

BC & Ropes & Gray International IP Summit

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Drug Development Timeline



De novo Drug Discovery and Development

- Low Success Rate
- Huge Cost and Time-consuming Development

Drug Repurposing

- Known Drug Safety
- Reduced Pharmacokinetic Uncertainty



Road to mRNA Vaccines

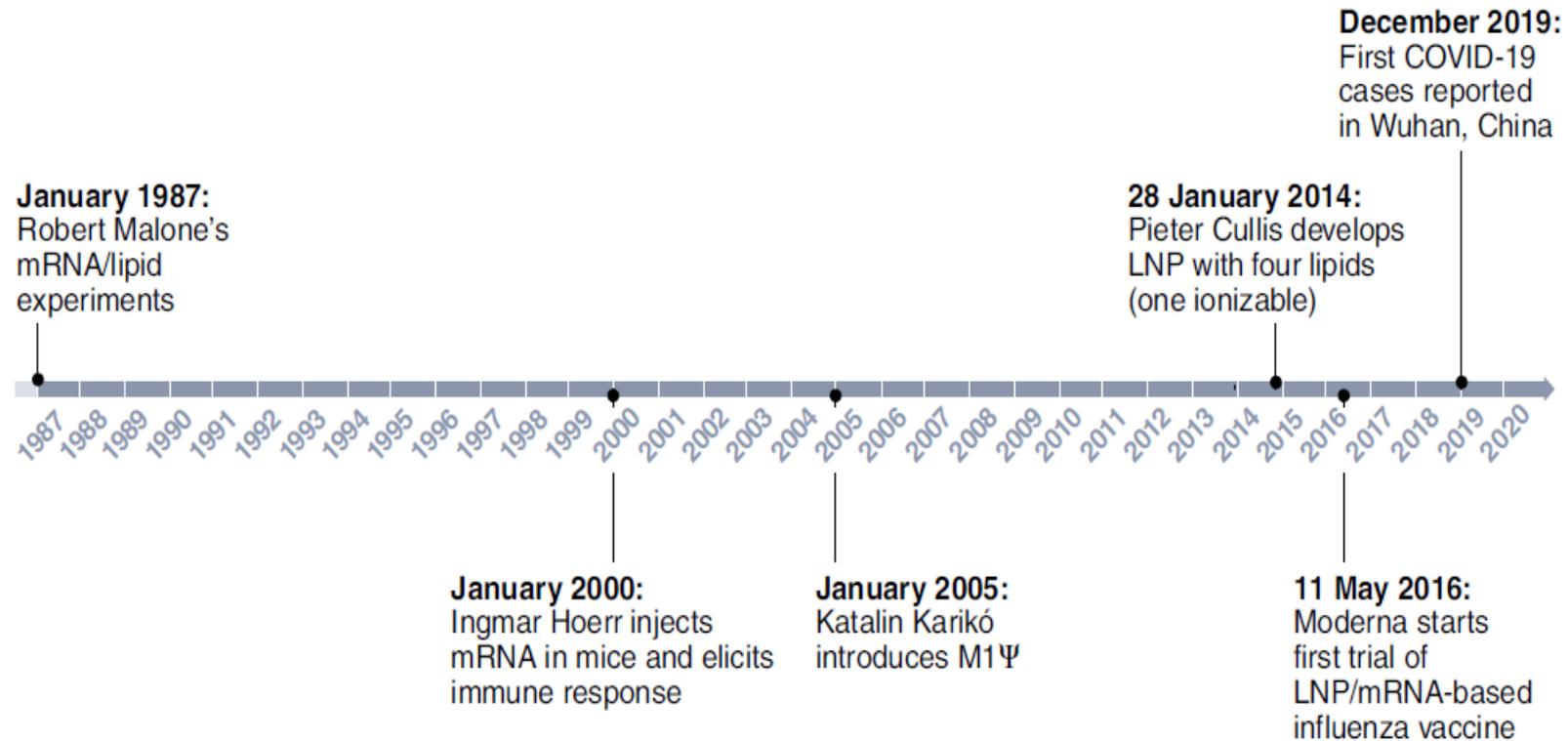


Fig. 1 | The long road to mRNA vaccines. As early as 1987, experiments using liposome-mediated mRNA transfection suggested that mRNA could be used as a drug.



Cost for Drug Development

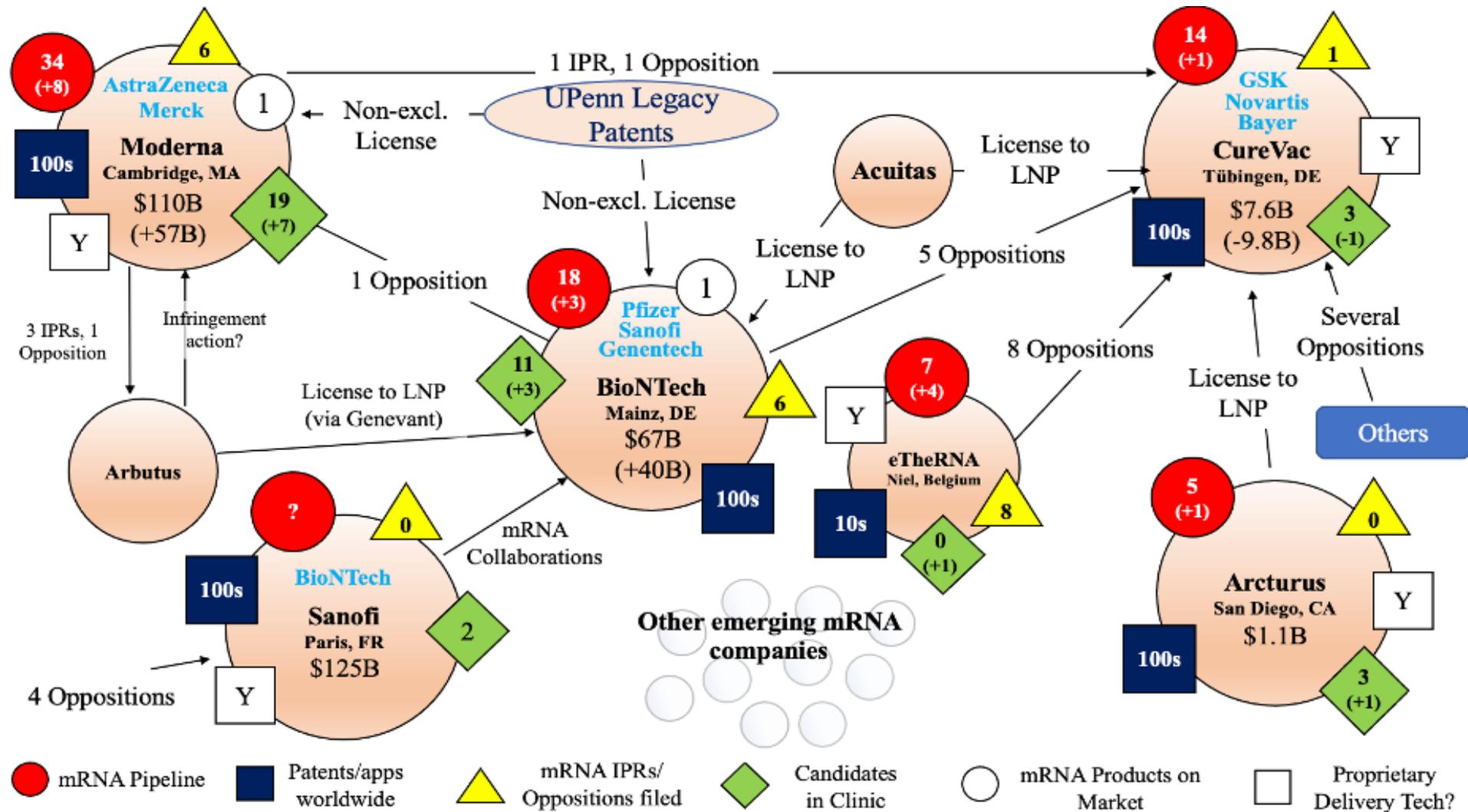
Developing a new prescription medicine that gains marketing approval is estimated to cost drugmakers **\$2.6 billion** according to a recent study by Tufts Center for the Study of Drug Development and published in the Journal of Health Economics.

Vaccine Development is challenging

Bob Langer's view:

“Every biotech startup still confronts a laundry list of obstacles. Those obstacles can be scientific criticism, difficulty getting grants, manufacturing hurdles, regulatory hurdles -- meaning the FDA -- clinical trials not necessarily going well, having difficulty raising money,” Langer says. “On and on. It doesn't stop.”

Incentivizing Collaboration?



mRNA Patent and Competitive Landscape: 2021 Year in Review and 2022 Outlook (Jan. 3, 2022), JD Supra, available at

<https://www.jdsupra.com/legalnews/mrna-patent-and-competitive-landscape-8092666/>

28 U.S.C. § 1498(a)

- “Eminent domain” provision for patents: “Whenever an invention described in and covered by a patent of the United States is **used or manufactured by or for the United States without license** of the owner thereof or lawful right to use or manufacture the same, 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.” 28 U.S.C. § 1498(a).
- Used by government during pandemic
 - Contained government authorization to use patented inventions without the permission of patent holders
 - Moderna dispute with Arbutus Biopharma Corp./Genevant Sciences
 - Filed partial motion to dismiss re: sales to U.S. government, arguing that only remedy was action against the U.S. government in the Court of Federal Claims