

# **IP Transactions Bootcamp:**

## **Day 2 – Patents**

October 21, 2025

## Key Takeaways

- Key elements of an agreement
  - Clarity
  - Risk reduction—think of how terms impact your client's best interests
  - Party Exits (from obligations)--
    - Planning for relationship ending
    - Is your client protected
- Issue spotting
- Agreements are complex
  - More than IP issues may be identified
  - Use specialists as needed (business, tax)

# Ownership of IP from Different Types of Transactions

- Fee for Service
  - Ex.: Vendor A providing services to Company B
  - Typically, Company B pay for services by Vendor A, and Company B owns patent rights
- Collaborative Research
  - Ex.: Company A bringing expertise X, Company B bringing expertise Y to jointly develop Z
  - Patent rights may be jointly owned or may divide based on each party's contributions
- Asset / Technology Transfer
  - Ex.: Company A sells technology and related patents to Company B
  - Typically, patent rights are assigned from Company A to Company B

## Background IP

- Defining Background IP:
  - Ex.: IP rights owned or controlled by party prior to effective date of agreement or is generated other than through performance of agreement
- Access to Background IP
  - Consider enabling license to Background IP to the extent necessary to carry out collaboration and to practice Agreement IP
- Typically excluded from designation of developed IP

# Patent Ownership Scenarios in a Collaboration

- Joint ownership
  - Each co-owner can use and grant non-exclusive license
  - Need all co-owners to grant exclusive license or to sue
- Ownership divided based on inventorship
  - Conception is the touchstone of inventorship
    - Definite and permanent idea -- when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.
    - *See e.g., Burroughs Wellcome Co. v. Barr Lab. Inc.*, 40 F.3d 1223 (Fed. Cir. 1994)
- Ownership divided based on subject matter
- One party owns everything
  - Consider asking for grant-back license

## Assignment Clause – which one?

- Any inventions conceived by Party A under this agreement shall be property of Party B
- Any inventions conceived by Party A under this agreement, shall be the property of Party B, and all rights thereto will be assigned to Party B by Party A
- Party A agrees to assign to Party B all inventions under this agreement
- Party A agrees to grant and does hereby grant all inventions conceived by Party A under this agreement

## Future vs. Present Assignment

- Any inventions conceived by Party A under this agreement shall be property of Party B
  - Statement of a future intention to assign. See *Omni Medsci, Inc. v. Apple Inc.* (Fed. Cir. Aug. 2, 2021)
- Any inventions conceived by Party A under this agreement, shall be the property of Party B, and all rights thereto will be assigned to Party B by Party A.
  - Agreement to assign, not a present assignment. See *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1580 (Fed. Cir. 1991).
- Party A agrees to assign to Party B all inventions under this agreement
  - Promise to assign in the future. See *IpVenture, Inc. v. ProStar Computer, Inc.*, et al. 503 F. 3d 1324 (Fed. Cir. 2007).
- Party A agrees to grant and does hereby grant all inventions conceived by Party A under this agreement
  - Present automatic assignment of a future interest. See *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1573 (Fed. Cir. 1991).

## Venue/Choice of Law

- Exclusive venues
- Exclusions
- Mutually unbiased



# License

- Exclusive License -- Licensee is the only party permitted to use
- Non-exclusive license -- Licensee is permitted to use by does not preclude other parties
- Sole License
- Restrictions on License
  - Field of Use – *e.g.*, for treating COVID-19
  - Geographic Region – *e.g.*, North America
  - Term
  - Research Use vs. Commercial Use
- Sublicense
- Consideration / Royalties

## License Example

[Party A] hereby grants to [Party B], and [Party B] accepts, an **exclusive** **[nonexclusive][sole]**, royalty-bearing license, **with the right to sublicense**, under the Patent Rights to import, make, **have made**, use, and sell Licensed Products in the Territory.

## Non-Exclusive License Example

[Party A] hereby grants to [Party B] a **non-exclusive license** in the Territory to practice under the Patent Rights to make, have made, use, import, sell and offer to sell Products in the Field. This license shall be **non-transferable and non-sublicensable, except that [Party b] is entitled to grant sublicenses to** practice under the Patent Rights (i) to its Affiliates, and (ii) to third parties, **but solely to the extent necessary to enable such Affiliates and third parties to make, have made,** use, import, sell and offer to sell Products in the Field together with [PartyB] or on [Party B]’s behalf (entities in (i) and (ii) referred to as “Sublicensees”). **Sublicensees include,** as an example, third parties or Affiliates that license intellectual property rights to Products from [Party B] in addition to any sublicense under the Patents.

## Standing from Licenses

- Assignee and exclusive licensee have standing to sue in patent cases
  - Often need to join the patent owner.
  - Transfer of “all substantial rights” can result in a “virtual” assignment and right to sue without licensor.
  - Bare license does not convey standing.
- Typically party cannot prove lost profits damages if it cannot prove lost sales.
  - *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004)
- Practicing entity more likely to prove irreparable harm for injunction relief.
- Ensure that entity that practices the invention will have standing to join the suit as either assignee or exclusive licensee.

## Control Of Generated IP

- Prosecuting patents
  - Who controls/pays?
  - Timeline for reporting/disclosing invention
- Enforcement of patents
  - Timeline for disclosing 3rd party infringement activity

## Right to Prosecute

**Why it is important: sets out expectations/responsibilities directed to who is protecting IP based on joint activities.**

Sample:

[Party 1] has the right to assume sole responsibility and sole control, **at its expense**, for the filing, prosecution and maintenance of patents and patent applications claiming [technical subject matter] and the uses thereof;

Provided, however [Party 2] will have the reasonable right to review and comment on patent prosecution matters.

What if Party 1 does not want to act on this right or wants to give up the right during prosecution?

## Reporting on the Development of Patentable Subject Matter

**Why it is important: the U.S. is a first to file jurisdiction**

Sample:

[Party 1] will submit to [Party 2] [annually, semi-annually] intellectual property reports relating to the technology, identifying all inventions conceived or first reduced to practice during the term, regardless of whether such intellectual property is independently or jointly conceived.

Conception and RTP both matter; the invention scope can change.

## Timeline For Disclosing 3rd Party Infringement Activity

Why it is important: enable to mitigate damages early on.

Sample:

Each party shall inform the other party **promptly** if it becomes aware of any infringement or potential or threatened infringement of any intellectual property rights related to the technology.

Who has the right to control litigation?



# Using (or misusing?) "Shall" in Contracts

- Guidance regarding proper usage of "shall" is unsettled.
  - "Though 'shall' generally means 'must,' legal writers sometimes use, or misuse, 'shall' to mean 'should,' 'will,' or even 'may.'"
    - *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1049 (N.D. Ill., 2003)
- B. Garner, *Dictionary of Modern Legal Usage* 939 (2d ed. 1995) ('Courts in virtually every English-speaking jurisdiction have held--by necessity that--*shall* means *may* in some contexts, and vice versa.').
- 2 Approaches to Consider:
  - Adams: make disciplined use of shall in business contracts, i.e., "shall" = "has a duty to."
  - Kenneth A. Adams, *A Manual of Style for Contract Drafting*, 2<sup>nd</sup> Ed., § 2.25, et seq. (ABA 2008)
    - Usage to express obligations, not to express future time or other purposes. *id.*
  - Garner: dispense with "shall" entirely
    - replace it with a clearer word more characteristic of American English: *must*, *will*, *is*, *may* or the phrase *is entitled to*.

## Common Agreement Terms

- Confidentiality
- Reps/Warrantees
- Control of indemnification.

## Define Confidentiality

**Why it is important: removes disputes as to what is subject to obligations.**

Sample:

“Confidential Information” shall mean any information whether disclosed **verbally, visually**, in machine-readable or written form, that is **communicated** by the disclosing party to the receiving party, including but not limited to ideas, discoveries, inventions, specifications, formulae, programs, plans, drawings, models, samples, requirements, standards, presentations, software and supporting documentation, financial data, trade secrets (including manufacturing and know-how), customers lists and data.

## Identify Exceptions

**Why it is important: narrows scope of confidential information, identifies burden to show exclusions.**

Sample:

Confidential Information excludes information that, the part can show in writing:

- (i) was generally known to the public prior to disclosure to the other party;
- (ii) becomes generally known to the public through no wrongful act or failure to act by the other party; or
- (iii) is disclosed to the other party by a source other than such party, which disclosure is not in breach or violation of any law or any obligation to such party or any other person or entity.

## Reps and Warrantees

**Why it is important: enables a party to learn information about activities of the other side.**

Also enables a party to rescind or void the terms of the contract, then go on to obtain funds for recovery of the time and money spent as part of the transaction.

If do not use at all: common law warranty (e.g., under UCC) may apply.

Sample:

The receiving Party understands and agrees that the disclosing Party makes no representations or warranties, express or implied of any kind to the receiving Party, including those of merchantability and fitness for purpose, with respect to any provided confidential information; including without limitation with respect to the accuracy or completeness thereof.

# Indemnification

**Why it is important: IP litigation is very expensive.**

Sample:

To the maximum extent allowed by law, [Party 1] shall indemnify, defend and hold harmless [Party 2] from and against any and all third-party claims, including reasonable attorneys' fees and expenses incurred in responding to such Claim, resulting from, arising out of or relating to any alleged infringement or violation of any IP Rights by:

- (i) any product made according to a specification provided by [Party 1];
- (ii) a modification of any product of [Party 2] to meet the operating environment, business requirements, or other needs of [Party 1];
- (iii) the use of any product delivered by [Party 2] in any way not accordance with [Party 2]'s then-current published specifications (including altering, modifying or converted the same without written authorization of [Party 1]).

# Limitations of Liability

Why it is important: limit scope of potential future damages

Sample:

Except for a breach of [X] or for claims of a Third party that are subject to Indemnification under [X], neither party will be liable under this agreement to the other party for **any indirect, incidental, consequential, special or punitive damages or lost profits or royalties, lost data or cost of procurement of substitute goods or services, tort (including negligence and strict liability)**, indemnity or contribution, and irrespective of whether that party or any representative of that party has been advised of, or otherwise might have anticipated the possibility of, any such loss or damage.

## Managing Investment/ Payment

- Royalties:
  - Valuation
  - Tiered – sales milestones
  - Reporting
  - Auditing rights
- Development
  - Milestones
  - Failure to meet



## Audit Rights

**Why it is important: proper accounting of earned revenues.**

Sample:

[Party 1] shall, both during the term of this Agreement, and for at least X years following termination or expiration of this Agreement, keep accurate records sufficient to permit determination of the payments due hereunder and shall, during such time, make such records available for examination by a third-party auditor designated by [Party 2] and reasonably acceptable to [Party 1], following reasonable advance notice...

If any such audit discloses underpayments of the amounts that were actually due, [Party 1] shall make an additional gross-up payment to compensate for that underpayment (plus interest as determined under Code § 7872(f)(2)(B)) within 10 days of the date the amount of the underpayment is finally determined.

## Development Milestones

**Why it is important: prevent dilatory licensee from maximizing revenue of your intellectual property.**

Sample:

[Party 1] shall use diligent efforts to achieve development milestone events specified in Schedule X by the dates set out therein.

In any instance in which it becomes apparent that a particular development milestone will not be met due to regulatory, technical, safety or efficacy-related reasons or Force Majeure event, the Parties in good faith will agree upon an appropriate adjustment of such milestone and any subsequent milestones.

If it becomes apparent that a material development milestone cannot be achieved within a reasonable period of the dates set forth in Schedule X, then [Party 2] shall have the option to terminate the Agreement for cause.

# Anatomy of the Royalty Provision

- Structure of the Payment
  - Running Royalty
  - Lump Sum
- Defines who is to pay the royalty
- Defines timing of the payment
- Defines the mechanism of payment
- Option to extend
- Provision that addresses uncertainty of validity/infringement of patent

## Royalties: How To Determine

- Other licenses for same or similar IP
- Market size projections (growing/shrinking)
- Industry CPM: comparable profit margins
- Remaining life of patents
- Scope of claims, including prosecution history, to determine design around options
- Business cycle (expansion/recession)
- Quality of potential build
- License restrictions (geographic/field of use)
- Is royalty tied to other IP (tradename)
- Is there active litigation (courts or IPR)
- Will there be joint development with the other party
- Hire an expert, consult with your business development teams

# Post Expiration Royalties

- *Brulotte v. Thys Co.*, 379 U.S. 29 (1964)

- License term extended beyond term of patents.
- Licensee defended on ground of misuse.
- Court held “[A] patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*.”
- License obligation to pay royalties unenforceable.
- License may be ground of patent misuse defense.

- *Kimble v. Marvel Ent., LLC.*, 135 S.Ct. 2401 (2015)

- Inventor licensed web-casting toy based on Spiderman
- Provided 3% royalty rate on future sales with no end date.
- Marvel sought declaratory judgment that obligation to pay royalties ended when patent expired
- Applying *stare decisis*, Supreme Court held that post-expiration royalty invalid in view of earlier opinion in *Brulotte v. Thys*.

- Set royalty to accomplish goal before expiration of patent.
- If looking to extend payments beyond expiration, will need to base payments on other rights/services/assets.
- Delay payment of pre-expiration royalties until post-expiration.  
*Kimble*, 135 S.Ct., at 2408.

## License Modification For Failure To Meet A Milestone

**Why it is important: minimize risk of loss with an otherwise potentially reliable licensee.**

Sample:

If [PARTY 1] fails to achieve the Milestone on or before [date or schedule], then at [PARTY 2]'s election in its sole discretion, (a) the license granted by [PARTY 2] to [PARTY 1] shall become non-exclusive.

## Settlement Agreements and Licenses

- What is being licensed?/who is receiving the license?
  - Product based?
  - Litigated patents?
  - Any patents that may cover product?
- Who is licensed?
  - Defendant?
  - Supplier?
  - Are third parties indemnified for infringement?
- Ability to Challenge Patents in Future
- Ability to Challenge Infringement in Future
- Launch Dates and Accelerators

# Patent Transactions: a view from the “inside”

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Eli Lilly and Company

October 21, 2025

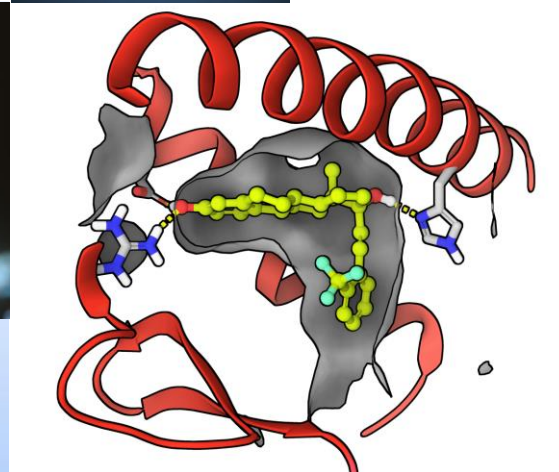
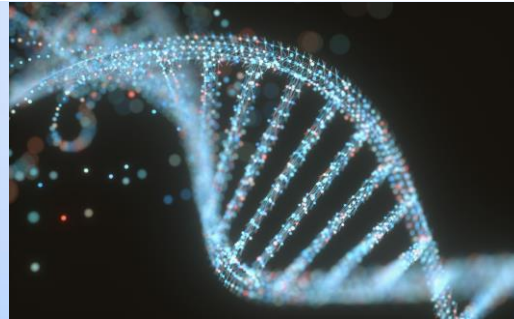
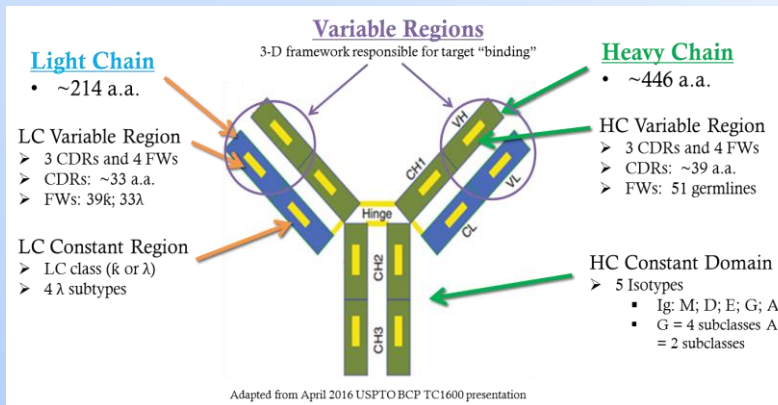


A hand is shown moving a black chess piece (a pawn) on a chessboard. The background is a blurred image of a chessboard with other pieces. The text is overlaid on the right side of the image.

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# Pharmaceuticals are COMPLEX



**Patent Transactions**  
**Do NOT Need to be Complex**

The “Right” Way ...

“It Depends”



The “Proper” Terms ...



No One Size Fits All Solution

# Game of Chess

1. Understand the "Board": Client's & "Opponent's" Business
2. Understand the "Game": GOAL of the Agreement
3. Understand Business Drivers: Risks & Values
4. Understand what is Essential and what can be Sacrificed: Rights, Control, Ownership, *etc.*





# Key Considerations

**Be  
Reasonable**

**Think Big  
Picture**

**Risk  
Benefit  
Continuum**

- ☐ Multiple sides
- ☐ Varying interests
- ☐ One sided consideration will preclude deals

- ☐ Business strategy
- ☐ Not one size  $\neq$  Fit all
- ☐ Freedom to Operate

- ☐ Benefit & Value
- ☐ Risk severity
- ☐ Likelihood of risk

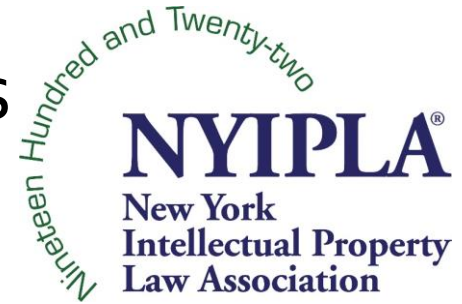


## Practical Tips

- Be reasonable
- Freedom to Operate (FTO) = Very Important Principle (VIP)
- Fit business strategy
- Rights needed will vary
- Further science and advance Products that matter

# IP & Contracts: Swipe Right for Strong Clauses

## Scenarios -October 21, 2025



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# Scenario 1

- Project "X" = NEW DEVELOPMENT
- RESEARCHER COMES TO YOU VERY EXCITED ABOUT A 3<sup>rd</sup> Party
  - 3<sup>rd</sup> Party
    - Supplier
      - "I WANT TO TALK TO THEM ABOUT XXXX THEY HAVE PUBLISHED/MARKETED TO SEE IF IT WILL MEET OUR NEEDS. XXXX MAY SOLVE MAJOR ISSUE WHICH IS HOLDING THE DEVELOPMENT BACK"
      - "SUPPLIER CAN CREATE A CUSTOM SOLUTION FOR US BASED ON OUR REQUIREMENT/DATA"
    - Expert
      - "THIS EXPERT IS AT THE TOP OF THE FIELD AND CAN REALLY TAKE OUR PRODUCT TO NEXT LEVEL"
  - "Need to discuss our project with them to find a solution"



## Scenario 1

### Considerations

- Project "X"
  - Has any information already been Exchanged?
  - Value of this project?
    - Normal Development
    - BET THE FARM
  - Are portions of the development
    - CONFIDENTIAL
    - Patent-Worthy
  - Who is involved in these conversations?
  - Timeline?



## Scenario 1

### Considerations

#### 3<sup>rd</sup> Party

- Who?
  - Commercial Entity
  - Research Organization
  - University
    - PROFESSOR OR STUDENT?
  - Size
- Where?
  - Location
    - Where will work be taking place?
- How?
  - Relationship
    - Do we already have an established relationship?
    - Is this a one-time issue or will it continue?
  - Conflicts of interest



## Scenario 1

### Considerations

- WHAT DO WE NEED
  - Freedom to operate
  - Exclusivity
  - Ownership
- WHAT DOES 3<sup>RD</sup> PARTY NEED
  - Ownership
  - Freedom to Operate
  - Licensing



## Scenario 1 Considerations

- Ownership Types
  - Joint
  - Single side ownership
  - License to other side for internal use
  - Concurrent development that will not lead to joint IP
    - if same idea developed separately



## Scenario 1 Considerations

- Which Party is responsible for:
  - Control
    - In case of disputes – who controls?
    - Reasonable Consideration Clause
  - Filing
  - Prosecution
    - Timing
    - Control
  - Payment
    - What are the requirements to be reimbursed?
    - Timely Notification
  - Tracking and Reporting
    - Milestones
    - New Inventions/Developments
  - Licensing



## Scenario 1

### Considerations

## Considerations

- What is the anticipated value of any potential contribution from 3<sup>rd</sup> Party to development and/or design?
- Where? (to be discussed in more detail later)
  - Are there legal jurisdictional issues based on the location of the work or the 3<sup>rd</sup> party?
    - Research
    - Filing
    - Inventorship
    - Renumeration
- What does the 3<sup>rd</sup> party want for the information received?





## Scenario 1

### Considerations

## Considerations

- Breach – Honeymoon is over...
  - Missed Milestones
  - Can't perform
  - Time to Cure
- Termination
  - Missed Milestones
  - Other fish in the sea
    - What do you own?
  - Priorities change
    - Early termination





## Scenario 1

### Output

#### Types of Agreements to consider

- Joint Development Agreement
- Collaboration Agreement
- Purchase Order
- Unilateral v. Bilateral Agreement
- Non-Disclosure Agreement (NDA)
  - Confidential Disclosure Agreement (CDA)
  - Secrecy Agreement
  - Confidentiality Agreement



## Scenario 2

- Project "Y" = Use of dataset to develop invention
  - RESEARCHER wants to use a dataset compiled by 3<sup>rd</sup> Party to develop potential Products
  - "I think this dataset is crucial to the development of invention"

## Scenario 2

### Considerations

- Project "Y"
  - All of questions previously asked
  - How will Data be used?
    - Validation of Method
    - Development of Method
    - Is the information necessary for another reason?
      - Regulatory Filing

## Scenario 2

### Considerations

- Project "Y"
  - Will Patent-Worthy inventions result?
  - What is the value of any potential inventions related to the data?
  - How much value does this dataset add?

## Scenario 2

### Considerations

- Who is the 3<sup>rd</sup> Party
- Relationship
  - Do we already have an established relationship?
  - Is this a one-time issue or will it continue?

## Scenario 2

### Considerations


- What do we need in order to commercialize
  - Freedom to operate
  - Exclusivity
  - Ownership
- What does 3<sup>rd</sup> party Need
  - Ownership
  - Freedom to Operate
  - Licensing



## Scenario 2

### Output

- Development Agreements
- Data Sharing Agreements
- Clinical Trial Agreements
- Licensing Agreements



## Scenario 3 – Publicly funded projects

- R&D project with a publicly funded partner (e.g., University, Research Institute)
  - Industry partner wants to exploit IP through (own) commercial use
    - Ownership of IP, or at least royalty-free license
  - Research partner wants to exploit IP through licensing
    - Ownership of IP, or at least royalties from the industry partner plus right to grant (sub-)licenses





## Scenario 3

### Legal limitations

## EU Antitrust law

- Each partner must have full access to the R&D results for the purpose of further R&D
- Exploitation can be limited to one partner
- Compensation between partners must not be so high as to effectively impede access



## Scenario 3

### Legal limitations

## EU State Aid law

- Granting the industry partner rights to IP created by the research partner may be considered indirect state aid, if such rights are not appropriately compensated



## Scenario 3

### Legal limitations

## EU State Aid law

- Results solely created by the research partner
  - Assignment of ownership of IP to industry partner only with appropriate compensation
  - Alternatively: royalty-bearing license to industry partner
  - Research partner must retain right to use IP for further own R&D (antitrust law)



## Scenario 3

### Legal limitations

## EU State Aid law

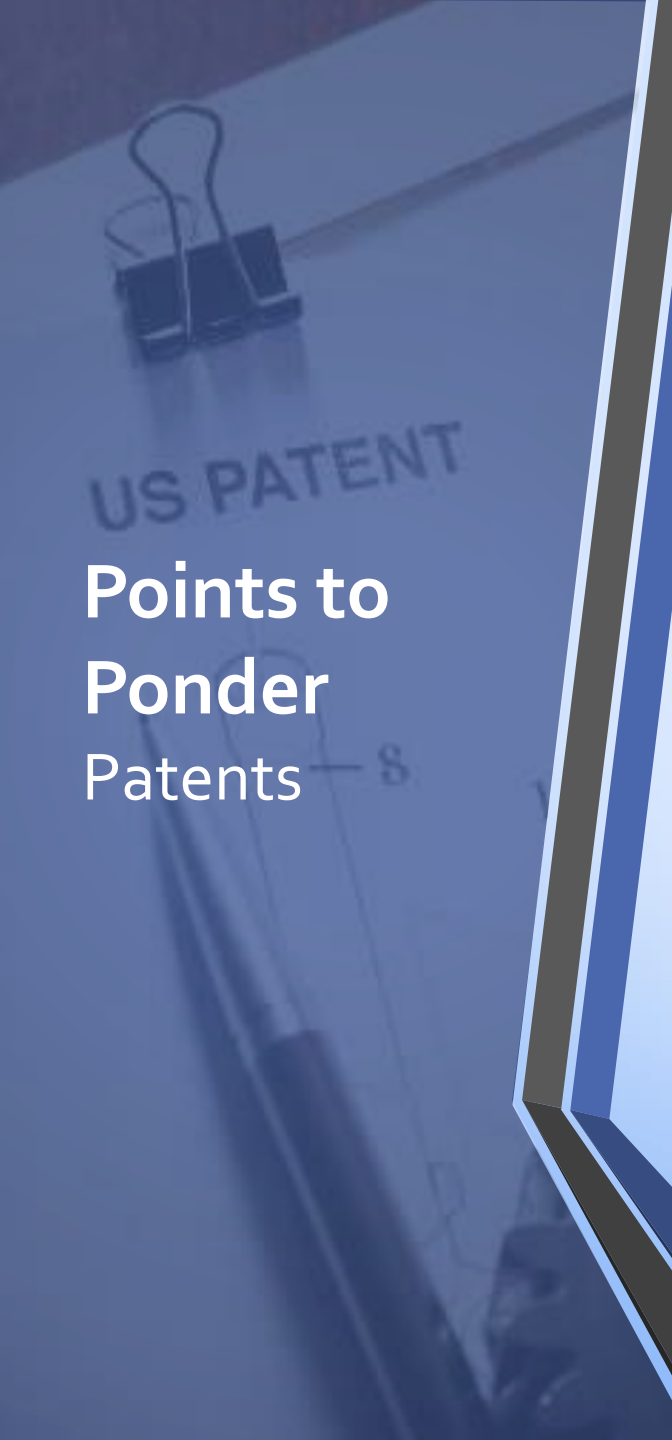
- Jointly created results
  - Sole ownership of IP by industry partner only with appropriate compensation to research partner
  - In case of joint ownership: compensation to research partner upon commercial exploitation (and vice versa)
  - Research partner must retain right to use IP for further own R&D (antitrust law)



# Points to Ponder Patents

## Points to Ponder

- The only constant is change
- Don't judge too harshly
  - Circumstances may have demanded compromise



## Points to Ponder Patents

- Role of Attorney
  - Fact Gathering
  - Issue spotting
  - Risk determination
- Remember - Essential terms of agreement come from the business
  - Attorneys Memorialize Agreed to terms
  - Attorneys don't give permission for business to move forward – just risk assessment



## Points to Ponder Patents

- Practice Tips
  - When determining risk put it in writing
  - Make sure that the identified risk is understood by person with signatory authority
  - Notes on negotiations
    - Leave a trail
      - Why?
      - Get up to speed faster on previous
    - Document future
      - Potential negotiating points



## Points to Ponder Patents

- Need to have an understanding of:
  - Business of both parties
  - Goal of agreement
  - Risks & Values
  - Essential Elements & Sacrificial Lambs
    - Rights
    - Control
    - Ownership





# Points to Ponder Patents

- What does Client/Internal Partner
  - Need?
    - Freedom to Operate
    - Exclusivity
    - Collaboration
      - Long-term
      - One and done
  - Consider?
    - Project Importance
      - Program
      - Specific value of Project
      - Relationship between parties



## Points to Ponder Patents

### Client/Internal Partner Considerations

- Who should be involved in determining the terms of the agreement & When?
  - Business Unit
  - Scientist
    - Some points of conflict may be better understood by scientists/technicians familiar with technology
- Attorneys
  - Inside v. Outside Counsel
  - IP, Operations (Supply Chain), Licensing



# Points to Ponder Patents

## Client/Internal Partner Considerations

- Who are the champions
  - Decision Makers
    - Ensuring message conformity within internal team
- Signature Authority
  - Does the person you are dealing with have authority to bind the company in this way?



## Points to Ponder Patents

# Client/Internal Partner Considerations

- Where is the associated work occurring?
  - Filing
    - If IP develops – some countries require you to file first in that country
      - United States (Foreign Filing License)
      - China – If completed in China – first filing should be in China
      - France
    - Foreign Filing Licenses
  - Ownership Provisions
  - Renumeration
    - Payments to Inventors/3<sup>rd</sup> Parties



## Points to Ponder Patents

### 3<sup>rd</sup> Parties

- Funding?
  - Is any external funding being used?
    - Government, NGO, or Consortiums
    - March in rights
    - Ownership issues
    - Renumeration
- Client/Internal Partner needs to:
  - Document what you know
    - Prior to collaboration
    - From collaboration
    - From other sources



# Points to Ponder Patents

- Partner
  - Relationship
  - Location
  - Size
  - Finances
  - Sensitivity to Publicity
    - Are they willing to go for an injunction?
  - What are they offering?
  - Internal partners – who & Positions
  - Legacy IP



## Points to Ponder Patents

### Partner Limitations


- Statutory Limitations on what can be agreed to
  - Universities
    - Professor or Students - Post-doctoral students
  - State Agencies
  - Federal Agencies
- Understand Rules of Engagement
  - Ownership Restrictions
  - Representations and Warranties



## Points to Ponder Patents

- Royalties – who will track this?
  - Do you have a system in place for ensuring
    - IP is in force?
    - Follow-on IP is addressed
    - Contracts are up to date and not in conflict?
  - Upfront
  - Milestone
  - Long-term





# Points to Ponder Patents

- Breach
  - Missed Milestones
  - Can't perform
  - Time to Cure
- Termination
  - Missed Milestones
  - Financial Disruption
    - Start-ups, smaller companies
    - Lack of payment – leads to potential assignment
  - Bankruptcy
    - Insolvency as trigger for license assignment
  - Other fish in the sea
    - What do you own?
  - Priorities change
    - Early termination
- Contacts
  - How and who?
  - Obligation to update



# Points to Ponder Patents

- Choice of Law and Venue
  - Choice of Law = Law that Governs Rights Under Agreement
  - Choice of Venue = Place Where Dispute to Be Resolved
- Silence
  - Parties may choose not to address this issue in the Agreement
- Perspectives Based on Party's Location, and Whether to Align or Not Align With Jurisdiction of Choice of Law
  - Considerations When Venue and Choice of Law Jurisdiction Align
  - Considerations When Venue Different From Choice of Law Jurisdiction
  - Trying to Align Similar Legal Systems When Non-Alignment of Venue and Choice of Law Jurisdiction



## Points to Ponder Patents

- Does the Choice of Venue Clause act as an exclusion for special “Venues or Courts”
  - PTAB
  - ITC
  - UPC
  - EPO
  - Individual Country Nullity/Opposition Proceedings



# Points to Ponder Patents

## Start with the End in Mind

- What is Business trying to accomplish?

The background features abstract, overlapping green geometric shapes, primarily triangles and polygons, in various shades of green, creating a modern and dynamic visual effect.

# Intellectual Property in University and Government Contracts 2025

# Speaker Biographies

- ▶ Jennifer Mandina Wiss is a contract negotiator at the University of Buffalo focused on industry engagement. She has a BA in English, minor in Accounting; a JD with a concentration in Financing Transaction; and an MS in Biomedical Engineering.
- ▶ Richard Kurz is a partner at Haug Partners LLP who focuses on intellectual property litigation and counselling. His litigation experience includes patent infringement, inventorship, business torts, and breach of contract claims. He also counsels clients concerning due diligence and freedom to operate matters, and for negotiating and drafting settlement, licensing, and collaboration agreements.
- ▶ Derek Maughan is the Chief IP Counsel and Deputy General Counsel for Battelle Memorial Institute at Pacific Northwest National Laboratory a \$1.8B multi-programmatic research organization owned by the United States Department of Energy's Office of Science and managed and operated by Battelle Memorial Institute since 1965.

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# Agenda

- ▶ Technology Transfer by Universities
- ▶ Government Control in Research Contracts
- ▶ Some Advanced IP Topics in Government Contracting
- ▶ Updates on March-In Rights





# TECHNOLOGY TRANSFER BY UNIVERSITIES

# IP Ownership and Rights Created During University Sponsored Research and During Federally Funded R&D



Primary forms of IP created: inventions, technical data (proprietary information, trade secrets), and software



University research can be sponsored by the U.S. Government or a private organization



When university research is sponsored by a private organization, the IP rights are determined by an agreement

Generally, the university will own the IP it solely creates

Generally, the private organization will get a license of a scope determined through negotiation (or selection from a list of options)



Comparison: R&D by a private corporation can be funded by the U.S. government or at private expense (IR&D)

# University SRAs

- ▶ SRA = Sponsored Research Agreement
- ▶ Sponsored Research Agreements are used whenever our industry partners engage with us for research.
- ▶ UB offers three different options from which to begin negotiations. All are designed to answer questions about IP. The three options are:
  - ▶ Exclusive option to negotiate license terms to any resultant IP
  - ▶ Pre-negotiate terms to any potential resultant IP
  - ▶ Exclusive license to any resultant IP
- ▶ SRAs:
  - ▶ Clarify the work that will be performed and its related deliverables
  - ▶ Have a clearly defined budget and milestones
  - ▶ Negotiate sponsor's rights to pre-publication review to identify any sponsor proprietary information and any disclosed inventions for which a pre-publication patent application filing may be warranted.

# Technology Transfer: What Is It?

- ▶ **General Definition**: Dissemination of skills, knowledge and technology to another party for some benefit
- ▶ **Specific Definition**: University Technology Transfer extends the benefit provided through federal funding by moving research closer to commercialization.
- ▶ This function is traditionally viewed as the patenting, marketing, and licensing University technologies.

# Licenses

- ▶ Licenses are used to transfer commercialization rights of university intellectual property to an industry partner
- ▶ It is a standard that the organization that owns the technology drafts the license
- ▶ Standard license terms include milestones, royalties, liability, and indemnification provisions
- ▶ Because many university technologies are early stage, many of them are licensed to start ups and UB has a specific licensing program for faculty start ups.

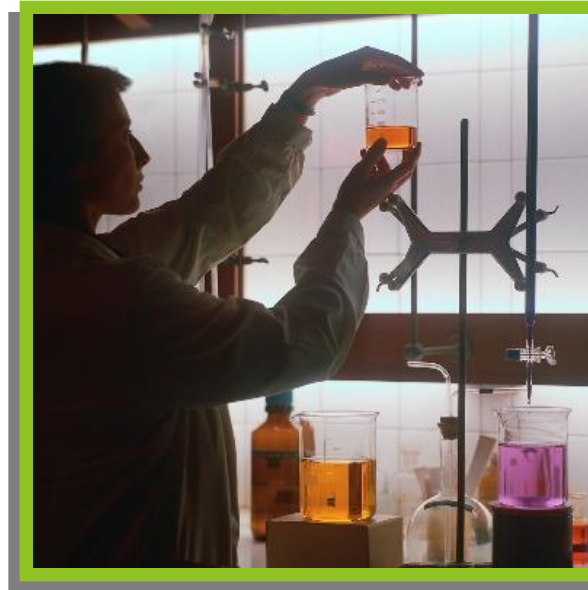
# UB Invention Lifecycle

- ▶ New Technology Disclosure (“NTD”)
- ▶ Report to sponsor
  - ▶ Federal, Institution, Corporation
- ▶ Assessments
  - ▶ Intellectual Property and Market Opportunity
- ▶ Elect title (Federal) and Inventor assignment
- ▶ File for patent/copyright
- ▶ Marketing/Customer Discovery
- ▶ Licensing

# Technology Transfer Assessment

## *Lab to Market*

- ▶ **Strength of intellectual property protection**
- ▶ Novelty, non-obviousness, usefulness, enablement
- ▶ Type: Composition, Device, Process
- ▶ Enforcement (detection and cost/benefit)
- ▶ Design around
- ▶ **Commercial opportunity**
- ▶ Solves a significant problem in the market
- ▶ Defined customer
- ▶ Sustainable competitive advantages
- ▶ Size and growth of the potential market
- ▶ **Stage of development**
- ▶ Investment and risk



### **Risk**

- Technical
- Intellectual Property
- Regulatory
- Market
- Financial



# How Corporations Think about Sponsoring University Research



Corporations generally like to use universities for basic research / early-stage technology development



Many universities today offer to later-stage technology development at a lower cost than commercial vendors



While the lower cost may be attractive to some at the corporation, counsel must advise the corporation on many issues presented by this approach



- ▶ Universities will generally own the IP they create
- ▶ Unlike a commercial vendor, a university will generally not agree to any warranties, indemnities, or carveouts to a consequential-damages waiver
- ▶ Many universities demand indemnification from the corporation for any liability they experience from the corporation's use of the research results
- ▶ Universities are generally unwilling or, in the case of state universities, unable to negotiate choice of law, choice of venue, and ADR options
- ▶ Many universities will not work with ITAR technical data
- ▶ Universities will often not agree to long protection periods for any company background proprietary information that the company needs to disclose for the development work

## Issues Presented by Using University for Later Stage Development

- ▶ CRADA = Collaborative Research and Development Agreement
- ▶ CRADAs are used to whenever two institutions are working together to perform in-kind research
- ▶ It is a standard that the institution that is primarily driving the research supplies the CRADA
- ▶ CRADAs:
  - ▶ Clearly define each investigators contribution
  - ▶ Permit joint and sole publications
  - ▶ Resolve IP ownership

## CRADAs for Universities

# Bayh-Dole Act

- ▶ Codified at 35 U.S.C. §§ 200-212; implementing regulations at 37 C.F.R. §§ 401.1-401.17
- ▶ Under Bayh-Dole, the Contractor can elect title to the inventions it creates during Federally funded R&D
- ▶ U.S. Government gets a broad license to practice and have practiced the invention for government purposes
- ▶ Bayh-Dole was a sea change when it was enacted in 1980; prior to Bayh-Dole, U.S. government owned all inventions created during Federally funded R&D and it licensed only a small percentage of them



# Bayh-Dole Act - Some Major Requirements

- ▶ Contractor must:
  - ▶ Report subject inventions to the U.S. Government within 2 months the inventor's submission of a written invention disclosure;
  - ▶ elect title to those inventions within 2 years of disclosure to the agency;
  - ▶ timely file patent application;
  - ▶ timely inform U.S. Government of intention not to file a patent application or continue prosecution of patent application; and
  - ▶ contractually require employees to disclose inventions created during federally funded R&D and to assign those inventions to the employer.
- ▶ Any exclusive licensee of the right to use or sell the invention in the United States must agree that articles embodying the invention are substantially manufactured in the United States (35 U.S.C. § 204).

- ▶ By statute, the U.S. Government can force the granting of licenses, if:
  - ▶ patent owner has not made sufficient efforts to commercialize the invention;
  - ▶ action is necessary to alleviate health or safety needs;
  - ▶ action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
  - ▶ holder of exclusive right to use or sell any subject invention in the United States has either not agreed to or is in breach of its agreement to require substantial manufacture of articles embodying the invention in the United States.

## 35 U.S.C. § 203 March-In Rights

# Recent March-in Rights Proposals

## 2023 NIST March-in Rights Proposal

- ▶ According to the RFI promulgated by NIST:
- ▶ “To date, no agency has exercised its right to march-in.”
- ▶ “Several agencies have considered march-in previously but have either declined to exercise it or worked with the parties to find an alternative solution to achieve the desired objectives.”
- ▶ “March-in is an important tool for agencies, but that tool is accompanied by potentially significant positive and negative ramifications.”
- ▶ “The exercise of march-in rights is just one tool that may be available to the government and use of march-in should be considered in the context of all tools at the agency's disposal to address situations.”

See <https://www.regulations.gov/document/NIST-2023-0008-0001> (emphasis added)

# 2023 NIST March-in Rights Proposal

## Interpretation Added Pricing Considerations

- ▶ “If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted.”
- ▶ “Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users.”
- ▶ “Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?”

See <https://www.regulations.gov/document/NIST-2023-0008-0001> (emphasis added)

# Déjà vu All over Again: The NIH Previously Tried to Use “Reasonable Pricing” Requirements in Cooperative Research and Development Agreements (CRADAs)

- ▶ In Fiscal Years 1990 - 1995, the NIH incorporated what it termed a “reasonable pricing” clause into its CRADAs, under which “a company taking an exclusive license to bring an NIH invention to market could be compelled by the NIH to submit documentation showing a ‘reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public.’”
- ▶ The NIH stopped this experiment in Fiscal Year 1995 by removing the “reasonable pricing” clause from its CRADAs when it became clear that the “the pricing clause has driven industry away from potentially beneficial scientific collaborations.”

See, e.g., The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995, <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>;  
NIH News, <https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>



# 2025 March-in Plans?

- ▶ U.S. Secretary of Commerce Howard Lutnick on Friday, August 8, sent a letter to Harvard University President Alan Garber informing him that the U.S. government will initiate the march-in process by granting third-party licenses to Harvard's patents or taking title over where it finds Harvard has failed to comply with the Act.
  - ▶ “Failures to comply with the requirements for timely disclosure and election of title under 35 U.S.C. § 202(c)(1) and 37 C.F.R § 401.14(d)(1)(i);
  - ▶ Failures to comply with the preference for United States industry as required by 35 U.S.C. 204 and 37 C.F.R 401.14(i); and
  - ▶ Failures to take effective steps to achieve practical application of subject inventions as required by 35 U.S.C. § 203(a)(1) and 37 C.F.R § 401.14(j)(1).”

See <https://x.com/howardlutnick/status/1953967726135063023/photo/1>;  
<https://ipwatchdog.com/2025/08/11/lutnick-warns-harvard-march-in-patents/id=191061/>

# 2025 - Revenue-Sharing Plans?

- ▶ On September 19, 2025, Law360 reported on U.S. Secretary of Commerce Secretary Howard Lutnick's comments that the government should get as much as half of the revenue that universities generate from patents developed with federal funding.
- ▶ Secretary Lutnick reportedly said in an interview with Axios that under current procedures, "the universities get the patents, and the funder of \$50 billion, the U.S. government, you know what we get? Zero."
- ▶ "In business, if I gave them 100% of their money, I would get half the profits, with the scientists," he said. "So I think if we fund it and they invent a patent, the United States of America taxpayer should get half the benefit."

<https://www.law360.com/articles/2390340/call-for-gov-t-cut-of-university-patent-cash-spurs-concern>

# IP Created in the Performance of U.S. Government Contracts

- ▶ Inventions
  - ▶ Federal procurement of R&D - governed by the Bayh-Dole Act (and March-in Rights)
  - ▶ CRADA w/ government - subject to terms of agreement
- ▶ Technical Data / Software
  - ▶ Federal procurement of R&D - governed by FAR (and DFARS) and SBIR Act
  - ▶ Cooperative w/ government - subject to terms of agreement (CRADA)
  - ▶ Generally
    - ▶ Contractor owns the technical data and software it creates, even when developed at exclusively at government expense
    - ▶ U.S. Government gets a license to the technical data / software it creates with federal funding or otherwise delivers to U.S. Government in performance of the contract; license scope varies

# Ownership/Rights in Technical Data / Software Created/Delivered During Federally Funded R&D

- ▶ Contractor will generally own the technical data/software it creates, and U.S. Government gets a nonexclusive license
- ▶ U.S. Government's rights in such technical data / software for Federal Procurement of R&D under FAR 15
  - ▶ Scope of rights
    - ▶ Unlimited Rights
    - ▶ Limited/Restricted Rights
    - ▶ Government Purpose Rights (defense contracts only)
    - ▶ Specifically Negotiated License Rights
    - ▶ Commercial Rights
  - ▶ Expense determinations made at lowest practicable level
  - ▶ Contractor must assert data rights that are more restrictive than unlimited rights
  - ▶ Data/software must be properly marked when delivered to the U.S. Government

# Ownership/Rights in Technical Data / Software Created/Delivered During Performance of SBIR Contract

- ▶ U.S. Government gets unlimited rights in background IP that contractor delivers to it
  - ▶ Contractors should endeavor to deliver form, fit, function data instead of valuable background IP
- ▶ U.S. Government gets SBIR data rights in data/software created by contractor during performance of the SBIR contract
  - ▶ SBIR data rights is similar to limited/restricted rights data except there is a fixed time period of protection, which is up to 20 years

# Ownership/Rights in Technical Data / Software Created/Delivered During Performance of Cooperative R&D

- ▶ U.S. Government will not disclose proprietary background IP it receives from private research partner to third parties
- ▶ U.S. Government will **not** disclose new data / software created by the private research partner during the collaboration and potentially certain new data / software that the government's employees create during the collaboration for up to five years (longer protection periods can be authorized)



# **SOME ADVANCED IP TOPICS IN GOVERNMENT CONTRACTING**

# Government Contracting vs. Private Contracting

- ▶ Private contracting - two parties exercising their freedom to contract to reach any deal they can agree to; - the deal is governed by the “four corners” of the contract; extrinsic evidence is not admissible unless the contract language is ambiguous
- ▶ Government contracting - a private contractor negotiating with a government contracting officer who is constrained by laws and regulations as to the scope of the deal, while these terms or conditions may not be spelled out they still apply.
  - ▶ Trust and Verify- ask for source documents, if someone represents that something is a contractual or government requirement ask them to provide a citation or at least a reference, asking for a copy of the prime contract or the authorizing document can be hugely helpful
- ▶ Private contracting Government contracting - language that does not appear in the contract can be read into it as a matter of law
  - ▶ *Christian doctrine - G.L. Christian & Assocs. v. United States*, 312 F.2d 418 (Ct. Cl. 1963)
    - ▶ Contract clauses that express a “deeply ingrained strand of public procurement policy” are incorporated by operation of law
    - ▶ Government contracts have more than four corners!
    - ▶ Does it apply to Bayh-Dole and data-rights framework in FAR/DFARS?
      - ▶ Are there additional terms that could present issues to transferability, claim or title or place other requirements that may not be appreciated?



# Considerations

- ▶ US Government dollars bring US Government requirements that are tipped in favor of the US taxpayer and US small businesses and policies and aims associated therewith.
  - ▶ Rights in IP- intended to prevent US Government from having to pay royalty to use IP that its resources helped create (leavening provisions)
  - ▶ Foreign Businesses may not be able to own IP (even if they pay for the research)
  - ▶ US Competitiveness- provisions in government sponsored IP that require that activities benefit US economy, may have requirements for
    - ▶ Reporting on activities related to the deployment of the IP,
    - ▶ Substantial US manufacture for all items covered by sponsored IP (or the obtaining of a waiver)
    - ▶ Sponsor approval for transfers of rights (licenses and assignments particularly if the other party is a non-US entity)
    - ▶ Look at contractual provisions and read links to items with terms like “Class Waiver”
      - ▶ <https://www.energy.gov/gc/class-patent-waivers>

# What is a Foreign Sponsor? DOE Order 485.1

“Foreign entities include:

- ▶ Any foreign government or foreign government agency, or instrumentality thereof;
- ▶ Any international organization
- ▶ Any form of business enterprise or legal entity organized, chartered or incorporated under the laws of any country other than the United States or its territories
- ▶ Any form of business enterprise organized or incorporated under the laws of the United States or a State or other another jurisdiction within the United States which *is owned, controlled or influenced by a foreign government agency, firm or corporation* and
- ▶ any person who is not a citizen or national of the United States.

# Authorization & Consent (28 U.S.C. § 1498)

Most government procurement contracts under FAR 15 have an A&C clause

Not always included in other government contracts, such as OTAs, CRADAs, SBIR agreements, etc.

Under A&C, a contractor can infringe a U.S. patent in its performance of a government contract without liability to the patent owner (US Government Steps in to address reasonable royalty)

Limited exception in production contracts for manufacturing procedures or equipment not required to perform the contract

Patent owner can sue the U.S. Government for the infringement, but the only remedy is reasonable monetary compensation

Injunctive relief is not available

Suit must be brought in the Court of Federal Claims

A&C is an application of “limited right” provided by the patent itself (Article I Section 8, 28 USC 1498 )

A&C does not apply to foreign patents

Suit against a foreign subcontractor for infringement of a foreign patent still available

Most developed nations have their own version of A&C

# Obtaining and Perfecting Rights in IP

- ▶ Understand the starting point- follow the money (Government rights do not attach to privately funded IP unless you contract it away)
- ▶ Follow instructions in agreement - recognize that terms typically flow from statute, regulation or administrative document such as a class waiver, know the source documents (ask if you need to) and don't try to vary too far or get too creative, look for preapproved alternative language
- ▶ FAR 52.227-14- Rights in Data general-tax payers pay, taxpayers have access unless permission to copyright is obtained
- ▶ FAR 52.227-15 -Limited Rights Data Representation
- ▶ FAR 52.227-11- Small entities have Bayh-Dole rights in inventions
- ▶ FAR 52.227-13 Government owns inventions, Large Entities and Foreign do not have Bayh-Dole Rights and must petition for waiver and exception

# Federal Acquisition Regulation

- ▶ 52.227-1 Authorization and Consent.
- ▶ 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement.
- ▶ 52.227-3, 4, 5 Patent Indemnity.
- ▶ 52.227-6 Royalty Information.
- ▶ 52.227-7 Patents-Notice of Government Licensee.
- ▶ 52.227-9 Refund of Royalties.
- ▶ 52.227-10 Filing of Patent Applications-Classified Subject Matter.
- ▶ 52.227-11 Patent Rights-Ownership by the Contractor.
- ▶ 52.227-13 Patent Rights-Ownership by the Government.
- ▶ 52.227-14 Rights in Data-General.
- ▶ 52.227-15 Representation of Limited Rights Data and Restricted Computer Software.
- ▶ 52.227-16 Additional Data Requirements.
- ▶ 52.227-17 Rights in Data-Special Works.
- ▶ 52.227-18 Rights in Data-Existing Works.
- ▶ 52.227-19 Commercial Computer Software License.
- ▶ 52.227-20 Rights in Data-SBIR Program.

A photograph of several hands raised in the air, indicating a question or a vote in a meeting. The hands are in the foreground, and the background is blurred. A green and grey diagonal graphic element separates the photo from the text.

# QUESTIONS?



# **OTHER AGREEMENTS THAT ADDRESS IP ISSUES**

# MTAs

- ▶ MTA = Material Transfer Agreement
- ▶ MTAs are used to memorialize the transfer materials between organizations
- ▶ It is a standard that the organization providing the material will supply the MTA
- ▶ If the material is not properly brought in:
  - ▶ Transfer of material not permitted until resolved
  - ▶ Creates question of ownership on inventions
  - ▶ Liability/Indemnification



# CDAs = NDAs = PIAs

- ▶ CDA = Confidential Disclosure Agreement
- ▶ NDA = Nondisclosure Agreement
- ▶ PIA = Proprietary Information Agreement
- ▶ CDAs provide the terms under which confidential information may be exchanged
- ▶ It is a standard that the organization providing the confidential information will supply the CDA
- ▶ If the information is exchanged without an agreement:
  - ▶ May be a publication for patenting purposes - may bar patent protection
  - ▶ No limitations on use
  - ▶ Liability/Indemnification

# IIAs

- ▶ IIA = Inter-Institutional Agreement
- ▶ IIAs are used whenever investigators from more than one entity contribute to an invention.
- ▶ It is a standard that the institution that will be responsible for leading the licensing efforts supplies the IIA.
- ▶ IIAs:
  - ▶ Define the roles of each institution
  - ▶ Determine control of patent process
  - ▶ Determine financial contribution to patent costs
  - ▶ Determine royalty split
  - ▶ List required terms of any license

# TAs/SAs

- ▶ TA = Testing Agreement
- ▶ SA = Services Agreement
- ▶ TAs and SAs are used when an organization is using university equipment/employees to conduct standard testing or services.
- ▶ Industry prefers to start from their template, all other organizations defer to the service/testing provider.
- ▶ TAs and SAs:
  - ▶ Specify the work to be performed, as dictated by the entity ordering the test/service
  - ▶ Give ownership of the results to the contracting party
  - ▶ Are generally silent on IP