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Technology Transfer

Applying for a Waiver From U.S. Manufacturing Requirements For Federally Funded Intellectual Property

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Countless ideas and inventions are developed at U.S. universities every year, often with federal funding. Many of these important ideas could not be commercialized for the public's benefit without the Bayh-Dole Act, which streamlined the transfer of university technology developed with federal support. The transfer of federally funded inventions is subject to several statutory constraints. This article describes one such requirement—the need to obtain a waiver from the government if an exclusive transferee wishes to exploit the federally funded invention to manufacture products outside the U.S. for sale in the U.S.

Background:

In 1980, the General Accounting Office (now the Government Accountability Office) reported to Congress that the federal government held title to approximately 28,000 patents; but that fewer than 5 percent of these patents were licensed to industry for development of commercial products due to inefficiencies in the ownership and licensing processes. Congress responded in December 1980 with passage of the Bayh-Dole Act, which became effective in 1981, ushering in a new era of federal technology transfer. Bayh-Dole allows universities, and other non-profit organizations such as hospitals and research institutes, to take title to inventions that arise from federally-funded research and license their title to such inventions. This allowed for more effective transfer of federally funded technologies from university research labs to commercial production. Universities have reaped rewards as they and their faculty inventors share in licensing revenue.

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This licensing, however, must be in accordance with 35 U.S.C. § 204, which imposes a preference for U.S. industry. The rationale behind this preference is straightforward: Congress intended that the American economy should reap the benefits from inventions funded with U.S. taxpayer dollars. The text of Section 204 is as follows:

> ''Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.''

The requirement that products embodying or manufactured using the invention be ''manufactured substantially in the United States'' can impose significant commercial challenges when costs of domestic production are substantially greater than those abroad. However, in an acknowledgment that commercial realities may necessitate flexibility in the application of the U.S. manufacturing preference, Section 204 also permits a federal agency to waive the preference under specified circumstances:

> However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential li-

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The Waiver Process at a Glance

WHO: The small business firm, nonprofit organization or assignee should submit the waiver application at the request of the licensee. Specifically, for universities, this entity would likely be the university's technology transfer office.

WHEN: The waiver process could take months, and so it is wise to do your due diligence prior to starting the waiver application. A waiver application should not be filed until a licensee, who wants an exclusive license to the university's federally funded intellectual property, actually requests one. This is because the licensee would best know whether it plans to substantially manufacture outside of the U.S., and thus need a waiver. Note that a waiver is not required if the license at issue is nonexclusive in nature, and it only applies to products manufactured for sale in the U.S.

WHERE: The agency or agencies that provided funding for the inventions at issue are responsible for granting any waiver. The federal government's main online tool for reporting under the Bayh-Dole Act, iEdison, is used by more than 30 agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, some (but not all) agencies of the Department of Defense and the National Science Foundation. Some agencies, such as the NIH, do not accept hard copy applications and instead rely exclusively on iEdison.

WHAT: The reviewing agency will require a very fact-specific application. The application will need to detail the efforts to manufacture in the U.S., with proof to back up these assertions. This means that the applicant will have to ask its licensee to provide comprehensive information regarding its plans for the invention in question.

WHY: Obtaining a waiver under 35 U.S.C. § 204 may determine whether a federally funded invention becomes the foundation of a successful business or languishes until the patent expires. It may open up new revenue streams for university research programs and reward investigators for their efforts. Prosecuting a successful waiver application demonstrates competence of the technology transfer office. Conversely, unfamiliarity with the process and missteps can burn precious deal time in the best case, and in the worst case result in failure of a potentially impactful deal.

censees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

This waiver process is time-consuming and very fact-specific, and is detailed in the remainder of this article.

Details on the Waiver Application Process

Although there may be some differences between federal agencies with regard to how streamlined the process is and how willing the agency is to grant waivers, the following tips are helpful when navigating the waiver application process. The government agency that provided funding may grant a waiver of the requirements in 35 U.S.C. § 204 if one of the following two scenarios is true:

Scenario 1: Section 204 allows for a waiver in the event that ''reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States.'' During the time period of 2011 through Feb. 24, 2015, 29 of the 31 waiver requests granted by the National Institutes of Health cited this as the reason or one of the reasons why the waiver was granted. To prove that unsuccessful efforts have been made to license the technology to a U.S. manufacturer, the application must include three things.

First, the application must explain the significance of the technology, including the availability of alternative products. Does anyone in the industry manufacture in the U.S.? Where are the competing products produced? If the application concerns a medical technology, it should discuss the size of intended patient populations. If it concerns an environmental technology, it should describe the affected population. For example, if seeking a waiver for a breakthrough medical device, it is important to note if there is no other device like it. If there is existing technology, discuss how it falls short. It is also important to be specific regarding the patient population. All assertions of fact should be supported by citations to sources. Published sources are best, but if an unpublished source is the only available reference, include it in the submission with an assertion of confidentiality.

Second, it is important to describe whether the requirement for U.S. manufacture will delay entry of the product or products derived from the subject product into the U.S. or foreign markets, and if so, the effect of such delay. The application should mention if it is possible to build manufacturing facilities in the U.S., but should also note if this will cause delay of entry into the market and what impact that will have. Such impact could be, for instance, to public health or to the environment.

Third, detail the efforts that were made to find a U.S. manufacturer. For example, the NIH's waiver application form asks for identification of past marketing strategy and efforts for the technology, including the number of companies contacted, the methods used for marketing and contacting companies, the types of licenses and terms offered to potential licensees, comparison of terms offered to foreign licensees and those offered to U.S. companies and the responses of companies to marketing efforts. Efforts to market the invention may take various forms, including e-mail marketing with nonconfidential summaries, marketing to companies that have come to visit your campus, marketing during partnering meetings at a conference and marketing via your tech locator online, among others. If a commercial licensee is seeking the waiver, it may have to employ investment bankers or licensing consultants to survey the market,

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contact likely candidates for domestic licensure and demonstrate the absence of interest. The waiver applicant must be able to demonstrate that it has marketed to suitable companies and done what is appropriate and reasonable in the industry.

Scenario 2: Section 204 also permits a waiver if ''under the circumstances domestic manufacture is not commercially feasible.'' To show this, the application must discuss the following items, which should be explained and detailed by the licensee company.

First, the application should discuss the factors that make domestic manufacture not commercially feasible, including the relative costs of U.S. versus foreign manufacturing, proximity to markets for the products, availability of raw materials and the technical experience of foreign versus domestic manufacturers to commercialize the specific product. For example, there may be significant differences in the cost to modify an existing facility abroad versus building a green-field facility in the U.S. If the manufacturing process is relatively untested, having facilities close to an existing engineering staff may be critical. Likewise, the need to recruit, hire and retain manufacturing, management and administrative talent in the U.S. to duplicate expertise that already exists abroad may significantly increase product costs.

Second, the application should detail what portion of the product described in the invention will be manufactured outside the U.S. It makes a difference whether the company will be creating the whole product outside of the U.S. or whether it will only be producing a small component of the product outside of the U.S. Note whether final assembly will be in the U.S., even if production of all of the components or precursors will not be.

Third, it is essential to enumerate the benefits to the U.S. economy that will result from exploiting the technology abroad, even if the products will not be substantially manufactured in the U.S. Such benefits might include: direct or indirect investment in U.S. plants or equipment, such as for marketing or packaging; the creation of new or higher quality U.S.-based jobs, such as research, application development, production of precursors or components, marketing or sales jobs; the enhancement of the domestic skills base; further domestic development of the technology (e.g., will improvements to the technology be made in the U.S.?); any positive impact on the U.S. trade balance, considering product and service exports as well as foreign licensing royalties and receipts (for example, will the licensee need to pay U.S. taxes on sales in the U.S.? If so, how much?); and whether the license will include provisions for cross-licensing, sublicensing, and/or reassignment provisions that seek to maximize benefits to the U.S. (i.e., the licensee will sublicense or cross-license to a U.S. company, or the licensee will pass through profits to a U.S. entity).

Although one can argue either scenario when applying for a waiver, if your facts support both scenarios outlined above, it is best to meticulously address both as it can bolster your application. In fact, one-third of the manufacturing waivers granted by NIH from 2011 through February 24, 2015 were granted on the basis of both scenarios being proven by the applicant.

Time-Saving Tips

Depending on the agency, once a complete waiver request is received, it can take 8 weeks or more for the application to be processed. Oftentimes, the application is not complete on the first try, so before you even begin to fill out the application, it is helpful to:

- Make sure the Statements of Government Interest have been recorded for the specific IP for which you are requesting a waiver. If they have not been recorded, you may have to ask your patent counsel to file certificates of correction for any issued patents or amendments for patent applications.
- Update the patent disclosure information in iEdison and in the waiver application in order to make sure that it is current.
- Find the relevant federal grant number and the agency or agencies that provided funding. If more than one agency provided funding, the agencies may claim that an application must be submitted to each. However, the regulations state that if a subject invention was made under funding agreements with more than one agency, the government is supposed to select a single agency to act on behalf of the entire government. If the rule is ignored, then the patent owner may request the government to appoint a single agency to process the request, and the agency is required to comply (37 CFR 401.13(a)).
- Pose questions early to the company regarding information it will need to provide for the waiver application.
- Speak to the company about limiting its request to a specific territory, as this will make it more likely that a waiver will be granted. If the company is headquartered in another country, for instance, that location would be a good choice. For example, the NIH granted 11 waivers to Samsung Electronics between 2011 and the beginning of 2015, and all of these were for South Korea, where it is headquartered and has the infrastructure in place to manufacture the subject invention in question. Limiting the request in this way also shows that you have put some thought into your plans.
- Collect historical marketing information within your office in order to show past efforts to find a U.S. manufacturer. This might require requesting files, going through email archives and computer folders, etc.

What Not to Do

As has been mentioned, the waiver application is very detailed, so it is important to be sufficiently prepared for the process. In order to increase the odds of your application's acceptance, here are some things NOT to do:

- In general, do not apply for a waiver unless and until you have been asked by a specific licensee to do so.
- Do not apply for a blanket waiver for all of the technologies in your portfolio.
- Do not try to get a waiver in advance for a federally funded technology prior to seeking out licensees in hopes that it will be easier to market the asset.
- Do not ask for a worldwide waiver, but instead limit your request to specific territories. For ex-

ample, certain countries are embargoed, and so for public policy reasons, a waiver that would include those countries would not likely be successful. Common countries for which the NIH has granted waivers include Japan, South Korea, China and certain European countries.

- Do not try to get a waiver if you have not sufficiently marketed your IP, or if you have not exhausted your possibilities of licensing to a company with U.S. manufacturing capabilities.

What If? The Potential Perils of Not Getting a Waiver

So what happens if the waiver is not granted and the licensee goes forward with its plans to manufacture outside of the U.S.? A breach of the U.S. manufacturing restriction does not invalidate the patent or subject either the licensor or licensee to claims for damages by the government. The government's sole remedy is to exercise march-in rights. These rights allow the funding agency, on its own initiative or by request of a third party, to grant additional licenses—exclusive, non-exclusive or co-exclusive—to other ''reasonable applicants,'' which could mean possible competitors. The right has not yet been exercised by a federal agency since the advent of the Bayh-Dole Act.

A New Jersey case during the 1990s, *Ciba-Geigy v. Alza Corp.*, addressed the limited circumstances in which an exclusive license can be transformed to a non-exclusive license using march-in rights under the Bayh-Dole Act. In this case, Ciba-Geigy obtained an exclusive license to a University of California patent for a nicotine patch, then sued Alza Corp. and its codefendant, Marrion Merrel Down Inc., for infringement of the patent. The defendants filed a counterclaim against the Regents of University of California, and argued that the license agreement between Ciba-Geigy and the university was illegal and unenforceable. Since federal funding was involved, and the active ingredients of the subject invention were being manufactured in Germany at the time of the case, the defendants used the U.S. manufacture requirements of the Bayh-Dole Act to support their claim. The federal funding at issue here comprised a grant from the Department of Health and Human Services (DHHS), as well as a grant from the National Institute of Drug Abuse (NIDA); both of these grants were given to the technology's inventors by the Regents of the University of California.

The court determined that the requirements of Bayh-Dole did not, in fact, apply in this case. The subject invention was not ''conceived or first actually reduced to practice in the performance of work under a funding agreement,'' as is required by Bayh-Dole in order for the U.S. manufacturing rule to apply. One grant was used to perform a pilot study using a different device from the subject invention, and the other was used to research the motivation for smoking; the court did not believe that either of these grants allowed the inventors to actually reduce the invention to practice. Additionally, there was no evidence of a funding agreement with the DHHS or NIDA in regards to the invention, which further supported the court's conclusion that neither agency had a claim to the nicotine patch and thus the Bayh-Dole Act did not apply.

As the court explained in its opinion, even if the technology at issue had been subject to the Bayh-Dole Act, the exclusive license would not have automatically transformed into a non-exclusive one simply because Ciba-Geigy chose to manufacture in Germany instead of the U.S. The appropriate federal agency has to actually exercise its march-in rights, which requires an evidentiary hearing and a fact-based determination that exercise of march-in rights is justified.

Role of the U.S. Manufacturing Rule in Acquisitions

A company with patents based on federally funded inventions should expect that its valuation and the structure of a merger or acquisition will be affected by the risk that the government may not approve a waiver of the U.S. manufacturing restriction covering key technology. A buyer will have to assess the likelihood that a waiver can be obtained, and the long term costs that it may incur if the wavier is denied. This risk can be reduced by the patent owner taking several steps as it prepares itself for sale:

- Analyze whether the subject inventions are essential elements of the total value of the company, and be prepared to segregate the value of at-risk patents from the total value of the company assets.
- Prepare a pro-forma U.S. manufacturing waiver justification demonstrating the strength of the waiver application.
- Consider vetting the waiver justification with the relevant agency and getting an informal reaction on the agency's points of concern.
- Be prepared to work with the acquirer to enhance the application through demonstration of economic benefits to the U.S. if the acquirer is permitted to manufacture abroad.
- Consider whether retaining a non-exclusive manufacturing right, or licensing on a non-exclusive basis to a domestic manufacturer for U.S. sales only, is a feasible business solution, because it avoids the need to obtain a waiver.

Although the Bayh-Dole Act did not apply in the above situation because the subject invention did not use federal funding, this case still provides important takeaways regarding march-in rights and the limits of Bayh-Dole. First, it is important to note that the subject invention must have been conceived or actually reduced to practice using federal funding in order for the Bayh-Dole requirements to be in play. In addition, this case demonstrates that nothing will happen to the exclusivity of the license unless the funding agency actually exercises its march-in rights.

Conclusion

An application for the waiver of the Bayh-Dole Act requirement that federally funded IP be substantially manufactured in the U.S. is a time-intensive and detailed process. It is important to fully understand all of the components that go into an application, and fastidiously provide as much information as possible for the best opportunity for success.

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