



MEDMARC[®]

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**mRNA and Lipid Nanoparticle
Competitive and Litigation Landscape**

Speaker:

Dan Shores

Rothwell Figg

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About the Speaker

- **Over 17 years biotech patent law experience**
 - Strategy, protection, high-stakes litigation, post-grant, deals, licensing, due diligence
- **Expertise in Lipid Nanoparticle (LNP) and mRNA IP space**
 - Leads LNP/RNA IP team
 - Navigates complex IP and litigation landscapes
 - Protects new innovations
 - Negotiates licensing and other deals



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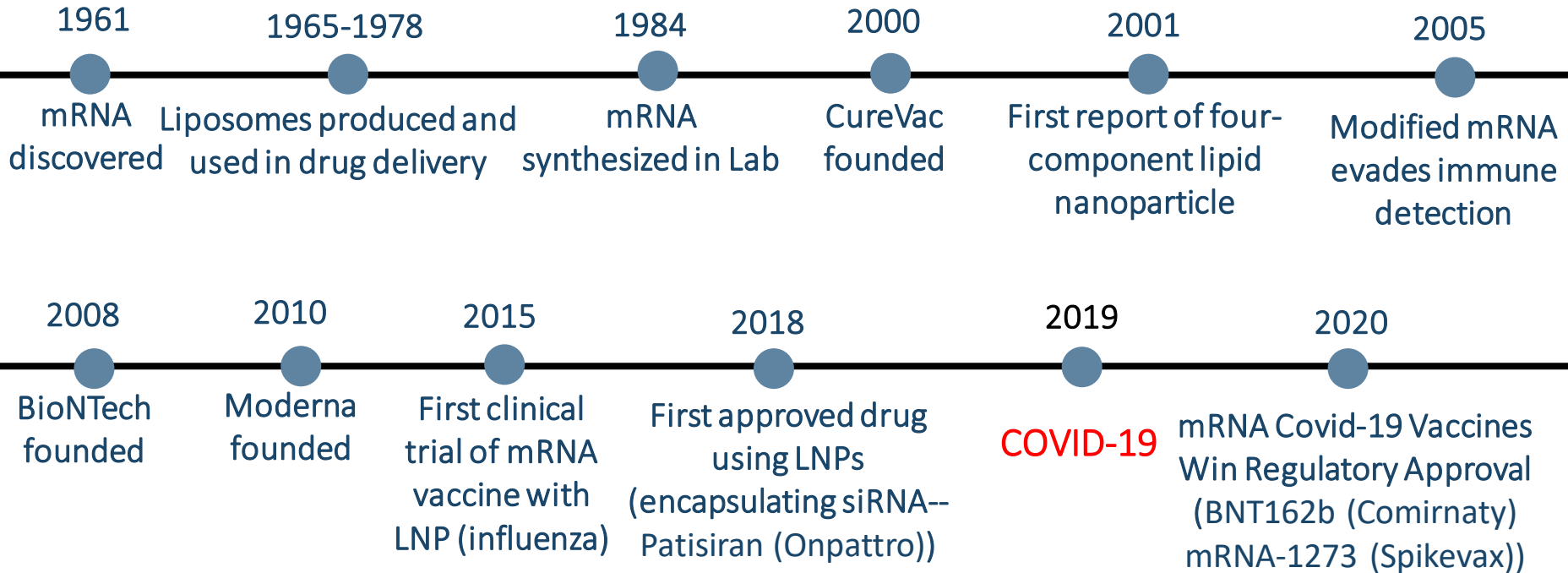
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mRNA-What a Story!



Primary Source: Dolgin, E., Nature, *The Tangled History of mRNA Vaccines*, Vol. 597 (Sep. 16, 2021)



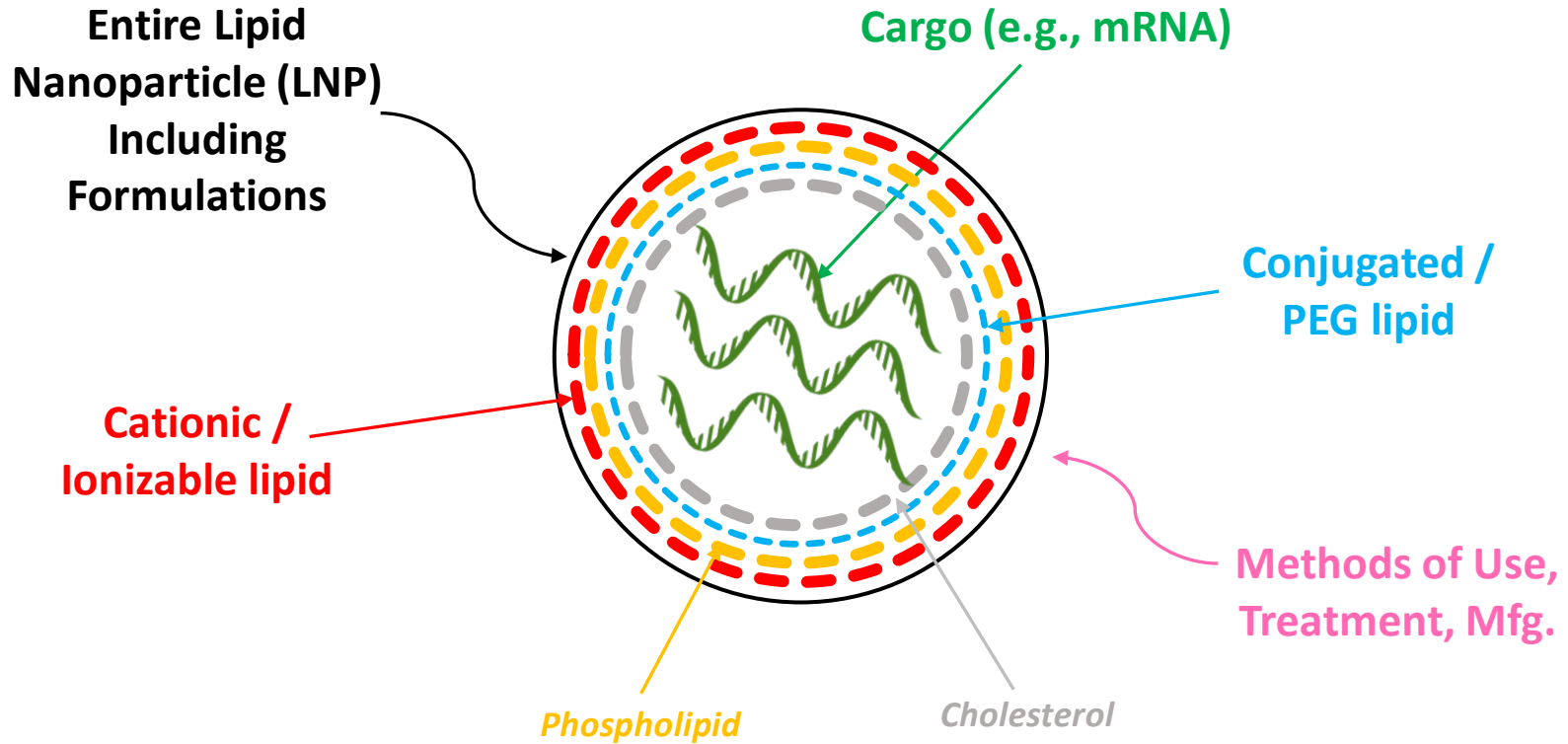
Exemplary Areas of Innovation & Patentable Subject Matter

RNA & Other Cargo	LNP/Other	Indication	Qualities	Administration
<ul style="list-style-type: none">• Modified• Si-RNA• Genome-editing• Circular• Self-amplifying• DNA• In-vivo CAR-T• Combination• Others	<ul style="list-style-type: none">• Cationic lipid• Conjugated lipid• Phospholipid• Entire formulation• Others	<ul style="list-style-type: none">• COVID-19• Influenza• CMV• RSV• Melanoma• Solid tumors• Malaria• Shingles• Cystic fibrosis• Herpes• Others	<ul style="list-style-type: none">• Reduced toxicity• Reduced off-target expression• Endosomal escape• Potency• Half-life• LNP stabilization• Transfection efficiency• Biodistribution• Cellular targeting• Others	<ul style="list-style-type: none">• Intravenous• Intramuscular• Subcutaneous• Intradermal• Intranodal• Intratumoral• Intraperitoneal• Inhalation• Intrathecal• Intravitreal• Oral• Ocular• Others



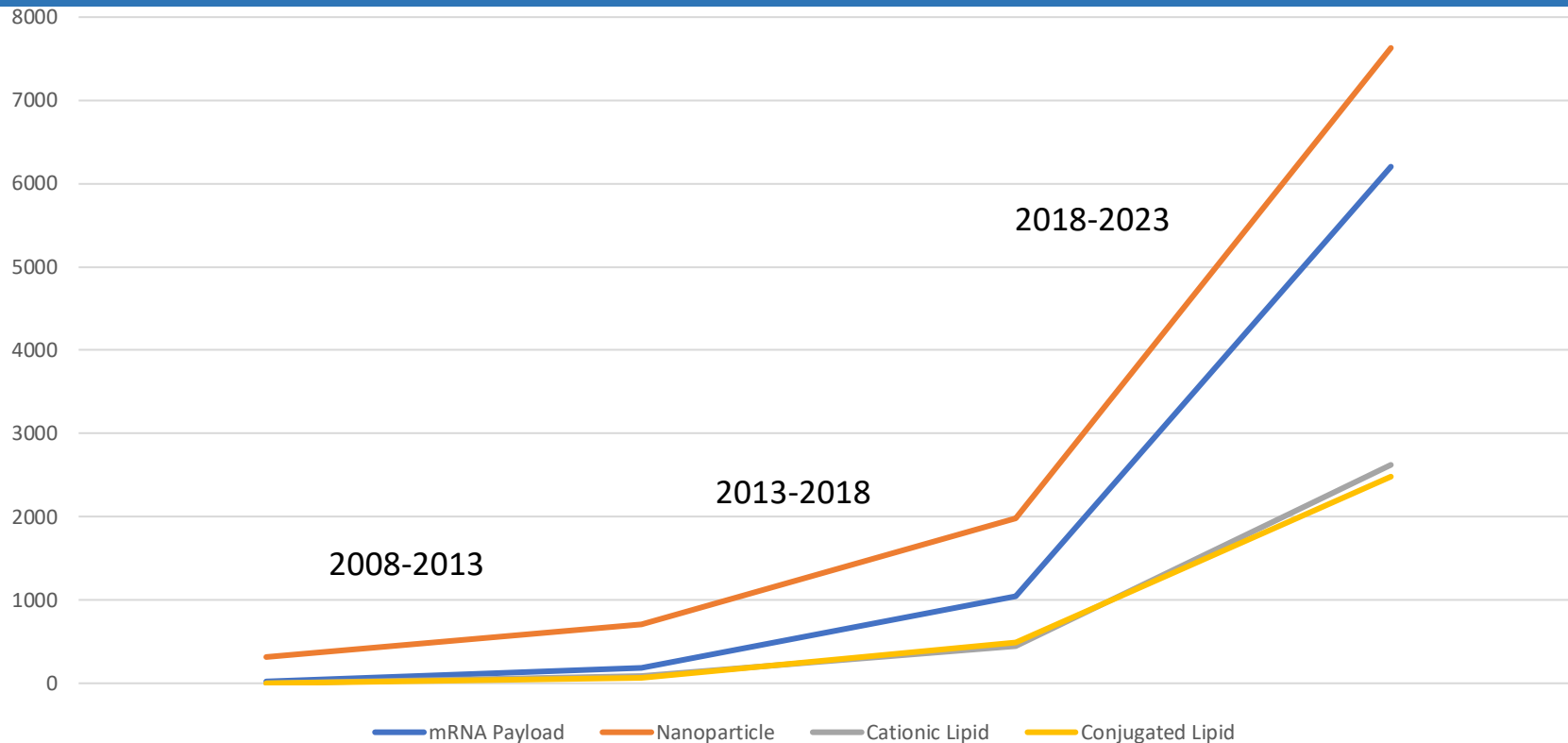


Exemplary Areas of Patentability-LNP





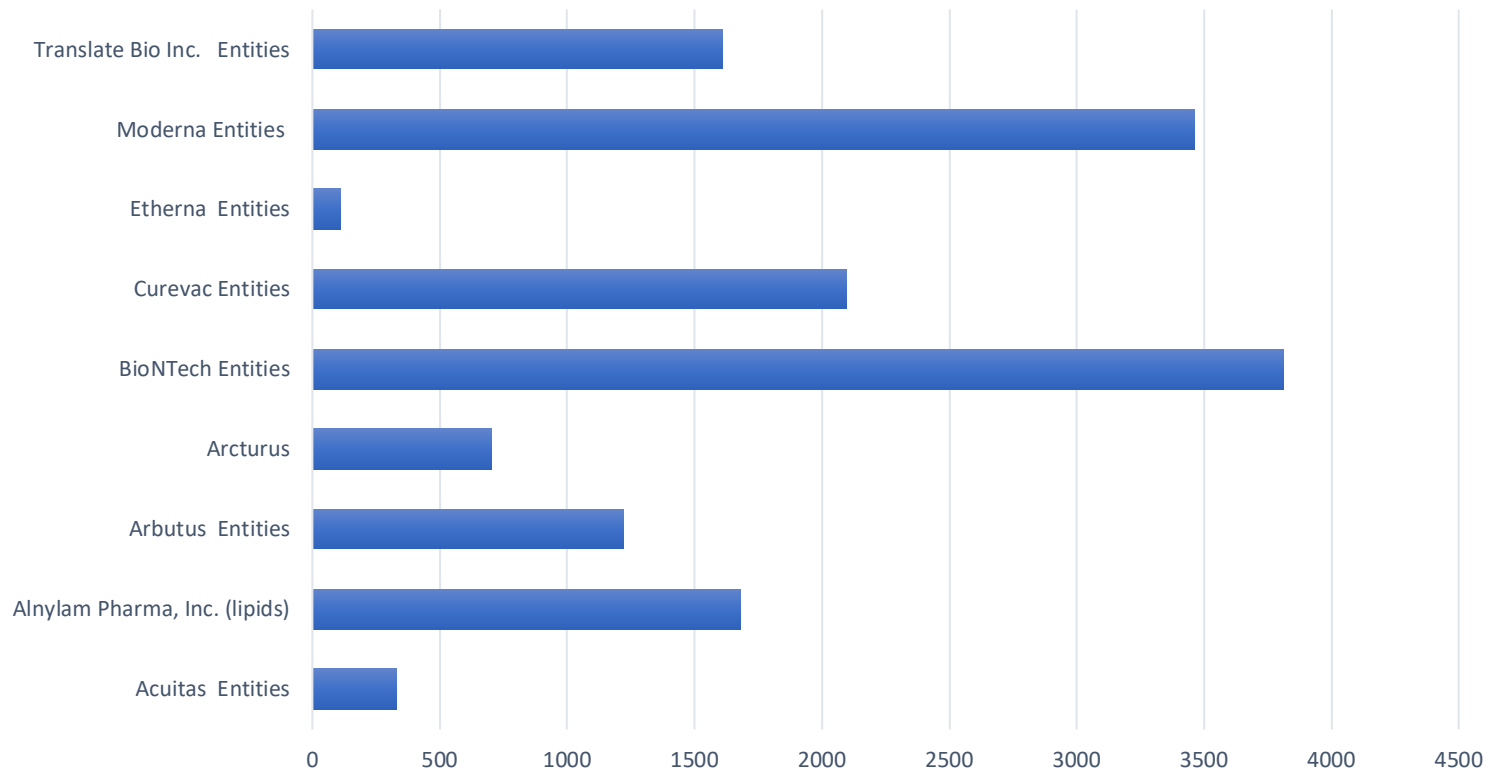
Patent Filing Trends



Source: PatSnap (derived from keyword searches in patent databases for worldwide patent filings).



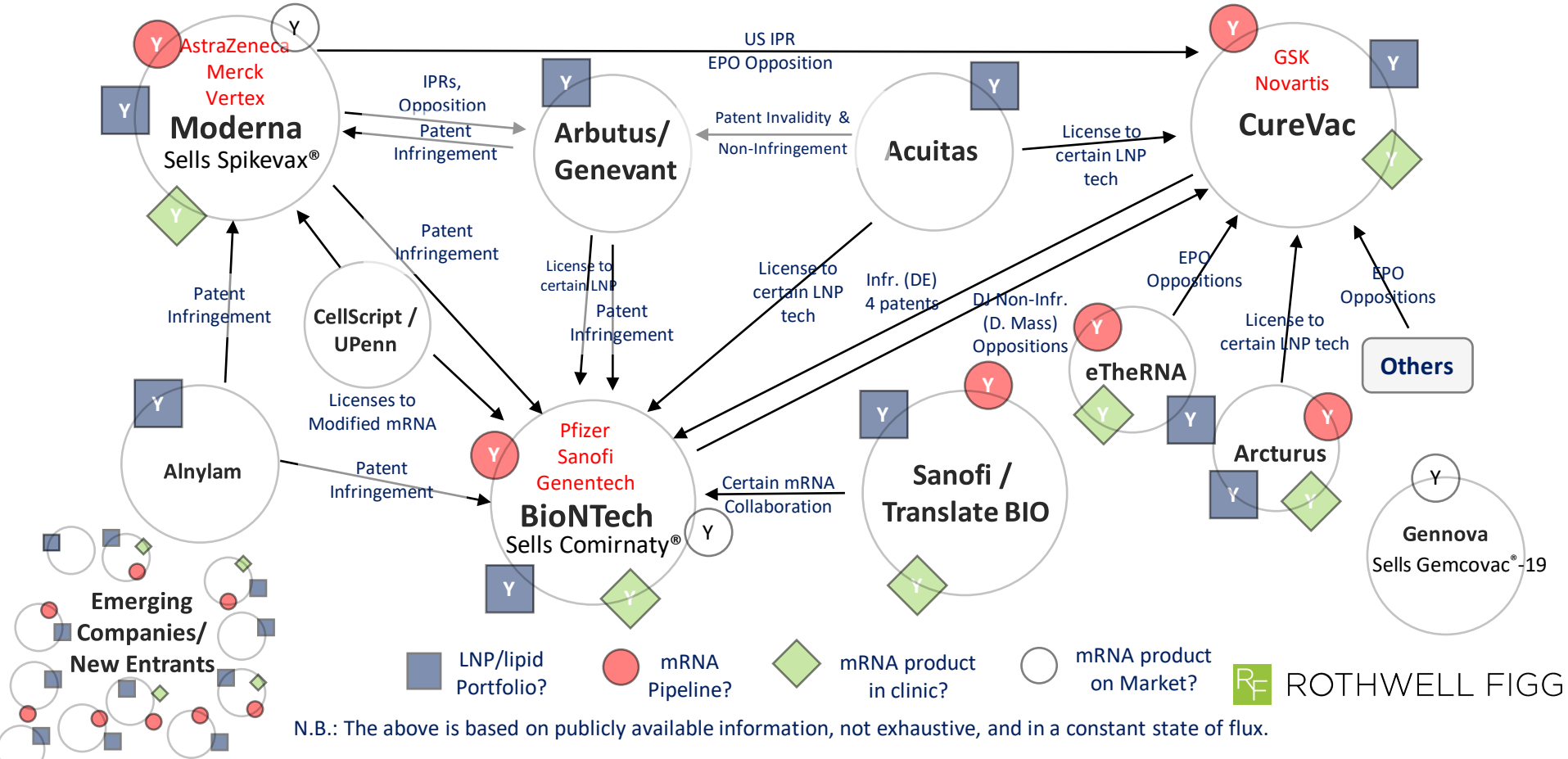
Patent Filings By Assignee



Source: PatSnap (derived from keyword searches in patent databases for worldwide patent filings).

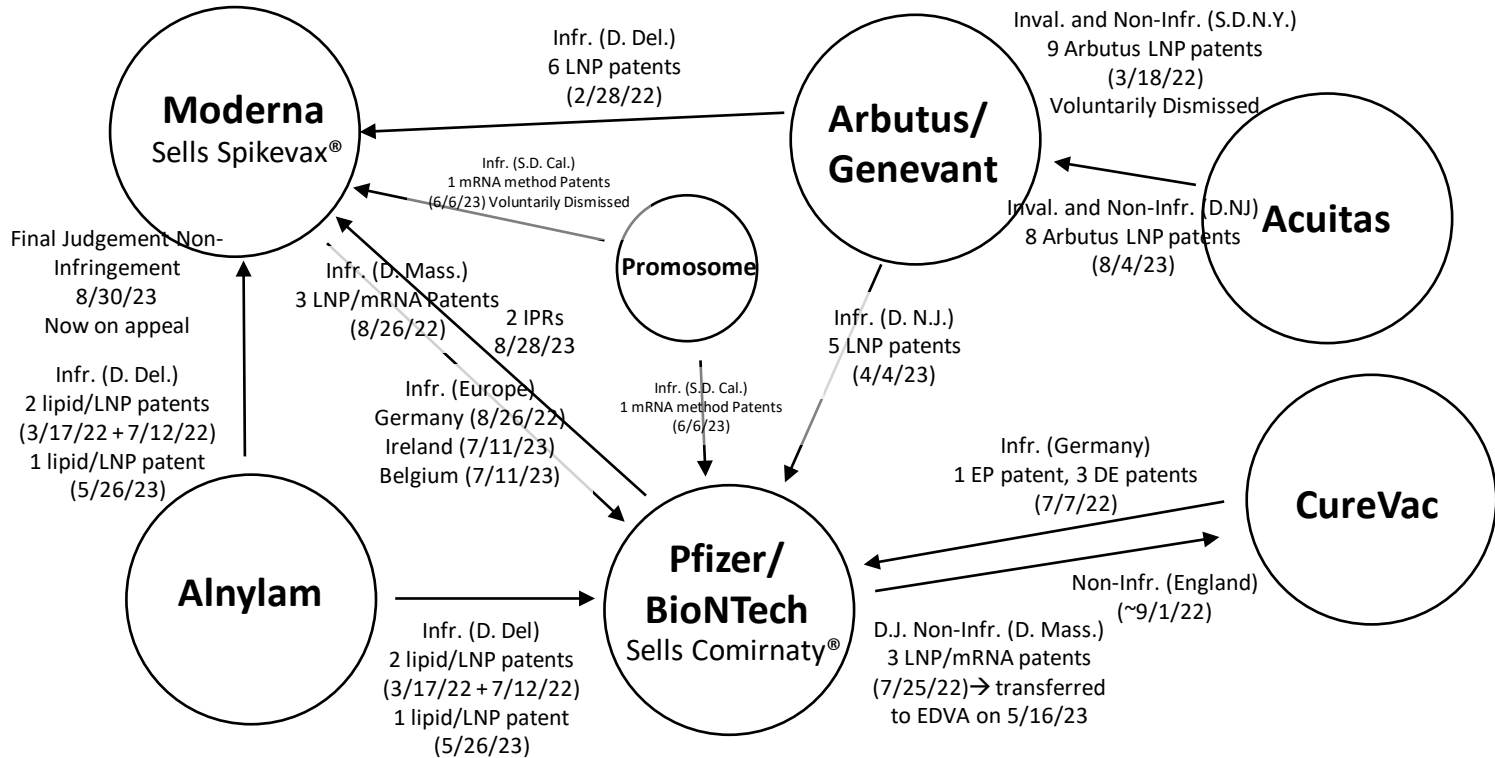


IP & Competitive Landscape





Patent Litigation Landscape



N.B.: The above is based on publicly available information, not exhaustive, and in a constant state of flux.

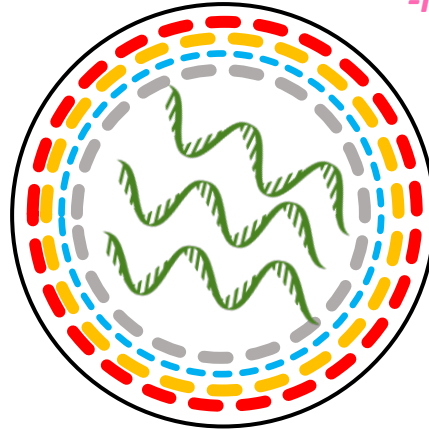


Technology At Issue

**Arbutus/Genevant
v. Moderna
v. Pfizer/BioNTech**
-LNP Formulations

**Promosome
v. Moderna
v. Pfizer/BioNTech**
-Methods

**Moderna
v. Pfizer/BioNTech**
-LNPs
-Methods
-mRNA Cargo



**Alnyam
v. Moderna
v. Pfizer/BioNTech**
-LNPs
-Cationic Lipids

**Acuitas
v. Arbutus/Genevant**
-LNPs

**Pfizer/BioNTech
v. CureVac**
-mRNA Cargo

**CureVac
v. Pfizer/BioNTech**
-mRNA Cargo



Strategy: Freedom to Operate

- **Commercial Product(s)**
 - Confirm desired formulation early
 - Apply to patent landscape
- **Patent landscape**
 - Search and analyze patents and apps
 - Manage scope (geography, timing, assignees, etc.)
 - Identify blocking patents and white space
 - Assess GTM timelines, expiration dates, safe harbor
 - Monitor apps (ref: 18-month “black box”)
 - **What you do up front matters most!**



Strategy: Innovation and Protection

- **Innovation**

- Fully understand the cutting edge (literature and patents)
- Build in white space and areas of growth
- Examples: payload-engineering, potency/cellular uptake/endosomal escape, biodistribution, cell/organ-specific targeting, stability/storage, administration routes, etc.

- **Protection**

- Build around commercial differentiators
- Move fast with provisional (first to file, publications)
- Build IP assets





Strategy: Licensing

- **Partners**
 - Choose wisely, long term relationship
- **Licenses**
 - Patents, know-how, exclusivity, territories, field
 - Licensing fees, royalties, milestone
- **IP and Regulatory**
 - Background IP, New IP, new filings
 - Regulatory: who funds, who owns, diligence
- **Parallel Strategies**
 - Product-by-product, short and long term





Strategy: IPR/PGR/Litigation

- **PGR/IPR/Opposition**
 - Identify blocking patents
 - Collect prior art (invalidity case), recruit experts
 - Assess merits and cost, worth it?
- **U.S. District Court**
 - Identify infringing products
 - Evaluate market and launch
 - Consider licensing strategies, remedies



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Thank you!

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A copy of this presentation is
available upon request.



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