporated in a drug-eluting coronary stent system. The high degree of complementary patented technologies observable in the NIH's choice of licensee came only slowly, over an extended time, for the USDA's estolide oils licensee. And that case is marked by a series of corporate reorganizations in search of the financial and technical know-how that could meet the quantities required by a potentially large international market for "green" oil with precise chemical qualities. From a scientific and technical standpoint, the NIH licensee took the lead in technology development and approval process and fought important patent litigation battles at considerable expense. USDA's transferred estolide oil technology, needed fine-tuning to match the demands of many niche green oil markets, from automotive lubricants to cosmetics. The initial exclusive licensee, Peaks & Prairies, LLC, was long on vision and entrepreneurial energy but short on scientific capability and received continuing support in terms of research contracts (from DoE and the U.S. Army) and a series of technology development collaborations with USDA that continue to this day.

While foreign patents were important for both commercialization efforts, the differences between the NIH and the USDA cases is stark. Because U.S. FDA approvals were required before commercialization could begin in the U.S., the foreign patents proved to be especially important for the timely launching of the paclitaxel-eluting coronary stent in the worldwide market and its rapid acceptance and ascendance as the leading drug-eluting coronary stent. Angiotech's successful defense of its patents in important infringement cases between 2005 and 2007 protected the viability of the combined NIH, Angiotech, and Boston Scientific (Angiotech's licensee) patent portfolios for the paclitaxel-eluting coronary stent. Without

these legal successes, sales of the NIH-based stent technology and license revenues for NIH would have been significantly eroded.

For Biosynthetic Technologies—the result of a long organizational metamorphosis of the USDA's initial licensee—the USDA foreign patents had an important strategic impact by keeping European competitors out of the world market for estolide oil. But, in this case, the implicit threat of litigation appears to have been enough to ward off potential rivals. It is worth noting too that even though the USDA's original patent expired in 2018, by that time the technology had been significantly improved—due to collaborations between organizational reincarnations of Peaks & Prairies, the initial exclusive licensee, and USDA—and surrounded by complementary Biosynthetics Technology patents, the majority of which are protected in foreign jurisdictions. Some of these are, or likely will be, assigned jointly to USDA and Biosynthetics Technology as a result of their continuing twenty-six years of technical public-private collaboration.

In conclusion, both case studies illustrate the challenges and the great uncertainty that characterize the process of technology transfer of a federal agency's invention created with R&D in a federal laboratory. They also illustrate the immense public benefits that can result from accepting the challenges of obtaining patents and granting licenses that result in the successful commercialization of federal agencies' patented technologies.

USDA's estolide oil patents expired in 2018. Assuming that USDA paid *all* the U.S. and foreign patenting costs, for these patents, it would have incurred costs with present value in 1998 of approximately $174,500 (in constant dollars of 2015) over the life of its two estolide patents. Without knowing the timing of the royalty payments to USDA, their present discounted value cannot be computed. But using the estimate of $2.6 million in revenues paid to USDA 2012-2016, centering the sum on 2014, and discounting the total with the OMB-mandated 7% opportunity cost of public investment funds, gives a present discounted value of $881,000 in revenues. Thus, using the narrowly financial measure of the return on the patenting costs, the ROI as measured with a very rough benefit-to-cost ratio of 5.0 surpasses

the benefit-to-cost ratio of 2.2 estimated for protecting the intellectual property of a USDA USPTO-patented technology with a foreign patent.[20]

NIH patents for the paclitaxel-eluting stents expired in 2013. The present discounted value of the royalties received by NIH, in constant dollars of 2012 discounted back to the time of the original patent application in 1993, is $57 million. Using the narrowly financial measure of the return on NIH's discounted patenting costs investment the benefit-to-cost ratio is 167.[21] This compares quite favorably to the benefit-to-cost ratio of 25.6 estimated for protecting the intellectual property of an HHS USPTO-patented technology with a foreign patent in a representative year.[22]

In both cases as well, the importance of having foreign as well as U.S. patents to protect the agencies' intellectual property is illustrated by the competitive struggles that face market entrants. The mere existence of complementary European patents proved effective in warding off estolide oil entrants, substantial litigation costs were required to protect the intellectual property in foreign markets—and income stream—in the case of NIH-invented and licensed coronary stent technology.

The NIH case, especially, illustrates that finding a potential licensing partner with a complementary set of patents can be critically important, and that the agency's patent portfolio will need foreign patent protection to help a federal agency find appropriate licensees if the technology is to be used in products sold in international markets. Both case studies show that having an appropriate portfolio of foreign patents enables the licensees to make what are likely to be relatively large investments in the commercialization phase of the lab-to-market process. In the NIH case its licensee also greatly reduced the federal agency's need to acquire and protect foreign patents itself because the licensee had a large collection of foreign patents on its own technology that complemented the NIH patents. In that case

[20] The 2.2 benefit to cost ratio for USDA is estimated in our Task 2 report found in Appendix B of this report.
[21] The estimate of patenting costs to NIH of 4 US patents and 15 foreign patents = $341,212.00 in 2015 dollars. See the Task 2 report in Appendix B, pp. 30-39. The HHS cost of an additional foreign patent is $15,632 (p. 39). The cost of an additional U.S. patent is $26,683 (pp. 30-33).
[22] The 25.6 benefit to cost ratio for HHS is estimated in the Task 2 report found in Appendix B.

Boston Scientific's risky, time-consuming series of clinical trials to determine the best combination of paclitaxel dosage and release rate paid big dividends by creating the bullet-proof product. While the USDA's licensee did not come to the license negotiating table with a complementary patent portfolio, the licensee transformed into such an organization because potential investors were attracted by Biosynthetic Technology's technology development strategy and patent portfolio.

Both case studies reinforce the hypothesis derived from the statistical analysis, discussed in Section 4 of this summary, that, without additional foreign patent protection, inventions protected by domestic patents alone, are viewed by potential licensees as "damaged goods."

3. Federal Agencies' Patent Portfolios

To characterize the extent to which federal agencies are protecting their inventions with foreign patents as well as U.S. patents, the patent portfolios of 11 federal agencies were followed from their applications to the United States Patent and Trademark Office (USPTO) and to foreign patent authorities captured by the European Patent Office's (EPO's) PATSTAT worldwide database. The review of 11 federal agency's patents covers fiscal years 2003 through 2017, and additionally the portion of filings that were currently available for fiscal year 2018 in the PATSTAT data for Spring 2019, the latest edition of the database available at the time the overview was prepared for this report. These 11 federal agencies report annually to Congress about their technology transfer activities in an annual publication produced by the National Institute of Standards and Technology: *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress* is the particular annual report used in the present study.

For each patent application a federal agency files with the USPTO, the extent to which the agency also *applied for* patent protection in non-U.S. jurisdictions is known, whether or not a patent was actually *granted*. Agencies file applications in other jurisdictions to obtain foreign patent protection to accompany the protection obtained with a patent from the USPTO. Multiple applications for the same invention are to obtain protection in different

countries and also may be for broader or narrower intellectual property claims concerning the invention.

The data gathered from PATSTAT is used to characterize the extent to which the agencies have acquired foreign patents for their inventions. The analysis begins with the determination of "invention families" (referred to in Appendix B as "USPTO-patent-application invention families"). For each of a federal agency's patent applications to the USPTO, the invention family consists of that application and all other patent applications by the agency that are based on essentially the same technology—the same "invention"—regardless of the patent authority to which the other applications are made.[23] For each USPTO application's invention family of patent applications, the patents granted were found, and after eliminating duplications, agencies' "distinct patents," "distinct foreign patents," and their proportions, are compared.

Table 1 summarizes the findings about the extent to which each of the federal agencies has obtained foreign patents as well as U.S. patents. For agencies' USPTO applications, the percentage of the inventions that have foreign patent protection ranges from zero—for the Department of Homeland Security and the Department of Transportation—to 50 percent for the Department of Health and Human Services. The range, across the agencies, for the percentage of each agency's total patents taken by foreign patents is shown in column (7) and is similar to the range for the percentage, shown in column (4), of each agency's "USPTO-patent-application invention families" with foreign patent protection in addition to U.S. patent protection, although it need not be the same.[24]

[23] European Patent Office refers to the DOCumentDataBase (DOCDB) simple patent family. See, https://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families/docdb.html.

[24] Columns (4) and (7) will in general differ for two reasons. For one, some of the applications in column (2) did not themselves result in a patent, but another application based on the same invention resulted in a patent. For another, the number of foreign patents for each USPTO patented invention can range from zero to several; and so, the percentage of foreign patents in the total patents will not in general be the same as the percentage of patented inventions that have foreign patents.

Table 1. The Extent of Foreign Patenting for U.S. Federal Agencies Associated with their Applications to USPTO for Fiscal Years 2003 through Fiscal Year 2018.[a]

(1) Agency[b]	(2) The number of applications to USPTO that resulted in a patent either for the application or for another USPTO application based on the same invention ("Invention Families")	(3) The number of the USPTO applications in column (2) for which the invention underlying the application is protected with foreign patents	(4) The proportion of USPTO applications in (2) for which the invention underlying the application is protected foreign patents[c]	(5) The total number of distinct patents[d]	(6) The number of distinct foreign patents[d]	(7) Distinct foreign patents as a proportion of total distinct patents[e]
USDA	792	104	0.131	982	193	0.197
DOC	200	8	0.0400	206	8	0.0388
DoD	6899	245	0.0355	7364	432	0.0587
DOE	5841	957	0.164	6844	1002	0.146
HHS	2112	1067	0.505	4379	2209	0.504
DHS	24	0	0.0	22	0	0.0
DOI	48	3	0.0625	48	1	0.0208
DOT	30	0	0.0	29	0	0.0
VA	488	184	0.377	756	292	0.386
EPA	91	16	0.176	132	33	0.25
NASA	1358	63	0.0464	1478	107	0.072

[a]Data for fiscal year 2018 is not complete.

[b]Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA).

[c]Either for the application or for another USPTO application based on the same invention; column (3) divided by column (2).

[d]The number is the number of distinct patents. When an agency has multiple patent applications to USPTO or to foreign patent authorities based on the same underlying invention, multiple patents associated with the related set of applications would be counted. Multiple counts of a patent are avoided by reporting the number of distinct patents.

[e]Column (6) divided by column (5). When comparing columns (7) and (4), observe that each USPTO patented invention could have several foreign patents; that is, the invention could be patented in several foreign countries.

More detailed findings about the number of agency patent applications, domestic and foreign, and the number granted foreign patents by agency, and a detailed description of the methodology used to obtain those findings can be found in Appendix A. Also detailed in Appendix A is a comparison of patent counts reported by the agencies in *Federal Laboratory*

Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress and counts presented in Table 1.

4. Benefits and Costs of Foreign Patent Protection for U.S. Federal Agencies' Technologies

4.1. An Estimated Model of Invention-Licensing Revenues and the Effect of Additional Foreign Patents

With the data available from 11 federal agencies reporting to NIST's annual *Federal Laboratory Technology Transfer, Fiscal Year 2015* report and worldwide patent records, the first question (about the dependent variable in the equations developed and estimated below) is: "What determines invention license revenues?" The second question is: "Are invention license revenues affected differently if federal agencies acquire only U.S. patents, or, if, in addition to acquiring U.S. patents, agencies also acquire patents in non-U.S. jurisdictions (foreign patents)?"

This report estimates a statistical model of U.S. federal agencies' invention-licensing revenues over time. That is, equations, one for each agency (because agencies will differ in many ways – from their missions to their negotiation skills and the business models of their licensees), are constructed that show annual federal agency licensing revenues as the "dependent variable" (the quantity explained) as a function of (explained by) annual values for a group of "independent variables." One of those independent variables is the foreign patents granted to an agency in any given year. The model begins with the observation that license revenues will depend on the history of the agency's applications for U.S. and foreign patents and on the history of the grants of U.S. and foreign patents to the agency. It is expected that each agency's invention-licensing revenues over time will be a function of the history of its patent applications and of its patents ultimately granted since the relationship between the past patents and the fiscal year's revenues recurs through time. Rather than showing the time series for each fiscal year's new USPTO applications and its new U.S. and new foreign patents extending into the past, the effect of those past applications and patent grants (applications and grants prior to year $t - 1$) is captured by estimating the explanatory

power, ceteris paribus, associated with y_{it-1}, the licensing revenue from fiscal year $t - 1$ which the history of those past applications and grants has determined. For that reason, the lagged dependent variable y_{it-1} is included as an explanatory variable in the model. Its coefficient, reflecting its partial effect after the other explanatory variables are included, will reflect the impact of the long history of applications and granted patents.

In addition to the effects of the history of applications and patents, other things will matter for an agency's invention-licensing revenues. Because the agencies differ in their missions and their technologies and their policies toward negotiating licenses, we also include in the model different constant terms for each agency that are denoted with A_i for the i^{th} agency's constant term. In the model the coefficients on the explanatory variables describing each agency's history of patent applications and grants are also allowed to differ across the agencies. Agencies will differ in the sizes of their patent portfolios and the value of their patents on average. The constant terms will adjust the overall level of the revenues that will be higher or lower depending on idiosyncratic characteristics of the agency such as its policy toward licensing negotiations. Some agencies will negotiate licensing fees that capture more of the commercial value that the licensee will create by commercializing the licensed technology. The coefficients on the explanatory variables describing the history of applications and patents will also vary across the agencies with the differences in the licensing revenues gained from adding a new patent to their portfolio.

Finally, to control for differences in revenue that are peculiar to a given fiscal year, these time effects are captured with qualitative variables d_year_t for each fiscal year. Any trend over time is captured with a variable *analytical_time* that equals the fiscal year minus 2002.[25] In all, with u_{it} denoting random error, and with the effects of the new U.S. and new foreign

[25] The analysis presented here is at the level of the total annual licensing revenues for the agency, not at the level of the annual revenues that the agency receives from each individual licensee. Thus, one can imagine many interesting questions and research designs that are not available with the aggregated data. The question that can asked and answered is how the patent revenues are related to the history of the domestic and foreign patent applications and the patents granted over time. The model is designed so that (as seen subsequently) the value of having the foreign patents as well as the domestic patents can be identified. In the course of the investigation it was discovered that some agencies' information systems could report the number of patents that generate license revenue and the amount of revenue. For some agencies that information is considered confidential.

patents extending into the past and captured with the partial effect for the lagged dependent variable as explained in the foregoing discussion, the estimable model of invention-licensing revenue is:

$$y_{it} = a_{1i}AppUSnoFN_{it-1} + b_{1i}AppUSFN_{it-1} + c_{1i}PatUS_{it-1} + d_{1i}PatFN_{it-1} + fy_{it-1} + A_i + \sum_t h_t d\_year_t + k(analytical\_time) + u_{it}$$

Table 2 provides the definitions for the symbols used in our description of the statistical model.

Table 2. Definitions.

Variable	Definition
y_{it}	the i^{th} agency's invention-licensing revenue, in thousands of constant 2015 dollars, in fiscal year t
$AppUSnoFN_{it}$	the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent but for which a foreign patent for the underlying technology was never granted
$AppUSFN_{it}$	the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent and for which at least one foreign patent for the underlying technology was also ultimately granted
$PatUS_{it}$	the number of new U.S. patents granted to the i^{th} agency in fiscal year t
$PatFN_{it}$	the number of new foreign patents granted to the i^{th} agency in fiscal year t
A_i	the i^{th} agency's constant term (a parameter of the model to be estimated)
d_year_t	A qualitative variable equal to 1 for fiscal year t and 0 otherwise
analytical_time	the fiscal year minus 2002

Source: Authors' definitions.

4.2. Estimated Agency-specific Invention-licensing Revenue Functions

To account for the heterogeneity of the agencies, the estimated function for each agency is allowed to differ. Agency-specific revenue functions are analyzed in two groups – one group includes the four agencies (DOD, DOE, HHS, and NASA) that together account for about 90% of the patenting activity of the 11 federal agencies that we are studying. The other group analyzed includes the seven agencies (USDA, DOC, DHS, DOI, DOT, VA, and EPA) that have far less patenting activity – about 10% of the total for all 11 agencies.

For summary purposes, first the agency-specific invention-licensing revenue functions are estimated and displayed graphically for the four federal agencies with the largest patent portfolios over the fiscal years 2003 through 2015. Over the 13 fiscal years, the 11 agencies were granted 12,992 U.S. patents; DoD, DOE, HHS, and NASA together were granted

11,920 U.S. patents, or 92% of the total. Over the 13 fiscal years, the 11 agencies were granted 2834 foreign patents; DoD, DOE, HHS, and NASA together were granted 2492 foreign patents; or 88% of the total.[26] Second, the licensing revenue functions for the remaining seven agencies are estimated and displayed graphically. Detailed statistics for the estimations of the 11 invention-licensing revenue functions are provided in Appendix B.[27]

Table 3 shows, for the four agencies with about 90% of the patenting activity, the descriptive statistics by agency for the dependent variable and the explanatory variables that describe the histories for the applications and patent grants. Observe in the detailed statistics for the models estimated that are presented in Appendix B that there are sufficient numbers of observations to estimate the models described in overview here.[28]

[26] The figures were tabulated by the authors from PATSTAT, available at https://www.epo.org/searching-for-patents/business/patstat.html#tab-1. These four agencies also contribute over 90% of the invention disclosures over the sample period. See Albert N. Link, "Technology Transfer at U.S. Federal Laboratories: An Analysis of Invention Disclosures," Working Paper, University of North Carolina at Greensboro, March 2020.

[27] For readability here in this summary, the individual estimated coefficients for the time dummies and the time trend are suppressed but included symbolically, shown with "hats", to indicate that these control variables, for which the coefficients are not of intrinsic interest, are indeed controlled in the specifications. For these controls and all of the other variables, the detailed numerical coefficients and their standard errors and *p*-values are included in Appendix B.

[28] Without looking at the detailed estimation in the appendix, one might count explanatory variables and reach a mistaken conclusion. With the pooled sample and the controls for idiosyncratic effects of the agencies for the patent histories and the controls for the macroeconomic effects, there are sufficient degrees of freedom as the detailed statistics in Appendix B show.

Table 3. Descriptive Statistics for the Variables for the Four Agencies with 90% of the Patenting Activity for Fiscal Years 2003 Through 2015.

Mean, (Standard deviation), [Minimum, Maximum]

Variable	Agency			
	DOD (n=13)	DOE (n=13)	HHS (n=13)	NASA (n=13)
y_{it}	13774 (4034) [6836, 21414]	36643 (6330) [28728, 47681]	99754 (23940) [69068, 147512]	3232 (1130) [1688, 5224]
$AppUSnoFN_{it}$	452.1 (42.2) [377, 506]	361.3 (51.8) [298, 452]	59.9 (8.7) [43, 74]	89.8 (13.5) [55, 109]
$AppUSFN_{it}$	17.5 (7.3) [5, 35]	38.4 (8.2) [23, 51]	74.5 (18.3) [45, 114]	4.85 (4.65) [1, 17]
$PatUS_{it}$	399.7 (162.2) [46, 577]	324.6 (162.8) [65, 547]	117.5 (66.8) [24, 230]	75.2 (41.8) [4, 118]
$PatFN_{it}$	24 (10.5) [4, 37]	46.8 (32.5) [6, 102]	114.4 (61.7) [24, 198]	6.46 (7.88) [0, 27]

Note: The variable y_{it} is measured in thousands of constant 2015 dollars.
Source: Authors' calculations.

The estimated model for DoD is:

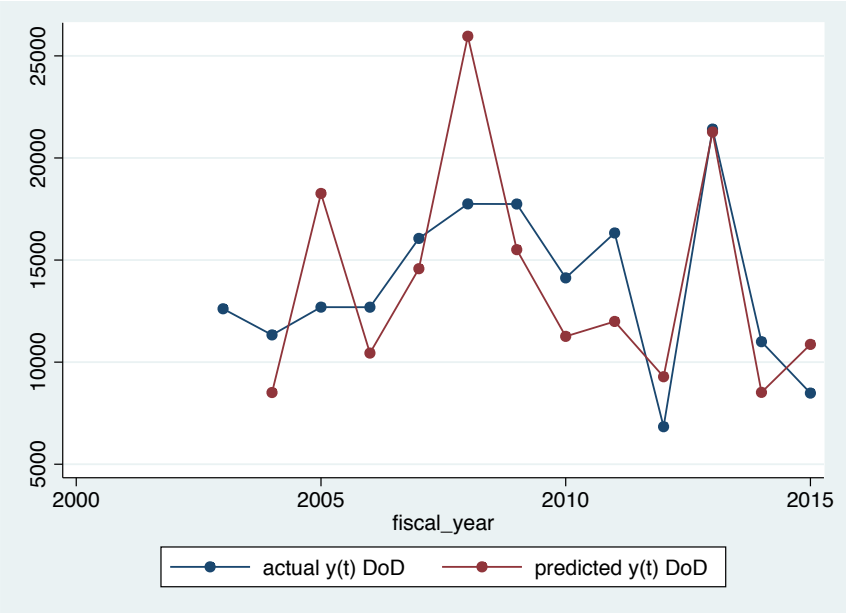
$$y_{it} = -114 AppUSnoFN_{it-1} + 1223 AppUSFN_{it-1} + 122 PatUS_{it-1} + 484 PatFN_{it-1}$$
$$+.33 y_{it-1} - 17500 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 2 compares DoD's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DoD.[29] In this figure and in those that follow, large dots are used to indicate the actual result or the prediction for each year. The dots are connected with straight lines to illustrate visually the direction of change from one year to the next for the fiscal year's actual or predicted licensing revenues. The actual and predicted amounts are the amounts for each of the fiscal years. If the amounts per unit of time (one

[29] Note that having the aggregate data for the total annual licensing revenues for an agency does not create a problem with the mixture of high royalty licenses and low or no royalty licenses in the agency's portfolio of licensed patented inventions. First note that the model estimates essentially the same way for all the agencies. Some have bigger revenue effects from their history of applications and patents, yet the same basic relationship holds. Second, note that the model is not looking at the individual licenses but the aggregation of them all and asking if the history of the applications and the patents has an effect on the aggregated revenues. Third, observe that the agencies that have more of the royalty-free licenses and fewer of the large royalty cases, then the history of the applications and patents will have less effect. It turns out that is what is found in the data, and by the conclusion of the report, very different values of obtaining foreign patents are found for the different agencies.

fiscal year) at each instant in time were being illustrated, a smooth, nonlinear line with no large dots would be more appropriate.[30]

Figure 2. Comparison of DoD's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



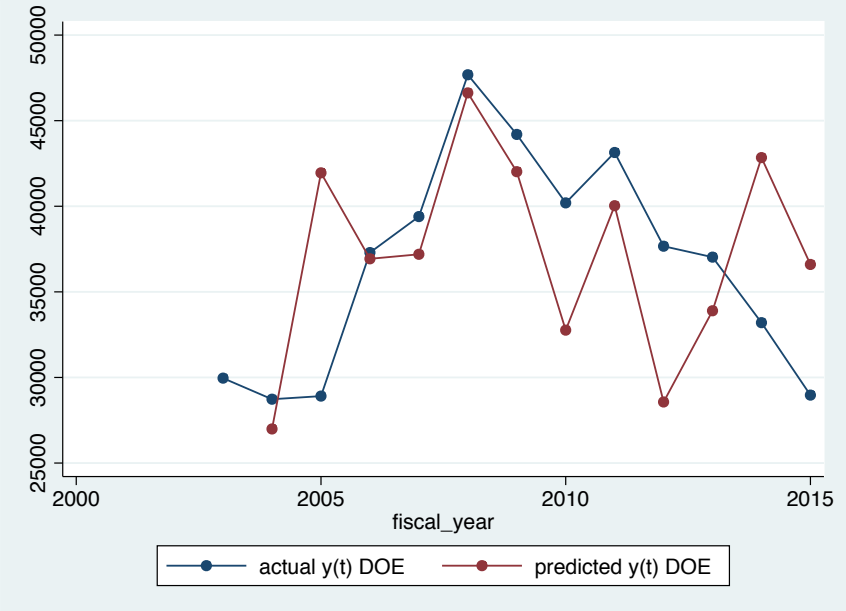
The estimated model for DOE is:

$$y_{it} = -177 AppUSnoFN_{it-1} - 84 AppUSFN_{it-1} + 153 PatUS_{it-1} + 142 PatFN_{it-1}$$
$$+ .33 y_{it-1} + 41182 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 3 compares DOE's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DOE.

[30] An alternative visualization that uses rectangular blocks to show the amounts for each fiscal year would not only convey the information in a less readily visualized way, but it would incorrectly convey that the actual and predicted amounts for each fiscal year were received continuously over the year at the constant actual or predicted amount per year at each instant of time.

Figure 3. Comparison of DOE's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

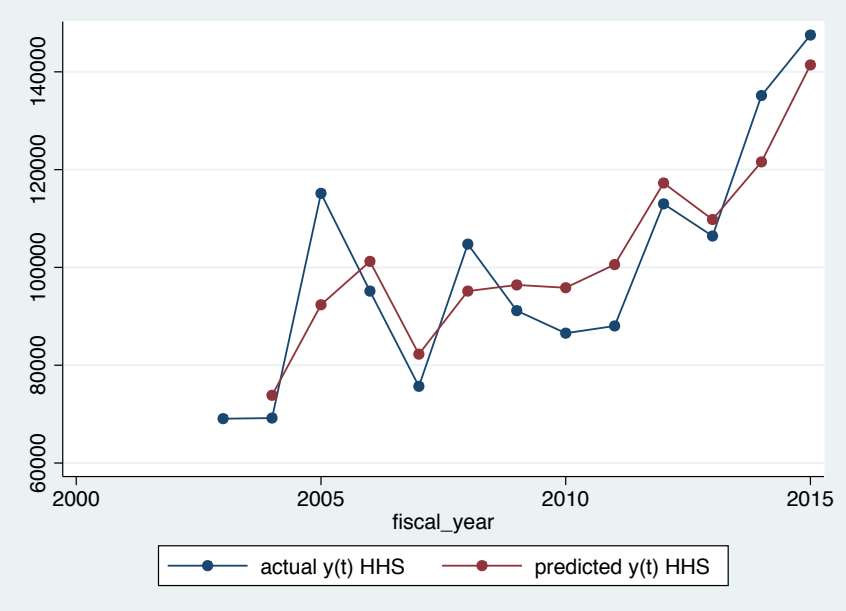


The estimated model for HHS is:

$$y_{it} = -138 AppUSnoFN_{it-1} + 124 AppUSFN_{it-1} + 424 PatUS_{it-1} + 54 PatFN_{it-1}$$
$$+ .33 y_{it-1} + 18096 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 4 compares HHS's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for HHS.

Figure 4. Comparison of HHS's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

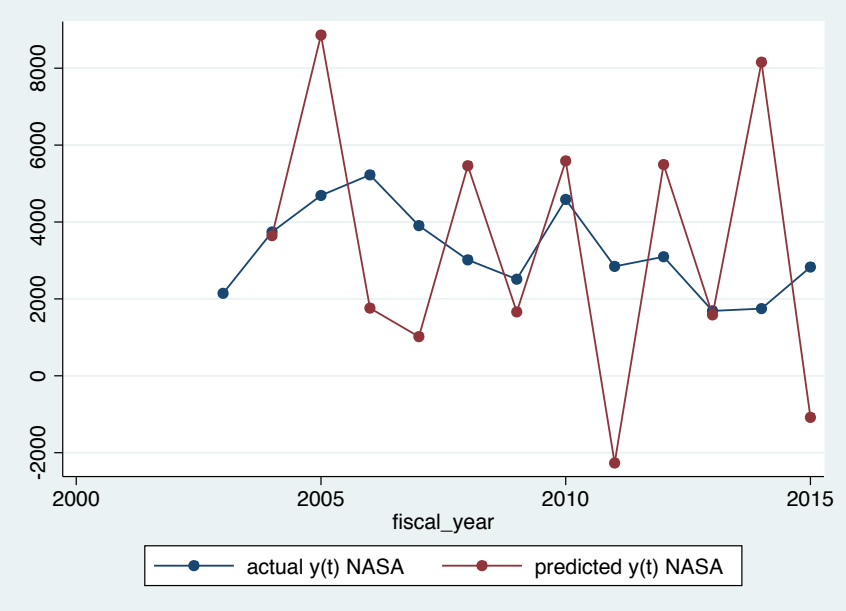


The estimated model for NASA is:

$$y_{it} = -228 AppUSnoFN_{it-1} + 483 AppUSFN_{it-1} + 400 PatUS_{it-1} + 930 PatFN_{it-1}$$
$$+.33 y_{it-1} - 11120 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 5 compares NASA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for NASA.

Figure 5. Comparison of NASA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



Turning now to the 7 agencies comprising approximately 10% of the 11 federal agencies' patenting activity, Table 4 provides the descriptive statistics for the dependent variable and the explanatory variables that describe the histories for the applications and patent grants.

Table 4. Descriptive Statistics for the Variables for the Seven Agencies with about 10% of the Patenting Activity for Fiscal Years 2003 Through 2015.

Mean, (Standard deviation), [Minimum, Maximum]

Variable	Agency						
	USDA (n = 13)*	DOC (n = 13)	DHS (n = 13)*	DOI (n = 13)	DOT (n = 13)	VA (n = 13)	EPA (n = 13)
y_{it}	4075 (848.0) [2666, 5838] (n = 12)	239.2 (65.4) [155, 369]	0 (0) [0. 0] (n = 9)	80.8 (22.0) [52, 122]	19.0 [13.9) [0, 48]	268.6 (113.6) [140, 426]	686.8 (312.1) [198,1149]
$AppUSnoFN_{it}$	45.1 (11.2) [28, 66]	11.2 (6.6) [2, 24]	1.2 (1.5) [0, 4]	2.8 (1.6) [0, 5]	1.8 (1.5) [0, 4]	16.8 (8.2) [8, 30]	5.5 (2.9) [1, 11]
$AppUSFN_{it}$	7.1 (3.4) [2, 15]	.62 (1.0) [0, 3]	0 (0) [0. 0]	.15 (.38) [0, 1]	0 (0) [0. 0]	11.2 (5.3) [6, 22]	1.2 (1.4) [0, 4]
$PatUS_{it}$	42.9 (26.4) [4, 86]	7.8 (7.2) [0, 19]	.69 (1.3) [0, 4]	2.6 (1.7) [0, 6]	1.5 (1.2) [0, 4]	20.1 (16.0) [0, 55]	6.8 (5.5) [0, 18]
$PatFN_{it}$	10.8 (6.3) [0, 23]	.23 (.60) [0, 2]	0 (0) [0. 0]	.08 (.28) [0, 1]	0 (0) [0. 0]	12.8 (8.2) [1, 29]	2.4 (3.1) [0, 10]

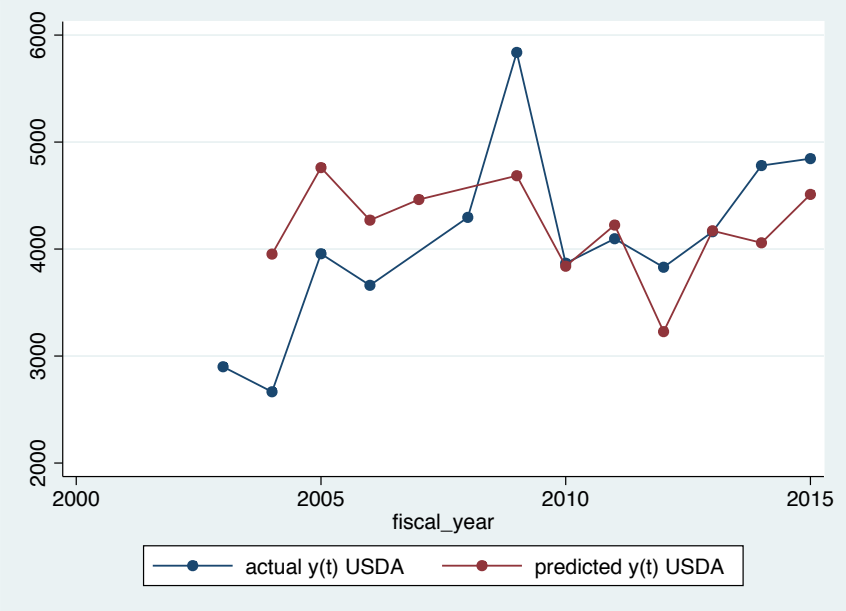
Notes: The variable y_{it} is measured in thousands of constant 2015 dollars. DHS did not report positive invention-licensing revenues until fiscal year 2016 (*Federal Laboratory Technology Transfer, Fiscal Year 2016: Summary Report to the President and the Congress*, National Institute of Standards and Technology, U.S. Department of Commerce, September 2019, p. 149, and the previous year's edition of the *Summary Report*, p. 161, available at https://www.nist.gov/tpo/reports-and-publications. Also see Excel spreadsheet, federal_lab_tt_database_v.2015.xlsx available at the same site.
*Exceptions for n are noted with the pertinent cases.

The estimated model for USDA is:

$$y_{it} = -58.5 AppUSnoFN_{it-1} - 26.0 AppUSFN_{it-1} + 9.6 PatUS_{it-1} + 48.9 PatFN_{it-1}$$
$$+.14 y_{it-1} + 5415.2 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 6 compares USDA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for USDA.

Figure 6. Comparison of USDA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

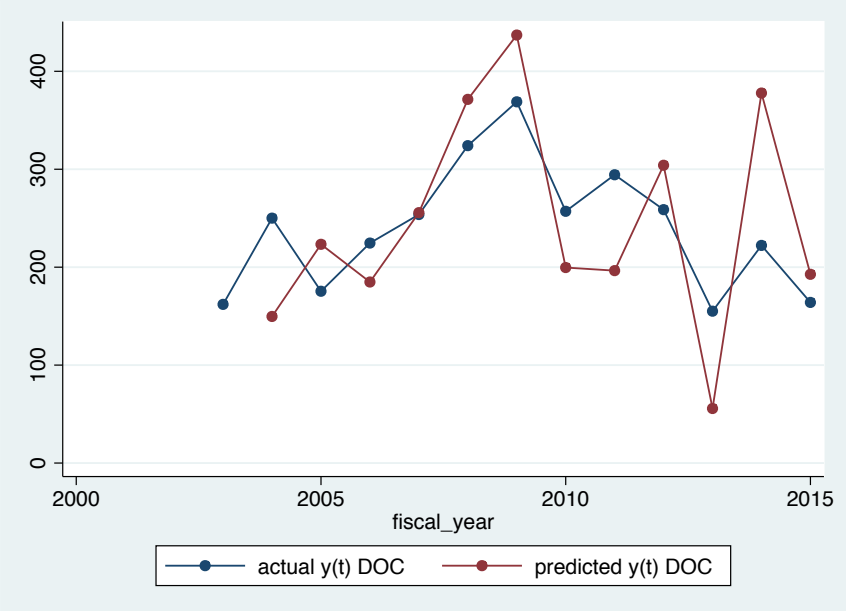


The estimated model for DOC is:

$$y_{it} = -1.9\,AppUSnoFN_{it-1} + 47.2\,AppUSFN_{it-1} + 1.2\,PatUS_{it-1} + 168.3\,PatFN_{it-1}$$
$$+.14\,y_{it-1} + .471 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 7 compares DOC's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DOC.

Figure 7. Comparison of DOC's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



The estimated model for VA is:

$$y_{it} = -24.5 AppUSnoFN_{it-1} + 22.1 AppUSFN_{it-1} + 14.9 PatUS_{it-1} - 10.9 PatFN_{it-1}$$
$$+.14 y_{it-1} + 71.3 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 8 compares VA's actual invention-licensing revenues with the estimated invention-licensing revenues.

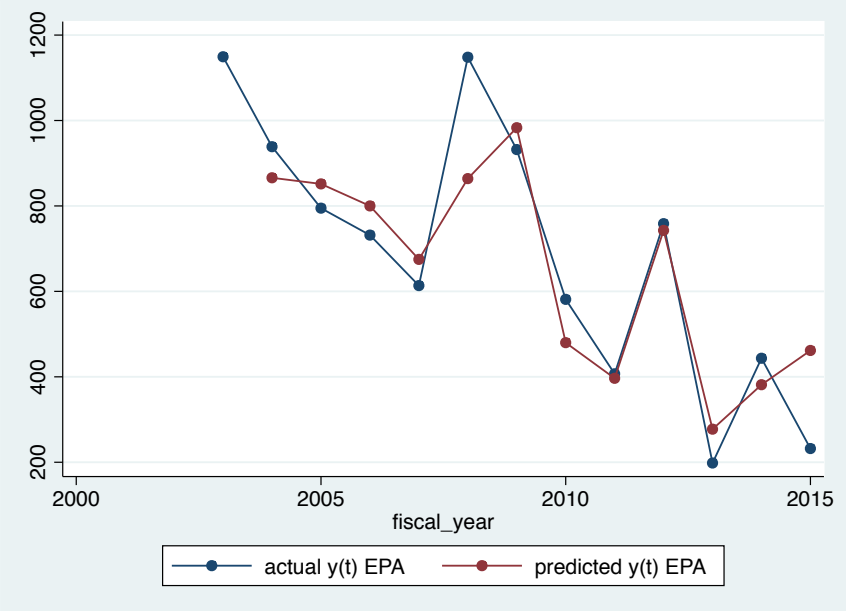
Figure 8. Comparison of VA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

The estimated model for EPA is:

$$y_{it} = -25.9\,AppUSnoFN_{it-1} + 39.5\,AppUSFN_{it-1} - 28.8\,PatUS_{it-1} + 18.4\,PatFN_{it-1}$$
$$+.14\,y_{it-1} + 612.6 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 9 compares EPA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for EPA.

Figure 9. Comparison of EPA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



Of course, not all of the agencies' patented technology is licensed and generating licensing revenues as illustrated by the case of DHS, founded in 2002. For the sample period, DHS had very little patenting activity. As shown in Table 4, neither DHS nor DOT had foreign patent applications or foreign patents in the sample period. The DHS and DOT estimated models are not informative for our purpose. For those two agencies, an individualized coefficient could not be estimated for either $AppUSFN_{it}$ or $PatFN_{it}$. Although DOI does have both some patenting activity and some licensing revenues, as reported in Table 4, it has just a single foreign patent pursuant to the applications that were made during our sample period. Thus, the estimated model for DOI is not useful for analyzing the impact of foreign patents on invention-licensing revenues, for essentially the same reason that the estimated models for DHS and DOT are not useful for that purpose. For the remaining agencies, even when they have relatively few royalty-bearing licensed technologies for their patented technologies, the model estimates well. We expect for those cases with relatively few royalty bearing licensed technologies that the estimation will show smaller effects of the application and patent histories on licensing revenues. Our model allows that result to be found, and indeed it is what we have found.

4.3. Interpretation of the Estimated Coefficients for the Explanatory Variables Describing the History of Patent Applications and Grants

For the four agencies with 90% of the patenting activity—DoD, DOE, HHS, and NASA—the estimated models are more statistically significant than the models estimated for the remaining agencies, although both sets of models are statistically significant. The estimated models for the agencies with the largest patent portfolios are informed by much more information about the relationship between the patenting activity and the licensing revenues that result. As expected, for those agencies, adding another patented technology to an agency's patent portfolio generates more revenue when the technology has foreign patent protection as well as a U.S. patent. Agencies will choose to pursue foreign patents for the more valuable technologies.

Beyond that, there is also evidence consistent with the hypothesis that a portion of the lower licensing revenues for technologies without foreign patents is *caused* by the absence of the foreign patents. In particular, by including the patent application history ($AppUSnoFN_{it}$ and $AppUSFN_{it}$) as well as the history of the timing for granted patents ($PatUS_{it}$ and $PatFN_{it}$) as explanatory variables in the statistical model, cases can be identified where adding U.S.-patented technologies that are not also protected with foreign patents actually has a negative effect on agencies' licensing revenues. One possible interpretation of that evidence is the hypothesis that agencies' acquisition of U.S. patents without also getting foreign patent protection reduces licensees' profitability when commercializing the federal agencies' technologies. Arguably, the reduction in the profitability would occur because the technology without foreign patent protection is available for foreign competitors to copy and compete with in international markets without incurring the costs of royalty payments for the use of the technology. In such a competitive environment, licensees would find the use of the technologies less profitable, and lower licensing fees would be negotiated for many of the agencies' technologies.

The results from the estimated model for the four agencies – DoD, DOE, HHS, and NASA – support the hypothesis that disseminating the federal agencies' technology without obtaining foreign patent protection may actually lower the profitability of the licensees that use the

U.S. patented technology. To understand why the results are consistent with that possibility, first consider an agency that adds to its patent portfolio a new patented technology that is protected with a U.S. patent and a foreign patent. The impact will be seen initially a period after the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ are each increased by 1. By contrast, consider an agency that adds a new patented technology but protects the intellectual property with a U.S. patent only. The impact will be seen initially a period after the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$ are each increased by 1. The sign and relative size of the difference between the two cases can be seen by comparing the sum of the coefficients for the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ with the sum of the coefficients for the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$ in the estimated models for each agency provided in the section above. What the model shows for the relationship between licensing revenues and the application and patent histories is remarkable. The pattern in the coefficients could have been very different, and the pattern that emerges reveals something fundamental about the importance of the foreign patents.

For the four agencies with the largest patent portfolios, the parameter sums respectively are for the case with foreign patent protection versus the case without: (1223 + 122 + 484) versus (–114 + 122) for DoD, (–84 + 153 + 142) versus (–177 + 153) for DOE, (124 + 424 + 54) versus (–138 + 424) for HHS, and (483 + 400 + 930) versus (–228 + 400) for NASA.[31] For all four agencies, the first sum is greater than the second; and thus, the addition to licensing revenues will be greater for the first case for which foreign patent protection is obtained than

[31] For the base agency, DoD, the estimated coefficients for $AppUSFN_{it-1}$, $PatUS_{it-1}$, and $PatFN_{it-1}$ are summed and compared with the sum of the coefficients for $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$. For each of the other three agencies, to each sum of coefficients for DoD, are added the coefficients for the interaction variables that multiply the agency's dummy variable times each of the explanatory variables in the sum for DoD. Thus, for DoD, we compare the sum of three estimated coefficients with the sum of two estimated coefficients. For the other agencies, we compare the sum of six estimated coefficients with the sum of four estimated coefficients. For each of these sums, the test statistic against the null hypothesis that the sum equals zero is distributed as chi-squared with one degree of freedom. The sum of the three coefficients for DoD in the case that foreign patents are granted is significant with the probability of a greater chi-squared statistic = 0.0003 against the null hypothesis that the sum is zero. The sum of the two coefficients in the case of no foreign patents is insignificantly different from zero. For the two DoD sums for the case with foreign patents versus the case without, the p-values are 0.0003 and 0.84 respectively. For DOE, the two sums for the case with foreign patents (a sum of six coefficients) and for the case without (a sum of four coefficients) have p-values equal to 0.28 and 0.58 respectively. For HHS, the sum of the six coefficients for the foreign patent case has p-value less than 0.0001, and the sum of the four coefficients for the case with no foreign patents has p-value = 0.12. For NASA, the sum of six coefficients for the foreign patent case has p-value = 0.0002, and the sum of the four coefficients for the case without foreign patents has p-value = 0.04.

for the second case when it is not. That much supports the expected causal story that greater licensing revenues are generated by the more valuable patented technologies for which both the agencies and its licensees are more likely to seek foreign patent protection.

But there is more. Looking at the patent history parameters for DOE's estimated model, for example, the sum for the second case is negative. Although the absolute amount is small and insignificantly different from zero, this case identifies an important issue, and as we see just below, the sum of the coefficients for the case with no foreign patents is also negative for USDA, DOC, VA, and EPA, with the result being statistically significant for USDA, VA, and EPA. In other words, systematically in the data across the very large number of U.S. patents acquired, adding a patented technology to the agency's patent portfolio and not securing foreign patent protection actually *lowers* the licensing revenues for DOE, USDA, DOC, VA, and EPA.

A possible reason would be that foreign competitors of the firms using the agency's technologies will be competing internationally without having to pay royalties and will therefore have lower costs for the high technology products and services that are commercialized using those technologies. Licensing the agencies' technologies would be less attractive; licensing negotiations would result in lower invention-licensing revenues.[32] With the DOE example in hand to identify the problem, observing that licensing revenues are less for all agencies when foreign patent protection is not obtained could reflect in part the lowering of licensees' profitability because of international competition from firms that copy the technology without paying royalties.

[32] David P. Leech and John T. Scott, "Foreign Patents for the Technology Transfer from Laboratories of U.S. Federal Agencies," *Journal of Technology Transfer*, forthcoming, provides a formal explanation of how "with inelastic demand for the agency's licenses, the marginal revenue from negotiated licenses can be negative; annual license revenue can fall with the negotiation of additional licenses as agencies work to fulfill the goal of transferring their technologies—with U.S. but not foreign patent protection—to the private sector." The article provides "a description of the effect on annual revenues of the increment to licenses associated with the increment to patented inventions. Marginal revenue is negative when the price elasticity is less than 1, i.e., when the demand for licenses is inelastic. … [T]he agency must lower the price (the annual royalty) by a greater percentage amount than the percentage increase in the number of licenses gained; and therefore, marginal revenue is negative. To meet the Congressionally mandated goal of transferring federal technology to the private sector, the agency lowers its requested royalties to negotiate more licenses and get more technology transferred. The agency's annual revenue from licensing its technology falls."

Turning to the agencies that together have only about 10% of the patenting activity, because they have far fewer patents, the estimated descriptions of their invention-licensing revenues as functions of their patent histories are less significantly estimated. For USDA, DOC, VA, and EPA, the numbers of patents are sufficient to sensibly consider their estimated functions and compare the results with those for DoD, DOE, HHS, and NASA.

Comparing the sum of the coefficients for the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ with the sum of the coefficients for the variables the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$. For USDA, the sums are (–26 + 9.6 + 48.9) and (–58.5 + 9.6). For DOC, the sums are (47.2 + 1.2 + 168.3) and (–1.9 + 1.2). For VA, the sums are (22.1 + 15.0 –10.9) and (–24.5 + 15.0). For EPA, the sums are (39.5 –28.8 + 18.4) and (–25.9 –28.8).[33] For all of these agencies, the first sum is greater than the second, and so just as in the cases of DoD, DOE, HHS, and NASA, the gain in value is greater for USPTO patented technology when it is also protected with a foreign patent than when it is not. Moreover, as was the case with DOE, the second sum is negative for USDA, DOC, VA, and EPA, supporting the hypothesis that obtaining a U.S. patent but not also protecting the technology with a foreign patent puts licensees at a disadvantage in international competition and lowers the negotiated licensing fees for an agency's technologies as a whole.

In sum and to reiterate, with the patent history used to explain license revenue, evidence is found that is consistent with the hypothesis that a portion of the shortfall in licensing revenues for technologies without foreign patents is *caused* by the absence of the foreign patents. That is, a broad set of cases is identified where adding U.S.-patented technologies that are not also protected with foreign patents actually has a *negative* effect on agencies'

[33] USDA is the base case, and both sums of coefficients are significantly different from zero; the p-values against the null hypothesis are less than 0.0001 for both the sum of the three coefficients for the foreign patent case and the sum of the two coefficients for the case without foreign patents. For DOC neither the sum of six coefficients for the case with foreign patents (p-value = 0.36) nor the sum of the four coefficients for the case without foreign patents (p-value = 0.96) is significantly different from zero. For VA, the sum of the six coefficients for the case with foreign patents is significant with p-value = 0.06, and the sum of the four coefficients for the case without foreign patents is marginally significant with p-value = 0.14. For EPA, the sum of the six coefficients for the case with foreign patents is insignificantly different from zero with p-value = 0.57, while the sum of the four coefficients for the case without foreign patents is significantly different from zero with p-value less than 0.0001.

licensing revenues. Note that there is no selection bias issue here that affects finding in the aggregated data that licensing revenues are a function of the application and patent histories. That is so because the fact that the technologies that are more valuable are expected, ceteris paribus, to be the ones that the agencies and the licensees will want to protect with foreign patents is controlled for. Moreover, the research design makes it possible to ask if adding U.S. patented technologies without getting foreign patent protection would not only be associated with a lower addition to licensing revenues (which could be explained because they are the less commercially valuable technologies), but would actually be associated with a reduction in the annual licensing revenues. The evidence of the negative effect (rather than simply a lower effect) is consistent with the following bold interpretation: ***An agency that obtains U.S. patents for its technology but does not obtain foreign patent protection may be – in some cases -- disadvantaging the corporations that license the agency's technologies and then face international competition from foreign firms that copy those technologies and compete with lower costs because they do not pay royalties for using them. The competition from lower-cost foreign firms would reduce the profitability of licensees and hence reduce the negotiated licensing fees that firms are willing to pay for the use of the agency's patented technologies across multiple inventions.***

If foreign competitors do not pay royalties, their costs per item in world-wide markets will be less, for example throughout Europe and Asia. Moreover, without the patent protection in Europe and Asia, all of the development costs that the licensee has put into developing the technology will be difficult and perhaps impossible to recover while competing in Europe and Asia with companies that did not incur the costs but just copied the technology. See the case study for the NIH drug-eluting stent case and observe the royalties paid on foreign sales, and also observe the litigation history. Having the foreign patents made it possible for Boston Scientific to sell in the foreign markets without the competition of others who tried to offer comparable products but were found to be infringing the foreign patents.

The bold interpretation is in fact a perspective held by some agency technology-transfer experts and private sector patent attorneys. In correspondence with those experts, we asked about the difficulties they faced during the invention selection and patenting process when

forecasting commercial use and practical application and deciding whether to apply for foreign patents. While discussing the difficulties, one expert responded, "I would also argue that foreign patenting also increases the value of US patenting to the prospective licensee. To have US-only rights in global market invites competition from overseas that will be strong US competitors once US rights expire and will provide an incentive for validity challenges in the US from these strong competitors outside the US. For products with global market potential, having US-only rights makes the products somewhat like "damaged goods" that have to be sold at a discount." In addition to the foregoing thoughts from a technology transfer expert at one of the federal agencies, a private sector attorney associated with the estolide oil case study considers the "damaged goods" hypothesis, "absolutely true."

Of course, when based on the estimated model, the bold interpretation must be tempered with all the caveats that accompany statistical results. As we explain above, we can use without bias the aggregated data combining each agency's royalty bearing and non-royalty bearing patented technologies because we allow each agency to have its own coefficients for the application and patent histories. Moreover, as we have explained above, we have controlled for the fact that more valuable patents are the ones that are most likely to have both foreign and domestic patent protection. Yet while the results of the estimated models are consistent with the interpretation, other reasonable interpretations may be possible. Moreover, the number of federal agencies with large portfolios of patents and a substantial number of foreign patents is limited, and the number of years in the time series for each agency is limited. Further, although the data for the history of the patent applications and grants are very detailed, the data for the agencies' invention-licensing revenues are aggregated by fiscal year.

4.4. Estimated Costs of Foreign vs. Domestic Patent Protection for Federal Agencies with Large and Small Patent Portfolios

In this section, the costs for foreign patent protection (application costs and maintenance costs) are estimated for federal agencies with different size patent portfolios and compared with the agencies' estimated costs for U.S. patent protection. The estimation shows that

acquisition and maintenance for foreign patents is not only more expensive than for U.S. patents but also that the cost of foreign patenting is much greater for agencies with small annual numbers of foreign applications than for the agencies with many applications.

Based on the advice of practitioners and as explained in Appendix B (the Task 2 report), it is assumed that an organizational infrastructure for dealing with the patents and licensing (an office of technology transfer) is in place and the internal staff need not expand when the number of filings for foreign patents increases.

Regression equations are estimated both for U.S. patents and for foreign patents for the annual variable costs of applying for patents and maintaining the granted patents. From these estimated equations, the additional cost for acquiring more foreign patents is computed. The cost data used for the estimations cover the fiscal years 2004 through 2018 for the maintenance (annuity) costs, and fiscal years 2006 through 2018 for the contracted law-firm costs for managing the patent portfolio. The nominal costs for each fiscal year are converted to constant 2015 dollars used for the estimations.

For each fiscal year, the regression equations developed assume that the annual annuity costs will be for patents received over the last 20 years, with different maintenance and renewal fees depending on the age of the patent and also the country granting the patent.[34] A patent is specified to have a potential life of 20 years, and over that lifetime annuity fees will average b per year. In its portfolio of patents for any given fiscal year t, an agency has x_t patents that have been granted over the last 20 fiscal years, and, as a rough approximation, those patents are assumed to be valuable (in other words, they are still within their useful lifetime), and it is assumed that the agency will be maintaining them. For the given fiscal year, the agency's patent annuity costs are y_t. Hence, the annuity cost regression equation is $y_t = bx_t$. U.S. patent maintenance (annuity) costs and foreign patent annuity costs were obtained for a large agency, with an internationally diverse patent portfolio. The PATSTAT worldwide patent database contains a complete record of the U.S. and the foreign patents that each agency

[34] An overview of annuity fees for the USPTO as well as for the patent authorities of other countries is available at https://www.renewalsdesk.com/patent-renewal-fees-by-country-2018/patent-renewal-fees-usa-2018/.

received in each fiscal year, from which has been gathered the necessary information about the agency's patent portfolio. The data are used to estimate *b*, the average annuity cost per fiscal year for a patent over its lifetime and to obtain an estimate for foreign patents for a comparison with U.S. patents.

The interpretation of the regression equation specification $y_t = bx_t$ is that *b*—the estimated annual fiscal-year annuity cost per U.S. patent, or, in the separately estimated equation for the foreign patent annuity costs, per foreign patent—is an average annual maintenance (annuity) cost over the patent's lifetime. Thus, for each year of the patent's lifetime, the estimated annual annuity cost for adding a U.S. patent or for adding a foreign patent will be the estimated *b* from, respectively, the U.S. annuity cost model or the foreign annuity cost model.

The variables that we use are $USannuity_t$ for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for U.S. patents; $FNannuity_t$ for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for foreign patents; $USpat20_t$ for fiscal year *t*, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years; and $FNpat20_t$ for fiscal year *t*, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years.[35] Table 5 provides the definitions and symbols for the variables used in the U.S. and foreign annuity cost models.

[35] PATSTAT was searched to identify and count all of the distinct U.S. patents and all of the distinct foreign patents granted to the agency during each of the 15 twenty-year periods FY1985-FY2004, FY1986-FY2005, FY1987-FY2006, FY1988-FY2007, FY1989-FY2008, FY1990-FY2009, FY1991-FY2010, FY1992-FY2011, FY1993-FY2012, FY1994-FY2013, FY1995-FY2014, FY1996-FY2015, FY1997-FY2016, FY1998-FY2017, FY1999-FY2018.

Table 5. Definitions for the Variables Used in the U.S. and Foreign Annuity Cost Regression Models.

Variable	Definition
$USannuity_t$	for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for U.S. patents
$FNannuity_t$	for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for foreign patents
$USpat20_t$	for fiscal year *t*, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years
$FNpat20_t$	for fiscal year *t*, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years

Source: Authors' definitions.

The U.S. annual annuities cost regression equation assumes that there are no annuity costs when the number of patents is zero. It estimates the average annual annuities cost for each patent based on the actual experience as of each fiscal year for the patent portfolio over the last 20 fiscal years.[36] Accordingly, the expected value of the annuity-cost portion of the costs of adding a US patent today, assuming that it is renewed throughout its lifetime, will be the present discounted value of the estimated average annual amount $285.5 (in constant dollars of 2015) incurred annually over the next 20 years, the approximation used for the useful lifetime of the patent.[37] Using the real discount rate of 0.07 or 7%, that present discounted value is $\$3{,}025 = \sum_{t=1}^{20} (\$285.5)/(1.07)^t$.[38] The expected value of the annuity-cost portion of the costs of adding a foreign patent today, assuming that it is renewed throughout its lifetime, will be the present discounted value of the estimated average annual amount $623.5 (in constant dollars of 2015) incurred annually over the next 20 years.[39] Using the real discount rate of 0.07 or 7%, that present discounted value is $\$6605 = \sum_{t=1}^{20} (\$623.5)/(1.07)^t$.

Another part of the annual costs for an agency's patent portfolio will be the expense of the services provided by law firms that manage the agency's patent portfolio. These "law firm

[36] Detailed statistics for the regression models of the annuities cost and annual law-firm costs model—U.S. and foreign—are provided in Appendix B as part of the complete Task 2 report.
[37] This is not the actual payment schedule. Recall that we have estimated the average annual cost throughout the lifetime of the patent. Hence, whatever the actual pattern of payments is, we estimate the payments with the stream of the estimated average annual payments.
[38] Use of the 7% social discount rate to evaluate streams of returns from U.S. federal government investments is described in Office of Management and Budget (OMB), Circular number A-94, *Guidelines and Discount Rates for Benefit-cost Analysis of Federal Programs* (Washington D.C.: Government Printing Office, 1992).
[39] Again, this is not the actual payment schedule. We have estimated the average annual cost throughout the lifetime of the patent. Whatever the actual pattern of payments is, we estimate the payments with the stream of the estimated average annual payments.

costs" are incurred for filing patent applications with the USPTO and foreign patenting jurisdictions, responding to technical challenges, and seeing the patenting process through to termination or publication. Law-firm expenses for managing U.S. patents and for managing foreign patents were obtained for a large federal agency with an internationally diverse patent portfolio. The complete record of the U.S. and the foreign patents that the agency has received in each fiscal year, and the complete record for the agency's applications for patents both in the U.S. and in foreign countries were obtained from the PATSTAT worldwide patent database. These data are used to estimate the contribution of a patent to the agency's law-firm costs for foreign patents and for U.S. patents.

The annual law-firm costs are assumed to have two parts. One part will cover the law-firm expenses for filing patents during the fiscal year; it depends on the number of patent applications filed in the fiscal year.[40] The other part will cover the law-firm expenses for handling the legal matters for maintaining the agency's portfolio of patents. These costs depend on the size of the patent portfolio.[41]

The variables that we use are $USlaw_t$ = agency's law firm costs in constant 2015 dollars for U.S. patents for fiscal year t; $FNlaw_t$ = agency's law firm costs in constant 2015 dollars for foreign patents for fiscal year t; $USapp_t$ = number of US patent applications filed by the agency in fiscal year t; $FNapp_t$ = number of foreign patent applications filed by the agency in fiscal year t; $USpat20_t$ = for fiscal year t, the number of U.S. patents that have been granted to the agency over the last 20 fiscal years; and $FNpat20_t$ = for fiscal year t, the number of foreign patents that have been granted to the agency over the last 20 fiscal years.[42] Table 6

[40] Recall that based on the advice of practitioners and as explained in Appendix B (the Task 2 report), it is assumed that an organizational infrastructure for dealing with the patents and licensing (an office of technology transfer) is in place and the internal staff need not expand when the number of filings for foreign patents increases.

[41] Any significant litigation costs would not typically be covered in these law firm costs for the handling of applications and maintenance of patents as reported by the technology transfer office for an agency. Such costs would be covered by the Office of the General Counsel and Department of Justice, and on rare occasions by licensees, according to technology transfer experts responsible for the patent portfolios.

[42] PATSTAT was searched to identify and count all of the distinct U.S. patents and all of the distinct foreign patents granted to the agency during each of the 13 twenty-year periods FY1987-FY2006, FY1988-FY2007, FY1989-FY2008, FY1990-FY2009, FY1991-FY2010, FY1992-FY2011, FY1993-FY2012, FY1994-FY2013, FY1995-FY2014, FY1996-FY2015, FY1997-FY2016, FY1998-FY2017, FY1999-FY2018.

provides the definitions and symbols for the variables used in the models of law-firm costs for U.S. and foreign patents.

Table 6. Definitions for Variables in the Models of Law-firm Costs.

Variable	Definition
$USlaw_t$	agency's law firm costs in constant 2015 dollars for U.S. patents for fiscal year *t*
$FNlaw_t$	agency's law firm costs in constant 2015 dollars for foreign patents for fiscal year *t*
$USapp_t$	number of US patent applications filed by the agency in fiscal year *t*
$FNapp_t$	number of foreign patent applications filed by the agency in fiscal year *t*
$USpat20_t$	for fiscal year *t*, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years
$FNpat20_t$	for fiscal year *t*, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years

Source: Authors' definitions.

Table 7 shows the descriptive statistics for the models of annual law-firm costs.

Table 7. Descriptive Statistics for the Variables Used to Estimate the Regression Model of an Agency's Annual Law-Firm Costs for U.S. and Foreign Patents: Using Cost Data from the Agency for Fiscal Years 2006-2018 and patent data from PATSTAT.

Variable	n	Mean	Minimum	Maximum
$USlaw_t$	13	5,159,787	3,337,975	7,174,423
$FNlaw_t$	13	7,460,121	5,682,800	9,528,603
$USapp_t$	13	177	88	247
$FNapp_t$	13	281	40	417
$USpat20_t$	13	2359	1698	2904
$FNpat20_t$	13	2504	1647	3244

Source: Authors' calculations.

According to regression equation estimates, an increase in annual fiscal-year law-firm costs from the addition of one new U.S. patent application with one new U.S. patent granted is $9806 in the year of the application and then $1299 in each year of a patent lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional U.S. patent would be $23,568 = $9806 + ($13,762 = $\sum_{t=1}^{20}(\$1299)/(1.07)^t$).

The regression model is slightly more complicated for foreign patents because of the way the foreign patent applications are filed.[43] The average number of foreign patent applications is quite low for many agencies, and their typical number of specific country applications for a

[43] For details, see the full Task 2 report contained in Appendix B.

WIPO or European Patent application would also be lower. Thus, the application cost for an additional foreign patent will be much higher than it would be for an agency with a large portfolio of foreign patents. From the estimated equation in Appendix B, for example, if the agency had 10 foreign patent applications in a fiscal year, then increasing by one the number of successful foreign patent applications would cost \$1,118,841/10 = \$111,884 in the year of the application and \$507 in each year of the patent's lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional foreign patent would be \$117,255 = \$111,884 + (\$5,371 = $\sum_{t=1}^{20} (\$507) / (1.07)^t$).

For an agency with many more foreign applications annually, the costs of filing for a foreign patent would be considerably less. For example, suppose that an agency filed 100 foreign patent applications annually. Cost savings from a larger portfolio itself and from the advantage of repeatedly using initial applications to WIPO or the European Patent Office (to acquire patents for a technology in additional foreign countries) are large.[44] The increase in the foreign law-firm costs in constant 2015 dollars for an additional foreign patent is estimated to be \$1,118,841/100 = \$11,188 in the year of the application and \$507 in each year of the patent's lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional foreign patent would be \$16,559 = \$11,188 + (\$5,371 = $\sum_{t=1}^{20} (\$507) / (1.07)^t$).

The preceding analysis shows that the costs of foreign patenting will vary considerably across the agencies. For example, summing the estimates of the annuity costs and the law-firm costs, for a federal agency currently applying for 10 foreign patents annually, the agency's filing costs for a typical foreign patent are estimates to be \$123,860, the present discounted value of the costs in constant 2015 dollars over a patent lifetime.[45] The estimated cost for adding a foreign patent falls considerably if the agency's number of annual

[44] This nonlinearity (i.e., annual law-firm expenses increasing at a decreasing rate) is captured in the regression equation specification of $FNapp_t$ as $\ln(FNapp_t)$, the natural logarithm of the number of annual foreign patent applications. For a detailed explanation, see the Task 2 reported included as Appendix B.
[45] The sum of the estimated annuities costs of \$6,605 and the estimated law-firm costs of \$117,255 is \$123,860.

applications for foreign patents is greater. For example, if the agency files 100 foreign applications annually, taking advantage of the cost savings a larger portfolio and from the WIPO and EPO filings, the estimated costs for an additional foreign patent are only $23,164, about the same as the cost of adding a U.S. patent.[46] For the typical U.S. patent, the present discounted value of the filing costs is estimated to be $26,593.[47] This finding is used to tailor each agency's return on investment in foreign patenting discussed in the following section.

4.5. Agency-Specific Return on Investment in Foreign Patents

The estimated rates of return on investment use each agency's invention-licensing revenues from its patented technologies to provide lower-bound estimates of benefits from patenting the technologies. The gains in licensing revenues net of the costs for additional foreign patents provide a very conservative lower bound for the social return on the investment in patenting.

Fundamental to this interpretation is the understanding that the invention-licensing revenues typically reflect, in part, market forces and the market values of the commercialized technologies. In the words of the U.S. Government Accounting Office (GAO) concerning the financial compensations arranged in the licenses:

> "[Licenses] typically establish financial terms on a case-by-case basis that are tailored to the specifics of the technology, licensee, and market conditions."[48]

The GAO description of the licensing process makes clear that commercialization of the transferred technologies is the goal, and that market value underlies and enables commercialization.

However, the particular mission of each federal agency provides an agency-specific motivation for technology transfer and its benefits. And the financial benefit of the licensing

[46] The sum of the estimated annuities costs of $6,605 and the estimated law-firm costs of $16,559 is $23,164.
[47] The sum of the estimated annuities costs of $3,025 and the estimated law-firm costs of $23,568 is $26,593.
[48] GAO, op. cit., p. 14, and limited exceptions noted there, and then see more generally pp. 12-16.

revenue, negotiated with the licensees of the agency's technologies, is not paramount. According to expert practitioners, federal agencies are not "… just seeking a financial return through revenue generation," but "… are looking to utilize licensing of nascent inventions as a way to increase new company formation …" and various other things that support the agency's mission.[49] Thus, the licensing revenues are not only a measure of a benefit received by the agency but they provide a lower bound on the social value of the technology. The entire social value includes the addition to the licensee's economic profits generated by its use of the technology, and the social value also includes value that spills over to other companies and to consumers.

Turning, now, to the agency-specific return on investment (ROI) in foreign patents, the cost and benefit estimates discussed in preceding sections allow the estimation of a conservative lower bound for the benefit-to-cost ratio and the net present value of obtaining additional foreign patent protection for each agency's patent portfolio. Because the licensing revenues reflect just a portion of the social value created by the transfer of the technology, the estimated returns on investment are very conservative lower bounds.

The estimated model of invention-licensing revenue for each agency, graphically presented in the subsection above, entitled, "Estimated Agency-specific Invention-licensing Revenue Functions," is used to estimate the change in expected licensing revenues when going from (1) the case when an agency applies for a U.S. patent that is ultimately granted but does not also obtain a foreign patent for the technology, to (2) the case when the agency does obtain a foreign patent in addition to the U.S. patent.

For summary purposes, the DoD license revenue function provides an example of the calculation. Only the result of the calculation will be presented for other agencies with the fully worked out examples for each agency provided in the Task 2 report contained in Appendix B.

[49] Steven M. Ferguson and Uma S. Kaundinya, op. cit., p. 191.

DoD's estimated model of invention-licensing revenue is:[50]

$$y_{it} = -114 AppUSnoFN_{it-1} + 1223 AppUSFN_{it-1} + 122 PatUS_{it-1} + 484 PatFN_{it-1}$$
$$+ .33 y_{it-1} - 17500 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

To estimate the change in expected revenues, suppose that DoD has applied for a U.S. patent that was ultimately granted but did not obtain a foreign patent. Then, according to the estimated regression model, what would be the effect on revenues if instead the agency had also obtained a foreign patent? In the fiscal year of the U.S. application, the variable $AppUSnoFN_{it-1}$ is decreased by 1, and the variable $AppUSFN_{it-1}$ is increased by 1; the variable $PatUS_{it-1}$ does not change; and the variable $PatFN_{it-1}$ is increased by 1 in the fiscal year when the foreign patent is ultimately received.[51]

Using DoD's estimated model as an example, in the period after the applications for the U.S. and the foreign patents, licensing revenues would increase by the negative of –$114,000 which is plus $114,000, because there is one less USPTO application that results in a patent for a technology that does not ultimately also have foreign patent protection. Also, the revenues in the period after the applications would increase by $1,223,000, because there is one more successful USPTO application that does ultimately have foreign patent protection too. Thus, there is a total increase of $1,337,000 from the change from a U.S. application without any foreign patent applications to one with them. In the next year, the revenues will increase by (0.33)*x*($1,337,000) = $441,210; in the following year revenues will increase by (0.33)*x*($441,210) = $145,599; and so on. The effect on the licensing revenues one period after the time that the new foreign patent is ultimately granted will be $484,000. In the next year, the revenues will increase by (0.33)*x*($484,000) = $159,720; in the following year, revenues will increase by (0.33)*x*($159,720) = $52,708; and so on.

[50] Recall, as explained above, the aggregated data combining each agency's royalty bearing and non-royalty bearing patented technologies can be used, without bias, because each agency has its own coefficients for the application and patent histories. Moreover, as explained above, the model controls for the fact that more valuable patents are the ones that are most likely to have both foreign and domestic patent protection.

[51] At the time that the USPTO application is filed, typically if foreign patents are anticipated, applications are also filed with the World Intellectual Property Organization (WIPO) and/or the European Patent Office (EP), and applications to particular cooperating foreign patent authorities are based on those WIPO and/or EP applications.

For DoD, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 2.8 years.[52] Conservatively assuming that the foreign patent is granted in the third year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7%, the benefit is:

$$\sum_{t=1}^{20}(0.33)^{t-1}(\$1{,}337{,}000)/(1.07)^{t} + \sum_{t=4}^{20}(0.33)^{t-4}(\$484{,}000)/(1.07)^{t}$$

$$= \$1{,}806{,}757 + \$533{,}903 = \$2{,}340{,}660.$$

In the preceding subsection, entitled, "The Estimated Costs of Foreign Patent Protection," cost functions for annuity costs and for law-firm costs for foreign patenting were estimated. The total variable cost of foreign patenting is the sum of the estimated annuity costs and the estimated law-firm costs. The change in those costs from adding another foreign patent depends on the agency's annual number of foreign patent applications, $FNapp_t$. The additional cost from adding another foreign patent is estimated to equal \$6605 + \$1,118,841/($FNapp_t$) + (\$5,371) = \$11,976 + \$1,118,841/($FNapp_t$) in constant dollars of year 2015. The estimated costs differ for each agency because the agencies differ in their typical annual number of foreign patent applications.[53]

For DoD, the cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. The following estimate uses DoD's annual number of applications for foreign patents in fiscal year 2015; the number was 106. Hence, DoD's estimated cost for acquiring another foreign patent is \$11,976 + \$1,118,841/106 = \$22,531, in constant 2015 dollars.

[52] Here and subsequently for the other agencies, the average time from the application for a foreign patent until it was granted was tabulated by the authors from the worldwide patent data PATSTAT that is maintained by the European Patent Office; https://www.epo.org/searching-for-patents/business/patstat.html#tab-1.

[53] For the calculations that follow, the annual number of foreign patent applications for each agency was tabulated from PATSTAT (https://www.epo.org/searching-for-patents/business/patstat.html#tab-1) by the authors.

Juxtaposing the benefits and costs, for DoD the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $2,340,660/$22,531 = 103.9; the lower-bound net present value is $2,340,660 – $22,531 = $2,318,129 in constant 2015 dollars.

The results of the above procedure carried out for eight of the 11 federal agencies are presented in Table 8 showing the estimated return on investment in additional foreign patents developed in this report.[54]

Table 8. Return on Investment in Additional Foreign Patents: Benefit-to-Cost Ratio and Net Present Value Using a Lower-bound Benefit for Protecting the Intellectual Property for a USPTO-patented Technology with a Foreign Patent.

Agency	Lower-bound Benefit-to-Cost Ratio	Lower-bound Net Present Value in Constant 2015 dollars
DoD	103.9	$2,318,129
DOE	14.5	$236,000
HHS	25.6	$383,866
NASA	27.3	$1,788,943
USDA	2.2	$37,373
DOC	1.5	$59,693
VA	1.7	$17,751
EPA	1.1	$8,510

Source: Authors' calculations.

Obviously, a dramatic difference exists between the large return on investment from adding foreign patent protection to a USPTO-patented technology for the four agencies with about 90% of the patenting activity and the small return for the other agencies. The metrics for the two groups differ by from one to two orders of magnitude. The agencies with the relatively small patent portfolios may at times simply find that the result of negotiating more licensing revenues for their patented technologies would be a substantial loss in the amount of the technology transfer for their relatively small numbers of patented technologies. That said, the estimated invention-licensing revenue functions developed above support the expectation that pursuing foreign patents along with their USPTO patents would increase the amounts of licensing revenues that could be negotiated. Further, as the cost functions estimated above indicate, with the pursuit of more foreign patents the cost of additional foreign patents should

[54] As discussed above, DHS, DOT, and DOI do not have enough foreign patent activity during our sample period to estimate equations for their invention-licensing revenues and their costs of foreign patenting as functions of their foreign patenting activity.

fall. Thus, it is possible that the pursuit of more foreign patents would result in higher net benefits for additional foreign patents.

For the agencies with small patent portfolios as well as for the four agencies with the large portfolios of patents, the metrics shown in Table 8, and the findings about the impacts on revenues and costs estimated above, support the expectation that pursuing additional foreign patents may not only result in greater net licensing revenues to offset the taxpayers' investments in federal agencies' technologies.[55] Additionally, obtaining more foreign patents would improve the international competitive position of firms that license the agencies' technologies. It would be easier to transfer technologies to be commercialized because the licensees would find that the technologies have greater commercial value when they have foreign patent protection.

5. Summary Report Conclusion

For some time there has been concern that the U.S. is missing opportunities to fully commercialize inventions arising from federal agency research. NIST's *Lab-to-Market* focus grew out of this concern. The data and analysis presented in this report suggest that opportunities are likely being missed to the extent that agencies are timid in their pursuit of IP protection in non-U.S. jurisdictions. That said, it is also clear that the challenges of identifying and negotiating financially successful licensing agreements are substantial, perhaps especially so where global markets are roiling and market outcomes are relatively far in the future.

As the case studies indicate, the long time-lag between invention and commercialization, and the many setbacks and complications that occur in the interim, stack the odds: against betting

[55] The foreign patents would make the technology that is transferred more valuable to the licensees, and consequently they would be willing to pay greater licensing fees. The negotiation of higher licensing fees would leverage the taxpayers' funds, enabling a given amount of funds to support a greater amount of R&D in the federal agencies. See John T. Scott, "Financing and Leveraging Public/Private Partnerships: The Hurdle-Lowering Auction," *STI (Science, Technology, Industry) Review*, No. 23, Paris, OECD, 1998, pp. 67-84, and also Stephen Martin and John T. Scott, "The Nature of Innovation Market Failure and the Design of Public Support for Private Innovation," *Research Policy*, Vol. 29, Nos. 4-5 (April 2000), pp. 437-447.

on the right invention to patent; against correctly judging the necessary technical and geographic scope of patent protection; and against betting on the success of the license negotiation process. Yet, as the case studies also illustrate, and the statistical analysis presented above clearly shows, the gains can be substantial *if* investment in domestic patents are complemented by patents in foreign jurisdictions. However, that result varies substantially across the agencies and specific licensing agreements as the EPA-related example (discussed above in Section 2) and the benefit-to-cost ratios in Table 8 show.

Agencies with smaller patent portfolios, like the EPA, are particularly challenged. The mandate to encourage the participation of small business firms that are less able to afford the higher costs of foreign patenting is one challenge. The higher costs for adding foreign patent protection for agencies with relatively small patent portfolios is another challenge. The USDA is one such agency but, as the estolide oils case study illustrates, with patience, a vision of sustained public-private collaboration, and entrepreneurial persistence, agencies with smaller portfolios can also see a positive ROI. As the statistical analysis presented here and both complete case studies appear to verify, with all the challenges and constraints that face federal technology transfer agents, despite the higher costs, the net gains of foreign patent protection appear to be worth the cost. According to the interpretation of all the evidence presented here, supported by case studies from agencies with large and small patent portfolios, the reason foreign patent protection pays off is because obtaining more foreign patents can improve the international competitive position of firms that license agencies' technologies. To put the same point differently, it appears that obtaining a U.S. patent, but not also protecting the technology in non-U.S. jurisdictions, lowers the negotiated licensing fees for an agency's technologies as a whole and disadvantages licensees as international competitors.

Appendix A. Review of Foreign Patent Filings by Federal Agencies (Task 1 Report)

I. Introduction and Summary of Findings

This memorandum is the deliverable for Task 1 of the project titled "Return on Investment of Foreign Patenting." The SOW for the project states:

TITLE: Return on Investment of Foreign Patenting
The Contractor shall complete the following tasks:
Task 1: Review foreign patent filings and identify those requested by federal laboratories.

Deliverable	Deliverable	Format	Due date
SOW Task 1	Conduct a review of foreign patent filing by federal labs	MS Word via email	Within two months after award of contract.

We have reviewed the foreign patent filings by the 11 federal agencies reporting annually to Congress about their technology transfer activities and whose reports have been gathered together by the National Institute of Standards and Technology in *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, National Institute of Standards and Technology, U.S. Department of Commerce, April 2018. To characterize the extent to which those federal agencies are protecting their intellectual property with foreign patents as well as U.S. patents, we examined the federal agencies' patented inventions for the period beginning with fiscal year 2003, the year when the agencies adopted uniform practices for reporting their annual technology transfer activities to Congress. Examining these years will not only provide a good assessment of the extent to which foreign patents are being obtained for the federal agencies' inventions, but the information can be combined with the information in the annual technology transfer reports and then used (in subsequent work for this project) to estimate a model of the impact of foreign patent protection on licensing revenues.[56]

[56] The patents obtained by the agencies are almost entirely utility patents, with exceptions to prove the rule. For the U.S. patents of the distinct patents reported subsequently for each federal agency, using the acronyms defined in the tables, for DHS, 1 of the 22 U.S. patents was a design patent; the rest were utility patents; for DOC, all 198 U.S. patents were utility patents; for DoD, of 6,932 U.S. patents, all were utility patents except for 46 design patents; for DOE, the 5,842 U.S. patents were all utility patents except for three design patents; for DOI, all 47 U.S. patents were utility patents; for DOT's 29 U.S. patents, two were design patents and the rest were utility patents; for EPA, all 99 U.S. patents were utility patents; for HHS, its 2170 U.S. patents were all utility patents; for NASA, among its 1,371 U.S. patents, only one is a design patent, and the rest are utility patents; for USDA, there are 75 plant patents among its 789 U.S. patents, with the patents other than the plant patents being utility patents; for the VA, there are 464 U.S. patents, with two of those being design patents and the rest utility patents. Thus the patents are almost entirely utility patents, as contrasted with design or plant patents (see https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-2). The patent authority for each country differs in the codes used to identify the types of patents granted, and we have the appropriate code for each of the patents. The codes for different kinds of patents are specific to the particular patent office issuing the patent. An up-to-date concordance with each country's "Kind Code" for the various types of patent documents is available as Concordance_20190909.xls and is also in PUBL1_20190909.xls at https://www.epo.org/searching-for-patents/helpful-resources/data/tables/regular.html.

In this section of the Task 1 report, we introduce and summarize our findings. Section II will provide detailed description of the methodology used to obtain those findings and the underlying details about the agencies' filings for patents. Section III provides additional details about our methodology by reporting and discussing the comparison of the patent counts reported in the agencies' annual reports with the counts that we found and present in this report. Section IV concludes this first report and describes the upcoming work for the project.

Table 1 summarizes the findings about the extent to which each of the federal agencies has obtained foreign patents as well as U.S. patents. For the agencies' United States Patent and Trademark Office (USPTO) applications, the percentage of the inventions that have foreign patent protection ranges from zero, for the Department of Homeland Security and the Department of Transportation, to 50 percent for the Department of Health and Human Services. The range across the agencies for the percentage of each agency's total patents taken by foreign patents is shown in column (7) and is similar to the range for the percentage, shown in column (4), of each agency's inventions with foreign patent protection, although it need not be the same.[57] It is noteworthy that the two agencies – Health and Human Services and the Veterans Affairs – with the highest percentages of inventions with foreign patent protection are focused on medical research.

[57] Columns (4) and (7) will in general differ for two reasons. For one, some of the applications in column (2) did not themselves result in a patent, but another application based on the same invention resulted in a patent. For another, the number of foreign patents for each USPTO patented invention can range from zero to several; and so, the percentage of foreign patents in the total patents will not in general be the same as the percentage of patented inventions that have foreign patents.

Table 1. The Extent of Foreign Patenting for U.S. Federal Agencies Associated with their Applications to USPTO for Fiscal Years 2003 through Fiscal Year 2018.[a]

(1) Agency[b]	(2) The number of applications to USPTO that resulted in a patent either for the application or for another USPTO application based on the same invention ("Invention Families")	(3) The number of the USPTO applications in column (2) for which the invention underlying the application is protected with foreign patents	(4) The proportion of USPTO applications in (2) for which the invention underlying the application is protected foreign patents[c]	(5) The total number of distinct patents[d]	(6) The number of distinct foreign patents[d]	(7) Distinct foreign patents as a proportion of total distinct patents[e]
USDA	792	104	0.131	982	193	0.197
DOC	200	8	0.0400	206	8	0.0388
DoD	6899	245	0.0355	7364	432	0.0587
DOE	5841	957	0.164	6844	1002	0.146
HHS	2112	1067	0.505	4379	2209	0.504
DHS	24	0	0.0	22	0	0.0
DOI	48	3	0.0625	48	1	0.0208
DOT	30	0	0.0	29	0	0.0
VA	488	184	0.377	756	292	0.386
EPA	91	16	0.176	132	33	0.25
NASA	1358	63	0.0464	1478	107	0.072

[a]Data for fiscal year 2018 is not complete.

[b]Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA).

[c]Either for the application or for another USPTO application based on the same invention; column (3) divided by column (2).

[d]The number is the number of distinct patents. As explained in Section II, when examining individual USPTO patent applications, we identify all of the other applications – both to the USPTO and to foreign patent authorities – that are based on the same underlying invention. Thus, when a USPTO application has not only any foreign patent applications based on the same underlying invention, but also it has other USPTO applications based on that invention, the patents associated with the related set of USPTO applications will be the same. In such cases, we avoided multiple counts of a patent, and hence we report here the number of distinct patents.

[e]Column (6) divided by column (5). When comparing columns (7) and (4), observe that each USPTO patented invention could have several foreign patents; that is, the invention could be patented in several foreign countries.

II. Methodology and Detailed Development of the Findings

We followed the federal agencies' applications to the United States Patent and Trademark Office (USPTO) and to foreign patent authorities for the agencies' patented inventions from

fiscal year 2003 through the most recent data available in the worldwide patent data base PATSTAT that is maintained by the European Patent Office (EPO).[58] Thus, our review is complete for the fiscal years 2003 through 2017, and additionally for the portion of filings that are currently available for fiscal year 2018 in the PATSTAT data for Spring 2019, the latest edition of the data. For each federal agency, we have found its inventions patented during the fiscal years 2003 through 2017, and then additionally those in 2018 that have already been included in the PATSTAT Spring 2019 worldwide database. For this first deliverable, we use the data that we have gathered to characterize the extent to which the agencies have acquired foreign patents for their inventions, and in subsequent reports we will make use of the time series dimension of the data that we have collected. That is, we have the dates at which the patents were received and we will use that information in conjunction with the data in the annual technology transfer reports and data about international trade to model the direct and indirect economic effects of the U.S. and foreign patents.[59]

For this report, an invention family is defined for each of a federal agency's patent applications to the USPTO. We now explain how for each federal agency we construct what we shall call its USPTO-patent-application invention families. A USPTO-patent-application invention family – referred to as an invention family for a short name – is defined as follows. For each of a federal agency's patent applications to the USPTO, the invention family consists of that application and all other patent applications by the agency that are based on essentially the same technology—the same "invention"—regardless of the patent authority to which the other applications are made. The notion of an invention here is the one used by the European Patent Office for what it calls the DOCumentDataBase (DOCDB) simple patent family: "A simple patent family is a collection of patent documents that are considered to cover a single invention. The technical content covered by the applications is considered to be identical. Members of a simple patent family will all have exactly the same priorities."[60]

In this report, the reason for having the families defined for each of a federal agency's patent applications to the USPTO is primarily because we want to document, for each particular patent application to the USPTO, the extent to which the agency also *applied for* patent protection in non-U.S. jurisdictions. Further, for all such applications, to the USPTO and to foreign authorities, we document whether or not a patent was actually *granted*. So, for each of a federal agency's applications to the USPTO for patent protection for a technology that an agency has developed, an agency has to various extents also applied for a patent on the same thing in other countries. Moreover, the agency may also have made other patent applications to the USPTO to protect the invention.

One might ask, why multiple applications for the same invention? One reason – the one that most interests us – is because the agency wants to file applications in other jurisdictions to obtain foreign patent protection to accompany its protection with a patent

[58] https://www.epo.org/searching-for-patents/business/patstat.html#tab-1

[59] The patent literature suggests that the foreign patents and their time series dimension will have an important impact on the value of the federal agencies' intellectual property. See Antoine Dechezleprêtre, Yann Ménière, and Myra Mohnen, "International Patent Families: From Application Strategies to Statistical Indicators," *Scientometrics*, 111 (2017), pp. 793-828.

[60] https://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families/docdb.html.

from the USPTO. Additionally, the multiple applications are for broader or narrower claims about the intellectual property associated with an invention.

Thus, we sometimes find an agency filing multiple applications for the same invention, regardless of the extent of foreign patenting. In such cases, setting aside the jurisdiction issue, why is the agency filing multiple applications for the same invention? The generic answer is that they are erecting property boundaries as tightly as they can on as many aspects of the invention as they can, and this is often an iterative process where the patent attorney learns the specifics of other property claims in the course of filing the application. For an example, the Department of the Interior had a USPTO application in 2005 for a *method* of removing phosphorus from wastewater, with a patent granted in 2007. Then, the Department of the Interior had another application in 2007 for an *apparatus* for removing phosphorus from wastewater, with a patent granted in 2009. The two applications, and their two resulting grants of patents, are in the same simple patent family because they are based on the same underlying invention.[61] As stated in a recent USPTO Working Paper,

> Typically, applicants have an incentive to file an application with the broadest claims to which they think they are entitled. There is no incentive for the applicant to excessively narrow the claims, ex ante, before the examiner has done her search; that would be the legal equivalent of leaving money on the table. Broader claims translate to a larger set of technologies that the owner can exclude others from using, and making it more difficult for competitors to invent around. During examination, a search may reveal prior art that renders the applicant's claim(s) unpatentable under novelty or obviousness standards. In that case, the examiner rejects the application and the applicant typically amends the claim(s) or abandons the application. In order to circumvent the prior art, claims must be narrowed so that they are not so broad as to overlap with the prior art. Consequently, amendments almost always involve narrowing. Further, this process almost always involves adding words to the claim: modifiers, qualifiers, or other details. The patent prosecution process itself provides it's own support: applicants have no incentive to narrow claims, except to respond to examiners' rejections. Yet, as we show below, the vast majority of independent claims grow longer during prosecution, in response to rejections.[62]

An application to the USPTO for the invention developed by the agency, along with whatever applications for that technology that the agency has also made to foreign authorities, and along with any other applications for the technology that it has made to the USPTO, constitutes an invention family for this report. So, in this report, we have an invention family defined for each of an agency's patent applications to the USPTO. Note that in cases where an agency has more than one USPTO application for a single invention, there will be more than one appearance of the same invention family in our data, and that is because we want to document over time the extent of foreign patent protection applied for and received that is associated with each time a federal agency files a USPTO application. Describing that history (that we summarize below) for each USPTO application

[61] To find all the foreign patent activity for a particular technology, the simple patent family is used. All of the applications have the same priority, and for the purposes of the patent family the two patents are for the same underlying idea from which the two patents came. That idea is here referred to as the invention, but some may prefer to think of the patents, even though they have the same priority, as two different inventions. That distinction is, for purposes here, not an important one.

[62] Marco, Alan C. and Sarnoff, Joshua D. and deGrazia, Charles, Patent Claims and Patent Scope (October 2016). USPTO Economic Working Paper 2016-04, p. 9. Available at: SSRN: https://ssrn.com/abstract=2844964.

that an agency makes for a particular invention will therefore result in multiple counts of patents if the patents are summed across the agency's USPTO applications, because the patents received for a particular invention will be seen in the history of each USPTO application that belongs to the simple family for that invention.

For example, if an agency has only one USPTO application for a particular invention, the patents that it receives for that invention are counted only once in the tabulations, across USPTO applications, of patents received for the invention families for the agency.[63] If it has two USPTO applications for a particular invention, the patents that the agency receives for that invention will be counted twice – once with each of the USPTO applications in the simple family. So, in our discussions and tables below, we provide a history of the extent of patent protection for each of an agency's USPTO applications over time, and then we also describe the number of distinct patents, without the multiple counts of patents that occur (in discussion and tabulations of the extent of patent protection for each of the agency's USPTO applications) for inventions for which the agency has multiple USPTO patent applications.

Observe then that in the description that we will now present of the extent of foreign patent protection for each agency, if over time an agency does not typically apply more than once to the USPTO for a single invention, the number of distinct patents received will not be much different from the total of the patents received across all of the agency's invention families defined for each of its USPTO applications. In contrast, if an agency typically applies more than once to the USPTO for a single invention, the number of distinct patents received will be considerably less than the sum of the patents received across the agency's USPTO-application invention families (with a family defined for each of its USPTO patent applications). That is because the patents are counted for each USPTO-application invention family, and when those different applications are based on the same underlying invention (as in the illustrative case, described above, of one application for a method, and then another for an apparatus, both from the same underlying invention), the patents received are counted for each of the USPTO applications. We then also report the number of distinct patents for the agency over the period where we have described the time series of the patent applications.

To restate and summarize, for the information that we will now report: By defining the invention family for each of the agency's USPTO applications, we can describe, and subsequently analyze the economic impact of, the history of the extent of foreign patent protection for an agency's intellectual property. However, because following that history over time means that for some inventions the same patents are recorded multiple times when an agency has multiple applications to USPTO for the same invention, we also tabulate the number of distinct patents granted to the agency by the USPTO and by foreign patent authorities. Thus we provide the history of each federal agency's USPTO patent applications by examining the invention family for each USPTO application. Further, we also consolidate the information – in that disaggregated, historical set of invention families for each USPTO application – and report the number of distinct patents received by each agency. We thus

[63] A reader asks: "Why would this be? The device and the means of making the device, if they each receive a patent, could be licensed separately." Yes, but then there would be two applications for the particular invention, and they are both in the same EPO patent family, and they can each receive a patent.

eliminate the multiple counts of patents that occur (in cases where an agency applies more than once to the USPTO for the same underlying invention) when we examine the set of USPTO-application invention families with an invention family defined for each separate USPTO patent application. In all, we have both the historical, time-series detail that is provided by having the information about what we have called the USPTO-application invention family for each separate USPTO application by a federal agency, and also the ultimate outcome for each agency in terms of the numbers of patents received from the USPTO and from foreign patent authorities.

In Table 2, we summarize the findings from tracing the history of patent applications for the patented inventions of each federal agency throughout the period since fiscal year 2003, when the agencies began using uniform reporting practices for the annual technology transfer reports. We obtained for each agency the history of its applications for U.S. and foreign patents.

From Table 2, we can see, for an example, that 48/106 or 45.3% of the EPA invention families in the data during the period FY 2003 through FY 2018 have non-U.S. applications, although some of those are to the World Intellectual Property Organization (WIPO), and thus they are simply applications for an option to make applications to cooperating countries for patent protection. Excluding both the U.S. applications and the applications to WIPO, 34/106 or 32.1% of the EPA invention families in the sample have actual applications for foreign patents. For the description of the applications, it is also interesting to determine the subset of the 106 EPA invention families that have non-U.S., non-WIPO, and non-EPO applications. The applications to the European Patent Office (EPO) are for patents—a grant of an EPO patent is indeed a patent. However, to enforce those EPO patents in a particular country cooperating with the EPO, the applicant must additionally apply to the patent office of the EPO country. So, we examine the EPA invention families that have what one might call "pure foreign patent applications", that is those with non-US, non-WIPO, and non-EPO applications, and we find 27/106 or 25.5% of the EPA invention families in the sample have "pure foreign patent applications".

Table 2 provides an overview of the agencies' application histories that underlie the ultimate results for the U.S. and foreign patents that are shown in Table 3. Table 3 shows the extent of foreign patent protection for the invention families that received patents for a USPTO patent application during the period from fiscal year 2003 through fiscal year 2017, plus the 2018 information currently available, for each of the 11 federal agencies that report their technology transfer activities in the annual reports to Congress. For example, for the complete set of 91 EPA USPTO-application invention families, 91 – 16 = 75 families (about 82%) have no foreign patents, and so although the average number of patents per family is about 2, the average number of foreign patents per EPA invention family is 48/91 = 0.53 or about 1 foreign patent for every two invention families. For NASA's 1358 USPTO-application invention families, 1358 – 63 = 1295 families (about 95%) do not have foreign patents. The average number of patents for NASA's invention families is 1.5, with the average number of foreign patents per family being just 148/1358 = 0.109 or roughly 1 foreign patent for every 9 USPTO-application invention families.

Recall that a USPTO-application invention family consists of a USPTO patent application by the federal agency along with any other applications from the agency that are based on the same basic invention. Thus, to this point in Table 3, we have described for each of the agency's U.S. patent applications, the number of patents for each such U.S. application that resulted from that application and also for the other applications that the agency made based on the same basic invention. Thus, when the invention family for a patent application to the USPTO, call it the agency's i^{th} application to the U.S. patent authority, includes other patent applications to the USPTO that are based on the same underlying invention, each of those other applications by the agency also appear in the data set with their own USPTO-application invention families that will include the i^{th} application. Hence, we have the last major column for Table 3, "Number of Distinct Patents," and its subcolumns for "Total," "Foreign," and "Proportion Foreign".[64]

[64] The earlier column totals worked with the number of patents per USPTO-application invention family summed over the families. The number of patents summed across the families then had counted more than once the patents in the applications to USPTO that have as family members other applications to USPTO. To show the number of distinct patents, we use the extra column in Table 3 with three sub-columns that show each agency's total number of distinct patents, number of distinct patents for the subset of foreign patents for the agencies, and the proportion of foreign patents.

Table 2. Patent Applications for U.S. Federal Agencies' Inventions (with an invention defined for the USPTO-patent-application invention family) during Fiscal Years 2003 through 2018.[a]

U.S. Agency[b]	Number of invention families in PATSTAT [c]	Number of applications				Number of invention families with non-U.S. applications	Number of non-U.S. applications			
		Total	Avg	Min	Max		Total	Avg	Min	Max
USDA	953	2716	2.8	1	23	418	1260	3.0	1	19
DOC	262	462	1.8	1	13	21	65	3.1	1	10
DoD	7714	14272	1.9	1	40	972	2680	2.8	1	34
DOE	6949	18367	2.6	1	52	2107	7250	23.4	1	34
HHS	2340	17710	7.6	1	60	1867	10624	5.7	1	54
DHS	41	63	1.5	1	10	3	11	3.7	1	9
DOI	56	82	1.5	1	5	9	12	1.3	1	2
DOT	37	64	1.7	1	9	5	17	3.4	1	7
VA	646	3916	6.1	1	42	402	2341	5.8	1	34
EPA	106	332	3.1	1	16	48	173	3.6	1	12
NASA	1523	2784	1.8	1	17	258	561	2.2	1	14

U.S. Agency[b]	Number of invention families with non-U.S. & non-WIPO applications[d]	Number of non-U.S. & non-WIPO applications				Number of invention families with non-U.S., non-WIPO, & non-EPO applications[e]	Number of non-U.S., non-WIPO, & non-EPO applications			
		Total	Avg	Min	Max		Total	Avg	Min	Max
USDA	180	828	4.6	1	18	168	692	4.1	1	17
DOC	13	43	3.3	1	8	11	30	2.7	1	6
DoD	437	1634	3.7	1	32	357	1200	3.4	1	26
DOE	1010	5011	5.0	1	30	931	4090	4.4	1	26
HHS	1464	8676	5.9	1	52	1288	6737	5.2	1	48
DHS	1	8	8	8	8	1	7	7	7	7
DOI	3	3	1	1	1	3	3	1	1	1
DOT	2	14	7	7	7	2	14	7	7	7
VA	267	1925	7.2	1	33	240	1519	6.3	1	31
EPA	34	127	3.7	1	11	27	92	3.4	1	10
NASA	102	314	3.1	1	13	92	276	3	1	12

[a]Data for fiscal year 2018 is not complete.

[b]Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA).

[c]Recall that we are working with what we have called USPTO-patent-application invention families – referred to as "invention families" for a short name. Note that our goal is to describe the patent application histories and the resulting patent portfolios for the federal agencies, and in particular, we want to describe the extent to which the agencies' inventions are protected with foreign as well as U.S. patents. Because of a procedural issue at the agencies vis-à-vis the patent office, not all applications that originated with inventors in the agencies will be in our data set. However, that is not of concern because the set of applications that we examine for each agency does include all of the inventions – and for each its simple family of applications for patents (a family is a group of filings for the same technology/invention) – that resulted in patents. The procedural issue is as follows. The numbers of patent applications according to the technology transfer reports could at times for some agencies be much greater than the number that we find associated with the agency in the EPO's PATSTAT worldwide data. The reason is that some of the agencies will have just the inventors' names on the original application, and then the procedure is that when the patent is granted by USPTO, the ownership is changed from the inventors to their employer. At that time, EPO's PATSTAT team will link that latest information to the application in PATSTAT and then the federal agency's name will appear as an applicant the application. What

this means is that for applications where no patent is granted, for agencies that have applications where only the inventors' names are listed on the original applications, the applications are not associated with the federal agency in the patent application data. This does not matter for this report because we want to characterize the agencies' patent portfolios. We nonetheless explain this procedural issue and observe that it will mean that some agencies will report more applications for patents in a fiscal year than we will have in our data set, but none of those applications that we do not observe were granted patents. So, excepting the applications for technologies that listed only the inventors, rather than their federal agency employer, as the applicants and never were granted a patent on the application, our tables provide all U.S. applications from the federal agencies and for each application the other applications in its simple family and with all of the information about foreign applications and about the grants of U.S. and foreign patents. When the agency lists only the inventors on the initial application, when a patent was ultimately granted, then the ownership is transferred to the agency, and the agency's name is added to all of the applications for the invention, and we then find the application under the agency's name and the associated patents worldwide. We can thus characterize completely the extent of foreign patent protection for the federal agencies' patents.

[d]Applications to the World Intellectual Property Organization (WIPO) simply provide an option to subsequently apply for a patent from the patent offices of the cooperating countries.

[e]Successful applications to the European Patent Office (EPO) do result in a patent. However, to enforce the patent in any particular country, the applicant must also apply to the patent office of the individual country.

Table 3. Foreign Patent Protection for U.S. Federal Agencies' Inventions (with an invention defined for the USPTO-patent-application invention family) during Fiscal Years 2003 through 2018.[a]

U.S. Agency[b]	Number of invention families with patents[c]	Number of patents for the invention families				Number of invention families with foreign patents	Number of foreign patents for the invention families				Proportion of invention families with patents that have foreign patents
		Total	Avg	Min	Max		Total	Avg	Min	Max	
USDA	792	1399	1.8	1	18	104	316	3.0	1	15	0.131
DOC	200	323	1.6	1	6	8	12	1.5	1	3	0.0400
DoD	6899	10640	1.5	1	18	245	687	2.8	1	14	0.0355
DOE	5841	10736	1.8	1	36	957	3300	3.4	1	23	0.164
HHS	2112	9496	4.5	1	32	1067	4683	4.4	1	24	0.505
DHS	24	28	1.2	1	2	0	0	–	–	–	0.0
DOI	48	63	1.3	1	4	3	3	1	1	1	0.0625
DOT	30	34	1.1	1	2	0	0	–	–	–	0.0
VA	488	1758	3.6	1	18	184	706	3.8	1	13	0.377
EPA	91	177	1.9	1	10	16	48	3	1	7	0.176
NASA	1358	2066	1.52	1	15	63	148	2.35	1	10	0.0464

U.S. Agency[b]	Number of distinct patents[d]		
	Total	Foreign	Proportion Foreign
USDA	982	193	0.197
DOC	206	8	0.0388
DoD	7364	432	0.0587
DOE	6844	1002	0.146
HHS	4379	2209	0.504
DHS	22	0	0.0
DOI	48	1	0.0208
DOT	29	0	0.0
VA	756	292	0.386
EPA	132	33	0.25
NASA	1478	107	0.072

[a]Data for fiscal year 2018 is not complete.

[b]Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA).

[c]Recall that to be able to trace the history of new patent applications, even when based on the same essential technology, we are working with what we have called USPTO-patent-application invention families – referred to as invention families for a short name and defined in the text.

[d]Here we count the number of patents received by each agency and how many foreign patents the agency received, removing any duplications because some USPTO-patent-application invention families receive the same patents as other families. See the discussion in the text.

III. Comparison with the Agencies' Annual Technology Transfer Reports

Our report provides new information about the federal agencies' patent portfolios because we have described the extent to which the agencies protect their intellectual property with foreign as well as U.S. patents. Table 4 reports the comparison of the patent counts reported in the agencies' annual reports with the counts that we found and reported in Table 3. Discussing the comparison provides more details about the methodology that we used.

The differences between the two counts of the patents – one reported in this report, and the other reported in the annual technology transfer reports can be summarized as follows.

For USDA, DOC, DoD, DOE, HHS, DHS, DOT, and EPA, the counts in the current report are consistent with those in the TT reports. For these 11 agencies, our count in the current report for the fiscal years 2003-2018 is higher than the count in the Technology Transfer (TT) reports for the fiscal years 2003-2015. The patent count in the current report and in the TT reports are quite consistent given that the current report covers an extra three fiscal years (but with the data for fiscal year 2018 being incomplete in the PATSTAT Spring 2019 database), and given allowance for cases where the most recent years reported in the TT reports data have markedly different patents received than the yearly average.

For DOI and NASA, the counts in our current report are somewhat lower than the counts reported in the TT reports. Cases where the patent count in the current report is somewhat less than the agency's count as reported in the TT reports are probably the result of one or more of three things. One possibility for the relatively small discrepancy being that the sum over the fiscal years 2003 through 2015 as reported in the TT reports could reflect a year-by-year count of issued patents with some of the patents in subsequent years being updates to existing patents via modifications to the patents received earlier. Another possible reason for the slight discrepancies would be that patents have been granted to inventors who are employed by an agency or to organizations sponsored and supported by an agency, and yet the agency's name does not appear on the published grant of the patent. A third possibility is that the assignee on the patent is the name of a part of the agency that we either did not include among the alternative names for the agency in our search or that is entered in a way that differs from the way we searched. We have sometimes discovered cases not picked up in our initial searches, and in such cases have added code to pick up the cases. It is of course possible that a relative handful of undiscovered patents remain. However, we expect that our characterization of the extent to which the patents assigned to the agencies have received foreign patent protection is a good one despite any slight discrepancies between the current report's counts of patents and the counts reported in the TT reports.

Finally, for VA our patent counts in the current report are far more than the counts reported for VA in the TT reports. The reason for the current report's larger number of patents counted for the Department of Veterans Affairs is probably because "VA's research program is different from other Federal technology transfer programs, because it is highly decentralized. The [Technology Transfer Program] TTP office is located in Washington DC; however, the actual research is conducted at more than 100 VA Medical Centers (VAMC),

all of which are Federal Laboratories."[65] The count in the current report gathered up the patents granted to the various VA Medical Centers, and it is possible that in the TT reports the VA reported just patents granted to the centralized VA operations. We will ask the points of contact for the VA about the difference between the current report's count of patents and the count for the VA in the TT reports.

Table 4. Patents received by U.S. Federal Agencies: TT Reports compared with Current Report.

U.S. Agency[a]	Number of patents granted	
	Current Report: FY 2003 through FY 2018[b]	Technology Transfer Reports: FY 2003 through FY 2015[c]
USDA[d]	982	676
DOC[d]	206	153
DoD[d]	7364	6815
DOE[d]	6844	6651
HHS[d]	4379	4215
DHS[d]	22	16
DOI[e]	48	57
DOT[d]	29	21
VA[f]	756	148
EPA[d]	132	127
NASA[e]	1478	1553

[a]Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA).

[b]Data for fiscal year 2018 is not complete.

[c]Source: https://www.nist.gov/tpo/reports-and-publications, Excel spreadsheet, federal_lab_tt_database_v.2015.xlsx, with the data by agency for patents, licenses, and income from licenses.

[d]The count in the current report for the fiscal years 2003-2018 is higher than the count in the Technology Transfer (TT) Reports for the fiscal years 2003-2015. The patent count in the current report and in the TT Reports are quite consistent given that the current report covers an extra three fiscal years (but with the data for fiscal year 2018 being incomplete in the PATSTAT Spring 2019 database), and given allowance for cases where the most recent years reported in the TT Reports data have markedly different patents received than the yearly average.

[e]Cases where the patent count in the current report is somewhat less than the agency's count as reported in the TT Reports are probably the result of one or more of three things. One possibility for the relatively small discrepancy being that the sum over the fiscal years 2003 through 2015 as reported in the TT Reports could reflect a year-by-year count of issued patents with some of the patents in subsequent years being updates to existing patents via modifications to the patents received earlier. Another possible reason for the slight discrepancies would be that patents have been granted to inventors who are employed by an agency or to organizations sponsored and supported by an agency, and yet the agency's name does not appear on the published grant of the patent. A third possibility is that the assignee on the patent is the name of a part of the agency that we either did not include among the alternative names for the agency in our search or that is entered in a way that differs from the way we searched. Even with the use of "wild cards" (special symbols used in the

[65] *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, National Institute of Standards and Technology, U.S. Department of Commerce, April 2018, p. 125. The report is available at https://www.nist.gov/tpo/reports-and-publications.

code to pick up a variety of letters that might appear in the item we are searching for; for example, using the wild card symbol %, the search for Veteran% would find both Veteran's and Veteran), we have sometimes discovered cases not picked up in our initial searches, and in such cases have added code to pick up the cases. It is possible, of course, that a relative handful of undiscovered patents remain. However, we expect that our characterization of the extent to which the patents assigned to the agencies have received foreign patent protection is a good one despite any slight discrepancies between the current report's counts of patents and the counts reported in the TT Reports.

[f]The reason for the current report's larger number of patents counted for the Department of Veterans Affairs is probably because "VA's research program is different from other Federal technology transfer programs, because it is highly decentralized. The TTP office is located in Washington DC; however, the actual research is conducted at more than 100 VA Medical Centers (VAMC), all of which are Federal Laboratories." (*Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, National Institute of Standards and Technology, U.S. Department of Commerce, April 2018, p. 125. The report is available at https://www.nist.gov/tpo/reports-and-publications) The count in the current report gathered up the patents granted to the various VA Medical Centers, and it is possible that in the TT reports the VA reported just patents granted to the centralized VA operations. We will ask the points of contact for the VA about the difference between the current report's count of patents and the count for the VA in the TT reports.

There are many reasons that the patent counts for a particular federal agency in Table 1, and then again in Table 3, could differ from those reported in other tabulations. One reason is that a search for applications by the agency must specify the agency's name, and that name will sometimes take many different forms in the database. We have spent a good deal of time searching for the many different ways that the name of each U.S. federal agency may have been entered into the USPTO database, and therefore also in the EPO PATSTAT worldwide database. Examples of the great variety of names used for an agency are provided in Appendix 1. A second reason is that rather than searching for records associated with an agency's name, some counts may begin by searching for all of the records associated with applications from organizations assigned to the sector of government non-profit organizations, and then from that set of records choose the records for the agency of interest. The problem with that approach is that in the PATSTAT worldwide database, sector assignments are sometimes incorrect or incomplete. In Appendix 1, we also provide examples of sector assignments that would reduce the patents found for federal agencies if the search for the patents was based on the sector assignment for the patent applications. The incorrect or incomplete sector assignments are corrected over time by the EPO's PATSTAT team, so such cases that we have noticed in the Spring 2019 edition of the PATSTAT worldwide database will probably be addressed in the next edition of PATSTAT. The EPO expert with whom we consulted about the technical details of the PATSTAT data requested our full set of examples of inaccurate sector assignments in order that the EPO team could address them in the next edition of PATSTAT. Another possible reasons for discrepancies between our counts and other published counts of a U.S. federal agency's patents would include the timing of the search for the patents. For example, if the search was made in 2015, there would be applications during that year that have not yet received the patents subsequently granted to the application in later years. Also, other searches might choose to restrict the patents to those where the federal agency is the sole recipient of the patent rather than sharing the patent with other applicants.

We plan to follow up with the points of contact for the agencies to develop our understanding of the differences between our patent counts and those in the TT reports. Our current thoughts about the reasons for the discrepancies have been discussed here in Section

III, and they are also included in the table's footnotes so that the table will be self-contained. We believe that based on our findings about the patents for each agency we are able to provide a good characterization of the extent of foreign patent protection for each agency's patented inventions.

IV. Conclusion

Section IV concludes this first report and describes the upcoming work for the project.

In this report, we have described that patent application history for the applications by the U.S. federal agencies to the USPTO and to foreign patent authorities. We have also described the patent grants that the federal agencies have received, both from the USPTO and from foreign patent authorities, as a result of their patent applications. In our upcoming reports we will model and estimate the *economic impact* of the foreign patent protection obtained and described in this first report, and then we will use the model to *predict* the economic impact that would be expected if the federal agencies increased the extent of the foreign patent protection that they obtain for their inventions. The benefits of increasing the extent of the foreign patent protection will be compared with the costs of applying for and maintaining the foreign patents.

APPENDIX 1. The Variety of Names for a U.S. Federal Agency and Incorrect or Incomplete Sector Assignments in PATSTAT, Spring 2019 Edition

Examples of the great variety of names used for an agency in the PATSTAT worldwide database are provided here in Appendix 1. The variety of names to indicate that a particular federal agency is an assignee for a patent can be illustrated with the portion of one of our queries to find the patents assigned to DoD as shown below.

Also, in the PATSTAT worldwide database, sector assignments are sometimes incorrect or incomplete. We provide examples here Appendix 1 by referring to a portion of our queries to find the patents assigned to NASA. The incorrect sector assignments are the result of the automated process using text search to determine the sector assignments, and EPO is continually updating the information. As one of EPO's PATSTAT experts put it: "[T]he assignation of the categories is based on a largely automated process trying to identify the category on the occurrence of certain words in the text. It will never cover all possibilities. We deem it sufficiently good for statistical analysis, but it will not be as good as a detailed manual check. If you send me a table with the person_id's you have identified as government institutions, we will add those into the detection process for the next release." We complied with that request, and for each of the 11 federal agencies we sent the requested information about the incorrect sector assignments that we had found.

Here reproduced just below is a portion of our "WHERE statement" from search queries about DoD patents when we gathered information about DoD's patents from the EPO's PATSTAT worldwide database. Within the portion of the WHERE statement, one can see the many alternative names that must be used in order to collect all of the granted patents for which DoD is an assignee. Also, we produce below a portion of the WHERE statement for our queries to find the patents assigned to NASA. In that portion of the NASA queries, in the restrictions in the code about exclusions of records from sectors other than GOVT NON-PROFIT, one can observe examples of incorrect sector assignments. Thus, the one example of DoD illustrates both the issue of needing to discover and code the great variety of ways by which a federal agency might be indicated as the assignee, and also illustrates the issue of incorrect sector assignments that must be uncovered and addressed (if one needs to code the exclusion of certain sectors) when gathering the complete set patents assigned to an agency. Note that because the PATSTAT team has received our list of incorrect sector assignments, in the next edition of PATSTAT the task of finding the patents will not be so difficult. However, the lesson is that when searching for the patents assigned to a particular organization, whatever the edition of the worldwide database, one must find the idiosyncratic cases in the data by studying the worldwide database.

Here to illustrate the variety of alternative names for an agency is the example of a portion of the WHERE statement from our queries about DoD.

```
WHERE . . .

and (psn_name like '%Department of Defense%' or psn_name like '%Secretary of Defense%' or psn_name like '%Secretary of the Army%' or psn_name like '%Secretary of the Navy%' or psn_name like '%Secretary of the Air Force%' or psn_name like '%Marine Corps%' or psn_name like '%Coast Guard%' or psn_name like '%Defense Advanced Research Projects Agency%' or psn_name like '%Space and Naval Warfare Systems Center Pacific%' or psn_name like '%Office of Research and Technology
```

```
Applications%' or psn_name like '%Army Material Command%' or psn_name like '%Army Medical Research%' or
psn_name like '%Army Medical Research and Materiel Command%' or psn_name like '%United States Transportation Command%'
or psn_name like '%Office of Research and Technology Applications%' or psn_name like '%National Security Agency%' or
psn_name like '%Missile Defense Agency%' or psn_name like '%Naval Sea Systems Command%' or psn_name like '%Naval
Surface Warfare Center%' or psn_name like '%Air Force Office of Scientific Research%' or psn_name like '%Office of Naval
Research%' or psn_name like '%Army Aviation and Missile Command%' or psn_name like '%Defense Threat Reduction Agency%' or
psn_name like '%Air Force Research Laboratory%' or psn_name like '%Army%' or psn_name like '%Navy%' or
psn_name like '%Air Force%' or psn_name like '%Army Research, Development and Engineering Command%' or
psn_name like '%Army Research Office%' or psn_name like '%Army Research Laboratory%' or psn_name like '%Walter Reed
Army Institute of Research%' or psn_name like '%Army Contracting Command%' or psn_name like '%Army Institute of Surgical
Research%' or psn_name like '%Army Natick Soldier Research, Development and Engineering Center%' or psn_name like '%Natick
Contracting Division%' or psn_name like '%Edgewood Chemical Biological Center%' or psn_name like '%Army Materiel Command%'
or psn_name like '%Naval Undersea Warfare Center%' or psn_name like '%Defense Medical Research and Development Program%' or
psn_name = 'DARPA')

. . .
/* inspection of results without restrictions identified invalid observations and then
the following code was used to eliminate the invalid observations */

and (psn_name != 'Swiss Army Brands' and psn_name != 'Army & Air Force Exchange Service' and
psn_name != 'Rotary Air Force Management' and psn_name != 'Navy Island Plywood' and psn_name
!= 'The Salvation Army'and psn_name != 'Warmy Toasty'and psn_name != 'Robotarmy
Corporation'and psn_name != 'Victorinox Swiss Army' and psn_name != 'Air Force Enterprises'
and psn_name != 'NAVYA NETWORK' and psn_name != 'Navy Federal Credit Union' and psn_name
!= 'Navy Island' and psn_name != 'HK ARMY' and psn_name != 'HK ARMY INC.')
```

Here to illustrate the issue of incorrect sector assignments for some of an agency's records is the example of a portion of the WHERE statement from our queries about NASA.

```
WHERE . . .

and (psn_name like '%National Aeronautics and Space Administration%' OR psn_name like '%NASA%' )


. . .
/* inspection of results without restrictions identified cases where restrictions
could not be used without qualification, and then the following code was used to
qualify the restrictions as necessary to keep valid observations */

and (psn_sector != 'COMPANY' OR (psn_sector = 'COMPANY' and psn_name = 'NASA
HEADQUARTERS'))
and psn_sector != 'UNIVERSITY'
and psn_sector != 'INDIVIDUAL'
and (psn_sector != 'UNKNOWN' OR (psn_sector = 'UNKNOWN' and (psn_name = 'National Aeronautics and
Space Administration' OR psn_name = 'NASA GLENN RESEARCH CENTER' OR psn_name like '%NASA HQ%'
OR psn_name = 'NASA LYNDON B. JOHNSON SPACE CENTER' OR psn_name = 'U.S.A. AS REPRESENTED BY THE
ADMINISTRATIONS OF THE NASA' OR psn_name = 'U.S.A. AS REPRESENTED BY THE ADMINSTRATOR OF NASA'
OR psn_name = 'United States of America, as represented by the Administrator of NASA' OR psn_name = 'The United States of
America as Represented by the Admin of National Aeronautics and Space Administration' OR psn_name = 'U.SA. as represented by the
Administrator of the National Aeronautics and Space Administration' OR psn_name = 'The United States of America as Represented by
the Administrator of National Aeronautics and Space Administration' OR psn_name = 'NASA LANGLEY RESEARCH CENTER')))

. . .
```

Appendix B. Benefits and Costs of Foreign Patent Protection for U.S. Federal Agencies' Technologies with U.S. Patents (Task 2 Report)

I. Introduction

This introductory section provides a concise statement of the key ideas and findings in the report. Also, it provides an overview of the sections of the report where the ideas and findings are explained.

Estimation of Agency-specific Lower-Bound Benefits of Foreign Patent Protection

In this report, to provide information about the benefits of foreign patent protection, we estimate a model of U.S. federal agencies' invention-licensing revenues. The agencies differ in their missions and in the technologies that are created by their laboratories and facilities. We therefore estimate different parameters for each agency's estimated function that relates the agency's licensing revenues to the evolving history of its domestic and foreign patent applications and granted patents.

The benefits and the motivations for the licensing of technologies of the federal agencies depend on the differing missions of the agencies and transcend the licensing revenues that are negotiated.[66] Nonetheless, the negotiated revenues reflect and are constrained by the technologies' commercialized value that is determined by market forces.[67] The U.S. Government Accounting Office (GAO) explains that the financial compensations arranged in the licenses "… typically establish financial terms on a case-by-case basis that are tailored to the specifics of the technology, licensee, and market conditions."[68] The GAO description of the licensing process makes clear that commercialization of the transferred technologies is the goal. Market value underlies and enables commercialization.

The invention-licensing revenues obtained from the licensees will reflect *in part* the market value of the commercialized technologies. Thus, the revenues are not only a measure of a benefit received by the agency; they also provide a lower bound on the social value of the technology. The entire social value includes the addition to the licensee's economic profits generated by its use of the technology, and the social value also includes value that spills over to other companies and to consumers. The amount of a technology's social value that is captured in an agency's licensing revenues will vary with the licensing negotiation process.

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[66] See Steven M. Ferguson and Uma S. Kaundinya, "Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs," chapter 14, pp. 185-206, in *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies*, Edited by Craig Shimasaki (Oxford, UK, and Waltham, MA U.S.A.: Academic Press, Elsevier, 2014).

[67] Ferguson and Kaundinya, *Ibid*., provide details about the licensing negotiations and about the financial arrangements used in the technology transfer operations of the federal agencies and laboratories.

[68] United States Government Accountability Office (GAO), *Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions* (GAO-18-327), Washington, D.C., June 2018, (https://www.gao.gov/products/GAO-18-327), p. 14, and limited exceptions noted there, and then see more generally pp. 12-16.

A Causal Effect of the Absence of Foreign Patents

Most federal-agency technologies with U.S. patents do not also have foreign patent protection. The research design employed allows us to capture for each agency the relationship between an agency's application and patent histories and its annual aggregated licensing revenues. For each agency the U.S. patented technologies that also have foreign patent protection generate greater licensing revenues on average than technologies with U.S. patents only. That finding is expected because the agencies will choose to pursue foreign patents for the more valuable technologies; and, for the cases where the agency leaves the pursuit of foreign patents entirely to the licensees, those patents are also pursued for the more valuable technologies. For more valuable technologies, greater licensing revenues can be negotiated. However, by controlling for the application history as well as the history of the timing for the patent grants, there is some support not just for the foregoing causal story (i.e., that U.S. and foreign-patented technologies generate more licensing revenues than technologies with only U.S. patents *because* the underlying inventions are more valuable) but an additional causal story as well.

With the application history controlled, we are able to find evidence supporting the hypothesis that a portion of the shortfall in licensing revenues for technologies without foreign patents is *caused* by the absence of the foreign patents. In particular, we are able to identify a broad set of cases where adding U.S.-patented technologies that are not also protected with foreign patents actually has a *negative* effect on agencies' licensing revenues. One possible interpretation of the evidence of the negative effect (rather than simply a lower effect as compared with technology having foreign patents) is the hypothesis that agencies' acquisition of U.S. patents without getting the foreign patent protection reduces licensees' profitability when commercializing the federal agencies' technologies. The reduction in the profitability would occur because arguably – again this is just a hypothesis that is consistent with our findings – the technology without foreign patent protection is out there for foreign competitors to copy and compete with in international markets without incurring the costs of royalty payments for the use of the technology. The competition from lower-cost foreign firms would reduce the profitability of licensees, and hence reduce the negotiated licensing fees that firms would be willing to pay for the use of the agency's patented technologies across multiple inventions. After presenting the estimation of our estimated agency-specific functions of invention-licensing revenue, we explain why the evidence supports the hypothesis that disseminating the federal agencies' technology without obtaining foreign patent protection may actually lower the profitability of the licensees that use the U.S. patented technology.

The Costs of Foreign Patents

To be able to license its technology, an agency must incur the costs of obtaining patent protection for its intellectual property (IP). To provide information about the costs of obtaining foreign patent protection, we have discussed those costs with technology transfer experts at the federal agencies and also gathered data about the patent application costs and the maintenance fees for patents and the associated legal expenses. We use the information

to formulate estimated equations for U.S. and for foreign patent costs, and from those equations we can estimate the cost of an additional foreign patent or an additional U.S. patent.

Agency-Specific Return on Investment for Foreign Patent Protection

Our cost estimates together with our benefit estimates allow us to estimate conservative lower bounds for the benefit-to-cost ratio and the net present value of obtaining additional foreign patent protection for each agency's patent portfolio. We find a dramatic difference between the large return on investment from adding foreign patent protection to a USPTO-patented technology for the four agencies with about 90% of the patenting activity and the small return for the other agencies. The metrics for the two groups differ by from one to two orders of magnitude. In our conclusion, we discuss the reasons for the difference across the agencies in their rates of return on the investment in foreign patenting.

Overview of the Sections of the Report

Section II of this report describes the federal agencies' processes for selecting the technologies to patent and for negotiating licenses for the transferred technologies. Section III presents our estimated model for invention-licensing revenues. A separate invention-licensing revenue function is estimated for each agency. After presenting the estimated functions, we explain how the estimates identify what can reasonably be interpreted as a causal effect of not acquiring foreign patents. Section IV presents our estimated costs for obtaining foreign patent protection; we explain how the estimates were formed. Section V concludes with our estimates for each individual agency of conservative lower bounds for the benefit-to-cost ratio and the net present value of obtaining foreign patent protection for USPTO-patented technologies. After explaining and presenting the estimates, we discuss implications of the report's findings. We find that acquiring foreign patent protection yields benefits exceeding costs, but the return on investment is dramatically higher for the four agencies with about 90% of the patenting activity. For the remaining seven agencies, the costs of obtaining foreign patents are higher, and the invention-licensing revenues are less. For the seven agencies with small patent portfolios as well as for the four agencies with the large portfolios of patents, the evidence supports the expectation that pursuing additional foreign patents may not only result in greater net licensing revenues to offset the taxpayers' investments in federal agencies' technologies. Additionally, obtaining more foreign patents would improve the international competitive position of firms that license the agencies' technologies. It would be easier to transfer technologies to be commercialized because the licensees would find that the technologies have greater commercial value when they have foreign patent protection.

Section II. Patenting and Licensing

In this section we review some of the processes and challenges associated with utilization of inventions developed within federal agencies. We begin with an overview of the federal patenting and licensing system and focus attention on the constraints and challenges of two stages within the process, invention selection and licensing. Some constraints are imposed

by policy and regulation while others are integral to the practical issues of projecting the future value of intellectual property (IP), and, very broadly, the range of strategies employed by federal agencies with respect to foreign patenting.

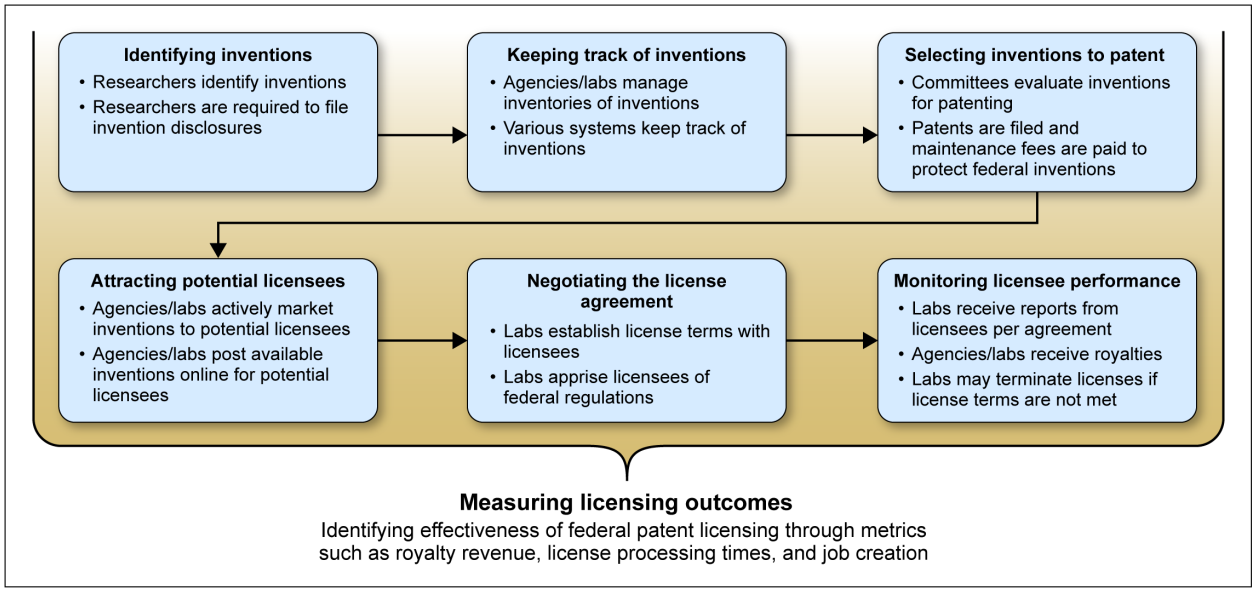
Overview of the Federal Patenting and Licensing Process

Numerous regulatory requirements have been established to help ensure that agencies commercialize inventions arising from R&D at federal laboratories.[69] Figure 1 presents an overview of the federal patenting and licensing process.[70] Here we wish to focus on some of the constraints faced by those involved in the invention patenting and licensing stages of the process as background for the analysis of foreign patenting outcomes presented in this Task 2 report.

[69] The federal agencies have authority to acquire, maintain and manage portfolios of U.S. and foreign patents for the technologies generated by the agencies. "Each Federal agency is authorized to … apply for, obtain, and maintain patents … in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest; grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration …; undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering royalties to the Federal Government in any invention …." U.S. Code, Title 35, Section 207, https://www.law.cornell.edu/uscode/text/35/207. Federal agencies use their authority (to obtain patents and license technology) to support the policy and objectives of Congress. "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 ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government …." U.S. Code, Title 35, Section 200, https://www.law.cornell.edu/uscode/text/35/200.

[70] In addition to technologies originating entirely in the agencies' laboratories, there will be those that evolve from cooperative work with partners – CRADA partners or Bayh-Dole contractors for inventions with co-inventors employed by the federal agencies. In those cases, industrial partners will be especially likely to manage the acquisition and maintenance of patents, with the federal agencies among the assignees, for jointly developed technologies. There are three parts of the U.S. Code under which inventions created in whole or in part by Federal employees may occur, 15 USC 3710a, 35 USC 202, 35 USC 207.

Figure 1. Federal Patenting and Licensing Process.[71]



Source: GAO analysis based on review of regulations and agency documentation. | GAO-18-327

We appreciate that selecting inventions to patent, selecting patents for protection in non-U.S. jurisdictions, attracting licensees, and negotiating licenses is a daunting task, and that it is difficult to generalize, but the data analysis we present in this report appears to show that, given all the constraints and peculiarities of invention patenting and licensing, more emphasis should be placed on acquiring foreign patents.

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 and development. As part of that objective the policy encourages maximum participation of small business firms in federally supported research and development efforts, and promotes collaboration between commercial concerns and nonprofit organizations subject to the constraints of U.S. competition policy. The policy also seeks to ensure that government agencies obtain sufficient rights in federally supported inventions, including those made at universities, while seeking to minimize the costs of administering policies pertaining to patent rights in inventions made with federal assistance.[72]

Encouraging the participation of small business, obtaining sufficient rights, and promoting collaboration, all while minimizing costs, singularly or combined, are tall orders that potentially entail competing goals. Moreover, these competing goals occur on a background of achieving an agency's first-order mission goals and, therefore, its technology mix. Some agencies are focused more on biotechnology, pharmaceuticals, and medical devices while

[71] GAO, op. cit., p. 11.
[72] U.S. Code, Title 35, Section 200, https://www.law.cornell.edu/uscode/text/35/200. See also U.S. Code, Title 35, Section 209, https://www.law.cornell.edu/uscode/text/35/209.

others are focused more on computer technology, machinery, and semiconductors.[73] An agency's technology mix will have some bearing on achieving its technology transfer goals.

Challenges and Constraints of Invention Patenting

The decision to apply for patent protection often involves evaluation committees comprised of inventors, technology transfer professionals, and patent attorneys. Among the factors considered are: whether the invention meets patentable criteria (useful, novel, and non-obvious[74]); how the invention relates to the laboratory's mission; and if patenting will likely bring the invention to commercial use and practical application.[75] GAO reports that federal agency laboratory officials cite the costs of patenting as a major challenge of selecting high-value patents.[76] While that is telling, setting those costs aside, the analytical hurdle of selecting future high-value patents should not be overlooked. If that were *not* the case, there would be scarce concern for resource constraints, license revenue would provide ample resources to fund many agency missions.[77] Alas, no one can routinely predict the future.

We do not know how many attempts at selecting high-value patents are successful, nor *how* successful. Our correspondence with technology professionals in federal agencies informs us that for some agencies — those with good information systems for tracking inventions — the first question (how many?) could be answered without great effort (in the sense that same agencies routinely identify patents that are licensed). Answering the second question (*how* successful, net costs?) would be a "heavy lift" even for agencies with good patent tracking information systems.

While we don't know how successful the invention selection process is at forecasting commercial use and practical application, there are reasons to suggest that these are rather difficult to project and achieve. The problem is in predicting what will be "high-value" inventions — those brought to the greatest commercial use and practical application. Some have expressed the view that the goal of technology transfer programs is primarily the transfer itself, not the associated license revenue.[78] Nonetheless, predicting the high-value inventions is a necessary part of the invention-selection process and agencies have developed

[73] National Institute of Standards and Technology (NIST), *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, U.S. Department of Commerce, April 2018, available at https://www.nist.gov/tpo/reports-and-publications.

[74] https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-4

[75] GAO, op. cit., p. 12.

[76] Ibid., p. 43.

[77] One reason federal agencies willingly engage in invention patenting and licensing is to generate revenue to fund mission research. See Ibid., p. 28.

[78] See, Kelly Day Rubenstein, "Transferring Public Research: the Patent Licensing Mechanism in Agriculture," *Journal of Technology Transfer*, Vol. 28, pp. 111-130, 2003. The GAO, too, has reported that "DOD, DOE, NASA, and NIH officials … stated that getting the technology *into the marketplace* is their primary goal in licensing (GAO, op. cit., p. 28). [Emphasis added.] Also, Ferguson and Kaundinya, op cit., pp. 191-192, observe: "Compared to biomedical licensing from corporations, the federal laboratories and universities bring a different focus and perspective to the table when negotiating the technology transfer agreements. Because these agreements are used to further overall institutional missions, representatives from such nonprofit institutions consider the public consequences of such licenses as their first priority, not the financial terms that may be involved."

strategies for lowering the inherent risks.[79] If we are to compare investments in the cost of patenting for two inventions being placed into the marketplace, economic logic suggests that the "higher value" project is the one having the greater addition to the licensee's economic profit stream (the addition measured as a present discounted value). That addition to value would reflect an addition to producer surplus that would be a part of the additional social value from the technology transfer. This social value would include additions to the profits of other firms that benefit from spillovers and additions to the consumer surplus of the customers of the firms that benefit from the transferred technology. The commercialized value for the licensee places an upper bound on the licensing fees that could be negotiated.

As discussed in the following section, it is widely recognized that the timespan from patent application to licensed production can be quite long. In the intervening years domestic and global market and technology dynamics are quite likely to change in ways that are often hard to forecast, reducing the likelihood of picking inventions that can eventually be successfully commercialized.

Moreover, what can be known about "practical use and application" of a specific invention, early-on, might only be the category of products or services to which it might eventually belong and how fast or slow the demand for that category is growing, and where, geographically. Of course, between the invention and the granted patent alone, things can change. Patent applications are often rejected, modified, refiled, and sometimes abandoned.

Our analysis of federal agency patent portfolios found that the average lapsed-time from application to patent grant is quite substantial, especially for foreign patents. For the 11 agencies that we study in this report, the lag time from the successful application for a patent until the patent was granted varies greatly over the sample for fiscal years 2003 through 2018 covered in our Task 1 report.[80] For USDA, the average lag for its U.S. patents was 3.02 years; for its foreign patents the average lag was 6.03 years. For DOC, the average lag was 2.68 years for its U.S. patents and 5.35 years for its foreign patents. For DoD, the average lags were 2.83 and 2.81 years for the U.S. and foreign patents respectively. For DOE, the average lag for its U.S. patents was 3.04 years, and it was 5.73 years for its foreign patents. For HHS, the lag for the U.S. patents averaged 3.85 years, and for the foreign patents it averaged 6.82 years. For DHS the average lag for its U.S. patents was 2.03 years; it had no foreign patents during the sample period. For DOI, the lag for its U.S. patents averaged 3.03 years; it had just one foreign patent during the sample period, and its lag was 0.54 year. DOT had no foreign patents during the sample period, and its U.S. patents had an average lag of 2.57 years. The average lags for the U.S. and foreign patents of the VA were 3.40 and 5.61 years respectively. For EPA, the average lags for the U.S. and foreign patents were 3.42 and 6.28 years respectively. For NASA, the average lags were 3.04 years for its U.S. patents and 4.48 years for its foreign patents.[81]

[79] Ferguson and Kaundinya, Ibid., pp., 189-90.

[80] The following information, about the average time from the application for a patent until it was granted, was tabulated by the authors from the worldwide patent data maintained by the European Patent Office; https://www.epo.org/searching-for-patents/business/patstat.html#tab-1.

[81] According to technology transfer experts, there is considerable effort dedicated to coordinating foreign patent applications and domestic applications. So, the lag times used in the statistical analysis presented in this report — computed as the difference between the formal application date to the date of the patent grant (computed

For the reasons that we have described, it is likely that only a small fraction of inventions projected to be "practically applicable" and/or "commercially useful" will turn out to be so.

As challenging as such analysis appears, we cannot ignore that agency technology professionals consider the costs of patenting inventions to be a relatively high hurdle. According to GAO analysts, *"*DOD, DOE, NASA, and NIH agency and lab officials cited selecting inventions to patent as a challenge because of the expense of patenting fees."[82] Federal agencies are charged patent fees at the same rate as large corporations, because they are classified as large entities and therefore pay undiscounted maintenance fees. Most fees, including maintenance fees, are discounted substantially for small entities and U.S. institutions of higher education.[83]

It appears that funding of patent applications is derived from budgets that are themselves spread thin.[84] So the struggle for funds may loom large relative to the otherwise daunting analytical tasks characterized above. This is particularly relevant for this study of foreign patenting practices because the evidence presented in this report suggests that *more* attention should be given to patenting in non-U.S. jurisdictions, and there is wide agreement that foreign patent protection is relatively expensive, although, in aggregate, we find the net return on that investment is high relative to patenting only in the U.S.

Challenges and Constraints of Patent Licensing

There are many legal and regulatory provisions that pertain to patent licenses that originate in federal laboratories. The GAO provides a useful summary of these:

> "[T]he law generally gives preference to small businesses that are capable of bringing the invention to practical application. There is a general preference for products that incorporate federal inventions to be manufactured substantially in the United States; however, on a case-by-case basis, agencies may waive this requirement. Applicable law also reserves certain rights for the government to protect the public's interests in federally funded inventions. For example, the government retains a royalty-free license to use inventions that are contractor owned or that are licensed exclusively. In addition, the

from PATSTAT) — understate the amount of time that passes from the invention to the granting of a foreign patent. Furthermore, referring back to the variability of the technology mix between agencies, some technology applications are more subject to regulatory regimens that add more time and risk to the lab-to-market process.

[82] GAO, op. cit., p. 28.

[83] Ibid., p. 42.

[84] According to a NIST survey, more than half of the Offices of Research and Technology Applications (ORTAs) report that either the ORTA (34%) or the corresponding laboratory (35%) paid for patent prosecution in FY 2016. Ten percent of ORTAs reported that their Office of General Counsel, or legal office equivalents, paid for patent prosecution. Three percent of ORTAs fund their patent operations through a combination of the ORTA, laboratory, and legal office. The remaining 18% consisted of answers such as overhead or royalty revenue. Nicole Gingrich, *Federal Office of Research and Technology Applications Survey Results*, Technology Partnerships Office, National Institute of Standards and Technology, August 2018, p. 7.

> Bayh-Dole Act provides the government march-in authority when certain statutory conditions have been met. Under this authority, an agency may grant a license to an invention developed with federal funding even if the invention is exclusively licensed to another party if, for example, it determines that such action is needed to alleviate public health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensee. A federal lab can also terminate a license when the licensee is not meeting its commitment to achieve practical application of the invention. The lab can also, through the license, grant permission to a licensee to pursue patent infringement cases."[85]

All agree that it is difficult to generalize about patent licensing beyond describing the stages of the process, not least because each federal agency designs its own program to meet technology transfer objectives consistent with its other mission responsibilities. The closer we move in the direction of the problems facing the license negotiators, about a particular license or group of licenses, the more difficult generalization becomes except to say that it is quite common for licensees to terminate their license agreement at some point during this overall process.

This report will say something general about pursuing foreign patents. But before we get there, we want to recognize how difficult that process must be *because* it is often essentially about negotiating a license on the basis of necessarily risky projections about future events. A close observer of federal laboratory license agreements addresses the need to generalize as follows:

> "[E]ach license is negotiated individually with particular idiosyncratic terms. Patent license agreements are typically structured to incentivize the licensee to develop the technology (e.g. with a performance diligence requirement delineating milestone targets for technology development) while returning a share of profits from commercializing the technology back to the lab. A [laboratory] license agreement typically includes terms for a license issuance fee due when a license is executed, patent cost reimbursement, a minimum annual royalty, and a running royalty equal to a fixed percentage of sales. License agreements can be terminated by the licensee, typically at any point, or by the lab if diligence requirements or royalty obligations are not met by the licensee. Finally, the U.S. government retains a "march-in" right to re-license an already licensed patent or to use a licensed patent discovered in a [laboratory] for purposes in the national interest."[86]

While a federal agency (licensor) and its licensees have common objectives — of enabling the licensee to make and sell the product and to reach the marketplace as soon as possible, of strong IP protection, of fairly allocating income from the technologies and any liabilities that might arise, of resolving disputes quickly and fairly, and of stopping infringers — they often come at these objectives from different perspectives. Hence, the license *negotiation* process

[85] GAO, op. cit., p. 15. See also U.S. Code, Title 35, Section 209, https://www.law.cornell.edu/uscode/text/35/209.
[86] Gabriel A. Chan, "The Commercialization of Publicly Funded Science: How Licensing Federal Laboratory Inventions Affects Knowledge Spillovers," mimeo, Harvard University, November 12, 2014.

is central and important. While we recognize that each licensor and licensee is different, there are common license negotiation issues.[87]

Among these, for example, are issues concerning the breadth of the licensing agreement. Federal agencies typically hope to limit the license to cover products the licensee will actually produce, whereas licensees hope for a broad license, perhaps an exclusive license, to stymie competitors and expand opportunities. There are issues concerning the speed with which the licensee brings the product to market. A federal agency likely prefers the licensee to prioritize the licensed product whereas the licensee may consider the product part of a portfolio of products among which priorities change with circumstances in each product market. Both the licensor and the licensee want to fairly share in the revenues from a license but the federal agency may want some pre-sale license revenues. The licensee may prefer to delay pre-launch payments as long as possible.

Given the sensitivity about the costs of patenting discussed in the preceding section, another very important issue may center on who bears the cost of patenting. Both licensor and licensee want strong, maybe international, intellectual property protection, but it is perceived as expensive. And that perception likely differs between large and small licensees. The federal agency may prefer that the licensee reimburse all patenting costs but the licensee would prefer those costs be shared. Some federal agencies routinely seek patent protection in selected, and changing, non-U.S. jurisdictions while other agencies routinely refuse to patent in non-U.S. jurisdictions. Just as perceived costs of aggressive patent protection may differ between large and small licensees, the costs of international patenting strategies among federal agencies may differ between agencies with relatively large and small patent portfolios. In the same vein, both the federal licensor and the licensee benefit from aggressively fighting patent infringement because infringement cuts into profits and licensing revenues.[88]

In addition to the negotiation issues arising from specific objectives of the licensor and licensee, negotiation strategies of the various agencies are nested within competing policy goals. For example, a focus on net license revenue might favor large, well-funded licensees over small firms and start-ups. But there is a clear policy goal to encourage the participation of small businesses and non-profits that may have less certain revenue streams. As well, the costs of an aggressive, perhaps international intellectual property protection strategy that favors the participation of small firms and start-ups could require the federal agencies to bear more of the costs of patenting and lower their expectations of capturing up-front license fees. At least in the short run, that would increase the need for the precious resources devoted to the patenting process and devoted to administering the policy.[89] Yet those heightened costs

[87] The description of basic licensing issues relies on, *Technology Licensing Guidebook*, the Law Firm of Williams Mullen and The University of Virginia Patent Foundation, 2007.
[88] The federal labs themselves cannot bring litigation or defend against Department of Justice actions. They need to rely on the Department of Justice or licensees for this.
[89] At this time, we are unaware of systematic time series data that characterizes the extent to which federal agencies' licensing practices — much less the distribution of license revenues — favor small firms and startups. Limited evidence, presented by the GAO's recent assessment of these practices, suggests that a large fraction of active licenses (at least 72 percent) was held by small firms and start-ups in fiscal year 2014. See, GAO, op. cit., Appendix III, p. 51.

would run counter to the policy prescription even as the emphasis on small firms and start-ups aligned with the policy prescription.[90]

Conclusion about the Invention Patenting and Licensing Process for the Federal Agencies

For some time there has been concern that the U.S. is missing opportunities to fully commercialize inventions arising from federal agency research. Indeed, NIST's *Lab-to-Market* focus was established as a result of this concern. The data and analysis presented in this report suggest that opportunities are likely being missed to the extent that agencies are timid in their pursuit of IP protection in non-U.S. jurisdictions. That said, it is also clear that the challenges of identifying and negotiating financially successful licensing agreements are substantial, perhaps especially so where global markets are roiling and market outcomes are relatively far in the future.

It has been observed that the idea of a simple license in an oxymoron. So too, we suspect, is the idea of a simple license negotiation process. The odds appear stacked against the success of betting on the right invention to patent, and the extent of patent protection, as well as betting on the success of the license negotiation process. And yet the analysis presented in this report clearly shows that for some agencies the return on investment on a domestic patent for a technology that does not also have foreign patent protection is somewhat negative, while the return on investment in domestic patents that are also protected in foreign jurisdictions is positive. The return on investment from adding the foreign patent protection varies substantially across the agencies, as we show in Section V of this report. The agencies with smaller patent portfolios are particularly challenged by the legislated mandate to encourage the participation of small business firms both because those firms are less able to bear the costs of prosecuting foreign patent protection and because, as we show in Sections IV and V, the agencies with smaller patent portfolios have higher costs for adding foreign patent protection for their USPTO-patented technologies. With all the challenges and constraints that face federal technology transfer agents, despite the higher costs, the net gains of foreign patent protection appear to be worth the cost. That said, how those additional costs are to be paid for, and how this would impact the distribution of the number of licenses, and license revenues, between small and large firms cannot be known at this time.

III. The Estimated Model of Invention-Licensing Revenues and the Effect of Additional Foreign Patents

This section explains our model of invention-licensing revenues, presents our estimations for the individual federal agencies, and then explains what the estimates imply about the effect of protecting USPTO-patented technologies with foreign patents.

[90] "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 ensure that the Government obtains sufficient rights in federally supported inventions …; and to minimize the costs of administering policies in this area." U.S. Code, Title 35, Section 200, https://www.law.cornell.edu/uscode/text/35/200.

Invention-licensing Revenue as a Function of the History of Patent Applications and Grants, *Ceteris Paribus*

To estimate how extending an agency's foreign patent protection affects the agency's invention-licensing revenues, we begin with the observation that those revenues will depend on the history of the agency's applications for U.S. and foreign patents and on the history of the grants of U.S. and foreign patents to the agency. Based on the agency's patent-pending and patented technology, licenses are negotiated, and licensing revenues are earned. From the worldwide patent data maintained by the European Patent Office, for each of the U.S. federal agencies in our study, we have gathered the information about the history of the applications for U.S. and foreign patents through time, and also the history of the granting of U.S. and foreign patents through time.[91] From the technology transfer reports gathered by NIST, we have the history of the licensing revenues for the agencies.[92]

We denote as y_{it} the i^{th} agency's invention-licensing revenue, in thousands of constant 2015 dollars, in fiscal year t. $PatUS_{it}$ denotes the number of new U.S. patents granted to the i^{th} agency in fiscal year t, and $PatFN_{it}$ denotes the number of new foreign patents granted to the i^{th} agency in fiscal year t. Because it takes time to arrange licenses based on the grants of patents, some time will pass from the grants of the patents until an impact on revenues begins. Moreover, in the model of invention-licensing revenues as a function of the history of the grants of U.S. and foreign patents, all of the lagged values of $PatUS_{it}$ and $PatFN_{it}$ are theoretically potential drivers of licensing revenue, although we expect the numbers of new patents in the more recent past to be the more important explanatory variables. Because some licenses and revenue from the licenses are negotiated on the basis of technology for which the agency has submitted a patent application to USPTO and the patent is pending, in addition to the history of the timing of the grants of the U.S. and foreign patents, we use the history of the timing of the applications for the original USTPO patents. $AppUSnoFN_{it}$, equals the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent but for which a foreign patent for the underlying technology was never granted. Also, we include $AppUSFN_{it}$, and it equals the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent and for which at least one foreign patent for the underlying technology was also ultimately granted. Again, because it takes time to arrange licenses based on the new patent applications to USPTO, some time will pass from the time of the applications for the patents until an impact on revenues begins. Moreover, all of the lagged values for new patent applications are potentially relevant drivers of the current fiscal year's licensing revenues, although we expect that more recent lags would be more important.

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[91] https://www.epo.org/searching-for-patents/business/patstat.html#tab-1.

[92] Our dependent variable, the annual invention-licensing revenue for each agency for each fiscal year from 2003 through 2015, is provided in nominal values (that we converted to constant 2015 dollars) in NIST's summary technology transfer report and in an Excel spreadsheet that is available with the report. National Institute of Standards and Technology (NIST), *Federal Laboratory Technology Transfer, Fiscal Year 2015: Summary Report to the President and the Congress*, U.S. Department of Commerce, April 2018, and Excel spreadsheet, federal_lab_tt_database_v.2015.xlsx The report and the Excel spreadsheet are available at https://www.nist.gov/tpo/reports-and-publications.

In sum, we expect that an agency's invention-licensing revenues over time will be a function of the history of its patent applications and of its patents ultimately granted. We observe the licensing revenues over fiscal years 2003 through 2015, and we observe how the applications for patents through time and the patents subsequently granted affect the licensing revenues observed.

Thus, with the complete histories for applications and granted patents as the drivers of license negotiations and ultimately licensing revenues, we would have a model that reflected the theory about what determines the invention-licensing revenues. The ith agency's revenues y_{it} are in part determined by the history:

$$
\begin{aligned}
&a_{1i}AppUSnoFN_{it-1} + b_{1i}AppUSFN_{it-1} + c_{1i}PatUS_{it-1} + d_{1i}PatFN_{it-1} \\
&+a_{2i}AppUSnoFN_{it-2} + b_{2i}AppUSFN_{it-2} + c_{2i}PatUS_{it-2} + d_{2i}PatFN_{it-2} \\
&+a_{3i}AppUSnoFN_{it-3} + b_{3i}AppUSFN_{it-3} + c_{3i}PatUS_{it-3} + d_{3i}PatFN_{it-3} \\
&+...
\end{aligned}
$$

However, given the practical constraint of a limited number of years for which the revenues are observed, a model with all of those terms could not be directly estimated. The relationship between the past patents and the fiscal year's revenues recurs through time, so that rather than showing the time series for each fiscal year's new USPTO applications and its new U.S. and new foreign patents extending into the past, we could capture the effect of those past applications and patent grants (applications and grants prior to year $t - 1$) by estimating the explanatory power, ceteris paribus, associated with y_{it-1}, the licensing revenue from fiscal year $t - 1$ which the history of those past applications and grants has determined. For that reason, we include the lagged dependent variable y_{it-1} as an explanatory variable in our model. Its coefficient, reflecting its partial effect after the other explanatory variables are included, will reflect the impact of the long history of applications and granted patents.

In addition to the foregoing history, other things will matter for an agency's invention-licensing revenues. Because the agencies differ in their missions and their technologies and their policies toward negotiating licenses, we also include in the model different constant terms for each agency that are denoted with A_i for the i^{th} agency's constant term, and we allow the coefficients on the explanatory variables describing each agency's history of patent applications and grants to differ across the agencies. Agencies will differ in the sizes of their patent portfolios and the value of their patents on average. The constant terms will adjust the overall level of the revenues that will be higher or lower depending on idiosyncratic characteristics of the agency such as its policy toward licensing negotiations. Some agencies will negotiate licensing fees that capture more of the commercial value that the licensee will create by commercializing the licensed technology. The coefficients on the explanatory variables describing the history of applications and patents will also vary across the agencies with the differences in the licensing revenues gained from adding a new patent to their portfolio.

Also, to control for differences in revenue that are peculiar to a given fiscal year, we capture time effects with qualitative variables d_year_t for each fiscal year. We capture any trend

over time with a variable *analytical_time* that equals the fiscal year minus 2002. In all, with u_{it} denoting random error, and with the effects of the new U.S. and new foreign patents extending into the past and captured with the partial effect for the lagged dependent variable as explained in the foregoing discussion, our estimable model of invention-licensing revenue is:

$$y_{it} = a_{1i}AppUSnoFN_{it-1} + b_{1i}AppUSFN_{it-1} + c_{1i}PatUS_{it-1} + d_{1i}PatFN_{it-1}$$
$$+ fy_{it-1} + A_i + \sum_t h_t d\_year_t + k(analytical\_time) + u_{it}$$

Estimated Agency-specific Invention-licensing Revenue Functions

Appendix 1 explains the technical details of the statistical methods that we used to estimate the model for each agency. To account for the heterogeneity of the agencies, as explained in Appendix 1, we allow the estimated function for each agency to differ. We estimate those functions by analyzing the agencies in two groups – one group includes the four agencies that together account for about 90% of the patenting activity of the 11 federal agencies that we are studying. The other group analyzed includes the seven agencies that have far less patenting activity – about 10% of the total for all 11 agencies.

First, we estimate licensing revenue functions for the four agencies the Department of Defense (DoD), the Department of Energy (DOE), the Department of Health and Human Services (HHS), and the National Aeronautics and Space Administration (NASA). During the sample period that we study, the applications and associated patents granted for those four agencies together account for 92% of the total patents granted and 88% of the foreign patents granted to the 11 federal agencies covered in NIST's summary technology transfer report.[93] We estimate the model over the fiscal years 2003 through 2015. Over the 13 fiscal years, the 11 agencies were granted 12,992 U.S. patents; DoD, DOE, HHS, and NASA together were granted 11,920 U.S. patents, or 92% of the total. Over the 13 fiscal years, the 11 agencies were granted 2834 foreign patents; DoD, DOE, HHS, and NASA together were granted 2492 foreign patents; or 88% of the total.[94]

Second, we estimate the licensing revenue functions for the seven agencies – the Department of Agriculture (USDA), the Department of Commerce (DOC), the Department of Homeland Security (DHS), the Department of the Interior (DOI), the Department of Transportation (DOT), the Department of Veterans Affairs (VA), the Environmental Protection Agency (EPA) – that together have about 10% of the patenting activity for the 11 federal agencies.

The detailed statistics for the estimations of the 11 invention-licensing revenue functions are provided in Appendix 1. For readability here in the body of the report, the individual

[93] Ibid. For the 11 federal agencies, the U.S. and foreign patent applications and patents granted are described in our Task 1 report using the worldwide patent database PATSTAT, available at https://www.epo.org/searching-for-patents/business/patstat.html#tab-1.

[94] The figures were tabulated by the authors from PATSTAT, available at https://www.epo.org/searching-for-patents/business/patstat.html#tab-1. These four agencies also contribute over 90% of the invention disclosures over the sample period. See Albert N. Link, "Technology Transfer at U.S. Federal Laboratories: An Analysis of Invention Disclosures," Working Paper, University of North Carolina at Greensboro, March 2020.

estimated coefficients for the time dummies and the time trend are suppressed but included symbolically, shown with "hats", to indicate that these control variables, for which the coefficients are not of intrinsic interest, are indeed controlled in the specifications. For these controls and all of the other variables, the detailed numerical coefficients and their standard errors and *p*-values are included in Appendix 1.

Table 1 provides the definitions for the symbols used in our description of the model.

Table 1. Definitions.

Variable	Definition
y_{it}	the i^{th} agency's invention-licensing revenue, in thousands of constant 2015 dollars, in fiscal year t
$AppUSnoFN_{it}$	the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent but for which a foreign patent for the underlying technology was never granted
$AppUSFN_{it}$	the number of new U.S. patent applications from the i^{th} agency in fiscal year t that were ultimately granted a U.S. patent and for which at least one foreign patent for the underlying technology was also ultimately granted
$PatUS_{it}$	the number of new U.S. patents granted to the i^{th} agency in fiscal year t
$PatFN_{it}$	the number of new foreign patents granted to the i^{th} agency in fiscal year t
A_i	the i^{th} agency's constant term (a parameter of the model to be estimated)
d_year_t	A qualitative variable equal to 1 for fiscal year t and 0 otherwise
analytical_time	the fiscal year minus 2002

Source: Authors' definitions.

Table 2, for the four agencies with about 90% of the patenting activity, and Table 3, for the remaining seven agencies, provide the descriptive statistics by agency for the dependent variable and the explanatory variables that describe the histories for the applications and patent grants.

Table 2. Descriptive Statistics for the Variables for the Four Agencies with 90% of the Patenting Activity for Fiscal Years 2003 Through 2015.

Mean, (Standard deviation), [Minimum, Maximum]

Variable	Agency			
	DOD (n=13)	DOE (n=13)	HHS (n=13)	NASA (n=13)
y_{it}	13774 (4034) [6836, 21414]	36643 (6330) [28728, 47681]	99754 (23940) [69068, 147512]	3232 (1130) [1688, 5224]
$AppUSnoFN_{it}$	452.1 (42.2) [377, 506]	361.3 (51.8) [298, 452]	59.9 (8.7) [43, 74]	89.8 (13.5) [55, 109]
$AppUSFN_{it}$	17.5 (7.3) [5, 35]	38.4 (8.2) [23, 51]	74.5 (18.3) [45, 114]	4.85 (4.65) [1, 17]
$PatUS_{it}$	399.7 (162.2) [46, 577]	324.6 (162.8) [65, 547]	117.5 (66.8) [24, 230]	75.2 (41.8) [4, 118]
$PatFN_{it}$	24 (10.5) [4, 37]	46.8 (32.5) [6, 102]	114.4 (61.7) [24, 198]	6.46 (7.88) [0, 27]

Note: The variable y_{it} is measured in thousands of constant 2015 dollars.
Source: Authors' calculations.

Table 3. Descriptive Statistics for the Variables for the Seven Agencies with about 10% of the Patenting Activity for Fiscal Years 2003 Through 2015.

Mean, (Standard deviation), [Minimum, Maximum]

Variable	Agency						
	USDA (n = 13)*	DOC (n = 13)	DHS (n = 13)*	DOI (n = 13)	DOT (n = 13)	VA (n = 13)	EPA (n = 13)
y_{it}	4075 (848.0) [2666, 5838] (n = 12)	239.2 (65.4) [155, 369]	0 (0) [0. 0] (n = 9)	80.8 (22.0) [52, 122]	19.0 [13.9) [0, 48]	268.6 (113.6) [140, 426]	686.8 (312.1) [198,1149]
$AppUSnoFN_{it}$	45.1 (11.2) [28, 66]	11.2 (6.6) [2, 24]	1.2 (1.5) [0, 4]	2.8 (1.6) [0, 5]	1.8 (1.5) [0, 4]	16.8 (8.2) [8, 30]	5.5 (2.9) [1, 11]
$AppUSFN_{it}$	7.1 (3.4) [2, 15]	.62 (1.0) [0, 3]	0 (0) [0. 0]	.15 (.38) [0, 1]	0 (0) [0. 0]	11.2 (5.3) [6, 22]	1.2 (1.4) [0, 4]
$PatUS_{it}$	42.9 (26.4) [4, 86]	7.8 (7.2) [0, 19]	.69 (1.3) [0, 4]	2.6 (1.7) [0, 6]	1.5 (1.2) [0, 4]	20.1 (16.0) [0, 55]	6.8 (5.5) [0, 18]
$PatFN_{it}$	10.8 (6.3) [0, 23]	.23 (.60) [0, 2]	0 (0) [0. 0]	.08 (.28) [0, 1]	0 (0) [0. 0]	12.8 (8.2) [1, 29]	2.4 (3.1) [0, 10]

Notes: The variable y_{it} is measured in thousands of constant 2015 dollars. DHS did not report positive invention-licensing revenues until fiscal year 2016 (*Federal Laboratory Technology Transfer, Fiscal Year 2016: Summary Report to the President and the Congress*, National Institute of Standards and Technology, U.S. Department of Commerce, September 2019, p. 149, and the previous year's edition of the *Summary Report*, p.

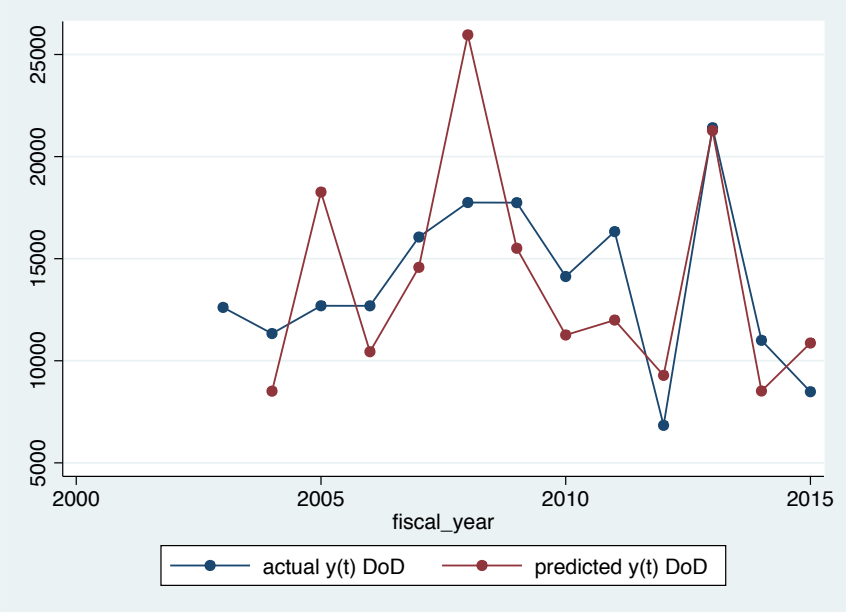
161, available at https://www.nist.gov/tpo/reports-and-publications. Also see Excel spreadsheet, federal_lab_tt_database_v.2015.xlsx available at the same site.
*Exceptions for *n* are noted with the pertinent cases.
Source: Authors' calculations.

The estimated model for DoD is:

$$y_{it} = -114 AppUSnoFN_{it-1} + 1223 AppUSFN_{it-1} + 122 PatUS_{it-1} + 484 PatFN_{it-1}$$
$$+.33 y_{it-1} - 17500 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 1 compares DoD's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DoD. In this figure and in those that follow, we use large dots to indicate the actual result or the prediction for each year. We connect the dots with straight lines to illustrate visually the direction of change from one year to the next for the fiscal year's actual or predicted licensing revenues. The actual and predicted amounts are the amounts for each of the fiscal years. If we were depicting the amounts per unit of time (one fiscal year) at each instant in time, we would use a smooth, nonlinear line with no large dots.[95]

Figure 1. Comparison of DoD's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



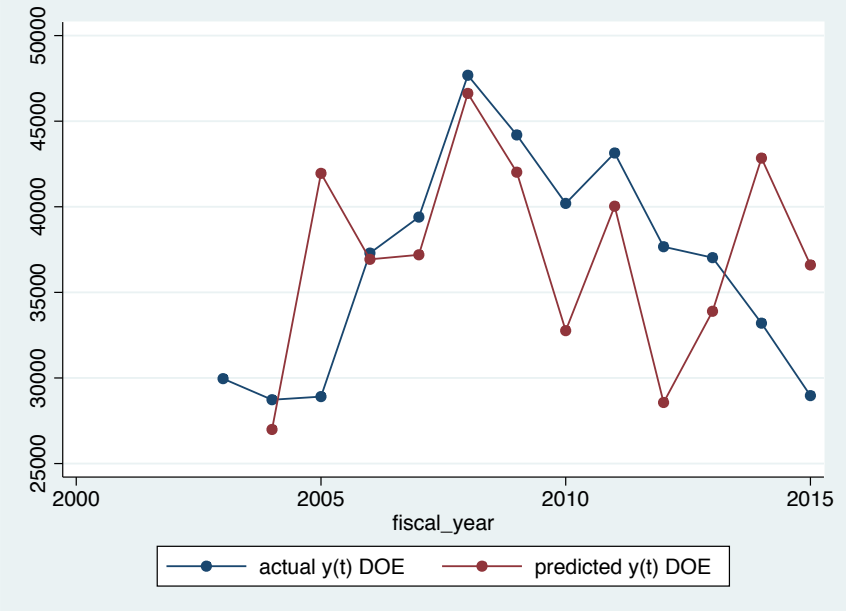
[95] An alternative visualization that uses rectangular blocks to show the amounts for each fiscal year would not only convey the information in a less readily visualized way, but it would incorrectly convey that the actual and predicted amounts for each fiscal year were received continuously over the year at the constant actual or predicted amount per year at each instant of time.

The estimated model for DOE is:

$$y_{it} = -177 AppUSnoFN_{it-1} - 84 AppUSFN_{it-1} + 153 PatUS_{it-1} + 142 PatFN_{it-1}$$
$$+.33 y_{it-1} + 41182 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 2 compares DOE's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DOE.

Figure 2. Comparison of DOE's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

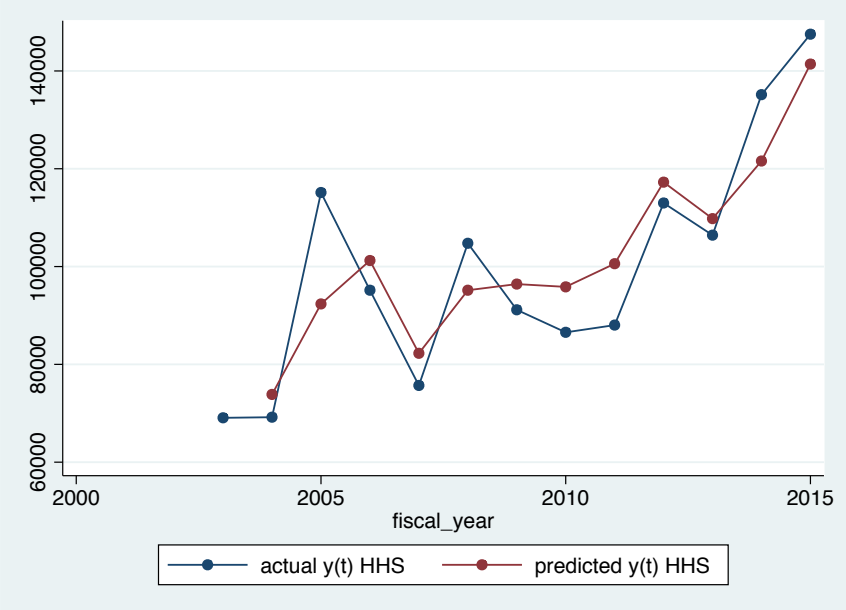


The estimated model for HHS is:

$$y_{it} = -138 AppUSnoFN_{it-1} + 124 AppUSFN_{it-1} + 424 PatUS_{it-1} + 54 PatFN_{it-1}$$
$$+.33 y_{it-1} + 18096 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 3 compares HHS's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for HHS.

Figure 3. Comparison of HHS's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

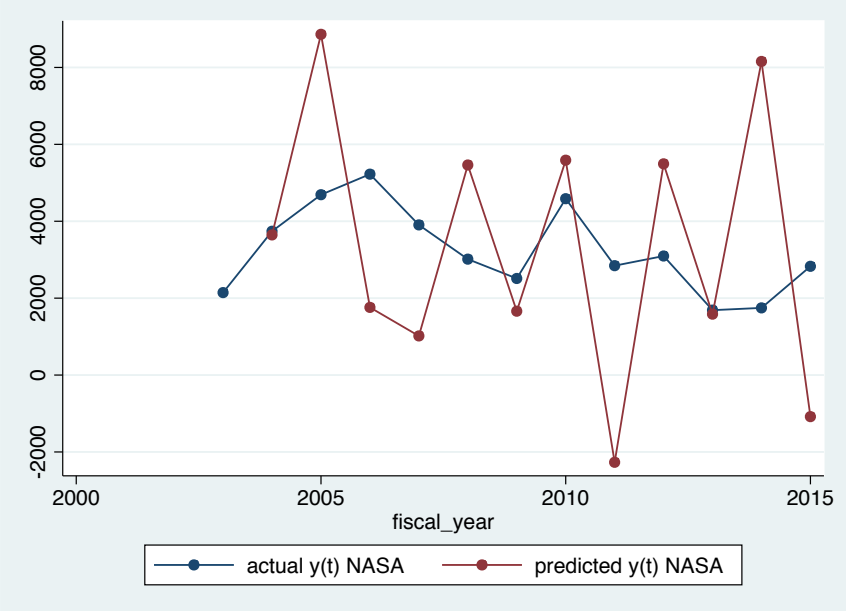


The estimated model for NASA is:

$$y_{it} = -228 AppUSnoFN_{it-1} + 483 AppUSFN_{it-1} + 400 PatUS_{it-1} + 930 PatFN_{it-1}$$
$$+.33 y_{it-1} - 11120 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 4 compares NASA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for NASA.

Figure 4. Comparison of NASA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



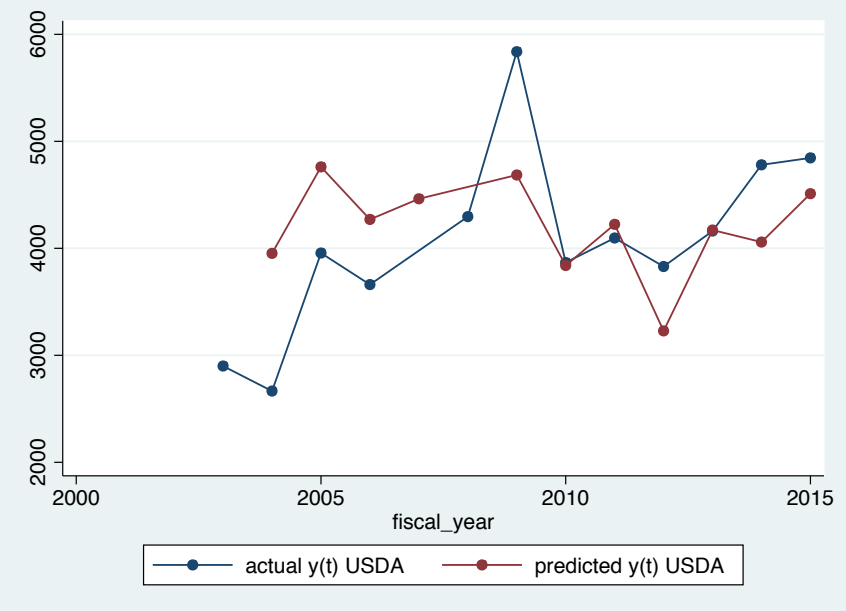
We turn now to the estimated invention-licensing revenue functions for the seven agencies with far less extensive patent portfolios that together comprise about 10% of the patenting activity for the 11 federal agencies.

The estimated model for USDA is:

$$y_{it} = -58.5 AppUSnoFN_{it-1} - 26.0 AppUSFN_{it-1} + 9.6 PatUS_{it-1} + 48.9 PatFN_{it-1}$$
$$+.14 y_{it-1} + 5415.2 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 5 compares USDA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for USDA.

Figure 5. Comparison of USDA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

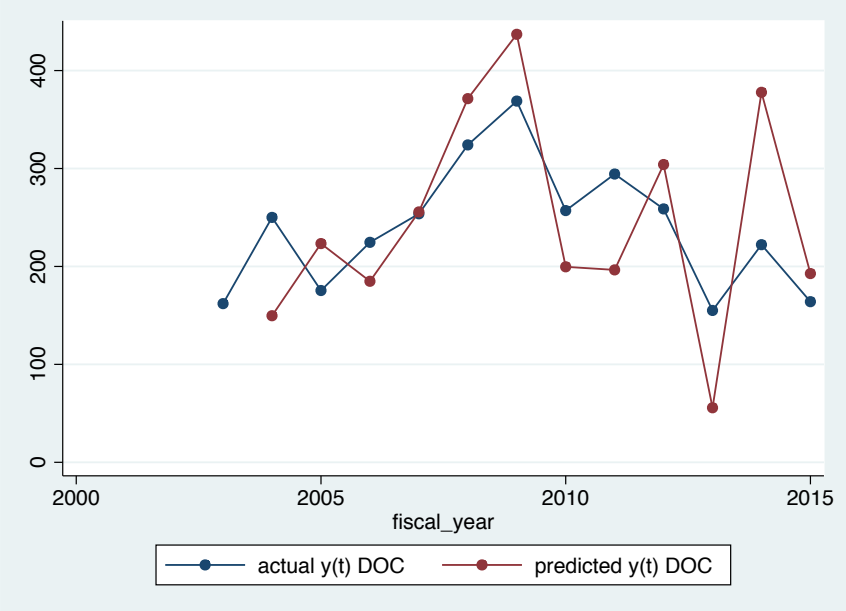


The estimated model for DOC is:

$$y_{it} = -1.9\,AppUSnoFN_{it-1} + 47.2\,AppUSFN_{it-1} + 1.2\,PatUS_{it-1} + 168.3\,PatFN_{it-1}$$
$$+.14\,y_{it-1} + .471 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 6 compares DOC's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for DOC.

Figure 6. Comparison of DOC's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

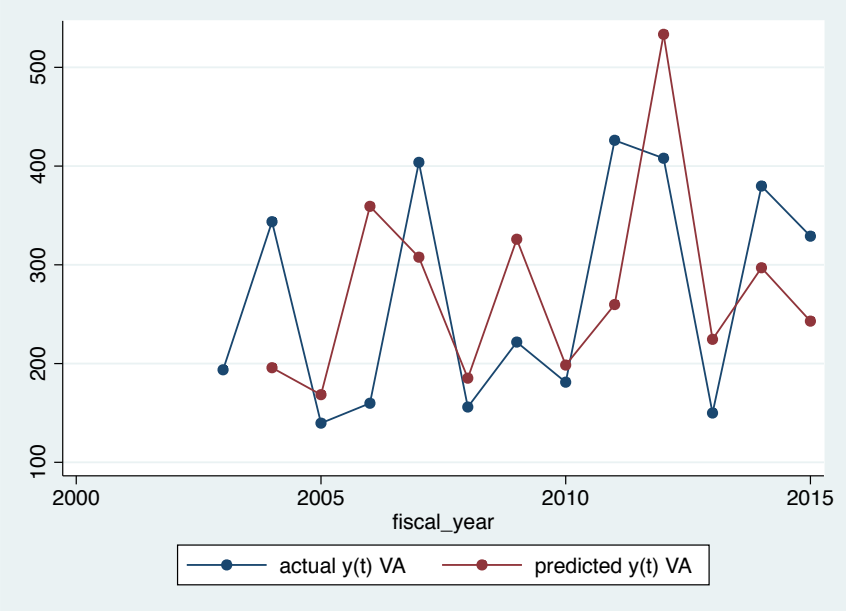


The estimated model for VA is:

$$y_{it} = -24.5AppUSnoFN_{it-1} + 22.1AppUSFN_{it-1} + 14.9PatUS_{it-1} - 10.9PatFN_{it-1}$$
$$+.14y_{it-1} + 71.3 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 7 compares VA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for VA.

Figure 7. Comparison of VA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).

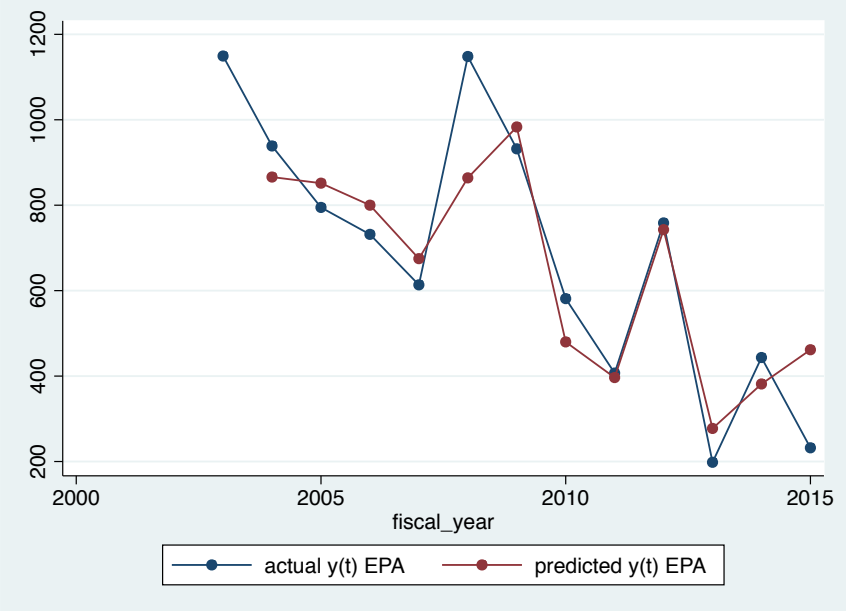


The estimated model for EPA is:

$$y_{it} = -25.9\,AppUSnoFN_{it-1} + 39.5\,AppUSFN_{it-1} - 28.8\,PatUS_{it-1} + 18.4\,PatFN_{it-1}$$
$$+.14\,y_{it-1} + 612.6 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

Figure 8 compares EPA's actual invention-licensing revenues with the estimated invention-licensing revenues using the model for EPA.

Figure 8. Comparison of EPA's Actual and Predicted Invention-Licensing Revenues (Thousands of Constant 2015 Dollars).



Not all of the agencies' patented technology is licensed and generating licensing revenues. That point is well illustrated by the case of DHS over our sample period. DHS was founded in 2002, and it was several years before it began reporting about its patents and licensing revenues. For our sample period, DHS had very little patenting activity and reported its first nonzero invention-licensing revenues in fiscal year 2016. Hence for our sample period, in the years after it began reporting, its invention-licensing revenues were zero. Thus, our graph of actual and predicted licensing revenues is uninformative, with the actual DHS revenues being a set of large dots at zero for each fiscal year. Also, individualized coefficients for the effects of foreign patents could not be estimated for DHS because it had no foreign patent activity during the sample period.

DOT also had no foreign patents in our sample period. The DOT estimated model is not informative for our purpose because it has no foreign patent activity; and therefore, just as for DHS, an individualized coefficient for DOT could not be estimated for either $AppUSFN_{it}$ or $PatFN_{it}$. Although DOI does have both some patenting activity and some licensing revenues, as reported in Table 3, it has just a single foreign patent pursuant to the applications that were made during our sample period. Thus, the estimated model for DOI is not useful for analyzing the impact of foreign patents on invention-licensing revenues, for essentially the same reason that the estimated models for DHS and DOT are not useful for that purpose.

Interpretation of the Estimated Coefficients for the Explanatory Variables Describing the History of Patent Applications and Grants

In Section V we use the estimated models for the agencies to develop for each an estimate of the addition to its invention-licensing revenues expected from the addition of another foreign patent. Here in Section III, we begin that process by observing the signs and relative

magnitude of the effects on licensing revenue of additional U.S. and foreign patents. We begin by examining the effects for the four agencies with 90% of the patenting activity – DoD, DOE, HHS, and NASA. Not surprisingly, the estimated models for those agencies are more statistically significant than the models estimated for the remaining agencies, although both sets of models are statistically significant. Intuitively, having much greater patenting activity, there are many more patents to observe over time for DoD, DOE, HHS, and NASA. Their estimated models are informed by much more information about the relationship between the patenting activity and the licensing revenues that result.

For the four agencies that together account for about 90% of the patenting activity, adding another patented technology to an agency's patent portfolio generates more revenue when the technology has foreign patent protection as well as a U.S. patent. The finding is expected because the agencies will choose to pursue foreign patents for the more valuable technologies. Or, for the cases where the agency leaves the pursuit of foreign patents entirely to the licensees, again the foreign patents are pursued for the more valuable technologies. For more valuable technologies, greater licensing revenues can be negotiated.

Beyond that, we also are able to find evidence that is consistent with the hypothesis that a portion of the lower licensing revenues for technologies without foreign patents is *caused* by the absence of the foreign patents. In particular, by controlling for the patent application history as well as the history of the timing for the patent grants, we are able to identify cases where adding U.S.-patented technologies that are not also protected with foreign patents actually has a negative effect on agencies' licensing revenues. One possible interpretation of that evidence is the hypothesis that agencies' acquisition of U.S. patents without getting the foreign patent protection reduces licensees' profitability when commercializing the federal agencies' technologies. The reduction in the profitability would occur because arguably – again this is just a hypothesis that is consistent with our findings – the technology without foreign patent protection is available for foreign competitors to copy and compete with in international markets without incurring the costs of royalty payments for the use of the technology. In such a competitive environment, licensees would find the use of the technologies less profitable, and lower licensing fees would be negotiated for many of the agencies' technologies.

The results from the estimated model for the four agencies – DoD, DOE, HHS, and NASA – support the hypothesis that disseminating the federal agencies' technology without obtaining foreign patent protection may actually lower the profitability of the licensees that use the U.S. patented technology. To understand why the results are consistent with that possibility, first consider an agency that adds to its patent portfolio a new patented technology that is protected with a U.S. patent and a foreign patent. The impact will be seen initially a period after the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ are each increased by 1. Then, second consider an agency that adds a new, patented technology but protects the intellectual property with a U.S. patent only. The impact will be seen initially a period after the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$ are each increased by 1. In addition to those initial impacts, there are further impacts that are picked up in the term with the lagged dependent variable as time passes, but the relative size and the signs for the two cases are preserved. Thus, the sign and relative size of the difference between the two cases can be seen by comparing the sum

of the coefficients for the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ with the sum of the coefficients for the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$.

Those sums respectively are for the case with foreign patent protection versus the case without: (1223 + 122 + 484) versus (–114 + 122) for DoD, (–84 + 153 + 142) versus (–177 + 153) for DOE, (124 + 424 + 54) versus (–138 + 424) for HHS, and (483 + 400 + 930) versus (–228 + 400) for NASA. For all four agencies, the first sum is greater than the second; and thus, the addition to licensing revenues will be greater for the first case for which foreign patent protection is obtained than for the second case when it is not. That much supports the expected causal story that greater licensing revenues are generated by the more valuable patented technologies for which both the agencies and its licensees are more likely to seek foreign patent protection.

However, look again at the sums. For DOE, the sum for the second case is negative. In other words, systematically in the data across the very large number of U.S. patents acquired, adding a patented technology to the agency's patent portfolio and not securing foreign patent protection actually *lowers* the licensing revenues for the agency. A possible reason for that, we suggest, would be that foreign competitors of the firms using the agency's technologies will be competing internationally without having to pay royalties and will therefore have lower costs for the high technology products and services that are commercialized using those technologies. Licensing the agencies' technologies would be less attractive; licensing negotiations would result in lower invention-licensing revenues. With the DOE example in hand to identify the problem, we add that the finding that licensing revenues are less for all agencies when foreign patent protection is not obtained could reflect in part the lowering of licensees' profitability because of international competition from firms that copy the technology without paying royalties.

Now, consider the estimated functions for the agencies that together have only about 10% of the patenting activity. Because they have far fewer patents, the estimated descriptions of their invention-licensing revenues as functions of their patent histories are less significantly estimated. For USDA, DOC, VA, and EPA, the numbers of patents are sufficient to sensibly consider their estimated functions and compare the results with those for DoD, DOE, HHS, and NASA.

Again we compare the sum of the coefficients for the variables $AppUSFN_{it-1}$ and $PatUS_{it-1}$ and $PatFN_{it-1}$ with the sum of the coefficients for the variables the variables $AppUSnoFN_{it-1}$ and $PatUS_{it-1}$. For USDA, the sums are (–26 + 9.6 + 48.9) and (–58.5 + 9.6). For DOC, the sums are (47.2 + 1.2 + 168.3) and (–1.9 + 1.2). For VA, the sums are (22.1 + 14.9 –10.9) and (–24.5 + 14.9). For EPA, the sums are (39.5 –28.8 + 18.4) and (–25.9 –28.8). For all of these agencies, the first sum is greater than the second, and so just as we found with DoD, DOE, HHS, and NASA, the gain in value is greater for USPTO patented technology when it is also protected with a foreign patent than when it is not. Moreover, just as we observed with DOE, the second sum is negative for USDA, DOC, VA, and EPA, supporting the hypothesis that obtaining a U.S. patent but not also protecting the technology with a foreign patent disadvantages licensees in international competition and lowers the negotiated licensing fees for an agency's technologies as a whole.

In sum and to reiterate, with the application history controlled, we are able to find evidence consistent with the hypothesis that a portion of the shortfall in licensing revenues for technologies without foreign patents is *caused* by the absence of the foreign patents. In particular, we are able to identify a broad set of cases where adding U.S.-patented technologies that are not also protected with foreign patents actually has a *negative* effect on agencies' licensing revenues. The evidence of the negative effect (rather than simply a lower effect) is consistent with the hypothesis that agencies' acquisition of U.S. patents without getting foreign patent protection reduces licensees' profitability when commercializing the federal agencies' technologies. The reduction in their profitability would occur because they would be competing in international markets with foreign competitors that do not incur the costs of royalty payments for the use of the technology. The evidence is consistent with the hypothesis that disseminating the federal agencies' technology without obtaining foreign patent protection may actually lower the profitability of the licensees that use the U.S. patented technology in international competition with foreign firms that copy it, and that in turn makes the licenses less attractive.

Our research design – that examines the effects of foreign patenting on agencies' invention-licensing revenues – arguably lets us identify a causal effect of not acquiring foreign patents. The findings are consistent with a bold interpretation: ***An agency that obtains U.S. patents for its technology but does not obtain foreign patent protection may be – in some cases -- disadvantaging the corporations that license the agency's technologies and then face international competition from foreign firms that copy those technologies and compete with lower costs because they do not pay royalties for using them. The competition from lower-cost foreign firms would reduce the profitability of licensees and hence reduce the negotiated licensing fees that firms are willing to pay for the use of the agency's patented technologies across multiple inventions.***

If foreign competitors do not pay royalties, their costs per item in world-wide markets will be less, for example throughout Europe and Asia. Moreover, without the patent protection in Europe and Asia, all of the development costs that the licensee has put into developing the technology will be difficult and perhaps impossible to recover while competing in Europe and Asia with companies that did not incur the costs but just copied the technology. See the case study for the NIH drug-eluting stent case and observe the royalties paid on foreign sales, and also observe the litigation history. Having the foreign patents made it possible for Boston Scientific to sell in the foreign markets without the competition of others who tried to offer comparable products but were found to be infringing the foreign patents.

The bold interpretation is in fact a perspective held by some agency technology-transfer experts. In correspondence with those experts, we asked about the difficulties they faced during the invention selection and patenting process when forecasting commercial use and practical application and deciding whether to apply for foreign patents. While discussing the difficulties, one expert responded, "I would also argue that foreign patenting also increases the value of US patenting to the prospective licensee. To have US-only rights in global market invites competition from overseas that will be strong US competitors once US rights expire and will provide an incentive for validity challenges in the US from these strong

competitors outside the US. For products with global market potential, having US-only rights makes the products somewhat like "damaged goods" that have to sold at a discount."

Of course, when based on our estimated model, the bold interpretation must be tempered with all the caveats that accompany statistical results. The results are consistent with the interpretation, but other reasonable interpretations may be possible. Moreover, the number of federal agencies with large portfolios of patents and a substantial number of foreign patents is limited, and the number of years in the time series for each agency is limited. Further, although the data for the history of the patent applications and grants are very detailed, the data for the agencies' invention-licensing revenues are aggregated by fiscal year. As is typically the case with statistical studies, more data could be helpful. Our research design allows us to work with the data available, but clearly more could be learned if the agencies' invention-licensing revenues were available disaggregated to the level of the individual licenses themselves.

After we develop the estimated costs for obtaining foreign patent protection in Section IV, Section V develops estimates about the return on the agencies' investments in foreign patents. We can then consider whether it would be useful for agencies to more actively pursue foreign patents for their USPTO-patent-protected technologies – even in cases where the prosecution of the foreign patents is relegated to the companies that license the technologies. With the caveats about the estimated models in mind, our conclusions in Section V are cautious observations for thought and discussion.

IV. The Estimated Costs of Foreign Patent Protection

Section IV provides an estimate of the filing costs – both application costs and maintenance costs once the patents are granted – associated with the foreign patent protection obtained by the U.S. federal agencies. Those costs for foreign patent protection are compared with the costs for U.S. patent protection that are also estimated in this section.

Background for Estimating the Costs of Acquiring Foreign Patents

In this section's examination of the costs of acquiring foreign patents, just as we saw in Section III's analysis of the impact of foreign patents on invention-licensing revenues, there is important heterogeneity among the agencies. The estimation shows that acquisition and maintenance for foreign patents is not only more expensive than for U.S. patents. Also, the estimation shows that the cost of foreign patenting is much greater for agencies with small annual numbers of foreign applications than for the agencies with many applications.

We use our discussions with the representatives of the agencies and detailed data to estimate equations for annual total variable costs and to predict the addition to costs for an agency that increases the foreign patent protection for its U.S. patented inventions.

To estimate the equations for the costs that the federal agencies incur when obtaining foreign patents, we first developed understanding of the costs by corresponding with points of

contact who are technology transfer experts in the agencies. We then estimated the costs for adding foreign or U.S. patents using data that were provided to us about the costs for a large agency with extensive experience with a large well-developed portfolio of U.S. and foreign patents. We believe that the agency's experience with the costs of obtaining foreign patents should provide a good estimate for the costs that would be expected for other agencies if they increased the proportions of foreign patents in their patent portfolios. Also, we use the data to estimate the difference in the cost of foreign patents for agencies with fewer applications for foreign patents versus those with more. We do so by juxtaposing the cost data provided with the information about the varying numbers over the years of U.S. and foreign patent applications and granted patents from the worldwide patent database PATSTAT that is maintained by the European Patent Office (EPO).[96]

To estimate the costs for extending federal agencies' foreign patent protection, we estimate the costs for acquiring patents, for both U.S. and foreign patents, given the technology transfer offices for the agencies. With that organizational infrastructure for dealing with the patents in place, the cost for an agency's technology transfer staff itself does not change appreciably when the number of filings for foreign patents is increased. That point is explained in the following paraphrased excerpt from one of our discussions with a technology transfer expert at an agency with a large portfolio of U.S. and foreign patents.

> Our question in the context of the interview: So, what is the effect of extending the number of foreign filings on the internal agency costs?
>
> Answer: There is not a noticeable effect. We just issue a task order for an additional country, and the cost burden falls on the contracted law firm and would be reflected in the law-firm fees. Within the agency, it is just a matter of a task order for 5 countries rather than 4 countries, and the task order goes to the law firm. Within the agency, incrementally it is not that different with the fifth country added. We have the process of documenting and tracking in place, and it's just a small incremental change for us within the agency. The extra cost would be with the law firm. It would be different if we were doing the prosecution, going to the extra country and filing the patent application, but the law firm does that. Also, the documenting and tracking within the agency is done by the more junior staff, and increasingly the process is automated, such as with bar coding. So, the costs are essentially those reflected in the data for the law firm expenses and the renewal fees. Also, note that for the holders of exclusive licenses, the agency will often turn over to the licensee the tasks of patent prosecution etc., and so in such cases, the agency would not even issue a task order for the additional country or countries. The licensee would file and pay the law firm directly. So that happens with the larger companies that can manage the process (small companies typically cannot manage the process), and then the licensee pays the costs of for the patent prosecution. The agency's exclusive license template gives the licensee the option of handling the patent prosecution for the pursuit of the additional patents. In these cases, the agency would not even incur the law firm and renewal fees.

Given the agency's technology transfer office, we estimate equations for the annual variable costs of applying for patents and then maintaining the granted patents. From the estimated equations, we can compute the addition to costs for acquiring more foreign patents. We turn now to estimating the equations for the costs for patents, first for the annuity costs and then for the law-firm costs. The two types of costs are introduced and defined in the discussions of the estimating equations. The cost data that we use for the estimations cover the fiscal years 2004 through 2018 for the annuity costs, and fiscal years 2006 through 2018 for the

[96] https://www.epo.org/searching-for-patents/business/patstat.html#tab-1

law-firm costs. We converted the nominal costs for each fiscal year to constant 2015 dollars and then use the constant dollar costs for our estimations.

Specifications for Annual Fiscal-Year Annuities Costs

Annuity fees are one part of the annual costs for an agency's patent portfolio. Payments, called annuity fees, or renewal fees, or maintenance fees, must be made to the patent office of the country granting the patent. The fees are necessary to keep in force a granted patent or a patent application.

In each fiscal year, our model will assume that the annual annuity costs will be for patents received over the last 20 years, with different maintenance and renewal fees depending on the age of the patent and also the country granting the patent.[97] The specification that we use for our estimation assumes that a patent has a potential life of 20 years, and over that lifetime will require annuity fees that average b per year. In its portfolio of patents for any given fiscal year t, an agency has x_t patents that have been granted over the last 20 fiscal years, and we assume as a rough approximation that those are the patents that are still valuable (in other words, are still within their useful lifetime) and that the agency will be maintaining. For the given fiscal year, the agency's patent annuity costs are y_t. Hence, $y_t = bx_t$. Using the data provided, we have data by fiscal year for the U.S. patent annuity costs and also for the foreign patent annuity costs. In the PATSTAT worldwide patent database, we have the complete record of the U.S. and the foreign patents that the agency received in each fiscal year, and from those data we gathered the necessary information about the patent portfolio. We use the data to estimate b, the average annuity cost per fiscal year for a patent over its lifetime, and we obtain that estimate for foreign patents and also, to allow a comparison, for U.S. patents.

The interpretation of the specification is that b – the estimated annual fiscal-year annuity cost per U.S. patent, or per foreign patent – is an average annual annuity cost over the patent's lifetime. Thus, for each year of the patent's lifetime, the estimated annual annuity cost for adding a U.S. patent or for adding a foreign patent will be the estimated b from, respectively, the U.S. annuity cost model or the foreign annuity cost model.

The variables that we use are $USannuity_t$ for the given fiscal year t, equal to the agency's annuity costs in constant 2015 dollars for U.S. patents; $FNannuity_t$ for the given fiscal year t, equal to the agency's annuity costs in constant 2015 dollars for foreign patents; $USpat20_t$ for fiscal year t, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years; and $FNpat20_t$ for fiscal year t, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years.[98] Table 4 provides the definitions and symbols for the variables used in the U.S. and foreign annuity cost models.

[97] An overview of annuity fees for the USPTO as well as for the patent authorities of other countries is available at https://www.renewalsdesk.com/patent-renewal-fees-by-country-2018/patent-renewal-fees-usa-2018/.

[98] PATSTAT was searched to identify and count all of the distinct U.S. patents and all of the distinct foreign patents granted to the agency during each of the 15 twenty-year periods FY1985-FY2004, FY1986-FY2005, FY1987-FY2006, FY1988-FY2007, FY1989-FY2008, FY1990-FY2009, FY1991-FY2010, FY1992-FY2011, FY1993-FY2012, FY1994-FY2013, FY1995-FY2014, FY1996-FY2015, FY1997-FY2016, FY1998-FY2017, FY1999-FY2018.

Table 4. Definitions for the Variables Used in the U.S. and Foreign Annuity Cost Models.

Variable	Definition
$USannuity_t$	for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for U.S. patents
$FNannuity_t$	for the given fiscal year *t*, equal to the agency's annuity costs in constant 2015 dollars for foreign patents
$USpat20_t$	for fiscal year *t*, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years
$FNpat20_t$	for fiscal year *t*, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years

Source: Authors' definitions.

Table 5 shows descriptive statistics for the data used to estimate the annuity-cost functions for the U.S. and the foreign patents.

Table 5. Descriptive Statistics for the Variables Used to Estimate the Model of an Agency's Annual Annuity Costs for U.S. and Foreign Patents: Using Cost Data from the Agency for Fiscal Years 2004-2018 and patent data from PATSTAT.

Variable	*n*	Mean	Minimum	Maximum
$USannuity_t$	15	714,868	423,528	953,362
$FNannuity_t$	15	1,975,003	1,494,521	2,583,791
$USpat20_t$	15	2255	1545	2904
$FNpat20_t$	15	2361	1375	3244

Source: Authors' calculations.

The U.S. annual annuities cost model assumes that there are no annuity costs when the number of patents is zero. It estimates the average annual annuities cost for each patent based on the actual experience as of each fiscal year for the patent portfolio over the last 20 fiscal years. Table 6 shows the estimated model for the U.S. annuities costs.[99]

Table 6. Prais-Winsten Regression for Annual U.S. Annuities Costs in Constant 2015 Dollars: Dependent Variable $USannuity_t$, $n = 15$.

Variable	Coefficient (standard error) [probability > |t|]
$USpat20_t$	285.5 (66.7) [0.001]
F(1, 14)	18.31
Probability > F	0.0008
R^2	0.567
ρ	0.821
Durbin-Watson statistic (original)	0.296
Durbin-Watson statistic (transformed)	1.63

Notes: The ordinary least squares model had Durbin-Watson d-statistic (1, 15) = 0.296, showing strong positive autocorrelation. Durbin's alternative test for autocorrelation gave a chi-squared statistic = 26.2, d.f. = 1, probability of a greater chi-squared against the null hypothesis of no autocorrelation = 0.0000. Hence, the Prais-Winsten model was estimated; the estimated first-order autocorrelation coefficient rho is denoted ρ.

Source: Authors' calculations.

[99] Here and subsequently in Section IV, we use Prais-Winsten regression. *Stata Release 15*, Statistical Software (College Station,Texas: StataCorp LLC, 2017) provides the implementation of the model with the procedure *prais* – Prais-Winsten and Cochrane-Orcutt regression. The procedure is well known and described fully in *Stata Time-Series Reference Manual*, Release 15 (College Station, Texas: StataCorp LLC, 2017).

The expected value of the annuity-cost portion of the costs of adding a US patent today, assuming that it is renewed throughout its lifetime, will be the present discounted value of the estimated average annual amount $285.5 (in constant dollars of 2015) incurred annually over the next 20 years, the approximation used for the useful lifetime of the patent.[100] Using the real discount rate of 0.07 or 7%, that present discounted value is $3,025 = $\sum_{t=1}^{20} (\$285.5) / (1.07)^t$.[101]

Table 7 shows the estimated model for the foreign annual annuities cost.

Table 7. Prais-Winsten Regression for Annual Foreign Annuities Costs in Constant 2015 Dollars: Dependent Variable $FNannuity_t$, $n = 15$.

Variable	Coefficient (standard error) [probability > |t|]
$FNpat20_t$	623.5 (185.2) [0.005]
F(1, 14)	11.34
Probability > F	0.0046
R^2	0.447
ρ	0.883
Durbin-Watson statistic (original)	0.177
Durbin-Watson statistic (transformed)	2.07

Notes: The ordinary least squares model had Durbin-Watson d-statistic (1, 15) = 0.177, showing positive autocorrelation. Durbin's alternative test for autocorrelation gave a chi-squared statistic = 39.5, d.f. = 1, probability of a greater chi-squared against the null hypothesis of no autocorrelation = 0.0000. Hence, the Prais-Winsten model was estimated; the estimated first-order autocorrelation coefficient rho is denoted ρ.
Source: Authors' calculations.

The expected value of the annuity-cost portion of the costs of adding a foreign patent today, assuming that it is renewed throughout its lifetime, will be the present discounted value of the estimated average annual amount $623.5 (in constant dollars of 2015) incurred annually over the next 20 years.[102] Using the real discount rate of 0.07 or 7%, that present discounted value is $6605 = $\sum_{t=1}^{20} (\$623.5) / (1.07)^t$.

Specifications for Annual Fiscal-Year Law-firm Costs

In addition to the annuity fees paid to the patent authorities in the countries where applications have been filed and patents have been granted, another part of the annual costs for an agency's patent portfolio will be the expense of the services provided by law firms that manage the agency's patent portfolio. We have the data by fiscal year for the law-firm expenses for U.S. patents and also for foreign patents. From the worldwide patent database,

[100] This is not the actual payment schedule. Recall that we have estimated the average annual cost throughout the lifetime of the patent. Hence, whatever the actual pattern of payments is, we estimate the payments with the stream of the estimated average annual payments.
[101] Use of the 7% social discount rate to evaluate streams of returns from U.S. federal government investments is described in Office of Management and Budget (OMB), Circular number A-94, *Guidelines and Discount Rates for Benefit-cost Analysis of Federal Programs* (Washington D.C.: Government Printing Office, 1992).
[102] Again, this is not the actual payment schedule. We have estimated the average annual cost throughout the lifetime of the patent. Whatever the actual pattern of payments is, we estimate the payments with the stream of the estimated average annual payments.

we also have the complete record of the U.S. and the foreign patents that the agency has received in each fiscal year, and we have the complete record for the agency's applications for patents both in the U.S. and in foreign countries. We use the data to estimate the contribution of a patent to the agency's law-firm costs, and we obtain that estimate for foreign patents and also, to allow a comparison, for U.S. patents.

The annual law-firm costs are assumed to have two parts. One part will cover the law-firm expenses for filing patents during the fiscal year; it depends on the number of patent applications filed in the fiscal year. The other part will cover the law-firm expenses for handling the legal matters for maintaining the agency's portfolio of patents; it depends on the size of the patent portfolio.[103]

The variables that we use are $USlaw_t$ = agency's law firm costs in constant 2015 dollars for U.S. patents for fiscal year t; $FNlaw_t$ = agency's law firm costs in constant 2015 dollars for foreign patents for fiscal year t; $USapp_t$ = number of US patent applications filed by the agency in fiscal year t; $FNapp_t$ = number of foreign patent applications filed by the agency in fiscal year t; $USpat20_t$ = for fiscal year t, the number of U.S. patents that have been granted to the agency over the last 20 fiscal years; and $FNpat20_t$ = for fiscal year t, the number of foreign patents that have been granted to the agency over the last 20 fiscal years.[104] Table 8 provides the definitions and symbols for the variables used in the models of law-firm costs for U.S. and foreign patents.

Table 8. Definitions for Variables in the Models of Law-firm Costs.

Variable	Definition
$USlaw_t$	agency's law firm costs in constant 2015 dollars for U.S. patents for fiscal year t
$FNlaw_t$	agency's law firm costs in constant 2015 dollars for foreign patents for fiscal year t
$USapp_t$	number of US patent applications filed by the agency in fiscal year t
$FNapp_t$	number of foreign patent applications filed by the agency in fiscal year t
$USpat20_t$	for fiscal year t, equal to the number of U.S. patents that have been granted to the agency over the last 20 fiscal years
$FNpat20_t$	for fiscal year t, equal to the number of foreign patents that have been granted to the agency over the last 20 fiscal years

Source: Authors' definitions.

Table 9 shows the descriptive statistics for the models of annual law-firm costs.

[103] Any significant litigation costs would not typically be covered in these law firm costs for the handling of applications and maintenance of patents as reported by the technology transfer office for an agency. Such costs would be covered by the Office of the General Counsel and Department of Justice, and on rare occasions by licensees, according to technology transfer experts responsible for the patent portfolios.

[104] PATSTAT was searched to identify and count all of the distinct U.S. patents and all of the distinct foreign patents granted to the agency during each of the 13 twenty-year periods FY1987-FY2006, FY1988-FY2007, FY1989-FY2008, FY1990-FY2009, FY1991-FY2010, FY1992-FY2011, FY1993-FY2012, FY1994-FY2013, FY1995-FY2014, FY1996-FY2015, FY1997-FY2016, FY1998-FY2017, FY1999-FY2018.

Table 9. Descriptive Statistics for the Variables Used to Estimate the Model of an Agency's Annual Law-Firm Costs for U.S. and Foreign Patents: Using Cost Data from the Agency for Fiscal Years 2006-2018 and patent data from PATSTAT.

Variable	n	Mean	Minimum	Maximum
$USlaw_t$	13	5,159,787	3,337,975	7,174,423
$FNlaw_t$	13	7,460,121	5,682,800	9,528,603
$USapp_t$	13	177	88	247
$FNapp_t$	13	281	40	417
$USpat20_t$	13	2359	1698	2904
$FNpat20_t$	13	2504	1647	3244

Source: Authors' calculations.

Table 10 shows the model of annual law-firm costs estimated for the US patents.

Table 10. Prais-Winsten Regression for Annual U.S. Law-firm costs in Constant 2015 dollars: Dependent Variable $USlaw_t$, n = 13.

Variable	Coefficient (standard error) [probability > |t|]
$USapp_t$	9805.6 (8556.9) [0.276]
$USpat20_t$	1298.6 (663.3) [0.076]
F(2, 11)	12.48
Probability > F	0.0015
R^2	0.694
ρ	0.763
Durbin-Watson statistic (original)	0.721
Durbin-Watson statistic (transformed)	2.07

Notes: The ordinary least squares model had Durbin-Watson d-statistic (2, 13) = 0.721, showing positive autocorrelation. Durbin's alternative test for autocorrelation gave a chi-squared statistic = 4.70, d.f. = 1, probability of a greater chi-squared against the null hypothesis of no autocorrelation = 0.030. Hence, the Prais-Winsten model was estimated; the estimated first-order autocorrelation coefficient rho is denoted ρ.

Source: Authors' calculations.

The interpretation of the estimates is that an increase in annual fiscal-year law-firm costs from the addition of one new U.S. patent application with one new U.S. patent granted is $9806 in the year of the application and then $1299 in each year of the patent's lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional U.S. patent would be $23,568 = $9806 + ($13,762 = $\sum_{t=1}^{20}(\$1299)/(1.07)^t$).

For the foreign patents, the model is slightly more complicated because of the way the foreign patent applications are filed. An application is filed with the World Intellectual Property Organization (WIPO), and then there is the option of applying to cooperating national patent authorities. With applications to the European Patent Office, an actual European patent is granted, but then if it is to be applied in the cooperating nations, an application is made to those authorities. Thus, one expects for the foreign patents that the annual law-firm expenses will increase at a decreasing rate with the number of annual applications since each single application to WIPO or EPO could support multiple applications to individual countries.

Table 11 shows the model of annual law-firm costs estimated for the foreign patents. The nonlinearity (i.e., annual law-firm expenses increasing at a decreasing rate) is captured with ln($FNapp_t$), the natural logarithm of the number of annual foreign patent applications. The derivative of annual foreign law-firm costs is the estimated coefficient on the logarithm of the number of applications divided by the number of applications; thus, if the estimated coefficient is positive, the application costs increase at a decreasing rate with the number of applications.

Table 11. Prais-Winsten Regression for Annual Foreign Law-firm Costs in Constant 2015 Dollars: Dependent Variable $FNlaw_t$, n = 13.

Variable	Coefficient (standard error) [probability > |t|]
ln($FNapp_t$)	1118841 (302309) [0.003]
$FNpat20_t$	506.9 (646.3) [0.449]
F(2, 11)	81.2
Probability > F	0.0000
R^2	0.936
ρ	0.467
Durbin-Watson statistic (original)	1.22
Durbin-Watson statistic (transformed)	2.01

Notes: The ordinary least squares model had Durbin-Watson d-statistic (2, 13) = 1.22, suggesting some positive autocorrelation. Durbin's alternative test for autocorrelation gave a chi-squared statistic = 1.55, d.f. = 1, probability of a greater chi-squared against the null hypothesis of no autocorrelation = 0.213. To be conservative, the Prais-Winsten model was estimated; the estimated first-order autocorrelation coefficient rho is denoted ρ.

Source: Authors' calculations.

To estimate the law-firm costs of adding a foreign patent, we evaluate the addition to costs from having one more foreign application and one more granted foreign patent given the context of the typical experience of multiple applications to cooperating countries based on a WIPO or European Patent application. The average number of foreign patent applications is quite low for many agencies, and their typical number of specific country applications for a WIPO or European Patent application would also be lower. Thus, the application cost for an additional foreign patent will be much higher than it would be for an agency with a large portfolio of foreign patents. From the estimated equation, for example, if the agency had 10 foreign patent applications in a fiscal year, then increasing by one the number of successful foreign patent applications would cost \$1,118,841/10 = \$111,884 in the year of the application and \$507 in each year of the patent's lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional foreign patent would be \$117,255 = \$111,884 + (\$5,371 = $\sum_{t=1}^{20} (\$507) / (1.07)^t$).

For an agency with many more foreign applications annually, the costs of filing for a foreign patent would be considerably less. For example, suppose that an agency filed 100 foreign patent applications annually. Cost savings from a larger portfolio itself and from the advantage (captured by the nonlinearity) of repeatedly using initial applications to WIPO or

the European Patent Office (to acquire patents for a technology in additional foreign countries) are large. The increase in the foreign law-firm costs in constant 2015 dollars for an additional foreign patent is estimated to be \$1,118,841/100 = \$11,188 in the year of the application and \$507 in each year of the patent's lifetime. Assuming a 20-year lifetime that begins at the application date, and using the real discount rate of 0.07 or 7%, the law-firm costs from the additional foreign patent would be \$16,559 = \$11,188 + (\$5,371 = $\sum_{t=1}^{20} (\$507) / (1.07)^t$).

Conclusion about the Costs of Foreign Patents

In conclusion for Section IV, we have used the statistical models to estimate the addition to costs for an agency that increases the foreign patent protection for its U.S. patented inventions. We have found that the costs of foreign patenting will vary considerably across the agencies, and we will use those findings to tailor to each agency the return on investment in foreign patenting that we estimate in Section V. For example, summing the estimates of the annuities costs and the law-firm costs, for a federal agency currently applying for 10 foreign patents annually, we estimate the agency's filing costs for a typical foreign patent are \$123,860, the present discounted value of the costs in constant 2015 dollars over the patent's lifetime.[105] The estimated cost for adding a foreign patent falls considerably if the agency's number of annual applications for foreign patents is greater. For example, if the agency files 100 foreign applications annually, taking advantage of the cost savings a larger portfolio and from the WIPO and EPO filings, the estimated costs for an additional foreign patent are only \$23,164, about the same as the cost of adding a U.S. patent.[106] For the typical U.S. patent, we estimate the present discounted value of the filing costs to be \$26,593.[107]

V. Return on Investment in Foreign Patents

In this concluding section, we use the invention-licensing revenue models of Section III and the patent cost models of Section IV to estimate for each federal agency the return on the investment in foreign patents to protect further the IP of the agency's USPTO-patented technologies.

Invention-licensing Revenues as a Lower-bound for Benefits from Patenting Federal Technologies

The estimated rates of return on investment use each agency's invention-licensing revenues from its patented technologies to provide lower-bound estimates of benefits from patenting the technologies. The gains in licensing revenues net of the costs for additional foreign patents provide a very conservative lower bound for the social return on the investment in patenting.

[105] The sum of the estimated annuities costs of \$6,605 and the estimated law-firm costs of \$117,255 is \$123,860.
[106] The sum of the estimated annuities costs of \$6,605 and the estimated law-firm costs of \$16,559 is \$23,164.
[107] The sum of the estimated annuities costs of \$3,025 and the estimated law-firm costs of \$23,568 is \$26,593.

Fundamental to that interpretation of the net gain from additional foreign patenting is the understanding that the invention-licensing revenues typically, and in part, reflect market forces and the market values of the commercialized technologies. The U.S. Government Accounting Office (GAO) explains that the financial compensations arranged in the licenses "… typically establish financial terms on a case-by-case basis that are tailored to the specifics of the technology, licensee, and market conditions."[108] The GAO description of the licensing process makes clear that commercialization of the transferred technologies is the goal, and market value underlies and enables commercialization. As observed by the GAO, "Federal law states that it is Congress's policy and objective to use the patent system to promote the commercialization and public availability of the inventions, and that technology transfer, including federal patent licensing, is the responsibility of each laboratory science and engineering professional."[109] Moreover, the Federal Technology Transfer Act of 1986 (Public Law 99-502) mandated the payment of at least 15 percent of an agency's licensing revenues received on account of any patented invention to the inventors if they were employed by the agency at the time that the invention was made.[110] Providing the incentives that Congress wanted requires negotiating licensing revenues. Patenting activity did respond to the incentive, grounded in the market value of the inventions, thereby provided to the agency's inventors.[111]

However, the particular mission of each federal agency provides an agency-specific motivation for technology transfer and its benefits. The financial benefit of the licensing revenue, negotiated with the licensees of the agency's technologies, is not paramount. Federal agencies are not "… just seeking a financial return through revenue generation," but "… are looking to utilize licensing of nascent inventions as a way to increase new company formation …" and various other things that support the agency's mission.[112] There are nonetheless a great variety of ways that the agencies can arrange for the licensing revenues that they do negotiate.[113] Moreover, the various forms in which the licensing revenues are collected yield substantial revenues.[114] The revenues negotiated are constrained by the market forces enabling commercialization. Among the many factors influencing royalty rate negotiations with federal laboratories is the market value of the product that uses the licensed technology.[115]

Given the GAO's detailed description of the process of licensing the patented technologies of the federal agencies and their laboratories, we see that the invention-licensing revenues

[108] GAO, op. cit., p. 14, and limited exceptions noted there, and then see more generally pp. 12-16.
[109] Ibid., p. 16.
[110] The Federal Technology Transfer Act of 1986 (Public Law 99-502) amends the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480).
[111] See Albert N. Link, op. cit., and also Albert N. Link, Donald S. Siegel, and David Van Fleet, "Public Science and Public Innovation: Assessing the Relationship between Patenting at U.S. National Laboratories and the Bayh-Dole Act," *Research Policy*, 40(8), October, 2011, pp. 1094–1099.
[112] Steven M. Ferguson and Uma S. Kaundinya, op. cit., p. 191.
[113] Ibid, pp. 192-196.
[114] For examples, see Ibid., Table 14.6, "Common Ranges of Financial Terms for Exclusive License Agreements," p. 196.
[115] Ibid., p. 192.

obtained from the licensees will reflect *in part* the market value of the commercialized technologies. Thus, the licensing revenues are not only a measure of a benefit received by the agency; they also provide a lower bound on the social value of the technology. The entire social value includes the addition to the licensee's economic profits generated by its use of the technology, and the social value also includes value that spills over to other companies and to consumers. The amount of a technology's social value that is captured in an agency's licensing revenues will vary with the licensing negotiation process.

Estimates of the Return on Investment in Foreign Patents

We now estimate a return on investment in additional foreign patent protection for each agency's USTPO-patented technology. In other words, we estimate what the benefits net of cost would be if the agency extended beyond the current level its amount of foreign patenting. We can provide the estimate for each agency because Section III's model of licensing revenue provides an estimate of the increase in revenues as foreign patenting increases, and Section IV's model of patenting costs provides an estimate of the increase in costs as foreign patenting increases. Because the licensing revenues reflect just a portion of the social value created by the transfer of the technology, the estimated returns on investment are very conservative lower bounds.

DoD

DoD's estimated model of invention-licensing revenue is:

$$y_{it} = -114 AppUSnoFN_{it-1} + 1223 AppUSFN_{it-1} + 122 PatUS_{it-1} + 484 PatFN_{it-1}$$
$$+ .33 y_{it-1} - 17500 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

We can use the estimated model to estimate the change in expected licensing revenues when going from (1) the case when DoD applies for a U.S. patent that is ultimately granted but does not also obtain a foreign patent for the technology, to (2) the case when the agency does obtain a foreign patent in addition to the U.S. patent.

To estimate the change in expected revenues, suppose that an agency has applied for a U.S. patent that was ultimately granted but did not obtain a foreign patent. Then, according to the estimated model, what would be the effect on revenues if instead the agency had also obtained a foreign patent? In the fiscal year of the U.S. application, the variable $AppUSnoFN_{it-1}$ is decreased by 1, and the variable $AppUSFN_{it-1}$ is increased by 1; the variable $PatUS_{it-1}$ does not change; and the variable $PatFN_{it-1}$ is increased by 1 in the fiscal year when the foreign patent is ultimately received.[116] Using DoD's estimated model, in the period after the applications for the U.S. and the foreign patents, licensing revenues would increase by the negative of –$114,000 which is plus $114,000, because there is one less USPTO

[116] At the time that the USPTO application is filed, typically if foreign patents are anticipated, applications are also filed with the World Intellectual Property Organization (WIPO) and/or the European Patent Office (EP), and applications to particular cooperating foreign patent authorities are based on those WIPO and/or EP applications.

application that results in a patent for a technology that does not ultimately also have foreign patent protection. Also the revenues in the period after the applications would increase by $1,223,000, because there is one more successful USPTO application that does ultimately have foreign patent protection too. Thus, there is a total increase of $1,337,000 from the change from a U.S. application without any foreign patent applications to one with them. In the next year, the revenues will increase by (0.33)*x*($1,337,000) = $441,210; in the following year revenues will increase by (0.33)*x*($441,210) = $145,599; and so on. The effect on the licensing revenues one period after the time that the new foreign patent is ultimately granted will be $484,000. In the next year, the revenues will increase by (0.33)*x*($484,000) = $159,720; in the following year, revenues will increase by (0.33)*x*($159,720) = $52,708; and so on.

For DoD, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 2.8 years.[117] Conservatively, assuming that the foreign patent is granted in the third year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20}(0.33)^{t-1}(\$1{,}337{,}000)/(1.07)^{t}+\sum_{t=4}^{20}(0.33)^{t-4}(\$484{,}000)/(1.07)^{t}$$

= $1,806,757 + $533,903 = $2,340,660.

From Section IV's estimated cost functions for annuity costs and for law-firm costs for the cost of foreign patenting, the total variable costs of foreign patenting is the sum of the estimated annuity costs and the estimated law-firm costs. As explained in Section IV, the change in those costs from adding another foreign patent depends on the agency's annual number of foreign patent applications, $FNapp_t$. The additional cost from adding another foreign patent is estimated to equal $6605 + $1,118,841/($FNapp_t$) + ($5,371) = $11,976 + $1,118,841/($FNapp_t$) in constant dollars of year 2015. The estimated costs differ for each agency because the agencies differ in their typical annual number of foreign patent applications.[118]

Thus, DoD's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use DoD's annual number of applications for foreign patents in fiscal year 2015; the number was 106. Hence, DoD's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/106 = $22,531, in constant 2015 dollars.

[117] Here and subsequently for the other agencies, the average time from the application for a foreign patent until it was granted was tabulated by the authors from the worldwide patent data PATSTAT that is maintained by the European Patent Office; https://www.epo.org/searching-for-patents/business/patstat.html#tab-1.

[118] For the calculations that follow, the annual number of foreign patent applications for each agency was tabulated from PATSTAT (https://www.epo.org/searching-for-patents/business/patstat.html#tab-1) by the authors.

Juxtaposing the benefits and costs, for DoD the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $2,340,660/$22,531 = 103.9; the lower-bound net present value is $2,340,660 – $22,531 = $2,318,129 in constant 2015 dollars.

DOE

DOE's estimated model of invention-licensing revenue is:

$$y_{it} = -177 AppUSnoFN_{it-1} - 84 AppUSFN_{it-1} + 153 PatUS_{it-1} + 142 PatFN_{it-1} + .33 y_{it-1} + 41182 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For DOE, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 5.7 years. Conservatively, assuming that the foreign patent is granted in the sixth year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20} (0.33)^{t-1} (\$93{,}000) / (1.07)^t + \sum_{t=7}^{20} (0.33)^{t-7} (\$142{,}000) / (1.07)^t$$

= $125,676 + $127866 = $253,542.

DOE's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use DOE's annual number of applications for foreign patents in fiscal year 2015; the number was 201. Hence, DOE's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/201 = $17,542, in constant 2015 dollars.

Juxtaposing the benefits and costs, for DOE the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $253,542/$17,542 = 14.5; the lower-bound net present value is $253,542 – $17,542 = $236,000, in constant 2015 dollars.

HHS

HHS's estimated model of invention-licensing revenue is:

$$y_{it} = -138 AppUSnoFN_{it-1} + 124 AppUSFN_{it-1} + 424 PatUS_{it-1} + 54 PatFN_{it-1} + .33 y_{it-1} + 18096 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For HHS, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 6.8 years. Conservatively, assuming that the foreign patent is granted in the seventh year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and

discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20}(0.33)^{t-1}(\$262{,}000)/(1.07)^{t}+\sum_{t=8}^{20}(0.33)^{t-8}(\$54{,}000)/(1.07)^{t}$$

= $354,054 + $45,444 = $399,498.

HHS's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use HHS's annual number of applications for foreign patents in fiscal year 2015; the number was 306. Hence, HHS's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/306 = $15,632, in constant 2015 dollars.

Juxtaposing the benefits and costs, for HHS the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $399,498/$15,632 = 25.6; the lower-bound net present value is $399,498 - $15,632 = $383,866.

NASA

NASA's estimated model of invention-licensing revenue is:

$$y_{it} = -228AppUSnoFN_{it-1} + 483AppUSFN_{it-1} + 400PatUS_{it-1} + 930PatFN_{it-1}$$
$$+.33y_{it-1} - 11120 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For NASA, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 4.5 years. Conservatively, assuming that the foreign patent is granted in the fifth year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20}(0.33)^{t-1}(\$711{,}000)/(1.07)^{t}+\sum_{t=6}^{20}(0.33)^{t-6}(\$930{,}000)/(1.07)^{t}$$

= $960,811 + $896,050 = $1,856,861

NASA's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use NASA's annual number of applications for foreign patents in fiscal year 2015; the number was 20. Hence, NASA's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/20 = $67,918, in constant 2015 dollars.

Juxtaposing the benefits and costs, for NASA the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $1,856,861/$67,918 = 27.3; the lower-bound net present value is $1,856,861 - $67,918 = $1,788,943.

USDA

USDA's estimated model of invention-licensing revenue is:

$$y_{it} = -58.5 AppUSnoFN_{it-1} - 26.0 AppUSFN_{it-1} + 9.6 PatUS_{it-1} + 48.9 PatFN_{it-1}$$
$$+.14 y_{it-1} + 5415.2 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For USDA, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 6.0 years. Conservatively, assuming that the foreign patent is granted in the seventh year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20} (0.14)^{t-1} (\$32{,}500) / (1.07)^t + \sum_{t=8}^{20} (0.14)^{t-8} (\$48{,}900) / (1.07)^t$$

= \$34,946 + \$32,745 = \$67,691.

USDA's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use USDA's annual number of applications for foreign patents in fiscal year 2015; the number was 61. Hence, USDA's estimated cost for acquiring another foreign patent is \$11,976 + \$1,118,841/61 = \$30,318, in constant 2015 dollars.

Juxtaposing the benefits and costs, for USDA the lower-bound benefit-to-cost ratio for adding an additional foreign patent is \$67,691/\$30,318 = 2.2; the lower-bound net present value is \$37,373.

DOC

DOC's estimated model of invention-licensing revenue is:

$$y_{it} = -1.9 AppUSnoFN_{it-1} + 47.2 AppUSFN_{it-1} + 1.2 PatUS_{it-1} + 168.3 PatFN_{it-1}$$
$$+.14 y_{it-1} + .471 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For DOC, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 5.4 years. Conservatively, assuming that the foreign patent is granted in the sixth year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20}(0.14)^{t-1}(\$49{,}100)/(1.07)^{t}+\sum_{t=7}^{20}(0.14)^{t-7}(\$168{,}300)/(1.07)^{t}$$

= $52,796 + $120586 = $173,382.

DOC's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use DOC's annual number of applications for foreign patents in fiscal year 2015; the number was 11. Hence, DOC's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/11 = $113,689, in constant 2015 dollars.

Juxtaposing the benefits and costs, for DOC the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $173,382/$113,689 = 1.5; the lower-bound net present value is $59,693, in constant 2015 dollars.

VA

VA's estimated model of invention-licensing revenue is:

$$y_{it} = -24.5AppUSnoFN_{it-1} + 22.1AppUSFN_{it-1} + 14.9PatUS_{it-1} - 10.9PatFN_{it-1}$$
$$+.14y_{it-1} + 71.3 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For VA, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 5.6 years. Conservatively, assuming that the foreign patent is granted in the sixth year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20}(0.14)^{t-1}(\$46{,}600)/(1.07)^{t}+\sum_{t=7}^{20}(0.14)^{t-7}(-\$10{,}900)/(1.07)^{t}$$

= $50,108 - $7810 = $42,298.

VA's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our estimate, we use VA's annual number of applications for foreign patents in fiscal year 2015; the number was 89. Hence, VA's estimated cost for acquiring another foreign patent is $11,976 + $1,118,841/89 = $24,547, in constant 2015 dollars.

Juxtaposing the benefits and costs, for VA the lower-bound benefit-to-cost ratio for adding an additional foreign patent is $42,298/$24,547 = 1.7; the lower-bound net present value is $17,751.

EPA

EPA's estimated model of invention-licensing revenue is:

$$y_{it} = -25.9 AppUSnoFN_{it-1} + 39.5 AppUSFN_{it-1} - 28.8 PatUS_{it-1} + 18.4 PatFN_{it-1}$$
$$+.14 y_{it-1} + 612.6 + \sum_t \hat{h}_t d\_year_t + \hat{k}(analytical\_time)$$

For EPA, over the period from fiscal year 2003 through fiscal year 2018, the average time lag from application to grant of a foreign patent was 6.3 years. Conservatively, assuming that the foreign patent is granted in the seventh year after the U.S. and foreign applications, truncating benefits after a patent life of 20 years that begins with the application, and discounting the stream of constant 2015-dollar benefits at the real rate of 0.07 or 7% the benefit is:

$$\sum_{t=1}^{20} (0.14)^{t-1} (\$65{,}400) / (1.07)^t + \sum_{t=8}^{20} (0.14)^{t-8} (\$18{,}400) / (1.07)^t$$

= \$70,323 + \$12,321 = \$82,644.

EPA's cost of obtaining another foreign patent will depend on the number of its applications for foreign patents in the year of the application. For our sample period, EPA's applications for foreign patents fell off dramatically after fiscal year 2010. Its technology transfer office has had more experience with applying for foreign patents than the recent record would indicate. In fiscal years 2007, 2008, and 2009, the annual numbers of foreign patent applications were 21, 17, and 16 respectively. For our estimate, we use the average number of foreign applications in those years; the number was 18. Hence, EPA's estimated cost for acquiring another foreign patent is \$11,976 + \$1,118,841/18 = \$74,134, in constant 2015 dollars.

Juxtaposing the benefits and costs, for EPA the lower-bound benefit-to-cost ratio for adding an additional foreign patent is \$82,644/\$74,134 = 1.1; the lower-bound net present value is \$8,510.

As discussed in detail in Section III, three of the 11 agencies – DHS, DOT, and DOI – do not have enough foreign patent activity during our sample period to estimate equations for their invention-licensing revenues and their costs of foreign patenting as functions of their foreign patenting activity. For the other eight agencies, Table 12 shows the estimated return on investment in additional foreign patents that we have developed in this report.

Table 12. Return on Investment in Additional Foreign Patents: Benefit-to-Cost Ratio and Net Present Value Using a Lower-bound Benefit for Protecting the Intellectual Property for a USPTO-patented Technology with a Foreign Patent.

Agency	Lower-bound Benefit-to-Cost Ratio	Lower-bound Net Present Value in Constant 2015 dollars
DoD	103.9	$2,318,129
DOE	14.5	$236,000
HHS	25.6	$383,866
NASA	27.3	$1,788,943
USDA	2.2	$37,373
DOC	1.5	$59,693
VA	1.7	$17,751
EPA	1.1	$8,510

Source: Authors' calculations.

Discussion and Possible Implications

Table 12 shows return on investment metrics that bring together Section III's estimated functions for invention-licensing revenue and Section IV's estimated functions for the cost of foreign patents. Examining the metrics in Table 12, the first thing that comes to mind is the dramatic difference between (1) the large return on investment from adding foreign patent protection to a USPTO-patented technology for the four agencies – DoD, DOE, HHS, and NASA – with about 90% of the patenting activity and (2) the small return for the other agencies. The metrics for the two groups differ by from one to two orders of magnitude.

Based on our discussions with technology transfer specialists at the agencies, and also based on our study of the agencies' patent portfolios and their costs, the large difference appears to be grounded in DoD, DOE, HHS, and NASA having a critical *absolute* mass of patenting activity for U.S. and foreign patents over time. On the revenue side, with a smaller amount of patented technology, some of the remaining seven agencies (that together have about 10% of the patenting activity) may choose to accomplish technology transfer without negotiating for licensing fees as substantial as might be possible. For example, when we asked one of these seven agencies about a recent technology that has, in addition to its U.S. patent granted in 2015, two foreign patents granted in 2018 and 2019, a technology transfer specialist for the agency explained that the agency did not earn any royalties on the technology because it seemed appropriate not to charge royalties given that the firm that has commercialized the technology paid the application fees for the patents. On the cost side, when they have very few foreign patents applications annually, the agencies will have higher costs because they do not take full advantage of spreading the application costs for WIPO and EP applications over multiple applications for foreign patents in different countries. A technology transfer specialist for one of the agencies among the seven with only about 10% of the patenting activity told us that the agency had stopped filing for foreign patents because they had never seen a good return on the investment. Our metrics in Table 12 certainly confirm that story.

The agencies with the relatively small patent portfolios may at times simply find that the result of negotiating more licensing revenues for their patented technologies would be a substantial loss in the amount of the technology transfer for their relatively small numbers of patented technologies. On the other hand, the estimated invention-licensing revenue

functions in Section III support the expectation that pursuit of foreign patents along with their USPTO patents would increase the amounts of licensing revenues that could be negotiated. Further, given the estimated functions for foreign patenting costs in Sections IV and V, with the pursuit of more foreign patents, the cost of additional foreign patents would fall. Thus, it is possible that the pursuit of more foreign patents would result in higher net benefits for additional foreign patents.

For the agencies with small patent portfolios as well as for the four agencies with the large portfolios of patents, the metrics shown in Table 12 and the findings about the impacts on revenues and costs estimated in Sections III and IV support the expectation that pursuing additional foreign patents may not only result in greater net licensing revenues to offset the taxpayers' investments in federal agencies' technologies.[119] Additionally, obtaining more foreign patents would improve the international competitive position of firms that license the agencies' technologies. It would be easier to transfer technologies to be commercialized because the licensees would find that the technologies have greater commercial value when they have foreign patent protection.

Appendix 1. Details about the Statistical Estimation for Section III

Our sample for estimating the benefits of obtaining foreign patents consists of 13 fiscal years of observations of the invention-licensing revenue for each of the 11 federal agencies reporting annually to Congress about their technology transfer activities and whose reports have been gathered together by the National Institute of Standards and Technology in a report to the President and the Congress.[120] The 11 agencies are the Department of Agriculture (USDA), the Department of Commerce (DOC), the Department of Defense (DoD), the Department of Energy (DOE), the Department of Health and Human Services (HHS), the Department of Homeland Security (DHS), the Department of the Interior (DOI), the Department of Transportation (DOT), the Department of Veterans Affairs (VA), the Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration (NASA). The 13 fiscal years are 2003 through 2015, the years in which the 11 agencies used the same methodology for reporting their invention-licensing revenue. In fiscal year 2003, the agencies began using uniform reporting practices for the annual technology transfer reports. Our dependent variable, the annual invention-licensing revenue for each agency for each fiscal year from 2003 through 2015, is provided in NIST's summary technology transfer report and in an Excel spreadsheet that is available with the report.[121]

[119] The foreign patents would make the technology that is transferred more valuable to the licensees, and consequently they would be willing to pay greater licensing fees. The negotiation of higher licensing fees would leverage the taxpayers' funds, enabling a given amount of funds to support a greater amount of R&D in the federal agencies. See John T. Scott, "Financing and Leveraging Public/Private Partnerships: The Hurdle-Lowering Auction," *STI (Science, Technology, Industry) Review*, No. 23, Paris, OECD, 1998, pp. 67-84, and also Stephen Martin and John T. Scott, "The Nature of Innovation Market Failure and the Design of Public Support for Private Innovation," *Research Policy*, Vol. 29, Nos. 4-5 (April 2000), pp. 437-447.
[120] NIST (2018), op. cit.
[121] Ibid.

This statistical appendix first reports the details for the estimated invention-licensing revenue models that are presented in Section III for DoD, DOE, HHS, and NASA. Those four agencies have roughly 90% of the patenting activity for the 11 agencies in NIST's summary report. Then after presenting those detailed results, we also present the estimated model for USDA, DOC, DHS, DOI, DOT, VA, and EPA. Those seven agencies have roughly 10% of the patenting activity. With regard to their patenting and licensing activity, the seven agencies are very different from the other four. By estimating the model for them separately, we allow the estimated coefficients for the control variables such as the year effects and time trend to take different values from those estimated for the other four agencies. We also use interaction terms to allow the different agencies to have their own estimated coefficients for the explanatory variables that describe the history of patent applications and grants.

To estimate the benefits of the federal agencies' foreign patents, we use a dynamic panel data model. The model is dynamic because we observe the patents and their benefits as they evolve through time, and because the relationship between past patents and the benefits that they generate is recurring through time. The data are panel data because we observe several different entities – the different federal agencies – through time. Thus, we have a panel of federal agencies and observe each member of the panel over time. Such data is also referred to as pooled cross-section time-series data because at any point in time we have a cross-section of different entities – the agencies in our case – and can look across them at that point in time, and then we also observe them over time. Because we look over time at the cross-section, observing the entities in the panel lengthwise through time, such data are also referred to as longitudinal data.

As developed in Section III, our estimable model of invention-licensing revenue is:

$$y_{it} = a_{1i}AppUSnoFN_{it-1} + b_{1i}AppUSFN_{it-1} + c_{1i}PatUS_{it-1} + d_{1i}PatFN_{it-1}$$
$$+ fy_{it-1} + A_i + \sum_t h_t d\_year_t + k(analytical\_time) + u_{it}$$

To estimate this dynamic panel data model, we use the estimator developed by Arellano and Bond (1991), and its implementation in the statistical software from Stata.[122] The estimator is constructed by first-differencing to remove the panel level effects, A_i, and using instruments to form the moment conditions.[123] As explained in Section III, including the

[122] Manuel Arellano and Stephen Bond, "Some Tests of Specification for Panel Data: Monte Carlo Evidence and an Application to Employment Equations," *Review of Economic Studies*, Volume 58, Issue 2 (April 1991), pp. 277-297, develops a consistent generalized method of moments (GMM) estimator for the parameters of the dynamic panel data model. *Stata Release 15*, Statistical Software (College Station,Texas: StataCorp LLC, 2017) provides the implementation of the model with the procedure *xtabond*. The Arellano and Bond estimator and the procedure *xtabond* are described fully in *Stata Longitudinal Data/Panel Data Reference Manual*, Release 15 (College Station, Texas: StataCorp LLC, 2017), pp. 24-43. We use the Arellano-Bond robust VCE estimator for their one-step GMM model. A detailed explanation of GMM estimators and the application for the Arellano and Bond estimator is provided in William H. Greene, *Econometric Analysis*, Seventh Edition (Upper Saddle River, New Jersey: Prentice Hall, 2012), pp. 455-508.

[123] With the first-differencing, the individualized constant terms for the agencies (the panel-level effects or the "agency effects") are removed before estimating the other parameters of the model with the differences of the variables. Those removed constants are constants in the level (not differenced) equation and are estimated using the errors for the level equation after the coefficients for the explanatory variables have been estimated.

lagged dependent variable as an explanatory variable solved the problem of representing the sequence of lagged explanatory variables in a way that left us with an estimable equation. However, that solution to the problem introduced another problem. Namely, we now have an endogenous variable among the explanatory variables. The solution to that problem is to use instrumental variables. However, as is often the case with econometric studies, finding good instruments external to our data set is difficult. To solve that problem we use the Arellano-Bond estimator. The estimator creates valid instruments from the data set by using higher-order lags of the dependent variable. It is a consistent generalized method of moments (GMM) estimator for the parameters of the dynamic panel data model.

Section III provides the definitions of the variables in the model as well as the descriptive statistics for the agencies for which the model is estimated. Table A1 shows the estimated model for invention-licensing revenue that is used to provide the estimates in Section III for the four agencies DoD, DOE, HHS, and NASA. To estimate the agency-specific coefficients for the patent history variables, we define the agency dummy variables *d_DOE*, *d_HHS*, and *d_NASA* which equal 1 when an observation is for the particular agency, and zero otherwise.

Table A1. Arellano-Bond Dynamic Panel-data Robust Estimation for DoD, DOE, HHS, and NASA of the Model of Invention-Licensing Revenue: Dependent variable is y_{it}, the i^{th} agency's invention-licensing revenue, in thousands of constant 2015 dollars, in fiscal year t, n = 44.[a]

Variable	Coefficient (robust standard error)[b] [probability > |z|]
y_{it-1}	0.331 (0.194) [0.089]
Patent history variables	
$AppUSnoFN_{it-1}$	–113.8 (46.8) [0.015]
$d\_DOE \times AppUSnoFN_{it-1}$	–63.1 (53.4) [0.238]
$d\_HHS \times AppUSnoFN_{it-1}$	–24.0 (233.5) [0.918]
$d\_NASA \times AppUSnoFN_{it-1}$	–113.8 (58.4) [0.051]
$AppUSFN_{it-1}$	1222.6 (350.1) [0.000]
$d\_DOE \times AppUSFN_{it-1}$	–1306.2 (391.7) [0.001]
$d\_HHS \times AppUSFN_{it-1}$	–1098.7 (398.7) [0.006]
$d\_NASA \times AppUSFN_{it-1}$	–739.9 (276.3) [0.007]
$PatUS_{it-1}$	122.0 (31.3) [0.000]
$d\_DOE \times PatUS_{it-1}$	31.4 (10.2) [0.002]
$d\_HHS \times PatUS_{it-1}$	302.2 (131.5) [0.022]
$d\_NASA \times PatUS_{it-1}$	278.4 (102.8) [0.007]
$PatFN_{it-1}$	484.1 (183.3) [0.008]
$d\_DOE \times PatFN_{it-1}$	–341.7 (163.6) [0.037]
$d\_HHS \times PatFN_{it-1}$	–430.1 (219.9) [0.051]
$d\_NASA \times PatFN_{it-1}$	445.9 (448.7) [0.320]
Fiscal year dummy variables[c]	
d_2006	–20644.6 (16952.1) [0.223]
d_2007	–48707.4 (29206.9) [0.095]
d_2008	–55808.3 (36595.9) [0.127]
d_2009	–77688.9 (49116.7) [0.114]
d_2010	–93244.8 (60876.2) [0.126]
d_2011	–113610.1 (72821.5) [0.119]
d_2012	–123111.7 (79632.9) [0.122]
d_2013	–146257.8 (90310.5) [0.105]

d_2014	–144252.8 (90175.4) [0.110]
d_2015	–170923 (104003.3) [0.100]
analytical_time	10813.3 (8895.9) [0.224]
Constant (A_i) terms[d]	
A_i for DoD	–17504.5 (1112.8) [0.000]
A_i for DOE	41181.6 (1932.1) [0.000]
A_i for HHS	18095.6 (2977.1) [0.000]
A_i for NASA	–11119.9 (1006.6) [0.000]

Notes:

[a]The group variable is the U.S. federal agency, and there are 4 groups. The time variable is fiscal year, and there are 13 time periods. The number of underlying observations is 52 (= 4*x*13). Then after the lags are taken and the Arellano-Bond differencing is done, there are 44 observations to use with the estimator. The basic model required taking the lags of the dependent variable and the explanatory variables. Thus, for the 4 agencies, there remained 12 fiscal years for the model with the lagged variables. Then Arellano-Bond estimation differences the equation; thus, forming the differences of the lagged variables leaves 11 fiscal years of observations for the 4 agencies or 44 observations. In other words, each of the four agencies after lags and differencing have used up two observations – the observations for fiscal years 2003 and 2004. For the instruments for the differenced equation, lags 2 through 4 for the dependent variable are used to form GMM-type instruments, and first differences of the exogenous variables are used as standard instruments. The Arellano-Bond test for zero autocorrelation does not reject the null hypothesis of no second-order autocorrelation in the first-differenced errors (against the null hypothesis, the statistic for the test is insignificant), supporting the moment conditions used by the Arellano-Bond estimator.

[b]The standard errors are adjusted for clustering by agency.

[c]The base year is 2005 (recall that the observations for 2003 are used when the lags are formed, and then the 2004 observations are used to form the Arellano-Bond differences). Thus, the estimated A_i for each agency is the constant for that agency in fiscal year 2005; in other years, the estimated effects for the various time dummies would be added.

[d]The constants are constants in the level equation and are estimated using the errors for the level equation; the other parameters of the model are estimated with the differences of the variables.

Source: Authors' calculations.

Table A2 shows the estimated model for invention-licensing revenue that is used to provide the estimates in Section III for the seven agencies USDA, DOC, DHS, DOI, DOT, VA, and EPA. To estimate the agency-specific coefficients for the patent history variables, we define the agency dummy variables *d_DOC*, *d_DHS*, *d_DOI*, *d_DOT*, *d_VA*, and *d_EPA* which equal 1 when an observation is for the particular agency, and zero otherwise.

Table A2. Arellano-Bond Dynamic Panel-data Robust Estimation for USDA, DOC, DHS, DOI, DOT, VA, and EPA of the Model of Invention-Licensing Revenue: Dependent variable is y_{it}, the i^{th} agency's invention-licensing revenue, in thousands of constant 2015 dollars, in fiscal year t, n = 70.[a]

Variable	Coefficient (robust standard error)[b] [probability > |z|]
y_{it-1}	.140 (.031) [0.000]
Patent history variables	
$AppUSnoFN_{it-1}$	–58.5 (5.03) [0.000]
$d\_DOC \times AppUSnoFN_{it-1}$	56.6 (8.04) [0.000]
$d\_DHS \times AppUSnoFN_{it-1}$	69.9 (68.6) [0.308]
$d\_DOI \times AppUSnoFN_{it-1}$	43.9 (37.9) [0.247]
$d\_DOT \times AppUSnoFN_{it-1}$	18.8 (21.6) [0.385]
$d\_VA \times AppUSnoFN_{it-1}$	34.0 (9.37) [0.000]
$d\_EPA \times AppUSnoFN_{it-1}$	32.6 (15.5) [0.036]
$AppUSFN_{it-1}$	–26.0 (7.12) [0.000]
$d\_DOC \times AppUSFN_{it-1}$	73.2 (78.6) [0.352]
$d\_DOI \times AppUSFN_{it-1}$	–125.6 (110.2) [0.254]
$d\_VA \times AppUSFN_{it-1}$	48.1 (18.5) [0.009]
$d\_EPA \times AppUSFN_{it-1}$	65.48629 (56.5) [0.246]
$PatUS_{it-1}$	9.63 (2.46) [0.000]
$d\_DOC \times PatUS_{it-1}$	–8.43 (7.34) [0.251]
$d\_DHS \times PatUS_{it-1}$	69.3 (58.2) [0.234]
$d\_DOI \times PatUS_{it-1}$	15.2 (26.2) [0.563]
$d\_DOT \times PatUS_{it-1}$	–38.2 (35.8) [0.286]
$d\_VA \times PatUS_{it-1}$	5.35 (8.00) [0.504]
$d\_EPA \times PatUS_{it-1}$	–38.5 (6.57) [0.000]
$PatFN_{it-1}$	48.9 (4.57) [0.000]
$d\_DOC \times PatFN_{it-1}$	119.4 (183.2) [0.515]
$d\_DOI \times PatFN_{it-1}$	–11.2 (81.7) [0.891]
$d\_VA \times PatFN_{it-1}$	–59.8 (7.38) [0.000]
$d\_EPA \times PatFN_{it-1}$	–30.5 (12.5) [0.014]
Fiscal year dummy variables[c]	
d_2006	–89.9 (114.8) [0.434]
d_2007	–91.7 (265.6) [0.730]
d_2008	–49.0 (384.7) [0.899]
d_2009	–35.0 (357.2) [0.922]
d_2010	–404.6 (688.5) [0.557]
d_2011	–508.4 (823.7) [0.537]
d_2012	–391.7 (777.0) [0.614]
d_2013	–684.0 (945.2) [0.469]
d_2014	–512.2 (986.9) [0.604]
d_2015	–837.6 (1151.3) [0.467]
$analytical\_time$	65.1 (110.5) [0.556]
Constant (A_i) terms[d]	
A_i for USDA	5415.2 (234.7) [0.000]
A_i for DOC	.4707 (23.2) [0.984]
A_i for DHS	–255.6 (45.5) [0.000]
A_i for DOI	–113.7 (31.7) [0.001]
A_i for DOT	–51.0 (27.8) [0.071]
A_i for VA	71.3 (33.5) [0.037]
A_i for EPA	612.6 (36.4) [0.000]

Notes:

[a]The group variable is the U.S. federal agency, and there are 7 groups. The time variable is fiscal year, and there are 13 time periods. Because 5 of the observations of the dependent variable are missing, there are 86 of the possible 91 (= 7x13) observations. Then after the lags are taken, there are 70 observations. The basic

model required taking the lags of the dependent variable and the explanatory variables. Thus, for the 7 agencies, there remained 12 fiscal years for the model with the lagged variables. Then Arellano-Bond estimation differences the equation; thus, forming the differences of the lagged variables leaves 11 fiscal years of observations for the 7 agencies or 77 observations. In other words, each of the four agencies after lags and differencing have used up two observations – the observations for fiscal years 2003 and 2004. However, USDA is missing the dependent variable in 2007, and so loses three additional observations – the 2007 observation and also the 2008 and 2009 observations because lag of the dependent variable cannot be formed for year 2008 and the difference in the lagged dependent variable cannot be formed for that year and also year 2009. Having lost the additional three observations for USDA, we are left with 74 observations. Then, DHS is missing the dependent variable in years 2003, 2004, 2005, and 2006. The first two years observations would have been lost to the lags and then the differencing of the equation, so we need to observe the implications of the missing data in 2005 and 2006. The implication is an additional four observations lost. In addition to the 2003 and 2004 observations that would be lost anyway because of taking lags and then differencing the equations, the lagged dependent variable additionally cannot be formed in 2005, 2006, and 2007, and the differenced lagged dependent variable cannot be formed in 2005, 2006, 2007, and 2008. Having lost the additional four observations for DHS, we have the final number of observations available, 70 = 74 – 4, for the Arellano-Bond estimator. For the instruments for the differenced equation, lags 2 through 4 for the dependent variable are used to form GMM-type instruments, and first differences of the exogenous variables are used as standard instruments. The Arellano-Bond test for zero autocorrelation does not reject the null hypothesis of no second-order autocorrelation in the first-differenced errors (against the null hypothesis, the statistic for the test is insignificant), supporting the moment conditions used by the Arellano-Bond estimator. Since DHS and DOT do not have any foreign patents (see Table 3), there are no interaction terms for the variables $AppUSFN_{it-1}$ and $PatFN_{it-1}$ for those agencies

[b]The standard errors are adjusted for clustering by agency.

[c]The base year is 2005 (recall that the observations for 2003 are used when the lags are formed, and then the 2004 observations are used to form the Arellano-Bond differences). Thus, the estimated A_i for each agency is the constant for that agency in fiscal year 2005; in other years, the estimated effects for the various time dummies would be added.

[d]The constants are constants in the level equation and are estimated using the errors for the level equation; the other parameters of the model are estimated with the differences of the variables.

Source: Authors' calculations.

Appendix C. Case Studies Showing ROI to Federal Agency Foreign Patenting (Task 3 Report)

Estolide Base Oils and Lubricants Case Study: USDA's Invention and Transfer of a Commercially Valuable Fatty Acid Molecule

I. Introduction

We are all familiar with tech-savvy software industry entrepreneurs, like Steve Jobs, Bill Gates, Larry Page, Ginni Rometty, Anne-Marie Imafidon, and many others. This case study focuses on tech-savvy green chemistry scientists and entrepreneurs *and* a long and winding road from lab-to-market. Along the way their efforts generated royalty revenues that reimbursed some of USDA's R&D expenditures and, today, they appear poised to greatly expand the commercialization of the underlying technology developed by scientists at the USDA in the early-1990s. The journey over the long road to commercialization success in this case has two legs. One leg of the journey focused on product and process technology improvements accomplished through a series of private and public-private collaborations that continue to this day. The other leg of the lab-to-market journey has been focused on building the kind of commercial organization that could secure the financial capital required to envision and meet the potentially global demand for biodegradable, safe, and sustainable base oils that are useful in a very wide range of products.[124]

Table 1 provides an overview of key events in the transfer and commercialization of USDA's estolide technology, a biodegradable base oil.

[124] "Base oils" are used to manufacture products including lubricating greases, motor oil, metal processing fluids, pharmaceuticals, and cosmetics. Different products require different compositions and properties in the base oil. < https://en.wikipedia.org/wiki/Base_oil>

Table 1. Key Events in the Technology Transfer of the USDA's Estolide Technology.

Date	Event
1991	A practical method to synthesize estolides from common fatty acids is developed by USDA's Agricultural Research Service (ARS) scientist Terry Isbell.
1994	CRADA is established between Calgene Chemical Inc. (later Lambent, later Petroferm, later Vantage) and ARS entitled "Evaluation of Estolides and Polyestolides as Lubricants and Industrial Fluids," resulted in patentable inventions jointly owned by USDA and Lambent. Lambent agrees to assign its rights in the estolide technology to USDA so that the agency could pursue other licensing opportunities. (This is inconsistent with the public record maintained by the USPTO but industry sources maintain that the public record is incorrect resulting from mutiple reorganizations. USDA CRADA project scientists are the source of the information that Lambent agreed to assign its rights in the estolide technology to USDA .)
1998	Steven Cermak joins the ARS research effort.
November 13, 1998	Patent application filed: Appl. No.: 09/191,907 (United States Patent 6,018,063)
1999	CRADA is established between Lambent (a division of Petroferm) and ARS entitled "Evaluation of Estolides and Polyestolides as Raw Materials or Certain Finished Products."
2000	United States Patent 6,018,063, Isbell , et al., granted, January 25, 2000: "Biodegradable oleic estolide ester base stocks and lubricants"
January 24, 2000	Patent application filed: Appl. No.: 09/490,360 (United States Patent 6,316,649)
November 13, 2001	United States Patent 6,316,649, Cermak , et al., granted, November 13, 2001: "Biodegradable oleic estolide ester having saturated fatty acid end group useful as lubricant base stock"
March 13, 2001	Federal Register / Vol. 66, No. 49, Notice of Government owned inventions (Patent # 6,316,649,) available for licensing.
2002	Montana EcoFuels of Thompson Falls changes its name to Peaks and Prairies Oils Seed Growers Cooperative
2004	Peaks & Prairies, LLC, estblished, with Kent Wasson (formerly of Montana EcoFuels and Peaks and Prairies Oils Seed Growers Cooperative) as president.
January 19, 2006	Federal Register notice to grant an exclusive license to Peaks & Prairies, LLC for USDA patented inventions United States Patents 6,018,063 (2000) and 6,316,649 (2001)
March 1, 2006	CRADA is established btween ARS and Peaks & Prairies, LLC, entitled, "Production of Canola Based Estilides."
2008	Peaks & Prairies signs an agreement with an unidentified finance company to raise money for building up to six manufacturing plants.
2010	Peaks & Prairies is reorganized as LubriGreen Biosynthetics when Allen Barbieri and Jakob Bredsguard join the Board of Directors.
2010	LubriGreen Biosynthetics changes its name to Biosynthetic Technologies with Allen Barbieri as CEO and Jakob Breadsguard as CTO.
2011	ARS enters into a CRADA with Biosynthetic Technologies, entitled, "Development of Biobased Lubricant."
2011	ARS is awarded the 2011 Federal Laboratory Consortium Award for excellence in the technology transfer effort for estolide development.
2012	Royalty payents to USDA from Biosynthetic Technologies to USDA begin (~2012-2016).
2013	The emergence of high oleic soybean oil as a commercial reality in the fall of 2013.
July 16, 2014	Evonik Venture Capital closes an equity investment in Biosynthetic Technologies, LLC (alluding to "previous financing rounds" [which] had included such large organizations as BP Ventures and the Monsanto Company").
2015	ARS is awarded the 2015 Federal Laboratory Consortium Award for excellence in the technology transfer effort for the commercialization of estolides as a biobased engine oil.
2016	Bredsguard, J.W., Thompson, T.D., Cermak, S.C., Isbell, T.A., "Estolides: Bioderived synthetic base oils," in Sharma, B.K., Biresaw, G., editors*Environmentally Friendly and Biobased Lubricants,* Boca Raton:LA, CRC Press, 2016, pp. 35-49.
March 23, 2018	Biosyntheitic Technologies is acquired by Biosyn Holdings.
2018	Expiration of United States Patent 6,018,063, Isbell , et al. January 25, 2000: "Biodegradable oleic estolide ester base stocks and lubricants" and United States Patent 6,316,649, Cermak , et al. November 13, 2001: "Biodegradable oleic estolide ester having saturated fatty acid end group useful as lubricant base stock"

In Section II, we describe the patented technology, the family of U.S. and foreign patents that evolved from the original application in 1998, and some initial information about the licensees. We discuss additional information about the licenses that were based on the patented estolide technology[125] in Section III, where we also discuss some important

[125] Other than suggesting that USDA's estolide patents would make a good case study for our larger foreign patenting analysis, the USDA's Office of Technology Transfer, apparently because of concerns about confidentiality (see 35 USC 209 and 18 USC 1905), provided *no* information about the costs of patenting these two patents. Nor did they provide any information about the license terms (other than what could be inferred from the published record, i.e., that the USDA *intended* to issue Peaks & Prairies, LLC an exclusive license) or royalty revenues generated, even though the patents expired in 2018. For whatever reason, other federal

technological and organizational milestones along the road to commercialization. Section IV concludes with an overall interpretation of the case study information, as well as observations about the licensing case study execution.

II. Obtaining Patents: The First Step in the Transfer and Commercialization Process for USDA's Estolide Technology

Background

The story of the estolide molecule begins with research conducted at USDA's research facility in Illinois by Dr. Terry Isbell and his colleagues in the early 1990s. A practical method to synthesize these unique compounds from unsaturated fatty acids was developed by Isbell in 1991.[126] The USDA researchers were trying to formulate a synthetic, vegetable-based oil that could compete with mineral-based products such as petroleum. Early research papers describe the attempt by Isbell's research group to formulate a "recipe" for a vegetable-derived oil with properties comparable to those long-believed to be achievable *only* with petroleum-based oils.[127] Additional improvements to the estolide technology were made through a series of research joint ventures (enabled by Cooperative Research and Development Agreements, CRADAs) with the private sector and other federal agencies. Dr. Steven Cermak joined the USDA's research effort in 1998 and participated in subsequent CRADAs.

In the early 1990's chemistry-based companies were also interested in developing renewable lubricants. In 1994, Calgene Chemical Inc. (later the Lambent Technologies unit of Petroferm[128]) and USDA's Agricultural Research Service (ARS), entered into a CRADA.

agencies *have* provided, in one instance, the identities of past licensees, rough estimates of total royalty revenues (though not by fiscal year) for specific licensed patents; and, in another instance, the identities of current licensees, points-of-contact within the licensee's organization, and the dollar amount of royalty revenues generated for the agency by fiscal year. On the private sector side, we found that in most instances companies refused to discuss the terms of their license agreement with the relevant federal agency, the value of royalty revenues paid, or the sales revenues from which some royalty payments derive. All these constraints make the development of case studies particularly difficult. Cooperation from *both* the federal agency licensor and the private sector licensee would be ideal.

[126] Terry Isbell, personal communication, June 15, 2020.

[127] Terry A. Isbell, Robert Kleiman and Beth A. Plattner, "Acid-Catalyzed Condensation of Oleic Acid into Estolides and Polyestolides," *Journal of Agricultural, Biological and Environmental Statistics*, Vol. 71, No. 2, February 1994.

[128] https://www.chemicalonline.com/doc/calgene-chemical-to-become-part-of-petroferms-0001.

As a result of the CRADA, first generation commercial *estolides were synthesized in pilot quantities* and their performance was evaluated by other industrial partners like Caterpillar.[129] That effort resulted in a joint patent for an estolide lubricant that served as the basis for all subsequent work.[130]

By 1997-1998 the researchers had succeeded, filing patent applications in the U.S., Canada, Spain, and Germany. Two years later they filed a companion patent. The two U.S. patents were granted in 2000 (U.S. Patent No. 6,018,063, "Biodegradable oleic estolide ester base stocks and lubricants") and 2001 (U.S. Patent No. 6,316,649, "Biodegradable oleic estolide ester having saturated fatty acid end group useful as lubricant base stock") respectively.

The Patent Family

Table 2 shows the patent families of the two original USDA estolide patents: US 6018063 and US 6316649.

Table 2. International Patent Families USDA's Original Estolide Patents.

Application*	Application Filing Date	Published Patent Document**	Publication Date
US19970065726P (US60/065,726)[a]	11/14/97		
US19980191907 (US09/191,907)[a]	11/13/98	US6018063A[b]	1/25/00
EP19980958608[d]	11/16/98	EP1051465B1	8/23/06
CA19982309914[d]	11/16/98	CA2309914C	3/6/07
ES19980958608T[d]	11/16/98	ES2272013T3	4/16/07
DE19986035694T[d]	11/16/98	DE69835694T2	8/23/07
AU1461399[d]	11/16/98		
WO1998US24469[d]	11/16/98		
AT19980958608T[d]	11/16/98		
US20000490360 (US09/490,360)[a]	1/24/00	US6316649B1[c]	11/13/01
AU20010032929[a]	1/24/01		
WO2001US02248[a]	1/24/01		

*Subsequent applications are continuations of the original application (US19980191907), rather than the provisional (P) patent application (US19970065726P). The provisional patent application secured a filing date without the filing costs associated with the nonprovisional patent application (US19980191907, resulting in the publication US6018063A), to which the subsequent patents are traced. The Canadian patent and the European patent (and those of the countries recognizing the EP patent) list priority to US09/191,907, November 13, 1998, but also as their earliest priority list US19970065726P, November 14, 1997. Country codes: AT = Austria, AU = Australia, CA = Canada, DE = Germany, EP = European Patent Office, ES = Spain, US = United States, WO = WIPO = World Intellectual Property Organization.

[129] Isbell, 2020, op. cit.

[130] One of the inventors of the USDA's foundational estolide patent (US 6,018,063) is Joseph E. Lohr, Jr. The United States Patent and Trademark Office's (USPTO) Public Patent Application Information Retrieval (PAIR) system indicates that Lohr assigned his intellectual property rights to Lambent Technologies, November 20, 2000.

** Publications with the T designations at the end denote translations of the European patent in the cooperating countries. For example, for the publications for Germany (DE), T2 denotes the translation of the corresponding European patent's specification. The T3 designation for Spain (ES) is notation indicating that the corresponding European patent specification is valid in Spain.
a. The application was filed by the USDA.
b. The patent was initially assigned to USDA, by inventors who were employees of the USDA, and to Lambent Technologies by employee-inventor Joseph Lohr Jr.
c. The patent was initially assigned to USDA.
d. These patent applications to EP, WO, and the cooperating countries, were made by Lambent Technologies and the USDA.

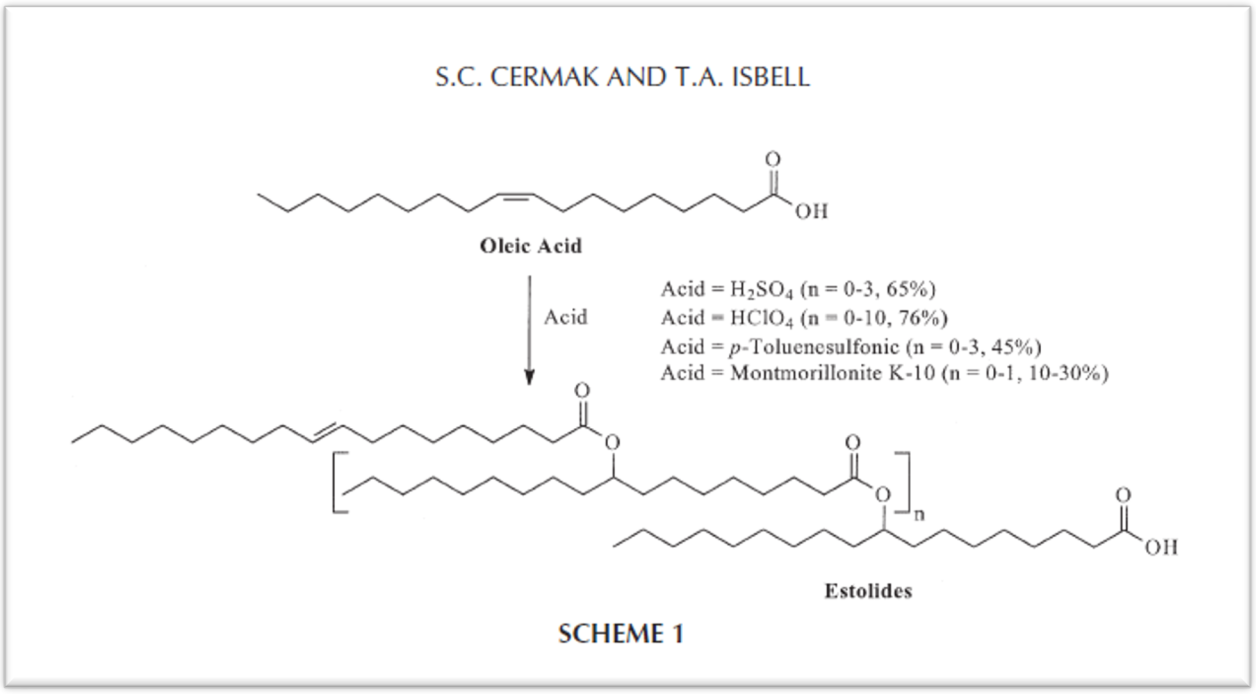
The family of patents all originate with a provisional patent application dated November 14, 1997, published as US6572697P, also referred to as US65726P. The two U.S. patents simply list the priority as the filing of the first of the two USPTO patents filed, so the priority date is November 13, 1998. The Canadian patent and the European patent (and hence the publications for Spain and for Germany) all list the priority as the November 14, 1997, filing US60/065,726 resulting in US6572697P; they also list the November 13, 1998 priority. Regarding the applications for Austria (AT) and Australia (AU), perhaps the USDA initially thought it would be worth applying for intellectual property protection in those jurisdictions but either AT and AU found reasons not to grant a patent or the USDA decided it wasn't worth the cost. Regarding the WO applications in 1998 and 2001, WO/ WIPO does not issue patents. Instead, a WO filing (also referred to as a PCT filing or a WIPO filing) gives the priority inventor the option to follow up with cooperating countries.

We believe that USDA frequently pays the costs of patenting and the maintenance fees but, in this case, some costs were borne by the licensee, Peaks & Prairies, LLC, and its subsequent incarnations as LubriGreen BioSynthetics and Biosythetic Techologies (discussed below). We have been able to ascertain very few specifics about who bore the costs of obtaining and maintaining the foundational USDA estolide patents that are the focus of this case study, or if those costs were borne differently for U.S. and foreign patents.

Estolide Technology & Its Commercial Significance[131]

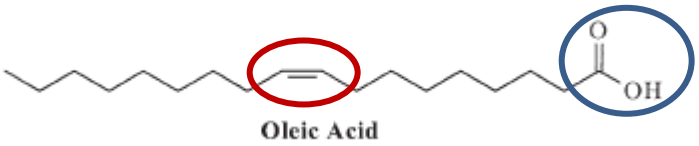
Estolides are a class of compounds that sometimes occur naturally and can be synthesized from fatty acids, such as oleic acid in the image below.[132]

[131] We thank Trevor Gauntlett, of Tevor Gauntlett Consulting <trevor@gauntlettconsulting.co.uk>, for his insights as a domain expert; for his explanations of the chemistry of estolides; and for his translation of the estolide chemistry graphics explained in this section of the case study.
[132] The image is reproduced from Steven C. Cermak and Terry A. Isbell, "Synthesis of Estolides from Oleic and Saturated Fatty Acids," *Journal of the American Oil Chemists' Society,* June 2001, p. 558.



Source: Cermak and Isbell, 2001, op. cit.

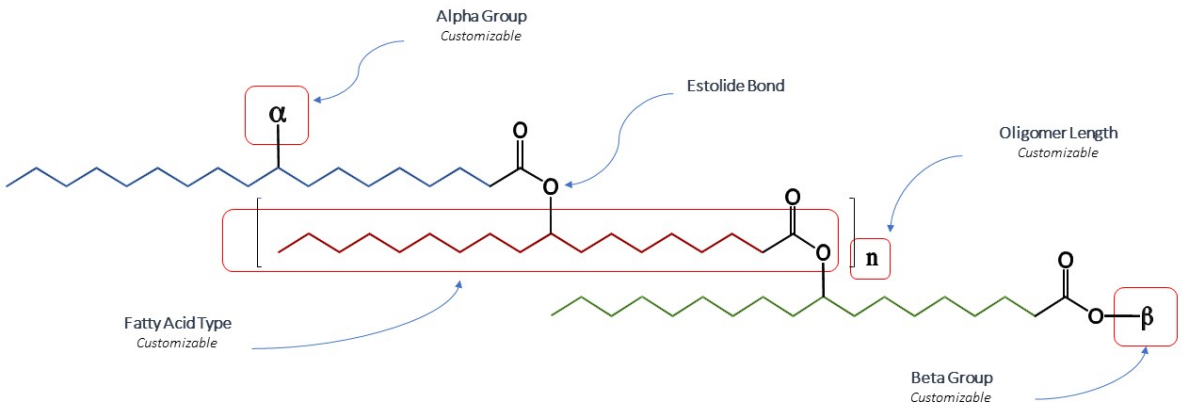
The active chemical sites of oleic acid can be thought of as a "loop" (outlined in red) and a "hook" (outlined in blue).



Two chemical terms that can be used to describe the loop are a "carbon-carbon double bond" or an "unsaturated bond." (Readers may be familiar with terms such as polyunsaturated or saturated fats, which refer to this type of chemistry in the fat from which the acid is derived.) The hook is called a carboxylic acid. The depiction of a molecule by the convention above (line to describe a chemical bond, all intersections of the jagged lines are carbon atoms with their hydrogen bound atoms assumed) allows focus on the key areas of chemistry: the hooks and loops.

One of the key successes of this and related work is that the inventors managed to make a controlled chemical reaction between the hooks and the loops of different fatty acid molecules. (A significant side reaction can involve the hook and loop combining in the same molecule.) The inventors also created something with economic value. The controlled nature of the reaction is important commercially.

If one hook reacts with one loop on another molecule of a fatty acid, the hook and the loop of the new molecule are almost unaffected. Therefore, they will react quickly with (respectively) another loop or another hook. In commercial chemistry, time is money. Thus, without control, all hooks react with all loops and create a resinous solid. *Stopping the reaction reproducibly is another key*. The modified Biosynthetic Technologies (hereafter BT) graphic below shows that part of the way to achieve this can be stopping the reactivity by capping the oligomeric fatty acid molecule (red) at the alpha position (loop) and the beta position (hook), as shown below.



Source: Trevor Gauntlett, 2020.

Based on our discussions with a consulting expert we believe that the equipment and chemicals required to manufacture and purify these estolides are all standard and relatively low in cost. The chemical reactions give a sufficiently high degree of conversion to the desired products that the cost of separating unreacted raw materials and disposing of, or re-using, by-products is low. This means that the estolides can be manufactured almost anywhere, resulting in relatively lower manufacturing cost and, potentially, sustainability benefits if manufacturing takes place close to sources of raw material supply and thereby reducing transport costs and environmental footprint.

Estolides as Lubricant Components

Estolides as described above have many performance attributes that make them ideally suited for many high value lubricants applications. Some are derived from their

chemistry and some from their shape. Some of the chemistry is that which made natural fats and oils (lard, tallow, olive oil etc.) the first lubricants.

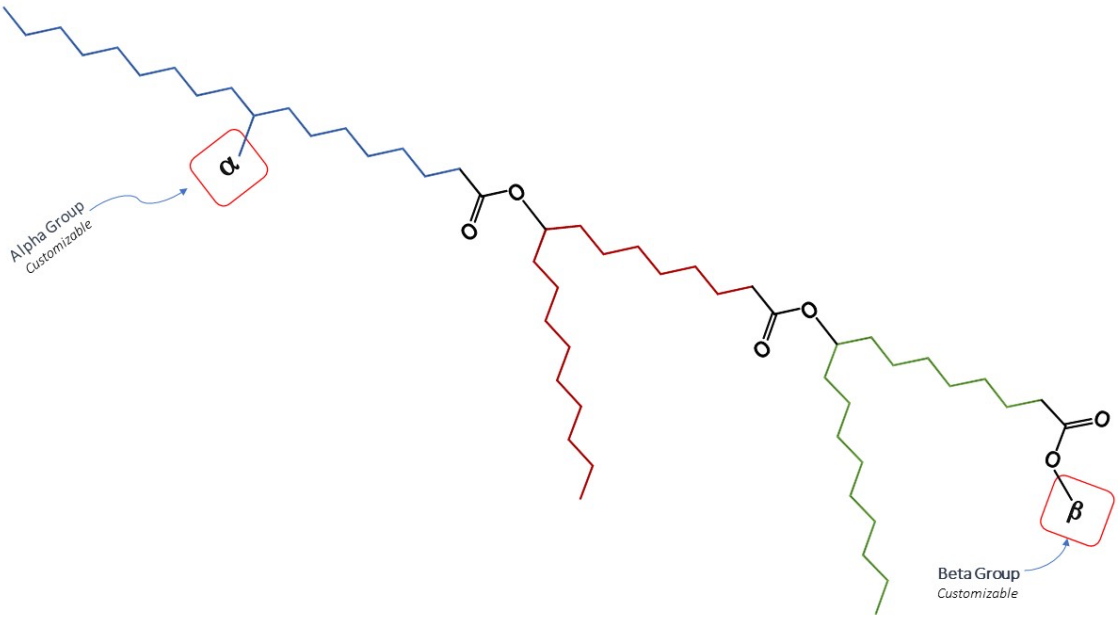
Molecular shape

A different way of looking at the estolide molecule in the modified BT graphic above, is shown in the graphic below, where oligomeric length (n) =1. It has been achieved by "twisting" the 2-dimensional shape above into another 2-dimensional one that is equally or more likely to occur. No stretching or distortions have taken place and all intersections between jagged lines are still 120°.

The key aspects of this representation are that the molecule is mostly straight, but with a couple of side branches. This is important to the function of estolides in high-performance lubricants.

The predominant linearity of the molecule means that the fluid (derived from billions upon billions of such molecules) will have a high *viscosity index*. This property is highly desirable in lubricants and represents how the viscosity changes with temperature. The viscosity of all fluids decreases with temperature, but a higher viscosity index, means that this rate of reduction with temperature is less. A formulator with a fluid with a high viscosity index can create a lubricant that has a higher viscosity at high temperatures than a competitor product or a lower viscosity at low temperature than a competitor, or both. Each property is desirable in different circumstances:

- Newton showed that the viscosity of a fluid holds the sliding surfaces of an engine, turbine, compressor etc. apart. The higher the viscosity at high temperatures, the more protection the lubricant imparts to the equipment in which it is installed.
- The downside of high viscosity is the energy lost in overcoming it. A lower viscosity at low temperatures means greater energy efficiency in a cold application (wind turbines at high altitudes or offshore) or in cold-start conditions (vehicles or factory equipment in cold weather).



Source: Trevor Gauntlett, 2020.

The branching means that it is difficult for estolide molecules to come to rest adjacent to each other, so the lubricant is less likely to become a solid in cold conditions. Under relatively rapid cooling, this property is referred to as the *pour point* and for lubricants the desirable property is as low as possible. If a lubricant solidifies, it doesn't flow between the parts when the equipment starts up, which can lead to rapid catastrophic failure as metal contacts metal.

Chemistry of Estolides in Lubricants

The alpha and beta parts of a commercialized estolide are essential for it to function effectively in a high-performance lubricant. The alpha group is essential to remove the unsaturation (i.e., convert the chemical bond between two carbon atoms into a single bond), which is susceptible to chemical attack (oxidation) during operation and is one of the main reasons why natural fats were replaced with crude oil-derived products for many lubrication applications in the early 20th century. The beta group is essential to ensure that there is no acid present, as acids lead to many degradation pathways in operation.

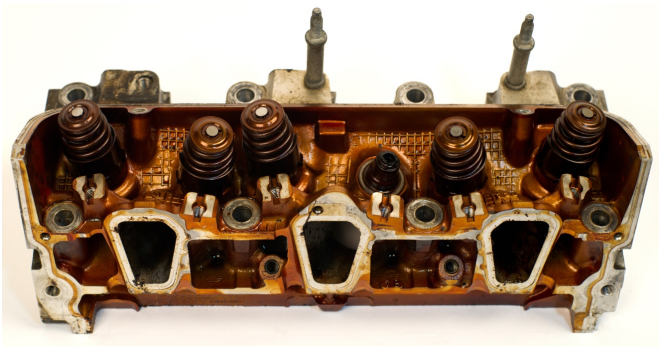
In the depiction above, the linear backbone contains three exposed oxygen atoms, denoted by "O". The presence of another element other than carbon means that the molecule has some *polarity* and the oxygen atoms are able to bind loosely onto a metal surface. This

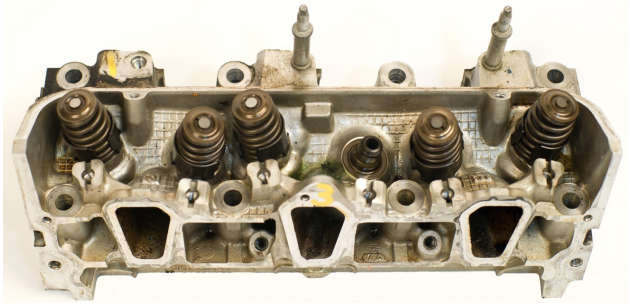
can protect the surface from wear and corrosion, plus it can help to reduce friction, all of which are desirable features of a lubricant. In comparison with PAO (see below), this is where estolides gain significant performance advantages.

Polarity is also beneficial in preventing the formation of sludges, gums and varnishes, which can cause problems at very low concentrations in the lubricant. The chemical precursors of these are degradation products of the lubricant, which are polar. They are formed at high temperatures in the presence of oxygen (usually from air) and/or water. This combination of conditions occurs in all combustion engines, turbines and air compressors. As a lubricant is relatively non-polar, these degradation products are attracted to each other and aggregate until they are large enough to block filters or stick to surfaces. The polarity of the estolide means that some (a small amount) of the estolide can bind to the degradation products and stop them agglomerating.

This type of resistance to high temperature degradation was demonstrated by BT in a Las Vegas taxi trial. The graphic below shows engine cylinder heads from two Chevy Impala 3.5 liter V6 engines used in an 18 month 150,000 mile field trial in Las Vegas, NV. The conventional motor oil formulation (top) had typical levels of varnish at the end of the test, while the estolide formulation (bottom) showed a high degree of overall cleanliness and minimal varnish.[133]

[133] Isbell, 2020, op. cit.





Estolides' Competitive Edge

An expert with whom we consulted was of the opinion that *there are no other molecules that bring to lubricant formulators the combination of properties outlined above.* It is also important in certain markets that estolides are derived from renewable sources, which can also be non-food sources — such as high oleic soybean oil — and that they are biodegradable. Indeed, finding a balance between durability in use and biodegradability at end of life or when spilled, experts say, has been something of a holy grail in lubricants for the past decade.

Estolides have similar physical properties to petroleum-based polyalphaolefins (PAOs), which are the current "gold standard" of lubricant base fluids for relatively mainstream high-performance products. Estolides are less stable in hot or hot/wet conditions but gain an advantage from their higher polarity. According to *Lubes'n'Greases* magazine, there are 300,000 tons per annum of PAO capacity globally.

Estolides appear to have better chemical properties than many petroleum-based polyalkylene glycols (PAGs) and high-performance esters, which, according to our expert consultant, can command high prices per ton, but are only found in relatively low volume applications. The renewable/biodegradable aspect of estolides also makes them potential

chemicals for use in personal care and cosmetics, where the quality and safety of ingredients provide value to consumers and high prices per ton for suppliers.

III. Licensing Estolide Technology

While the original patent for estolides was assigned jointly to the USDA and Lambent Technologies (a subsidiary of Petroferm), Petroferm chose to invest in the development of petroleum-based synthetic oils, rather than vegetable-based oils, and agreed to assign its rights in the estolide technology to USDA so that the agency could pursue other licensing opportunities.[134] The license to commercialize biodegradable lubricant base stocks was granted exclusively to the Montana-based company, Peaks & Prairies, LLC (hereafter P&P), in 2006.[135]

P&P had evolved from a regionally-focused oil seed growers cooperative, Montana EcoFuels of Thompson Falls, founded in the early 2000s.[136] Montana EcoFuels was looking to move up the value chain from raw materials — mustard seed, chia seed, rapeseed, and soybeans — to lubricants and fuel additives. They also hoped to create manufacturing jobs in their largely agricultural region of Montana.[137] Much of the original focus appears to have been supplying seed and converting it to oils for biodiesel and envisioning a processing plant (or plants) capable of producing 1 million gallons of vegetable oil a year.[138]

According to regional news accounts, Montana EcoFuels worked with Montana State University's Bio-based Institute in Bozeman and the Northwestern Agricultural Research Center in Kalispell, Montana, to apply for grant money ($40,030) to develop a feasibility study and business plan for processing oil seed crops grown in Montana into industrial grade vegetable oil and biodiesel additives.[139] The initial plan was for the grower's cooperative to start producing enough oil seed to supply a processing plant in the following growing season and to assess the best location for a combination pressing plant-biorefinery.[140] In 2002,

[134] Isbell, op. cit., 2020.
[135] *Federal Register*, Vol. 71, No. 12, Thursday, January 19, 2006, p. 3049.
[136] https://www.montana.edu/news/582/oil-crop-growers-form-biofuel-co-op.
[137] Jan Falstadof, "Company sees oilseeds as economic fuel in Montana," *Billings Gazette,* Apr 12, 2008.
[138] Mikkel Pates, "Oilseed Time," https://www.iatp.org/news/oilseed-time, May 15, 2006.
[139] https://missoulian.com/uncategorized/small-business-group-announces-recipients-of-agricultural-grants/article_4e0197de-62c8-53e0-a6c2-0ed8a55d8ea8.html.
[140] "Oil-crop growers form biofuel co-op," *MSU News Service,* October 31, 2002, <https://www.montana.edu/news/582/oil-crop-growers-form-biofuel-co-op>.

Montana EcoFuels changed its name to Peaks and Prairies Oils Seed Growers Cooperative because some of the Montana EcoFuels investors dropped out.[141] In 2004 the cooperative changed its name and legal status to Peaks & Prairies, LLC — in part to be eligible for larger grants — with Kent Wasson as its president.[142] Wasson was one of the original members of the Montana EcoFuels seed growers cooperative and, until recently, on Biosynthetic Technologies' Board of Directors.

The year 2006 was a busy one for the nascent vegetable oil producer. USDA entered into a CRADA with P&P to develop the estolide class of biodegradable lubricants.[143] At the time, USDA CRADAs were generally understood to be licensing opportunities and a long-term partnership.[144] Accordingly:

> "Peaks & Prairies, teamed with the USDA, set out to create a superior biobased motor oil using the patented estolide molecule. Lead scientists Dr. Steve Cermak and Dr. Terry Isbell participated in a technology transfer program to teach Peaks & Prairies' Chemical Engineer, Brett Earl, all the intricacies and processes of producing the estolide molecule. In the early phases of the project, Cermak, Isbell, and Earl worked together at the USDA NCAUR laboratory in Peoria, IL, to pinpoint the estolide base stock that would be the most suitable for the development of the biobased motor oil."[145]

The project, which spanned 2006-2008, is reported to have met with mixed success:

> "After pinpointing the estolide base stock, [P&P engineer, Brent Earl] went on to develop three grades of motor oil, 5W40, 10W30, and 15W40. The 5W40 was his first creation, which turned out to be an excellent learning tool to find additives to improve pour point and oxidative stability. Montana State University-Northern's Advanced Technology Center aided Peaks & Prairies in their research and development by creating a motor oil testing facility. By utilizing MSU-Northern's

[141] Kent Wasson, personal communication, July 12, 2020.
[142] Pates, op. cit.
[143] "DE-FG36-06GO16052 Peaks & Prairies, LLC. Eco Oil — Superior — Performance, Bio-Based Motor Oil," an undated mimeo, appears to be a progress report on the CRADA.
[144] Richard J. Brenner, "Technology Transfer Transactions: Implications to supporting policy, statutes, and enhanced partnership opportunities," APHIS Annual Agreements Conference, Riverdale, MD, April 7, 2009. ("Signing a CRADA is an obligation to a future licensing negotiation by USDA, and the relationship will last long beyond the CRADA.")
[145] DE-FG36-06GO16052, op. cit.

technology facilities, Peaks & Prairies was able to carry out preliminary testing at a fraction of the independent lab costs, establish benchmarks, and gain confidence prior to engaging in the more expensive certified testing.

By the fall of 2007, Peaks & Prairies was testing a 4 cycle biobased motor oil, 10W30, in a 5.5 horse Honda motor at MSU-N. The preliminary test results were impressive even though the formula still needed some tweaking. At that point, Peaks & Prairies began investigating the procedures to undergo API [American Petroleum Institute] testing at Southwest Research Institute (SWRI).

In July of 2008, a batch of 10W30 was shipped to SWRI to undergo the IIIG testing protocol, the most severe test of the API battery of tests. The 10W30 passed the weighted piston deposit, average cam-plus-lifter wear, hot stuck rings, and the oil consumption test; however, the formulation did not pass the viscosity increase test.
…
Earl also formulated a 15W40 to undergo military testing. Currently the viscosity index is being modified to meet military specifications. Once the formula has been modified, a sample will be sent to the U.S. Army's TARDEC facility for testing. [The document indicates that meeting the military specifications will take more research, development and testing.]

Throughout the course of the project, Peaks & Prairies discovered that there are many commercial avenues for the estolide molecule, i.e. cosmetics, inks, textiles, and lubricants. *Peaks & Prairies' initial goal is to capture 3% of the synthetic motor oil market in the U.S., which is a feasible goal once our Eco Oil 4 passes the API testing.* Our secondary goal is to find a niche for our estolide, other than lubricants, in the commercial markets. At this point, Peaks & Prairies holds the key to some viable intellectual property. *Seeking capital to make our presence [known] in the marketplace is our final move for success.*" [Emphasis added][146]

In 2006 P&P also received a two-year grant through the Department of Energy (DoE), to support the battery of tests required to meet American Petroleum Institute

[146] Ibid.

guidelines for vegetable-based motor oil.[147] Both the USDA CRADA, and the DoE grant, indicate the extent and nature of the collaboration between the private and public sectors (DoE, Montana State University, U.S. Army, and USDA) and the primary technical and business issues involved in what will turn out to be a long road to commercialization: formula tweaking and re-tweaking (to achieve the performance required of vegetable-based oils as discussed in the discussion of estolide technology above), testing and re-testing, identifying reliable suppliers, finding the right product niches, and finding the capital to scale to a commercial-level quantity, quality, and price.

While the full extent of the public-private collaborations that have helped bring the original USDA estolide molecule to market is not known to the authors, USDA's collaboration has spanned the long commercialization process. Subsequent estolide-related CRADAs were initiated in 2011, with LubriGreen Biosynthetic (entitled "Development of Biobased Lubricant") and, in 2020, with BT. All the details of the latter are confidential. USDA's ARS was twice awarded the Federal Laboratory Consortium Award for Excellence in Technology Transfer for the "Commercialization of Estolides as a Biobased Functional Fluid" (2011) and for the "Commercialization of Estolides as a Biobased Engine Oil" (2015).[148]

Other than the approximate date, and exclusive nature of the license to P&P, no other details about the license agreement itself, between the USDA and P&P and its successor organizations (LubriGreen Biosynthetics and BT), were discovered in literature searches and communications with the USDA and BT. [149]

Total license royalties paid by P&P and its successor organizations to USDA are estimated at approximately $2.6 million total (2012-2016) but the contractual nature of these royalty payments — fixed, tiered, percent of net sales, technical progress, etc. — is unknown. Furthermore, because P&P and its successors are privately held, very few public records (e.g.

[147] Pates, op. cit.
[148] https://federallabs.org/successes/awards/awards-gallery/2011/commercialization-of-estolides-as-a-biobased-functional-fluid; https://federallabs.org/successes/awards/awards-gallery/2015/commercialization-of-estolides-as-a-biobased-engine-oil.
[149] As this report was being finalized, the following information was conveyed by the former CEO of Peaks & Prairies, LLC (Kent Wasson, personal communication, August 16, 2020.): "[Six] Montana farmers made an initial down payment on the patent plus maybe one other prior to [when Biosynthetic Technologies] took over then I believe they negotiated lesser payments." This is interpreted to mean that initial fees and perhaps some of the annuity payments to keep the patents active were borne by Peaks & Prairies. It is unknown if these costs were borne differently between U.S. and foreign patents.

Security and Exchange Commission records) are available, so sales-related information — which might have provided insights into any special significance of USDA's foreign patent filings concerning the foundational estolide patents — is unavailable. That said, based on information we ascertained through interviews and other communications with BT principals, their estolide-based oil inventories are roughly split 50:50 between potential North American and European customers and the foreign patent protection granted the USDA's foundational estolide patents have had an important business strategic impact. Accordingly, BT affirms that foreign patent coverage was a critical part of their unfolding business opportunities. According to BT sources, the patents kept European competitors out of the market:

> "[W]e had more than one large EU chemical manufacturer verbally confirm that they avoided the estolide market because of the USDA patents in Europe."

The costs of the USDA research in support of the estolide technology, generally, or to P&P and its successor organizations specifically, are unknown.[150] The exclusively licensed USDA patents for the estolide technology expired in 2018. The specific costs of acquiring and maintaining the domestic and foreign patents, and of negotiating the licenses and CRADAs, are unknown.

III. Business-Strategic Commercialization Milestones and the Market for Green Oil.

The effort that became P&P started, catch-as-catch-can, by kludging together used equipment intended for other purposes, utilizing various oil seed varieties and seed suppliers, and relying on contributions of a few thousands of dollars from several individual seed grower-investors to build a seed-crushing capacity. This technical approach, and the one-member/one-vote structure of the growers' cooperative, was considered by the principals of

[150] One of the chief scientists involved in the USDA's estolide technology development was unwilling to estimate these costs, especially given the age of the records involved, the time it would take to discover them (if they were available), and the guesswork that would be entailed in estimating how the time of many researchers was allocated among many more or less related projects.

P&P to be unattractive to potential large investors.[151] And growing demand for biodegradable lubricants was looming.

According to a former P&P board member,

> "Initially, they were targeting oilseed crushing and … biodiesel … but there weren't incentives in the marketplace for the oil. They were thinking about a 1 million-gallon-a-year plant, and the initial feasibility studies [presumably, a finding of the 2006 CRADA with USDA discussed in the section above] said you needed to be a larger producer."[152]

So, P&P turned its attention to smaller-scale markets for things such as dust suppressants, bar and chain oil, lubricants and penetrating oils.

In the background, the 2002 farm bill's BioPreferred Program required that the federal government use 20 percent biodegradable products, where available and affordable, and created a labeling program to enable the marketing of biobased products.[153] In 2006, P&P's Wasson observed that the farm bill mandates hadn't been strongly enforced.[154] The Food, Conservation, and Energy Act of 2008 (also known as the 2008 U.S. Farm Bill) expanded the federal biobased program.[155] By 2012, the market for biobased lubricants accounted for only 1-5% of the total lubricants market according to estimates at the time. Demand was thought to be growing at an annual rate of 5-10%.[156] The USDA's BioPreferred Program was reauthorized and expanded as part of the Agriculture Improvement Act of 2018 (2018 Farm Bill) with the intention of spurring economic development, creating new jobs, providing new markets for farm commodities, decreasing the nation's reliance on petroleum, increasing the use of renewable agricultural resources, and contributing to the reduction in adverse environmental and health impacts of petroleum-based products.[157]

By 2018 — the year the USDA's foundational estolide patents expired — interest in products based on natural fats or oils derived from fatty acids were once again on the rise.

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[151] Pates, op. cit.
[152] Ibid.
[153] Jim Martin, Bart J. Bremmer, and Larry Plonsker, "Bio-Based Lubricants: A Market Opportunity Study Update, United Soybean Board, September 2013.
[154] Ibid.
[155] Ibid.
[156] Cynthia Challener, "Base oils supplement: betting on bio for better base oils," *Inform*, Vol. 23, No. 6, June 2012, pp. 383-84.
[157] https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml

Over the 10 preceding years the lubricant trade press observed an explosion of bio-derived molecules in the lab and on the market. Accordingly, an industry expert cited market research observing that, "while esters are a small segment of the synthetic lubricants group, the global esters lubricants market is expected to grow to an estimated U.S. $1.83 billion by 2022 from $1.17 billion in 2012."[158] This expert heralded "a new phase of synthetic base fluid development":

> "A host of molecules have recently become available to lubricants formulators and the chemicals industry that are based on novel chemistry and biochemistry. While some are completely new chemicals, the others are existing molecules historically manufactured as petrochemicals,…. [T]hese molecules come from renewable sources, most are biodegradable, and many have low toxicity, which is especially useful for food and pharmaceutical- grade applications. …. [T]here are companies – some with big financial backers – that are developing processes and product lines that have direct application in lubricants. These processes involve novel chemistry, or biochemistry based on bacteria, algae and other, often genetically modified, organisms … Estolides are another naturally sourced option to create synthetic base stock that has strong performance characteristics for oxidative and hydrolytic stability, volatility, biodegradability and renewable carbon content."[159]

In the long-term, and in retrospect, the market for estolide-based oils is, and has been, on the rise due to its chemical qualities, its relatively low production costs, and growing global concerns about sustainability. Sometime between 2008 and 2010, after years of efforts to refine, test, and market its products and processes (in partnership with USDA), as well as secure sufficient private equity funding to finance large-scale production, P&P was reorganized into LubriGreen Biosynthetics, perhaps based on plans to raise money for building as many as six manufacturing plants.[160] Lubrigreen Biosynthetics marketed Peaks &

[158] Trevor Gauntlett, "Beyond Esters to Next-Generation Synthetic Base Fluids: The resurgence of naturally sourced, renewable synthetic base fluids," *LUBES'N'GREASES — EUROPE-MIDDLE EAST-AFRICA*, March 2018, pp. 26-30.
[159] Ibid.
[160] This is an unconfirmed conjecture based on the cited 2008 regional news report quoting Kent Wasson, the fact that the USDA/Peaks & Prairies CRADA was completed in 2008, and a 2014 report by an equity investor in Biosynthetic Technologies — Evonik — that "previous financing rounds" had included such large organizations as BP Ventures and the Monsanto Company (https://corporate.evonik.com/en/evonik-invests-in-biosynthetic-technologies-105249.html). Perhaps these "previous financing rounds" coincided with the transition from Peaks & Prairies to LubriGreen Biosynthetics.

Prairies' estolide-based lubricants under the brand name, LubriGreen® Biosynthetic Oils. Lubrigreen Biosynthetics was renamed BT in 2010.[161] Beginning with P&P's estolide oil technology, BT enhanced the oil's physical properties to address technical shortcomings (acid content, pour point, etc.) and created a more commercially-viable "Estolide 2.0" product. In 2011, BT entered into a CRADA with USDA entitled "Development of Biobased Lubricants."

During the transitional arc from P&P to BT, different business plans were presented to potential investors as alterative paths to commercial-scale operations. An early LubriGreen Biosynthetics plan was to develop the licensed USDA technology using a large-scale, continuous process manufacturing process. This approach didn't generate enough interest among investors. Promoting a financial package to build a dedicated manufacturing plant for the production of just one molecule — an estolide molecule, that wasn't yet well-accepted in the market — was a "tough sell" according to a close observer.

A second market plan led onto the path of developing scores of patents — the vast majority of which reference the original USDA estolide patents and/or papers by the USDA inventors[162] — that protected the estolide molecule and, especially (given that the foundational estolides patents would expire in 2018), protected the production process itself and its employment in various end use applications. Regarding the production process, in lieu of a single large-scale production facility, BT has had to secure its intellectual property against encroachment by "toll manufacturers," domestic and foreign.[163] This patenting strategy protects multiple end users against a scenario in which BT supplies estolide base oils to a customer with a specific application and that customer patents *that use* of the estolide thereby excluding other potential customers from making that product under license from BT.

[161] https://www.sec.gov/Archives/edgar/data/1577689/000157768913000001/xslFormDX01/primary_doc.xml.
[162] The authors examined 53 granted patents assigned to Biosynthetic Technologies by the USPTO in 2020 and all reference U.S Patents No. 6018063 and/or No. 6316649.
[163] In toll manufacturing, one company provides raw materials (or semi-finished goods) to a third-party, who will then provide the rest of the services (manufacturing). Typically, the third-party company will already have particular equipment and organizational models in place, and they can supply subclasses of manufacturing processes for the first company for a fee – or toll. https://www.sierracoating.com/toll-manufacturing-versus-contract-manufacturing/

Patent licenses can be an important asset in fund-raising and acquisition efforts. According to patent strategy experts:

> "Patents are often crucial for companies to raise funding or be acquired. If keeping the company's inventions secret would cripple its ability to secure funding or business partners, then patent protection is probably a better choice. This is likely to apply to small companies that don't yet have any products and where the value of the company lies primarily in its patents. Also, obtaining patents can sometimes deter competitors from developing similar products."[164]

During the transition from P&P to BT, this patenting strategy allowed BT to raise approximately $60 million in venture capital.[165] In conjunction with increasing global concerns about environmental protection and sustainability, the strategy attracted another venture capital organization. Biosyn Holdings — a partnership of the Heritage Group and Calumet Specialty Products — purchased BT in March 2018.[166]

Today, BT appears poised for take-off in the global market for bio-based lubricants, having: capitalized on the USDA's original estolide invention; refined the applicability of estolides to a wide range of products; advanced and protected the technology's further commercialization potential through a robust patenting strategy; and secured substantial equity investments, over time, for development and further commercialization of the estolide technology in the future. The announcement of the purchase of BT by the venture capital company Biosyn Holdings projected the future of the estolide technology that originated at USDA:

> "Biosyn Holdings intends to continue Biosynthetic Technologies' efforts to commercialize its estolides technology for applications across a diverse portfolio of products and solutions in a variety of end-markets. This could include internal or external licensing or the sale of the technology for applications across a diverse portfolio of products and solutions in a variety of end-markets."[167]

The story of the full economic impact of that technology, and the continuing public-private collaboration with the USDA, is yet to be written.

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[164] Mike Fuller & Kim Kennedy, "Trade Secrets Or Patents?," *Life Science Leader,* May 1, 2020.
[165] https://www.linkedin.com/in/allenbarbieri/.
[166] https://www.sec.gov/Archives/edgar/data/1340122/000134012219000040/clmt-20181231x10k.htm.
[167] https://www.biosynthetic.com/storage/BT-Acquisition-PR_Modified.pdf

IV. Conclusion

This case study is a study in "patient capital," of the public sector, private sector, and public-private varieties. In part it is a story about patient "intellectual capital" that has spanned a professional lifetime and has bequeathed an intellectual inheritance to the next generation of scientist-entrepreneurs. Dr. Terry Isbell developed a practical method to synthesize the unique estolide compounds from common fatty acids in 1991. With a long and continuing career, 25 years later, he co-authored a review of estolides with Jakob Bredsguard, the former chief technology officer and current executive vice president of BT.[168] The patents that Isbell and Cermak and Isbell applied for in 1998 and 2000, respectively, expired some 20 years later (2018) and earned USDA millions of dollars in revenues along the way. The first estolide-related CRADA started in 1994 and subsequent technical collaborations occurred and continue to occur in 2020; twenty-six years of technical public-private partnership.

The long and steady flow of technical know-how may, or may not, have been a success in terms of a narrowly financial return-on-investment in patenting costs (as contrasted with the much larger commercial impacts of the technology transfer). We haven't been able to discover little those costs and who bore them. But it surely has been a success in terms of what is arguably the primary purpose of federal agencies' technology transfer efforts: commercialization of the agencies' inventions.

How could the USDA's Office of Technology Transfer have foreseen these developments when they decided, somewhat before 1998, that these inventions were worth the cost of applying for, acquiring, and maintaining patent protection? They couldn't. But clearly, as the careers of the USDA inventors demonstrate, the technology was consistent with USDA's mission and clearly, too, there was (and continues to be) private sector interest in completing the long journey from lab-to-market. These were likely two key considerations – the agency's mission and the private sector's interest in environmentally friendly, biobased lubricants – in USDA's original decisions to patent the estolides inventions.[169]

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[168] Bredsguard, J. W., et al. "Estolides: Bioderived synthetic base oils." *Environmentally Friendly and Biobased Lubricants,* 2016, pp. 35-49.

[169] United States Government Accountability Office (GAO), *Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions* (GAO-18-327), Washington, D.C., June 2018.

On the private sector side, as well, the persistence of some of the early oilseed grower entrepreneurs is remarkable. Even if the original vision of an increase in local manufacturing jobs may not have been achieved on the scale initially envisioned, the persistent belief that the right estolide-based oil formulations would eventually find a place in the right expanding product markets certainly has been vindicated. Knowing, too, that large scale operations required large-scale financial commitment, appears to have propelled reorganization after reorganization which has come to rest with a long-lived, and apparently relatively successful venture capital backed company: Biosyn Holdings, combining significant venture investment (HG Ventures) with an experienced and executive team focused on changing and, in the long-term, growing markets for estolide base oils.

The econometric analysis of which this case study is part, stresses the high return-on-investment (ROI) to costs incurred by foreign patenting, relative to the costs of acquiring and maintaining domestic patenting alone across federal agency invention portfolios. On the basis of that analysis, we hypothesize that licensed technologies protected with U.S. patents but without complementary protection in non-U.S. jurisdictions may be perceived as "damaged goods" in the intellectual property market; that without foreign patent protection foreign competitors can compete in the international markets without incurring the costs of royalty payments for the use of the technology. This case study is clarifying in that regard. Foreign patent protection was obtained by USDA for the estolide compounds (though the details of who paid, and how much, is unknown) in Canada, Europe, Germany and Spain, and BT representatives confirm our "damaged goods" hypothesis, observing that the USDA foreign patents had an important strategic impact by keeping European competitors out of the world market for estolides. It appears that P&P bore some of the patenting and maintenance costs but we have not yet been able to confirm this with a private sector representative. If true, the overall narrow financial ROI, based on royalties alone, to the USDA of its patenting cost investment in foundational estolide technologies would be improved. In the context of the broader returns and USDA's mission, the returns to the patenting costs have been and are expected to continue to be very substantial. Moreover, the commercialization of USDA's patented technology is also protected by the foreign patents that have been acquired by BT. In the families of BT's patents for its USPTO patent applications from 2011 onward, the U.S. and foreign patents in the families were published between August 2011 and January 2020.

There are 88 distinct patents in the families, and 29 of those are foreign patents.[170] The original USDA foreign patents played the crucial strategic role of protecting the transferred technology in its incipiency from foreign competitors and allowing time to establish the large patent family that protects BT's estolides technology today.

If our hypothesis concerning the ROI on foreign patenting (across 11 federal agencies) is correct, the apparent success of the license in generating an estimated $2.6 million (2012-2016) is, in part, a testimony to the strategic value of foreign patent protection. The larger testimony is the large patent family that has grown from the original USDA patents and the high-growth possibilities for the commercialization of the estolides technology.

Our econometric analysis estimated that for USDA the present discounted value of its costs for a typical foreign patent over its lifetime would be $30,318 (in constant 2015 dollars). The present discounted value of its costs for a typical U.S. patent was estimated to be $26,593 (in constant 2015 dollars) over the patent's lifetime.[171]

If we assume that the costs of the foundational estolide patents are in the neighborhood of the patenting costs cited above, and we assume that USDA paid *all* the U.S. and foreign patenting costs, USDA would have incurred costs with present value in 1998 of approximately $174,500 (in constant dollars of 2015) over the life of the two USDA estolide patents. Without knowing the timing of the royalty payments, we cannot compute their present discounted value, but using the estimate of $2.6 million in revenues paid to USDA 2012-2016, centering the sum on 2014, and discounting the total with the OMB-mandated 7% opportunity cost of public investment funds, would give a present discounted value of $881,000. Thus, even using the narrowly financial measure of the return on the patenting costs, the ROI as measured with a very rough benefit-to-cost ratio of 5.0 surpasses the benefit-to-cost ratio of 2.2 estimated for protecting the intellectual property of a USDA

[170] The numbers are based on the authors' compilations from PATSTAT, Spring 2020 edition, https://data.epo.org/expert-services/.

[171] The estimated costs are the present discounted values over the patent's lifetime of the sum of the maintenance fees (referred to as annuities costs) and law firm costs. Cost of adding a U.S. patent = $26,593 = (Annuity cost for U.S. patent = $3,025) + (law firm cost for U.S. patent = $23,568) as estimated in Section IV of our Task 2 report. Cost for USDA of adding a foreign patent = $30,318 = (Annuity cost for foreign patent = $6605) + (law firm cost estimated for USDA = $23,713) as estimated in Section V of our Task 2 report. The estimated costs differ for each agency because the agencies differ in their typical annual number of foreign patent applications.

USPTO-patented technology with a foreign patent.[172] If P&P or its subsequent incarnations paid any of the patenting costs, the ROI to USDA's investment in estolide patents is greater still. But that is just the narrow, financial return to USDA from the royalties. The commercialization benefits are of course much greater. The post-patent, "second generation" commercialization benefits of transferring the estolide technology are likely to be even greater in the years to come.

Finally, we observe that if "patience" is a quality that characterizes the long-term commitment to commercialization of the USDA, other public sector organizations, and the private sector organizations that evolved from Montana EcoFuels of Thompson Falls, patience is also a quality that might characterize the research required to bring licensing case studies to fruition. With rare exceptions, "confidentiality" clings to license collaborators, public and private. Without a congenial phone interview with the current CEO of BT, that sketched out only the broad outlines of the narrative developed here, and his forbearance, within limits, in the face of too many detailed follow-up questions, there would have been no skeleton story to fill in and dress up. Most candidate case studies suggested by (few) of the 11 federal agencies responding to our simple survey could not be pursued because either the agency contact in the Office of Technology Transfer (representing the licensor) felt that s/he could not discuss *any* details pertaining to a potential case study, or the private sector counterparts (licensee) felt the same. While one agency did respond with genuinely helpful details — private sector licensing contact information and royalty revenues by fiscal year — they were obtained well after the other 11 suggested case study candidates had been "necked down" to one: USDA's licensee, Biosynthetic Technologies.

Consistent with the pattern among most other federal agencies, USDA's OTT provided almost no useful information. This is an observation not a complaint and it is made as a way of asking, "What *is* the federal and business policy regarding confidentiality?" Why can one organization — public or private — provide some details while another provides none, or next to none. Clarifying the answer to this question could be useful as leverage in obtaining (perhaps prying) information from agencies and companies in future licensing case studies. Ideally, licensors and licensees would agree to share information with the case study researcher. In lieu of that, knowing what information can and cannot be legitimately

[172] The 2.2 benefit to cost ratio for USDA is estimated in our Task 2 report.

discussed within the context an existing or expired license would be helpful in countering claims — perhaps legitimate — that *no* information may be discussed. In another case study for this project, legal documents contained some detailed license information. Some was redacted, some was not. Presumably the information that was *not* redacted is, in fact, legitimately accessible, blanket claims of complete confidentiality to the contrary.

The Drug-Eluting Coronary Stent: the National Institute of Aging (NIA) within the National Institutes of Health (NIH) Invention and Technology Transfer of Taxol (Paclitaxel) Coated Coronary Stents[173]

I. Introduction.

This case study describes the invention of drug-eluting stents in the research laboratories at the National Institute of Aging (NIA) within the National Institutes of Health (NIH) and the successful transfer of the technology as commercialized for use in interventional cardiology in the worldwide coronary stent market. The technology earned millions of dollars in royalties for the U.S. government, repaying many times over the public's investment in the research project that created the invention. Even more importantly, the technology, when successfully transferred as the commercialized Taxol (paclitaxel) coated coronary stents used in interventional cardiology, has allowed millions of patients to avoid coronary bypass surgery.[174]

In 2006, the *NIH Record* observed[175]:

> To say that NIH intramural researchers had a banner year in 2005 is an understatement, at least according to one business standard. Last year, the NIH Office of Technology Transfer collected close to $100 million in royalties from products or processes invented by scientists working here. That's nearly double the $56 million-plus NIH inventions earned for 2004. Even better for medical research are the millions more people these new concepts will help by going commercial. Take, for example, one of the top NIH inventions in recent years—the Taxol-coated stent. Both the drug Taxol (paclitaxel) and the stent were already on the market separately, being used to treat cancer and heart disease, respectively. Who would have thought of combining the two—coating the stent with Taxol—for even further benefit? Two NIA scientists did. Dr. Steven Sollott and Dr. James Kinsella found that implanting stents coated with the chemotherapy drug significantly reduces re-clogging of arteries. The invention, which went on the U.S. market in 2004, has been a medical marvel for the more than half a million Americans each year who now can avoid heart bypass surgery by having the stent placed instead. It was also the top commercially successful intramural invention for fiscal year 2005, based on royalty income.

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[173] We thank Robert S. Danziger, Professor of Medicine, Pharmacology, Physiology and Biophysics, University of Illinois at Chicago, for his insights as a domain expert in the subject area of this case study and for his research in a paper that we use and cite, Robert S. Danziger and John T. Scott, "Government Royalties on Sales of Pharmaceutical and Other Biomedical Products Developed with Substantial Public Funding," June 2020, Working Paper. Professor Danziger's willingness to share his knowledge made this case study possible.

[174] The drug-eluting coronary stents that have evolved from the NIA/NIH invention are implanted in more than 500,000 patients every year in the U.S. alone (Giulio G. Stefanini and David R. Holmes, Jr., *New England Journal of Medicine*, vol. 368, no. 3 (January 17, 2013, pp. 254-265, at p. 254).

[175] Carla Garnett, "2005 Royalties Nearly Double from '04: Tech Transfer Helps NIH Breakthroughs Break Through," *NIH Record*, Vol. LVIII, No. 9 (May 5, 2006), p. 1, continued on p. 8, https://nihrecord.nih.gov/sites/recordNIH/files/pdf/2006/NIH-Record-2006-05-05.pdf.

Table 1 provides an overview of key events in the technology transfer story for the paclitaxel-eluting coronary stents. Accomplishing the successful technology transfer for an invention resulting from the research in a federal agency's laboratory is often difficult and risky and lengthy. The story of the technology transfer of the drug-eluting coronary stent attests to the length of the process, as seen in Table 1. Approval by the FDA and the commercial introduction in the United States came over a decade after the initial patent application was filed with the U.S. Patent and Trademark Office (USPTO).

As seen in Table 1, our story about the technology transfer process for the paclitaxel-eluting coronary stent begins in 1993 with the original USPTO application by the inventors, Dr. Sollott and Dr. Kinsella, and ends in 2013 with the expiration of the USPTO patents that followed from that original application. The application and the grant of worldwide, limited field of use, rights to practice the inventions embodied in whatever U.S. and foreign patents ensued from that application formed the basis for NIH's grant to Angiotech Pharmaceuticals of an exclusive license to use the invention. Holding that license, Angiotech granted co-exclusive licenses for production and sale of products using the technology to Cook Incorporated and Boston Scientific Corporation. As the technology transfer process played out, Cook decided to abandon coronary stents and to focus on paclitaxel-eluting peripheral vascular and gastrointestinal stents; and thus, Boston Scientific was granted an exclusive license for the coronary stents. Boston Scientific continually developed the paclitaxel-eluting coronary stent technology and sold the stent systems worldwide, generating billions of dollars in sales and paying millions of dollars in royalties to Angiotech Pharmaceuticals. Angiotech in turn paid millions of dollars in royalties to NIH over the lifetime of the patents.

In Section II, we describe the patented technology and the family of U.S. and foreign patents that evolved from the original USPTO application in 1993 by Dr. Sollott and Dr. Kinsella for the NIA/NIH technology that their research created. Section II also discusses from NIH's perspective the difficulty and riskiness of initiating the technology transfer process and obtaining the patents while the future for whatever commercialization would actually occur is completely uncertain.

Section III describes the licenses that were based on the patented paclitaxel-eluting stent technology. Also discussed are the special attributes – that helped to make the

technology transfer successful – of NIH's exclusive licensee, Angiotech Pharmaceuticals, and Angiotech's co-exclusive licensees, Cook and Boston Scientific.

Section IV describes the history of the commercialized technology, providing details about sales, in the U.S. and internationally, and about the royalties earned by NIH relative to the returns to the licensees of the technology.

Section V describes the importance of the foreign patents obtained by NIH. The foreign patents were important for the success of the commercialization. However, the foreign patenting process is not as simple as filing the applications and receiving the grants. The foreign patents also required litigation, and that too is discussed.

Section VI concludes by emphasizing the importance of the NIA paclitaxel-eluting stent invention for the evolution of the worldwide coronary stent market, and by summarizing the ways that foreign patents were important for the successful transfer of the NIH paclitaxel-eluting stent technology.

Table 1. Key Events in the Technology Transfer of the Paclitaxel-Eluting Coronary Stent.

Date	Event
7/29/93	Patent application Ser. No. 08/099,067 (subsequent applications are continuations of this original application and the resulting publication, US9906793A to which the subsequent patents are traced)
4/18/96	Patent application (ultimately granted as US5616608A and published 4/1/97)
11/7/96	*Federal Register*, Vol. 61, No. 217, p. 57694, publishes the pre-license notification of the intent to grant an exclusive license to Angiotech Pharmaceuticals, Inc. to practice the inventions in the patents and patent applications related to U.S. Patent Application Serial No. 08/099,067 filed July 29, 1993; and all continuation applications, divisional applications, continuation-in-part applications, and foreign counterpart applications related to U.S. Patent Application Serial No. 08/099,067.
3/21/97	Patent application (ultimately granted as US6429232B1 and published 8/6/02)
4/1/97	US5616608A published, priority to US9906793A
7/9/97	Angiotech Pharmaceuticals, Inc. grants co-exclusive license to Boston Scientific Corporation and Cook Incorporated for the drug-eluting stent technology for which Angiotech will be granted an exclusive license in 11/19/97 agreement with NIH.
11/19/97	NIH grants exclusive license to Angiotech Pharmaceuticals, Inc.
8/17/00	Patent application (ultimately granted as US6403635B1and published 6/11/02)
January, 2002	Cook files for approval to market in the European Community its paclitaxel-eluting coronary stent to combat restenosis, making it the first company to submit for regulatory approval anywhere in the world to market a paclitaxel-eluting coronary stent to combat restenosis.
4/11/02	Patent application (ultimately granted as US6500859B2 and published 12/31/02)
6/11/02	US6403635B1 published, priority to US9906793A
8/6/02	US6429232B1 published, priority to US9906793A
September, 2002	Cook receives CE Mark approval for its paclitaxel-eluting ACHIEVE™ coronary stent in the European Community. It will not be launched in Europe until a ruling is reached regarding litigation around the stent.

September, 2002	Cook receives CE Mark approval to market it paclitaxel-eluting V-Flex™ Plus PTX coronary stent in the European Community. Cook will begin selling its new drug-eluting coronary stent to European medical institutions immediately.
12/31/02	US6500859B2 published, priority to US9906793A
January, 2003	Boston Scientific receives CE Mark approval for its TAXUS™ paclitaxel-eluting coronary stent system and plans to launch the product next month in Europe and other international markets; it plans to launch the product in the United States later in the year.
February, 2003	Boston Scientific initiates the launch in Europe and in other international markets of its TAXUS™ paclitaxel-eluting coronary stent system.
September, 2003	Boston Scientific receives approval for sale of its TAXUS™ paclitaxel-eluting coronary stent system in Canada and plans to launch the product immediately in Canada.
March, 2004	Boston Scientific receives U.S. FDA approval to market its TAXUS™ paclitaxel-eluting coronary stent system and plans to launch the product in the U.S. immediately.
September, 2004	Angiotech Pharmaceuticals, Inc. and Cook Incorporated announced changes to their license agreement regarding paclitaxel-eluting stent products and related technologies. The 1997 Angiotech License Agreement has been restructured to accommodate Cook's election to exit the coronary vascular field for business reasons and to focus on the development of paclitaxel-eluting peripheral vascular and gastrointestinal stents.
September, 2004	TAXUS™ was approved for sale in Europe on January 21, 2003 and in the U.S. on March 4, 2004. As of September 30, 2004, U.S. TAXUS™ sales surpassed $1.0 billion (U.S. dollars) and total worldwide sales exceeded $1.6 billion (U.S. dollars), making the launch of TAXUS™ one of the most successful commercial launches in medical history.
November, 2004	Boston Scientific Corporation becomes the exclusive worldwide licensee to Angiotech's coronary drug-eluting stent technology. Under the terms of the 1997 License Agreement between Boston Scientific and Angiotech, Boston Scientific's royalty obligation for sales of licensed coronary vascular products (*e.g.,* TAXUS™) will be increased by one percent. This will have the effect of increasing Angiotech's TAXUS™ royalty revenues by approximately 14% (elevating the royalty tiers to 6%, 8%, and 11%, respectively).
January, 2005	Boston Scientific launched its TAXUS™ Liberte™ paclitaxel-eluting coronary stent system in 18 countries outside of the European Union and the U.S. The TAXUS Liberte stent system features Boston Scientific's next-generation Liberte™ coronary stent.
January, 2005	Boston Scientific announces the implantation of its millionth TAXUS® Express2™ paclitaxel-eluting coronary stent system, marking a major milestone for Boston Scientific and for the treatment of coronary artery disease.
September, 2005	Boston Scientific begins selling the TAXUS Liberté paclitaxel-eluting coronary stent system in Europe.
April, 2005	Boston Scientific Corporation receives CE Mark approval for three large vessel sizes (4.0mm, 4.5mm and 5.0mm) of its TAXUS® Express2(TM) paclitaxel-eluting coronary stent system in Europe and other international markets. BSC plans to launch the new sizes immediately and will continue to supply all sizes of its TAXUS stent systems. Previously, the largest drug-eluting stent system size available was 4.0mm, which limited clinicians' options for treating patients with large vessels. The launch of Boston Scientific's three large vessel TAXUS stent systems completes its line of sizes available in Europe and international markets, making it the first company to offer a full range of stent sizes.
April, 2007	Boston Scientific receives Japanese approval for the TAXUS® Express2™ stent system.
April, 2008	Boston Scientific receives approval for sale in Canada of the TAXUS® Liberté™ paclitaxel-eluting coronary stent system.
September, 2008	Boston Scientific receives approval from the U.S. Food and Drug Administration (FDA) to market and sell the Taxus Express2 Atom™ Paclitaxel-Eluting Coronary Stent System in the United States. The TAXUS Atom stent systems are the only drug-eluting stents available that are specifically designed to treat lesions with diameters as small as 2.25 millimeters.
October, 2008	Boston Scientific receives approval from U.S. Food and Drug Administration (FDA) to market and sell the second generation TAXUS Liberté® Paclitaxel-Eluting Coronary Stent System in the United States.

May, 2009	Boston Scientific begins sales of the TAXUS Liberté Atom Paclitaxel-Eluting Coronary Stent System in the U.S.
July, 2009	Boston Scientific begins sales in the U.S. of the TAXUS Liberté Long Stent, which at 38 millimeters is the longest available drug-eluting stent.
June, 2010	Boston Scientific began sales of the TAXUS Element paclitaxel-eluting coronary stent in the Europe, its third-generation paclitaxel-eluting coronary stent.
12/29/10	Angiotech entered into an amendment to the November 1997 exclusive license agreement with NIH. Per the amendment, NIH agreed to eliminate (i) approximately $7.2 million of unpaid royalties and interest due on sales of TAXUS by Boston Scientific, and (ii) future royalties payable on licensed products sold by Boston Scientific going forward, in exchange for a 0.25% increase on the existing royalty rates for licensed products sold by Cook and an extension of the term for payment for such royalties of approximately two years.
February, 2012	Boston Scientific receives U.S. FDA approval for the use of the TAXUS Liberte™ and the TAXUS ION™ coronary stent systems in patients experiencing an acute myocardial infarction (heart attack).
7/29/13	US6500859B2 expires
7/29/13	US6429232B1 expires
7/29/13	US6403635B1 expires
7/29/13	US5616608A expires

Source: Danziger and Scott, op. cit.; compilations from U.S. Securities and Exchange filings, and from the European Patent Office's worldwide patent database PATSTAT, and from USPTO.

II. Patented Technology and the Process of Obtaining Patents: The First Step in the Technology Transfer Process for NIH's Patented Taxol (Paclitaxel) Coated Coronary Stent Technology.

In this section, we describe the patented technology developed by Dr. Sollott and Dr. Kinsella at NIA within NIH. We describe how it is used commercially. We then describe the family of U.S. and foreign patents that evolved from the original patent application to USPTO in 1993. We also discuss the difficulty and riskiness of initiating the technology transfer process by obtaining the patents while the future for whatever commercialization would actually occur is completely uncertain.

The patented technology. As observed in the Section I, when coronary stents can be used successfully, the patient is spared the ordeal of major surgery that coronary bypass operations entail. As we will see in Section IV, Boston Scientific Corporation successfully commercialized the paclitaxel-eluting coronary stent that began with the invention in the laboratories of NIA. Appropriately, then, to explain the technology, we begin with Boston Scientific's own explanation.

In its "Patient Information Guide" provided for each type of stent that it sells, Boston Scientific provides a helpful sketch of a heart that illustrates the major arteries into which coronary stents are typically placed.[176] The sketch is shown in Figure 1.

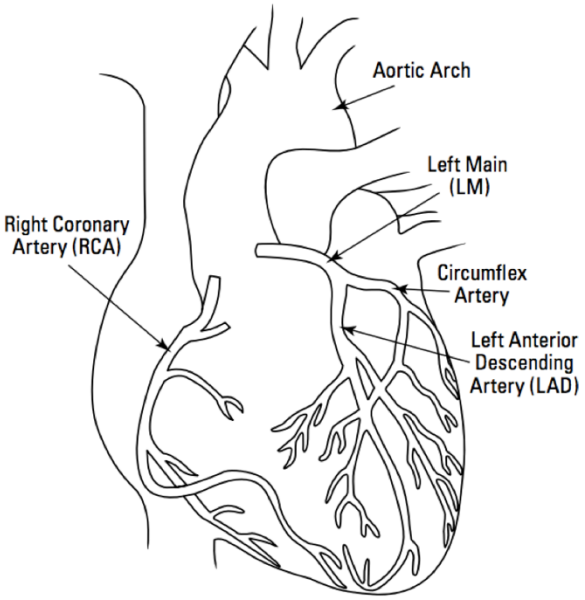

Figure 1. The Major Arteries of the Heart.
Source: Boston Scientific's "Coronary Stent System: Patient Information Guide," https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90996662-02A_PromusPremier_patgde_en_US_S.pdf.

Boston Scientific provides heart patients who are the recipients of its coronary stents with the following description of "How Coronary Stents Work," along with the illustration of the stent procedure shown in Figure 2.[177]

> Coronary stents are small, wire, mesh tubes that help widen a clogged artery and restore adequate blood flow to the heart. During the procedure, your cardiologist will place the stent over a thin, long tube with a balloon tip called a catheter and insert it into an artery in your groin or arm. Once the stent reaches the clogged artery, your doctor will inflate the balloon to expand the stent. When the stent reaches the desired size to widen the clogged artery, your doctor will deflate and remove the balloon. The stent will stay in place permanently to help prop open the artery and decrease its

[176] For example, see ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System: Patient Information Guide, https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90461990-02C_ION_patgde_us_S.pdf, or "Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System Patient Information Guide," https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90996662-02A_PromusPremier_patgde_en_US_S.pdf.
[177] https://www.bostonscientific.com/en-US/patients/about-your-device/coronary-stents/how-coronary-stents-work.html

chance of narrowing again. Over time, the inner lining of the artery will grow over the surface of the stent, making it a permanent part of your artery.

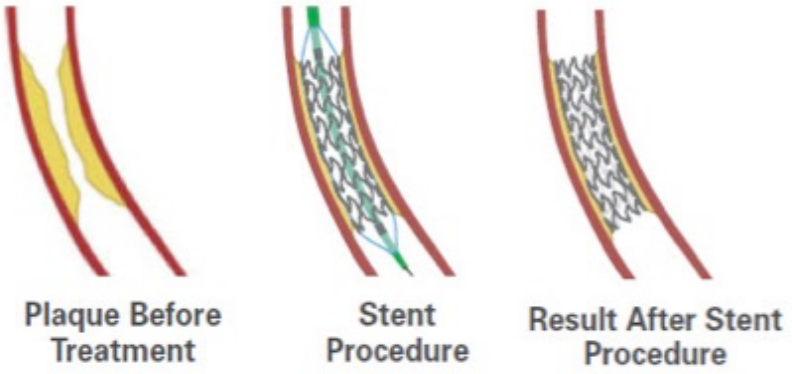

Figure 2. The Stent Procedure Illustrated with a Side View of a Coronary Artery.
Source: Boston Scientific, "How Coronary Stents Work," https://www.bostonscientific.com/en-US/patients/about-your-device/coronary-stents/how-coronary-stents-work.html

Recall from Table 1 that in February 2012, Boston Scientific received U.S. FDA approval for the use of the TAXUS Liberte™ and the TAXUS ION™ coronary stent systems in patients experiencing an acute myocardial infarction (MI), commonly referred to as a heart attack. It is worth noting that when a patient arrives at a hospital emergency room in the midst of an acute heart attack, the left-most panel in Figure 2, that depicts the artery before treatment, may be completely blocked because soft plaque has ruptured and completely blocked the flow of blood.[178]

Boston Scientific explains the distinction between bare-metal stents (BMS) and the drug-eluting stents (DES) that were pioneered by the paclitaxel-eluting coronary stent invented by Dr. Sollott and Dr. Kinsella at NIA.[179]

Bare-Metal Stents
Bare-metal stents are tiny wire mesh tubes that help widen a clogged artery, but are not coated with a polymer or drugs to help prevent re-blockage of the artery. This type of stent may be used in patients who are allergic to either the polymer or drugs used in drug-eluting stents.

[178] One of the authors of this report, Scott, experienced just such an acute MI, and Boston Scientific's stents were placed in the left anterior descending artery and the circumflex artery. Since then, he has carried in his wallet a card provided by Boston Scientific with the picture shown in Figure 1, and with his cardiologist's addition to the figure of the locations of the stents.
[179] https://www.bostonscientific.com/en-US/patients/about-your-device/coronary-stents/how-coronary-stents-work.html

Drug-Eluting Stents
A drug-eluting stent is a bare-metal stent that has been coated with a polymer that gradually releases a drug over the time when re-blockage is most likely to happen. This helps reduce the chance of the artery becoming blocked again.

In the context of its importance for interventional cardiology, Dr. Robert S. Danziger has described the drug-eluting stent technology invented at NIA within NIH. Dr. Danziger, a cardiologist and Professor of Medicine, observes[180]:

> Heart disease is the leading cause of death in America, and coronary artery disease or narrowing, secondary to atherosclerosis, that reduces blood flow to the heart is the most common type of heart disease.[181] However, the incidence of coronary artery disease related deaths has declined over the past 40 years.[182] This has in large part been due to "mechanical" ways to treat narrowing of the coronary arteries. The first method used is a form of surgery, known as a coronary artery bypass graft (CABG), in which veins from the legs are used to bypass narrowings in the arteries and thereby increase blood flow to the heart. This requires major surgery and has gradually been replaced in many cases by innovations in interventional cardiology, a field that utilizes the insertion of a catheter (usually through the femoral artery in the leg) into the coronary arteries and, for which, the Nobel Prize in Medicine or Physiology in 1956 was awarded to Werner Forssmann. In 1977, Andreas Gruentzig, a German radiologist, showed that you could reduce the narrowing in a coronary vessel by putting a "balloon" on the end of a catheter and inflating it, i.e., "balloon angioplasty" … , thereby initiating the field of percutaneous coronary interventions or percutaneous coronary angioplasty (PCI or PTCA). However, initially these vessels frequently narrowed again, i.e., "re-stenosed." In a major milestone, expandable "bare metal stents" (BMS) were introduced in 1986. These self-expanding stents are placed on the PCI balloon and left in place … . However, these arteries were found to frequently re-stenose as well and another innovative approach was clearly needed.
>
> It was at this time, that the importance of the endothelium, or innermost layer of cells in an artery, in preventing the proliferation of underlying vascular smooth muscle cells was realized. The endothelium releases nitric oxide, which diffuses into adjacent vascular smooth muscle cells and, by activating guanylyl cyclase, prevents the smooth muscle cells from proliferating and obstructing arteries. When there is atherosclerosis, the endothelium is damaged and the smooth muscle cells proliferate and narrow the artery. For these discoveries, Robert F. Furchgott, Louis J. Ignarro, and Ferid Murad were awarded the Nobel Prize in Physiology or Medicine in 1998. With the commercialization in 2003-04 of their early-1990s invention, Steven Sollott and James Kinsela, at the National Institute of Health, translated this knowledge into the treatment of coronary artery disease by coating a metal stent with taxol, an anti-microtubule chemical agent. They reasoned that this would prevent the vascular smooth muscle cells from proliferating and migrating into the coronary vessel until the endothelium could reform on the stent and prevent restenosis. The efficacy of this strategy in preventing in-stent restenosis was first reported in clinical

[180] Danziger and Scott, op. cit.
[181] https://www.cdc.gov/heartdisease/facts.htm: Heart Disease. Edited by Control CfD2020.
[182] J. E. Dalen, J. S. Alpert, R. J. Goldberg, and R. S. Weinstein, "The Epidemic of the 20(th) Century: Coronary Heart Disease" *American Journal of Medicine*, 127 (2014), pp. 807-812.

trials in 2003 and followed by several other supporting studies.[183] This was the birth of the drug eluting stent (DES).[184]

DES's have approximately 95% of the stent market and have evolved through multiple generations and improvements. The first generation of stents was the Taxol-coated stent (Boston Scientific) and the Sirolimus coated stent, which is an immunosuppressive agent that also inhibits smooth muscle cell proliferation. These were followed by a second generation of stents when it was realized that "late" stent thrombosis, i.e., over 30 days after placement, occurred with these stents.[185] The second generation of DES was defined by the use of different materials for the stent. The stents continued to use a medical grade metal to provide structural support for the artery, but new biocompatible polymers were used to control the release of the eluted drug. The eluted drugs for the second generation of stents included zotarolimus, everolimus, and novolimus. Thus, the metal stent has a thin coating of the drug – for example, everolimus – that is gradually eluted, slowly released into the artery wall around the stent from a thin polymer (a type of plastic) coating. The stent provides mechanical support to the artery while the everolimus is slowly released into the artery wall around the stent from a thin polymer coating that helps control the release of the drug. The release of the drug is intended to limit the overgrowth of tissue within the coronary stent – i.e. restenosis.[186] These second-generation stents were shown to be associated with fewer heart attacks and in stent thromboses (clotting). These stents have now become the most widely used in the world. However, efforts to improve upon them continue, with polymer-free drug eluting, biodegradable, and bioabsorbable stents. However, these stents build upon the concept of incorporating a drug or compound that prevents in stent restenosis.

Although market competition continues to increase through new products and innovation, industry analysts project the overall global stent market to grow to $11.3 billion in 2027, expanding at cumulative average growth rate of 4.7%.[187] However, as the treatment of coronary artery disease has evolved, medical management with drugs, such as statins that treat lipid abnormalities and anti-hypertensive agents, along with diet and lifestyle modifications have also taken on a greater role. Importantly, the results of numerous clinical trials have helped to narrow the clinical indications for stents (versus medical management alone and/or coronary artery bypass surgery). These may cause growth to be in more focused areas.

[183] B. Tomberli, A. Mattesini, G. I. Baldereschi, and C. Di Mario, "A Brief History of Coronary Artery Stents," *Revista Español de Cardiología* (English Edition), 71 (5) (May 2018), pp. 312-319.
[184] Stefanini and Holmes, op. cit.
[185] E. Camenzind, E., P. G. Steg, and W. Wijns, "Stent Thrombosis Late after Implantation of First-Generation Drug-Eluting Stents: A Cause for Concern" *Circulation*, 115 (March 20, 2007), pp. 1440-1455; discussion p. 1455.
[186] For the discussion here about the second generation of stents, see Boston Scientific, PROMUS® Everolimus-Eluting Coronary Stent System: Patient Information Guide https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/EL2077745_Promus_patgde_us_S.pdf; also see D. Fornell, "New Directions and Trends in Coronary Metallic Stents: Recent Advances in Drug-Eluting Stent Technology," *Diagnostic and Interventional Cardiology* (DAIC), January 29, 2019. https://www.dicardiology.com/article/new-directions-and-trends-coronary-metallic-stents.
[187] https://www.grandviewresearch.com/industry-analysis/coronary-stents-industry.

The patent family. Table 2 shows the complete set of patent applications, both U.S. and foreign, and the granted patents that resulted from the research of Dr. Sollott and Dr. Kinsella at NIA. The applications and patents trace back to the original application in July of 1993.

Subsequent to the original application on July 29, 1993, resulting in patent document US9906793A that became the priority for the family of patents, ultimately NIH received four U.S. patents. It also received two patents from the European Patent Office, and also the recognition of those two patents by the cooperating national authorities Austria, Denmark, Germany, Portugal, and Spain. Additionally, it received three patents from Japan. The patent family made possible the licensing agreements to be discussed in Section III, and those agreements made possible the billions of dollars in sales of the commercialized paclitaxel-eluting stents and the tens of millions of dollars in royalties earned by NIH that are described in Section IV. The hugely successful commercialization required the protection of the intellectual property provided by the patent portfolio shown in Table 2. In Section V, we will describe in some detail the importance of the foreign patents for the success of the commercialization of the invention. Because U.S. FDA approvals were required before commercialization could begin in the U.S., the foreign patents proved to be especially important for the timely launching of the paclitaxel-eluting coronary stent in the worldwide market and its rapid acceptance and ascendance as the leading drug-eluting coronary stent.

Table 2. The Family of NIH Patents for the Paclitaxel-Eluting Stent: Applications for "Method of treating atherosclerosis or restenosis using microtubule stabilizing agent."

Application*	Filing Date	Published Patent Document**	Publication Date
U.S. Ser. No. 08/099,067	7/29/93	US9906793A	–
EP19940924519	7/29/94	EP0711158B1	12/3/03
AT19940924519T	7/29/94	AT255412T	12/15/03
DK19940924519T	7/29/94	DK0711158T3	3/22/04
PT19940924519T	7/29/94	PT711158E	4/30/04
ES19940924519T	7/29/94	ES2210258T3	7/1/04
DE1994633381T	7/29/94	DE69433381T2	10/7/04
EP20000128626	7/29/94	EP1118325B1	1/4/06
AT20000128626T	7/29/94	AT314845T	2/15/06
DK20000128626T	7/29/94	DK1118325T3	3/20/06
PT20000128626T	7/29/94	PT1118325E	5/31/06
ES20000128626T	7/29/94	ES2255477T3	7/1/06
DE1994634598T	7/29/94	DE69434598T2	10/5/06
JP19950505996	7/29/94	JP4850985B2	1/11/12

WO1994US08578	7/29/94	–	–
DE1994634598	7/29/94	–	–
EP20050027952	7/29/94	–	–
DE1994633381	7/29/94	–	–
AU19940074768	7/29/94	–	–
US19960633185	4/18/96	US5616608A	4/1/97
US19970821906	3/21/97	US6429232B1	8/6/02
US20000641549	8/17/00	US6403635B1	6/11/02
US20020121500	4/11/02	US6500859B2	12/31/02
US20020272496	10/15/02	–	–
US20050304362	12/14/05	–	–
JP20060128856	5/8/06	JP4615478B2	1/19/11
US20060644411	12/21/06	–	–
US20080072067	2/21/08	–	–
US20090618481	11/13/09	–	–
JP20100125458	6/1/10	JP4997318B2	8/8/12
US201113086277	4/13/11	–	–
US201113327548	12/15/11	–	–
US201313904928	5/29/13	–	–

*Subsequent applications are continuations of the original application, patent application Ser. No. 08/099,067 resulting in publication US9906793A, to which the subsequent patents are traced. Country codes: AT = Austria, AU = Australia, DE = Germany, DK = Denmark, EP = European Patent Office, ES = Spain, JP = Japan, PT = Portugal, US = United States, WO = WIPO = World Intellectual Property Organization.
** Publications with the T designations at the end denote translations of the European patent in the cooperating countries. For example, for the publications for Germany (DE), T2 denotes the translation of the corresponding European patent's specification. The T3 designation for Denmark (DK) is Denmark's notation indicating that the corresponding European patent specification is valid in Denmark. The publications for Portugal (PT) with the E designations denote the national translations of the two European patents.
Source: Authors' compilations from the European Patent Office's worldwide patent database PATSTAT and from USPTO data.

The story of the drug-eluting coronary stent illustrates the difficulty and riskiness of the technology transfer process. The process of transferring a technology based in an invention created with the research in a federal laboratory is difficult, fraught with uncertainty and time-consuming attention to detail. Yet, as the story of NIH's Taxol (paclitaxel) coated coronary stent technology exemplifies, the benefits from the effort of both the inventors and NIH's Office of Technology Transfer (OTT) can be extraordinary. Before those benefits could materialize, NIH needed to get the patents, foreign as well as U.S. patents. It is the crucial first step on the way to commercializing an invention created in the federal agency's laboratories.

In Section I, we recounted the story of the invention of drug-eluting stents by Dr. Sollott and Dr. Kinsella in a NIA laboratory. The *NIH Record* reports "OTT has dozens of similar success stories about brainstorms-turned breakthroughs by NIH inventors—ideas that may never have reached nearly as many people without going through the patenting/licensing

process that OTT oversees."[188] Here in Section II, we emphasize the importance of that process and discuss both its challenges and benefits.

First, obtaining patents and granting licenses are important because they enable the realization of substantial benefits from the inventions from the federal laboratories. The *NIH Record* observes:

> NIH inventions boost the nation's return on its investment in medical research. In an era of flat budgets, that's news everyone wants to share. NIH director Dr. Elias Zerhouni made that case Apr. 6 [2006] to Congress at the House appropriations hearing. Showing the stent and a few other successful NIH inventions, he pointed out the broad health dividends the American public receives compared to the relatively small amount it spends per capita on medical research.[189]

In addition to the broad health benefits from the technology transfer enabled by patenting and licensing, the process also generates royalties for the U.S. government. The *NIH Record* reports:

> "NIH's intramural inventions generated about $100 million in royalties last year, which is much larger than other science-oriented federal agencies such as NASA," notes OTT director Dr. Mark Rohrbaugh. In fact, NIH's OTT accounts for more than half of all royalties for all federal laboratories, due in part to the nature of the research conducted here. The world's hunger for more effective, easier and faster therapies, medical procedures and methods to diagnose ailments only grows stronger every year. Also, much of NIH's royalty income is generated by biological material licenses that are aimed more at research than clinical/medical use in patients, points out Laurie Arrants of the NINDS [National Institute of Neurological Disorders and Stroke] Office of Technology Transfer. With an 80-person staff, including contractors, OTT currently manages more than 1,500 active licenses for NIH and the Food and Drug Administration. By law, inventions that emerge from NIH labs belong to the federal government. Successful commercial products that license and incorporate NIH discoveries bring in royalty income that the originating IC [NIH Institute or Center] can pump back into its research program to pay tech transfer costs and continue work on other projects. The inventor as well can earn up to $150,000 per year in royalty payments.[190]

Second, the patenting and licensing process requires teamwork. As observed in the *NIH Record*:

> The first step to commercializing an invention is sharing your idea with your IC [NIH Institute or Center] tech transfer component, [OTT Director] Rohrbaugh said. Each IC has a tech transfer staff that initiates the process by working with the investigators to claim and report inventions. Technology development coordinators (TDCs) for each IC are listed online at the OTT web site. The IC's tech development staff does an initial review of the

[188] Garnett, C., "2005 Royalties Nearly Double from '04: Tech Transfer Helps NIH Breakthroughs Break Through," *NIH Record*, Vol. LVIII, No. 9 (May 5, 2006), p. 1, continued on p. 8-9, at p. 8, https://nihrecord.nih.gov/sites/recordNIH/files/pdf/2006/NIH-Record-2006-05-05.pdf.
[189] Ibid.
[190] Ibid.

> idea before an employee invention report is passed along to OTT staff, who determine patentability and work with the inventor and the TDC to file for a patent. In essence, OTT and TDCs work together to help investigators protect the invention and otherwise navigate the paperwork. "It takes this teamwork of inventors, ICs and OTT to successfully begin commercialization with a strong patent strategy," [Laurie Arrants of the NINDS OTT] says.[191]

Third, the teamwork at the heart of the patenting and licensing process provides a support process for the inventors for whom the patenting and licensing process presents special challenges. Engaging with the patenting and licensing process takes valuable time for the inventors, and the outcome is less certain than the publications that they might have produced if the time to become involved with patenting and licensing had instead been devoted to additional research. The *NIH Record* observes:

> So if patenting a concept is that beneficial to public health, the public's balance sheet, the NIH research enterprise as well as its scientists, why are some researchers reluctant to enter the arena? "Probably one of the strongest factors influencing the investigators is both in volume and length of time it can take to go through the initial paperwork and the review process of filing for a patent," [NINDS OTT's Laurie] Arrants explains. "Whereas an investigator may be able to prepare several publications in a 2- to 3-year period, a single patent can take 2-3 years just to get to first review. Clinical investigators have the additional process of regulatory review by the FDA. Meanwhile, the scientist wants to publish—and publishing certainly gains attention for licensing—but early-on disclosure of the invention must be avoided if commercialization is being considered, which sometimes results in rushed patent filings or delayed publications. "So an investigator's reluctance is easy to understand in light of getting the moons and stars of scientific research, patenting and the regulatory process to align into a smooth, integrated pattern, and not getting as much recognition in their review from commercialization as is given for publication," says Arrants. "It is also why technology transfer in a federal lab is very much an art and dependent on tedious attention to detail and luck."[192]
>
> "Asking an inventor to participate in the patent and licensing process is very labor intensive," agrees NHLBI [National Heart, Lung, and Blood Institute] Technology Transfer and Development Director Lili Portilla, who has been involved in tech transfer since 1989. She remembers when most TDCs did tech development only part-time, in addition to their regular jobs. "Now the process and the profession have become very sophisticated," she says. Still, old perceptions about the difficulty of the process may also cause would-be inventors moments of pause. OTT began handling technology in 1989 and the learning curve seemed steep. "Navigating the realm of technology transfer takes time and effort away from science," acknowledges Donald Bortner, NIA administrative officer and TDC. "It requires persistence in overcoming barriers to commercialization and tolerance working under a complex set of laws and rules. The early years of technology transfer presented challenges associated with less experience. Some scientists remain apprehensive about devoting too much time to commercializing discoveries at the expense of missed scientific opportunities and fewer publications. NIH's experienced cadre of

[191] Ibid., p. 9.
[192] Ibid., pp. 8-9.

> technology licensing transfer attorneys and specialists, coupled with better contract support with law firms, enhances the likelihood of success by providing more support for scientists."[193]

Fourth, ideally inventors are incentivized to participate in the patenting and licensing process while at the same time maintaining their research agendas. The NIH OTT personnel and the scientists in the laboratories emphasize the need to work to ensure that scientists have time to further their research agendas and also to participate in the technology transfer process for the inventions that result from their research. The *NIH Record* observes:

> [Engaging with the patenting and licensing] process is not for every scientist, nor should it be, says Dr. Robert Balaban, chief of NHLBI's Laboratory of Cardiac Energetics. His research group invented an imaging technique that is among the top 20 royalty generators for 2005. Success didn't happen overnight, he says, and not without a lot of hard work. "I believe the NIH process has improved greatly from when we did our original filing many years ago," he recalls. "Frankly, our original experience was quite painful. Over the last several years the applications we have filed have been much easier and more streamlined. We have enjoyed working with some very skilled contract lawyers and advisors in putting together sensible packages. Some of this is likely due to our own experiences in this process." The NIH mission to get the benefits of medical research delivered to the public it serves is paramount, Balaban stresses, and a scientist should do a lot of soul searching before beginning tech transfer procedures. "The patent experience has really not changed my research agenda, nor do I believe it should," he explains. "We completed what I thought we could contribute to the field more than 8 years ago and rather than 'milk' more applications for this technology, my lab has moved on to many other topics using the unique NIH resource. Though I believe the patent process is critical for the translation and commercialization of technology, as well as recouping some of the research costs, I do not believe that NIH research should be guided by the pursuit of intellectual property alone. When an opportunity arises where protecting an invention can enhance the public investment, this should be done and it is a very important aspect of the translation of basic research to clinical or practical application." OTT chief Rohrbaugh agrees completely. "We're always working to find the right balance," he concludes. "We try to find ways to stimulate tech transfer without inhibiting further research and development."[194]

In all, the patenting and licensing process is a crucial step in transferring the inventions created in the federal laboratories into the commercialized products that create social economic benefits. With the case of the invention of the drug-eluting stent, billions of dollars of sales and health benefits for millions of heart patients attest to the benefits. Further, the millions of dollars in royalties for NIH resulting from those sales have several benefits for the process of technology transfer. A part of the royalty income from the licenses of the patented technologies is shared with the inventors, providing incentive for

[193] Ibid., p. 9.
[194] Ibid.

them to engage with the difficult and lengthy technology transfer process. The other part of the royalty income provides support for the federal agencies' technology transfer efforts, including paying expenses of administering and licensing their intellectual property. The royalty income provides support for the scientific research and development consistent with the agencies' missions.[195]

III. Licensing the Technology: The Second Step in the Technology Transfer Process for NIH's Patented Taxol (Paclitaxel) Coated Coronary Stent Technology.

In this section, we describe the licenses that were based on the patented paclitaxel-eluting stent technology.[196] Federal law encourages U.S. federal agencies to license the inventions originating in their laboratories. Licensing the technology to business enables the commercialization of the inventions. With commercialization, the public can realize the benefits of the inventions created in the federal laboratories.

The Stevenson-Wydler Technology Innovation Act of 1980[197] as amended by the Federal Technology Transfer Act of 1986[198] sets out guidelines to encourage commercialization through licensing of the inventions owned by the federal government. To promote the development and commercialization of federally owned inventions, the federal agencies are authorized by the Bayh-Dole Act[199] to execute license agreements with commercial firms and to collect royalties for the licenses.[200]

As we have discussed in Section II, NIH's OTT manages the patenting and licensing of the inventions originating in NIH's federal laboratories, such as the NIA laboratory where the invention of Dr. Sollott and Dr. Kinsella originated. As the GAO reports[201]:

> OTT oversees patent prosecution, negotiates and monitors licensing agreements … . NIH's stated goals with regard to the technology transfer process are, in order of priority, to foster

[195] The foregoing summarizing statement of the benefits of the royalties is paraphrased from United States General Accounting Office (GAO), *Technology Transfer: NIH-Private Sector Partnership in the Development of Taxol*, GAO-03-829, June 2003, p. 8.
[196] We are able to provide the licenses in Appendix B and Appendix C because they were used as exhibits in court cases.
[197] Pub. L. No. 96-480, 94 Stat. 2311.
[198] Pub. L. No. 99-502, 100 Stat. 1785.
[199] Pub. L. No. 96-517, §6(a), 94 Stat. 3019.
[200] For general discussion of the three laws cited in this paragraph and their application in the context of transferring technology for which NIH is the assignee for the patented inventions, see United States General Accounting Office (GAO), *Technology Transfer: NIH-Private Sector Partnership in the Development of Taxol*, GAO-03-829, June 2003, Report to the Honorable Ron Wyden, U.S. Senate, pp. 5-8.
[201] Ibid., pp. 6-7.

> scientific discoveries, to facilitate the rapid transfer of discoveries to the bedside, to make resulting products accessible to patients, and to earn income. NIH has broad authority under the statutes described above to negotiate agreements with outside partners in pursuit of its technology transfer goals.
>
> NIH scientists and laboratories, scientists and laboratories in academia or other research institutions that receive public funding, and industry researchers are often all involved in the development of pharmaceuticals. Usually, government and academic scientists conduct basic research on the biology of a disease and identify compounds, methods, and chemical reactions and pathways that may be of value in treating disease. They also conduct preclinical and clinical testing of drugs (phase 1 and 2 trials). Industry conducts more extensive clinical trials (phase 3 trials) and markets the drugs, although there is some overlap in these roles.[202] NIH's overall mission and authority, as well as the requirements of the Federal Food Drug and Cosmetic Act, suggest that NIH cannot sponsor a drug through FDA's new drug application (NDA) process. This act requires those who submit NDAs to FDA to provide "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing, of such drug."[203] While NIH conducts its own research and funds biomedical research at other institutions, it does not have a manufacturing, processing, or packing facility.
>
> NIH can, however, license inventions directly to pharmaceutical firms … .

NIH found an ideal firm to be the exclusive licensee for NIH's patented paclitaxel-eluting stent technology. NIH chose Angiotech Pharmaceuticals, a company founded in 1989 by Dr. William L. Hunter who ulitimately became President and CEO of the company. Dr. Hunter had developed a portfolio of patents for Angiotech complementary to those obtained by NIH. The entire family (closely related to the NIH patents for the paclitaxel-eluting stents) of Dr. Hunter's Angiotech patents, including those added after NIH granted his company the exclusive contract, is shown in Table 3. Note in particular that Dr. Hunter and Angiotech had blanketed the world's patenting authorities with patents, providing additional intellectual property protection to augment what NIH had obtained. Moreover, Table 3 shows only the simple family of patents for Angiotech's filings with the European Patent Office based on the specific invention described in what would be known as the Hunter patent. Angiotech's entire patent portfolio includes many patents covering various aspects of the technology that is incorporated in a paclitaxel-eluting coronary stent system.

[202] Phase 1 studies of an investigational new drug for cancer are generally conducted in a small group of cancer patients to test for safety; phase 2 studies are generally conducted to test for safety and effectiveness in several hundred patients who have the condition under investigation; and phase 3 studies, which are performed after preliminary evidence suggesting effectiveness has been obtained in phase 2 trials, may include several hundred to several thousand people.
[203] 21 U.S.C. § 355(b)(1)(D) (2000).

Clearly NIH OTT's choice for the exclusive license to its paclitaxel-eluting coronary stent system was ideal.

After the original application, U.S. patent application Ser. No. 08/094,536, filed July 19, 1993, resulting in publication US9453693A, to which the subsequent patents are traced, the first of the Angiotech patents to be issued was EP0706376B1, "the Hunter patent" as the European Patent Office referred to it when upholding the patent and those in its family. The patents are for "Anti-Angiogenic Compositions and Methods of Use." The abstract for the patent reads (note in particular that taxol, i.e., paclitaxel, is an anti-angiogenic factor; also recall from the description of the drug-eluting coronary stents in Section II, that the eluted drug is carried in a polymer):

> The present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier. Representative examples of anti-angiogenic factors include Anti-Invasive Factor, Retinoic acids and derivatives thereof, and taxol [paclitaxel]. Also provided are methods for embolizing blood vessels, and eliminating biliary, urethral, esophageal, and tracheal/bronchial obstructions.

The Hunter patent and the family of patents that were based upon it, in conjunction with the NIH family of patents for the paclitaxel-eluting stent, provided the intellectual property protection needed to allow successful technology transfer of the NIH technology when it was commercialized by Boston Scientific Corporation, the company to which Angiotech ultimately granted an exclusive license, in its successful paclitaxel-eluting coronary stent program.

Table 3. Angiotech Pharamaceuticals, Inc., Family of Patents for "Anti-Angiogenic Compositions and Methods of Use" for Angiotech's filings with the European Patent Office.

Application[a,b]	Filing Date	Published Patent Document[c]	Publication Date
EP19940920360	7/19/94	EP0706376B1	6/25/97
DK19940920360T	7/19/94	DK0706376T3	10/13/97
ES19940920360T	7/19/94	ES2106553T3	11/1/97
DE19946003966T	7/19/94	DE69403966T2	2/5/98
AU19940071192	7/19/94	AU693797B2	7/9/98
RU19960105391	7/19/94	RU2180844C2	3/27/02
JP19950504823	7/19/94	JP3423317B2	7/7/03
CN19941003379	7/19/94	CN1138505C	2/18/04
CA19942167268	7/19/94	CA2167268C	9/28/04
EP20010117872	7/19/94	EP1155690B1	9/29/04
DE19946034048T	7/19/94	DE69434048T2	10/6/05
EP20010117863	7/19/94	EP1155689B1	9/20/06
DK20010117863T	7/19/94	DK1155689T3	11/20/06
PT20010117863T	7/19/94	PT1155689E	1/31/07

DE19946034856T	7/19/94	DE69434856T2	3/1/07
ES20010117863T	7/19/94	ES2267638T3	3/16/07
EP20010117873	7/19/94	EP1159974B1	7/18/07
PT20010117873T	7/19/94	PT1159974E	10/31/07
DK20010117873T	7/19/94	DK1159974T3	11/26/07
ES20010117873T	7/19/94	ES2290074T3	2/16/08
DE19946035002T	7/19/94	DE69435002T2	3/20/08
EP20010117882	7/19/94	EP1159975B1	9/10/08
EP20010117876	7/19/94	EP1155691B1	9/17/08
EP19960119361	7/19/94	EP0797988B1	1/14/09
DK19960119361T	7/19/94	DK0797988T3	5/11/09
PT19960119361T	7/19/94	PT797988E	5/19/09
ES19960119361T	7/19/94	ES2321241T3	6/3/09
CA19942472373	7/19/94	CA2472373C	10/13/09
CN200510082207	7/19/94	CN1704121B	8/18/10
EP20050020792	7/19/94	EP1695698B1	3/23/11
EP20050020782	7/19/94	EP1652539B1	3/23/11
CN200610099888	7/19/94	CN101185759B	5/25/11
EP20050020791	7/19/94	EP1632259B1	12/21/11
KR20117007294	7/19/94	KR101222904B1	1/17/13
EP20100153077	7/19/94	EP2226085B1	11/27/13
DK20100153077T	7/19/94	DK2226085T3	2/3/14
PT20100153077T	7/19/94	PT2226085E	3/4/14
ES20100153077T	7/19/94	ES2449311T3	3/19/14
DE19946035141	7/19/94		
CN200310119882	7/19/94		
NZ19940268326	7/19/94		
AT20010117873T	7/19/94		
AT20050020782T	7/19/94		
EP20080006468	7/19/94		
DE19946035185	7/19/94		
DE19946035341	7/19/94		
NZ19940511762	7/19/94		
CA19942472404	7/19/94		
EP20050020783	7/19/94		
KR20097015869	7/19/94		
DE19946035002	7/19/94		
AT20050020791T	7/19/94		
NZ19940523799	7/19/94		
CA19942468375	7/19/94		
DE19946035139	7/19/94		
DE19946035342	7/19/94		
AT19960119361T	7/19/94		
AT20010117863T	7/19/94		
DE19946003966	7/19/94		
DE19946034048	7/19/94		
WO1994CA00373	7/19/94		
AT20050020792T	7/19/94		
DE19946034856	7/19/94		
CN200610099887	7/19/94		
CN200610099889	7/19/94		
NZ19940533467	7/19/94		
AT20010117872T	7/19/94		

AT19940920360T	7/19/94		
AT20010117876T	7/19/94		
AT20010117882T	7/19/94		
CN200610099890	7/19/94		
NO19960000226	1/18/96	NO324275B1	9/17/07
KR19960700266	1/19/96	KR100389223B1	10/8/03
GR19970402471T	9/24/97	GR3024833T3	1/30/98
NZ19970329193	11/17/97		
US19990294458	4/19/99	US6506411B2	1/14/03
US20010925220	8/8/01	US6544544B2	4/8/03
US20010927882	8/9/01		
RU20010132111	11/28/01	RU2304433C2	8/20/07
JP20020066179	3/11/02	JP4476536B2	6/9/10
HK20020103990	5/29/02		
KR20027016338	11/29/02	KR100934111B1	12/31/09
US20030389262	3/13/03		
US20030390534	3/14/03		
US20040959349	10/7/04	US7820193B2	10/26/10
US20040959398	10/7/04		
US20050151399	6/14/05		
US20060332170	1/17/06		
HK20060102632	2/28/06		
US20060435742	5/18/06		
US20060435854	5/18/06		
US20060435780	5/18/06		
JP20060239650	9/4/06	JP4920353B2	4/18/12
JP20060331088	12/7/06	JP4597115B2	12/15/10
RU20070111679	3/29/07		
NO20070003066	6/15/07		
US20070830240	7/30/07		
US20070830080	7/30/07		
US20070830208	7/30/07		
US20070830186	7/30/07		
KR20087007363	3/26/08		
US20080098173	4/4/08		
US20100716854	3/3/10	US8221794B2	7/17/12
US20100817682	6/17/10		
US20100820572	6/22/10		
US20100820614	6/22/10		
US20100820523	6/22/10		
US201213549282	7/13/12		
LU20140092423C	4/3/14	LU92423I2	1/20/15
LU20140092422C	4/3/14	LU92422I2	1/20/15

[a]Subsequent applications are continuations of the original application, U.S. patent application Ser. No. 08/094,536, filed July 19, 1993, resulting in publication US9453693A, to which the subsequent patents are traced. It is the earliest of the two priorities listed for "the Hunter Patent" EP0706376B1. The European Patent Office lists its priorities as WO1994CA00373 19940719 and US19930094536 19930719. The WIPO priority is PCT application CA94/00373, filed July 19, 1994.

[b]Country codes: AT = Austria, AU = Australia, CA = Canada, CN = China, DE = Germany, DK = Denmark, EP = European Patent Office, ES = Spain, GR = Greece, HK = Hong Kong (S.A.R.), JP = Japan, KR = Korea (South), LU = Luxembourg, NO = Norway, NZ = New Zealand, PT = Portugal, RU = Russian Federation, US = United States, WO = WIPO = World Intellectual Property Organization.

Source: Authors' compilation from the European Patent Office's worldwide patent database PATSTAT.

[c]The various national authorities have different ways of dealing with the foreign applications that typically originate with PCT (WO or WIPO) or European Patent Office filings. Some issue their own patents; for example, the C designation for Canada (CA) and China (CN), the C2 designation for Russia (RU), the B designation from China (CN), the B1 designation from South Korea (KR), and the B2 designation for Japan (JP) denote patents issued by those national authorities. Some specify a designation for their own patents issued after a period during which the application is open for inspection. For example the B2 designation for Australia (AU) denotes such a patent. Publications with the T designations at the end denote translations of the European patent in the cooperating countries. For example, for the publications for Germany (DE), T2 denotes the translation of the corresponding European patent's specification. The T3 designation for Denmark (DK) is Denmark's notation indicating that the corresponding European patent specification is valid in Denmark. The publications for Portugal (PT) with the E designations denote the national translations of the European patents. Luxembourg (LU) uses the designation I2 to denote what that country's patenting authority calls a supplementary protection certificate.
Source: Authors' compilations from the European Patent Office's worldwide patent database PATSTAT.

In November of 1996, the *Federal Register* published the notice that NIH intended to grant an exclusive license to Angiotech Pharmaceuticals, Inc. to practice the inventions described in the patent applications and patents in what would become the NIH paclitaxel-eluting stent family of patents described in Table 2 of Section II.[204] Appendix 1 provides the *Federal Register*'s published notice of the pre-license notification of NIH's intent to grant an exclusive license to Angiotech Pharmaceuticals, Inc.

Observe that the notice published in the *Federal Register*, and reproduced in Appendix 1, emphasizes the large potential benefit to the public that could result from the successful commercialization of the paclitaxel-eluting stents. The purpose of the invention is to reduce the rate of restenosis after interventional cardiology implantation of stents, which prior to the invention of Dr. Sollott and Dr. Kinsella at NIA had been performed with bare metal stents. The *Federal Register* notice states:

> Restenosis, the natural regrowth of muscle cells, has been noted as the single greatest complication (30–50%) of interventional intravascular procedures which number approximately 500,000 procedures annually, and at $10,000 per procedure is costing the health care system approximately $5 billion annually. While both interventional and invasive treatments continue to improve, restenosis causes a first-time failure rate of up to 50% or more. Reduction in the restenosis rate for cardiovascular disease procedures is cited as the most critical factor in future improvements. If the rate could be reduced to 25%, it would represent a savings to the health care system of around $1 billion annually.

From the announcement in the *Federal Register*, clearly NIH was motivated to license the invention of the paclitaxel-eluting stent because transferring the technology had the potential to bring great public benefits. The benefits were realized. In September 2003,

[204] *Federal Register*, Vol. 61, No. 217, Thursday, November 7, 1996, p. 57694.

almost seven years after the publication of the foregoing information in the *Federal Register*, and after the development of the paclitaxel-eluting coronary stents and the completion of a crucial clinical trial, the product to be commercialized had reduced the restenosis rate to 7.9%; the restenosis rate (despite the improvements in BMS technology over the years since the *Federal Register* notice) for the control group was much higher, about 3.4 times greater.[205]

The exclusive license was granted to Angiotech Pharmaceuticals on November 19, 1997. The heavily redacted license is provided in Appendix 2. We were able to obtain the license because it was an exhibit in a court case, but federal law requires the confidentiality of the portions of the license that are redacted. However, from the history that we have developed with publicly available documents, some knowledge of redacted material can be gained. For example, on the cover page for the license agreement, is listed the licensed patented technology – as it existed at the time of the license, but the license specifies that all the future patents, U.S. and foreign, resulting for the technology as traced to the original patent application are being licensed. The cover page of the license agreement, reproduced in Appendix 2, states the serial numbers of the licensed patents as follows, with *** in the place of the redacted information:

Serial Numbers of Licensed Patents

U.S. Patent Application Serial No. [***], filed [***];

U.S. Patent Application Serial No. [***], filed [***], now issued as U.S. Patent No. [***] on [***]; and

U.S. Patent Application Serial. No. [***], filed [***]

From Table 2 in Section II where we provide the complete patent family for the invention, we can see what the redacted patent application and patent numbers were. So, using Table 2, we can provide the missing information and have the information as follows.

Serial Numbers of Licensed Patents

[205] "Angiotech Pharmaceuticals, Inc. … was notified today by its corporate partner, Boston Scientific Corporation, of the nine-month results from its TAXUS IV clinical trial. The trial enrolled 1,326 patients at 73 sites in the United States, assessing the safety and efficacy of a slow-release formulation paclitaxel-eluting stent. Boston made the announcement at the annual Transcatheter Cardiovascular Therapeutics symposium in Washington, D.C. News release, September 15, 2003, "Angiotech Partner, Boston Scientific, Announces Positive Results from its Pivotal TAXUS IV Drug-Eluting Stent Trial: U.S. study reports in-segment restenosis rate of 7.9 percent." https://sec.report/Document/0001176256-03-000195/.

U.S. Patent Application Serial No. [***], filed [***] would, from Table 2, be original application, US9906793A, patent application Ser. No. 08/099,067, filed on July 29, 1993 and to which the subsequent patents are traced;

U.S. Patent Application Serial No. [***], filed [***], now issued as U.S. Patent No. [***] on [***] would be U.S. patent application US19960633185, filed April 18, 1996, now issued as U.S. patent US5616608A on April 1, 1997; and

U.S. Patent Application Serial. No. [***], filed [***] would be U.S. patent application US19970821906, filed March 21, 1997.

Of course the details about the royalties and milestone fees for the exclusive license that NIH granted Angiotech Pharmaceuticals are redacted in the copy of the licensing agreement provided in Appendix 2. However, we have been able to recover the "bottom line" for that information, and in Section IV we present the annual payments to NIH under the agreement.

In July of 1997, Angiotech Pharmaceuticals had granted a co-exclusive license to Boston Scientific Corporation and Cook Incorporated for the use of the paclitaxel-eluting stent technology for which it would subsequently be granted an exclusive license by NIH in November, as well as for the use of the related patents held by Angiotech. The November agreement between NIH and Angiotech, provided in Appendix 2, observes that NIH had already granted Angiotech a nonexclusive agreement. Angiotech needed to find partners to develop the technology for the paclitaxel-eluting coronary stent, getting it through the necessary clinical trials and then ultimately launched in worldwide markets. The backstory to Angiotech deciding to partner with Boston Scientific and Cook is interesting because it illustrates just how uncertain and risky is the successful commercialization that is needed for completion of technology transfer.

Angiotech's founder and chief scientific officer, Bill Hunter, made the rounds of the likely partners to help Angiotech develop and commercialize the paclitaxel-eluting coronary stent.[206] Those partners included pharmaceutical giant Johnson & Johnson, the market leader for sales of bare metal coronary stents. Johnson & Johnson was already developing its own drug-eluting coronary stent using the drug sirolimus. But Cook, Inc. and Boston Scientific

[206] Jim Kling, "The Lucrative Elution," *MIT Technology Review*, October 1, 2005, https://www.technologyreview.com/2005/10/01/101134/the-lucrative-elution/

joined together and proposed to Angiotech that combining their strengths, together they would be able to be the effective partner that Angiotech needed.

The MIT Technology Review reported[207]:

> As he pondered his options, Hunter received an unusual offer. Cook and Boston Scientific were longtime competitors, but in order to make a more attractive offer to Angiotech, they had decided to band together, proposing a joint agreement that would allow both to develop paclitaxel-coated stents. The financial terms for both companies would be identical.
>
> "They said, 'We understand that if you want to deal with one company, it would be the market leader [J&J], but would you be more interested in dealing with the number two and number three companies?' We thought it would be a phenomenally good idea," says Hunter, especially in light of the situation in Europe, where, he says, "cardiologists were switching brands almost monthly. It became very difficult to predict who would have the best stent." And no matter how good the drug, if it were matched with a lousy stent, it wouldn't have a chance. "We felt with two horses, we doubled our chances that we would be competitive." In the summer of 1997, the three companies signed a pact.

The co-exclusive license agreement, granted by Angiotech to Cook, Inc. and to Boston Scientific Corporation, is provided unredacted in Appendix 3. It would be another six years, from when the agreement was signed in 1997, until the paclitaxel-eluting coronary stent was commercialized. As shown in the chronological sequence of events in Table 1 of Section I, Cook in 2002 would be the first to win approval to market the paclitaxel-eluting coronary stents. But after some disappointing clinical trials and a failed attempt to merge with Guidant (later acquired by Boston Scientific), it decided to exit the coronary stent market to focus on peripheral vascular applications of the stents. Thus, in September 2004, Angiotech revised Cook's license, and in November 2004 granted an exclusive license for the coronary stents to Boston Scientific. Appendix 4 provides the amendments to the July 1997 co-exclusive licensing agreement that resulted in Boston Scientific having the exclusive license for the paclitaxel-eluting coronary stent.

Boston Scientific had been extraordinarily cautious and deliberative in its development of its TAXUS™ paclitaxel-eluting coronary stent system, taking its time – causing concern for top executives at both Boston Scientific and Angiotech who did not want Johnson & Johnson to beat them to market with its sirolimus-eluting stent – as Jim Barry, who would become Boston Scientific's Vice President of Corporate Research and Advanced

[207] Ibid.

Technology Development, worked to find the best drug dosage and rate of release to perfect the stent system's performance.[208] The deliberative development strategy paid off, culminating, as discussed above, with the successful TAXUS IV clinical trial announced in September 2003 at the Transcatheter Cardiovascular Therapeutics symposium in Washington, D.C. With its 2003 approvals to market the stents in Europe and other international markets and then in Canada, and finally with the U.S. FDA approval in 2004, the painstaking development strategy paid off as Boston Scientific quickly passed Johnson & Johnson and became the market leader with an estimated 70% of the market for drug-eluting stents soon after it launched its paclitaxel-eluting stent system.[209]

IV. Commercialization of the Technology: The Third Step in the Technology Transfer Process for NIH's Patented Taxol (Paclitaxel) Coated Coronary Stent Technology.

In this section, we describe the history of the commercialized technology, providing details about Boston Scientific's paclitaxel-eluting coronary stent sales in the U.S. and internationally from the time the sales began through the last year before the U.S. patents expired. We also provide details about the royalties and milestone payments earned by NIH, and we show the size of those payments relative to the returns to the licensees of the technology.

As we have discussed in Section III, Angiotech Pharmaceuticals, holding the exclusive license to use the technology protected with the family of NIH patents for the paclitaxel-eluting coronary stent, granted co-exclusive licenses for production and sale of products using the technology. The co-exclusive licenses were granted to Cook Incorporated and Boston Scientific Corporation. As the technology transfer process played out, Cook decided to abandon coronary stents and to focus on paclitaxel-eluting peripheral vascular and gastrointestinal stents, and so Boston Scientific was granted an exclusive license for the coronary stents. Boston Scientific continually developed the paclitaxel-eluting coronary stent technology and sold the stent systems worldwide. As seen in Table 4, Boston Scientific's TAXUS paclitaxel-eluting coronary stents generated billions of dollars in sales

[208] Ibid.

[209] "Taxus overtook Cypher, J&J's sirolimus-eluting stent, quickly. Boston Scientific sold about $42 million worth of Taxus stents in the first 10 selling days alone. A little more than a month after launch, the company estimated the Taxus accounted for 70 percent of DES sales." Ibid.

and paid millions of dollars in royalties to Angiotech Pharmaceuticals. Angiotech in turn paid millions of dollars in royalties to NIH over the lifetime of the patents.

Recall from the quoted material in the *NIH Record* article discussed above that the paclitaxel-eluting stent was NIH's top royalty earner for the banner fiscal year of 2005 when NIH's royalties were almost $100 million. The annual sales and royalty earnings shown in Table 4 for each year actually correspond to the NIH fiscal years, which run from October 1 of the preceding year through September 30 of the year reported, because the annual royalties reported by Angiotech through December 31 are for Boston Scientifics' sales from October 1 of the preceding year through September 30. From Table 4, we see that the drug-eluting stents, as the top NIH performer in fiscal year 2005, generated about $28 million for NIH that year.

Table 4. Royalties and Sales for Paclitaxel-Eluting Coronary Stents.

U.S. nominal $, millions	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Boston Scientific's sales of paclitaxel-eluting coronary stents[a]												
total			54.9[b]	1426[c]	2400	2200	1600	1200	926	539	363	230
U.S.			0	788[c]	1700	1500	1000	637	411	271	242	149
Rest of world			54.9[b]	638[c]	700	700	600	563	515	268	121	81
Royalties, milestone payments, and other license agreement payments for paclitaxel-eluting coronary stents paid to Angiotech by Boston Scientific[d]	0.0[e]	6.4[f]	4.2[g]	112.3[h]	183.6	159.5	110.5	84.1	57.4	31.0	20.7	15.1
Royalties, milestone payments,	0.0[e]	0.0[f]	1.8[g]	18.1	28.3	26.0	18.7	14.3	10.4	5.89	0.332[j]	0.618[k]

and other license fees for paclitaxel-eluting coronary stents paid to NIH by Angiotech[i]												

[a]Boston Scientific's net sales, on which royalty payments in a given year to Angiotech Pharmaceuticals are based, are for the period October 1 of the preceding year to September 30 of the given year.

[b]Royalties on sales actually made during the period ending December 31, 2003, were only $2.36 million because Boston Scientific prepaid royalties made on sales in the first quarter of 2004. Angiotech took $1.84 million (U.S.) of the prepayment in 2003, and the rest was taken in 2004. Royalties actually made through December 31, 2003, were approximately 4.3% of eligible drug-eluting stent sales worldwide (there were not yet sales in the U.S. or Japan), so the estimate of worldwide paclitaxel-eluting coronary stent sales is $2.36 million/(0.043) = $54.9 million.

[c]In the years before Angiotech submitted 10K reports, it did not report the sales on which its royalties were based, but it did provide the average ratio of its royalties to date as of the end of 2004 to the eligible net sales worldwide. That ratio of 6.9% was used with the royalties (just royalties, no milestone payments or up-frout licensing fees) of $98.4 million for the year to estimate worldwide sales of the stents. The worldwide sales of $1426 million = U.S. sales + rest-of-world sales. From the SEC reports, Angiotech reported the royalty rate on sales in the U.S. was approximately 8.1%, and on sales in the rest of the world was approximately 5.45%. So, (0.081)x(U.S. sales) + (0.0545)x(rest-of-word sales) = $98.4 million. Solving the two equations, U.S. sales were approximately $788 million, and the sales in the rest of the world were approximately 638 million.

[d]Angiotech Pharmaceutical's royalties and milestone payments received from Boston Scientific for the indicated year ended December 31. Prior to Cook existing the drug-eluting coronary stent business by the agreement with Angiotech in September 2004 and with Boston Scientific becoming the exclusive licensee in November 2004, some of these royalty and milestone payments to Angiotech are from Cook.

[e]For the 12 months ending September 30, 2001.

[f]For the 12 months ending September 30, 2002; includes $4.6 million in milestone payments from Boston Scientific and Cook (royalties on sales were just $0.005 million). The milestone payment from Cook was triggered by Cook filing for regulatory approval to market the paclitaxel-eluting coronary stent in Europe. The milestone payment from Boston Scientific was triggered by its initiation of commercial sales outside the regulated markets of Europe, the U.S., and Japan.

[g]The 2003 amount is for the 15 months ending December 31, 2003.

[h]Includes a $13.9 million payment from Boston Scientific to Angiotech (in conjunction with the November 2004 grant of the exclusive worldwide license for the drug-eluting coronary stents) for the right to sublicense the drug-eluting coronary stent technology to third parties.

[i]For the indicated year ended December 31; includes shared patent costs reimbursed to NIH. The amount will be an overestimate of the payments to NIH for the coronary stents. Although large payments to licensors are noted in the SEC filings and not included in the tabulation of payments to NIH as recorded in this table, the reports to the SEC otherwise describe Angiotech's license and royalty payments to licensors as primarily relating to payments to NIH based on the paclitaxel-eluting coronary stent system royalty revenue that Angiotech received from Boston Scientific. Although any noted payments to other licensors are deducted from the amounts reported here, some smaller amounts may be included. Also, some payments to NIH for Cook's use of the paclitaxel-eluting stent technology for applications other than coronary stents may be included, although such amounts are deducted when identified the SEC reports.

[j]The decline from 2010 to 2011 is due to an amendment to Angiotech's exclusive worldwide license agreement with NIH; the amendment eliminated certain license and royalty fees payable to NIH on the future sales of TAXUS by Boston Scientific Corporation. In particular, on December 29, 2010, Angiotech entered into an amendment to the November 1997 exclusive license agreement with NIH. Per the amendment, NIH agreed to eliminate (i) approximately $7.2 million of unpaid royalties and interest due on sales of TAXUS by Boston

Scientific, and (ii) future royalties payable on licensed products sold by Boston Scientific going forward, in exchange for a 0.25% increase on the existing royalty rates for licensed products sold by Cook and an extension of the term for payment for such royalties of approximately two years.
[k]The increase from 2011 to 2012 is primarily due to certain shared patent costs for which NIH was reimbursed in 2012.
Source: Danziger and Scott, op. cit.; tabulations based on information in Angiotech Pharmaceutical's filings with the U.S. Securities and Exchange Commission.

To provide some perspective about relative magnitudes of sales and earnings, Table 5 provides rough estimates of Boston Scientific's annual gross profits from the sales of the stents, and then shows the relative sizes of Boston Scientific's profits for the stents and Angiotech Pharmaceutical's and NIH's royalties and milestone payments.[210] As shown in Table 5, Boston Scientific's gross profits on the stents were about ten times its payments to Angiotech for the exclusive license Angiotech had granted to Boston Scientific. From the time that U.S. sales began in 2004 until NIH agreed on December 29, 2010, to eliminate the requirement for Angiotech's payments of royalties, Angiotech's royalties and milestone revenues from Boston Scientific's payments for its exclusive license were about six times Angiotech's payments to NIH for the exclusive license that NIH had granted to Angiotech.

Table 5. Profits and the Relative Sizes of Sales, Profits, and Royalties for Paclitaxel-Eluting Coronary Stents.

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Boston Scientific's total sales (U.S. $, millions) of paclitaxel-eluting coronary stents[a]	54.9	1426	2400	2200	1600	1200	926	539	363	230
Estimate of Boston Scientific's gross profits (U.S. $, millions) for paclitaxel-eluting coronary stents[b]	39.7	1098	1871	1579	1152	832.0	634.7	359.5	236.4	155.5
Royalties, milestone payments, and other license agreement payments (U.S. $, millions) for paclitaxel-eluting coronary stents paid to Angiotech by Boston Scientific[c]	4.2	112.3	183.6	159.5	110.5	84.1	57.4	31.0	20.7	15.1
Royalties, milestone payments, and other license fees (U.S. $, millions) for	1.8	18.1	28.3	26.0	18.7	14.3	10.4	5.89	0.332	0.618

[210] Gross profits are net sales minus the cost of the products sold. For the firm as a whole, the gross profits must cover operating expenses (selling, general and administrative expenses), R&D expenses, royalty expenses, and litigation expenses, among other things.

paclitaxel-eluting coronary stents paid to NIH by Angiotech[d]										
Boston Scientific's gross profits for the stents / Angiotech's revenues from the stent royalties, milestones, etc.	9.5	9.8	10.2	9.9	10.4	9.9	11.1	11.6	11.4	10.3
Angiotech's revenues from the stent royalties, milestones, etc. received from Boston Scientific / NIH revenues from the coronary stent royalties, milestones, etc. received from Angiotech	2.3	6.2	6.5	6.1	5.9	5.9	5.5	5.3	62.3	24.4

[a]From Table 4; see notes there. Dollar figures are nominal dollars as reported in the SEC filings.

[b]Gross profits on the paclitaxel-eluting coronary stents are very roughly estimated as the product of Boston Scientific's net sales of the stents for the year (shown in the first row) and Boston Scientific's ratio for the year of total gross profits to its total net sales as reported in its annual 10K reports to the U.S. Securities and Exchange Commission.

[c]From Table 4; see notes there.

[d]From Table 4; see notes there.

Source: Danziger and Scott, op. cit.; Table 4 and compilations from Boston Scientific's filings with the U.S. Securities and Exchange Commission.

In 2003, the first year of Boston Scientific's sales of the paclitaxel-eluting coronary stents, when milestone payments would be expected to be a prominent part of the royalties and related payments, the Angiotech's payments to NIH were 3.3% of sales. After that the payments were consistently about 1.2% of sales through 2010, the last year of payments before NIH and Angiotech negotiated an end to royalty payments based on the sales of the coronary stents. The royalties and related payments as a percentage of Boston Scientific's sales were 1.3% in 2004, 1.2% in 2005, 1.2% in 2006, 1.2% in 2007, 1.2% in 2008, 1.1% in 2009, and 1.1% in 2010.

Table 6 shows the stream of royalty and milestone payments to NIH through 2010 (the last year of payments before NIH and Angiotech agreed to stop them) in nominal dollars and also in constant dollars of 2012 (the last year before the expiration of the USPTO patents on NIH's paclitaxel-eluting stent technology). When discounted at the 7% that OMB mandated as the opportunity cost for the taxpayer's funds, the present discounted value of the stream of royalties in constant dollars of 2012 is $57 million in 1993, the priority date for the

original application by NIH for a patent on the invention.[211] Certainly Dr. Sollott and Dr. Kinsella used the accumulated knowledge acquired from many other NIH research projects, but those projects' costs are not a part of the drug-eluting stent research project's cost. That cost would have been far less than $57 million; the project was not a large, costly one, but rather the carrying out of the proof of concept for what turned out to be an extraordinarily important insight.[212] It would appear that the taxpayers' earned a return far in excess of the OMB's estimate of the opportunity costs of the public's funds. Stated differently, discounted back at the internal rate of return that would make the present discounted value of the stream of royalties equal to the cost of the project as of 1993, that internal rate of return would be greater than the 7% mandated by OMB as the opportunity cost of the inverted funds. Further, the benefits to society as a whole from the innovation of the drug-eluting stent were immensely more than the stream of royalty payments to NIH; there is, above and beyond those payments, the economic surplus generated for the producers and the consumers of the technology.

Table 6. NIH Licensing Revenues from Royalties, Milestones, and Licensing Fees for the Paclitaxel-Eluting Coronary Stent.

Year	Angiotech's Payments to NIH	
	Nominal $s (millions)	Constant 2012 $s (millions)[a]
2003	1.8	2.18
2004	18.1	21.35
2005	28.3	32.37
2006	26	28.87
2007	18.7	20.22
2008	14.3	15.17
2009	10.4	10.95
2010	5.89	6.13

[a]Constant 2012 dollars using the U.S. GDP implicit price deflator.
Source: Table 4; see notes there.

[211] In millions, from Table 6, $56.6 = 2.18/(1.07)^{10} + 21.35/(1.07)^{11} + 32.37/(1.07)^{12} + 28.87/(1.07)^{13} + 20.22/(1.07)^{14} + 15.17/(1.07)^{15} + 10.95/(1.07)^{16} + 6.13/(1.07)^{17}$. For the 7% discount rate, see U.S. Office of Management and Budget (OMB), Circular number A-94, *Guidelines and Discount Rates for Benefit-cost Analysis of Federal Programs* (Washington D.C.: Government Printing Office, 1992).

[212] R. Nijhara, J. L. Tidwell, S. Ferguson, and K. Balakrishnan, "Bypassing Bypass Surgery and Other Success Stories from the National Institutes of Health," *Journal of the Association of University Technology Managers*, Vol. 17, No. 2 (Fall 2005), pp. 1-16, report (pp. 3-4) that "Taxol, originally discovered in the 1960s, and its equivalents are currently the most successful anticancer drugs on the market. However, nobody thought of using paclitaxel to prevent arterial re-clogging until, over lunch, NIH inventors Steven Sollott, MD, and James Kinsella, MD, brainstormed this very idea. … The experiments were initiated, proof of concept was shown in rat models, and a patent application was filed."

We conclude this section by observing that all of the detailed information given about the royalties was obtained from Angiotech Pharmaceutical's publicly available filings with the U.S. Securities and Exchange Commission (SEC). Because the royalties from Boston Scientific's sales of the paclitaxel-eluting stent were such an important source of revenue for Angiotech, in its annual reports, Angiotech provided unusually detailed accounts of those royalties and the milestone payments and fees received, breaking out the payments and discussing them.

It was fortunate that Angiotech provided such detailed information in its filings with the SEC. We discovered in our research and correspondence for all of our case studies that the details at the level that we have uncovered them for this case study are typically highly confidential. Neither the licensing companies' representatives nor the technology transfer offices at the federal agencies provide such detail because of the confidentiality of the information. Indeed, federal law requires the confidentiality. As GAO observes[213]:

> Federal laws also generally prohibit agencies from disclosing information that concerns or relates to trade secrets, processes, operations, statistical information, and related information.[214] Therefore the federal technology transfer process that NIH engages in with the private sector is not entirely transparent to the general public, nor are the details of the negotiations and agreements that NIH makes with industry partners publicly known. However, information may be disclosed to those who have oversight authority over the agencies that generate such information, such as the Congress and its oversight bodies. In this way, information about the details of the federal investment and return on investment in the commercialization of a drug like Taxol can be examined for policymaking purposes.

Finally, we observe the many ways that the millions of dollars in royalties, earned for NIH by licensing the technology for the paclitaxel-eluting coronary stents and shown in Tables 5 and 6, contribute to the technology transfer process and the agency's mission more generally.

As GAO observes[215]:

> Under federal law and NIH policy, royalty income from license agreements is shared between the inventors and the institute or center within NIH in which the technology was developed. NIH uses the royalties for multiple purposes that contribute to the technology transfer program and the research of its laboratories. Specifically, the royalty payments can

[213] United States General Accounting Office (GAO), *Technology Transfer: NIH-Private Sector Partnership in the Development of Taxol*, GAO-03-829, June 2003, Report to the Honorable Ron Wyden, U.S. Senate, p. 8.
[214] See 15 U.S.C. § 3710a(c)(7); 18 U.S.C. § 1905 (2000). See Public Citizen v. NIH, 209 F. Supp. 2d 37 (D.D.C. 2002), see also, 5 U.S.C. § 552(b)(4) (2000), which exempts trade secrets, and commercial and financial information that is privileged or confidential, from public disclosure.
[215] GAO (2003, op. cit., p.8).

be used to (1) reward employees of the laboratory, (2) further scientific exchange among the laboratories of the agency, (3) educate and train employees of the agency or laboratory, (4) support other activities that increase the potential for transfer of the technology of the laboratories of the agency, (5) pay expenses incidental to the administration and licensing of intellectual property by the agency or laboratory, and (6) support scientific research and development consistent with the research and development missions and objectives of the laboratory.

V. The Importance of Foreign Patents.

In this section, we describe the importance of the foreign patents obtained by NIH to protect its intellectual property for the NIA invention of the paclitaxel-eluting coronary stent. The foreign patents are shown, along with the entire portfolio of NIH patents for the paclitaxel-eluting coronary stent, in Table 2 in Section II. As discussed there, after the initial USPTO application and the resulting publication in 1993 that served as the priority for the family of patents, NIH was granted four U.S. patents, three patents from Japan, and two European patents, with recognition of those two patents by the cooperating national authorities of Austria, Denmark, Germany, Portugal, and Spain.

The foreign patents were important for the success of the commercialization of the stent. Table 4 in Section IV shows $10.94 billion in worldwide sales for Boston Scientific's paclitaxel-eluting coronary stent over the years from the launch in 2003 through 2012, with $4.24 billion of the total coming from foreign sales over the decade. The very first year, with $55 million in sales all coming outside the U.S. in the international market, was crucial for the commercial success of the innovation. The fact that NIH OTT applied for the portfolio of foreign patents enabled the early launch of the paclitaxel-eluting coronary stent in international markets even before U.S. FDA's approval for sales in the U.S. As recounted in Section III, those early sales in foreign markets established the product and helped Boston Scientific to surge quickly past Johnson & Johnson to become the leading seller of drug-eluting coronary stents with 70% of the worldwide market. The necessity of the foreign patents for the sustained commercial success over the decade from 2003 through 2012 is seen in the litigation battles that had to be won if foreign sales were to proceed. The litigation was necessary to establish that the paclitaxel-eluting coronary stent was indeed patent-protected intellectual property that did not infringe on the intellectual property of foreign stent producers.

Recall from Section IV that the gross margins on the sales of a licensee of a federal agency's patented technology must cover many things. R&D and the expense of clinical trials, as the invention is developed into a commercialized product, come to mind first. Additionally, the gross margins must cover litigation costs. The licensee, not the federal agency that licensed its patented technology, typically pays those costs, and the case of the paclitaxel-eluting coronary stent is no exception. Moreover, litigation to defend the foreign patents in international markets is expected, and again, the experience for Angiotech Pharmaceuticals and its exclusive licensee Boston Scientific with the paclitaxel-eluting coronary stent is not an exception. Angiotech and Boston Scientific fought and won cases that enabled their coronary stent, developed from the licensed patented invention of NIH, to become the leading seller in the worldwide DES market.

Recall from Section III that Angiotech, to which NIH granted the exclusive license for the paclitaxel-eluting stent technology, had a complementary set of patents (shown in Table 3 of Section III) that together with the NIH family of patents (shown in Table 2 of Section II) protected the Boston Scientific coronary stent program. The two families of patents made possible the successful international launch of Boston Scientific's TAXUS™ stent in 2003 and then its successful U.S. launch in 2004.

Angiotech successfully defended its patents, and hence the viability of the combined NIH and Angiotech patent portfolios for providing the necessary IP protection of the paclitaxel-eluting coronary stent, in an important case early in 2005. A press release posted in a U.S. Security and Exchange Commission (SEC) filing on January 24, 2005, stated:

> VANCOUVER, January 24, 2005 -- Angiotech Pharmaceuticals, Inc. … today announced a favorable decision on its European Patent (No. 0706 376) from the European Patent Office Opposition Division. The European Patent Office maintained the validity of Angiotech's patent with various claims, including claims to stents coated with paclitaxel and a polymeric carrier. This decision reaffirms Angiotech's continued patent protection in Europe. This patent is one of many in Angiotech's portfolio of patents protecting its pioneering technology, including the Boston Scientific TAXUS™ stent program.

A week later, Angiotech and Boston Scientific initiated a joint lawsuit in the Netherlands against Conor Medsystems. The brief press release posted in an Angiotech SEC filing on February 1, 2005, stated:

> VANCOUVER, February 1 , 2005 -- Angiotech Pharmaceuticals, Inc. … today announced that they along with corporate partner Boston Scientific have initiated legal proceedings in the Netherlands against Conor Medsystems. On January 24th, 2005, the European Patent

Office maintained the validity of Angiotech's patent (No. EP 0 706 376) with various claims, including claims to stents coated with paclitaxel and a polymeric carrier.

Angiotech posted another SEC filing on February 18 to update investors:

> VANCOUVER, February 18, 2005 -- As previously announced on February 1st, 2005, Angiotech Pharmaceuticals, Inc. … along with its corporate partner Boston Scientific initiated legal proceedings in the Netherlands against Conor Medsystems after the validity of one of Angiotech's European patents (No. EP 0 706 376) was upheld by the European Patent Office Opposition Division. Angiotech anticipates that Conor Medsystems will, in response to those legal proceedings take various defensive acts, including the present challenge in the United Kingdom. As legal proceedings can historically be a drawn-out process in multiple jurisdictions, Angiotech will pursue and defend against, to the fullest, any and all actions of Conor Medsystems respecting Angiotech's extensive patent portfolio and pioneering technology.

On August 3, 2005, Angiotech announced, in another SEC filing, a broad victory in a case that had been before the European Patent Office:

> VANCOUVER, BC, August 3rd, 2005 – Angiotech Pharmaceuticals, Inc. … today announced that each of the parties who opposed the grant of Angiotech's European Patent (No. 0 706 376) in 1998 has irrevocably withdrawn, or abandoned its opposition efforts before the European Patent Office, leaving the patent valid and enforceable.
>
> The written Decision from the European Patent Office was issued on 19 April 2005 and gave the opponents approximately two months to file an appeal. The deadline to file an appeal has passed and none of the companies has filed. Pending resolution of all outstanding matters, including issuing formal notice to Angiotech, it is expected that the European Patent Office will publish Angiotech's patent as amended.
>
> The grant of European Patent (No. 0 706 376) was originally opposed by five parties, who cited over 50 documents to support their invalidity arguments, including patent applications filed by Wolff, and Kopia, as well as a page from a book published by Alberts. In addition, the European Patent Office considered arguments that the term "coating" in the claims of the patent should be limited to mean that a polymer/paclitaxel composition must be formed as a film over the surface of the stent. After fully considering the documents and extensive written and oral arguments of opposing counsel, the European Patent Office announced its decision, favorable to Angiotech, on January 24, 2005 and issued it in writing on 19 April 2005.
>
> This patent is one of many in Angiotech's extensive portfolio of patents protecting its pioneering technology, including the Boston Scientific TAXUS™ stent program.

On January 17, 2006, Angiotech announced victory in the litigation in the Netherlands in a press release posted in a SEC filing that stated:

> January 17, 2006
> Angiotech Wins Patent Infringement Case in the Netherlands
> Conor Enjoined From Selling The Costar™ Stent In The Netherlands

VANCOUVER, Jan. 17 [2006] … Angiotech Pharmaceuticals, Inc. …, announced today that they received a favorable decision from a Dutch Court in a patent dispute against Conor Medsystems, Inc. ("Conor").

The District Court in The Hague held that Conor's CoStar™ paclitaxel stent infringes a key claim of the Dutch version of an important Angiotech European stent patent, and that Conor is therefore immediately enjoined from selling CoStar™ in the Netherlands.

"This is a significant victory in a key area of our intellectual property," said Dr. William L. Hunter, President and CEO of Angiotech. "Conor's attempt to design around our patented technology has failed. Not only did the Court uphold Angiotech's patent rights in the Netherlands, it also ruled that Conor's stent infringes upon that intellectual property."

"We are pleased that this important European patent has now been enforced twice by the Dutch Court in two separate court actions, and we will continue to vigorously defend our important proprietary technologies in various jurisdictions around the world," added Dr. Hunter.

Angiotech anticipates that there will continue to be additional review and further hearings of the various patent claims in this case, and that there are likely to be appeals with respect to this court decision.

Illustrating just how risky the patent litigation can be for successful commercialization of an innovation, on February 24, 2006, Angiotech announced a setback with the following press release filed with the SEC:

February 24, 2006
ANGIOTECH TO APPEAL UK JUDGMENT REGARDING UK PATENT
UK DECISION AFFECTS ONLY UK PATENT

VANCOUVER, BC, February 24, 2006 – Angiotech Pharmaceuticals, Inc. … announced that it intends to appeal a UK trial court decision to revoke Angiotech's UK designation of its European Patent No. 0,706,376. The UK trial court ruled today that Angiotech's UK Patent lacked inventive step in light of certain prior art in a challenge brought by Conor MedSystems (Conor) filed in February 2005. This Patent, which applies to the UK only, is only one of a number in Angiotech's portfolio of patents protecting its pioneering paclitaxel stent technology, which cover the Boston Scientific TAXUS™ stent.

The Angiotech European Patent remains valid and enforceable in the other designated States in Europe, in light of Angiotech's successful defense of the patent at the January 2005 European Patent Office Opposition Division decision which maintained the validity of this Patent, including claims related to stents coated with paclitaxel and a polymeric carrier. The UK decision affects only the UK version of the maintained European Patent.

Angiotech President and CEO William L. Hunter, MD, MSc commented: "This UK decision is contrary to the thorough consideration of the European Patent Office, which after extensive Opposition proceedings, upheld the validity of Angiotech's European counterpart of this UK Patent. We are committed to protecting our intellectual property rights and intend to appeal the UK trial court's judgment."

The setback was followed by a victory announced on May 3, 2006 with another SEC filing:

May 3, 2006
Boston Scientific and Angiotech Win Patent Infringement Case
Against Sahajanand in the Netherlands

Natick, MA and Vancouver, BC (May 3, 2006) -- Boston Scientific Corporation (NYSE: BSX) and Angiotech Pharmaceuticals, Inc (NASDAQ: ANPI, TSX: ANP) announced today that they received a favorable decision from a Dutch court in a patent dispute against Sahajanand Medical Technologies Pvt. Ltd. Boston Scientific and Angiotech alleged that Sahajanand's Infinnium paclitaxel-eluting stent infringed two claims of an Angiotech patent directed to paclitaxel stents. The Court found that the asserted claims were infringed and valid.

The Court granted Boston Scientific and Angiotech an injunction against Sahajanand, prohibiting the company from selling, bringing onto the market and delivering -- as well as importing, offering or keeping in stock for one of these purposes -- the infringing Infinnium paclitaxel stent in the Netherlands. The Court also ordered Sahajanand to pay damages and/or surrender profits resulting from the infringement. The Court's decision can be appealed by Sahajanand.

"We are pleased the Dutch court upheld the validity of this important patent and found that it had been infringed," said Paul LaViolette, Chief Operating Officer of Boston Scientific.

"This is a significant victory in a key area of our intellectual property," said Dr. William L. Hunter, President and CEO of Angiotech Pharmaceuticals.

In the following year, ligation victories continued for Angiotech and Boston Scientific when the European Patent Office rejected appeals of two of the victories reported above. In an Angiotech SEC filing posted March 15, 2007:

March 15, 2007
ANGIOTECH RECEIVES FAVOURABLE DECISION FROM THE EUROPEAN PATENT OFFICE: EPO Rejects Attempted Intervention and Appeals of Conor Medsystems and Sahajanand Medical

VANCOUVER, BC, March 15, 2007 – Angiotech Pharmaceuticals, Inc. … a global specialty pharmaceutical and medical device company, announced a favourable decision regarding its Hunter Patent from the European Patent Office (EPO) in Munich, Germany.

The EPO's Technical Board of Appeal rejected the attempt by Conor Medsystems Inc. and Sahajanand Medical Technologies Pvt. Ltd. to intervene and appeal an earlier decision by the Opposition Division of the European Patent Office, which upheld the Hunter patent. The decision found that these appeals were "inadmissible."

"We are pleased with the EPO's decision, and Angiotech views this outcome as yet another confirmation of the strength and validity of our patent portfolio," said Dr. William Hunter, President and CEO of Angiotech.

> "We continue to have great success defending our intellectual property, and we remain committed to vigorously protect our important proprietary technologies in jurisdictions around the world," added Dr. Hunter.

Finally, in September 2007, all outstanding litigation was settled. In a SEC filing, Angiotech posted:

> September 17, 2007
> ANGIOTECH REACHES AGREEMENT WITH JOHNSON & JOHNSON
> TO SETTLE OUTSTANDING PATENT LITIGATION
>
> VANCOUVER, BC, September 17, 2007 – Angiotech Pharmaceuticals, Inc. … , announced today that it reached a favourable agreement with Johnson & Johnson's subsidiary, Conor Medsystems ("Conor") to settle all outstanding patent litigation with respect to Conor's CoStar® paclitaxel stent.
>
> "With this agreement now in place, Angiotech expects that the resources required to defend and enforce our intellectual property should decrease," said Dr. William Hunter, President and CEO of Angiotech.
>
> At the time of the settlement, there was ongoing litigation in three jurisdictions: the UK, the Netherlands and Australia.

As the history of the litigation necessary to protect Boston Scientific's sales of its paclitaxel-eluting coronary stent shows, the extensive foreign patent portfolio – shown in Tables 2 of Section II, and in Table 3 of Section III – was absolutely necessary to protect the technology from infringement that, if allowed, would have greatly eroded sales of the stent.

VI. Conclusion.

The approximately $11 billion in sales over the decade from launch through the last year before the USPTO patents expired does not really convey the magnitude of the impact of the NIA invention of the paclitaxel-eluting coronary stent on the worldwide market for coronary stents. The reason is that the NIA invention was the pioneering one that underlies the evolution of subsequent drug-eluting stents and stent systems. It was the first drug-eluting coronary stent, and it was the market leader during the first generation of drug-eluting coronary stents.

The case of the NIA paclitaxel-eluting coronary stent illustrates the challenges and the great uncertainty that characterizes the process of technology transfer of a federal agency's invention created with R&D in a federal laboratory. Yet, it also illustrates the

immense public benefits that can result from accepting the challenges of obtaining patents and granting licenses that result in the successful commercialization of federal agencies' patented technologies. Moreover, the case illustrates the importance of having foreign as well as U.S. patents to protect the agencies' intellectual property.

The foreign patents were crucial for the commercial success that enabled the pioneering legacy of the NIA's invention of the drug-eluting coronary stent. We conclude with a summary, based on this case study of the paclitaxel-eluting coronary stent, of lessons learned about the importance of foreign patents for successful technology transfer of federal agencies' inventions. The lessons are based on the ways that foreign patents were important for the successful transfer of the NIH paclitaxel-eluting stent technology.

First, a well-designed portfolio of foreign patents will help a federal agency find appropriate licensees for its patented technology. When an agency's office of technology transfer applies for an EP patent, i.e., a patent from the European Patent Office (EPO), and also makes a PCT (Patent Cooperation Treaty) application (also known as a WO application, i.e., WIPO, World Intellectual Property Organization application) and then follows up with applications to the national authorities (cooperating with EPO or WIPO) where the commercialized version of the federal agency's patented technology might be sold, the agency will often be better able to find a licensee. As we reported in our Task 2 report, an expert, among the agencies' technology transfer officers that we corresponded with, observed that trying to license USPTO-patented technologies that were not also protected with foreign patents was like trying to market "damaged goods."

Second, finding the right licensee can greatly reduce the federal agency's need to acquire the foreign patents itself, in some cases. Ideally an agency will know of a potential licensing partner with a complementary set of patents, or with the willingness to acquire those patents, that will, together with the agency's patents for the technology, provide the protection of the intellectual property necessary for successful commercialization. If the agency does find such a prospective partner, the expense of applying for and maintaining the full complement of foreign patents can be avoided. NIH found just such a partner with its exclusive licensee, Angiotech Pharmaceuticals. Angiotech had already applied for the foreign patents necessary to complement the NIH patents and complete the IP protection of the commercialized pioneering paclitaxel-eluting coronary stent.

Third, the federal agencies will typically be able to avoid the biggest cost of having a portfolio of foreign patents. The biggest cost will often be the litigation costs needed to defend the patents. Those costs are not typically paid by the federal agencies, but instead, as well illustrated in the case of the NIA/NIH paclitaxel-eluting coronary stent, the litigation costs are paid by the licensees of the federal agencies' technologies. Angiotech Pharmaceuticals and Boston Scientific successfully defended, in the litigation reviewed in Section V, the patents that protected the intellectual property behind the successful commercialization of the paclitaxel-eluting coronary stents.

Fourth, having an appropriate portfolio of foreign patents enables the licensees to invest in the development of the commercialized version of the product. As we discussed in Section III, Boston Scientific's Jim Barry's risky, time-consuming series of clinical trials to determine the best combination of paclitaxel dosage and release rate paid big dividends by creating the bullet-proof product that he wanted to ensure. The Boston Scientific team knew that when they had it all just right, the intellectual property behind the TAXUS™ coronary stent system would be well protected by the combined portfolio of patents that NIH and Angiotech Pharmaceuticals had obtained. Indeed, as we have recounted, the intellectual property was upheld in the litigation that followed the launch of the product in international markets.

We conclude with a sketch of the social economic benefits created by the NIA/NIH invention of the drug-eluting coronary stent. Boston Scientific's paclitaxel-eluting coronary stent system "… was arguably the most successful new medical product in history, netting more than $1.4 billion in sales in its first nine months in the U.S. alone."[216] We calculated the present discounted value in constant dollars of 2012 (the last year before the USPTO NIH patents for the paclitaxel-eluting stents expired) of the stream of licensing revenues received by NIH prior to NIH and Angiotech agreeing to discontinue the royalty payments. Discounted back to the time of the original patent application in 1993, the present discounted value was $57 million, an amount far in excess of the cost of Dr. Sollott's and Dr. Kinsella's NIA research project. Thus, the NIH licensing revenues from the project repaid NIH's costs many times over, and yet those revenues were just a very small fraction of the benefits generated by the commercialized invention. The social economic benefits from the invention

[216] Kling, op. cit.

additionally include the economic profits earned by Angiotech and Boston Scientific from the sales of the coronary stent systems. Those profits (producer surplus) too are a part of the social economic benefits generated. The hospitals (that performed the cardiac interventions implanting the coronary stents) realized producer surplus as well, and also the insurance companies and other intermediaries that were involved in the delivery of the medical services using the stents realized producer surplus. All of that producer surplus would be part of the social economic benefits. Finally, there is great value to consumers, in whose hearts the drug-eluting coronary stents were placed, who receive the benefits of forgoing major surgery, extended life, and improved quality of life. The value (consumer surplus) to the consumers above and beyond the price paid for the medical services received is part of the total social economic benefits of the commercialized invention.

In all, the NIA/NIH invention of the drug-eluting coronary stent generated extraordinarily large social economic benefits. Moreover, the invention was the pioneering one that created the market for drug-eluting coronary stents that has continued to evolve and grow with new generations of drug-eluting stents that build on the idea introduced in the invention of Dr. Sollett and Dr. Kinsella in the laboratories of the NIA at NIH.

Appendix 1. Federal Register Notice of Prospective Grant of Exclusive License to Angiotech Pharmaceuticals, Inc.

57694 Federal Register / Vol. 61, No. 217 / Thursday, November 7, 1996 / Notices

Prospective Grant of Exclusive License: Therapeutic Uses of Microtubule Stabilizing Agents Including Taxol (Paclitaxel) for Fibroproliferative Vascular Diseases Including Atherosclerosis and Restenosis and Excluding Cancer AGENCY: National Institutes of Health, Public Health Service, DHHS. ACTION: Notice. SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the inventions embodied in the patents and patent applications referred to below to Angiotech Pharmaceuticals Inc. of Vancouver, British Columbia, Canada. The patent rights in these inventions have been assigned to the government of the United States of America. The patents and patent applications to be licensed are: ''Methods of Treating Atherosclerosis or Restenosis Using Microtubule Stabilizing Agent,'' U.S. Patent Application Serial No. 08/ 099,067 filed July 29, 1993; and all continuation applications, divisional applications, continuation-in-part applications, and foreign counterpart applications related to U.S. Patent Application Serial No. 08/099,067. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within ninety (90) days with the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

SUPPLEMENTARY INFORMATION: Atherosclerosis is the cause of the vast majority of cases of chronic peripheral arterial occlusive disease. The arteries most frequently involved, in order of occurrence, include femoropoplitealtibial, aortioiliac, carotid and vertebral, splanchnic and renal, and brachycephalic. Fibromuscular dysplasia, inflammatory arteridities, and congenital arterial malformations are much rarer causes of arterial insufficiency. The process of repair after angioplasty continues over several months, involving re-endothelialization, proliferation of vascular smooth muscle cells, and remodelling of the extracellular matrix proteins. Restenosis, the natural regrowth of muscle cells, has been noted as the single greatest complication (30–50%) of interventional intravascular procedures which number approximately 500,000 procedures annually, and at $10,000 per procedure is costing the health care system approximately $5 billion annually. While both interventional and invasive treatments continue to improve, restenosis causes a first-time failure rate of up to 50% or more. Reduction in the restenosis rate for cardiovascular disease procedures is cited as the most critical factor in future improvements. If the rate could be reduced to 25%, it would represent a savings to the health care system of around $1 billion annually.

Preventing or reducing fibroproliferative vascular disease in a patient may be achieved by treating the patient with a pharmaceutical preparation comprising a therapeutically effective amount of a microtubule stabilizing chemotherapeutic agent such as taxol (placlitaxel). In particular, treatment with a low dose of a microtubule stabilizing agent such as taxol or a water-soluble taxol derivative may present or reduce atherosclerosis or restenosis after arterial injury. The low dose used prevents artery blockage while minimizing any negative side effects associated with the drug. Unlike classical anti-microtubule agents like colchicine and the vinca alkaloids which induce depolymerization of microtubules, taxol induces tubulin polymerization and forms extremely stable and nonfunctional microtubules.

ADDRESS: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to: J. Peter Kim, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852– 3804; Telephone: (301) 496–7056, ext. 264; Facsimile: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before February 5, 1997 will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information

Act, 5 U.S.C. 552. Dated: October 29, 1996. Barbara M. McGarey, Deputy Director, Office of Technology Transfer. [FR Doc. 96–28633 Filed 11–6–96; 8:45 am]

Appendix 2. The license agreement between NIH and Angiotech Pharmaceuticals, granting Angiotech an exclusive license to the invention of the paclitaxel-eluting coronary stent.

Appendix 2 was attached as a separate document with the original Task 3 report.

Appendix 3. The license agreement between Angiotech Pharmaceuticals and Cook Incorporated and Boston Scientific Corporation, in which Angiotech granted Cook and Boston Scientific co-exclusive licenses to the paclitaxel-eluting coronary stent

Appendix 3 was attached as a separate document with the original Task 3 report.

Appendix 4. The amendments (resulting in Boston Scientific having an exclusive license for the paclitaxel-eluting coronary stent) to the license agreement between Angiotech Pharmaceuticals and Cook Incorporated and Boston Scientific Corporation, in which Angiotech granted Cook and Boston Scientific co-exclusive licenses to the paclitaxel-eluting coronary stent

Appendix 4 was attached as a separate document with the original Task 3 report.