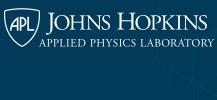
Inventor's Guide to Technology Transfer



Office of





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The "Inventor's Guide to Technology Transfer" outlines the essential elements of technology transfer at the Johns Hopkins University Applied Physics Laboratory (APL). It is organized to answer the most common questions APL's Office of Technology Transfer typically fields from APL staff members and provides a broad overview of the technology transfer process and services available at the Laboratory. The guide is for <u>Informational Purposes Only</u>. APL staff members should refer to the applicable guidance and policy (G&P) documents for the Laboratory's official policies on the topics discussed in the guide.

This guide focuses on the transfer of technology from APL to external parties. Identification of potentially beneficial technology elsewhere and its use by APL to further the Laboratory's support of its sponsors will be covered in separate guidance.

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MISSION







TRANSFER

PARTNER

DISCOVER

As part of the Johns Hopkins University's Innovation Ecosystem, the commercialization and technology transfer strategy of the Johns Hopkins University Applied Physics Laboratory (APL) seeks to:

- transfer knowledge and technology responsibly and with speed, agility, and transparency;
- partner strategically with others to support research and development;
 and
- **discover** technological advances throughout the world to help solve the nation's most complex national security and space exploration challenges.

The APL Office of Technology Transfer (OTT) manages APL-affiliated intellectual property (IP) to help ensure its broadest possible impact, including in fields advancing health-enhancing capabilities. APL staff members are encouraged to explore how to disclose their IP and participate in the technology transfer process. The role of OTT and its experienced licensing staff is to support APL inventors in this process—balancing catalyzing innovation with the protection of APL IP.

Office of Technology Transfer

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Mailstop 7-127

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Internal website: https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx

External website: http://www.jhuapl.edu/About/OTT

TECHNOLOGY TRANSFER OVERVIEW

What is technology transfer?

Technology transfer is broadly defined as the overall process by which knowledge, facilities, or capabilities promote U.S. innovation and industrial competitiveness in order to enhance economic security and improve quality of life. It can occur in many ways, such as through publications, exchanges at conferences, and relationships with industry. However, for the purposes of this guide, "technology transfer" refers to the formal licensing of technology and IP to other parties to benefit APL, the rest of Johns Hopkins University (JHU), sponsors, the nation, and, when appropriate, international persons.

It is important to note a distinction between technology transition and technology transfer. Transition is typically made directly to the U.S. government or a government-selected contractor for further development of the technology and/or production and integration into operational systems. Technology transition is the primary method by which APL transfers knowledge/IP to the U.S. government in furtherance of APL's mission. Transfer is typically made to an industrial/commercial entity for the purpose of generating new products or services for public use.

What is intellectual property?

IP represents creations of the mind, such as inventions, literary and artistic works, software, proprietary information, and designs as well as symbols, names, and images used in commerce. IP is protected by, for example, patents, copyrights, trade secrets, and trademarks, which enable IP owners to earn recognition and financial benefit from what they invent or create.

How is technology transferred?

Technology is typically transferred through a license agreement in which APL grants its rights in the defined technology to a third party (the licensee) for a period of years. This license agreement is sometimes limited to a particular field of use and/or region of the world. The licensee may be an established company or a new business start-up. Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to APL.

These payments are shared with the inventors and are used to provide support for further research and development (R&D) and participation in the technology transfer process.

Why would APL staff members want to participate in the technology transfer process?

The reasons may include:

- attracting R&D sponsors and additional funding;
- meeting the obligations of a R&D contract;
- making a positive impact on society;
- achieving recognition and financial rewards; and
- feeling a sense of personal fulfillment.



What is the Bayh-Dole Act?

The U.S. Bayh-Dole Act of 1980 allows universities and other nonprofit institutions to obtain title to inventions developed from federally funded R&D provided certain obligations are met. These obligations include trying to protect (when appropriate) and commercialize the discoveries. submitting progress reports to the funding agency, giving preference to small businesses that demonstrate sufficient capability, and sharing any resulting revenues with the inventors. The Bayh-Dole Act is credited with stimulating interest in technology transfer activities and generating increased R&D, commercialization, educational opportunities, and economic development in the United States.

What is the Office of Technology Transfer (OTT) and what does it do?

OTT is an enterprise group within the Legal and Commercialization Branch of APL's Central Laboratory. It includes technology managers who have strong technical backgrounds and who are highly experienced in IP management, licensing, and business development. Aligned with one or more APL sectors, departments, and mission areas, each technology manager works closely with management and technical staff as a trusted partner to ensure that APL's IP objectives are met in accordance with sponsor sensitivities and APL's overall goals as a university affiliated research center (UARC). Furthermore, OTT works to ensure that any specific IP-related priorities of particular sectors and departments

are addressed with regard to the technology transfer process.

OTT provides guidance on transferring APL-developed technologies and other IP to further sponsor-directed production or commercial development and distribution.

NOTE: Throughout this guide, unless specifically described otherwise, the term "inventor" includes individuals listed on patents or patent applications as well as contributors who have created IP that is not patented.



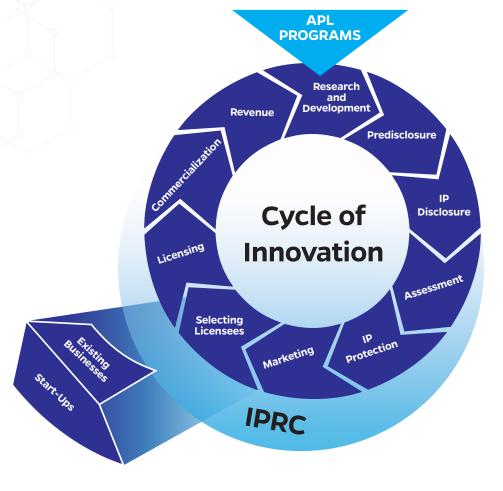
TECHNOLOGY TRANSFER PROCESS

How do I work with OTT?

You are encouraged to contact OTT (https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx) during your early R&D activities. The staff at OTT will work with you to make you aware of and advise you of the options that will best leverage the commercial potential of your technology. The technology managers in OTT are trained to assist you with questions related to marketability, patenting and other protection methods, new business start-up considerations, APL policies and procedures, and much more.

How long does the technology transfer process take?

The process of protecting the technology and finding the right licensing partner may take months or even years to complete. The length of time will depend on the development stage of the technology, the market for the technology, competing technologies, the amount of work needed to bring a new concept to market-ready status, and the resources and willingness of the licensees and the inventors.



10 STEPS TO COMMERCIALIZATION

The process of technology transfer is summarized in the steps that follow. Note that these steps can vary in sequence and often occur simultaneously.

1. RESEARCH AND DEVELOPMENT

Observations and experiments during R&D activities often lead to discoveries and the creation of IP. Often, multiple inventors will have contributed to the IP.

2. PREDISCLOSURE

An early contact with OTT in which you discuss your IP with a technology manager, who provides guidance with respect to the disclosure, evaluation, and protection processes.

3. IP Disclosure

The written notice of IP creation to OTT that begins the formal technology transfer process. An IP Disclosure remains a confidential document and should fully document your IP so that the options for commercialization can be evaluated and pursued.

4. ASSESSMENT

The period in which your technology manager reviews the IP Disclosure, conducts a patentability review, and analyzes the market and competitive technologies to determine the IP's commercialization potential.

This evaluation process will guide the strategy on whether to focus on licensing to an existing company or to a new business start-up.

5. IP PROTECTION

Safeguarding IP with protection through patents and copyrights is crucial to fostering innovation because without protection, inventors may be stymied in continuing to develop their ideas and commercialization partners may be reluctant to invest capital to bring IP to market in a good or service.

Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent and Trademark Office (USPTO) and, when applicable, with foreign patent offices. Once a patent application has been filed, it typically will require several years and tens of thousands of dollars to obtain issued U.S. and foreign patents. Other APL protection methods include copyright, trademark, tangible R&D property (e.g., biological material), and contractual use restrictions (e.g., for databases and materials). OTT works with the Intellectual Property Review Committee (IPRC) to determine the most appropriate IP protection strategy.

6. MARKETING

The technology manager identifies candidate companies that have the expertise, resources, and business networks to bring the technology to market. This may involve marketing to an existing company or a start-up. Your active involvement can dramatically help facilitate the marketing process.

7. SELECTING LICENSEES

OTT is committed to selecting licensees who have the greatest potential to commercialize the invention/technology. After companies are selected, the technology manager will work with those potential licensees to develop the appropriate financial and diligence terms to fully commercialize the technology. In some cases, APL IP may be licensed to APL start-ups, which have access to Johns Hopkins Tech-

nology Ventures' various resources (https://ventures.jhu.edu/), including the Fast Forward incubator and Mentors-in-Residence program.

8. LICENSING

Once a licensee has been identified, an agreement has been negotiated. and the IPRC has considered the potential licensee, OTT will execute a license agreement. A license agreement is a contract between APL and a third party in which APL's rights to a technology are licensed, without relinquishing ownership, for fair consideration (e.g., an up-front fee, milestone payments, royalties) and other benefits. License agreements are used with both new start-up businesses and established companies. An option agreement is sometimes used to enable a third party to evaluate the technology and its market potential for a limited time before making a decision about licensing.

9. COMMERCIALIZATION

The licensee continues the advancement of the technology and makes other business investments to develop the product or service. This step may entail further development, regulatory approvals, sales and marketing support, training, and other activities.

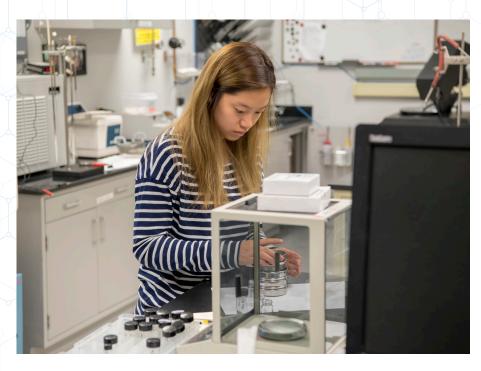
10. REVENUE

Revenues received by APL from licenses are shared among APL, inventors, JHU, and, if applicable, partnering institutions to fund additional R&D and education and to encourage further participation in the technology transfer process.

How can I help in this process?

- Contact OTT (https://aplweb.jhuapl.edu/innovation/ott/
 Pages/default.aspx) when you believe you have created, discovered, or authored something unique with potential commercial or R&D value.
- Next, complete and submit the IP Disclosure form at https://aplweb.jhuapl.edu/insideapl/cll/IP/Pages/Intellectual-Property-Disclosure.aspx.
- It is critical to contact OTT
 before submitting a manuscript
 for review and publication,
 publicly disclosing your technology, or holding any discussions
 with people outside of APL.
 Failure to do so may result in
 loss of patent rights and
 possibly hinder the opportunity
 to market your IP.
- If you must present or discuss your technology with an outside party, please notify the technology manager of any

- such meeting or discussion before disclosing the information so that the technology manager can have them sign a nondisclosure agreement to protect your IP.
- On the IP Disclosure form, include companies and contacts you believe might be interested in the IP or who have already contacted you about the IP.
- Respond to OTT and IP counsel requests. While some aspects of the patent and licensing process may require significant participation on your part, OTT will strive to make efficient use of your valuable time.
- Keep OTT informed of upcoming publications or interactions with companies related to your IP.



R&D CONSIDERATIONS

Will I be able to publish the results of my R&D and still protect the commercial value of any related IP?

Yes. Because patent rights are affected by these activities, it is best to submit an IP Disclosure form well before communicating or disclosing your invention to people outside of APL. There are significant differences between the United States and other countries as to how early publication affects a potential patent. Once publicly disclosed (published or presented in any form), an invention may have restricted or minimal potential for patent protection outside of the United States. Be sure to inform the technology manager assigned to you of any imminent or prior presentation, lecture, poster, abstract, website description, R&D proposal submission, dissertation, publication, or other public presentation including the invention.

May I use material or IP from third parties in my R&D?

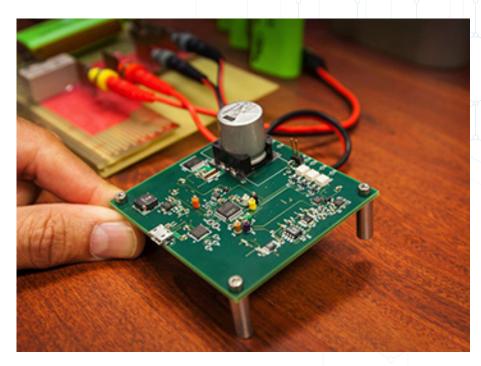
Generally yes, as long as the Laboratory has obtained the appropriate authorizations from the third parties (with exceptions for certain commercial-of-the-shelf materials). This may be done in a variety of ways but typically involves APL Legal's review and execution of any applica-

ble third-party license agreements, nondisclosure agreements (NDAs), and/or material transfer agreements (MTAs). For sponsored R&D, the use of third-party IP or materials may be restricted and/or subject to the sponsor's preapproval. In all cases, use of third-party IP or materials should be in compliance with the terms of any applicable third-party agreements or licenses. This includes the use of open-source software, which may be available for use at no charge but may impose certain restrictions and obligations on its use, as specified in an open-source license. Furthermore, it is important to carefully document the use of third-party IP or materials to allow for the determination of any impact on the ownership and license rights of your subsequent R&D results.

Will I be able to share materials, R&D tools, or IP with others to further their R&D?

It depends on several factors, including authorization from your management chain, approval through the Laboratory's public release process, any sponsor requirements and sensitivities, and IP protection considerations.

Contact OTT (https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx) for additional information.





What rights does an R&D sponsor have to any discoveries or IP associated with my R&D?

For federally funded R&D, the rights of the U.S. government are provided by federal laws and regulations specifically incorporated into government contracts. In these arrangements, APL typically retains ownership of IP generated from the R&D and has the ability to commercialize the IP subject to certain conditions and requirements, while the U.S. government obtains a free, nonexclusive license to use the IP for government purposes.

For R&D funded by industry or another non-U.S. government sponsor, APL typically negotiates to retain ownership of IP that it generates from the R&D as well as nonexclusive rights to practice the IP for internal R&D and U.S. government purposes. The industry sponsor will usually seek exclusive rights to exploit the IP for commercial purposes and may seek to impose obligations on APL with regard to reporting and protecting any generated IP and publishing R&D results.

What about consulting?

When APL staff members enter into consulting agreements, they are deemed to be acting outside the scope of their employment. Prior to entering into such agreements, APL staff members must obtain approval from their management chain and the APL Principal Ethics and Compliance Officer (PECO) to engage in this form of outside activity. Furthermore, while personal consulting agreements are

reviewed by APL as part of the approval process, they are not negotiated by APL on the staff member's behalf. APL staff are expected to ensure that the terms of the consulting arrangement are consistent with APL policies, including those related to IP ownership, employment responsibilities, and use of APL IP and resources.

IP DISCLOSURES

What is an IP Disclosure?

An IP Disclosure is a written description of your invention or development. Staff should provide in the IP Disclosure, for example, a list of all inventors (or authors), information about any funding used to develop the IP, a full description of the IP, and details of any prior or planned public disclosures or uses of the IP. Any additional relevant material may be included in (or as an attachment to) the IP Disclosure. IP Disclosures are internal APL documentation and remain confidential to APL. They do not, in and of themselves, protect the underlying IP.

After the IP Disclosure has been received and processed, OTT will set up an initial meeting between an assigned technology manager and one or more of the APL inventors listed on the IP Disclosure to discuss and assess the technical details, any mission area or sponsor sensitivities, plans for further development, possible commercial applications, and steps that may be required to appropriately protect the IP.

How do I submit an IP Disclosure?

You can download an IP Disclosure form and instructions at the following link: https://aplweb.jhuapl.edu/ insideapl/cll/IP/Pages/Intellectual-Property-Disclosure.aspx.

Submitted IP Disclosures are received and processed by APL Legal and are then assigned to technology managers in OTT. Contact APL Legal (https://

aplweb.jhuapl.edu/insideapl/cll/Pages/default.aspx) or OTT (https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx) with any questions.

When should I submit an IP Disclosure?

You should complete and submit an IP Disclosure whenever you feel you have discovered or developed something unique with possible commercial value. For inventions, IP Disclosures should generally be submitted once a definite idea of the complete and operative invention has been conceived. This does not necessarily require extensive testing of a proof of concept or a working prototype of the invention, but it does require more than identifying a problem to be solved coupled with a general but incomplete concept for solving the problem. For copyrighted works, IP Disclosures should be submitted

once the work is fixed into a tangible medium such as a book, software code, video, etc.

To the extent possible, an IP Disclosure should be submitted well before the discovery is presented (e.g., through publications, poster sessions, conferences, or press releases), included in a proposal or contract, or delivered to a sponsor or contractor. Once the IP is publicly disclosed or in public use, a 1-year grace period within which to file a patent application is triggered in the United States, and the invention may have restricted or minimal potential for patent protection outside of the United States. As a result, be sure to inform OTT of any imminent or prior public use, presentation, lecture, poster, abstract, website description, R&D proposal, dissertation, publication, or



other public presentation that includes the invention.

Why should I submit an IP Disclosure?

APL staff members are required to disclose all IP that they develop while employed by the Laboratory, regardless of how, when, or where the IP was made and regardless of the source of funds (if any) used in its development. This requirement is outlined in APL's Intellectual Property Agreement (see https://aplweb.jhuapl.edu/insideapl/ cll/IP/Documents/APL%20Intellectual %20Property%20Agreement.pdf), which is executed by all APL staff as a condition of their employment. Once an IP Disclosure is received, APL Legal determines whether the IP constitutes APL IP in consultation with OTT, the respective APL inventor(s), and if necessary, the IPRC or respective mission area executives (MAEs).

Timely disclosure of IP enables the Laboratory to comply with the Bayh-Dole Act as well as other statutory and contractual requirements to properly report IP to government sponsors, and ultimately, it ensures APL's ability to compete for future work from government sponsors. Furthermore, statistics on IP Disclosures are an important metric used by the Laboratory when evaluating the effectiveness of innovation investments (e.g., Project Catalyst, independent research and development [IRAD]).

How do I know if my discovery is an invention?

You are encouraged to submit an IP Disclosure for all inventions and developments that you feel may solve a significant problem and/or have significant value. If you are in doubt, contact OTT (https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx) to discuss the invention and strategies for commercialization.

Should classified IP be submitted in an IP Disclosure?

Yes, IP that is classified should still be submitted, but steps should be taken to appropriately limit the classified details of the IP that are provided in the IP Disclosure form. Contact APL Legal (https://aplweb.jhuapl.edu/insideapl/cll/Pages/default.aspx) before submitting such a disclosure.



OWNERSHIP OF IP

What is APL's policy on ownership of IP?

APL's Intellectual Property Agreement applies to all APL staff members and specifies APL's policies in accordance with G&P #002-0015, Intellectual Property Agreement (https://ecm. jhuapl.edu/sites/GP/_layouts/15/ WopiFrame.aspx?sourcedoc=/sites/ GP/Docs/Intellectual_Property_ Agreement.docx&action=default& DefaultItemOpen=1), regarding its ownership of IP developed by APL staff while employed by APL. JHU owns and APL manages IP that is made, conceived, first reduced to practice (e.g., putting a concept into practice or applying a concept), created, or authored by APL staff members (solely or jointly with others) while employed by APL that meets at least one of the following criteria:

- The IP is funded in whole or in part by APL or a sponsor of APL.
- The IP involves the use of APL facilities, personnel, equipment, materials, or APL proprietary information.
- The IP is prepared within the scope of the staff member's employment.
- 4. The IP is related to APL programs or activities.

For course materials, such as lectures and related notes, syllabi, presentations, and textbooks, IP ownership belongs to the APL staff member(s) who prepared the materials (subject to third-party interests) as long as none of the first three criteria apply to the development of the course materials and the course materials do not include information specific to an APL program or activity. Questions regarding APL's IP ownership policies should be directed to APL Legal (https://aplweb.jhuapl.edu/insideapl/cll/Pages/default.aspx).

Does APL enforce its IP?

Since APL IP is owned by JHU, APL will work with JHU to defend its IP against infringement by others who have not secured a license from APL. Such actions are rare, but OTT

welcomes the input of inventors when they are aware of infringement by others.

Should I list researchers from other institutions on my IP Disclosure?

All contributors to the ideas leading to a discovery should be noted in your IP Disclosure, even if they are not APL employees. OTT, along with APL Legal, will determine the rights of such persons and their respective institutions and, if appropriate, negotiate inter-institutional agreements to address how jointly developed IP will be managed with regard to protection and commercialization. It is prudent to discuss with OTT all working relationships (preferably before they begin) so that the implications for any subsequent IP can be understood better.



ASSESSMENT OF AN IP DISCLOSURE

How does OTT assess IP Disclosures?

Technology managers in OTT examine each IP Disclosure to review and evaluate the IP on the basis of several criteria. These include the problem to be solved, magnitude of the proposed solution, size of the unmet need and potential market, potential customers and market segments, competitive landscape, capital requirements, milestones to move the technology to market, and companies that might commercially license the technology. OTT also carefully considers preexisting rights associated with the IP and also investigates any actual or potential sponsor or mission area sensitivities.

How does OTT decide whether to commercialize with a traditional or an "open-source" license for software?

Generally, OTT supports APL software developers who desire to make software open source provided that APL retains the right to distribute the program freely, open sourcing is consistent with obligations to sponsors, and the developer's management chain and mission area support the decision. As a first step, developers should seek authorization from their management chain and MAE. Additional information on opensource software development is provided at https://aplweb.jhuapl. edu/insideapl/cll/IP/Pages/Open-Source.aspx.

Will APL honor specific preferences of inventors with regard to technology transfer strategies?

OTT will work with you to develop the appropriate technology transfer strategy for the IP. The strategy will be selected with the best interests of the Laboratory in mind and will be subject to overall direction from the IPRC as well as sector and department priorities. Some technologies lend themselves to nonexclusive licensing (licensing to multiple parties), while others will only reach the commercial marketplace, and therefore the public, if they are licensed on an exclusive basis. Some technologies are suitable only for transition to another party at the direction of a sponsor. Although APL will give careful consideration to the preferences of APL staff with regard to technology transfer, any final decision will be determined by the IPRC, in consultation with OTT, on the basis of an objective assessment of approaches that will best protect APL's interests while producing the greatest impact.



PATENTS AND IP PROTECTION

What is a patent?

In the United States, a patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention. A patent does not necessarily provide the holder any affirmative right to practice a technology since it may fall under a broader patent owned by others. Instead, it provides the right to exclude others from practicing the invention. Patent claims are the legal definition of an inventor's protectable invention.

Patents may provide protection of ideas and concepts that are novel, not obvious, and constitute patent-eligible subject matter. Since the scope of protection may extend to base ideas and concepts, i.e., beyond a particular implementation of an idea or concept, patents offer a potentially broad scope of protection. As a result, patents are

generally considered a strong form of IP protection and are often highly valued by industry for commercial purposes and as an indication of technical innovation.

What type of subject matter can be patented?

Patentable subject matter includes processes (including some forms of computer-implemented software or algorithms), machines, articles of manufacture, and compositions of matter. In general, abstract ideas, laws of nature, and natural phenomena are not eligible for patent protection.

What is the U.S. Patent and Trademark Office (USPTO)?

The USPTO is a federal agency, organized under the U.S. Department of Commerce, that administers

patents on behalf of the government. The USPTO employs patent examiners skilled in all technical fields in order to appraise patent applications. It also issues federal trademark registrations.

What is the definition of an inventor on a patent and who determines this?

Under U.S. law, a patent inventor is a person who takes part in the conception of the ideas represented by the claims of a patent. A person who merely provides routine assistance in implementing the invention, but does not contribute toward the conception of the novel ideas, is not considered to be an inventor for patent purposes. Ultimately, determining inventorship is a legal issue that may require review and determination by APL Legal. APL inventors may be required to execute assignment documents that formalize APL's (JHU's) ownership of the IP.



Patent filling decisions are made by OTT (in consultation with APL Legal) in view of several inputs, including market research, patentability evaluations, mission area and sponsor sensitivities, feedback from inventors, and budget constraints. APL Legal oversees the preparation and management of patent applications and issued patents in consultation with OTT. APL Legal will typically engage outside patent counsel to prepare and prosecute U.S. nonprovisional and international patent applications on APL's behalf. Inventors work with



outside patent counsel in drafting patent applications and responses to worldwide patent offices.

OTT ultimately makes the final decision whether to file a patent application or seek another form of protection.

Why does APL protect some IP through patenting?

Patent protection is often a requirement of a potential commercialization partner (licensee) because it can protect the commercial partner's often sizable investment, which is required to bring the technology to market. Due to their expense and the length of time required to obtain a patent, patent applications are not possible for all APL inventions. OTT carefully reviews the commercial potential of an invention before investing in the patent process. However, because the need to commence a patent filing usually precedes finding a licensee, OTT looks for creative and cost-effective ways to seek early protections for as many promising inventions as possible.

What is the patenting process?

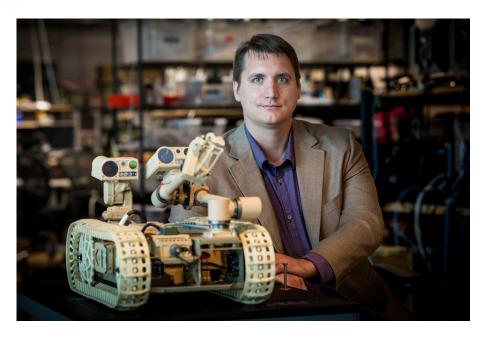
APL Legal will request outside patent counsel to work with the APL inventor(s) to prepare U.S. nonprovisional and international patent applications. The outside patent counsel will schedule an initial call with the primary APL inventor point of contact (POC) to discuss the invention, determine whether additional materials are needed from the inventors, and

discuss a mutually acceptable schedule for drafting and reviewing the application. Outside patent counsel will typically send a first draft of the patent application to the APL inventor POC within 1-2 weeks of the initial call and request feedback on the technical accuracy and completeness of the application as well as the scope of the claims. Once the feedback is received, outside patent counsel will typically iterate to provide a second draft within 1 week for final technical review by the APL inventor POC. After any final inventor feedback is incorporated into the draft, outside patent counsel will send the final draft to APL Legal for final review before the application is filed at the USPTO. The entire preparation process, i.e., from the initial call with the APL inventor POC to USPTO filing, can take 4-6 weeks but varies based on the technical complexity of the invention, any

additional iterations of the draft that may be required, and the availability and responsiveness of the APL inventor POC during the review period.

After filing, patent applications are initially treated on a confidential basis by the USPTO, but most are published by the USPTO 18 months after the application's earliest effective filing date. All issued patents are published by the USPTO. Since issued patents and most patent applications are made available to the public, seeking patent protection may not be suitable for all APL inventions because of the nature of the inventions and/or sponsor sensitivities.

Within approximately 1–2 years of the filing date, depending on the technology, APL Legal will receive written notice from the USPTO as to whether the application and its claims have



been accepted in the form as originally filed. More often than not, the USPTO rejects the application because the claims are determined to be unpatentable over the "prior art" (for example, in the form of earlier patents or publications in the relevant technical field). The written notice sent by the USPTO is referred to as an Office Action.

If the application is rejected, APL Legal coordinates with outside patent counsel to prepare a written response to the Office Action, and this response is typically filed at the USPTO within 3 months of the date of the Office Action. Generally, the written response may seek to amend the claims to overcome the teachings in the prior art and/or point out why the USPTO's previous rejection was incorrect. This procedure of receiving an Office Action and submitting a written response to persuade the USPTO to withdraw its rejection and allow the patent application to issue as a patent is referred to as patent prosecution. It is not unusual for several iterations of patent prosecution to take place before the USPTO allows the patent application or a decision is made to abandon the patent application. During the patent prosecution process, APL Legal may request input from the inventor(s) to confirm the technical aspects of the invention and/or the prior art cited against the application by the USPTO. It may take on average 2-4 years for a patent to be issued after the patent application filing date.

What if I created the invention with someone from another institution or company?

If you created the invention under a sponsored R&D agreement with a company, OTT in coordination with APL Legal will need to review the agreement to determine ownership and other rights associated with the invention and to determine the appropriate next steps. If the technology was jointly developed with staff from another academic institution, OTT will usually enter into an inter-institutional agreement that outlines which institution will take the lead in protecting and licensing the invention, how expenses associated with the patenting process will be shared, and how licensing revenues will be allocated.

Will APL initiate or continue patenting activity without an identified licensee?

APL may choose to accept the risk of filing a patent application before a licensee has been identified. After APL's rights have been licensed to a licensee, the licensee generally pays the patenting expenses. At times OTT may discontinue further patent prosecution after a reasonable period of attempting to identify a licensee (or if it is determined that APL cannot obtain reasonably valuable claims from the USPTO).

Is there such a thing as a provisional patent?

No. However, there is a provisional patent application, which is described below.



What is the difference between a provisional patent application and a regular (or nonprovisional) patent application?

In certain circumstances, OTT may decide to pursue a U.S. provisional patent application as a potential precursor to a subsequent U.S. nonprovisional or international patent application. There are often various advantages to doing this, including delaying the expense and effort required to prepare a nonprovisional or international patent application until the invention has been further developed, the commercial market for the invention has been more fully assessed, or additional funds are made available to pursue patent protection. Filing a provisional patent application may provide these advantages while preserving patent rights to the invention. A related regular (nonprovisional) U.S. patent application and international patent applications must be filed within 1 year of the provisional patent application in order to receive its earlier filing date. However, an applicant receives the benefit of the earlier filing date only for material that is adequately described and enabled in the provisional patent application. As a result, it is important to include all up-to-date materials in the provisional patent application.

How much does it cost to obtain a patent?

Preparing and filing a U.S. nonprovisional or Patent Cooperation Treaty patent application is very expensive. Life cycle costs can reach into the tens of thousands of dollars.

What is the time line of the patenting process and resulting protection?

Currently, the average U.S. utility patent application is pending for about 2–4 years, depending on the technology involved. Once a patent is issued, it is enforceable for 20 years from the initial filing date of the patent application that resulted in the patent, assuming that USPTO-mandated maintenance fees are paid after the patent issues.

What other forms of IP protection are considered besides patents?

OTT coordinates with APL Legal to determine what form of IP protection is most appropriate and necessary based on, for example, the nature of the IP and how the IP is likely to be utilized and/or commercialized. Besides patents, other forms of IP protection include copyrights, trade secrets, and trademarks.

Copyrights are a form of IP protection provided by federal laws to the authors of "original works of authorship." These include literary, dramatic, musical, artistic, and certain other intellectual works, including computer software. This protection is available to both published and unpublished works. The federal Copyright Act generally provides the owner of a copyright the exclusive right to conduct and authorize various acts, including reproduction, public performance, and making derivative works of the original work. Copyright protection is automatically secured



when a work is fixed into a tangible medium such as a book, software code, video, etc. In some instances, a copyright may be registered, but registration is generally unnecessary until a commercial product is ready for manufacture or a copyright enforcement action is ready to be initiated.

Copyrights in "works made for hire"—e.g., works made by APL staff within the scope of their employment at APL—vest with the author's employer and last for the lesser of 95 years from publication or 120 years from creation. "Personal" copyrights generally last for the life of the author plus 70 years.

A "derivative work" is a work based on one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgment, condensation, or any other form in which a work may be recast, transformed, or adapted. A work consisting of editorial revisions, annotations, elaborations, or other modifications that, as a whole, represent an original work of authorship is a "derivative work." The owner of a copyright generally has the exclusive right to create derivative works.

Copyrights are applicable to IP such as books, images and photographs, and technical papers. Software developed by APL staff is also primarily protected by copyright. In all cases, staff should use proper copyright markings (see https://aplweb.jhuapl.edu/insideapl/cll/IP/Pages/Copyright-Markings.aspx).

Trade secrets are proprietary information (e.g., practices, formulas, processes, designs, compilations) that derive value from not being known by the public and that are reasonably protected to maintain secrecy. Once a

trade secret is disclosed (for example, in a patent), it is no longer a trade secret.

Trade secret protection attaches immediately with no requirement for registration. The duration of protection may last indefinitely as long as the proprietary information remains secret. However, the protection may be fragile as inadvertent disclosure of the proprietary information may negate the protection.

Trademarks include any word, name, symbol, device, or combination that is used in commerce to identify and distinguish the goods of one manufacturer or seller from those manufactured or sold by others, and also to indicate the source of the goods. In short, a trademark is a brand name. A service mark is any word, name, symbol, device, or combination that is used, or intended to be used, in commerce to identify and distinguish the services of one provider from those of others, and to indicate the source of the services.

Trademark registration is a procedure in which the USPTO determines rights based upon legitimate use of the mark. However, it is not necessary to register a trademark or service mark to prevent others from using the trademark. Trademarks generally become protected as soon as they are adopted by an organization and used in commerce, even before registration. With a federal trademark registration, the registrant is presumed to be entitled to use the trademark throughout the United States for the



goods or services for which the trademark is registered.

How is IP handled in APL's R&D contracts with the U.S. government?

The "rules" concerning ownership and rights in inventions and copyrighted works created in performing work under a U.S. government contract primarily come from standard government contract clauses implementing provisions in the Federal Acquisition Regulations (FAR) and, for Department of Defense (DoD) contracts, the DoD FAR Supplement (DFARS).

For inventions/patents, APL usually owns inventions that are conceived or first actually reduced to practice in the performance of work under a government contract ("subject inventions"), while the government obtains license rights to use (or allow others to use) the subject inventions. However, failure to comply with the requirements in a contract may result in the government obtaining ownership of the invention from APL. Some sample contractual requirements include disclosing the invention to the government, reporting publications, describing the invention, and filing patent applications within specified periods of time. APL Legal is responsible for ensuring that these requirements are met. IP Disclosures should be submitted even if the IP is developed outside a set of task deliverables.

For copyrighted works developed under a government contract, including technical data and computer software, APL usually owns the copyrighted works it creates, while the government retains certain rights to those works. The government's rights are primarily based on funding. For example, if the work was developed exclusively at the government's expense, the government obtains "unlimited rights" to the work. However, if APL funds some (or all) of the work, the government generally is entitled to lesser rights: "government purpose rights" for mixed funding under DoD contracts and "limited rights" (in technical data) or "restricted rights" (in computer software) for exclusive APL funding. Furthermore,

the government obtains "unlimited rights" to works that are delivered under a contract, regardless of the funding source, unless APL takes certain steps, including: (1) asserting proper restrictions on the government's rights; (2) marking the technical data/software with the appropriate restrictive markings; and (3) maintaining records to substantiate the asserted restrictions. Failure to take these steps in a timely manner may result in APL forfeiting IP rights to the government, government contractors, and possibly even other commercial entities.



MARKETING TO FIND A LICENSEE

How does OTT market IP?

OTT technology managers use many sources and strategies to identify potential licensees and to market IP. These include leveraging existing relationships of the inventors, the OTT staff, and other researchers; conducting market research; examining other complementary technologies and agreements; using the external OTT website to post IP and related marketing materials; and seeking direct contacts through conferences and industry events. Staff publications and presentations often serve as excellent marketing tools as well.

How are most licensees found?

Studies have shown that 70% of licensees in university-based technology transfers are already known to inventors. Thus, inventors are often the primary source for potential licensees. Licensees are also identified through existing relationships of the OTT staff. APL licensees often license more than one technology from APL. OTT attempts to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events, and the cultivation of existing licensing relationships.

How long does it take to find a potential licensee?

It can take months and sometimes years to locate a potential licensee, depending on the attractiveness of the IP, its stage of development, competing technologies, and the size and intensity of the market. Most APL IP tends to be in the early stage in the development cycle and thus requires substantial commercialization investment, making it difficult to attract a licensee.

How can OTT help improve the marketability of early-stage IP?

OTT manages a small IRAD budget that focuses on investing in IP with a technology readiness level (TRL) that can be increased with a small amount of funding. The appropriateness of this funding for a given IP is often discussed as part of the initial inventor discussion with OTT. Proposals are solicited and may be awarded throughout the fiscal year.

How can I assist in marketing IP?

Your active involvement can dramatically improve the chances of match-

ing IP to an outside company. Your R&D and (if applicable) consulting relationships are often helpful in identifying both potential licensees and technology champions within companies. Once interested companies are identified, the inventor is the best person to describe the details of the IP and its technical advantages. The most successful technology transfer results are usually obtained when the inventor and OTT work together as a team to market the technology. OTT welcomes input from inventors during its marketing and licensing efforts.

Can there be more than one licensee?

Yes, IP can be licensed to multiple licensees, either nonexclusively to several companies or exclusively to several companies, each for a unique field of use (application) or geography.



LICENSES AND OTHER AGREEMENTS

What is a license?

A license is a permission granted to another party to use or exploit IP under mutually agreed-upon terms.

What is a license agreement?

APL license agreements describe the rights and responsibilities related to the use and exploitation of IP developed at APL. APL negotiates to retain the ability to use any of its licensed IP for internal use and for government purposes and to include various provisions intended to protect APL's interests. APL staff should contact OTT (https://aplweb.jhuapl.edu/innovation/ott/Pages/default.aspx)

with any questions on how to continue to use IP for internal and government purposes when that IP has been licensed to other parties. Additionally, APL commercial license agreements usually require that the licensee diligently seek to bring the IP into commercial use and provide a reasonable return to APL. For the purposes of transitioning sponsor-funded IP to another party (e.g., at the direction of a sponsor and with approval from the IPRC), a no-cost, nonexclusive government purpose license may be generated by OTT.

How is a company chosen to be a licensee?

For a commercial license, a licensee is generally chosen, barring any objections or concerns expressed by the IPRC, based on its ability to commercialize the technology for the benefit of the general public.

Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a start-up company is a better option. OTT conducts market research, taps its professional networks, and performs various evaluations and due diligence to determine the most suitable licensee. In the case of transitioning IP, generally the sponsor will specify the desired licensee. It is rare for APL to have multiple potential licensees bidding on its IP.

What can I expect to gain if my IP is licensed?

Per APL policy, APL inventors share in licensing income resulting from APL technology transfer agreements, including licenses. In addition, most inventors enjoy the satisfaction of knowing that their IP is being deployed for the benefit of the general public or to support the critical mission needs of our government sponsors. New and enhanced relationships with businesses and sponsors are another outcome that can augment R&D efforts. In some cases, additional sponsored R&D may result from the license.

What is the relationship between an inventor and a licensee, and how much of my time will it require?

Many licensees request and offer to fund the active assistance of the

inventor to facilitate their commercialization efforts, at least at the early stages of development. This assistance can range from infrequent, informal contacts outlined in an IP license agreement to a more formal consulting relationship facilitated through APL Contracts. Working with a new business start-up can require substantially more time, depending on the inventor's role in or with the company and their continuing role at APL. Participating in a start-up while being concurrently employed by APL is subject to APL's personal conflict of interest (PCOI) policies and contingent on the approval of your management chain and APL's PECO.

What other types of agreements and considerations apply to technology transfer?

NDAs are contracts that specify confidential or proprietary information to be shared by a disclosing party with a receiving party, and any conditions and obligations to be placed on the receiving party in using or sharing the disclosing party's information with other entities. NDAs are often used to protect the confidentiality of IP during evaluation by potential licensees. APL staff should request NDAs before sharing APL proprietary information with external parties. Standard NDAs can be requested via the online Agreement Records System (see https://secureapps.jhuapl.edu/

legal/nonDisclosure/login/signin.aspx?backto=myForm).

APL staff should not negotiate or execute NDAs on their own but instead should seek assistance and review from APL's NDA manager (see https://aplweb.jhuapl.edu/services/Pages/NDA.aspx) or APL Legal (https://aplweb.jhuapl.edu/insideapl/cll/Pages/default.aspx).

- MTAs, used in association with incoming and outgoing materials at APL, are administered by OTT (outgoing materials) or APL Legal (incoming materials). These agreements describe the terms under which APL staff members and outside researchers may share materials, typically for R&D or evaluation purposes. IP rights may be endangered if materials are used without a proper MTA in place.
- Inter-institutional agreements
 (IIAs) describe the terms under which two or more institutions will collaborate to assess, protect, market, license, and share in the revenues received from licensing jointly owned IP.
- responsible to the terms under which APL performs R&D services for sponsors in exchange for financial support provided by the sponsors to APL. In certain circumstances, APL may seek to subcontract with other

- entities to perform R&D services for APL. These agreements are negotiated and administered by the Business, Communications, and Facilities Department in coordination with the APL R&D team and the respective mission area as well as APL Legal and OTT, when appropriate.
- Cooperative research and development agreements (CRADAs) are joint R&D agreements in which APL works in collaboration with a government agency, each making in-kind contributions to the effort.



COMMERCIALIZATION

What activities occur during commercialization?

Most licensees continue to develop IP to enhance the technology, reduce risk, prove reliability, and satisfy the market requirements for adoption by customers. This can involve additional testing; prototyping for manufacturability, durability, and integrity; and further development to improve performance and other characteristics. Documentation for training, installation, and marketing is often created during this phase. Benchmarking tests are often required to demonstrate the product/service's advantages and to position the product in the market.

What is my role during commercialization?

Your role can vary depending on your level of interest and desire to be

involved, the licensee's interest in engaging with APL inventor(s) to further support transition of the technology, and any contractual obligations related to the license. Any role outside of your employment at APL is governed by APL's PCOI policy and should be reviewed by your management chain and APL's PECO before it is undertaken.

What revenues are generated for APL if commercialization is successful?

Most licensees are obligated to pay licensing fees that can be very modest (for start-ups or situations in which the value of the license is deemed to warrant a modest license fee) or can reach hundreds of thousands of dollars. Royalties on the eventual sales of licensed products or services based on APL IP can generate revenues, although this can take years to occur.

Equity, if included in a license, can yield returns but only if a successful equity liquidation event (e.g., public equity offering or a sale of the company) occurs. As a result, most licenses do not yield substantial revenues, especially in the near term.

A recent study of licenses at U.S. universities demonstrated that only 1% of all licenses yield over \$1 million. However, the rewards of APL IP reaching the market and making an impact are often more significant than the financial considerations alone. Licenses used to transition APL IP to another party at the direction of a sponsor are typically provided at no cost because of organizational conflict of interest (OCOI) concerns. However, these licenses are vital to the support of APL's overall mission.

What will happen to APL IP if a start-up company or licensee is unsuccessful in commercializing the technology? Can the IP be licensed to another entity?

Licenses typically include performance milestones, and not meeting those milestones can result in a license being changed from exclusive to nonexclusive, a license's field of use being narrowed, or even a license being terminated. These measures would enable subsequent licensing to another company.



NAVIGATING CONFLICTS OF INTEREST

The DoD UARC Management Plan requires UARCs to have a comprehensive organizational and personal conflicts of interest policy to ensure that the integrity and objectivity of UARC work is not compromised and does not appear to be compromised because of the presence of competing financial or personal interests.

How does APL's status as a UARC and trusted advisor to the federal government impact technology transfer at APL?

APL does not engage in relationships with industry that create actual and/or perceived OCOIs or erode the Laboratory's long-term, strategic relationship with the DoD. Any technology transfer agreement that requires APL to conduct development work for the industry licensee must adhere to G&P #001-0009, Work For Industry (https://ecm.jhuapl.edu/sites/GP/_layouts/15/WopiFrame2.aspx?sourcedoc=/sites/GP/Docs/Work For Industry. docx&action=default&DefaultItemOpen=1). In addition, APL maintains a WFI Business List (https://aplworks. jhuapl.edu/dept/cl/bc/Shared%20 Documents/Work%20For%20 Industry/WFI%20Business%20 List%202017_10_16%20final.xlsx) of industry contractors whose products or services APL evaluates on behalf of the government and with whom APL must maintain an independent and objective relationship. Any technology transfer agreement involving firms on the WFI Business List must be supported by the mission area and approved

by the Assistant Director of Programs, and in some cases may require approval of the DoD UARC Management Office.

A technology transfer agreement with industry may create actual and/or perceived OCOI or erode APL's long-term, strategic relationship with the DoD in a number of situations, such as where APL provides evaluation, advice, or requirements development for a sponsor regarding:

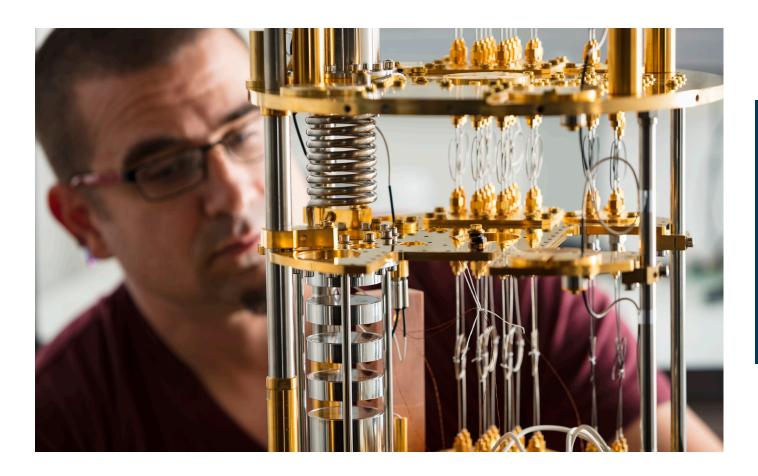
- a product/system for which APL receives royalties or other financial interests;
- a product/system that competes with a product/system for which APL receives royalties or other financial interests;
- a product/system of a company for which APL has an ownership interest:
- a potential solution or situation that involves a product/system or supplier for which APL receives a royalty, or has ownership or other financial interest: or
- any situation where APL's technology transfer agreement or association with the licensee could compromise or appear to compromise APL's integrity or objectivity.

In certain circumstances, it may be possible and desirable to enter into a technology transfer agreement despite the concerns outlined above

by implementing appropriate mitigation measures. For example, in some cases, APL may elect to transfer technology for less financial benefit (e.g., one-time license fee without the possibility of future royalties) or even forego licensing revenue altogether. In other cases, APL may provide the licensee with nonexclusive rights only or conversely publish or provide the technology on an open-source basis. In some situations, APL may transfer management of the technology transfer agreement to Johns Hopkins Technology Ventures. For all of these mitigation measures, or any others that APL implements, the purpose is to ensure that the integrity and objectivity of APL's UARC work is not compromised due to competing financial or personal interests while still enabling APL to generate and share license revenue with API inventors.

What is APL's policy on PCOIs with regard to outside activities?

APL enjoys significant benefits due to its status as a UARC. In order to maintain this status, APL and all APL staff must conduct business with a high degree of objectivity, integrity, and trust by avoiding any actual or potential PCOI, both as an organization and as individuals. Each staff member's actions can affect APL as a whole, and any unmitigated actual or potential PCOI could constitute a breach of contract or disqualify APL from performing work for our sponsors.



PCOIs are evaluated on a case-by-case basis by APL's PECO in accordance with G&P #001-0029, Outside Activities and Financial Interests (https://ecm.jhuapl.edu/sites/GP/Docs/Outside_Activities_and_Financial_Interests.docx). Staff members must also obtain prior supervisory approval of all outside employment or other outside activities that may present even the appearance of a conflict of interest. In general, outside activities must not interfere or conflict with a staff

member's role and responsibilities at APL. Additionally, a PCOI can occur if a staff member performs work for another organization (with or without pay) that would call into question the staff member's or APL's objectivity.

Involvement by APL staff members in any outside activity that presents an actual or potential PCOI that cannot be mitigated, including the activities of corporations, companies, sole proprietorships, nonprofit organizations, defense contractors, or labor

organizations that are directly or indirectly involved with APL, will not be permitted. In particular, APL staff members may not be employed by companies that have signed or are negotiating technology transfer agreements with APL without prior clearance from the PECO. APL staff members must not participate in the activity or enter into any agreements until final approval is obtained from the PECO.

INTELLECTUAL PROPERTY REVIEW COMMITTEE (IPRC)

What is the IPRC?

The IPRC (https://aplweb.jhuapl.edu/insideapl/cll/IP/Pages/IPReview
Committee.aspx) was formed in 2016 to provide guidance and direction to
OTT regarding the potential commercialization and licensing of APL IP.

The IPRC has a variety of roles and responsibilities, including enhancing senior-level visibility into the IP created in each sector and department to better facilitate Laboratory-wide collaboration; determining a disposition for key IP, including whether the IP should be kept confidential/ proprietary, made public, protected (e.g., patented), commercialized, given back to the sponsor, given back to staff, or deferred for a later decision; and determining whether conflict of interest issues exist, or are likely to arise, that will create impediments to effective licensing of the APL IP.

Who are the members of the IPRC?

The APL Assistant Director of Programs and the APL General Counsel currently cochair the IPRC. Key voting members of the IPRC include all APL MAEs (or their designees). IPRC advisory members include representatives from the engineering and technical staff as well as representatives from the Research and Exploratory Development Department, OTT, APL Legal, and the Business, Communications, and Facilities Department.

What is the inventor's role in the IPRC?

APL inventors may be called upon to assist OTT and the IPRC by providing technical details and insight into the IP they develop. Staff may also participate by serving as one of the technical representatives on the IPRC.

How are staff notified of IPRC decisions?

All staff members who have submitted an IP Disclosure for a given review period of the IPRC will receive a letter from OTT notifying them of the IPRC determination regarding their respective IP. Generally, the determination will be "Approved for Commercialization." "Not Approved for Commercialization," or "Hold" until a future date for further evaluation at the request of one or more IPRC members. Additionally, two technical representatives from the APL engineering and technical staff are appointed to the IPRC for 2-year terms. The technical representatives (https://aplweb.jhuapl.edu/ news/Pages/IPRCTechReps.aspx) serve as conduits between the IPRC and staff to ensure that staff concerns are represented on the IPRC.

What is the IPRC's role in licensing?

All potential licensees are brought by OTT to the IPRC for final approval, even when the IP in question has been "Approved for Commercialization."

This ensures that any mission area and

sponsor sensitivities and contractual obligations are properly considered prior to execution. Licenses are typically brought up for review at one of the quarterly IPRC meetings or via an out-of-cycle email approval process if time is of the essence or the IP in question was disclosed before the existence of the IPRC.

Can an IPRC decision be appealed?

OTT technology managers can bring an appeal to the relevant members of the IPRC when appropriate. An appeal decision may be made at the next scheduled IPRC meeting or via an out-of-cycle email approval process. Additionally, on an annual basis, if an inventor has requested reassessment by the IPRC, or if OTT has identified IP to have high commercial potential and/or high likelihood of improving the lives of people, the IPRC may reassess whether sponsor sensitivities are still present. If they are not present, the IPRC may redesignate the IP matter. If sponsor sensitivities persist but OTT strongly recommends that the IP matter be considered for commercialization, the IPRC can consider whether sponsor-related concerns can be ameliorated through a mitigation plan.

REVENUE DISTRIBUTIONS

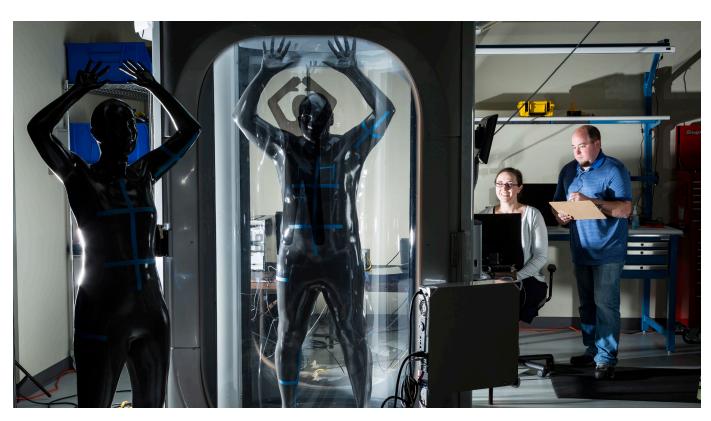
How are license revenues distributed?

OTT is responsible for managing the patent expenses and license income (e.g., derived from license execution fees, milestone payments, royalties) associated with technology transfer agreements. APL's primary goal with respect to technology transfer is to make an impact for the benefit of the nation, our sponsors, and the public at large—not to generate licensing income. However, to incentivize staff participation in the technology transfer process, APL shares license income earned from commercialization of IP with APL inventors. Accounting and Finance distributes license income from technology transfer agreements as follows:

- The first \$5,000 is split among the inventors.
- After deductions for expenses and administrative fees, the net cash income is further divided as follows:
 - 30% to the inventors
 - 60% to the APL Development Fund (supports technology transfer activities, including technology transfer grants, inventor engagement, recognition events and awards, development funding, and education and training)
 - 10% to the JHU Discretionary
 Fund

Therefore, technology transfer activities at APL may generate income that is shared among APL, its inventors, JHU, and, if applicable, partnering institutions. This income is reinvested in additional R&D and education, thus fostering the creation of the next generation of R&D, inventors, and entrepreneurs.

In addition, the resultant relationships created and deepened with these technology transfer activities support APL's mission. They result in additional R&D projects and broader R&D opportunities, collaborative investments, and an enhanced ability to create, retain, and share valuable resources.



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