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The Absolute Essentials of Bayh-Dole Compliance!

Welcoming remarks will begin at
11:55 a.m. Eastern Time.

The formal presentation will begin at Noon Eastern

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The following presentation reflects the personal views and thoughts of Rolande Johndro, and Ann Hammersla and is not to be construed as representing in any way the corporate views or advice of the Massachusetts Institute of Technology, or National Institutes of Health and their Affiliates, Subsidiaries or Divisions, nor the views or advice of the Association of University Technology Managers (AUTM). The content is solely for purposes of discussion and illustration, and is not to be considered legal advice.

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The Absolute Essentials of Bayh-Dole Compliance!

Speakers:

Ann M. Hammersla, J.D., *National Institutes of Health (NIH)*
Rolande Johndro, *MIT Technology Licensing Office*

April 5, 2016

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Questions?

We will be taking questions at the conclusion of the presentation.

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Ann M. Hammersla, J.D.,
National Institutes of Health

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Rolande Johndro
MIT Technology Licensing Office

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The Absolute Essentials of Bayh-Dole Compliance!

Bayh-Dole

- Adopted in 1980
- Bi-Partisan Legislation
- Codified in 35 U.S.C. § 200-212
- Implemented by 37 CFR 401
- Allows universities, small businesses, non-profits to elect ownership in federally funded inventions for the purpose of commercialization
- Kick started Tech Transfer
- Created Biotech Industry in U.S.

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Important Clauses

- Sec. 401.14 Standard patent rights clauses.
- (a) Definitions
- (1) ***Invention*** means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).
- (2) ***Subject invention*** means any invention of the *contractor* conceived or first actually reduced to practice in the performance of work under this *contract,* provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of *contract* performance
- (4) ***Made*** when used in relation to any invention means the conception or first actual reduction to practice of such invention.

401.14 cont.

- (b) Allocation of Principal Rights
- The ***Contractor*** may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.
- AKA – Confirmatory License

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Importance of Reporting

- Reporting Subject Inventions
  - Identifies potentially (at the time of reporting) promising discoveries using the definitions of Patenting:
    - Novel
    - Not obvious (to a person of ordinary skill in the area)
    - Has Utility (Useful)
    - & Also Plant Variety Protectable (different definitions than above; uncommon for NIH-very common for USDA/Agricultural Colleges)

Importance of Reporting Cont.

- These are indications of the productivity of Research Funding measured by items in above area in addition to research publications
- Links the potentially patentable (or plant variety protectable) Subject Inventions
  - To the Scientific Programs that funded them via the Award number(s) cited
  - Provides a conceptual basis of the discovery that may lead to a Patent/PVP application in the future
  - Ensures that different agencies are aware of combined efforts that may result in a single invention through the funding of multiple Federal agencies
  - Is a required obligation of the Contractor-patenting, though desirable, is not required, however Invention and Patent reporting is a Requirement

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Invention Disclosures

- (1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency,* the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor.*

Initial Notification

- Disclose 2 months from receipt of disclosure.
- Names of Inventors (not Authors.)
- Include all grant/contract numbers.
  - Must match Agency formatting.
  - If the format does not match, please verify by consulting original Award document face page or the Awarding Agency
  - If valid and does not work, please request the Agency to let NIH know – new Award formats do come out from time to time and NIH is not always aware of them when they are issued.
- Include technical description.
- Date of publication/public use (don't enter anticipated pub dates – no one knows if that publication will actually happens.)

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Best Practices for Managing & Reporting New Subject Inventions

- Always confirm funding with inventors – even/especially when they say the invention was not funded.
- Always record all funding in one centralized location in your database. (joint owner funding etc.)
- Always update the disclosure page to capture any additional/different contracts once funding sources have been confirmed.(will help avoid rejections.)
- Always collaborate with joint owners!!!
- No longer need to add EIR # to disclosure PDF before uploading.
- Run every month for the next 2 months.

Managing Jointly Owned Inventions

- Make sure both parties have disclosure & agree on Lead Compliance Inst.
- Confirm funding with inventors.
- Share & document case #s
- *Record all funding sources*

Made-up Sponsor Name –
Enter it for Each Non-MIT Govt. Sponsor.
Also Have One for Non-MIT Non-Federal Funding.
Makes reporting/managing SOGS easier.

Number & Name	Project	OSP Grant	Sponsor Comment
+ 000500 - NSF	6925633	CCF-1138967	
+ 5961 - NON-MIT GOVERNMENT SPONSOR		EFRI-1240383	NSF-Harvard

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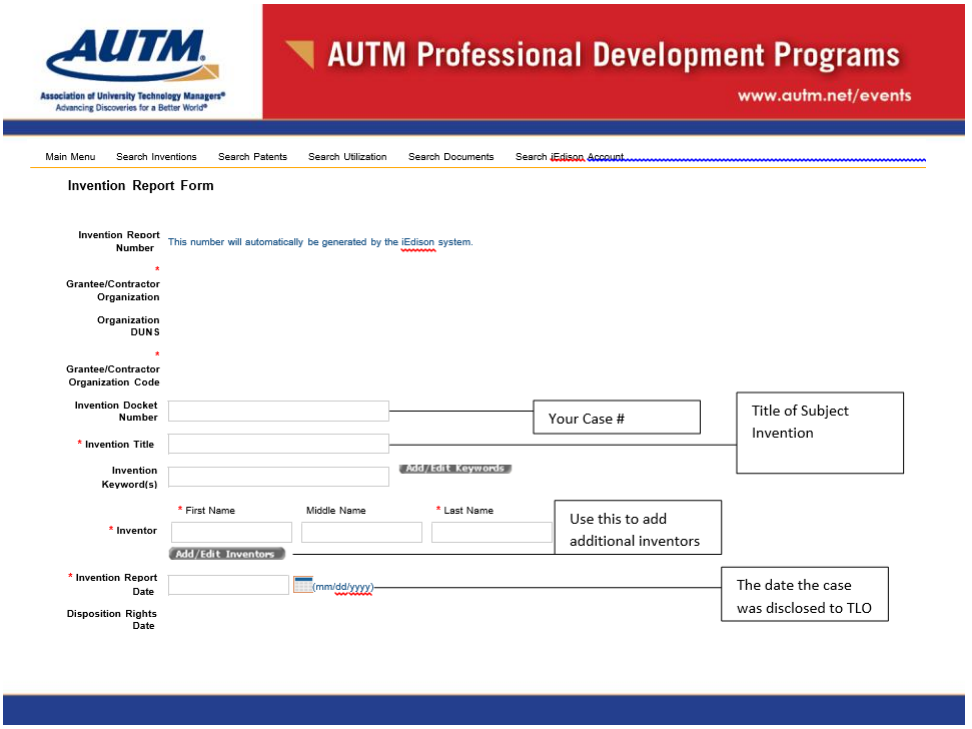
Reporting Jointly Owned Inventions

- Lead Inst. Should:
  - Share EIR # with JO
  - Include JO's Organization Code
  - Check in at Election Decision
  - Check in at filing of 1st non-provisional application to confirm SOGS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Main Menu
Search Inventions
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Search Utilization
Search Documents
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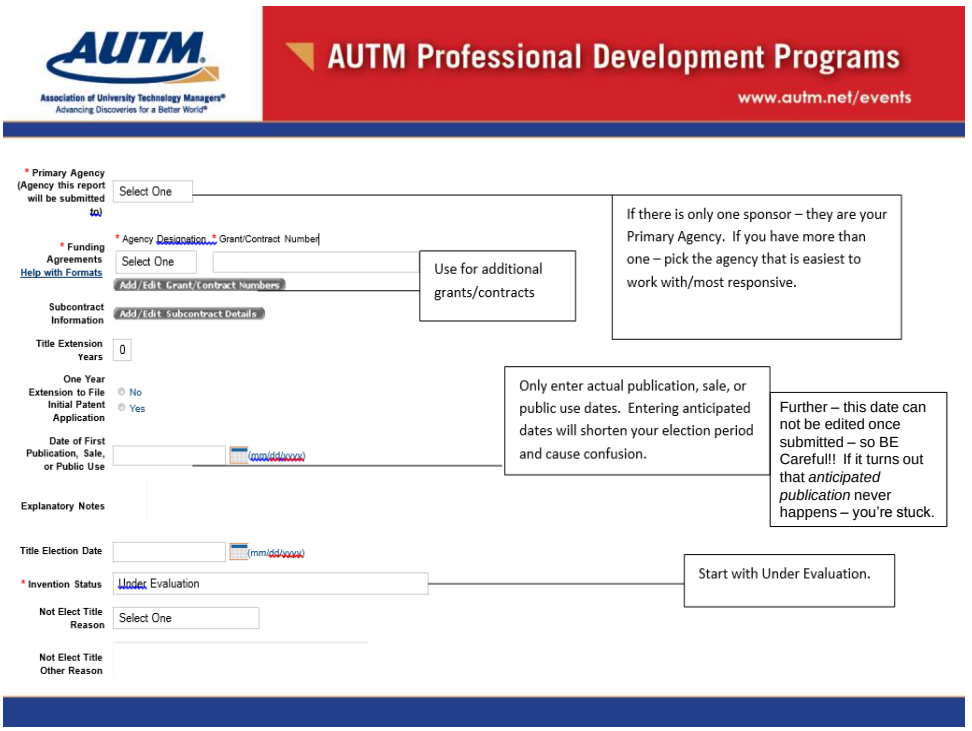
Invention Report Form
Invention Report Number
This number will automatically be generated by the iEdison system.
* Grantee/Contractor Organization
Organization DUNS
* Grantee/Contractor Organization Code
Invention Docket Number
Your Case #
* Invention Title
Title of Subject Invention
Invention Keyword(s)
Add/Edit Keywords
* Inventor
* First Name
Middle Name
* Last Name
Add/Edit Inventors
Use this to add additional inventors
* Invention Report Date
(mm/dd/yyyy)
The date the case was disclosed to TLO
Disposition Rights Date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* Primary Agency (Agency this report will be submitted to)
Select One
If there is only one sponsor – they are your Primary Agency. If you have more than one – pick the agency that is easiest to work with/most responsive.
* Funding Agreements
Help with Formats
* Agency Designation
* Grant/Contract Number
Select One
Add/Edit Grant/Contract Numbers
Use for additional grants/contracts
Subcontract Information
Add/Edit Subcontract Details
Title Extension Years
0
One Year Extension to File Initial Patent Application
No
Yes
Date of First Publication, Sale, or Public Use
(mm/dd/yyyy)
Only enter actual publication, sale, or public use dates. Entering anticipated dates will shorten your election period and cause confusion.
Further – this date can not be edited once submitted – so BE Careful!! If it turns out that anticipated publication never happens – you're stuck.
Explanatory Notes
Title Election Date
(mm/dd/yyyy)
* Invention Status
Under Evaluation
Start with Under Evaluation.
Not Elect Title Reason
Select One
Not Elect Title Other Reason

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Name of Third Party to Which Title is Waived

Waiver Date (mm/dd/yyyy)

Final Invention Rights Determination

Parent Invention Report Number

Organization Code for Other Organizations to View Invention and Related Patents

If an invention is jointly owned – enter the joint owner's iEdison Org. Code here so they can have Read Access to the record.

Invention Disclosure Document Type: Select One

Choose PDF

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Invention Disclosure File Location

To appropriately protect Personally Identifiable Information (PII) of your staff/personnel, you should review your submissions and redact information as appropriate prior to submitting to iEdison.
Please include a permanent identifying number within the uploaded disclosure (e.g. iEdison Invention Report [EIR] Number: XXXXXXX-XX-XXXX) to permanently associate the upload with the iEdison Invention Report record.

Browse... No file selected.

Invention Disclosure Text

To add a text file, paste a document here. Use ASCII text only. Maximum of 20 pages; text will be truncated if it is long

It's best to do this after saving the invention report so you can enter the Invention Report # on top. (Saves you from rejections.) Also – make sure to include a coversheet or update the disclosure to include the correct inventors and funding if not already provided at the time of disclosure.

Invention Disclosure Receipt Date

Invention Disclosure Reject Date

Invention Disclosure Reject Comment

These 3 fields are entered by the Agency.

This comment will tell you why the disclosure was rejected. It will also be in your iEdison Notifications

Upload Other Document

Please click on the file name to view.

* Document Name	File Name	* File Location	* File Type	* Document Category	Create Date	Last Update User	Last Update Date	Delete
	Browse... No file selected.		Select One	Select One				

* Any uploaded documents will be visible to all agencies that have funded the Invention.
* Upon uploading each document, in order to complete the reporting submission, you must also send an email to the Primary Agency identifying the type of document uploaded and the associated EIR Invention Record or Patent Record.
* Maximum 20 documents can be uploaded.

Submit Cancel

IEDISON-2000

Home | Main Menu | Change Passw
E-mail the NIH administrator | OMB Burden Statement | iEdis

You need to click Submit twice. It gives you a chance to check over data before actual submission. Once you've clicked Submit the second time, iEdison will generate your Invention Report Number (EIR #). Record this on your disclosure form before uploading.

Once you've uploaded the disclosure, you'll have to go through the double submit again. It's good to print the report form for your case file.

Common Reasons for EIR Rejection by NIH

- If the Invention Disclosure describes what the inventors hope to prove and not "the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention"- did the description come from a grant application? It should instead describe "how to" perform the discovery
- An abstract usually does not provide sufficient detail information of the invention
- Disclosure not dated when the TTO received the disclosure
- Not ALL awards included
- Not ALL federally-funded inventors included
- Check that the title in the invention report matches the document title

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Common Reasons for EIR Rejection by NIH cont.

- Check that the inventors match. If an unpublished manuscript is being used as a substitute for the disclosure and a 'contributor/author' is NOT an inventor, add a note to the document so agencies are aware
- If a manuscript is used, all grants listed are in the invention report, or indicate on the document the grants that did not contribute to the invention
- A manuscript can be used for the invention description:
  - Must state on manuscript that it was or was not submitted for publication
  - If published must have publication date and place of publication
  - Publication date must be added to Edison as required by BD
- Do not resubmit EIR without making corrections or without explaining why corrections were not made

Common Reasons for EIR Rejection by NIH cont.

- A patent application that is used for the invention disclosure:
  - The patent record needs to be FIRST entered in Edison – including a provisional or a PCT patent record for NIH.
  - Patent filing date and number and patent issuance date and number also must be included in patent record.

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Electing Title

- (2) The Contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

- (4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency,* be granted.

Electing Title

- 22 Months from the date of initial disclosure OR 10 months from date of publication. (If unpublished can request up to two 1 year extensions).
- Grantee/contractor organization must notify the federal agency sponsor that it will retain ownership of invention and take steps to commercialize the invention.

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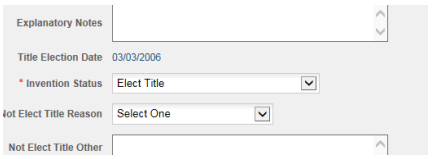
Best Practices

- Run report every 3 months for cases with upcoming Election Decisions.
- Provide Officers with case data, inventors, and existing filings (provisional), and any possible publications.
- Currently managed as a table within an email. Systems are Critical
- TLOs need to copy compliance on any decision to discontinue patent prosecution OR not pay annuity/maintenance fee.



- Change status to 'Elect Title' and insert the date of title election
- Must have filed/plan to file a US designating, Non-Provisional Application w/in the year

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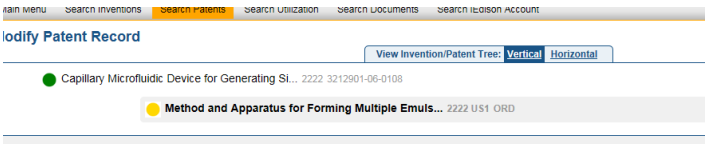

Government Support Clause – AKA – GSC, SOGS, etc.

- Required for all filed U.S. patent applications & issued patents
- Cited from 37 CFR Sec. 401.14(a)(f)(1) and applicable NIH Grants Policy Statement or FAR 52.227-11. The inclusion should be this exact sentence.
- Make sure your patent counsel has this language and checks with you prior to filing any application!
- Always match the grant/contract formatting you use in iEdison to your GSC!!

"This invention was made with government support (GRANT/CONTRACT#) awarded by the (AGENCY). The government has certain rights in the invention.

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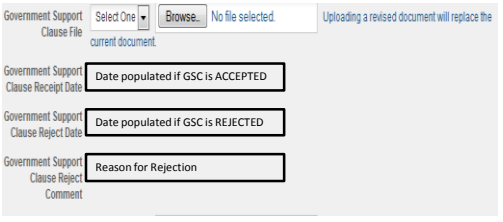
Submitting Govt. Support Clauses

- GSCs for Non-Provisional Applications must either have the following or they will be rejected:
  - An (electronic) filing receipt from the USPTO; or
  - The cover page of the non-provisional patent application that identifies the U.S. patent application number and filing date.



- Provisional Patent Applications must include a GSC and must include either:
  - A filing receipt from the USPTO
  - A completed and signed USPTO Provisional Cover Sheet (electronic signature is acceptable)
  - The 2nd "Yes" box on the 2nd page must be checked with the NIH identified as the federal agency
  - Must include an NIH contract (or Grant) award number

Common Errors

- Grant number does not match;
  - NIH example - most often the preceding zero is not included on the grant or award number or rarely the last digit is missing
    - All NIH Grants and Cooperative Agreements were converted to six digit serial numbers in circa 2006
- Grant number is missing/Extra grant numbers; one or more grant numbers are entered in iEdison and are not in the GSC or are in the application, but not iEdison.
  - Confirm with inventors – sometimes they add grants when talking to attorneys.
- The Government Support Clause states that the government "may" have certain rights (it needs to not equivocate: *the government has certain rights in the invention.*)
- USE STATUTORY LANGUAGE – NO CREATIVE WRITING

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Confirmatory License

- (f) *Contractor* Action to Protect the Government's Interest
- (1) The *contractor* agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to
- establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and
- convey title to the *Federal agency* when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

- Review all US designating applications for correct SOGS.
- Upload application to iEdison.
- Use iEdison to generate CL.
- Get CL signed by someone with Signature Authority for the university.
- Can request a 1 year extension.
- Uploading a patent application when an invention is barred will unbar the record.

Waiving Title to Government

- Grantee/contractor organization must notify the federal sponsor that it will not retain ownership of an invention
  - Within two years of reporting to Federal Agency Sponsor (If disclosed publicly, this period is decreased)
- Effectively a waiver to the Government. After further review the Federal Agency Sponsor may elect title on behalf of the Government. Title does not actually vest with the Government until Government elects to retain title.

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Waiving Title to Government Cont.

* Invention Status	Not Elect Title - Waive to Government
Not Elect Title Reason	Low Commercial Potential
Not Elect Title Other Reason	
Name of Third Party to Which Title is Waived	
Waiver Date	08/22/2011 MM/DD/YYYY

Waiving Title to Inventors

- If your office chooses to waive title in an invention back to the govt, the inventors *may* request title to the invention.
- This title can NOT be transferred to the inventors from the university W/O agency consent.
- Waive title to government.
  - Use iEdison for a guide - https://public.era.nih.gov/iedison/public/invention/InventorWaiver.jsp
  - Have your inventors fill out the Inventor Waiver Request Form –
  - https://public.era.nih.gov/iedison/public/utilization/CommercializationQuestions.jsp
  - There are specific questions for inventor and TLO.

- *Use NIH materials as a reference for working with other agencies who may not structured processes.*

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Govt May Obtain Title:

- The *contractor* will convey to the *Federal agency,* upon written request, title to any subject invention—
- (1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times.
- (2) In those countries in which the *contractor* fails to file patent applications within the times specified in (c) above; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the *Federal agency,* the *contractor* shall continue to retain title in that country.
- (3) In any country in which the *contractor* decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

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Utilization Reporting

- (h) Reporting on Utilization of Subject Inventions
- The *Contractor* agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the *contractor* or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commerical sale or use, gross royalties received by the contractor, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

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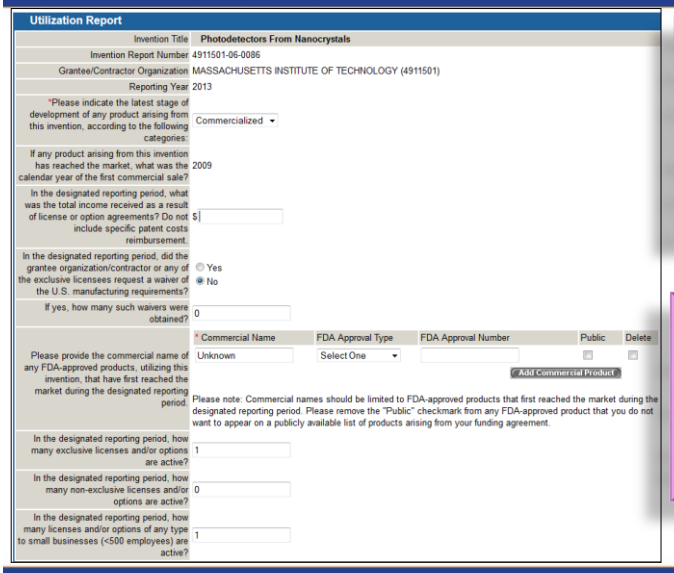

Utilization Report

Invention Title	Photodetectors From Nanocrystals
Invention Report Number	4911501-06-0086
Grantee/Contractor Organization	MASSACHUSETTS INSTITUTE OF TECHNOLOGY (4911501)
Reporting Year	2013
*Please indicate the latest stage of development of any product arising from this invention, according to the following categories:	Commercialized
If any product arising from this invention has reached the market, what was the calendar year of the first commercial sale?	2009
In the designated reporting period, what was the total income received as a result of license or option agreements? Do not include specific patent costs reimbursement.	$
In the designated reporting period, did the grantee organization/contractor or any of the exclusive licensees request a waiver of the U.S. manufacturing requirements?	Yes / No
If yes, how many such waivers were obtained?	0
Please provide the commercial name of any FDA-approved products, utilizing this invention, that have first reached the market during the designated reporting period.	* Commercial Name: Unknown; FDA Approval Type: Select One; FDA Approval Number; Public; Delete; Add Commercial Product. Please note: Commercial names should be limited to FDA-approved products that first reached the market during the designated reporting period. Please remove the "Public" checkmark from any FDA-approved product that you do not want to appear on a publicly available list of products arising from your funding agreement.
In the designated reporting period, how many exclusive licenses and/or options are active?	1
In the designated reporting period, how many non-exclusive licenses and/or options are active?	0
In the designated reporting period, how many licenses and/or options of any type to small businesses (<500 employees) are active?	1

Stage of Development

Products on the Market

Total Income Received
- Net Patent Costs

Waiver for U.S. Manufacturing

FDA Approval?

# of Licences

Should be Tracked in Database

Entered by TLO/TLA/Finance

Part of Licensee Diligence Reporting

US Manufacture Waiver Request

- (i) Preference for United States Industry
- Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions 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. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee 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 or that under the circumstances domestic manufacture is not commercially feasible.

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Filing your Request

- Use NIH resources as starting point – no matter who your sponsor is.
  - https://public.era.nih.gov/iedison/public/utilization/ManufacturingWaiver.jsp
- Have your licensee draft a formal letter detailing why it is not commercially feasible to substantially manufacture in the U.S. This gives them a chance to elaborate on the 500 character limit with the NIH.
- Your licensing officer responsible for the deal should also work with your director to draft a similar letter supporting the licensee's request and detailing their actions in attempting to license this technology.
- Bundle it all up and forward to your agency contact.
- Always acknowledge the specific Clause that allows for this request in case it is an agency that does not receive many of these requests.
- Stay on them. This takes time. Don't forget about it or be forgotten.
- This is a utilization statistic – make sure you capture it in your database.

Invention Report Errors

- Edison Invention Disclosure Messages:
  - Message 120 – No written invention disclosure:
    - Submit a disclosure
  - Message 130 – Invention Disclosure Rejected:
    - Agency message states reasons why – need to correct
    - Submit a revised disclosure
- Instructional Resources:
  - Frequently Asked Questions – Edison sign-in page
  - https://www.youtube.com/user/nihgrants
    Scroll down to Extramural Inventions & Technology Resources

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Electing/Waiving Title Errors

- Message 100: Title to this invention must be timely elected – NIH
  - Edison # not used for DOD (Army/MRMC; DOD/DMEA; USAF/AFOSR; USAF/ESC; Navy/ONR; Army/SSC) DOE, or NASA
- Correction: Trigger – less than 90 days until 2 years plus any extension granted by agency.
  - Elect Title or Waive Title

GSC/SOGS Errors

- 220 – GSC is missing for a non-provisional
- 230 or 231– GSC is not accepted – reasons will be given.
- 221 – GSC is missing for an issued patent
- How to Correct: See reason for non-acceptance and correct.

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Confirmatory License Errors

- 240 – Confirmatory license is missing for a non-provisional patent filing.
- How to correct: add the confirmatory license either to the specific non-provisional or add to the first of the patent applications/issued patents in the specific patent family.

Use of NIH/EPAS

- To assist NIH funding recipients in their Bayh-Dole compliance requirements.
- NIH does not have the statutory authority to waive any compliance requirement in BD.
- NIH/EPAS process can be used for all NIH records waived to the government with outstanding GSC and CL.
  - No PTO filing charge to user.
  - Corrected documents are filed with theUSPTO and NIH/Edison.
  - NIH still reviews and accepts EPAS GSC and CLs.

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Use of NIH/EPAS

- NIH has worked with over 100+ funding recipients in their use of the NIH/EPAS process.
- Process begins with a 15-10 group of NIH funding Recipients on a 2 hour conference call.
  - Information about and instructions for the use of EPAS is provided and reviewed during conference call.
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- If you want to participate let NIH know through Edison.gov and we will contact you as the new groups are being formed.

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