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## **mRNA Patent Wars Update: Litigations Expand and Key Rulings Expected in 2025**

**Speaker:**  
**Dan Shores**  
**Rothwell Figg**  
**May 14, 2025**



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# About the Speaker

- **20 years biotech patent law experience**
  - Strategy, FTO, protection, deals, licensing, due diligence, litigation, IPR/post-grant
- **Expertise in Lipid Nanoparticle (LNP) IP space**
  - Leader in firm's LNP/RNA IP team
  - Navigates complex IP and litigation landscapes
  - Protects new innovations
  - Negotiates licensing and other deals
  - Conducts due diligence



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# Rothwell's mRNA/LNP Team



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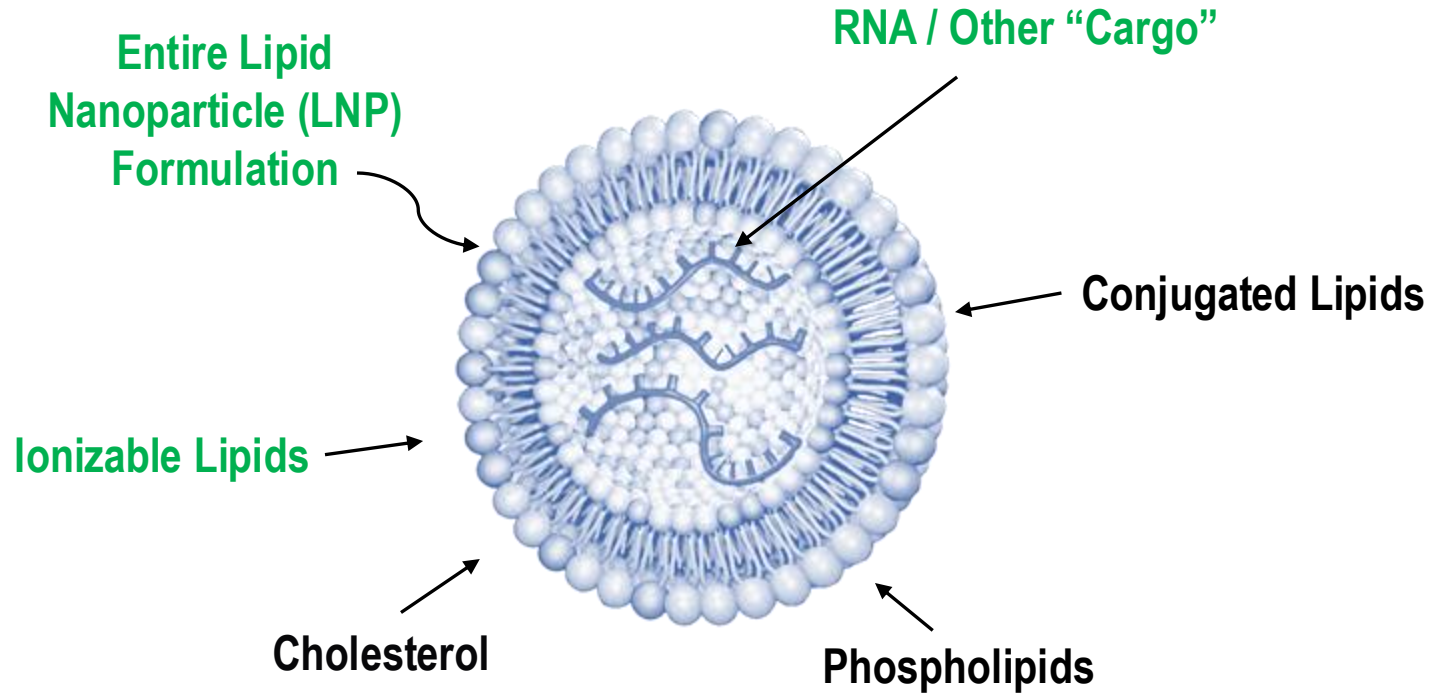


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Associate

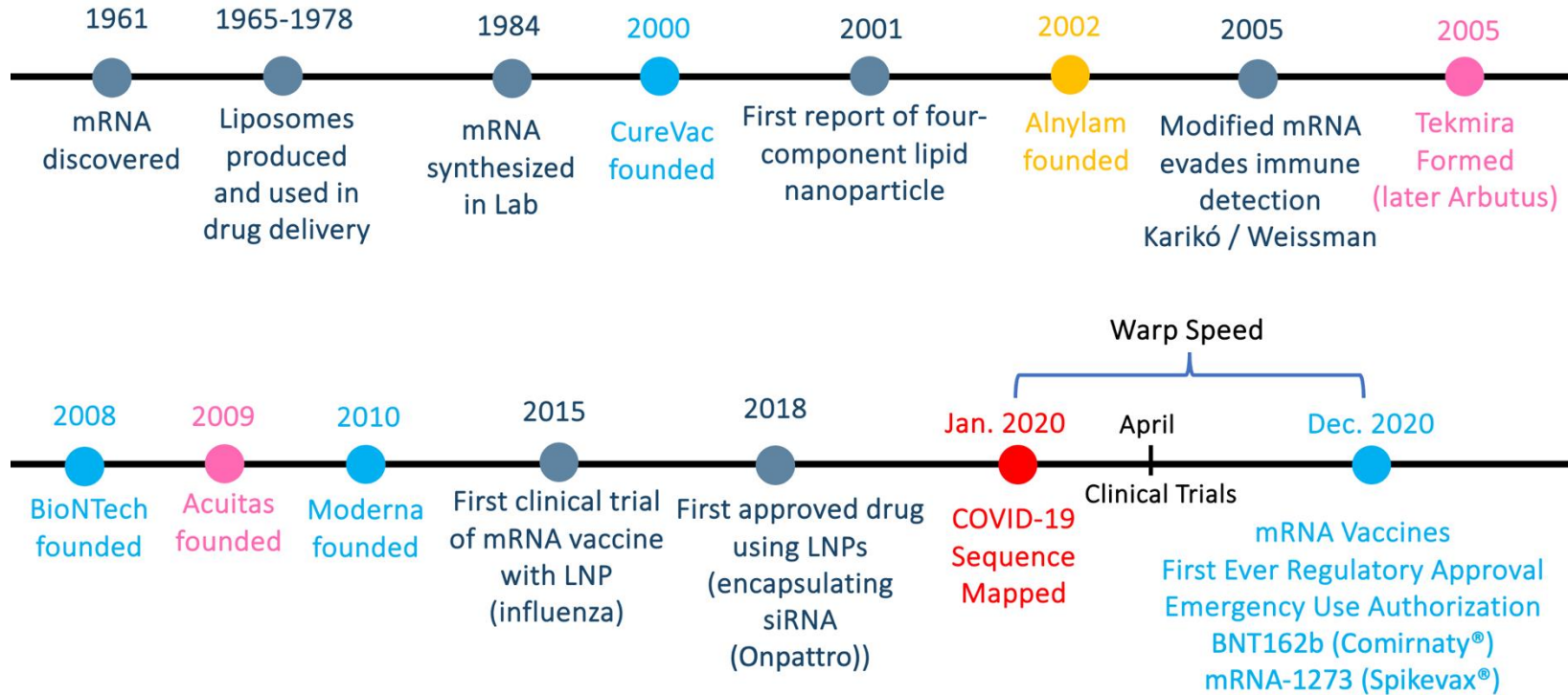


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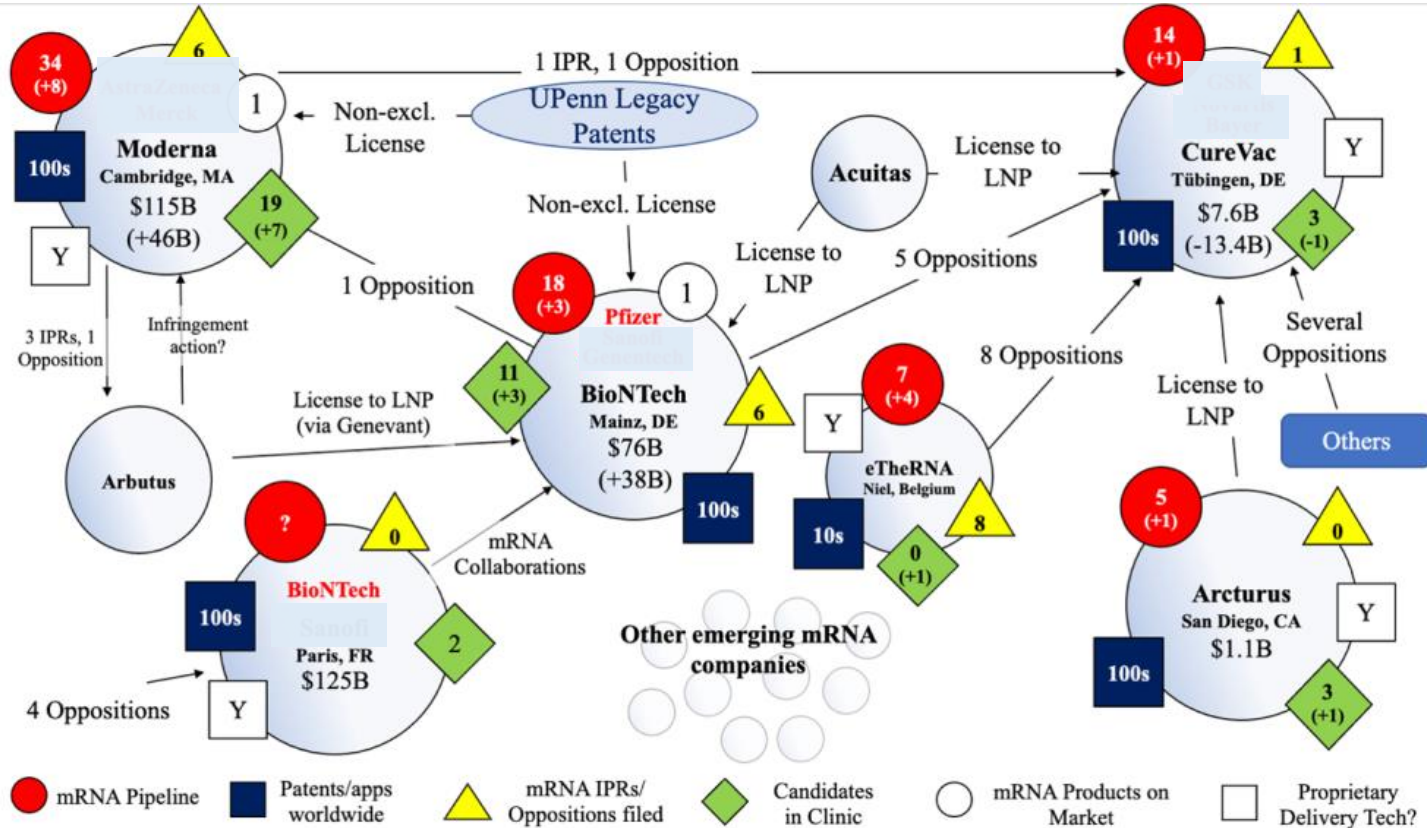
# LNPs: Key Components



# mRNA-What a Story!



# IP & Competitive Landscape ~2021



# 2021 COVID Vaccine Sales

**Comirnaty® = ~\$36.7 billion**

[https://www.pfizer.com/sites/default/files/investors/financial\\_reports/annual\\_reports/2021/performance/](https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/performance/)

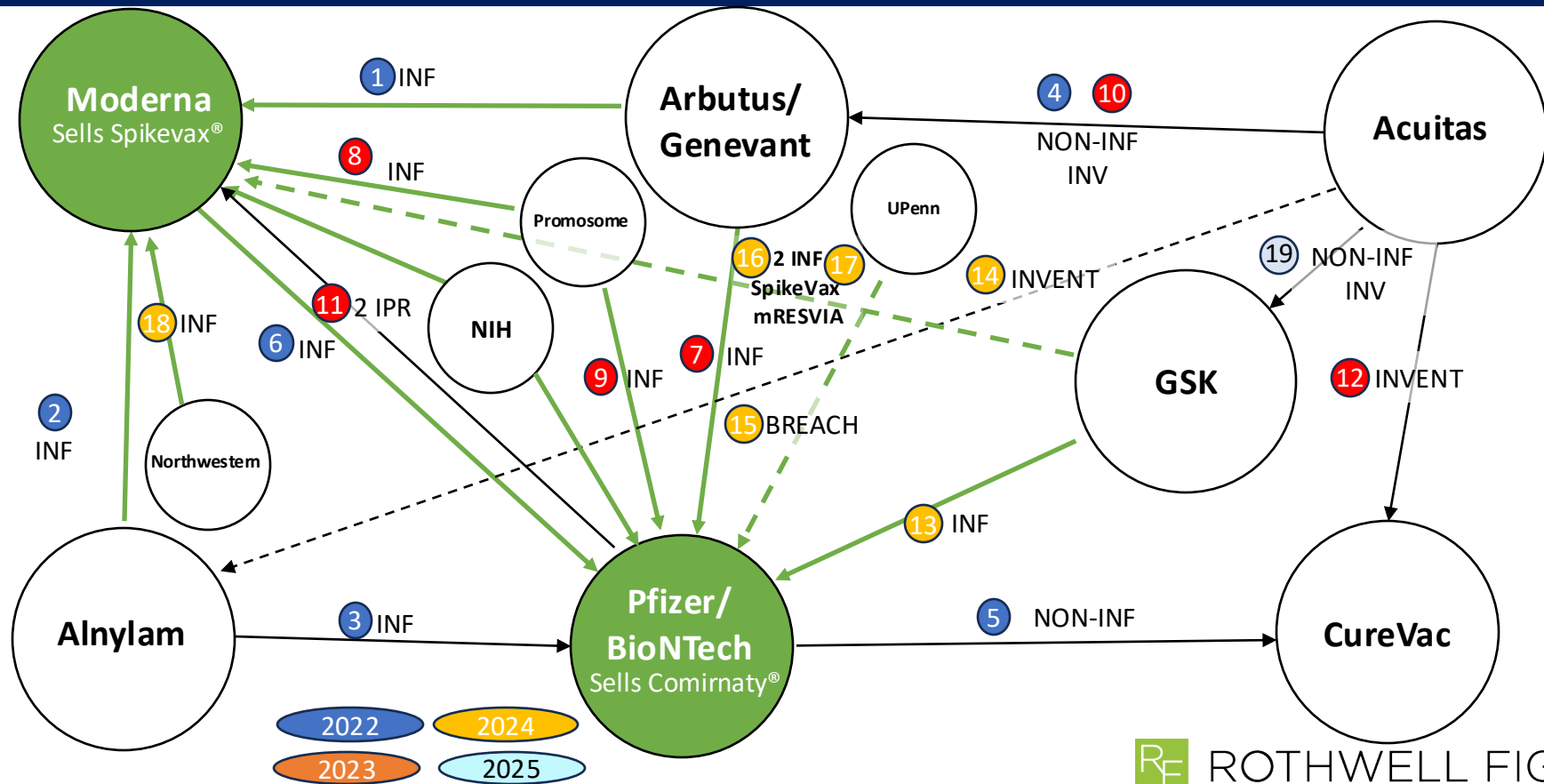
**Spikevax® = ~\$17.7 billion**

<https://investors.modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx>





# U.S. Litigation Timeline 2022-Present





# Non-U.S. Litigations

| Abroad        |                   |                   |                    |                                    |   |
|---------------|-------------------|-------------------|--------------------|------------------------------------|---|
| Date(s) Filed | Plaintiff(s)      | Defendant(s)      | Cause(s) of Action | Jurisdiction(s)                    | Status  |
| Jul 2022      | CureVac           | BioNTech          | Infringement       | Germany                            | CureVac patents invalid ( <b>December 2023</b> )      |
| Aug 2022      | Moderna           | BioNTech + Pfizer | Infringement       | Düsseldorf Regional Court, Germany | Infringement found ( <b>March 2025</b> )              |
| Aug 2022      | Moderna           | BioNTech + Pfizer | Infringement       | UK                                 | 1 patent infringed and 1 invalid ( <b>July 2024</b> ) |
| Aug 2022      | Moderna           | BioNTech + Pfizer | Infringement       | Netherlands                        | 1 patent invalid ( <b>December 2023</b> )             |
| Sep 2022      | BioNTech + Pfizer | CureVac           | Non-infringement   | England                            | CureVac patents invalid ( <b>October 2024</b> )       |
| Jul 2023      | Moderna           | BioNTech + Pfizer | Infringement       | Ireland                            | Pending   |
| Jul 2023      | Moderna           | BioNTech + Pfizer | Infringement       | Belgium                            | Pending   |
| Mar 2025      | Arbutus           | Moderna           | Infringement       | Canada                             | Case pending, very early stages                       |
| Mar 2025      | Arbutus           | Moderna           | Infringement       | Japan                              | Case pending, very early stages                       |
| Mar 2025      | Arbutus           | Moderna           | Infringement       | Switzerland                        | Case pending, very early stages                       |
| Mar 2025      | Arbutus           | Moderna           | Infringement       | UPC-1                              | Case pending, very early stages                       |
| Mar 2025      | Arbutus           | Moderna           | Infringement       | UPC-2                              | Case pending, very early stages                       |

Disclaimer: the information provided above was sourced via news articles and may not be fully accurate.



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# Arbutus v. Moderna

| Item                    | Current Status   |
|-------------------------|--|
| Trial Date              | September 29, 2025 (Jury Trial)  |
| Jurisdiction            | D. Del. (Judge Noreika)  |
| No. of Patents Asserted | 6  |
| Issues                  | Infringement and Invalidity  |
| Relief Sought           | Monetary damages; willful infringement; no injunction.                 |
| Key Case Happenings     | Moderna's 12(b)(6) motion to dismiss claims under Section 1498 denied. |



# Key Exposure Issues

28 U.S.C. § 1498: “Whenever an invention ... covered by a patent ... **is used or manufactured by or for the United States ... the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims** for the recovery of his reasonable and entire compensation for such use and manufacture....”

# U.S. Patent No. 8,058,069

1. A nucleic acid-lipid particle comprising:

(a) a nucleic acid;

(b) a **cationic** lipid comprising from **50 mol % to 65 mol %** of the total lipid present in the particle;

(c) a **non-cationic** lipid comprising a mixture of a **phospholipid and cholesterol** or a derivative thereof, wherein the phospholipid comprises from **4 mol % to 10 mol %** of the total lipid present in the particle and the cholesterol or derivative thereof comprises from **30 mol % to 40 mol %** of the total lipid present in the particle; and

(d) a **conjugated** lipid that inhibits aggregation of particles comprising from **0.5 mol % to 2 mol %** of the total lipid present in the particle.



# Alnylam v. BioNTech + Pfizer

| Item                    | Current Status  |
|-------------------------|---|
| Trial Date              | July 7, 2025 (Jury Trial)   |
| Jurisdiction            | D. Del. (Judge Connolly)  |
| No. of Patents Asserted | 6   |
| Issues                  | Infringement, Validity, Unenforceability (Patent Misuse)  |
| Relief Sought           | Monetary damages; no injunction   |
| Key Case Happenings     | Asserted patents filed after Pfizer + BioNTech vaccine approved<br>1 of the 6 asserted patents voluntarily dismissed with prejudice |

# BioNTech + Pfizer v. CureVac

| Item                | Current Status  |
|---------------------|---|
| Trial Date          | September 8, 2025 (Jury Trial)  |
| Jurisdiction        | E.D.V.A. (Judge Walker)   |
| No. of Patents      | 10  |
| Issues              | Infringement and Validity   |
| Relief Sought       | Declaratory Judgment  |
| Key Case Happenings | Court granted Acuitas motion to intervene and stay (Apr 2024). Acuitas claimed rights in the ownership of certain asserted patents. Acuitas filed suit for correction, the case settled, CureVac withdrew certain asserted patents. Acuitas dismissed. Case now has 7 asserted patents. |



# Moderna v. BioNTech + Pfizer

| Item                | Current Status   |
|---------------------|--|
| Trial Date          | Not set. Stayed pending appeal of 2 IPRs   |
| Jurisdiction        | D. Mass.   |
| No. of Patents      | 3  |
| Issues              | Infringement and Validity  |
| Relief Sought       | Damages (including lost profits); no injunction  |
| Key Case Happenings | "Consistent with Moderna's patent pledge, Moderna is not seeking damages for activities occurring before March 8, 2022. And Moderna is not seeking damages related to Pfizer and BioNTech's sales to the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment." |

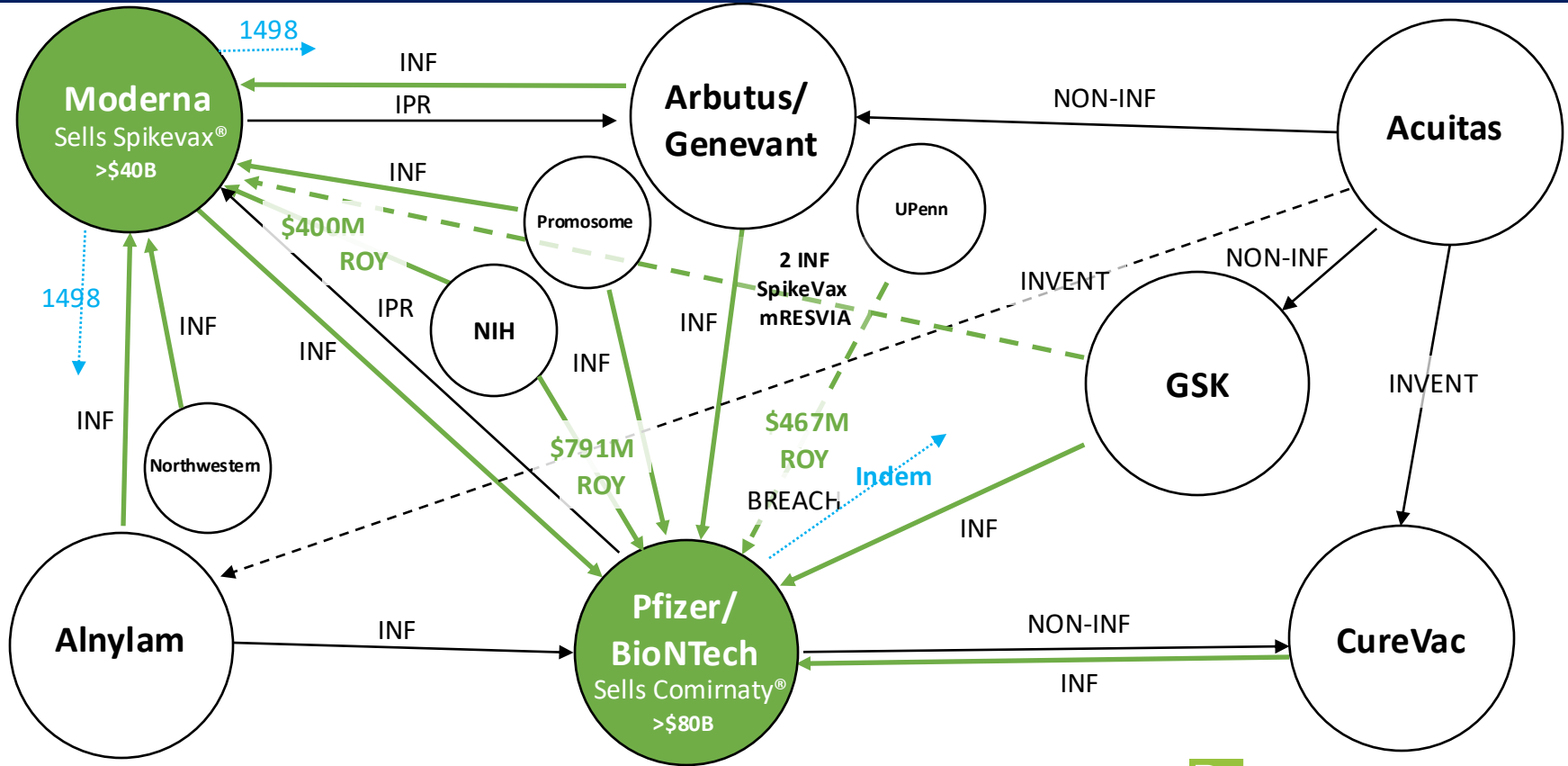




# Key Exposure Issues

- **Available remedies**
  - Injunction: None sought against COVID vaccines
  - Reasonable royalties: Hypothetical negotiation, licensing models
  - Lost profits: “But for” infringement sale would have been made
  - Basis for Calculation: **>\$100B in Combined Sales**
- **Invalidity/Cancellation**
  - Licensing business models
- **Exposure management**
  - 28 U.S.C. § 1498: Whenever an invention ... covered by a patent ... **is used or manufactured by or for the United States ... the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims**
  - Indemnification
  - International sales
  - Settlement/trial risk analyses

# Exposure Landscape



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# Summary

- **Over 30 known disputes in U.S. and Abroad since 2022**
  - 17 cases pending (10 U.S., 7 abroad)
  - 3 trials scheduled for 2025
  - 9 lower court rulings (4 U.S., 5 abroad)
  - 6 settlements (U.S.)
- **What is at stake for litigants**
  - Maker revenues
  - Patent-holder patents
- **Effect on space**
  - Market players to assess results, FTO and behavior
  - Great opportunity to innovate and build assets
  - The platform tech will persevere





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# Thank you!

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available upon request.



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