**Response to “Request for Information regarding Federal Technology Transfer Authorities and Processes” NIST Department of Commerce Docket Number; 180220199-819-01**

As a recently retired federal government patent advisor/attorney with more than 25 years of experience, my observation is that there are several issues in the federal patenting and licensing process that could improve federal technology transfer and increase the licensing of federal technologies thereby improving American competitiveness and helping American businesses. I applaud Secretary of Commerce Ross’s interest in this topic. I believe that red tape, internal bottlenecks and roadblocks, and multiple, unnecessary layers of agency review and processing are impeding successful technology transfer of federal government R&D investment.

The heart of the issue is that the federal government has thousands of patented technologies that are not licensed and likely cannot be licensed. For some, there is no market, some have strong competing technologies, and some are not developed far enough to generate industrial interest. Many of the remaining viable technologies are delayed from proceeding to commercialization due to inefficiencies in the federal licensing process. My comments are directed to both increasing efficiency in determining which technologies are licensable and to improving the federal licensing process.

My comments in brief are:

* Encouraging federal agencies to adopt a university invention evaluation model to determine patentability/commercialization potential
* Whether US Patent and Trademark Office fees (associated with filing a jointly-owned invention with a cooperator) provide a disincentive to cooperators to work with the federal government;
* Inability to simultaneously license both background and developed federal technology;
* Delays in handling Federal Register Notice (See 37 CFR);
* Consideration whether FR is an appropriate public outreach in digital age;
* Consideration of “business plan” requirement (See 37 CFR) for federal licenses
* Unrealistic licensing fees charged by federal agencies

Federal agencies need to implement an invention evaluation process similar to the university model. (Note that this does not include CRADA inventions: a CRADA to develop a provisional or other patent application, preferably including collaborative reduction to practice of the technology under the CRADA, is an excellent way to improve the transfer of the federal technology). This would mean that thorough prior art searches are completed prior to filing any patent application, provisional patent applications are filed prior to a utility applications, industry needs are evaluated and industrial input is solicited, and technology development partners are sought early in the process to develop (and hopefully commercialize) the technology. Patent applications would only be filed on those inventions that need patent protection for commercialization and the remainder of the technology would be released to public domain via scientific publications, agency websites, professional meetings, and the like. Thus, less patents applications are filed (saving time and federal funds), more partnerships are developed and more patented technology transferred.

The next issue is related to how the federal government cooperates with universities and companies. As background, at the US Patent and Trademark Office (PTO), fees are charged for various steps in the patenting process. PTO fees are either: large, small or micro entity. Small companies as defined by Small Business Administration to be any company with up to 500 employees. The federal government is required to pay large entity fees. Some feel that the higher fees drive collaborators to exclude federal co-inventors (by not including claims to which the federal inventor has contributed) from patent applications. Based on my experience, this is not the case. My observation is that it is not related to PTO fees but rather, that by limiting filed claims to not include federal inventors’ is the best way to better define and control the invention, thus providing the collaborator with a better “return on investment” (ROI) by not having to negotiate with the federal government regarding license and by eliminating royalty sharing with the federal government. Very seldom is this an issue when there is an established, strong research collaboration exists between the institutions. On the contrary, my observation is that if a federal agency diligently works to actively collaborate with universities and companies to further develop inventions/technologies so they can be commercialized, this issue does not occur.

Next is the current inability of a collaborator to license technologies as a package, e.g. a background technology and a developed technology. Companies on their own, or in partnership with universities, are not going to invest time and funds in a federal invention/technology without assurances that they will be able to obtain an exclusive license to both the background technology and the developed technology as a **package**. Since most inventions/patents/technologies require further development prior to commercialization, no company is going to take a license to an early stage technology due to high risks and capital requirements. Some federal agencies are hesitant to exclusively license an early-stage technology which often then becomes a death knell for the project and the technology (and obviously the federal investment to that point). The win-win for federal technology transfer is to find a partner to collaboratively develop the invention/technology to commercial viability, then exclusively license that technology package to that partner so the commercialization can continue.

The next issue is the required advertising of exclusive licenses per 37 CFR Part 404.7. Under this regulation, a Federal Register (FR) Notice must be published notifying the public of the federal government’s intent to grant an exclusive license. After the minimum FR Notice period (15 days) has run, and if there are no objections, the license can then be finalized. If objections are received, then the agency needs to consider granting co-exclusive licenses, dividing geographic distribution areas, determining field-of-use restrictions, and related options so all parties interested in the technology have an opportunity to commercialize it. Most companies are not aware that the federal government requires advertising prior to granting an exclusive license. **Note that Universities do not have this burden.**

The current FR Notice requirement, as implemented by some agencies, is unfortunately a time consuming nightmare that most partners walk away from so the Notice requirement should be standardized and expedited. For background licenses, to entice a company and/or university to partner with a federal agency for the further development, the company must be assured of an exclusive license early in the collaboration. This would apply to both background technology and any developed technology on a federally owned invention/technology. For federal technologies to be licensed, the FR process must proceed quickly so appropriate business decisions can be implemented in real time.

The CFR states that the Notice it should be “provided in an appropriate manner at least 15 days before the license is granted”. The regulations provide no guidance to agencies and their Offices of General Counsel on a time line for the review and posting of FR notices. For some agencies, posting a FR notice can routinely take several months to over a year due to multiple reviews and internal agency delays by which time the partnership has often been lost, especially if it is a development partnership. The time required to post a Notice must be expedited to comply with realities of the business world. This problem could be remedied by revising CFR language by removing “at least” to make 15 days consistent across all federal agencies. Currently, some agencies are 30 days or other time periods. In my observation, a longer time period unnecessarily delays the process.

Also, the CFR should require that the internal federal agency public notice process be completed in 30 days. This period of time, time, along with the 15 days of public posting provides a very **reasonable 45 days -- not several months to a year**. The ability for federal agencies to develop partnerships in a reasonable time frame on both background and developed technologies would greatly improve outcomes from federal R&D investments. The public notice regulations need to reflect business realities requiring licensing efficiencies. For this reason, I recommend revising the CFR to expedite and standardize the process within all federal agencies/Departments.

Currently, to many partners, the licensing of federal inventions/technologies is next to impossible due to many federal agencies’ overreaching processes, policies, and procedures. It seems that there have been too many opportunities for the agencies to say “no” to potential collaborators/licensees. Thus, many partners avoid collaborating with the federal government on technology development due to the onerous collaboration process. I have observed excessive, unnecessary delays due to multiple layers of review and internal agency bottlenecks.

In addition, consider whether a FR notice is an “appropriate manner” to advertise? As FR Notices are more commonly used for policy directives or comments, it seems that in the internet age, <https://www.fbo.gov/> (fedbizopps), agency web pages or the Federal Laboratory Consortium’s webpage would be a better way to advertise the federal government’s intent to grant exclusive licenses.

The next issue is that the CFR states that a “plan for development or marketing of the invention” is required for a license. Note that this is directed to “licenses”, not cooperative research and development agreements (CRADAs). This is not a problem except that development partners often want assurances that they will be able to get an exclusive license after the development is complete so they are not then stalled by agency process requirements. The assurance of the collaborator’s personnel, facilities and funding should be adequate to post the FR Notice (or some other form of notification as earlier suggested). Again, there is no consistency across federal agencies. Some agencies still see this as a “license” application needed when in fact it is not (as it to do further development) and companies may not want to execute a license until after the product and market development are complete.

The last issue is directed to the licensing fees charged by federal agencies. Licensing fees charged within the licensing community can be an execution fee at time of signing, annual maintenance fees (paid while the technology is brought to commercial reality), and/or royalties based on sales of licensed product/process/etc. My experience is that there is no reason for a federal agency to always require an execution fee or an annual maintenance fee. This was true especially if the technology was developed jointly, if the company is small or if the technology is early stage. Charging these fees reduce the collaborators’ funds available for product development thereby slowing or stalling the technology’s commercialization. If the technology is successful, then royalties are where the majority of license income should be derived. I saw many licensees walk away from a license due to commercially onerous licensing fees, especially the fees charged early in the collaboration.

Thank you for your consideration of my comments and I hope they are helpful. Again, I fully support your efforts to examine how federal technology transfer works and how it can provide a better “return on investment” to the taxpayer. I am happy to provide further assistance and answer any questions.

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