

WHAT DOES LICENSE MONITORING & ENFORCEMENT INVOLVE?

Technology licenses are “executory contracts” where each party to the agreement (licensor & licensee) has pledged to fulfill certain obligations.

Royalty payments are only one type of obligation licensees have under license agreements.

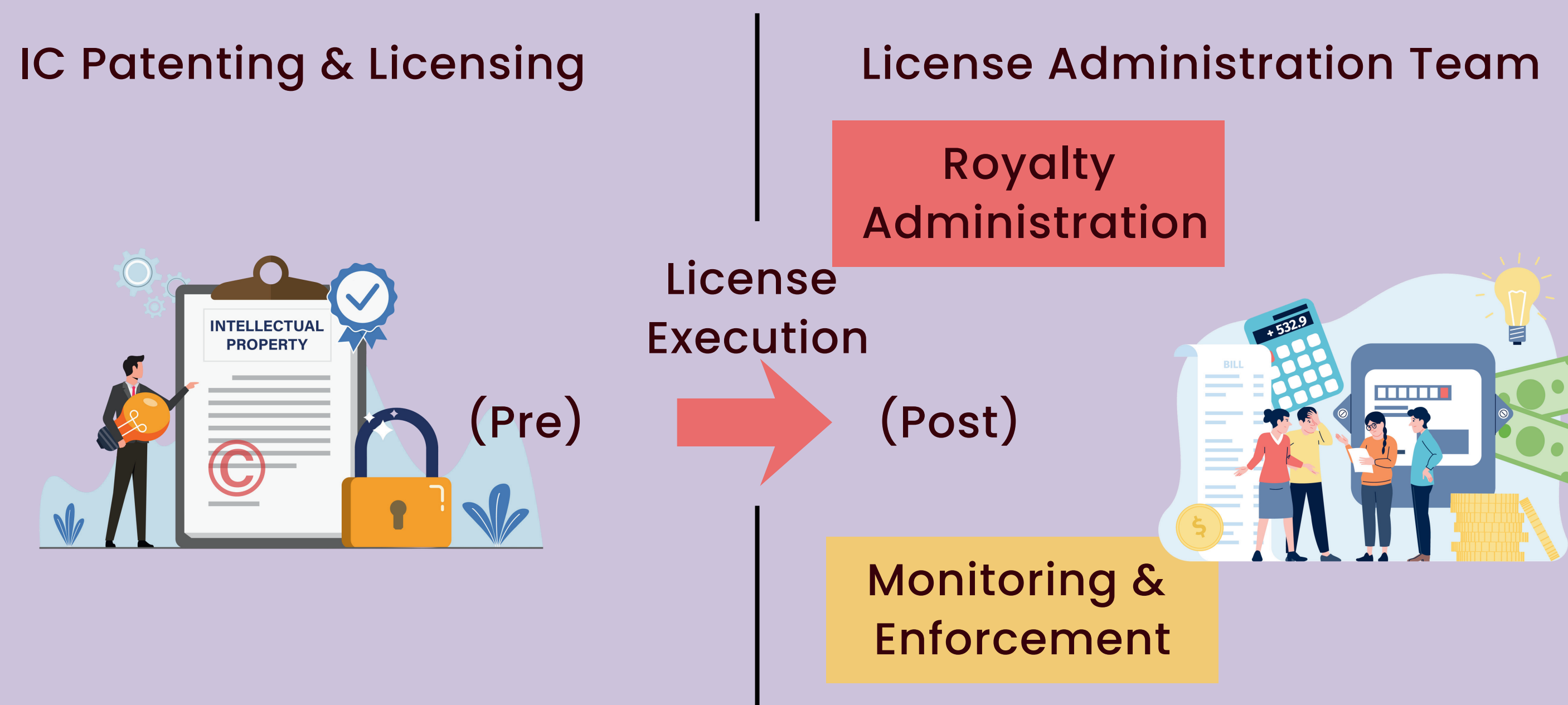
Licensee Obligations Include:

- Periodic reports for development or research progress.
- Periodic reports of sales and earned royalty calculations.
- Notices of milestone/benchmark accomplishment.
- Notices of first commercial sale.
- Requests for written consent – to assign, sublicense, US manufacturing waiver.
- Certificates of material destruction upon license expiration or termination.
- Providing additional information upon request.

Licensor has obligations to the licensee. These include:

- Prosecuting & maintaining licensed patents.
- Maintaining confidentiality of sensitive information submitted by licensees.
- Accurately collecting & recording royalty payments.
- For IIAs (inter-institutional agreements), providing periodic reports of NIH led patenting and licensing activity.
- Royalty payouts to inventors & labs at institution.

WHERE DOES MONITORING & ENFORCEMENT FIT?



LICENSE MONITORING & ENFORCEMENT AT NIH

Keeping an Eye on NIH's Assets!

Royalty Administration

- Sends Out Royalty Due Notices & Late Notices
- Records & Applies Royalties Received
- Prepares Patent Expense Reports & Invoices
- Maintains & Updates Internal Royalty Distribution
- Material Release Authorization & Shipping Confirmation
- Audits Internal Royalty Records
- Reconciles Royalty Records w/ Receipts
- Responds to Royalty-Related Questions
- Collects Overdue License Royalties

Monitoring & Enforcement

- Reviews Sales & Progress Reports
- Collects Overdue Sales & Progress Reports
- Monitors Commercial Development vs Milestones
- Reviews Requests to Assign or Sublicense
- Reviews Requests for US Manufacturing Waiver
- Negotiates Amendments – term extensions & other
- Handles 3rd Party Audits of Licensees
- Investigates Infringement of Patents
- Negotiates Infringement Settlements

WHY DOES NIH HAVE A MONITORING & ENFORCEMENT FUNCTION?

- Ensure Licensee is complying with agreement terms.
- Determine what the Licensee is doing with the technology.
- Assure all technology users are licensed.
- Determine if royalties are overdue.
- Determine if royalties have been properly paid.
- Assure all Licensees are treated fairly.

LICENSE COMPLIANCE

License Compliance Review:

- Read license agreement – note specific terms.
- Review licensee reporting record.
- Is licensee using or developing the technology?
- Have performance benchmarks been met?
- Are sales and sales reports correct and up-to-date?
- Has/have the license or licensed patents expired?

Non-Compliance Requiring Action:

- Royalties are not being paid or are overdue.
- Obligatory reports are not being submitted.
- Commercial development plan is off-track.
- Underreporting of licensed product sales.
- Errors in calculation of earned royalties.
- Failure to report sublicense agreements.
- Failure to seek consent for license assignment.

Options for Achieving Compliance:

- Inform/educate licensee of their obligation(s).
- Set deadlines for receipt of royalties/reports owed.
- Threaten or impose “additional royalties” (interest)
- Suspend other licensing until owed royalties are paid.
- Threaten with debt collection, credit bureau reporting, & excluded parties listing.
- Negotiate amendment to restore compliance/settle dispute.
- 90-day notice of license termination.

MONITORING & ENFORCEMENT OFFICER ACTIVITIES

Settling License Disputes:

- Investigate Licensee compliance in detail.
- Separate contract law from patent law issues.
- Offer a compromise solution if dispute is valid.
- Seek outside opinion if dispute persists.
- Offer a solution consistent with outside opinion.
- Discuss offer in person, if necessary.
- Amend license to correct the problem; collect royalties.
- Terminate license; collect unpaid royalties.

Collecting Overdue Royalties

- Find responsible person at licensee.
- Establish reason(s) for non-payment.
- Settle any problems/disputes holding up payment.
- Use an effective collection letter.
- Follow-up frequently until payment is sent.
- Verify receipt of payment.