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LIFE SCIENCES INSURANCE

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

Speaker:
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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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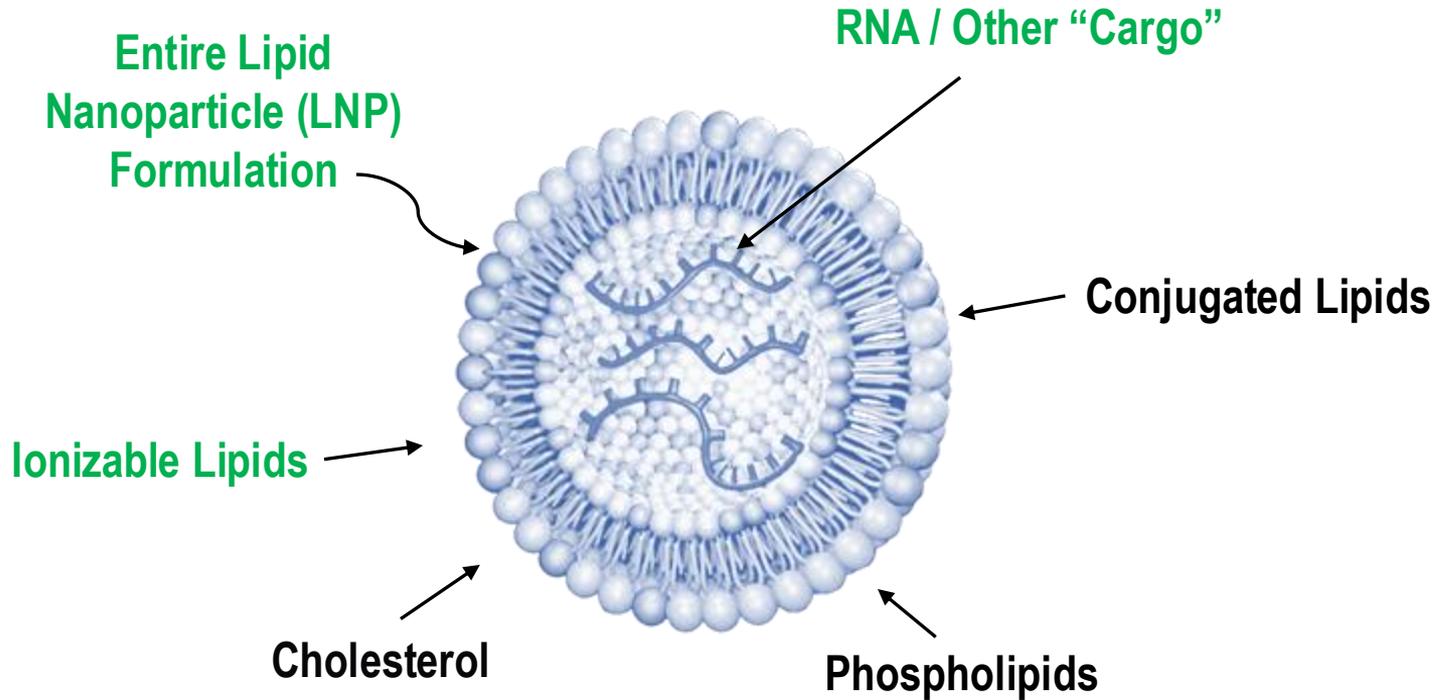


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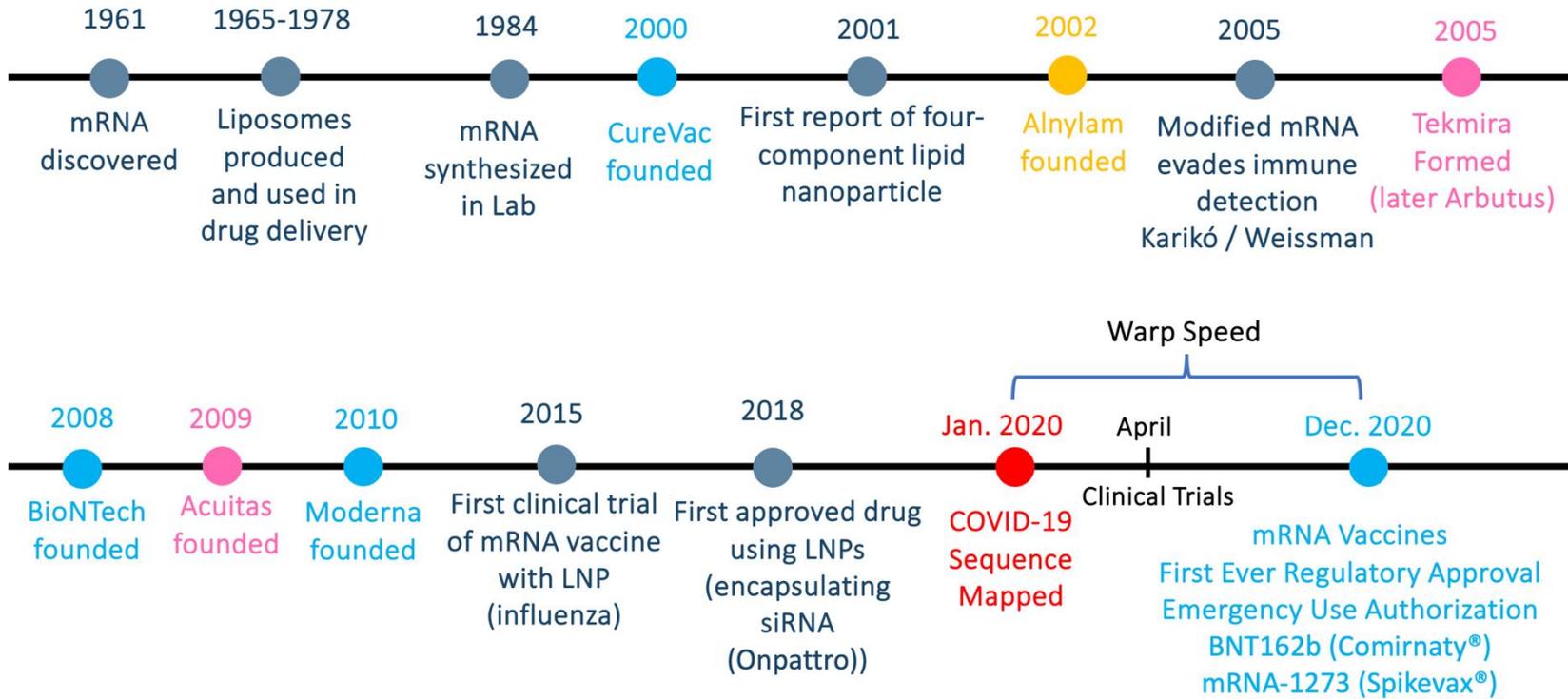


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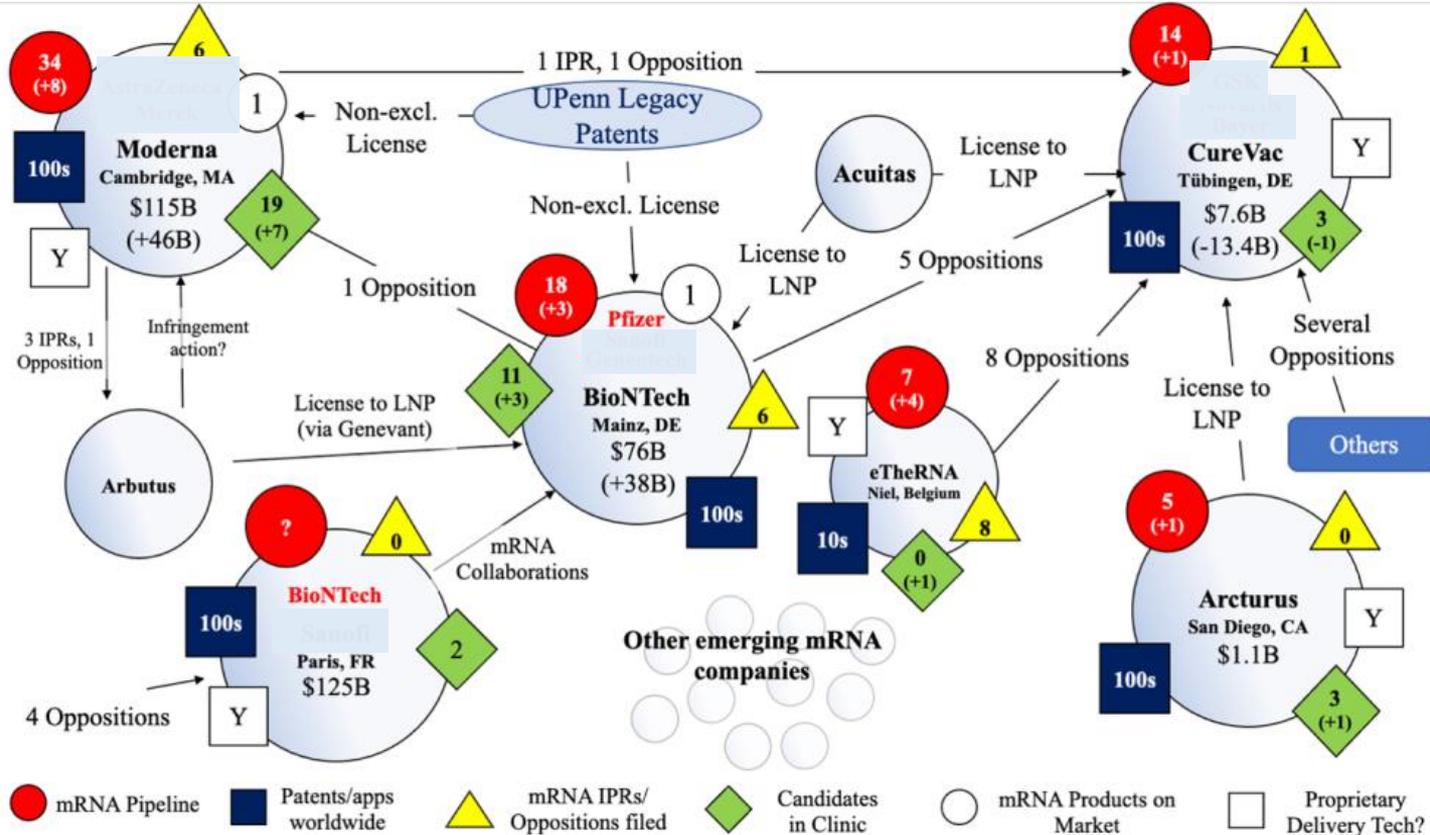
LNPs: Key Components



mRNA-What a Story!



IP & Competitive Landscape ~2021



2021 COVID Vaccine Sales

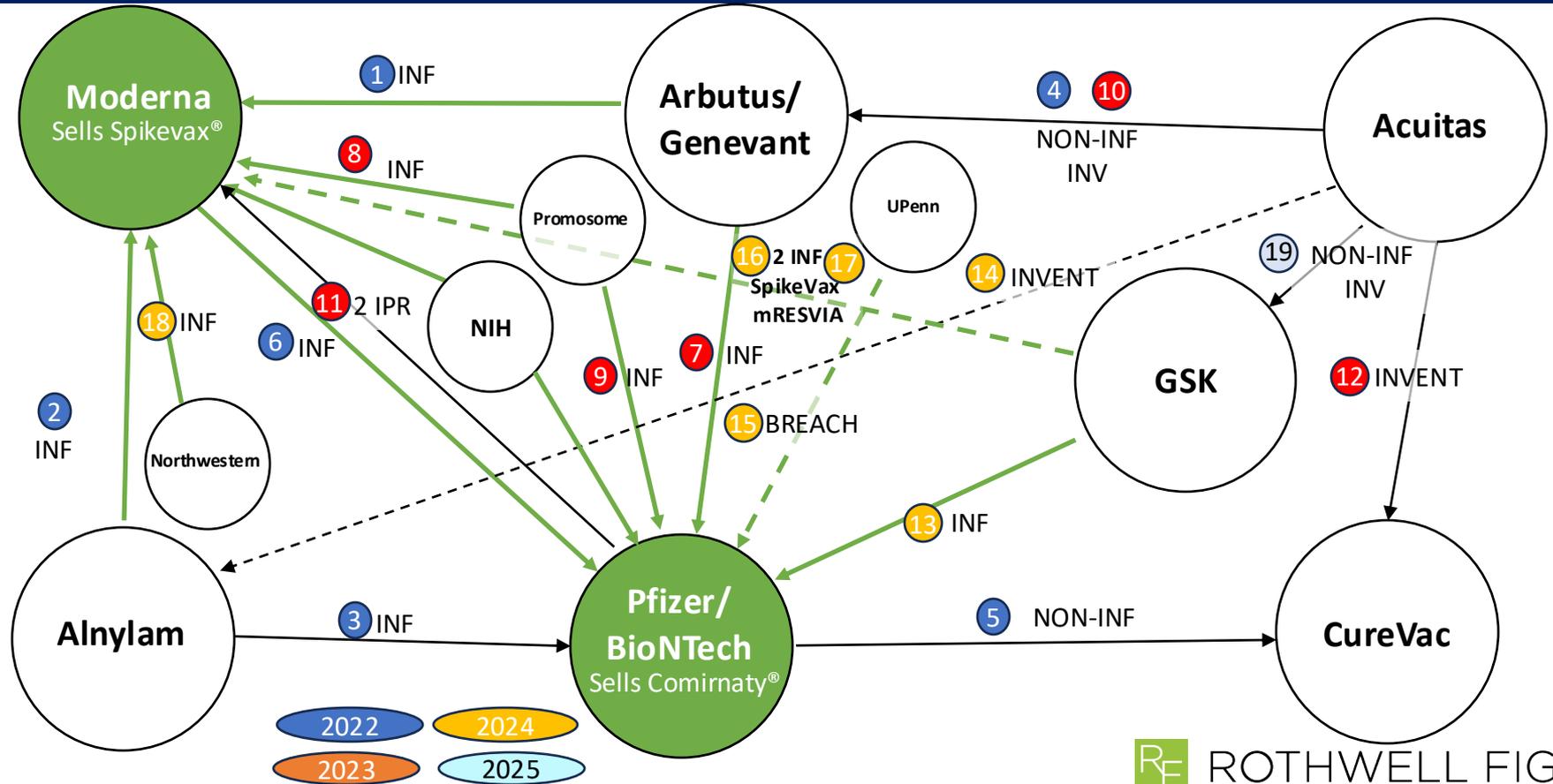
Comirnaty[®] = ~\$36.7 billion

https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/performance/

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 (December 2023)
Aug 2022	Moderna	BioNTech + Pfizer	Infringement	Düsseldorf Regional Court, Germany	Infringement found (March 2025)
Aug 2022	Moderna	BioNTech + Pfizer	Infringement	UK	1 patent infringed and 1 invalid (July 2024)
Aug 2022	Moderna	BioNTech + Pfizer	Infringement	Netherlands	1 patent invalid (December 2023)
Sep 2022	BioNTech + Pfizer	CureVac	Non-infringement	England	CureVac patents invalid (October 2024)
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.

Anylam 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 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.

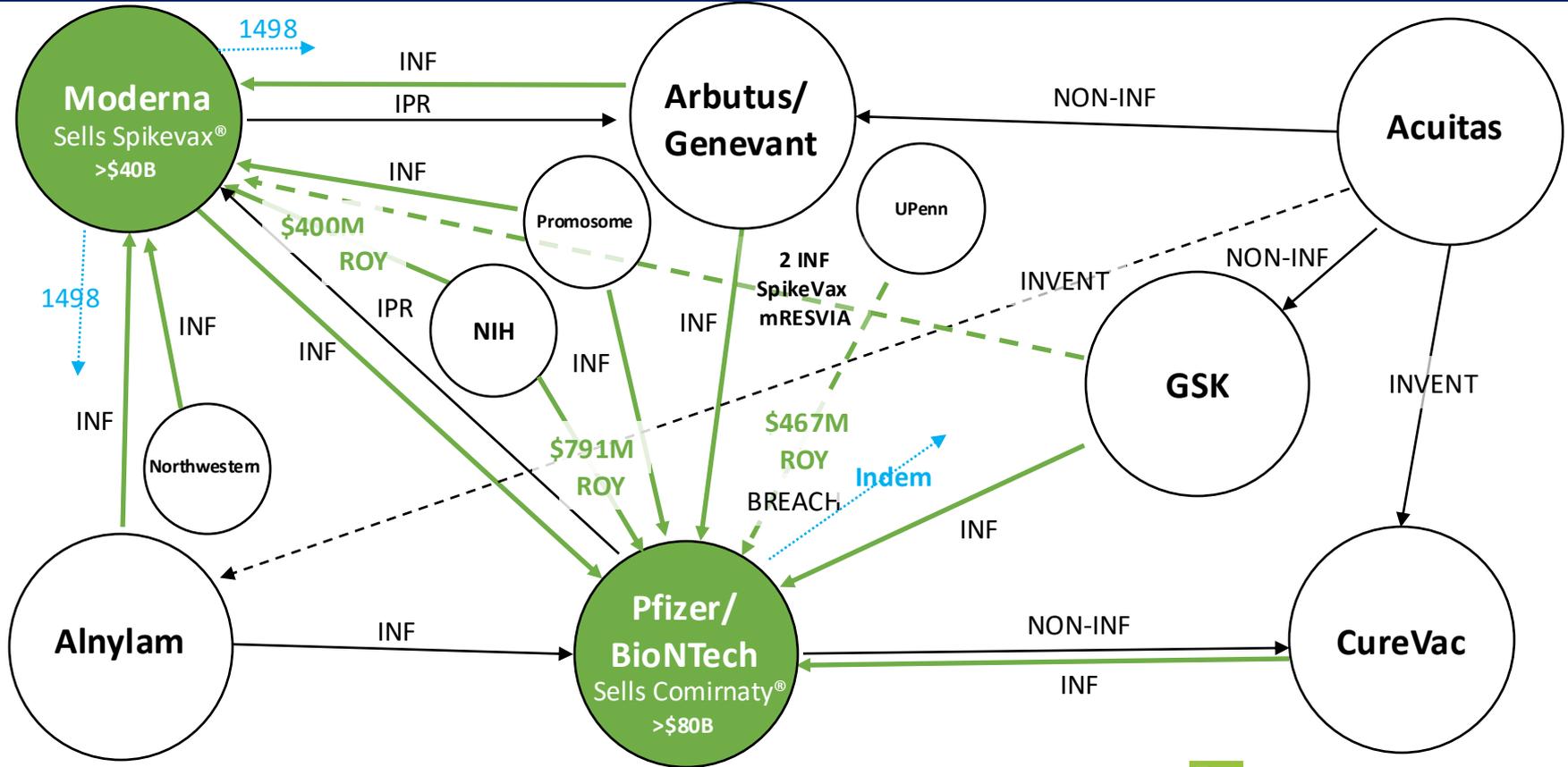
Moderna v. BioNTech + Pfizer

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



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

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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A copy of this presentation is
available upon request.



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