Transforming Discoveries into Products: *Maximizing NIH's Levers to Catalyze Technology Transfer*

How NIH Negotiates License Terms

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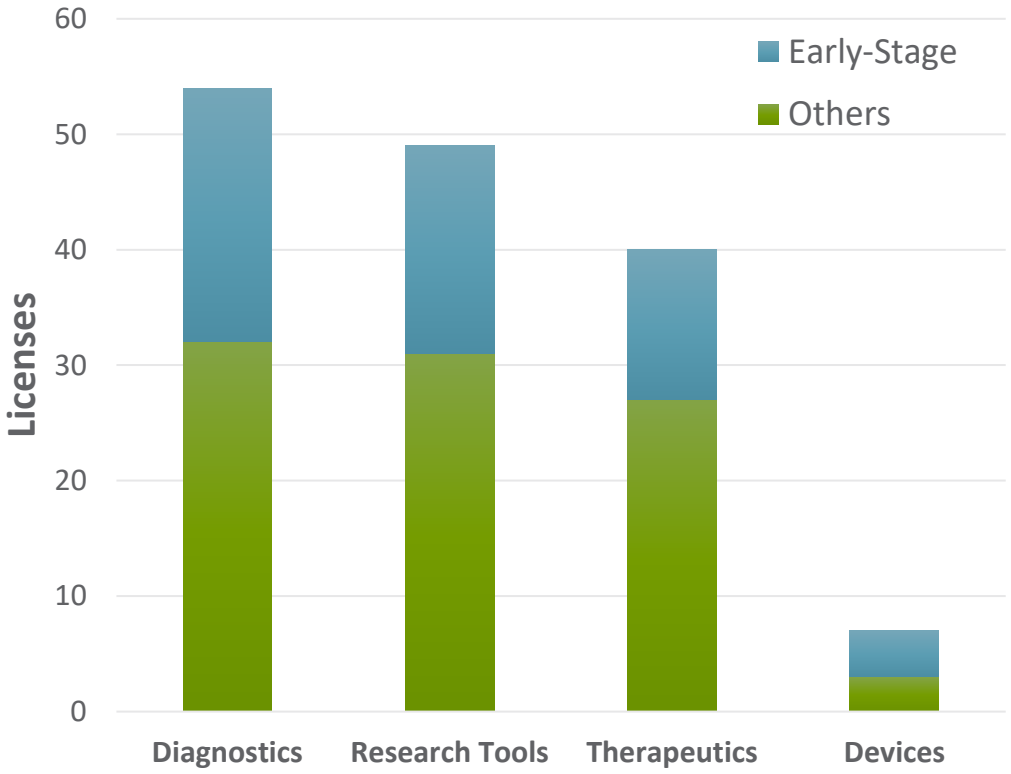
National Institutes of Health
Turning Discovery Into Health

NIH Licenses Yield Substantial Public Health Benefits

- Broad range of technologies reflecting intramural program's diverse research
- More than 1,000 products brought to market
  - 39 FDA-approved vaccines and therapeutics
- Licensed IP utilized in over 1,200 clinical trials
- Over 60% of NIH licenses are for research tools
- Most licenses are non-exclusive

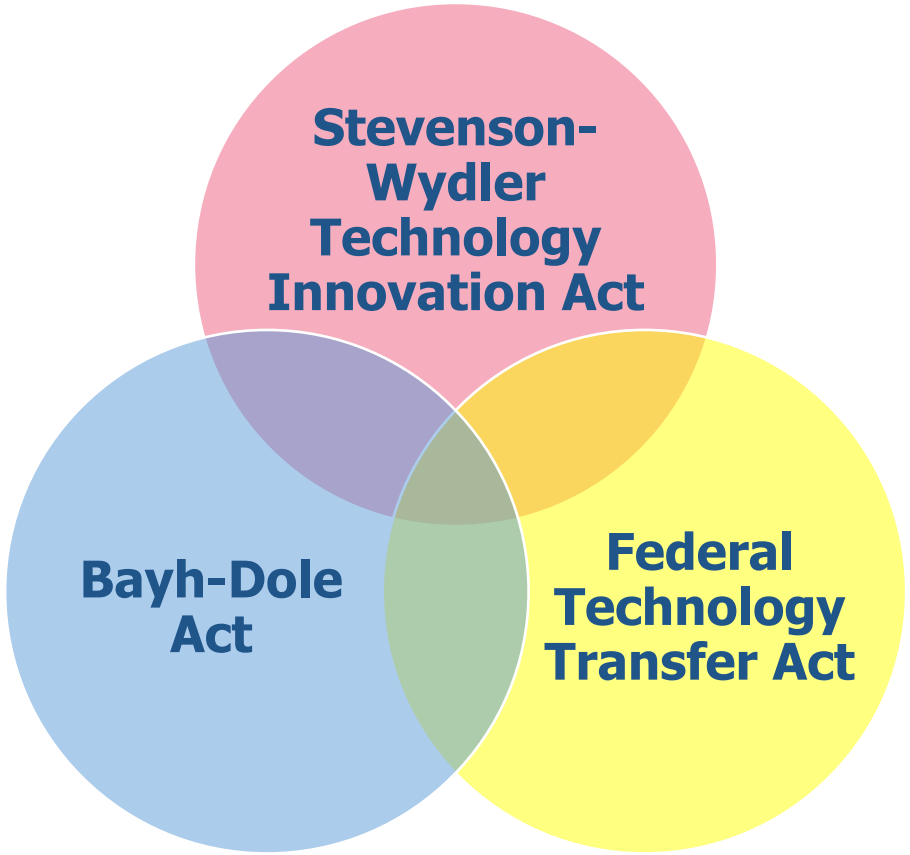
Who Licenses NIH Technologies?



- Not just big companies!
- About 1/3 of NIH's most successful technologies were licensed by early-stage companies.
- Overall, for every 2 U.S. licensees there is 1 foreign licensee.

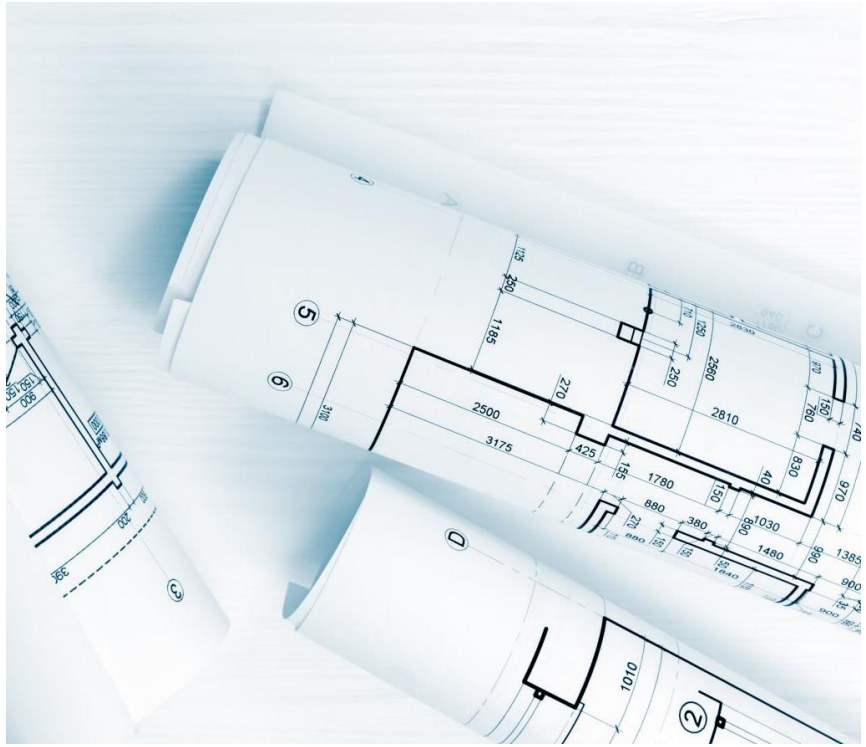
Source: Public Health & Economic Impact Study of NIH Intramural Technology Transfer Licensing

Legal Framework for NIH Licensing



- 35 U.S.C. § 207-209
  - Domestic and foreign protection of federally owned inventions
- 37 C.F.R. § 404
  - Licensing of Government-owned Inventions

37 C.F.R. § 404 – Licensing Blueprint



Addresses:

- Information that applicants need to provide
- What kinds of licenses the Government can grant
- Restrictions and conditions on all licenses
- Special requirements for exclusive licenses
- Government right to terminate or modify

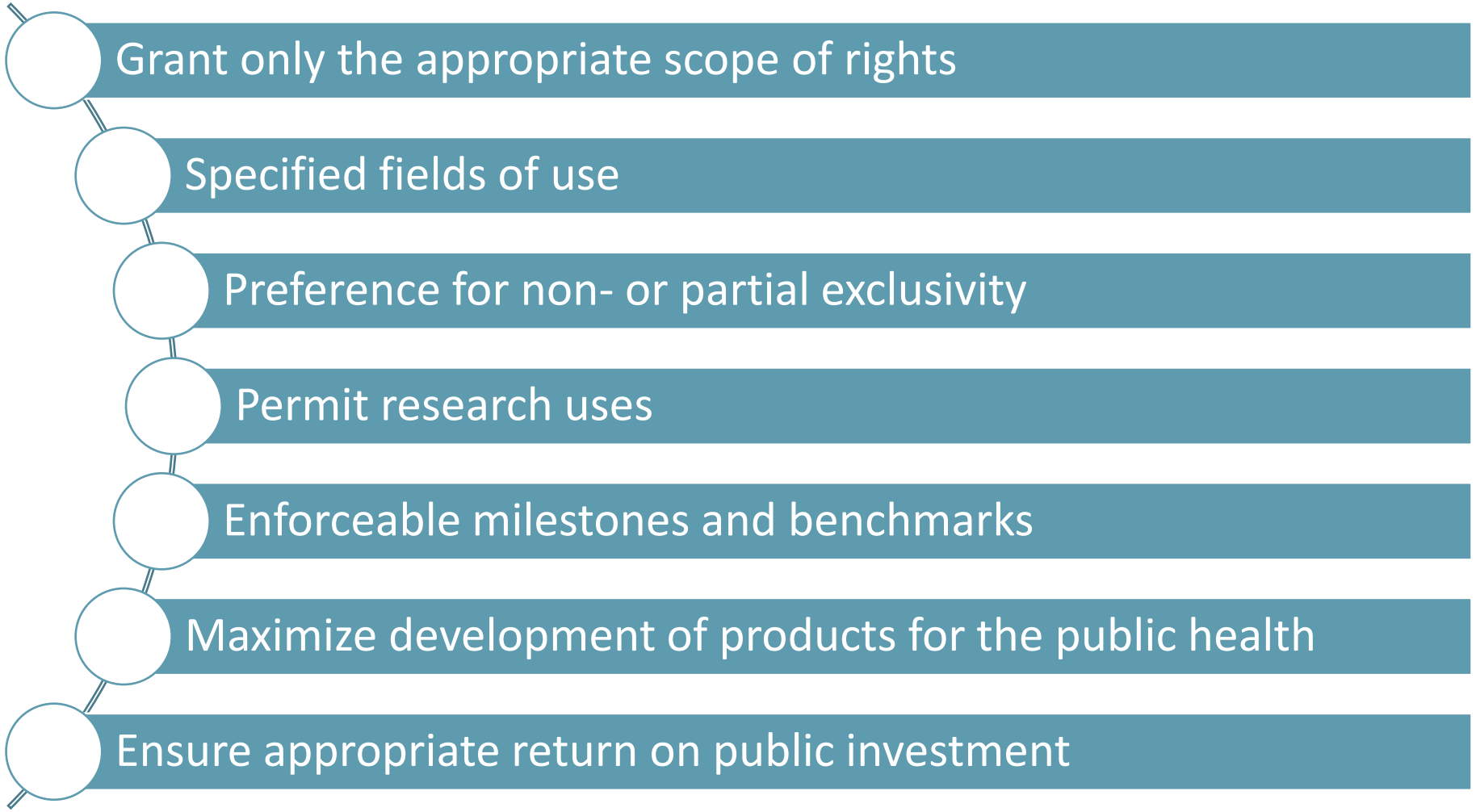
NIH Licensing Goals

- "It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process."
- What does this mean?
  - Utilize IP appropriately as incentive for commercial development of technologies
  - Attract new R&D resources
  - Obtain return on public investment
  - Stimulate economic development

And:

<u>Benefit the public health</u>

NIH Licensing Principles



Challenge: Licensing Early-Stage Technologies

- Often 10-15 years from executed license to marketed product
- How to determine most effective licensing strategy?
  - Market may not yet exist
  - Regulatory landscape may change (or be unknown)
  - Who will need it most?
  - Where to seek patent protection?
  - Patents may expire before product even comes to market
  - Is the licensee the company that will eventually market the product?
  - What kind of licenses will be needed? Exclusive, non-exclusive, both?

Starting Point for Negotiations

- Information from applicants
  - Development, marketing plans required as part of application
- Comparables
  - Similar licenses that NIH has done before
- Market research/valuations
  - But can be highly speculative for early-stage technologies
- What we <u>don't</u> use:
  - Inventor input, particularly on financial terms

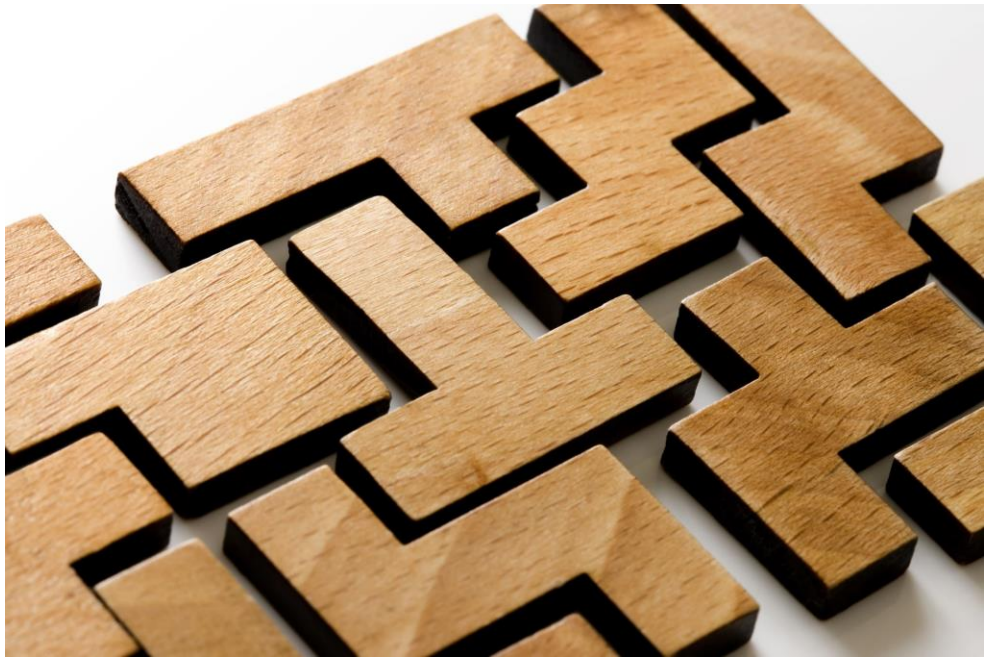
Negotiating the Terms

- Financials are just one part of the puzzle
- Scope of license grant (exclusivity, patents, products, territory?)
- Development timeline and associated benchmarks
- Reporting and other diligence requirements
- Sublicensing requirements
- Public benefit ("White Knight") provisions

Examples of “White Knight” Terms

- Supply back of Licensed Products or Services
- Health education programs (web or print)
- Indigent access programs for Licensed Products
- Developing country access for Licensed Products
- Biodiversity compliance for natural products

Financial Terms



- Based on multiple factors
- Usually includes:
  - Upfront fee
  - Earned royalties on sales
  - Milestone payments
  - Sublicensing payments
  - Patent expenses
- For technologies that are high risk (e.g., early stage), payments generally shifted towards the "back end" – we succeed when licensee succeeds
- Also take into account licensee resources – terms should not hinder ability to develop and market the technology
- Other, non-financial terms also part of the equation

Tracking Licensee Progress

- Executing a license is the start of a multi-year relationship
- NIH has to ensure that the licensee holds up its end of the bargain
- How? Through periodic review of things like
  - Progress reports
  - Benchmarks
  - Payments
  - Review of public information
- License includes variety of levers for NIH to use if licensee is not performing

When There's a Problem

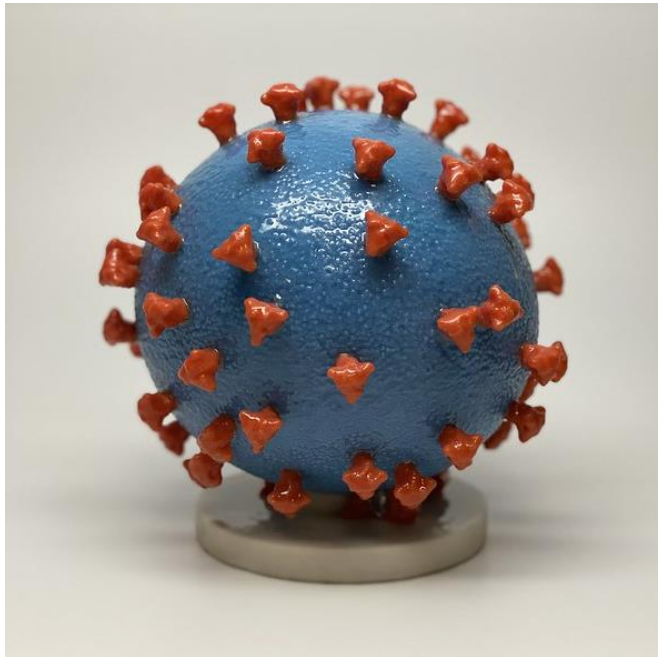
- Risky early-stage technologies mean plans can get derailed
- Often best option is to amend the license
  - Appropriate if license is diligent but needs help getting back on track
  - NIH can modify requirements, terms in exchange for flexibility
  - Revisit scope of license – has the situation changed?

- Warning signs
  - Seems unable to move technology forward
  - May be "shelving" the technology
  - Lack of communication and/or failure to provide required reports

- Last resort: license termination
  - Risk: technology will not be developed
  - Licensee on the hook for unpaid obligations
  - May impact ability to obtain other licenses, or work with the NIH at all.

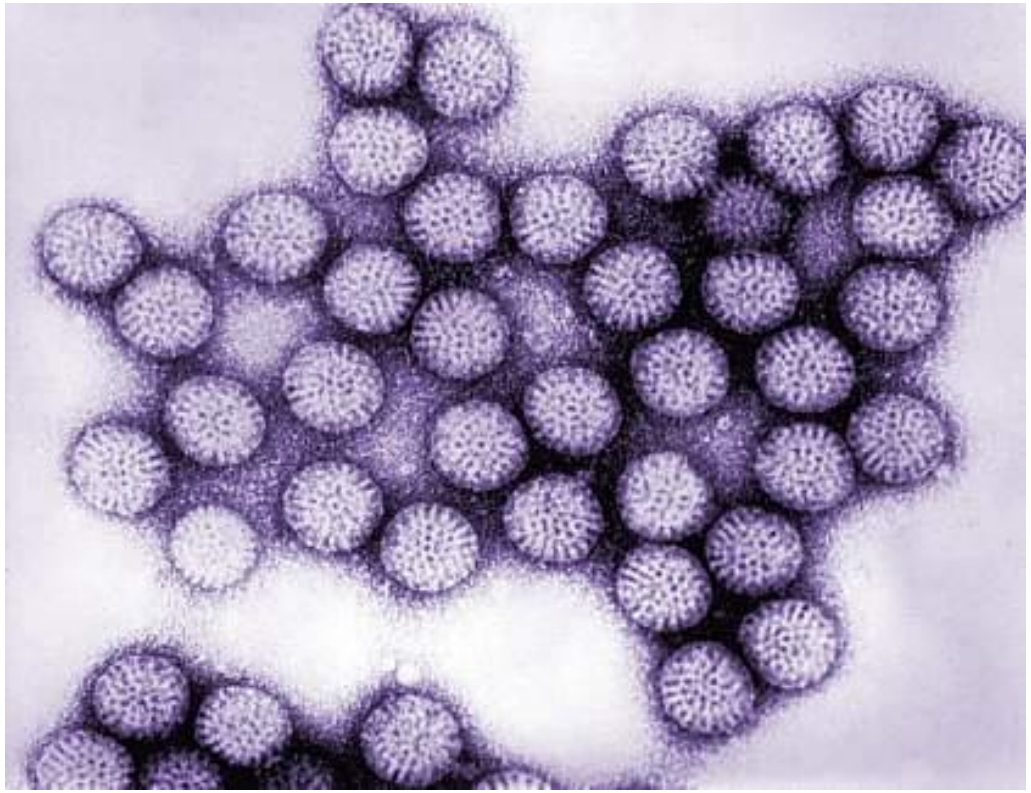
Other NIH Strategies for Facilitating Access

- Participation in patent pools
  - Medicines Patent Pool (HIV medicines)
  - MPEG LA/Librassay® (diagnostic technologies)
  - WHO COVID-19 Technology Access Pool (vaccines)
- Special license models
  - Non-Profit Licenses (for vaccines, therapeutics related to NTDs)
  - Start-Up Licenses (for vaccines, therapeutics & certain devices, largely deferred financial terms)



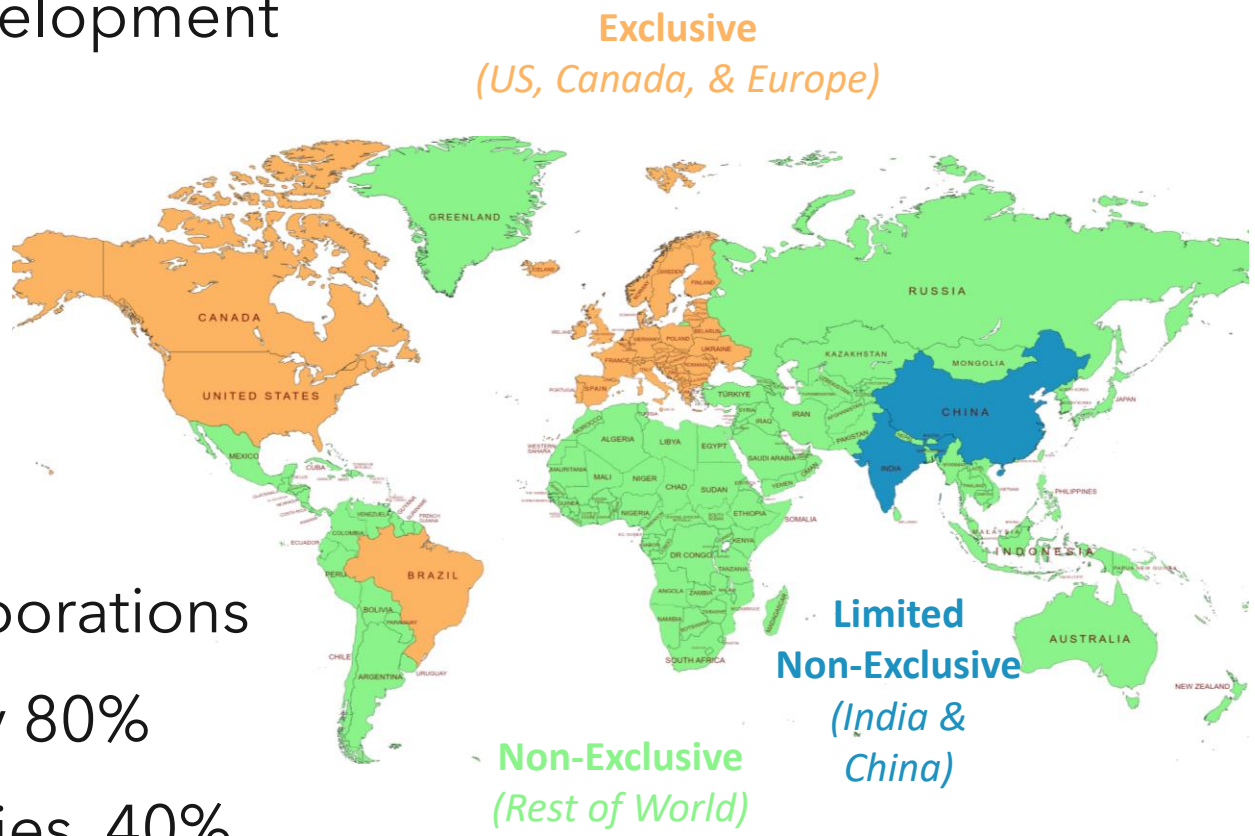
Snapshot: Regional Licensing to Facilitate Access

- Rotavirus is a highly contagious virus that can cause severe diarrhea and vomiting, especially in infants.
- Before a vaccine was available, rotavirus was responsible for half a million child deaths each year
- Previous vaccine efforts failed, leading to NIH development of a 2nd generation vaccine



Snapshot: Regional Licensing to Facilitate Access

- Maximize opportunity for successful development and global distribution of technology
  - 14 commercial licensees
    - Biological materials
    - Access to inventor for technical input
  - Regional expertise
  - Regional vaccine programs
- Establish relationships and enable collaborations
- Result in US: hospitalizations reduced by 80%
- ROW: available in more than 100 countries, 40% decrease in hospital admissions for young children, reduced deaths



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Source: *Public Health & Economic Impact Study of NIH Intramural Technology Transfer Licensing*

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Thank you!