UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC. *Petitioner* v. MODERNA TX, INC. *Patent Owner*	IPR2023-01358 U.S. Patent No. 10,702,600 IPR2023-01359 U.S. Patent No. 10,933,127

DECLARATION
REGARDING COMMERCIAL SUCCESS

August 30, 2024

Respectfully Submitted,

W. Christopher Bakewell

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1 INTRODUCTION

1.1 Qualifications and Experience

1. I am a Vice President and officer of Charles River Associates ("CRA"), a consulting firm that provides economic, financial, and strategic expertise to clients around the world.[1] My primary responsibility at CRA is to provide consulting services involving valuation and related issues in connection with technology-rich businesses and intellectual property. I have other leadership responsibilities as well.

2. Over the course of my career, I have performed valuations of businesses and intangible assets, provided management consulting services related to the commercialization of intellectual property, as well as quantified damages and assessed the commercial success of inventions in a variety of intellectual property-related disputes; these areas comprise the focus of my professional practice.

3. I am often invited to speak on subject matters involving intangible asset valuation, intellectual property strategy, and international trade. I have authored numerous peer-reviewed articles, as well as textbook

[1] CRA's compensation is not contingent upon the outcome of this litigation. CRA bills at hourly rates for the time incurred by its professional staff on this engagement. My hourly billing rate is $950.

chapters. I have guest lectured at several universities and I have been interviewed by the media, including the *Wall Street Journal.* I have received numerous recognitions, including being recognized in the top tier of economic expert witnesses in each edition of the *IAM Patent 1000 The World's Leading Patent Practitioners*.

4. I earned a B.S. degree *magna cum laude* from Bradley University in Peoria, Illinois. I also earned an MBA degree from the University of Maryland at College Park, where I was a Graduate Fellow. I am an Accredited Senior Appraiser in Business Valuation, a professional designation of the American Society of Appraisers ("ASA"). Among other things, this designation requires 10,000 hours of documented experience in valuing assets and businesses; I acquired most of this experience through the valuation of intellectual property rights and technology-rich business enterprises. I served on the Board of Directors of the Houston Chapter of the ASA.

5. I am a Certified Licensing Professional, a professional designation of the Licensing Executives Society intended to distinguish those who have demonstrated experience, proficiency, knowledge, and exposure to licensing and commercialization of intellectual property. I earned this designation based upon my experience both as a management consultant, and as a real-world manager.

6. Prior to graduate school, I programmed computer systems involving early-stage cellular technology. During graduate school, I interned at the U.S. Securities and Exchange Commission. After graduate school, I held senior roles in corporate finance and business development, where my responsibilities included contract and license negotiation, financial reporting, financial analysis, market analysis, and strategic planning. For the last two decades, I have provided management consulting and financial advisory services to a wide range of leading firms, start-ups, investors and inventors. Through these experiences, I gained substantial real-world experience in commercial issues involving technology-rich businesses, licensing and contract negotiation, as well as financial reporting and corporate finance.

7. An updated copy of my curriculum vitae, including my current and past employment and professional affiliations, is included as **Attachment A**. Described therein are my publications, which include chapters covering the cost of capital in intellectual property damages, as well as articles published in professional journals. I have been an invited speaker on topics involving intellectual property valuation and damages quantification. An updated list of my trial and deposition testimony is included as **Attachment B**.

1.2 Overview of Assignment

8. I am retained as an expert on technology commercialization, damages, intellectual property valuation, and licensing-related issues by the law firms Paul Hastings LLP and Williams & Connolly LLP on behalf of their clients, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. (collectively, "BioNTech"), and Pfizer Inc. ("Pfizer"). The purpose of this declaration is to respond to a May 29, 2024 declaration submitted by Mr. James Malackowski (the "Malackowski Declaration") and to address opinions he has offered asserting commercial success as a secondary consideration of non-obviousness.

9. I understand that the present *Inter Partes Reviews* relate to two patents owned by ModernaTX, Inc. and Moderna US, Inc. (collectively, "Moderna"): U.S. Patent Nos. 10,702,600 ("the '600 patent") and 10,933,127 ("the '127 patent").[2] In a pending district-court proceeding, Moderna accused Pfizer and BioNTech of infringing these two patents, as well as a third patent not at issue in this proceeding.[3]

[2] IPR2023-01358 regarding U.S. Patent No. 10,702,600 and IPR2023-01359 regarding U.S. Patent No. 10,933,127.
[3] *See* Exhibit 2012 (Complaint for Patent Infringement, *ModernaTX, Inc. et al v. Pfizer Inc. et al*, Case No. 1:22-cv-11378, August 26, 2022).

10. Moderna claims that its COVID-19 vaccine, marketed under the brand name Spikevax®, practices certain claims of the '600 patent and the '127 patent.[4] Moderna also alleges that the Pfizer and BioNTech COVID-19 vaccine, Comirnaty®, infringes claims of the '600 patent and the '127 patent.[5]

11. Pfizer and BioNTech contest that Comirnaty® infringes the '600 patent and the '127 patent. For purposes of my declaration, however, I will assume that both Comirnaty® and Spikevax® incorporate claims of the '600 patent and the '127 patent. That said, I am informed that there are many significant technologies and features of Comirnaty® and Spikevax® that are not claimed in the '600 patent and the '127 patent.[6]

12. I am specifically requested to evaluate the economic nexus between the '600 patent and the '127 patent and the commercial success of Comirnaty® and Spikevax®.[7] My expert opinions, as well as the bases for

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[4] Exhibit 2197 (Malackowski Declaration), ¶ 9.
[5] Exhibit 2197 (Malackowski Declaration), ¶ 9.
[6] Interview of Dr. Griffin.
[7] I understand that in establishing the commercial success of an alleged patented product as evidence that weighs against a finding of obviousness, the patentee must establish a "causal nexus" between a product in the marketplace and the claimed invention. *See Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *WesternGeco LLC v. ION Geophysical Corporation*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018); *Tokai Corp. v. Easton Enterprises, Inc.,* 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011). I also understand that "causal nexus" means that the commercial success must be a direct result of the claimed invention. *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *WesternGeco LLC v. ION Geophysical Corporation*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018); *Tokai Corp. v. Easton Enterprises, Inc.,* 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011). I understand that obviousness of an invention is established "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date

these opinions, are explained throughout this declaration. A list of materials cited is included as **Attachment C**.

1.3 Summary of Opinions

13. According to Mr. Malackowski, "the tremendous market success of Spikevax® and Comirnaty® is a direct result of the inventions claimed in the '600 and '127 patents."[8] This, Mr. Malackowski said, was based upon his understanding from Moderna's technical expert, Dr. Krause, that there is a nexus between sales of Spikevax® and Comirnaty® and Moderna's patents.[9]

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of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." *See* 35 U.S.C. § 103. I also understand that an analysis of obviousness must include the evaluation of secondary considerations such as the commercial success of the invention (*KSR Intern. Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1734 (2007)), and that evidence of commercial success is only significant if a nexus is demonstrated between the claimed invention and the alleged commercial success. My opinions are economic and commercial in nature and do not depend on whether or not there is a presumption of nexus in this matter.

[8] Exhibit 2197 (Malackowski Declaration), ¶ 10.

[9] Exhibit 2197 (Malackowski Declaration), ¶ 23 ("I rely on the opinions of Dr. Krause concerning the nexus between the challenged claims of the '600 and '127 patents and the market success of Spikevax® and Comirnaty®. According to Dr. Krause, Comirnaty® and Spikevax® embody the challenged claims of the '600 and '127 patents. I further understand that Dr. Krause's opinion is that the betacoronavirus mRNA-LNP vaccine platform claimed by the '600 and '127 patents is critical to the clinical success of Spikevax® and Comirnaty® and that the patented features are responsible for driving safety and efficacy of Spikevax® and Comirnaty®."). *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 32-33 ("Q. And you didn't do the analysis to determine whether there was nexus? A. I rely upon Dr. Krause, as described in my report. Q. So you don't have an opinion on whether or not there's nexus? A. I'm not offering that technical opinion as to whether or not there's nexus or a legal opinion. It is my understanding that there is based upon the work with Dr. Krause."). *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 32 (stating, "my understanding in the framework for my analysis was that it's binary, that there is there a nexus or there is not. There may be a nexus with more than just the technology. But as long as the technology is – meets the threshold, then it should be considered.").

14. Moderna claims priority dates in October 2015 for the ’600 patent and the ’127 patent.[10] This is approximately five years before Spikevax® and Comirnaty® were created and released in 2020. Mr. Malackowski did not sufficiently explain how he took this five-year period into account, if at all. There is no claim for commercial success before the release of Spikevax® or Comirnaty®.

15. Starting in 2020, the evidence demonstrates that non-patented circumstances directly led to the commercial success of Spikevax® and Comirnaty®, such as the prevalence of the COVID-19 virus.[11] As I will discuss further in **Section 2.4**, the U.S. Federal government purchased excess COVID-19 vaccine supply in 2020, well before Spikevax® or Comirnaty® were manufactured and well before either vaccine received authorization by the U.S. Food and Drug Administration (“FDA”).[12] Mr. Malackowski did not consider this, either.

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[10] Exhibit 1001 (’600 patent proceeding); Exhibit 1001 (’127 patent proceeding); Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01358, p. 3; Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01359, p. 4; Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 2; Exhibit 2200 (Krause Declaration, ¶ 26).

[11] Exhibit 1166 (“COVID-19 Timeline,” CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).

[12] Exhibit 1167 (“After nearly $1B in research funding, Moderna takes $1.5B coronavirus vaccine order from U.S.” Fierce Pharma, August 12, 2020 (accessed: https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s)).

16. Mr. Malackowski testified that he did not consider other contributors to the demand for Spikevax® or Comirnaty®, and that other factors are "not required" for his analysis of commercial success.[13] In setting aside anything but the '600 patent and the '127 patent, Mr. Malackowski's analysis means little, if anything, from an economic perspective. And as a result of this narrow view, Mr. Malackowski disregarded a variety of considerations—including various patented and other technologies, intangible assets such as know-how and assembled workforce, and broader economic circumstances—that resulted in the commercial success of Spikevax® and Comirnaty®. It is commercially unreasonable for Mr. Malackowski to claim that only the '600 and '127 patents drove the commercial success of Spikevax® or Comirnaty®.

17. According to Mr. Malackowski, despite "extensive efforts to develop COVID-19 vaccines using other technologies, the vaccines that have achieved the greatest market success are the two that utilize the '600 and '127 patents."[14] Mr. Malackowski disregarded that Spikevax® and Comirnaty® each incorporate many components, technologies, and intangibles that

[13] Exhibit 2197 (Malackowski Declaration), ¶ 11; Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 46-50. *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 21-30 (testifying that he did not measure, for example: the impact of government investment, government contracts, purchasing excess demand, vaccine mandates, the availability of vaccines free of charge for consumers, branded and unbranded vaccine marketing).
[14] Exhibit 2197 (Malackowski Declaration), ¶ 9.

contribute to the commercial viability of the products.[15] Moderna, BioNTech, and many others were working on and contributing towards the ultimate success of mRNA technologies and therapeutics for decades.[16] Decades of research have resulted in several significant technological breakthroughs,[17] as evidenced by the fact that Moderna and BioNTech/Pfizer each have in-house technological platforms for mRNA and also in-licensed some of the same important technologies. This includes patents based upon mRNA technology research by Dr. Katalin Karikó and Dr. Drew Weissman at the University of Pennsylvania and spike stabilization technology owned by the National Institutes of Health ("NIH").[18]

18. Mr. Malackowski also took the unreasonable position that Spikevax® and Comirnaty® are not complex multicomponent vaccines.[19] I understand that the '600 patent and the '127 patent are asserted to generally claim certain aspects of the overall Spikevax® and Comirnaty®.[20]

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[15] Interview of Dr. Griffin.
[16] Interview of Dr. Griffin; Interview of Dr. Moon. *See, e.g.*, Exhibit 1168 ("The biotech targeting personalized medicine, CNBC, May 13, 2015 (accessed: https://www.cnbc.com/2015/05/12/moderna-therapeutics-is-trying-to-cure-disease-with-mrna-drugs.html)); Exhibit 1169 ("Our History," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/history.html)); Exhibit 1170 ("Collaboration to Develop mRNA Vaccines Expands," CureVac press release, August 4, 2015 (accessed: https://www.curevac.com/en/collaboration-to-develop-mrna-vaccines-expands/)).
[17] Interview of Dr. Griffin.
[18] Interview of Dr. Griffin.
[19] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 73-75.
[20] Interview of Dr. Griffin.

19. Mr. Malackowski even disregarded other Moderna patents. In the stayed lawsuit, Moderna claimed that U.S. Patent No. 10,898,574 ("the '574 patent") was practiced by Spikevax® and Comirnaty®.[21] Mr. Malackowski, who was Moderna's damages expert in that case, testified here that he has not considered the relative impact of the '574 patent when compared to the '600 patent and the '127 patent.[22] Moderna also identified an additional nine patents that it claims relate to Spikevax® (other than the '574 patent and the '600 patent).[23] Mr. Malackowski did not acknowledge these other patents or consider whether they contribute to the commercial success of Spikevax®.[24]

20. The existence of other Moderna patents illustrates the lack of economic analysis by Mr. Malackowski in this case. Instead of investigating

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[21] Exhibit 2012 (Complaint for Patent Infringement, *ModernaTX, Inc. et al v. Pfizer Inc. et al*, Case No. 1:22-cv-11378, August 26, 2022). Moderna claims a priority date of March 2011 for the '574 patent, which is also years before Spikevax® and Comirnaty® were created.

[22] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 100-102 ("Q. You have an understanding that Moderna has claimed that U.S. patent number 10,898,574 is also practiced by Spikevax and Comirnaty, correct? A. I understand that from the district court litigation, yes. Q. Did you evaluate that technology and how it impacts demand and commercial success for your report in this case? A. Not as identified here in this case. In this case stands alone based upon the two patents that are asserted. Q. So does the '574 patent impact demand and therefore commercial success of Spikevax and Comirnaty? MS. CURTIS: Object to form. THE WITNESS: That is outside the scope of what I have done here. I'm not presenting a conclusion on the commercial success for purposes of nonobviousness as it relates to that patent. And I haven't prepared such analysis. Q. So you haven't considered it one way or the other? MS. CURTIS: Object to form. THE WITNESS: I understand that it's within the products -- it's asserted to be within the products that are at issue here. I don't dispute that it has contribution to nexus and commercial success. But as I understand the legal test for what's at issue in this case, the fact that there may be a third Moderna patent that is also responsible for success does not diminish the conclusions that I've reached.")

[23] Exhibit 2034 ("Patents," Moderna website (accessed: https://www.modernatx.com/en-US/patents)).

[24] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 76-80.

the financial and economic issues, Mr. Malackowski unreasonably set aside other technologies and opined that the "direct" cause of the commercial success of Spikevax® and Comirnaty® is entirely based on the '600 patent and the '127 patent.[25]

21. Even if Mr. Malackowski had shown that the '600 patent and the '127 patent have some meaningful economic nexus to the commercial success of Spikevax® and Comirnaty®, Mr. Malackowski did not account for the impact of other technologies, patents and economic considerations. As Moderna itself has stated, as a company, it "combines mRNA engineering, delivery system discovery, and clinical manufacturing platforms within a single, fully-integrated organization."[26]

22. As I will explain in greater detail below, in addition to the technologies and components of Spikevax® and Comirnaty®, there are other commercial and COVID-19 marketplace considerations (*i.e.,* intangibles) that directly contributed to the success of Spikevax® and Comirnaty®. Advances were made in manufacturing and distribution infrastructure and expertise, for example. There were also broader economic and regulatory considerations

[25] Exhibit 2197 (Malackowski Declaration), ¶ 10.
[26] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf)), slide 16.

that helped create a marketplace for COVID-19 vaccines. For example, government purchasing programs played a significant role in guaranteeing demand for both Spikevax® and Comirnaty®.[27] The U.S. Federal government, other governmental agencies, and the private sector also undertook significant efforts to encourage the public to get vaccinated, using vaccine subsidies and marketing to assure the public of the safety, importance, and efficacy of COVID-19 vaccines.[28]

23. As I explain in this report, these technical, commercial, and other marketplace considerations led directly to the commercial success of Spikevax® and Comirnaty®. It is not reasonable for Mr. Malackowski to claim that the '600 and '127 patents drove the success of Spikevax® and Comirnaty®; when the broader landscape is considered, the '600 and '127 patents are at best one of many considerations that related to the success of Spikevax® and Comirnaty®.

24. My opinions are based upon my analysis of the information available to date. I may review and consider additional information that may

[27] Prior to September 2023, 100% of U.S. revenues and doses sold for both Spikevax® and Comirnaty® were to governmental agencies. According to the U.S. Department of Health and Human Services ("HHS"), vaccine ordering through U.S. Government processes began to phase out on August 3, 2023, "with a formal transition to the commercial market expected in mid-to-late September" of 2023. *See* Exhibit 1171 ("COVID-19 Commercialization," HHS website (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)).

[28] Exhibit 1172 ("Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)).

be produced by the parties to this dispute. I intend to supplement my opinions based upon that review, if it is appropriate to do so.

2 BACKGROUND

25. This report section includes background on the parties, Spikevax® and Comirnaty®, the ’600 and ’127 patents, and the competitive environment for COVID-19 vaccines.

2.1 Overview of Moderna and Spikevax®

26. Founded in 2010, Moderna is a biotechnology company focused on mRNA technology.[29] As of 2023, Spikevax® was Moderna’s first and only commercial product.[30]

27. Prior to the release of Spikevax® and the emergence of COVID-19, scientists from the NIH and Moderna began to collaborate on developing vaccines that used viral mRNA to treat emerging viruses such as the Middle East respiratory syndrome (“MERS”) coronavirus.[31] Although the ’600 patent and the ’127 patent discuss animal testing of a MERS vaccine with a wild-

[29] Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023, p. 7).
[30] Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023, p. 6). As of May 2024, Moderna received FDA approval for an began marketing a second product, a vaccine for RSV. *See* Exhibit 1304 (Moderna Form 10-Q for the quarterly period ended June 30, 3024, p. 13).
[31] Exhibit 1173 (Moderna Form 8-K, March 16, 2020, Exhibit 99.1).

type antigen target,[32] Moderna did not commercialize a MERS vaccine.[33] I understand that this is the only betacoronavirus vaccine reported to have been made and used in the '600 patent and the '127 patent.[34] Mr. Malackowski did not acknowledge a MERS vaccine as part of his assessment of commercial success.[35]

28. COVID-19 first emerged in December 2019.[36] In January 2020, the World Health Organization ("WHO") declared COVID-19 a Public Health Emergency of International Concern ("PHEIC").[37] In March 2020, the WHO declared COVID-19 a global pandemic.[38]

29. In early 2020, Moderna began developing Spikevax® with the NIH.[39] Spikevax® began clinical trials on March 16, 2020.[40] Operation Warp

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[32] Interview of Dr. Griffin.
[33] Spikevax® was Moderna's first and only commercial product as of 2023. *See* Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023, p. 6).
[34] Interview of Dr. Griffin.
[35] Mr. Malackowski also testified that he did not know whether the MERS vaccine practiced either the '600 patent or the '127 patent. *See* Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 116.
[36] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[37] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[38] Exhibit 1174 ("WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," WHO website, March 11, 2020 (accessed: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)).
[39] Exhibit 1175 ("Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study," Moderna website, February 24, 2020 (accessed: https://investors.modernatx.com/news/news-details/2020/Moderna-Ships-mRNA-Vaccine-Against-Novel-Coronavirus-mRNA-1273-for-Phase-1-Study/default.aspx)); Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[40] Exhibit 2126 ("Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus," Moderna website, March 16, 2020 (accessed: https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-First-Participant-Dosed-in-NIH-led-Phase-1-Study-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx)).

Speed, which provided $10 billion in funding, was an initiative launched under a partnership between multiple U.S. Federal government agencies in May 2020.[41] Moderna received $955 million from Operation Warp Speed to advance its clinical trials.[42]

30. Moderna received an initial $483 million from the U.S. Department of Health and Human Services office, known as the Biomedical Advanced Research and Development Authority ("BARDA") in order to support "the scale up of mRNA-1273 and clinical development."[43] In July 2020, Moderna announced that it would be receiving an additional $472 million in support from BARDA.[44] This added funding was to support late-stage clinical development and Phase III studies for the mRNA vaccine

[41] Exhibit 1176 ("Operation Warp Speed Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges," GAO website, February 5, 2021 (accessed: https://www.gao.gov/assets/gao-21-319.pdf)).
[42] Exhibit 1177 ("Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," Moderna website, July 26, 2020 (accessed: https://web.archive.org/web/20200726212828/https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase/)).
[43] Exhibit 1177 ("Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," Moderna website, July 26, 2020 (accessed: https://web.archive.org/web/20200726212828/https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase/)).
[44] Exhibit 1177 ("Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," Moderna website, July 26, 2020 (accessed: https://web.archive.org/web/20200726212828/https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase/)).

candidates, which Moderna stated that it was "working closely with Operation Warp Speed and the NIH" to conduct.[45]

31. On December 18, 2020, the U.S. Food and Drug Administration ("FDA") granted an emergency use authorization of Spikevax® for people aged 18 and older.[46] On January 31, 2022, the FDA granted full approval of Spikevax®.[47]

2.2 Overview of BioNTech, Pfizer, and Comirnaty®

32. BioNTech is a biotechnology company founded in 2008 and focused on mRNA technology.[48] BioNTech stands for "Biopharmaceutical New Technologies."[49] Since BioNTech was co-founded by Chief Executive Officer, Dr. Uğur Şahin, the team at BioNTech have spent over two decades researching RNA and have "established different layers of mRNA vaccine

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[45] Exhibit 1177 ("Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," Moderna website, July 26, 2020 (accessed: https://web.archive.org/web/20200726212828/https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase/)).
[46] Exhibit 1178 ("FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine," FDA website, December 18, 2020 (accessed: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid)).
[47] Exhibit 1179 ("Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax," Moderna website, January 31, 2022 (accessed: https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx)).
[48] Exhibit 1169 ("Our History," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/history.html)).
[49] Exhibit 1180 ("Welcome to our investor page," BioNTech website (accessed: https://investors.biontech.de/)).

optimization."[50] BioNTech also worked on vaccines against cancer using mRNA.[51]

33. BioNTech began working on a COVID-19 vaccine in January 2020.[52] As BioNTech progressed in its development efforts, it partnered with other companies for clinical trials, manufacturing, and commercialization to aid in the development of this critical vaccine. In March 2020, BioNTech announced that it would work with Pfizer "regarding the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection."[53]

34. Pfizer is a U.S. biopharmaceutical company, founded in 1849 and incorporated in 1942.[54] Pfizer primarily focuses on products related to rare diseases, internal medicine, inflammation and immunology, vaccines, oncology, and anti-infectives.[55]

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[50] Exhibit 1181 ("Vision & Mission," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/vision-and-mission.html)).

[51] Exhibit 1181 ("Vision & Mission," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/vision-and-mission.html)).

[52] Exhibit 1182 ("The Husband-and-Wife Team Behind the Leading Vaccine to Solve Covid-19," The New York Times, November 10, 2020 (accessed: https://www.nytimes.com/2020/11/10/business/biontech-covid-vaccine.html)).

[53] Exhibit 1183 ("Pfizer and BioNTech to Co-develop Potential COVID-19 Vaccine," BioNTech press release, March 17, 2020 (accessed: https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-co-develop-potential-covid-19-vaccine)).

[54] Exhibit 1184 (Pfizer Form 10-K for the year ended December 31, 2023), p. 3; Exhibit 1185 ("About," Pfizer website (accessed: https://www.pfizer.com/about/history)).

[55] Exhibit 1186 ("Science," Pfizer website (accessed: https://www.pfizer.com/science)).

35. Prior to 2020, Pfizer had experience designing novel vaccines based on new delivery systems.[56] Pfizer has supplied vaccines to more than 165 countries and distributed more than one billion doses of vaccines with unprecedented reliability.[57] Pfizer vaccine Prevnar 13 was its bestselling product for years, and it was the bestselling vaccine in pharmaceutical history.[58]

36. Cooperation on the COVID-19 vaccine was not the first time that BioNTech and Pfizer had worked together. In the 2017-2018 timeframe, the companies collaborated on research into an mRNA-based influenza vaccine.[59]

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[56] Exhibit 1187 ("Ongoing Vaccine Research and Development at Pfizer," Pfizer website (accessed: https://www.pfizer.com/science/vaccines/research)).

[57] Exhibit 1188 ("How will Pfizer maintain vaccine integrity during distribution?" Pfizer website (accessed: https://www.pfizer.com/science/coronavirus/vaccine/manufacturing-and-distribution)); Exhibit 1189 ("Working to Make COVID-19 Vaccines Accessible to Everyone, Everywhere," Pfizer website, Pfizer website (accessed: https://www.pfizer.com/science/coronavirus/vaccine/working-to-reach-everyone-everywhere)).

[58] Exhibit 1190 ("A vaccine is Pfizer's best-selling drug," Axios website, February 5, 2019 (accessed: https://www.axios.com/2019/02/05/pfizer-vaccine-prevnar-top-selling-drug)); Exhibit 1191 ("Top selling vaccines in pharmaceutical history," Proclinical website, December 9, 2016 (accessed: https://www.proclinical.com/blogs/2016-9/top-selling-vaccines-in-pharmaceutical-history)).

[59] Exhibit 1192 ("BioNTech Signs Collaboration Agreement with Pfizer to Develop mRNA-based Vaccines for Prevention of Influenza," Pfizer press release, August 16, 2018 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/biontech-signs-collaboration-agreement-pfizer-develop-mrna)).

37. The FDA granted emergency use authorization ("EUA") for Comirnaty® on December 11, 2020.[60] The FDA granted full approval to market Comirnaty® on August 23, 2021.[61]

2.3 Overview of the Competitive Environment for COVID-19 Vaccines

38. This section, for background purposes, provides a brief overview of the COVID-19 pandemic and the competitive environment for COVID-19 vaccines.

39. As I noted in **Section 2.1**, on January 31, 2020, the WHO declared COVID-19 a PHEIC.[62] Also in January 2020, Chinese scientists released the genetic sequence of SARS-CoV-2 with the NIH database GenBank.[63]

40. On March 11, 2020, the WHO declared COVID-19 a global pandemic.[64] Two days later, on March 13, 2020, the U.S. Federal government

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[60] Exhibit 1193 ("FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine," FDA press release, December 11, 2020 (accessed: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)).
[61] Exhibit 1194 ("FDA grants full approval to Pfizer-BioNTech's Covid shot, clearing path to more vaccine mandates," CNBC, August 23, 2021 (accessed: https://www.cnbc.com/2021/08/23/fda-pfizer-biontech-covid-vaccine-wins-full-approval-clearing-path-to-mandates.html)).
[62] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[63] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[64] Exhibit 1174 ("WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," WHO website, March 11, 2020 (accessed: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)).

declared a "nationwide emergency and issue[d] an additional travel ban on non-U.S. citizens traveling from 26 European countries due to COVID-19."[65] Days later, U.S. states began to implement shutdowns to prevent the spread of COVID-19.[66]

41. In May 2020, the U.S. Federal government announced Operation Warp Speed, "designed as a public-private partnership with almost $10 billion in initial funding to accelerate the development, production, and distribution of vaccines, treatments, and diagnostics for Covid-19."[67] Under Operation Warp Speed, the U.S. government negotiated deals for vaccine development and production with Moderna, a Sanofi-GlaxoSmithKline partnership, Novavax, Johnson & Johnson, and AstraZeneca.[68]

42. Moderna received $955 million in funding for its development efforts.[69] Pfizer/BioNTech did not accept research and development funding

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[65] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[66] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[67] Exhibit 1176 ("Operation Warp Speed Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges," GAO website, February 5, 2021 (accessed: https://www.gao.gov/assets/gao-21-319.pdf)).
[68] Exhibit 1195 (U.S. Department of Health and Human Services, Explaining Operation Warp Speed (accessed: https://www.nihb.org/covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf)); Exhibit 1196 ("The U.S. has already invested billions in potential coronavirus vaccines. Here's where the deals stand," CNBC, August 14, 2020 (accessed: https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html)).
[69] Exhibit 1197 (Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021 (accessed https://crsreports.congress.gov/product/pdf/IN/IN11560/7)).

from the Operation Warp Speed initiative; they only participated as a COVID-19 vaccine supplier.[70]

43. COVID-19 vaccination rates received unprecedented governmental support. By August 2020, prior to any vaccines being approved for an EUA, the U.S. government had secured 800 million doses of vaccines.[71] This was greater than the roughly 660 million doses needed to vaccinate 100% of the U.S. population (assuming two doses per person), but procuring an oversupply would ensure that even if some vaccines failed to get authorization or suffered delays in production, the U.S. would still be able to vaccinate the entire country as fast as possible.[72] In total, the U.S. government secured advance commitments for more than one billion doses of several vaccines between 2020 and 2021.[73]

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[70] Exhibit 1198 (CNN, Facts First (accessed: https://www.cnn.com/factsfirst/politics/factcheck_565aa63a-4c46-4eea-9586-093253d1bdf3)).

[71] The secured doses were spread across six vaccine developers including Pfizer, Moderna, Sanofi and GlaxoSmithKline, Novavax, and Johnson & Johnson, who all agreed to initially deliver 100 million doses each and AstraZeneca, who agreed to deliver 300 million doses. *See* Exhibit 1167 ("After nearly $1B in research funding, Moderna takes $1.5B coronavirus vaccine order from U.S.," Fierce Pharma, August 12, 2020 (accessed: https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s)).

[72] Exhibit 1199 ("The U.S. Government's Role in Domestic and Global COVID-19 Vaccine Supply and Distribution: Frequently Asked Questions," Congressional Research Service, February 17, 2022 (accessed: https://crsreports.congress.gov/product/pdf/IF/IF12013)).

[73] Exhibit 1197 ("Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021 (accessed https://crsreports.congress.gov/product/pdf/IN/IN11560/7)).

44. On December 11, 2020, the FDA issued an EUA of Comirnaty®.[74] Moderna's Spikevax® was authorized for emergency use approximately one week later, on December 18, 2020.[75] On February 27, 2021, the FDA authorized the emergency use of the Johnson & Johnson single-dose vaccine, known as the Janssen COVID-19 vaccine.[76]

45. Initially, COVID-19 vaccinations were allotted to those of immediate risk such as senior citizens and essential workers and as supplies increased, the states determined which groups of people, such as grocery store workers, firefighters and other essential workers, would be next to receive a vaccination.[77] By April 2021, suppliers to the U.S. had "produced enough vaccines for all adults."[78]

46. After efforts to secure supply, the U.S. Federal government, along with other governmental agencies and the private sector, undertook

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[74] Exhibit 1193 ("FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine," FDA press release, December 11, 2020 (accessed: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)).

[75] Exhibit 2229 ("Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine," FDA press release, January 31, 2022 (accessed: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine)).

[76] Exhibit 1200 ("Johnson & Johnson Updates U.S. COVID-19 Vaccine Fact Sheet," Johnson & Johnson press release, May 5, 2022 (accessed: https://www.jnj.com/johnson-johnson-updates-u-s-covid-19-vaccine-fact-sheet)).

[77] Exhibit 1201 ("From zero to 500 million: America's vaccination effort in 4 charts," NBC News, December 30, 2021 (accessed: https://www.nbcnews.com/news/all/zero-500-million-america-s-vaccination-effort-4-charts-n1286773)).

[78] Exhibit 1201 ("From zero to 500 million: America's vaccination effort in 4 charts," NBC News, December 30, 2021 (accessed: https://www.nbcnews.com/news/all/zero-500-million-america-s-vaccination-effort-4-charts-n1286773)).

significant efforts to encourage the public to get vaccinated, using vaccine subsidies and marketing to assure the public of the safety, importance, and efficacy of COVID-19 vaccines.[79] I will discuss this further in **Section 4.3**.

47. In April 2021, the daily number of COVID-19 vaccine doses administered in the U.S. peaked at 3.5 million.[80] By December 2021, daily does administered were less than two million per day[81] and approximately 85% of U.S. adults had received at least one vaccine dose.[82]

48. The majority of the shots given in 2021 were from Pfizer-BioNTech (comprising 58% of shots administered in the U.S. as of December 2021), Moderna (comprising 38% of shots administered in the U.S. as of

[79] Exhibit 1172 ("Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)).
[80] Exhibit 1202 ("Daily COVID-19 vaccine doses administered," Our World in Data, March 9, 2023 (accessed: https://ourworldindata.org/grapher/daily-covid-19-vaccination-doses?tab=chart&country=~USA)).
[81] Exhibit 1202 ("Daily COVID-19 vaccine doses administered," Our World in Data, March 9, 2023 (accessed: https://ourworldindata.org/grapher/daily-covid-19-vaccination-doses?tab=chart&country=~USA)).
[82] Exhibit 1203 ("Household Pulse Survey Shows Many Don't Trust COVID Vaccine, Worry About Side Effects," United States Census Bureau, December 28, 2021 (accessed: https://www.census.gov/library/stories/2021/12/who-are-the-adults-not-vaccinated-against-covid.html)).

December 2021), and Johnson & Johnson[83] (a non-mRNA-based vaccine, comprising 3.5% of shots administered in the U.S. as of December 2021).[84]

49. On July 13, 2022, the Novavax vaccine ("Nuvaxovid™") was the fourth vaccine to be granted EUA by the FDA[85] (approval of Nuvaxovid™ was delayed due to the FDA investigation of Novavax's manufacturing process).[86] Nuvaxovid™ was part of Operation Warp Speed and received $1.8 billion in U.S. Federal funding.[87] Nuvaxovid™ is not an mRNA vaccine, but is instead a protein-based vaccine.[88] Nuvaxovid™ is 90%

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[83] In April 2021, the FDA issued a recommendation to pause use of Jcovden™ due to safety risks. In December 2021, after reviewing updated vaccine effectiveness and safety data, the Advisory Committee on Immunization Practices made "a preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen adenoviral-vectored COVID-19 vaccine in all persons aged over 18 years in the United States." On May 5, 2022, the FDA limited use of the J&J vaccine to patients who were not able to receive mRNA-based vaccines. As of May 2023, Jcovden™ was no longer available in the United States. *See* Exhibit 1204 ("Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine," FDA website, April 13, 2021 (accessed: https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine)); Exhibit 1205 ("Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals," FDA news release, May 5, 2022 (accessed: https://web.archive.org/web/20220505225458/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals)); Exhibit 1206 ("Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices," CDC website, January 21, 2022 (accessed: https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm)).

[84] Exhibit 1201 ("From zero to 500 million: America's vaccination effort in 4 charts," NBC News, December 30, 2021 (accessed: https://www.nbcnews.com/news/all/zero-500-million-america-s-vaccination-effort-4-charts-n1286773)).

[85] Exhibit 1127 ("U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted for Individuals Aged 18 and Over," Novavax press release, July 13, 2022 (accessed: https://ir.novavax.com/press-releases/2022-07-13-U-S-FDA-Grants-Emergency-Use-Authorization-for-Novavax-COVID-19-Vaccine,-Adjuvanted-for-Individuals-Aged-18-and-Over)).

[86] Exhibit 1207 ("What You Need to Know About the Novavax Protein-Based Vaccine," Johns Hopkins, July 14, 2022 (accessed: https://publichealth.jhu.edu/2022/what-you-need-to-know-about-the-novavax-protein-based-vaccine)).

[87] Exhibit 1207 ("What You Need to Know About the Novavax Protein-Based Vaccine," Johns Hopkins, July 14, 2022 (accessed: https://publichealth.jhu.edu/2022/what-you-need-to-know-about-the-novavax-protein-based-vaccine)).

[88] Exhibit 1207 ("What You Need to Know About the Novavax Protein-Based Vaccine," Johns Hopkins, July 14, 2022 (accessed: https://publichealth.jhu.edu/2022/what-you-need-to-know-about-the-novavax-protein-based-vaccine)).

effective at preventing COVID-19.[89] Nuvaxovid™ is currently authorized in 33 countries.[90]

50. In 2022, vaccination rates began to decline from peak levels, falling further throughout 2023.[91] In May 2023, WHO declared that the COVID-19 global health emergency had ended.[92] In October 2023, the U.S. Federal government announced that it was "no longer purchasing COVID-19 vaccines" and providers were encouraged to commercially procure further doses to continue administering to patients.[93]

51. Through the beginning of September 2023, 100% of U.S. revenues and doses sold for both Spikevax® and Comirnaty® were to governmental agencies.[94] The transition away from government purchasing

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[89] Exhibit 1208 ("What is the Novavax vaccine, and why does the world need another type of COVID-19 vaccine?" Gavi, February 14, 2022 (accessed: https://www.gavi.org/vaccineswork/what-novavax-vaccine-and-why-does-world-need-another-type-covid-19-vaccine)).
[90] Exhibit 1209 ("Tracking Coronavirus Vaccinations Around the World," The New York Times, March 13, 2023 (accessed: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html)).
[91] Exhibit 1202 ("Daily COVID-19 vaccine doses administered," Our World in Data, March 9, 2023 (accessed: https://ourworldindata.org/grapher/daily-covid-19-vaccination-doses?tab=chart&country=~USA)); Exhibit 1210 ("Covid vaccine rates in the U.S. are slumping — and it will be a challenge to boost them," CNBC, November 30, 2023 (accessed: https://www.cnbc.com/2023/11/30/us-covid-shot-rates-are-low-and-it-will-be-a-challenge-to-boost-them.html)).
[92] Exhibit 1211 ("WHO chief declares end to COVID-19 as a global health emergency," UN News, May 5, 2023 (accessed: https://news.un.org/en/story/2023/05/1136367)).
[93] Exhibit 1212 ("CDC COVID-19 Vaccination Program Provider Requirements and Support: 10/6/2023 Update," CDC website, October 6, 2023 (accessed: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html)).
[94] According to the U.S. Department of Health and Human Services ("HHS"), vaccine ordering through U.S. Government processes began to phase out on August 3, 2023, "with a formal transition to the commercial market expected in mid-to-late September" of 2023. *See* Exhibit 1171 ("COVID-19 Commercialization," HHS website (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)).

programs, simply referred to as "commercialization," represented "the transition of COVID-19 medical countermeasures, including vaccines, treatments, and test kits previously purchased by the U.S. government, to more established standard pathways of procurement, distribution, and payment by both public and private payers (i.e., the traditional health care marketplace)."[95]

52. Even after commercialization, vaccines remained available at no cost to insured and uninsured recipients.[96] However, by the end of 2023, sales of both Spikevax® and Comirnaty® had gone down precipitously.[97]

53. This brief overview of the COVID-19 pandemic begins to illustrate the significant role that governments and public health officials

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[95] Exhibit 1171 "COVID-19 Commercialization," HHS, July 13, 2023 (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)).

[96] Exhibit 1213 ("HHS Launches Bridge Access Program to Safeguard Free COVID-19 Vaccination for Uninsured and Underinsured Adults," CDC Newsroom Releases, September 14, 2023 (accessed: https://www.cdc.gov/media/releases/2023/p0914-uninsured-vaccination.html)); Exhibit 1214 ("FACT SHEET: How Are COVID-19 Vaccines Covered by Insurance?" Covid-19 Vaccine Education and Equity Project, September 2023 (accessed: https://covidvaccineproject.org/wp-content/uploads/2023/09/CVEEP_Youre-Covered_Coverage-Overview_0923.pdf)).

[97] For example, there were less than 500 million doses of Comirnaty® delivered worldwide in 2023, compared to approximately 2.6 billion and 2 billion doses in 2021 and 2022, respectively, when governments were more active purchasers. Moderna sales of Spikevax® also declined in 2023 compared to earlier time periods. *See* Exhibit 1215 ("BioNTech Announces Fourth Quarter and Full Year 2023 Financial Results and Corporate Update," BioNTech press release, March 20, 2024, p. 1 (accessed: https://investors.biontech.de/system/files-encrypted/nasdaq_kms/assets/2024/03/20/8-02-08/BNTX%20Q4%202023%20Press%20Release_EN_post-issuance%20update.pdf)); Exhibit 1216 ("BioNTech Announces Fourth Quarter and Full Year 2022 Financial Results and Corporate Update," BioNTech press release, March 27, 2023, p. 2 (accessed: https://investors.biontech.de/node/14871/pdf)); Exhibit 1217 ("BioNTech Announces Fourth Quarter and Full Year 2021 Financial Results and Corporate Update," BioNTech press release, March 30, 2022, p. 1 (accessed: https://investors.biontech.de/node/11911/pdf)); Exhibit 1218 ("Moderna Covid vaccine sales plunge by two-thirds in 2023, but meet company's $6 billion forecast," CNBC, January 8, 2024 (accessed: https://www.cnbc.com/2024/01/08/moderna-covid-vaccine-sales-plunge-in-2023-but-meet-company-forecast.html)).

played in the COVID-19 marketplace, including ensuring vaccine supply for the public and maintaining demand for vaccines in 2023; these considerations contributed to the success of Spikevax® and Comirnaty®. Mr. Malackowski testified that he did not consider them.[98] I discuss this further in **Section 4.3**.

2.4 Overview of the '600 Patent and the '127 Patent

54. This section provides my understanding of the '600 patent and the '127 patent based on information and opinions provided by others, including Moderna, Dr. James Moon and Dr. Daniel Griffin.[99]

55. The '600 patent and the '127 patent are both titled "Betacoronavirus mRNA Vaccine."[100] The '600 patent issued on July 7, 2020, and I understand that it is set to expire on October 23, 2036.[101] The '127 patent issued on March 2, 2021, and I understand that it is also set to expire on October 23, 2036.[102]

56. The named inventors of the '600 patent and the '127 patent include Giuseppe Ciaramella and Sunny Himansu.[103] Moderna claims priority

[98] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 21-30 (testifying that he did not measure, for example: the impact of government investment, government contracts, purchasing excess demand, vaccine mandates, the availability of vaccines free of charge for consumers, branded and unbranded vaccine marketing). *See also,* Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 45-51.
[99] I am not a technical expert, and I do not offer any technical opinions in this case.
[100] Exhibit 1001 ('600 patent); Exhibit 1001 ('127 patent).
[101] Exhibit 1001 ('600 patent).
[102] Exhibit 1001 ('127 patent).
[103] Exhibit 1001 ('600 patent); Exhibit 1001 ('127 patent).

dates in October 2015 for the ’600 patent and the ’127 patent. This was approximately five to six years before the patents issued, and before the emergence of COVID-19.[104]

57. I understand that claim 1 of the ’600 patent is directed to an mRNA composition in a general way and does not recite a specific betacoronavirus or any specific formulation.[105] I understand that claim 1 of the ’600 patent generally claims an mRNA encoding for a betacoronavirus spike protein or spike protein subunit, formulated in a lipid nanoparticle.[106]

58. Moderna also claims that its ’600 patent “reflects the inventors’ work to construct compositions including vaccines against betacoronaviruses and test them for efficacy.”[107] For example, claim 1 of the ’600 patent recites a “composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.”[108]

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[104] Exhibit 1001 (’600 patent); Exhibit 1001 (’127 patent); Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01358, p. 3; Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01359, p. 4; Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 2; Deposition 2200 (Krause Declaration), ¶ 26.
[105] Interview of Dr. Griffin.
[106] Interview of Dr. Griffin.
[107] Patent Owner’s Preliminary Response, Case No. IPR2023-01358, December 8, 2023, p. 14.
[108] Exhibit 1001 (’600 patent), claim 1.

59. I understand claim 1 of the ’127 patent is like claim 1 the ’600 patent, but adds, at a general level, the use of a vaccine — inducing an immune response.[109] As with claim 1 of the ’600 patent, it does not recite specific mRNA or any specific formulations.[110]

60. At a high level, I am informed that the scope of the ’600 patent and the ’127 patent are substantially similar.[111] Moderna claims that ’600 patent and ’127 patent disclose results that its “mRNA-LNP vaccine encoding a betacoronavirus S protein or S protein subunit proved immunogenic” and “was potent enough to produce a strong immune response.”[112] The main difference between the ’600 patent and the ’127 patent, as I understand from Dr. Griffin, is that the ’600 patent claims a vaccine containing a lipid nanoparticle (“LNP”) and the ’127 patent claims a method of treatment by administering a vaccine containing an LNP to induce an immune response.[113] I understand that this is not material from a technological standpoint.[114]

61. Moderna alleges that Spikevax® embodies and is coextensive with the claims of the ’600 patent and ’127 patent.[115] Moderna cites its patent

[109] Interview of Dr. Griffin.
[110] Interview of Dr. Griffin.
[111] Interview of Dr. Griffin.
[112] Exhibit 2200 (Krause Declaration), ¶ 201.
[113] Interview of Dr. Griffin
[114] Interview of Dr. Griffin
[115] Patent Owner’s Preliminary Response, Case No. IPR2023-01358, December 8, 2023, p. 65; Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 62.

marking website to allege Spikevax® embodies the ’600 patent (as part of a list that encompassed eight patents in 2020 and eleven patents by 2023).[116] Moderna also alleges that Spikevax® practices the methods claimed in the ’127 patent.[117]

62. Mr. Malackowski, citing Dr. Krause, stated that “the betacoronavirus mRNA-LNP vaccine platform claimed by the ’600 and ’127 patents is critical to the clinical success of Spikevax® and Comirnaty®.”[118] Even if this is assumed to be so, I also understand that the ’600 and ’127 patents were filed before COVID-19 existed and do not describe a COVID-19 vaccine.[119] I further understand that the formulation used in the ’600 and ’127 patents for the MERS vaccine is not the formulation used in Spikevax® or Comirnaty®.[120]

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[116] Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 62, citing Exhibit 2034. In October 2020, Moderna listed seven U.S. patents. By December 2021, the number of Moderna’s patents had grown to eight. In December 2022, Moderna updated the list to nine U.S. patents. In 2023, Moderna listed ten patents in March before adding an additional patent to list eleven patents total in December. *See* Exhibit 1219 (“Patents,” Moderna website, October 8, 2020 (accessed: https://web.archive.org/web/20201008145751/https://www.modernatx.com/patents)); Exhibit 1220 (“Patents,” Moderna website, December 1, 2021 (accessed: https://web.archive.org/web/20211201193750/https://www.modernatx.com/patents)); Exhibit 1221 (“Patents,” Moderna website, December 5, 2022 (accessed: https://web.archive.org/web/20221205004929/https://www.modernatx.com/patents)); Exhibit 1222 (“Patents,” Moderna website, March 8, 2023 (accessed: https://web.archive.org/web/20230308131232/https://www.modernatx.com/patents)); Exhibit 1223 (“Patents,” Moderna website, December 9, 2023 (accessed: https://web.archive.org/web/20231209004401/https://www.modernatx.com/en-US/patents)).
[117] Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 63.
[118] Exhibit 2197 (Malackowski Declaration), ¶ 23.
[119] Interview of Dr. Griffin.
[120] Interview of Dr. Griffin.

3 OVERVIEW OF THE APPLICABLE LEGAL FRAMEWORK

63. I am not an attorney and I do not offer any legal opinions here. For background purposes, this section provides an overview of what I am requested to assume regarding the applicable legal framework.

64. I understand that evidence of the commercial success of an alleged patented product weighs against a finding of obviousness only if there is a causal "nexus" between the claimed invention and the commercial success.[121] I also understand that "causal nexus" means that the commercial success must be a direct result of the claimed invention, not other considerations such as marketing, pricing, or subsidies.[122] I further understand that where the secondary consideration results from something

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[121] *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *WesternGeco LLC v. ION Geophysical Corporation*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018); *Tokai Corp., et al. v. Easton Enterprises, Inc.,* 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011).

[122] *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *WesternGeco LLC v. ION Geophysical Corporation*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018); *Tokai Corp., et al. v. Easton Enterprises, Inc.,* 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011); *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008); *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1101 (Fed. Cir. 2015); *In re Hubbell Inc.*, 644 Fed. App'x 1004, 1008 (Fed. Cir. 2016); *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1354 (Fed. Cir. 2016). I understand that obviousness of an invention is established "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." *See* 35 U.S.C. § 103. I also understand that an analysis of obviousness must include the evaluation of secondary considerations such as the commercial success of the invention (*KSR Intern. Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1734 (2007)), and that evidence of commercial success is only significant if a nexus is demonstrated between the claimed invention and the alleged commercial success. I understand that no nexus exists if commercial success is due to an element in the prior art. *See Tokai Corp. v. Easton Enters., Inc.,* 632 F.3d 1358, 1369 (Fed. Cir. 2011). *See also In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) ("The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . .. [and] in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." (citations omitted)).

other than what is both claimed and novel in the claim, there is a failure to show nexus to the merits of the claimed invention.[123]

65. I understand that a nexus may be presumed for commercial success "when the patentee shows that the asserted objective evidence is tied to a specific product, and that product embodies the claimed features, and is coextensive with them."[124] I understand that a product is "coextensive" with the invention when the product "*is* the invention disclosed and claimed, … when, for example, the unclaimed features amount to nothing more than additional insignificant features."[125] I understand that "[w]hen the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process, the patentee is not entitled to a presumption of nexus."[126]

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[123] *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention."); *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011), quoting *Wyers*, 616 F.3d at 1246. *See also S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (affirming a finding of no nexus where the patent owner "failed to connect the evidence of industry praise to the novel elements of the claims," given that "the praise was particularly directed to . . . an element already known in the prior art"); *Tokai Corp., et al. v. Easton Enterprises, Inc.,* 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011); *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *WesternGeco LLC v. ION Geophysical Corporation*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018).

[124] *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal quotation marks omitted).

[125] *Campbell Soup Company v. Gamon Plus, Inc.*, 10 F.4th 1268, 1275-76 (Fed. Cir. 2021) (emphasis in original and internal quotation marks omitted).

[126] *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal quotation marks omitted).

66. I am informed that a presumption of nexus, even if it exists, may be rebutted. Mr. Malackowski and I do not agree on whether he has established a presumption of nexus; my opinions are economic in nature and my understanding is that they can also apply as rebuttal to a presumption of nexus.

67. In a multicomponent product, I understand that rebutting a presumption of nexus (or proving the absence of nexus) depends on the relative importance of the patented and non-patented factors to the objective indicium.[127] For example, I understand that there is no nexus if the commercial success is attributable to features of the invention that were known in the prior art.[128] I further understand that a nexus may not exist if commercial success is attributable to other unclaimed features of the product or external factors such as marketing, pricing, subsidies, packaging, or

[127] *Oren Techs., LLC v. Proppant Express Invs. LLC*, No. 2019-1778, 2021 WL 3120819, at *6–7 (Fed. Cir. July 23, 2021).

[128] More specifically, I understand that if the commercial success "is due to an unclaimed feature of the device," or if the feature that creates the commercial success "was known in the prior art, the success is not pertinent." *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006); *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017). In *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008), the trial court concluded that patent owner Asyst failed to link the commercial success to the claimed invention because the proffered evidence lacked a nexus to any feature of the invention's commercial embodiments that was not already disclosed in the prior art. I understand the Federal Circuit found that "even though commercial embodiments of [Asyst's] invention may have enjoyed commercial success, Asyst's failure to link that commercial success to the features of its invention that were not disclosed in [the prior art] undermines the probative force of the evidence pertaining to the success of Asyst's [ ] products."

manufacturing know-how.[129] Moreover, I understand that "objective indicia relating to a product consisting of components that are not part of asserted claims do not necessarily show that what is patented is non-obvious."[130]

68. I also understand that care must be taken in drawing an inference of non-obviousness from commercial success, and particularly the specific financial success that is identified by a patent owner.[131] I understand that even if a feature contributes to a product's success, that does not necessarily mean that the feature was inventive as opposed to a product of ordinary skill in the art.[132]

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[129] *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1393 (Fed. Cir. 1988); see also WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1329 (Fed. Cir. 2016); Ritchie v. Vast Resources, Inc., 563 F.3d 1334, 1336 (Fed. Cir. 2009)* ("The commercial success of a product can have many causes unrelated to patentable inventiveness; for example, the commercial success of an 'invention' might be due not to the invention itself but to skillful marketing of the product embodying the invention.")*; In re Kluter, 92 F.2d 906, 908 (CCPA 1937)* ("Salesmanship, manufacturing costs, advertising, and many other things may have brought about commercial success where there was no inventive act whatever.")*; Prometheus Labs., Inc. v. Roxane Laboratories, Inc., 805 F.3d 1092, 1101-02 (Fed. Cir. 2015)* (affirming district court's obviousness ruling where nexus was rejected because revenue growth owed to marketing and pricing practices); *Media Technologies Licensing, LLC v. Upper Deck Co., 596 F.3d 1334, 1339 (Fed. Cir. 2010)* (manufacturing and packaging drove commercial success and prevented finding of nexus). I also understand that in *Tokai Corp. v. Easton Enterprises, Inc.,* the CAFC upheld the district court's ruling that Tokai's use of its sales data was deemed insufficient in establishing a causal nexus to its patented invention. *See Tokai Corp., et al. v. Easton Enterprises, Inc., et al., 632 F.3d 1358, 1370 (Fed. Cir. 2011).*

[130] *TalexMedical, LLC v. Becon Med. Ltd.*, No. 2021-2069, 2022 WL 2898934, at *9–10 (Fed. Cir. July 22, 2022).

[131] *Textile Mach. Works v. Louis Hirsch Textile Mach.*, 87 F.2d 702, 704 (2d Cir. 1937) (Hand, J.).

[132] Order Granting in Part and Denying in Part Motions to Exclude Expert Testimony, Denying Motion to Bifurcate Trial, Denying Motion for Preclusive Sanctions in the matter of *Mformation Techs., Inc. v. Research in Motion, et al*., 5:08-cv-04990-JW (N.D. Cal. 2012); *Ericsson, Inc. v. D-Link Systems, Inc.,* 773 F.3d 1201, 1226 (Fed Cir. 2014). *See also*, *VirnetX, Inc. v. Cisco Sys.,* 767 F.3d 1308 (Fed. Cir. 2014); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011)); *Power Integrations, Inc. v. Fairchild Semiconductor International, Inc.,* 894 F.3d 1258 (Fed. Cir. 2018). feature was inventive as opposed to a product of ordinary skill in the art. I understand that "the rationale for commercial success as an indicium of non-obviousness is that 'the possibility of market success attendant upon the solution of an

69. In summary, I understand that market realities can impact an assessment of whether a patented feature has a nexus to commercial success for the purpose of determining non-obviousness. I have been requested to address the following issues, from a financial and economic point of view: (i) considerations that led to the commercial success of Comirnaty® and Spikevax®; and (ii) what role the '600 patent and the '127 patent play from a commercial perspective.

4 FINANCIAL ANALYSIS OF COMMERCIAL SUCCESS

70. According to Mr. Malackowski, "[t]he two vaccines that utilize the inventions claimed by the '600 and '127 patents—Spikevax® and Comirnaty®—have achieved unprecedented market success, which is remarkable in terms of its absolute scale and how quickly that success was achieved."[133] As I will explain in the following sections, there were many considerations unrelated to the '600 patent and the '127 patent (including, other technologies, intangible assets, and broader economic and marketplace

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existing problem may induce innovators to attempt a solution. If in fact a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and have failed.'" *See* Note, Subtests of "Nonobviousness:" A Nontechnical Approach to Patent Validity, 112 U. Pa. L.Rev. 1169, 1175 (1964); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016). I am further informed that reaching that conclusion may require "a chain of inferences" that depend on a specific market context. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1377 (Fed. Cir. 2005).

[133] Exhibit 2197 (Malackowski Declaration), ¶ 9.

circumstances) that contributed to the commercial success of Spikevax® and Comirnaty®.[134]

71. COVID-19 was a unique global event.[135] COVID-19 had a threatening rate of asymptomatic airborne transmission, and there were global lockdowns aimed at mitigating the spread of the disease.[136] These circumstances caused the need to secure "safe and effective vaccines," and "became a priority for politicians, business leaders, and public health officials."[137] After Chinese scientists released the genetic sequence of SARS-CoV-2 with the NIH database GenBank in January 2020,[138] it took less than one year for the first patient to be injected with an approved COVID-19 vaccine, Comirnaty®.[139]

72. The COVID-19 pandemic began years after Moderna's alleged inventions of the '600 patent and the '127 patent. The following chart,

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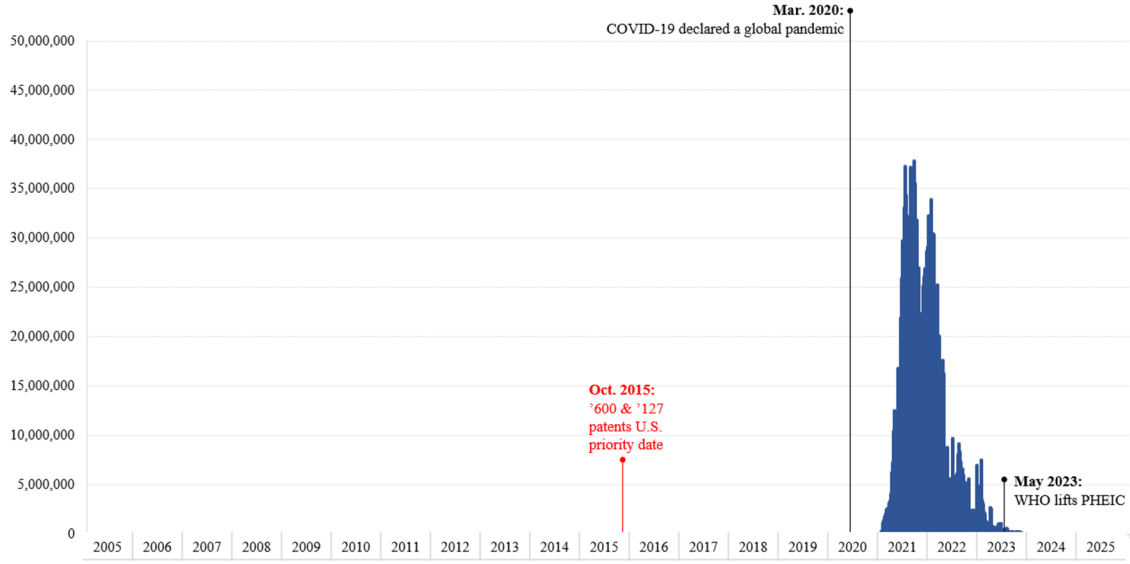
[134] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 21-30 (testifying that he did not measure, for example: the impact of government investment, government contracts, purchasing excess demand, vaccine mandates, the availability of vaccines free of charge for consumers, branded and unbranded vaccine marketing).
[135] Exhibit 1224 ("Why Did The World Shut Down For COVID-19 But Not Ebola, SARS Or Swine Flu?" ABC News, April 14, 2020 (accessed: https://fivethirtyeight.com/features/why-did-the-world-shut-down-for-covid-19-but-not-ebola-sars-or-swine-flu/)).
[136] Exhibit 1224 ("Why Did The World Shut Down For COVID-19 But Not Ebola, SARS Or Swine Flu?" ABC News, April 14, 2020 (accessed: https://fivethirtyeight.com/features/why-did-the-world-shut-down-for-covid-19-but-not-ebola-sars-or-swine-flu/)).
[137] Exhibit 1225 (Bishai, D., Brenzel, L., and Padula, W., *Handbook of Applied Health Economics in Vaccines*, 2023), p. 16.
[138] Exhibit 1166 ("COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)).
[139] Exhibit 1226 ("Landmark moment as first NHS patient receives COVID-19 vaccination," NHS England, December 8, 2020 (accessed: https://www.england.nhs.uk/2020/12/landmark-moment-as-first-nhs-patient-receives-covid-19-vaccination/)).

depicting daily new COVID-19 vaccinations worldwide, illustrates the timing of the COVID-19 pandemic (in black text) relative to the priority date of the ’600 patent and the ’127 patent (in red text):

New COVID-19 Vaccinations per Day (Worldwide)[140]
Patent Priority Dates



73. Mr. Malackowski claimed to rely on the number of doses of Spikevax® and Comirnaty® that were delivered,[141] stating that Spikevax® and Comirnaty® “were available at the time that the world faced its greatest

[140] Exhibit 1227 (Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/covid-vaccinations);) Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01358, p. 3; Decision Granting Institution of Inter Partes Review and Granting the Parties’ Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01359, p. 4; Patent Owner’s Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 2; Exhibit 1174 (“WHO Director-General’s opening remarks at the media briefing on COVID-19 - 11 March 2020,” WHO website, March 11, 2020 (accessed: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)); Exhibit 1211 (“WHO chief declares end to COVID-19 as a global health emergency,” UN News, May 5, 2023 (accessed: https://news.un.org/en/story/2023/05/1136367)).
[141] Exhibit 2197 (Malackowski Declaration), ¶¶ 19-20.

need for COVID-19 vaccines."[142] Mr. Malackowski acknowledged that the "emergence of COVID-19 in early 2020 set off a global race to develop vaccines against the virus."[143] However, Mr. Malackowski did not meaningfully consider the impact of the COVID-19 pandemic and government intervention on driving these immunizations.

74. In 2020, COVID-19 was the third-leading cause of death in the U.S., directly causing over 350,000 deaths.[144] In 2021, the death toll rose to over 450,000, with the number of hospitalizations peaking at over 150,000 per day in January 2022.[145] Through the end of 2023, COVID-19 claimed the lives of over one million people in the United States.[146] These circumstances provided an unusual opportunity for COVID-19 vaccines, including Comirnaty® and Spikevax®.

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[142] Exhibit 2197 (Malackowski Declaration), ¶ 18.
[143] Exhibit 2197 (Malackowski Declaration), ¶ 13.
[144] Exhibit 1228 ("2020 Final Death Statistics: COVID-19 as an Underlying Cause of Death vs. Contributing Cause," National Center for Health Statistics, January 7, 2022 (accessed: https://www.cdc.gov/nchs/pressroom/podcasts/2022/20220107/20220107.htm#print)).
[145] Exhibit 1229 ("Provisional Mortality Data — United States, 2021," CDC website, April 29, 2022 (accessed: https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e1.htm)); Exhibit 1230 ("COVID-19 hospitalizations," Our World in Data, (accessed: https://ourworldindata.org/covid-hospitalizations)).
[146] Exhibit 1231 ("US death rate dropped 6% in 2023, with Covid-19 falling to 10th leading cause of death, CDC says," CNN, August 8, 2024 (accessed: https://www.cnn.com/2024/08/08/health/us-death-rate-2023-cdc/index.html)).

75. Mr. Malackowski, citing Dr. Krause, stated that the ’600 patent and the ’127 patent impacted “speed of development.”[147] However, Mr. Malackowski disregarded the role that governments and public health officials played in speeding up the development process. I will discuss this further in **Section 4.3**.

76. According to Mr. Malackowski, “Nuvaxovid™ has failed to gain traction in the market for COVID-19 vaccines,” and this was due to its lack of use of the ’600 patent and the ’127 patent.[148] But Mr. Malackowski ignores that Nuvaxovid™ was introduced years after Spikevax® and Comirnaty®, at a time when overall vaccination rates were much lower than the 2021-2022 timeframe.[149] In other words, the launch of Nuvaxovid™ occurred during a time of limited demand; it is unreasonable for Mr. Malackowski to disregard that lower sales than Spikevax® and Comirnaty® are a function of timing and

[147] Exhibit 2197 (Malackowski Declaration), ¶ 27. *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 55-56 (“Q. Your report did not disclose any investigation by you into how much slower or faster the development of Spikevax or Comirnaty was due to the '600 patent, correct? A. Not specific to the patents at issue. There is some general discussion of product development time. And, again, I do refer back to Dr. Krause's report. Q. And your report does not disclose any investigation into how much slower or faster the development of Spikevax or Comirnaty was due to the '127 patent, correct? A. Same answer.”).

[148] Exhibit 2197 (Malackowski Declaration), ¶ 28 (“Without the benefit of the inventions of the ’600 and ’127 patents,
Nuvaxovid™ has failed to gain traction in the market for COVID-19 vaccines.”).

[149] Exhibit 1232 (“FDA authorized Novavax COVID-19 vaccine for emergency use in US,” ABC News, July 13, 2022 (accessed: https://abcnews.go.com/Health/fda-authorizes-novavax-covid-19-vaccine-emergency-us/story?id=86769988)); Exhibit 1227 (Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/covid-vaccinations)).

opportunity—including not benefitting from government intervention and societal reactions to the pandemic—rather than technological differences.

77. Novavax has also stated that its delay in entering the U.S. market was the result of testing, internal quality-control, and regulatory issues (not development timing).[150] Neither the '600 patent nor the '127 patent are claimed to relate to manufacturing processes and regulatory issues. These are examples of intangible assets, separately distinguishable from the '600 and '127 patents, of which commercial success was unquestionably a function.

78. There were also other products that were developed as quickly as Spikevax® and Comirnaty®, namely the Oxford-AstraZeneca vaccine, Vaxzevria®.[151] Vaxzevria® (previously known simply as the "COVID-19 Vaccine AstraZeneca") was first available in the United Kingdom in December 2020.[152] By November 2022, Vaxzevria®, a viral vector vaccine, received full market authorization in the European Union and was used in 185

[150] Exhibit 1233 ("Novavax Says U.S. Will Pause Funding for Production of Its Vaccine," The New York Times, August 8, 2021 (accessed: https://www.nytimes.com/2021/08/06/us/politics/novavax-coronavirus-vaccine.html)).
[151] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 60-63.
[152] Exhibit 1234 ("AstraZeneca's COVID-19 vaccine authorised for emergency supply in the UK," AstraZeneca press release, December 30, 2020 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2020/astrazenecas-covid-19-vaccine-authorised-in-uk.html#)); Exhibit 1209 ("Tracking Coronavirus Vaccinations Around the World," The New York Times, March 13, 2023 (accessed: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html)).

countries, making it the most widely used vaccine in terms of country count.[153] Although the efficacy of Vaxzevria® is somewhat less than reported efficacy rates for Spikevax® and Comirnaty®, the efficacy of Vaxzevria® is above stated thresholds for a U.S. vaccine and I understand that it is considered safe.[154]

79. Mr. Malackowski, citing Dr. Krause, stated that the efficacy of Spikevax® and Comirnaty® was "attributable to the technologies claimed in the '600 and '127 patents."[155] Mr. Malackowski disregarded that although Nuvaxovid™ is not an mRNA vaccine, it is said to be 90% effective at

[153] Exhibit 1235 ("Vaxzevria receives full marketing authorisation in the EU for the prevention of COVID-19," AstraZeneca, November 1, 2022 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2022/vaxzevria-receives-full-marketing-authorisation-in-the-eu-for-the-prevention-of-covid-19.html)); Exhibit 1209 ("Tracking Coronavirus Vaccinations Around the World," The New York Times, March 13, 2023 (accessed: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html)).

[154] Interview of Dr. Griffin. In April 2021, the White House stated that "[t]he AstraZeneca vaccine is highly safe and effective, and approved in many parts of the world." *See* Exhibit 1236 ("Press Briefing by White House COVID-19 Response Team and Public Health Officials, April 27, 2021 (accessed: https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/27/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-32/)); Exhibit 1237 ("AZD1222 US Phase III primary analysis confirms safety and efficacy," AstraZeneca, March 25, 2021 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2021/azd1222-us-phase-iii-primary-analysis-confirms-safety-and-efficacy.html)).

[155] Exhibit 2197 (Malackowski Declaration), ¶ 17. *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 54 ("Q. Your report did not disclose any investigation into how much more effective Spikevax and/or Comirnaty are due to the '600 patent, correct? A. Not other than the statements I cite to Dr. Krause, correct. Q. And your opinion did not disclose any investigation by you into how much more effective Spikevax and Comirnaty are due to the '127 patent, correct? A. Same answer.").

preventing COVID-19 and is considered safe.[156] Nuvaxovid™ is currently authorized in 33 countries.[157] Nuvaxovid™ usage is also expected to grow.[158]

80. Mr. Malackowski testified that Spikevax® and Comirnaty® are not complex multicomponent products, that the '600 patent and the '127 patent "cover the vaccines" and the "patented technology can't be separated."[159] I am informed that Spikevax® and Comirnaty® have many significant unpatented features, and thus I understand that they are not coextensive with the asserted claims.[160] (I understand that, from a legal point of view, there may be no presumption of nexus in this matter due to this lack of coextensiveness).[161]

81. From a commercial perspective, as I have explained, there is not any one technology or consideration that led to the commercial success of Spikevax® and Comirnaty®, as these are complex, multicomponent product

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[156] Interview of Dr. Griffin; Exhibit 1208 ("What is the Novavax vaccine, and why does the world need another type of COVID-19 vaccine?" Gavi, February 14, 2022 (accessed: https://www.gavi.org/vaccineswork/what-novavax-vaccine-and-why-does-world-need-another-type-covid-19-vaccine)).
[157] Exhibit 1209 ("Tracking Coronavirus Vaccinations Around the World," The New York Times, March 13, 2023 (accessed: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html)).
[158] Exhibit 1238 ("Is Novavax a Buy Now?" The Motley Fool, March 4, 2024 (accessed: https://www.fool.com/investing/2024/03/04/is-novavax-a-buy-now/)); Exhibit 1239 ("Novavax's COVID-19 Shot Just in Time, Optimism Surrounds As Demand Picks Up Momentum," Business Insider, October 4, 2023, (accessed: https://markets.businessinsider.com/news/stocks/novavax-s-covid-19-shot-just-in-time-optimism-surrounds-as-demand-picks-up-momentum-1032679259)).
[159] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 73-75.
[160] Interview of Dr. Griffin.
[161] I understand that "'when the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process,' the patentee is not entitled to a presumption of nexus." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

offerings[162] that came to market at a time of an unprecedented widespread pandemic. This is discussed in greater detail below.

82. Mr. Malackowski relied upon Dr. Krause's opinions regarding the nexus between sales of Spikevax® and Comirnaty® and the '600 patent and the '127 patent.[163] Mr. Malackowski then stated that "the tremendous market success of Spikevax® and Comirnaty® is a direct result of the inventions claimed in the '600 and '127 patents."[164] Mr. Malackowski did not provide economic, financial, or commercial evidence or analysis supporting that Spikevax® and Comirnaty® are the direct result of the claims of the '600 patent and '127 patent.

83. As I will discuss, Mr. Malackowski also did not account for unpatented or broader economic factors driving the success of Spikevax® and Comirnaty®. Governments and public health officials played a significant

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[162] Interview of Dr. Griffin.

[163] Exhibit 2197 (Malackowski Declaration), ¶ 23 ("I rely on the opinions of Dr. Krause concerning the nexus between the challenged claims of the '600 and '127 patents and the market success of Spikevax® and Comirnaty®. According to Dr. Krause, Comirnaty® and Spikevax® embody the challenged claims of the '600 and '127 patents. I further understand that Dr. Krause's opinion is that the betacoronavirus mRNA-LNP vaccine platform claimed by the '600 and '127 patents is critical to the clinical success of Spikevax® and Comirnaty® and that the patented features are responsible for driving safety and efficacy of Spikevax® and Comirnaty®."). Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 32-33 ("Q. And you didn't do the analysis to determine whether there was nexus? A. I rely upon Dr. Krause, as described in my report. Q. So you don't have an opinion on whether or not there's nexus? A. I'm not offering that technical opinion as to whether or not there's nexus or a legal opinion. It is my understanding that there is based upon the work with Dr. Krause."). *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 32 (stating, "my understanding in the framework for my analysis was that it's binary, that there is there a nexus or there is not. There may be a nexus with more than just the technology. But as long as the technology is – meets the threshold, then it should be considered.").

[164] Exhibit 2197 (Malackowski Declaration), ¶ 10.

role in the vaccine development process and encouraging public adoption of mRNA vaccines through vaccine subsidies and significant marketing efforts, for example.

84. I organize the remainder of this section as follows. First, I discuss mRNA technologies in general, and various technological developments related to mRNA. Next, I discuss other considerations that are unique to mRNA vaccines, including unique distribution requirements and other intangibles. Finally, I discuss broader economic circumstances, and the roles that regulatory forces, including the U.S. Federal government, and vaccine subsidies played in the commercial success of mRNA technologies.

4.1 mRNA Technological Developments

85. Mr. Malackowski did not opine that the '600 patent or the '127 patent creates the sole basis for demand for Spikevax® or Comirnaty®, treating the nexus inquiry as purely "binary."[165] According to Mr. Malackowski, "there may, in fact, be other technologies" in Spikevax® or and Comirnaty®, and the '600 and '127 patents met a "threshold" in his mind.[166]

[165] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 44-45. *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 32 (stating, "my understanding in the framework for my analysis was that it's binary, that there is there a nexus or there is not. There may be a nexus with more than just the technology. But as long as the technology is – meets the threshold, then it should be considered.").
[166] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 32 and 47.

86. Mr. Malackowski conceded that the ’600 and ’127 patents do not account for the majority of the commercial success of Spikevax® and Comirnaty®.[167] However, Mr. Malackowski did not evaluate the impact of other technologies on demand for Spikevax® or Comirnaty®.[168]

87. As this section will cover, there are numerous technologies that drove the commercial success of Spikevax® and Comirnaty® unrelated to the ’600 and ’127 patents that Mr. Malackowski disregarded. The contributions of these patents are more limited than Mr. Malackowski claims.

88. For discussion purposes, I address this topic in the following categories: prior art, in-licensing activity and information related to showing multiple technological components. As I will explain in greater detail below, while Comirnaty® and Spikevax® were the first mRNA vaccines that were commercialized,[169] there are other mRNA technologies that impacted the success of these vaccines and limit the nexus of the ’600 and ’127 patents to the commercial success Spikevax® and Comirnaty®.[170] Mr. Malackowski did

[167] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 101-103. Mr. Malackowski also did not meaningfully consider the relative impact of the ’600 patent or the ’127 patent on driving demand. Here, too, Mr. Malackowski testified that his understanding is that there is no “requirement to say that the patented technology here must be the most important or the most impactful in order to meet the conditions of commercial success.” *See* Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 47-51.
[168] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 47.
[169] Exhibit 1240 (“This was mRNA’s breakout year,” ACS Publications website, December 6, 2021 (accessed: https://pubs.acs.org/doi/10.1021/cen-09944-cover2)).
[170] Interview of Dr. Griffin.

not support his conclusion that commercial success is attributable to the ’600 patent and/or the ’127 patent.

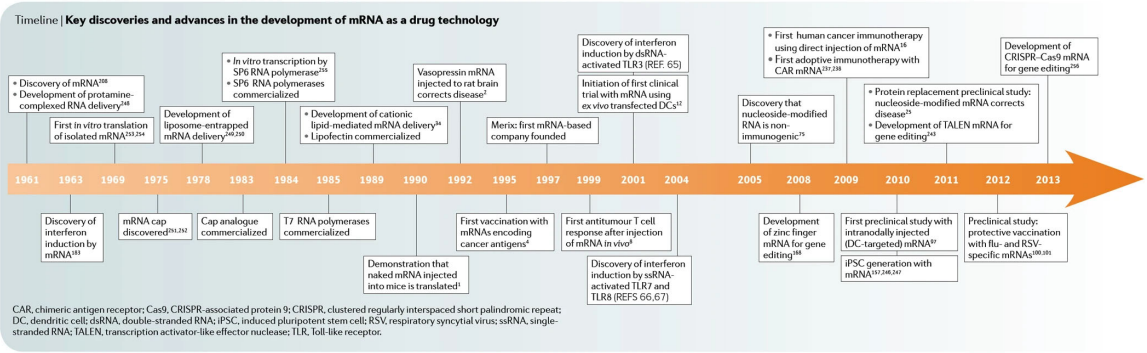
mRNA Vaccine Technologies: Prior Art and Moderna's Place in the Technological Path

89. As Mr. Malackowski acknowledged, the “emergence of COVID-19 in early 2020 set off a global race to develop vaccines against the virus.”[171] However, mRNA advancements were decades in the making before the asserted priority dates of the ’600 patent, the ’127 patent, and long before Comirnaty® and Spikevax® were developed and approved.[172]

90. Simply put, there have been decades of research by many hundreds of scientists towards mRNA vaccine technology.[173] A summary of some of the discoveries and advances in the development of mRNA drug technology is provided below:

[171] Exhibit 2197 (Malackowski Declaration), ¶ 13.
[172] Interview of Dr. Griffin; Interview of Dr. Moon.
[173] Interview of Dr. Griffin; Interview of Dr. Moon.

Timeline of Discoveries and Advances in the Development of mRNA Drug Technology[174]



91. There have been countless innovations and several advancements, in particular, have been widely regarded as significant.[175] To this end, Moderna and BioNTech/Pfizer have licensed in some of these same technologies, including patents based upon mRNA technology research by Dr. Katalin Karikó and Dr. Drew Weissman at the University of Pennsylvania and spike stabilization technology owned by the NIH.[176]

92. Not only is the technology in mRNA vaccines complex, through its actions, Moderna recognizes that it does not own exclusivity in the subject matter of these patents.[177] Moderna recognized Dr. Karikó and Dr. Weissman

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[174] Exhibit 1133 (Sahin, U., Kariko, K., and Türeci, O. "mRNA-based therapeutics —developing a new class of drugs" Nature Reviews Drug Discovery, 13, 759–780 (2014) (accessed: https://doi.org/10.1038/nrd4278)).
[175] Interview of Dr. Griffin. *See also*, Exhibit 1241 (Lalani, Hussain S., et al. "US public investment in development of mRNA covid-19 vaccines: retrospective cohort study." British Medical Journal, 380: e073747, March 1, 2023 (accessed: https://doi.org/10.1136/bmj-2022-073747 and https://doi.org/10.1136/bmj.p587)); Exhibit 1133 (Sahin, U., Kariko, K., and Türeci, O. "mRNA-based therapeutics —developing a new class of drugs" Nature Reviews Drug Discovery, 13, 759–780 (2014) (accessed: https://doi.org/10.1038/nrd4278)).
[176] Interview of Dr. Griffin.
[177] Interview of Dr. Griffin.

for their contributions to mRNA research after the Drs. were awarded the 2023 Nobel Prize in Physiology or Medicine for their discoveries.[178] Moreover, Moderna has emphasized the importance of mRNA technologies unrelated to the '600 patent and the '127 patent in the development of mRNA medicines.[179]

93. I understand that many of the discoveries and advances in the development of mRNA as a drug therapy predated the '600 and '127 patents and are not claimed by the '600 and '127 patents.[180] Moderna's previous attempts to commercialize a product with the '600 and '127 patents demonstrate that these patents did not make for a commercially successful product. And to further illustrate this point, the '600 patent discusses a MERS vaccine with a wild-type betacoronavirus target;[181] Moderna did not commercialize a MERS vaccine.[182]

94. Mr. Malackowski did not address the Moderna '574 patent, which is asserted by Moderna against Pfizer and BioNTech in the underlying

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[178] In a congratulatory statement posted on the company's LinkedIn page in response to the award, Moderna stated, "[t]heir work in #mRNA research has helped pave the way for transformative medicines and bring us closer to conquering some of the most challenging diseases. Thank you for your contributions to mRNA research!" *See* Exhibit 1242 (Moderna LinkedIn post (accessed: https://www.linkedin.com/posts/modernatx_breaking-news-the-nobel-assembly-at-karolinska-activity-7114610548184334336-NP4y?utm_source=share&utm_medium=member_desktop)).
[179] *See e.g.,* Exhibit 1243 ("How researchers unlocked mRNA: Learn about mRNA research history," Moderna website, video transcript (accessed: https://www.modernatx.com/en-US/power-of-mrna/about-mrna#how-researchers-unlocked-mrna)).
[180] Interview of Dr. Griffin; Interview of Dr. Moon.
[181] Interview of Dr. Griffin.
[182] Spikevax® was Moderna's first and only commercial product. *See* Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023, p. 6).

lawsuit.[183] Mr. Malackowski concedes that he has not considered the relative impact of the ’574 patent to the ’600 and ’127 patents.[184] Between 2020 and 2023, Moderna’s website listed at least nine additional patents that allegedly cover Spikevax® (other than the ’574 patent and the ’600 patent).[185] Again, Mr. Malackowski set aside all technologies besides the ’600 and ’127 patents.

mRNA Vaccine Technology: In-Licensing Activity

95. There were numerous technological advancements not claimed by the ’600 and ’127 patents that were widely recognized as enabling mRNA

[183] Exhibit 2012 (Complaint for Patent Infringement, *ModernaTX, Inc. et al v. Pfizer Inc. et al*, Case No. 1:22-cv-11378, August 26, 2022).

[184] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 100-102 (“Q. You have an understanding that Moderna has claimed that U.S. patent number 10,898,574 is also practiced by Spikevax and Comirnaty, correct? A. I understand that from the district court litigation, yes. Q. Did you evaluate that technology and how it impacts demand and commercial success for your report in this case? A. Not as identified here in this case. In this case stands alone based upon the two patents that are asserted. Q. So does the ’574 patent impact demand and therefore commercial success of Spikevax and Comirnaty? MS. CURTIS: Object to form. THE WITNESS: That is outside the scope of what I have done here. I'm not presenting a conclusion on the commercial success for purposes of nonobviousness as it relates to that patent. And I haven’t prepared such analysis. Q. So you haven't considered it one way or the other? MS. CURTIS: Object to form. THE WITNESS: I understand that it’s within the products – it’s asserted to be within the products that are at issue here. I don’t dispute that it has contribution to nexus and commercial success. But as I understand the legal test for what’s at issue in this case, the fact that there may be a third Moderna patent that is also responsible for success does not diminish the conclusions that I’ve reached.”)

[185] Exhibit 2034 (“Patents,” Moderna website (accessed: https://www.modernatx.com/en-US/patents). In October 2020, Moderna listed seven U.S. patents. By December 2021, the number of Moderna’s patents had grown to eight. In December 2022, Moderna updated the list to nine U.S. patents. In 2023, Moderna listed ten patents in March before adding an additional patent to list eleven patents total in December. *See* Exhibit 1219 (“Patents,” Moderna website, October 8, 2020 (accessed: https://web.archive.org/web/20201008145751/https://www.modernatx.com/patents)); Exhibit 1220 (“Patents,” Moderna website, December 1, 2021 (accessed: https://web.archive.org/web/20211201193750/https://www.modernatx.com/patents)); Exhibit 1221 (“Patents,” Moderna website, December 5, 2022 (accessed: https://web.archive.org/web/20221205004929/https://www.modernatx.com/patents)); Exhibit 1222 (“Patents,” Moderna website, March 8, 2023 (accessed: https://web.archive.org/web/20230308131232/https://www.modernatx.com/patents)); Exhibit 1223 (“Patents,” Moderna website, December 9, 2023 (accessed: https://web.archive.org/web/20231209004401/https://www.modernatx.com/en-US/patents)).

vaccines. Some of these technologies are reflected in the in-bound licensing activities of Moderna and BioNTech.

96. BioNTech in-licenses patents for Comirnaty® from at least Cellscript LLC ("Cellscript") and the NIH.[186] Moderna also entered into license agreements with Cellscript and the NIH.[187] Mr. Malackowski did not evaluate the impact of this licensed technology on the commercial success of Spikevax® or Comirnaty®.[188] I discuss these agreements and the related intellectual property further below, beginning with the Cellscript patent licenses.

97. The technology that Moderna and BioNTech licensed from Cellscript relates to Dr. Karikó's and Dr. Weissman's work, widely recognized as foundational to the development of mRNA therapeutics.[189] Derrick Rossi, Moderna co-founder, described Dr. Karikó's and Dr. Weissman's work as '"fundamental to th[e] entire field,'" stating that '"it

[186] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, pp. 60, 154-155).
[187] Exhibit 1026 (Patent Sublicense Agreement Between Cellscript, LLC and ModernaTX, Inc.); Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023, pp. 132-133).
[188] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 109-110.
[189] Interview of Dr. Griffin. *See also, e.g.*, Exhibit 1025 ("Katalin Karikó and Drew Weissman awarded Horwitz Prize for pioneering research on COVID-19 vaccines," Columbia University Irving Medical Center, Aug. 16, 2021 (accessed: https://www.cuimc.columbia.edu/news/horwitz-prize-2021)); Exhibit 1124 (Nobel Prize press release, October 2, 2023 (accessed: https://www.nobelprize.org/prizes/medicine/2023/press-release/)).

really is what allows these mRNA vaccines and any mRNA therapeutic down the road.'"[190]

98. According to the American Association for the Advancement of Science, Dr. Karikó's and Dr. Weissman's discovery "that pseudouridine modification of mRNA species enhances their cellular uptake while simultaneously decreasing their immunogenicity and increasing their stability" was a "key discovery in getting mRNA vaccine technology to work, and the research along these lines, which had already been going on for years before the coronavirus pandemic, is absolutely a reason why we had effective vaccines available so quickly."[191] Dr. Karikó and Dr. Weissman were awarded the 2023 Nobel Prize in Physiology for Medicine "for their discoveries concerning nucleoside base modifications that enabled the development of effective mRNA vaccines against COVID-19."[192]

99. The licensing chain for Dr. Karikó's and Dr. Weissman's patented inventions highlights the importance of their discoveries. The

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[190] Exhibit 1024 ("The messenger RNA pioneers everyone ignored," Bloomberg, Nov. 23, 2021 (accessed: https://www.bloomberg.com/news/newsletters/2021-11-23/themessenger-rna-pioneers-everyone-ignored)).
[191] Exhibit 1244 ("A Nobel for Modified mRNA," American Association for the Advancement of Science, October 2, 2023 (accessed: https://www.science.org/content/blog-post/nobel-modified-mrna)).
[192] Exhibit 1124 (Nobel Prize press release, October 2, 2023 (accessed: https://www.nobelprize.org/prizes/medicine/2023/press-release/)). *See also*, Exhibit 1024 ("The messenger RNA pioneers everyone ignored," Bloomberg, Nov. 23, 2021 (accessed: https://www.bloomberg.com/news/newsletters/2021-11-23/themessenger-rna-pioneers-everyone-ignored)), in which Moderna co-founder, Derrick Rossi, stated '"I believe it's going to earn [Dr. Karikó and Dr. Weissman] a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutic down the road."

Trustees of the University of Pennsylvania provided mRNA RiboTherapeutics, Inc. ("mRNA RiboTherapeutics") with an exclusive license "for certain intellectual property comprising patents, patent applications and technology relating to the use of modified ribonucleic acid (RNA) technology which was developed by Drs. Drew Weissman and Katalin Karikó of Penn's Perelman School of Medicine…"[193]

100. Subsequently, Cellscript received a sublicense from mRNA RiboTherapeutics in certain fields of use, with rights to further sublicense all or any part of the rights granted to Cellscript to other parties.[194] In 2017, Cellscript sublicensed these patent rights to both Moderna[195] and BioNTech.[196]

101. Both Moderna and BioNTech pay royalties to Cellscript for Spikevax® and Comirnaty®.[197] Nevertheless, Mr. Malackowski did not evaluate the impact of the Cellscript patents to the commercial success of Spikevax® or Comirnaty®.[198]

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[193] Exhibit 1026 (Patent Sublicense Agreement Between Cellscript, LLC and ModernaTX, Inc.); Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, Exhibit 4.12).
[194] Exhibit 1026 (Patent Sublicense Agreement Between Cellscript, LLC and ModernaTX, Inc.); Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, Exhibit 4.12).
[195] Exhibit 1026 (Patent Sublicense Agreement Between Cellscript, LLC and ModernaTX, Inc.).
[196] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, Exhibit 4.12).
[197] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 109.
[198] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 109-110.

102. The NIH technology licensed to Moderna[199] and BioNTech[200] relates to another important development in stabilizing the spike protein, this being largely credited to Dr. Graham and the National Institute of Allergy and Infectious Diseases ("NIAID") at the NIH related to the antigen.[201] Moderna described the NIH technology as "patent rights concerning stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products."[202] Mr. Malackowski admitted that he did not evaluate the impact of the NIH patents to the commercial success of Spikevax® or Comirnaty®, either.[203]

103. The agreements discussed above illustrate that in this vaccine field, and for Spikevax® and Comirnaty®, we are dealing with complex, multicomponent technologies.[204] Mr. Malackowski disregarded this—and, indeed, did not view the vaccines as being multicomponent products nor

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[199] Exhibit 1272 (Moderna Form 10-K for the year ended December 31, 2022), p. 46. Moderna has paid more than $400 million to NIH. *See* Exhibit 1245 ("Moderna Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Updates," Moderna press release, February 23, 2023 (accessed: https://investors.modernatx.com/news/news-details/2023/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2022-Financial-Results-and-Provides-Business-Updates/default.aspx)).
[200] Exhibit 1246 (NIH Technology Transfer Annual Report for the year ended December 31, 2021, pp. 48-49 (accessed: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/FY2021%20NIH%20Technology%20Transfer%20Annual%20Report.pdf)); Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, p. 147).
[201] Interview of Dr. Griffin.
[202] Exhibit 2125 (Moderna Form 10-K for the year ended December 31, 2023), p. 147.
[203] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 113-114.
[204] Interview of Dr. Griffin.

evaluate the effect of any technologies on their success other than the ’600 and ’127 patents.[205]

104. Moreover, there are technologies specific to LNPs and lipid delivery system technology.[206] For example, Moderna claims that it “invested heavily in delivery science” by December 2018.[207] A recognized leader in lipid technology during that timeframe was Acuitas,[208] and its founder, Dr. Pieter Cullis, is credited with groundbreaking work that helped develop lipid nanoparticles.[209] Acuitas has been able to “synthesize over 500 novel cationic lipids,” evaluating these compounds in LNP.[210]

105. In 2017, BioNTech and Acuitas entered into a Development and Option Agreement under which BioNTech had “options to take licenses under the Acuitas LNP Technology[211] with respect to BioNTech’s mRNA

[205] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 73-75
[206] Interview of Dr. Moon.
[207] Exhibit 1247 (Moderna Form 10-K for the year ended December 31, 2018), p. 14.
[208] Interview of Dr. Moon; Exhibit 1248 (“Acuitas Therapeutics Non-Confidential Presentation,” Acuitas website, November 11, 2018 (accessed: https://acuitastx.com/wp-content/uploads/2018/11/Acuitas-non-confidential-overview_Nov_2018.pdf)).
[209] Interview of Dr. Moon; Exhibit 1241 (Lalani, Hussain S., et al. “US public investment in development of mRNA covid-19 vaccines: retrospective cohort study.” British Medical Journal, 380: e073747, March 1, 2023 (accessed: https://doi.org/10.1136/bmj-2022-073747 and https://doi.org/10.1136/bmj.p587)).
[210] Exhibit 1249 (“Our Journey,” Acuitas website (accessed: https://acuitastx.com/company/our-journey/)).
[211] “Acuitas LNP Technology” was defined as “any and all LNP Technology Controlled by Acuitas or any of its Affiliates as of the License Agreement Effective Date or at any time during the Term, including Acuitas’ right and interest in any Technology created, conceived or reduced to practice under the Development and Option Agreement and necessary or useful for the research, development, manufacturing and commercialization of Licensed Products. Unless otherwise set forth herein, Acuitas LNP Technology will exclude Jointly Owned Patents and Dual Improvement Patents.” *See* Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023, Exhibit 4.37).

constructs."[212] In April 2020, BioNTech entered into a Non-Exclusive License Agreement with Acuitas,[213] licensing BioNTech under "Acuitas's LNP technology to develop, manufacture and commercialize licensed products directed to the SARS-CoV-2 surface glycoprotein."[214] According to BioNTech, the licensed technology is "relevant to proprietary lipid nanoparticles and formulations used in BNT162b2" (*i.e.,* Comirnaty®).[215]

mRNA Vaccine Technology: Multiple Technological Components

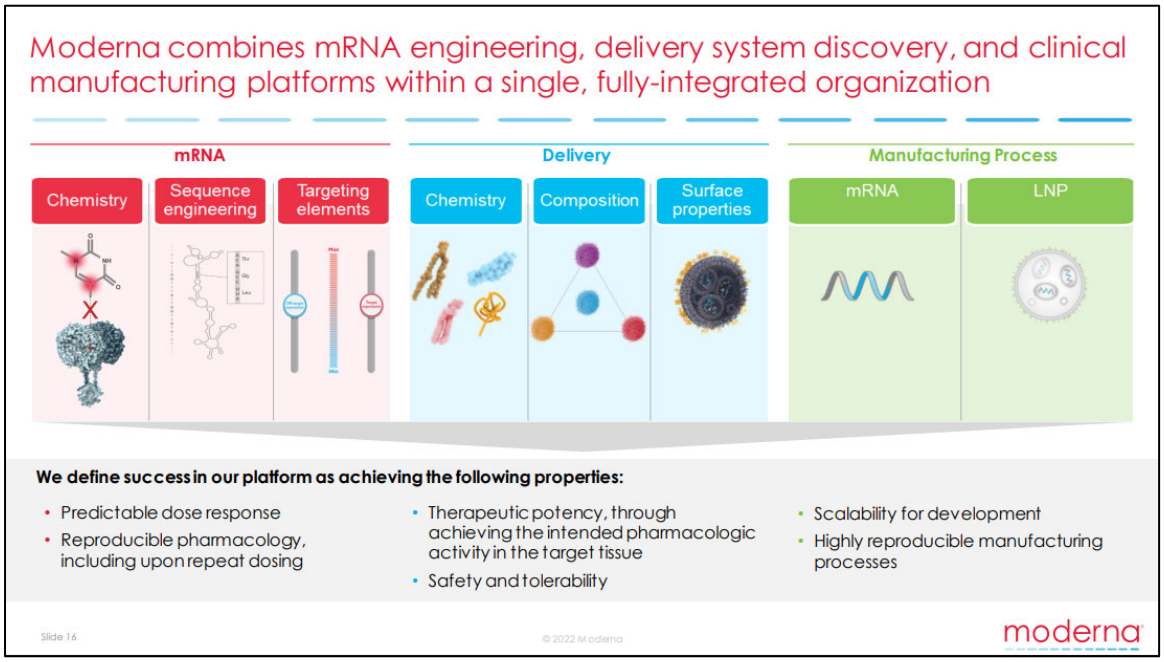
106. While I just recapped some of the more widely mentioned mRNA technologies, I understand there to be additional technological components of a COVID-19 mRNA vaccine.[216] Indeed, according to Moderna, achieving the pharmacologic properties by which it defines the success of its mRNA platform "requires many, often interdependent, technological solutions."[217]

107. The following page from a May 2022 Moderna presentation documents the multi-component nature of mRNA products.[218] As one slide

[212] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023), Exhibit 4.37.
[213] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023), p. 155 and Exhibit 4.37.
[214] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023), p. 155.
[215] Exhibit 2121 (BioNTech Form 20-F for the year ended December 31, 2023), p. 148.
[216] Interview of Dr. Griffin; Interview of Dr. Moon.
[217] Exhibit 1247 (Moderna Form 10-K for the year ended December 31, 2018), p. 11.
[218] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf), slide 16).

describes, Moderna "combines mRNA engineering, delivery system discovery, and clinical manufacturing platforms within a single, fully-integrated organization:"

Excerpt From Moderna May 2022 Presentation
Moderna Science & Technology Day[219]



108. According to the red, blue and green headers on Moderna's slide, there are three steps involved in the mRNA platform: mRNA, delivery, and manufacturing process.[220] There are also multiple aspects within each of the three major categories shown: mRNA (chemistry, sequencing engineering,

[219] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf), slide 16).
[220] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf), slide 16).

and targeting elements), delivery (chemistry, composition, and surface properties), and manufacturing process (mRNA as a drug substance, and LNP as a drug product).[221] The Moderna document indicates that these can be further broken down into smaller sub-components. For example, the chemistry of the product can be disaggregated into several sub-components, such as the particular ionizable lipid, sterol, phospholipid, and PEG lipid.[222]

109. Remarkably, Mr. Malackowski testified that he "wouldn't view it [Spikevax®] as multiple parts or components of technology."[223] While Mr. Malackowski acknowledged that "there was engineering related to the development of the product that spanned a number of technologies," he also testified "I would view the vaccine as a product, which is based on a formulation or certain engineering. But *I don't see this as a componentized product*."[224]

110. Although they are vaccines, Spikevax® and Comirnaty® are complex, multicomponent products.[225] There are many technologies, many of which can be claimed to be of "critical importance." This limits the impact

[221] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf), slide 16).
[222] Exhibit 1102 ("Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf), slides 19-20).
[223] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), p. 73.
[224] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 73-74. Emphasis added.
[225] Interview of Dr. Griffin.

of any one specific patented technology, even if it is "critically important." By his own admission, Mr. Malackowski did not consider this dynamic. Mr. Malackowski also did not, and cannot, support his claim that the commercial success of Spikevax® and Comirnaty® are owed specifically to the '600 and the '127 patents.

4.2 Other Intangible Contributions Towards COVID-19 Product Commercialization

111. In addition to patented technologies, there are also other considerations that relate to Spikevax® and Comirnaty®. Other intellectual property (*e.g.,* trade secrets, as discussed above) and intangible assets (*e.g.,* know-how and assembled workforce) can contribute to the commercial

success of a product.[226] There are also macroeconomic and regulatory considerations.[227] That is all very much the case here.

112. According to Mr. Malackowski, citing Dr. Krause, "the superior efficacy, safety, and rapid development timelines for Spikevax® and Comirnaty® are attributable to the technologies claimed in the '600 and '127 patents."[228] But as I will explain below, that is an oversimplification.[229]

Research and Development Efforts: Significant Intangible Assets

113. Pfizer and BioNTech "tested at least 20 vaccine candidates for COVID-19 utilizing different RNA technologies and encoding for different antigens;" according to Mr. Malackowski, this is evidence of the commercial success of these two patents.[230] Mr. Malackowski did not identify particular

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[226] According to the Appraisal Foundation, when valuing intangible assets, "the valuation specialist needs to identify other assets that are contributing to the generation of the asset group's earnings." When allocating value to the various intangible assets of a business, it is important to identify and measure the value of not just the pivotal intangible assets, but also the routine intangible assets, each of which may contribute to value. That is because products, services, or processes of a successful business evolve from investments in developmental, operational, and commercial activities. Pivotal assets have also been referred to as unique or scarce assets as their functions are not available from alternative sources. "Best Practices for Valuations in Financial Reporting: Intangible Asset Working Group – Contributory Assets, The Identification of Contributory Assets and Calculation of Economic Rents." The Appraisal Foundation, May 31, 2010. The American Institute of Certified Public Accountants ("AICPA") accounting practice and valuation guide describes that "the estimate of an intangible asset's fair value" includes deductions for "Contributory asset charges, also referred to as *economic rents*… to isolate remaining or 'excess earnings' attributable solely to the intangible asset being valued." According to the AICPA, "[t]he contributory asset charge is a deduction for the contribution of supporting assets (for example, net working capital, fixed assets, customer relationships, trade names, and so on) to the generation of the prospective cash flows." "Assets Acquired to Be Used in Research and Development Activities." *See* Exhibit 1250 (AICPA Accounting & Valuation Guide, updated as of May 1, 2013).
[227] For simplicity and clarity of discussion, I refer to this together with "intangibles," or "intangible assets."
[228] Exhibit 2197 (Malackowski Declaration), ¶ 17.
[229] I interviewed Dr. Griffin about this, and he shares this view.
[230] Exhibit 2197 (Malackowski Declaration), ¶¶ 10 and 14.

inventions of the ’600 or ’127 patents that caused those candidates to be selected, or identify which of the candidates included the ‘600 or ‘127 patents. Mr. Malackowski also did not evaluate the actual technologies within Spikevax® and Comirnaty®.[231] Mr. Malackowski thus cannot reasonably claim that the reason the chosen candidate was selected was attributable to the ’600 and ’127 patents.[232]

114. In short, Mr. Malackowski merely cited that the selected candidates practice these patents. I understand that this is not sufficient for establishing nexus.[233]

115. Instead of testing one candidate or prototype at a time, BioNTech and Pfizer decided to build and test multiple vaccines in parallel.[234] Doing so

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[231] Exhibit 2197 (Malackowski Declaration), ¶ 23 (“I rely on the opinions of Dr. Krause concerning the nexus between the challenged claims of the ’600 and ’127 patents and the market success of Spikevax® and Comirnaty®. According to Dr. Krause, Comirnaty® and Spikevax® embody the challenged claims of the ’600 and ’127 patents. I further understand that Dr. Krause’s opinion is that the betacoronavirus mRNA-LNP vaccine platform claimed by the ’600 and ’127 patents is critical to the clinical success of Spikevax® and Comirnaty® and that the patented features are responsible for driving safety and efficacy of Spikevax® and Comirnaty®.”). Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 32-33 (“Q. And you didn’t do the analysis to determine whether there was nexus? A. I rely upon Dr. Krause, as described in my report. Q. So you don’t have an opinion on whether or not there's nexus? A. I’m not offering that technical opinion as to whether or not there's nexus or a legal opinion. It is my understanding that there is based upon the work with Dr. Krause.”).

[232] Interview of Dr. Griffin.

[233] *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006); *Novartis AG v. Torrent Pharmaceuticals Limited*, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017); *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008).

[234] Exhibit 1251 (“First Quarter 2020: Corporate update and financial results,” BioNTech website, May 12, 2020, slides 4-5 (accessed: https://investors.biontech.de/static-files/7700eaa3-12b1-43e1-855e-d7c08856b9b8)).

required a highly skilled, assembled workforce, including extensive scientific knowledge and know how. This is an intangible asset in and of itself.[235]

116. Moderna's approach was different. Moderna "spent more than a decade developing [its] platform to advance mRNA medicines."[236] Moderna's CEO, Stéphane Bancel, stated that Moderna had invested "more than $2 billion of capital" in the decade prior to the COVID-19 pandemic.[237] Moderna thus took one candidate, mRNA-1273, to clinical trials.[238] Nevertheless, even for Moderna, assets and intangibles that were not the '600 patent and the '127 patent contributed to the speed of development for Spikevax®.

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[235] Exhibit 1254 ("A Guide to Valuation of the Assembled Workforce Intangible Asset," American Bankruptcy Institute website, October 1, 2006 (accessed: https://www.abi.org/abi-journal/a-guide-to-valuation-of-the-assembled-workforce-intangible-asset)).
[236] Exhibit 1255 ("Leveraging 13 Years of Investment in mRNA Innovation for Future Pandemic Preparedness," Moderna website (accessed: https://www.modernatx.com/en-US/media-center/all-media/blogs/leveraging-13-years-of-investment-in-mrna)); Exhibit 1256 ("How the Moderna Covid-19 mRNA vaccine was made so quickly," CNBC website, July 3, 2021 (accessed: https://www.cnbc.com/2021/07/03/how-moderna-made-its-mrna-covid-vaccine-so-quickly-noubar-afeyan.html)).
[237] Exhibit 1257 ("How Moderna is racing to a coronavirus vaccine," MIT Sloan website, April 3, 2020 (accessed: https://mitsloan.mit.edu/ideas-made-to-matter/how-moderna-racing-to-a-coronavirus-vaccine)).
[238] Exhibit 1175 ("Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study," Moderna press release, February 24, 2020 (accessed: https://s29.q4cdn.com/435878511/files/doc_news/2020/02/24/moderna-ships-mrna-vaccine-against-novel-coronavirus-mrna-1273.pdf)).

Complex Supply Chain Requirements: Other Intangibles

117. There are "many technical peculiarities of vaccines, such as their production and delivery, that have economic policy implications."[239] With vaccines, developing and managing the supply chain and distribution channels is critical, and "standards are set for transporting and storing vaccines from production to using a cold chain."[240] Overcoming supply and distribution challenges for Spikevax® and Comirnaty®—in the face of a pandemic—was yet another consideration in the commercial success of Spikevax® and Comirnaty®. Moreover, governments and public health officials also led efforts to help ensure vaccine supply (*see* **Section 2.3**).

118. Pfizer's infrastructure as a global vaccine supplier provided an advantage in commercializing Comirnaty®.[241] Prior to the pandemic, Pfizer had established chemistry, manufacturing, and controls ("CMC"); distribution; and regulatory capabilities.[242] Pfizer has extensive

[239] Exhibit 1225 (Bishai, D. et al, *Handbook of Applied Health Economics In Vaccines,* Oxford University Press, 2023), p. 3.
[240] Exhibit 1225 (Bishai, D. et al, *Handbook of Applied Health Economics In Vaccines,* Oxford University Press, 2023), p. 5.
[241] I understand that pre-existing market share can be a consideration. *See Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC,* 618 F.3d 1294, 1304 (Fed. Cir. 2010).
[242] *See, e.g.*, Exhibit 1258 ("The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine: From the Pharmaceutical Scientists' Perspective," NIH website, September 18, 2022 (accessed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9482796/)).

commercialization and manufacturing expertise.[243] Moderna has also touted its history with mRNA, including development of "storage and handling requirements."[244] These are also intangible assets that contribute towards commercial success.

119. But this was not enough; from both Pfizer/BioNTech's and Moderna's perspectives, supply chain developments and efforts contributed to the commercial success of Comirnaty® and Spikevax®.[245]

120. Pfizer, BioNTech and Moderna had to develop distribution channels and supply chains for mRNA. Mike McDermott, Chief Global Supply Chain Officer and Executive Vice President at Pfizer, led efforts to scale up and manufacture the vaccine.[246] According to Mr. McDermott, who

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[243] In an interview with Industry Week, Mike McDermott, Chief Global Supply Chain Officer and Executive Vice President at Pfizer, stated, that prior to the pandemic, Pfizer was able to "produce 200 million doses of all our vaccines combined." According to Mr. McDermott, Pfizer had "35 manufacturing locations around the world, and we repurposed 10 of those almost overnight to produce the vaccines." Additionally, Mr. McDermott said Pfizer was able to leverage its "30,000 colleagues around the world and they brought forward their best ideas and their experience." *See* Exhibit 1259 ("Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)).

[244] Exhibit 1260 ("The power of mRNA," Moderna website (accessed: https://www.modernatx.com/en-US/power-of-mrna/modernas-mrna-platform)); Exhibit 1261 ("Updated vaccines. Consistent storage," Moderna website (accessed: https://spikevax.com/healthcare-provider-guide/helpful-vaccine-resource-tools)).

[245] *See, e.g.,* Exhibit 1262 ("Shot of a Lifetime: How Two Pfizer Manufacturing Plants Upscaled to Produce the COVID-19 Vaccine in Record Time," Pfizer website (accessed: https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_two_pfizer_manufacturing_plants_upscaled_to_produce_the_covid_19_vaccine_in_record_time)); Exhibit 1263 ("None of us were ready" to manufacture genetic vaccines for a billion people," MIT Technology Review, December 17, 2020 (accessed: https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability-stephane-bancel-ceo/)).

[246] Exhibit 1259 ("Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)).

was interviewed by Industry Week, Pfizer was '"able to leverage our core capabilities of making high-quality medicine and vaccines, and then apply it in a different way"' despite the fact that "the technology to produce the mRNA vaccine commercially was new."[247]

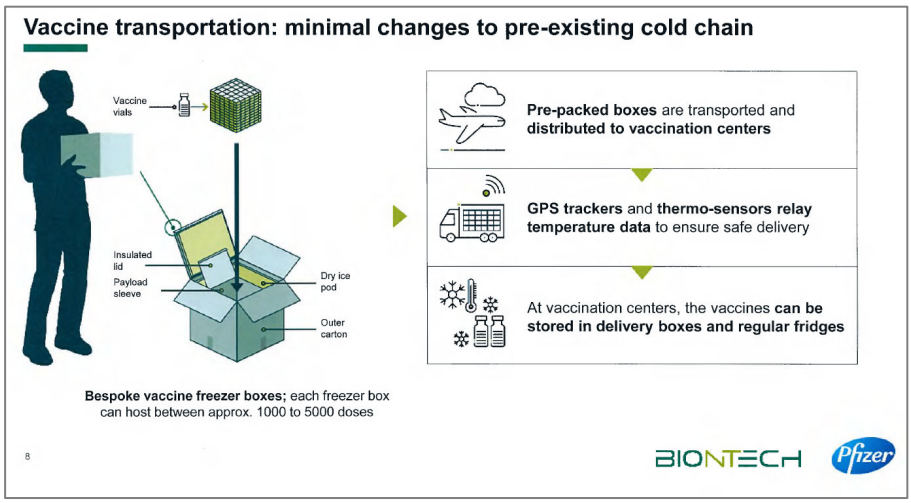
121. One specific challenge was that Comirnaty® needed to be stored at around -70 degrees Celsius.[248] To address this need, Pfizer designed specialty boxes that could deliver the vaccines—and, in fact, became the biggest manufacturer and producer of dry ice in the world.[249] Pfizer also established "freezer farms" where doses could be stored at ultra-low temperatures before or after shipment.[250] When many flights were grounded due to COVID-19, Pfizer chartered more than 500 aircraft to ensure delivery

[247] Exhibit 1259 ("Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)).
[248] Exhibit 1264 ("Here's Why COVID-19 Vaccines Like Pfizer's Need to be Kept So Cold," Science News, November 20, 2020 (accessed: https://www.sciencenews.org/article/coronavirus-covid-19-why-vaccines-cold-freeze-pfizer-moderna)).
[249] Exhibit 1262 (Shot of a Lifetime: How Two Pfizer Manufacturing Plants Upscaled to Produce the COVID-19 Vaccine in Record Time," Pfizer website (accessed: https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_two_pfizer_manufacturing_plants_upscaled_to_produce_the_covid_19_vaccine_in_record_time)).
[250] Exhibit 1259 ("Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)); Exhibit 1265 ("Accelerating Digital Technology for the COVID-19 Vaccine Rollout," Pfizer website, March 2022 (accessed: https://www.pfizer.com/news/behind-the-science/accelerating-digital-technology-covid-19-vaccine-rollout)).

of its vaccines, coordinating with United Airlines to convert passenger aircraft to ship its product.[251]

122. A summary of vaccine transportation for Comirnaty® is provided in the following document:

Excerpt From December 2020 Presentation
Comirnaty® Vaccine Transportation[252]



123. As this shows, vaccine transportation for Comirnaty® required "bespoke vaccine freezer boxes,"[253] and considerable other logistical effort and innovation. In 2022, Pfizer received the 2022 Supply Chain Award for Customer or Patient Innovation from Gartner, recognizing Pfizer and

[251] Exhibit 1266 ("United Airlines Begins Pfizer COVID-19 Vaccine Charter Flights," Airline Geeks website, November 28, 2020 (accessed: https://airlinegeeks.com/2020/11/28/united-airlines-begins-pfizer-charter-flights/)).
[252] Exhibit 1267 ("Update on our COVID-19 vaccine," BioNTech website, December 22, 2020 (accessed: https://investors.biontech.de/static-files/3193fc38-2158-45df-a19c-b9e294db3f11)).
[253] Exhibit 1267 ("Update on our COVID-19 vaccine," BioNTech website, December 22, 2020 (accessed: https://investors.biontech.de/static-files/3193fc38-2158-45df-a19c-b9e294db3f11)).

BioNTech's innovations that enabled storing and shipping doses of the vaccine at an extremely low temperature.[254]

124. A November 2020 press release describes how Pfizer and BioNTech came together to create supply chain channels.[255] Pfizer and BioNTech created additional value towards commercial success by developing a chain for global distribution, including raw materials, packaging supplies, drug substance (mRNA), drug product formulation, vial filling, and cold storage.[256]

125. As for Moderna, in an interview with the MIT Technology Review, Mr. Bancel highlighted the importance of supply and manufacture of large volumes compared to vaccine technology.[257] And in 2021, Moderna

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[254] Exhibit 1269 ("Pfizer Wins 2022 Supply Chain Award," Gartner (accessed: https://www.gartner.com/en/supply-chain/trends/supply-chain-award-winner-2022-pfizer)).

[255] Exhibit 1268 ("Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints," Pfizer website, November 18, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine)). *See also*, Exhibit 1251 ("First Quarter 2020: Corporate update and financial results," BioNTech website, May 12, 2020, slide 8 (accessed: https://investors.biontech.de/static-files/7700eaa3-12b1-43e1-855e-d7c08856b9b8)).

[256] Exhibit 1259 ("Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)); Exhibit 1270 ("Pfizer and BioNTech Achieve First Authorization in the World for a Vaccine to Combat COVID-19," Pfizer website, December 2, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-achieve-first-authorization-world)).

[257] Exhibit 1263 ("None of us were ready" to manufacture genetic vaccines for a billion people," MIT Technology Review, December 17, 2020 (accessed: https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability-stephane-bancel-ceo/)). In Mr. Bancel's words, '"I am not worried about the EUA [emergency-use authorization], because the data is the data. I am worried about making more product."'

addressed issues scaling production in Europe and supplying doses to the United Kingdom.[258]

126. Both Moderna and Pfizer worked with various public sector entities to commercialize each company's COVID vaccines, including the U.S. government in particular. There was widespread recognition that such efforts and commitments helped to develop supply chains and support overall confidence in mRNA vaccines (*see* **Section 2.3**). Even after September 2023, Moderna and Pfizer contracted with retail customers, clinics, hospitals, universities, and other types of purchasers for Spikevax® and Comirnaty®.[259]

127. Manufacturing processes for pharmaceuticals fall under FDA regulation.[260] Know-how associated with obtaining FDA approval, and the know-how associated with the ability to conduct clinical trials and comply with the rigors of regulation provide examples of intangible assets related to commercial success.[261]

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[258] Exhibit 1271 ("Moderna struggling to supply promised doses of Covid vaccine," The Guardian, April 16, 2021 (accessed: https://www.theguardian.com/world/2021/apr/16/moderna-struggling-to-supply-promised-doses-of-covid-vaccine)).

[259] Exhibit 1272 (Moderna Form 10-K for the year ended December 31, 2022), p. 10; Exhibit 1184 (Pfizer Form 10-K for the year ended December 31, 2023), p. 55.

[260] Exhibit 1273 (FDA, Current Good Manufacturing Practices (CGMP) Regulations (accessed: https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmpregulations)).

[261] Illustrating this, Novavax's failure to secure timely regulatory approval of its manufacturing process was a reason its efficacious vaccine did not achieve earlier commercial success. *See* Exhibit 1207 ("What You Need to Know About the Novavax Protein-Based Vaccine," Johns Hopkins, July 14, 2022 (accessed:

Other Intangible Assets

128. There are still other considerations that helped lead towards commercial success. One is marketing.[262] This was not just traditional marketing, either. Pfizer undertook significant efforts to educate consumers on the burden of disease and the need to get vaccinated, as well as to reduce vaccine hesitancy and misinformation.[263] The U.S. government and the private sector also made significant investments in marketing to assure the public of the safety, importance, and efficacy of COVID-19 vaccines. I will discuss this further in **Section 4.3**, when I address macroeconomic and regulatory considerations.

129. If the '600 and '127 patents played as large a role as Mr.

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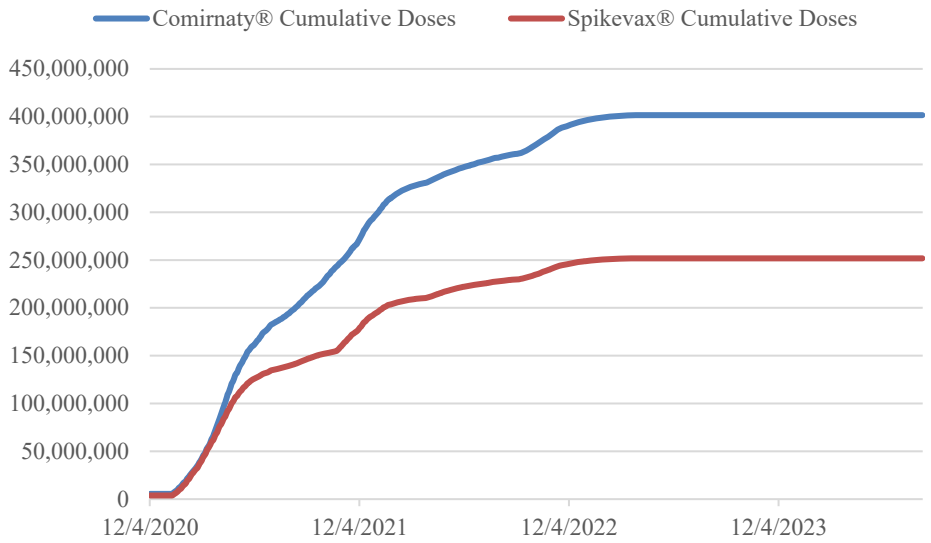
https://publichealth.jhu.edu/2022/what-you-need-to-know-about-the-novavax-protein-based-vaccine)). There are also potentially trade secrets (intellectual property) and assembled workforce (intangible asset), particularly scientific and regulatory talent. *See* Exhibit 2123 (Pfizer Inc. Form 10-K, for the fiscal year ended December 31, 2023), p. 22; Exhibit 1272 (Moderna Form 10-K for the year ended December 31, 2022), p. 42. There are economies of scale and network effects here as well, as organizations and ecosystems are developed around these activities. These are yet other intangible assets that have contributed towards commercial success. *See* Exhibit 1274 ("What Is the Network Effect?" Wharton University of Pennsylvania, January 17, 2023 (accessed: https://online.wharton.upenn.edu/blog/what-is-the-network-effect/)).

[262] *See, e.g.*, *Ritchie v. Vast Resources, Inc.*,563 F.3d 1334, 1336 (Fed. Cir. 2009) ("The commercial success of a product can have many causes unrelated to patentable inventiveness; for example, the commercial success of an 'invention' might be due not to the invention itself but to skillful marketing of the product embodying the invention."); *In re Kluter*, 92 F.2d 906, 908 (CCPA 1937) ("Salesmanship, manufacturing costs, advertising, and many other things may have brought about commercial success where there was no inventive act whatever."); *Prometheus Labs., Inc. v. Roxane Laboratories, Inc.*, 805 F.3d 1092, 1101-02 (Fed. Cir. 2015) (affirming district court's obviousness ruling where nexus was rejected because revenue growth owed to marketing and pricing practices).

[263] In Pfizer's Form 10-K for the year ended December 31, 2020, Pfizer reported sponsoring general advertising to educate the public on "disease awareness" and "prevention and wellness", while adapting their promotional platform by "amplifying" their existing digital capabilities to provide education to customers. *See* Exhibit 1275 (Pfizer Form 10-K for the year ended December 31, 2020), pp. 5 and 27.

Malackowski contends, one would expect for the vaccines' financial performance to be nearly the same. However, as of August 2024, there have been decidedly more Comirnaty® vaccines and boosters administered in the U.S. than Spikevax® vaccines and boosters.[264] The cumulative number of doses administered for Spikevax® and Comirnaty® in the U.S. is illustrated below:

COVID-19 Vaccine Doses Administered By Manufacturer in the United States[265]



130. As illustrated in the foregoing chart, cumulative administered doses of Spikevax® reached approximately 250 million in the United States,

[264] Exhibit 1227 (Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/grapher/covid-vaccine-doses-by-manufacturer?country=~USA)); Exhibit 1276 ("Number of COVID-19 vaccine doses administered in the United States as of April 26, 2023, by vaccine manufacturer," Statista, April 2023 (accessed: https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/)).
[265] Exhibit 1227 (Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/grapher/covid-vaccine-doses-by-manufacturer?country=~USA)).

compared to approximately 400 million for Comirnaty®. From an economic point of view, what this data illustrates is that something else must be driving the difference in the commercial success and consumer preference between the products, even if, as Mr. Malackowski contends, both companies' products allegedly use the '600 patent and the '127 patent.[266] Mr. Malackowski's view that only the '600 patent and the '127 patent matter to the commercial success of Spikevax® and Comirnaty® is further shown to be unreasonable due to this.

131. Business partnerships and relationships are yet another intangible. A September 2021 study published in *Vaccine* found that "nearly one third of all [COVID-19] vaccine candidates were developed by partnerships."[267]

132. BioNTech partnered with both Pfizer and Fosun (as a development and distribution partner in China) to bring a COVID-19 vaccine to patients.[268] Moderna also partnered with NIH to develop and manufacture

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[266] In Pfizer's 2021 fourth quarter earning presentations, dated February 2022, Pfizer informed investors that it was leading in "brand reputation" and 61% of Americans viewed Pfizer favorably, which was up by 33% compared to 2020. *See* Exhibit 1277 ("Fourth Quarter 2021 Earnings Teleconference," Pfizer website, February 8, 2022 (accessed: https://s28.q4cdn.com/781576035/files/doc_financials/2021/q4/Q4-2021-Earnings-Charts-FINAL.pdf)).

[267] Exhibit 1278 (Druedahl, Louise C et al., "Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships," *Vaccine* vol. 39,42, September 2021, 6291-6295 (accessed: doi:10.1016/j.vaccine.2021.08.101)).

[268] See Exhibit 1183 ("Pfizer and BioNTech to Co-develop Potential COVID-19 Vaccine," BioNTech press

Spikevax®.[269] Other notable COVID-19 vaccine collaborations include the vaccine developed by AstraZeneca and University of Oxford, Vaxzervria,[270] as well the VidPrevtyn Beta vaccine developed by Sanofi Pasteur and GSK.[271]

133. The partnerships and relationships led to increased know-how. Such considerations played an important role in expediting the development process, time to market, and distribution. According to a May 2021 McKinsey article, "[a]bove all, the development programs for COVID-19 vaccines will be remembered for an unprecedented level of collaboration among mature, global pharmaceutical companies; young biotech companies; health

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release, March 17, 2020 (accessed: https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-co-develop-potential-covid-19-vaccine)); Exhibit 1279 ("Collaborators," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/collaborators.html)); Exhibit 1278 (Druedahl, Louise C et al., "Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships," *Vaccine* vol. 39,42, September 2021, 6291-6295 (accessed: doi:10.1016/j.vaccine.2021.08.101)). I discuss other agreements that related to the development of Comirnaty® above. I understand BioNTech and Moderna had distribution partnerships as well. *See, e.g.,* Exhibit 1280 ("Pfizer and BioNTech Announce Collaboration With Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America," Pfizer website, August 26, 2021 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-brazils)).

[269] Exhibit 1281 ("As COVID vaccine patent dispute drags on, Moderna forks over $400M to NIH," ARS Technica, February 24, 2023 (accessed: https://arstechnica.com/science/2023/02/moderna-forks-over-400m-to-nih-amid-dispute-over-covid-vaccine-ip/)). I discuss other agreements that related to the development of Spikevax® above.

[270] Exhibit 1282 ("What happened to the AstraZeneca vaccine? Now rare in rich countries, it's still saving lives around the world," The Conversation, May 23, 2022 (accessed: https://theconversation.com/what-happened-to-the-astrazeneca-vaccine-now-rare-in-rich-countries-its-still-saving-lives-around-the-world-181791)); Exhibit 1283 ("Vaxzevria (previously COVID-19 Vaccine AstraZeneca)," European Medicines Agency (accessed: https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca)).

[271] Exhibit 1284 ("VidPrevtyn Beta," Very Well Health, European Medicines Agency (accessed: https://www.ema.europa.eu/en/medicines/human/EPAR/vidprevtyn-beta); Exhibit 1285 ("Coronavirus vaccine trial begun by drug firms GSK and Sanofi," BBC, September 3, 2020 (accessed: https://www.bbc.com/news/business-54009633)).

authorities and regulatory agencies; and a range of public and private institutions that committed funding, research, and other resources."[272]

134. This all further goes to show that commercial success in this field was hardly the function of the laboratory of any one company, any one or two people, or any one or two patented technologies. Adding these facts into the picture that Mr. Malackowski tries to paint markedly attenuates the nexus between the '600 and '127 patents and the commercial success of Comirnaty® and Spikevax®.

4.3 Macroeconomic and Regulatory Considerations

135. Governments and public health officials played a unique and significant role in speeding up the development process, incentivizing the development process for a vaccine, and encouraging public adoption of mRNA vaccines through vaccine subsidies and significant marketing efforts, for example. These types of considerations and actions provided an unusual opportunity for COVID-19 vaccines, including Comirnaty® and Spikevax®. These are additional intangible contributions that helped overcome (at least in large part) issues and concerns with mRNA technology, and were

[272] Exhibit 1286 ("Fast-forward: Will the speed of COVID-19 vaccine development reset industry norms?" McKinsey & Company, May 13, 2021 (accessed: https://www.mckinsey.com/industries/life-sciences/our-insights/fast-forward-will-the-speed-of-covid-19-vaccine-development-reset-industry-norms)).

undoubtedly significant in terms of the commercial success of those two vaccines.[273] Remarkably, Mr. Malackowski did not acknowledge these considerations, or attempt to address whether they contributed to the commercial success of Spikevax® or Comirnaty®.[274] Without this, Mr. Malackowski's conclusions lack context and basis.

136. Let's briefly look at the expedited approval process. The FDA is permitted to "relax its rules and allow certain experimental products to be used by the general population when no proven alternatives existed."[275] By offering EUA—and as the name of Operation Warp Speed itself indicates—the U.S. Federal government expedited COVID-19 vaccine availability.[276] In

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[273] *See, e.g.*, *Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010) (providing that evidence of commercial success "carries little weight" where it may be ascribed to "pre-existing market share"); *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008) (stating, "[w]e have held on a number of occasions that evidence of commercial success alone is not sufficient to demonstrate nonobviousness of a claimed invention. Rather, the proponent must offer proof 'that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter."); *Riverwood Intern. Corp. v. Mead Corp.*, 212 F.3d 1365, 1367 (Fed. Cir. 2000), *reversed on other grounds by Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319 (Fed. Cir. 2004) (stating that evidence of commercial success did not overcome conclusion of obviousness where much of the success was "attributable to factors outside the scope of the claims").

[274] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 21-30 (testifying that he did not measure, for example: the impact of government investment, government contracts, purchasing excess demand, vaccine mandates, the availability of vaccines free of charge for consumers, branded and unbranded vaccine marketing). *See also,* Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 45-51.

[275] Exhibit 1225 (Bishai, D. et al, *Handbook of Applied Health Economics In Vaccines,* Oxford University Press, 2023), p. 28.

[276] Exhibit 1287 ("Emergency Use Authorization for Vaccines Explained," FDA website, November 20, 2020 (accessed: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)). This speedy approval process was not specific to Comirnaty® and Spikevax®. The U.S. government also granted EUAs for Johnson & Johnson's viral vector vaccine and Novavax's viral vector vaccine. *See* Exhibit 1288 ("FDA Issues Emergency Use Authorization for Third COVID-19

fact, governments around the world dedicated funding to vaccine and treatment development for COVID-19.[277]

137. As part of Operation Warp Speed, the U.S. government passed an initial $8.3 billion aid package, including more than $3 billion for vaccine research.[278] The package included negotiated deals for vaccine development and production with Moderna, which received $955 million in funding for development of Spikevax®,[279] a Sanofi-GlaxoSmithKline partnership, Novavax, Johnson & Johnson, and AstraZeneca.[280] Pfizer negotiated an advance supply agreement but did not receive funding.[281]

Vaccine," FDA website, February 27, 2021 (accessed: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine)). Worldwide, AstraZeneca's viral vector vaccine was the first COVID-19 vaccine to be used and comprised the greatest number of doses under some measures. *See* Exhibit 1209 ("Tracking Coronavirus Vaccinations Around the World," New York Times, March 13, 2023 (accessed: https://www.nytimes.com /interactive/2021/world/covid-vaccinations-tracker.html)); Exhibit 1289 ("Oxford / AstraZeneca vaccine reaches two billion dose milestone," University of Oxford website, November 16, 2021 (accessed: https://www.ox.ac.uk/news/2021-11-16-oxford-astrazeneca-vaccine-reaches-two-billion-dose-milestone)).

[277] In Europe, "the European Commission dedicated several hundred million euros to COVID-19 vaccine development." In China, "the government closely oversaw efforts, with developers including Sinopharm being state-run." In addition, the WHO, the World Bank, and others "focused on financing and manufacturing COVID-19 vaccines for global use." *See* Exhibit 1290 ("A Guide to Global COVID-19 Vaccine Efforts," Council on Foreign Relations, December 5, 2022 (accessed: https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts)).

[278] Exhibit 1291 ("Trump signs $8.3 billion emergency coronavirus spending package," CNBC News, March 6, 2020 (accessed: https://www.cnbc.com/2020/03/06/trump-signs-8point3-billion-emergency-coronavirus-spending-package.html)).

[279] Exhibit 1197 ("Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021 (accessed https://crsreports.congress.gov/product/pdf/IN/IN11560/7)).

[280] Exhibit 1196 ("The U.S. has already invested billions in potential coronavirus vaccines. Here's where the deals stand," CNBC, August 14, 2020, (accessed: https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html)).

[281] Exhibit 1292 ("Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2," Pfizer press release, July 22, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government)).

138. Yet another consideration towards commercial success was the guarantee of demand from government purchases. This provided assurance to the overall supply chain that companies would be compensated for taking risks they otherwise might not have. Incentives were provided by governments around the world,[282] and the "massive public investments to subsidize supply of and stimulate demand for COVID-19 vaccines were predicated on a sure forecast that without public investment the free market was doomed to fail."[283]

139. The impact of government purchasing programs was significant for both Spikevax® and Comirnaty®. For several years (*i.e.,* prior to September 2023, when U.S. Federal government purchasing ended), 100% of U.S. revenues and doses sold for both Spikevax® and Comirnaty® were to governmental agencies.[284] By the end of 2023, vaccine sales had gone down precipitously compared to the start of the pandemic. There were less than 500 million doses of Comirnaty® delivered worldwide in 2023, compared to

[282] Exhibit 1241 (Lalani, Hussain S., et al. "US public investment in development of mRNA covid-19 vaccines: retrospective cohort study." British Medical Journal, 380: e073747, March 1, 2023 (accessed: https://doi.org/10.1136/bmj-2022-073747 and https://doi.org/10.1136/bmj.p587)).
[283] Exhibit 1225 (Bishai, D. et al, *Handbook of Applied Health Economics In Vaccines,* Oxford University Press, 2023), p. 3.
[284] According to the U.S. Department of Health and Human Services ("HHS"), vaccine ordering through U.S. Government processes began to phase out on August 3, 2023, "with a formal transition to the commercial market expected in mid-to-late September" of 2023. *See* Exhibit 1171 ("COVID-19 Commercialization," HHS website (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)).

approximately 2.6 billion and two billion doses in 2021 and 2022, respectively.[285] Moderna sales of Spikevax® also declined decidedly in 2023.[286] Mr. Malackowski did not specifically state that there was commercial success in 2024, after government purchasing ended.[287]

140. Providing COVID-19 vaccines for free provided an added incentive and contributed towards commercial success.[288] The U.S. Federal government mandated that insurance companies reimburse healthcare providers for the cost of administering vaccines, but "not for the vaccine itself, since the vaccine was free to providers through the U.S. government

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[285] Exhibit 1215 ("BioNTech Announces Fourth Quarter and Full Year 2023 Financial Results and Corporate Update," BioNTech press release, March 20, 2024, p. 1 (accessed: https://investors.biontech.de/system/files-encrypted/nasdaq_kms/assets/2024/03/20/8-02-08/BNTX%20Q4%202023%20Press%20Release_EN_post-issuance%20update.pdf)); Exhibit 1216 ("BioNTech Announces Fourth Quarter and Full Year 2022 Financial Results and Corporate Update," BioNTech press release, March 27, 2023, p. 2 (accessed: https://investors.biontech.de/node/14871/pdf)); Exhibit 1217 ("BioNTech Announces Fourth Quarter and Full Year 2021 Financial Results and Corporate Update," BioNTech press release, March 30, 2022, p. 1 (accessed: https://investors.biontech.de/node/11911/pdf)). As noted above, 100% of U.S. revenues and doses sold for Comirnaty® were to governmental agencies. *See* Exhibit 1171 ("COVID-19 Commercialization," HHS website (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)).

[286] *See e.g.* Exhibit 1218 ("Moderna Covid vaccine sales plunge by two-thirds in 2023, but meet company's $6 billion forecast," CNBC, January 8, 2024 (accessed: https://www.cnbc.com/2024/01/08/moderna-covid-vaccine-sales-plunge-in-2023-but-meet-company-forecast.html)).

[287] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 20-27 (stating "I don't present a chronology by year or an opinion by year of commercial success this year, not the prior year, or not the following year, for example…" and "I'm not providing year-by-year analysis.")

[288] Exhibit 1293 ("The Covid Vaccine Is Free, but Not Everyone Believes That," The New York Times, June 1, 2021 (accessed: https://www.nytimes.com/2021/06/01/upshot/covid-vaccine-hesitancy-cost.html)).

purchased inventory."[289] Even after government purchasing programs ended, vaccines remained available at no cost to insured and uninsured recipients.[290]

141. There was additional regulatory help. Insurance companies were barred from charging co-payments or deductibles for the vaccines; the vaccine supply agreements that doctors and hospitals signed specified that they could not bill patients for the service.[291]

142. Governments also helped overcome public perceptions about the new vaccines, particularly the mRNA vaccines. According to the *Handbook of Applied Health Economics in Vaccines*, "[i]n many countries, even with the public sector investments, a COVID-19 vaccine at a price of $0 was not attractive to many who were at lower risk and did not appreciate the benefits their shot would offer their community."[292] In the U.S., the Federal

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[289] Exhibit 1294 ("Commercialization of COVID-19 Vaccines, Treatments, and Tests: Implications for Access and Coverage," KFF, February 6, 2024 (accessed: https://www.kff.org/coronavirus-covid-19/issue-brief/commercialization-of-covid-19-vaccines-treatments-and-tests-implications-for-access-and-coverage/)).

[290] Exhibit 1213 ("HHS Launches Bridge Access Program to Safeguard Free COVID-19 Vaccination for Uninsured and Underinsured Adults," CDC Newsroom Releases, September 14, 2023 (accessed: https://www.cdc.gov/media/releases/2023/p0914-uninsured-vaccination.html)); Exhibit 1214 ("FACT SHEET: How Are COVID-19 Vaccines Covered By Insurance?" Covid-19 Vaccine Education and Equity Project, September 2023 (accessed: https://covidvaccineproject.org/wp-content/uploads/2023/09/CVEEP_Youre-Covered_Coverage-Overview_0923.pdf)). The U.S. Federal government also offered vaccines at no cost to citizens without insurance. *See* Exhibit 1295 ("COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured," HRSA, January 1, 2024 (accessed: https://www.hrsa.gov/provider-relief/about/covid-uninsured-claim)).

[291] Exhibit 1296 ("Government Warns Doctors and Insurers: Don't Bill for Covid Vaccines," The New York Times, June 9, 2021 (accessed: https://www.nytimes.com/2021/06/09/upshot/covid-vaccines-government-warning-bills.html)).

[292] Exhibit 1225 (Bishai, D. et al, *Handbook of Applied Health Economics In Vaccines,* Oxford University Press, 2023), p. 3.

government initiated a marketing campaign to educate and build trust surrounding COVID-19 vaccines.[293] In late 2020, the U.S. Federal government began placing radio spots and social media ads.[294] And in 2021, there was a larger initiative with television commercials, public service announcements, radio and online ads. [295]

143. Several states offered creative support for vaccination, including million-dollar lottery entries and college scholarships.[296] Momentum came from other non-government sources, too. For example, Uber and Lyft offered free ride sharing to vaccination centers.[297] Some employers awarded additional paid-time-off and cash rewards to employees who got vaccinated.[298]

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[293] Exhibit 1172 ("Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)).
[294] Exhibit 1172 ("Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)).
[295] Exhibit 1172 ("Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)). Prior to commercialization of the vaccines, advertising conducted in the U.S. was generally "unbranded" initiatives encouraging the public to get vaccinated, and directed patients to websites dedicated to helping patients find doses of either Comirnaty® or Spikevax®. Dr. Fauci, Director of the NIAID, acted as a spokesperson for digital and social media video ads. During the summer of 2021, incentives to encourage the adult population to get vaccinated began, including by the President who asked states to use funds from the American rescue plan to offer $100 vaccine incentives. Exhibit 1303 ("Covid-19: Biden tells states to offer $100 vaccine incentive as cases rise," BBC, July 30, 2021 (accessed: https://www.bbc.com/news/world-us-canada-58020090)).
[296] Exhibit 1297 ("Incentives for COVID-19 Vaccination: Food, Cash, & Other Perks," GoodRx Health, June 24, 2021 (accessed: https://www.goodrx.com/health-topic/vaccines/covid-19-vaccination-incentives)).
[297] Exhibit 1297 ("Incentives for COVID-19 Vaccination: Food, Cash, & Other Perks," GoodRx Health, June 24, 2021 (accessed: https://www.goodrx.com/health-topic/vaccines/covid-19-vaccination-incentives)).
[298] Exhibit 1297 ("Incentives for COVID-19 Vaccination: Food, Cash, & Other Perks," GoodRx Health, June 24, 2021 (accessed: https://www.goodrx.com/health-topic/vaccines/covid-19-vaccination-incentives)).

144. There were also vaccine requirements which took various forms across the country. For example, in November 2021, the city of Los Angeles began enforcing some of the strictest vaccine requirements in the U.S. by requiring residents to show proof of full vaccination before entering restaurants, movie theaters, gyms and other public spaces.[299] In January 2022, the city of Chicago began requiring anyone age five and older to provide vaccination proof to dine indoors, go to a gym, or enter entertainment venues where food and drinks were served.[300] Philadelphia required a vaccine card for entry to any establishment where food and drinks were being served.[301] Some cities enforcing proof of vaccination also fined businesses and individuals for failing to comply.[302]

145. Public health officials also encouraged patients to get booster vaccines.[303] For example, the FDA approved the practice of receiving a

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[299] Exhibit 1298 ("LA Has Imposed One of the US's Strictest Vaccine Mandates. Will It Prevent a Covid Surge?" The Guardian, November 13, 2021 (accessed: https://www.theguardian.com/us-news/2021/nov/13/los-angeles-vaccine-mandate-covid-surge)).
[300] Exhibit 1299 ("Here Are The U.S. Cities Where You Need A Covid Vaccine To Dine In A Restaurant," Forbes, December 22, 2021 (accessed: https://www.forbes.com/sites/carlieporterfield/2021/12/22/here-are-the-us-cities-where-you-need-a-covid-vaccine-to-dine-in-a-restaurant/)).
[301] Exhibit 1299 ("Here Are The U.S. Cities Where You Need A Covid Vaccine To Dine In A Restaurant," Forbes, December 22, 2021 (accessed: https://www.forbes.com/sites/carlieporterfield/2021/12/22/here-are-the-us-cities-where-you-need-a-covid-vaccine-to-dine-in-a-restaurant/)).
[302] Exhibit 1300 ("Key to NYC': Indoor vaccine mandate begins on Tuesday," ABC 7 News, August 16, 2021 (accessed: https://abc7ny.com/nyc-vaccine-pass-proof-of-vaccination-key-to-mandate/10954428/)); Exhibit 1301 ("NYC Slaps 14 Businesses With $1,000 Fines for Violating Vaccine Mandate," Eater, October 12, 2021 (accessed: https://ny.eater.com/2021/10/12/22722297/nyc-business-vaccine-mandate-violations-fines)).
[303] Exhibit 1302 ("Moderna vs Pfizer: Is it OK to mix and match the updated COVID-19 booster shots?" Los Angeles Times, September 23, 2022 (accessed: https://www.latimes.com/california/story/2022-09-23/moderna-vs-pfizer-is-it-ok-to-mix-and-match-the-updated-covid-19-booster-shots)).

different mRNA booster than the original vaccine administered. In addition to providing potential benefits related to efficacy, this was perceived to help with vaccine supply constraints.[304]

146. To recap, in addition to the urgency of the pandemic itself (*see* **Section 2.3**) there was a plethora of macroeconomic and regulatory considerations that drove and supported the commercial success of mRNA COVID-19 vaccines.

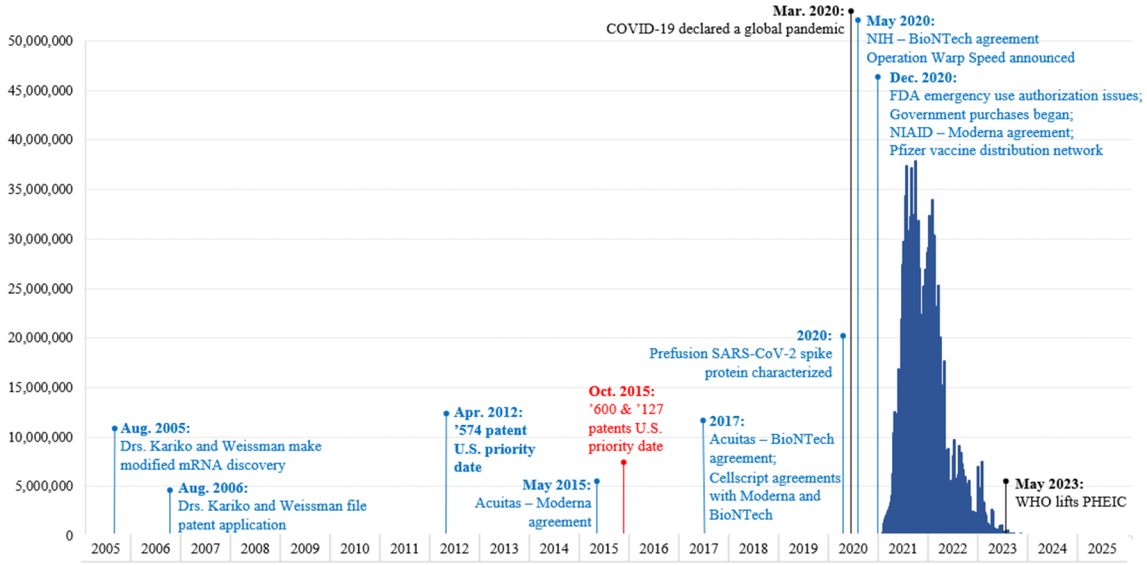
4.4 Conclusion

147. As I have described, a variety of considerations—including various patented and other technologies, intangible assets such as know-how and assembled workforce, marketing, pricing subsidies, and broader economic circumstances—contributed to the commercial success of Comirnaty® and Spikevax®. The foregoing discussion provides only examples of such other contributing technologies and assets, and it is not meant to provide a comprehensive listing of every contributing factor.

148. A summary of new COVID-19 vaccinations (worldwide) with some of the dates discussed throughout this declaration follows:

[304] Exhibit 1302 ("Moderna vs Pfizer: Is it OK to mix and match the updated COVID-19 booster shots?" Los Angeles Times, September 23, 2022 (accessed: https://www.latimes.com/california/story/2022-09-23/moderna-vs-pfizer-is-it-ok-to-mix-and-match-the-updated-covid-19-booster-shots)).

New COVID-19 Vaccinations per Day (Worldwide)[305]
Patent Priority Dates



149. COVID-19 vaccinations worldwide increased years after the priority date of the '600 and '127 patents (noted in red text) and declined precipitously when WHO lifted the PFEIC (noted in black text). Even before 2015, there were numerous advancements in mRNA technology, including the work of Drs. Karikó and Weissman (noted in blue text).[306] Even Moderna's own '574 patent has a claimed priority date before the '600 and

[305] Exhibit 1227 (Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/covid-vaccinations)); Decision Granting Institution of Inter Partes Review and Granting the Parties' Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01358, p. 3; Decision Granting Institution of Inter Partes Review and Granting the Parties' Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01359, p. 4; Patent Owner's Preliminary Response, Case No. IPR2023-01359, May 31, 2024, p. 2; Exhibit 1174 ("WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," WHO website, March 11, 2020 (accessed: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)); Exhibit 1211 ("WHO chief declares end to COVID-19 as a global health emergency," UN News, May 5, 2023 (accessed: https://news.un.org/en/story/2023/05/1136367)).

[306] Exhibit 1133 (Sahin, U., Kariko, K., and Türeci, O. "mRNA-based therapeutics —developing a new class of drugs" Nature Reviews Drug Discovery, 13, 759–780 (2014) (accessed: https://doi.org/10.1038/nrd4278)).

’127 patents (noted in blue text). And leading up to increased vaccination rates were the BioNTech and Moderna agreements with Acuitas, Cellscript, and NIH (noted in blue text). This timeline illustrates if there is a nexus between the commercial success of Comirnaty® and Spikevax® and Moderna’s ’600 patent and ’127 patent, it is tenuous and would be deserving of little, if any, weight; many other technologies, intangible assets, and economic and market considerations contributed to the commercial success of these two vaccines.

150. Mr. Malackowski testified that he did not consider other contributors to the demand for Spikevax® and Comirnaty®, taking the position that it was “not required.”[307] But this renders his analysis, at best, incomplete. Mr. Malackowski’s opinion that “the tremendous market success of Spikevax® and Comirnaty® is a direct result of the inventions claimed in the ’600 and ’127 patents” is conclusory, and more economic analysis should have been done.[308]

151. Mr. Malackowski also disregards that the ’600 and ’127 patents claim only one aspect of the overall multicomponent Comirnaty® and

[307] Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 45-51. *See also*, Exhibit 1157 (Deposition of James Malackowski, July 22, 2024), pp. 21-30 (testifying that he did not measure, for example: the impact of government investment, government contracts, purchasing excess demand, vaccine mandates, the availability of vaccines free of charge for consumers, branded and unbranded vaccine marketing).
[308] Exhibit 2197 (Malackowski Declaration), ¶ 10.

Spikevax® products.[309] To the extent that the ’600 patent and the ’127 patent have a nexus to the commercial success of Comirnaty® and Spikevax®, it is limited due to this as well.

5 AFFIRMATION AND RESERVATION OF RIGHTS

152. I declare under penalty of perjury that the foregoing is true and correct. I also hereby declare that all statements made herein on my knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

153. My opinions are based upon my analysis of the information available to date. I may review and consider additional information that may be produced by the parties to this dispute. I intend to supplement my opinions based upon that review, if it is appropriate to do so. I also reserve the ability to provide rebuttal opinions and testimony in this matter.

154. This declaration was prepared for these IPR proceedings and is only to be used for its stated purpose.

[309] Interview of Dr. Griffin.

Attachment A

CRA Charles River Associates

W. Christopher Bakewell

Vice President

MBA, University of Maryland at College Park (Graduate Fellow)

BS, magna cum laude, Bradley University

W. Christopher (Chris) Bakewell is a vice president in the Intellectual Property Practice of CRA in Houston, TX.

Mr. Bakewell's client assignments include valuation and strategic management of technology-rich businesses and intellectual property rights, valuation of companies and intangible assets in connection with business transactions, licensing, transaction-related advice, and due diligence, as well as audits and investigations. He is consistently recognized as a top economic expert witness, including in the IAM Patent 1000 and as an IAM Global Leader.

Mr. Bakewell also has expertise in matters involving patent infringement, breach of contract, theft of trade secrets, diminution of business value, trademark and copyright infringement, injunctive relief (including analyses of irreparable harm and ongoing royalties), international trade issues (including analyses of domestic industry, remedy, and bonding) as well as other matters. In addition, Chris has experience in matters involving anti-trust and unfair competition.

Mr. Bakewell has been qualified and testified as an expert witness in various forums, including federal court, state court, domestic and international arbitration, and the International Trade Commission.

Summary of experience

Valuation, finance, and other opinion-related services

- In the course of providing financial and valuation analyses, focused on issues related to discounted cash flow, evaluation of market and competitive dynamics, determination of capital structure, transaction and market multiples, control premiums/minority discounts, discounts for lack of liquidity, and other transferability considerations.
- Prepared fairness opinions; for example, in connection with a financial transaction involving medical device companies.
- Performed solvency analyses.
- Performed valuations of various businesses including minority and control blocks of closely held businesses and marketability discounts. These valuations of businesses and assets include manufacturing, distribution, retail, and services sectors.
- Performed purchase price allocations for financial reporting purposes.
- Performed valuations of software and IP assets, including patents, trademarks, copyrights, and trade secrets.

Royalty analyses and studies

- Completed numerous in-depth royalty rate and licensing analyses to assist clients in the development of licensing programs, evaluation of terms in licensing and contract negotiations, determination of fair market value for asset transfers, as well as determination of investment value.
- Reviewed and analyzed the terms and conditions of thousands of license agreements, as well as numerous other contracts.
- Evaluated royalties under various technical standards; studied and analyzed royalty rates in FRAND and RAND licensing contexts.
- Evaluated “most favored licensee” and “most favored nations” (i.e., MFN) clauses.
- Evaluated royalty rates and other terms between multinational enterprises for tax and transfer pricing purposes.

Market assessments

- Assisted clients in determination of new markets to be developed via licensing, evaluation of potential counterparties and structuring/negotiation of licensing arrangements, and ongoing business analysis.
- Assisted with the determination of the optimal structure for licensing of technology.
- Determined licensing counterparties, structuring of the potential licensing arrangements, evaluation of royalty rates, evaluation of market opportunities, assessment of the economic implications of technical alternatives (e.g., design-arounds, design-outs, and non-infringing alternatives), identification and analysis of potential markets and market segments (including the analysis of injunctive relief), ongoing analysis of “IP rich” investments, surveys, advanced analytical tools (e.g., statistical and correlation analyses) as well as IP analytics and data mining.

Investigations, royalty audits, and audits of contractual rights

- Conducted royalty audits and other investigations related to contract compliance, including due diligence related to business transactions and fraud.

Business leadership and contract negotiation assistance

- Served as business unit financial leader for enterprises engaged in asset ownership, manufacturing, power generation, and construction.
- Structured, negotiated and evaluated investment opportunities and international trade issues throughout the world.
- Participated in the negotiation of licenses, joint venture agreements, partnership agreements, buy-sell arrangements, and other contracts.

Damages and economic analysis

- Broad range of experience in business disputes in a variety of litigation settings, including state court, federal court, International Trade Commission, bankruptcy court, arbitration, and mediation. Performed various services, analyses, and other activities in connection with dispute-related negotiations, both pre- and post-litigation.
- Determined and testified regarding economic damages in connection with alleged patent, trademark, and copyright infringement as well as other forms of intellectual property (e.g., trade secrets and know-how) and contractual rights.
- Determined economic damages related to theft of trade secrets and proprietary information, diminution of business value, and diminution of business value related to alleged wrongful acts.
- As a testifying expert, performed analyses of reasonable royalties, ongoing royalties, lost profits damages, price erosion damages, and other opinions regarding damages/remedies. Work has included the use of statistics, survey evidence, and other advanced analytical techniques.

Publications

"Valuation of Intellectual Property and Intangible Assets." In *The Lawyer's Business Valuation Handbook*, (3rd ed.), in publication (co-author).

"The CHIPS and Science Act – What Will It Achieve?" *Kroll Institute*, March 9, 2023 (co-author).

Guillot, Craig. "5 Signs There Could be IP Theft in Your Supply Chain." *Financial Management Magazine*, February 1, 2021 (interviewed/quoted).

Kiernan, Paul. "U.S. Dominance in Global Services Weakens." *Wall Street Journal*, December 3, 2019 (interviewed/quoted).

"IP Protection in a Borderless World." In *Global Fraud and Risk Report 2019/20, Mapping the New Risk Landscape*, 11th Annual Edition (co-author).

"Cost of Capital in Intellectual Property Disputes." Section in "How Courts View Cost of Capital," in Shannon P. Pratt and Roger J. Grabowski, *Cost of Capital: Applications and Examples* (chapter 38), 2014 (co-author).

"Cost of Capital in Intellectual Property Disputes." In Shannon Pratt and Roger Grabowski, *The Lawyer's Guide to Cost of Capital* (chapter 14), August 2014 (co-author).

"Cost of Capital in Intellectual Property Disputes." With Raji Seshan. In Shannon P. Pratt and Roger J. Grabowski, *Cost of Capital in Litigation: Applications and Examples* (chapter 7), 2011.

"Churchill on Bilski." *Duff & Phelps Client Alert,* July 2010 (co-author).

"Valuation of Patents." With Bruce G. Dubinsky. *The Value Examiner: Professional Development Journal of the National Association of Certified Valuation Analysts*, May/June 2009.

"Negotiating Patent License Agreements." *Kroll Global Fraud Report*, January 2008.

"SFAS 157: An Overview of Fair Value and Valuation Standards for Intangibles." With Bryan Benoit. *Business Valuation Review: The Quarterly Journal of the Business Valuation Committee of the American Society of Appraisers*, 26, no. 4, Winter 2007.

"A Step Forward for the Valuation Community: SFAS 157 And Fair Value Measurements: An Important New Standard In the Valuation Of Assets For Financial Reporting." With Bryan Benoit. *les Nouvelles*, July 2007.

Journal Referee (editorial review board), *World Patent Information—The International Journal for Industrial Property Documentation, Information, Classification and Statistics, an Elsevier Journal,* Spring 2007.

Article regarding innovation in the oil sector, *Oil and Gas Financial Journal*, June 2005.

Speeches and presentations

"Whole Hog or a Hill of Beans: A Conversation About Disgorgement and Apportionment," 2023 Eastern District of Texas Bench Bar Conference, October 2023 (panelist).

"FRAND – Patent Damage Session," 24th Annual Eastern District of Texas Bench Bar Conference, October 2021 (panelist).

"ITC Investigations: Economic Issues," Continuing Legal Education Program for Faegre Drinker Biddle & Reath LLP, November 2020 (co-presenter).

"Lessons from the Trenches: Damages Experts," TexasBarCLE 32nd Annual Course Advanced Intellectual Property Law, February 2019 (panelist and contributor to course materials).

2018 IP Value Summit, Duff & Phelps LLC, November 2018 (program moderator).

"The Evolving Patent Valuation Landscape," University of Texas Advanced Patent Law Institute, November 2017 (panelist).

"Patent Licensing Workshop: Practical Licensing Advice and the Lost Profit Analysis," National Chiao Tung University, School of Law, two-day seminar, Taipei and Hsinchu, Taiwan, April 2017 (presenter).

"IP Asset Management: Patent Maintenance and Renewal," Orrick, Herrington & Sutcliffe, LLP, AU Optronics Corp., Hsinchu, Taiwan, April 2017 (panelist).

2016 IP Value Summit, Duff & Phelps LLC, December 2016 (program moderator).

"Litigation on the Cutting Edge – Protecting and Promoting Your Business in the Evolving Digital Marketplace," Litigation Symposium, October 2016 (panelist).

"Hot Topics in IP – International Focus Panel Discussion," 2015 IP Value Summit, Duff & Phelps LLC, December 2015 (moderator).

"Patent Damages Roundtable," University of Texas Advanced Patent Law Institute, November 2015 (panelist).

"Patent Values and Litigation: The New Normal?," Licensing Executives Society, Silicon Valley Chapter Meeting, February 2015 (moderator).

"IP Hot Topics," 2014 IP Value Summit, Duff & Phelps Corp., November 2014 (moderator).

"Global Perspective on the Importance of Patent Rights," Consulate General of France, Houston, March 2014 (presenter).

"Recent Trends in IP Damages Law and International Trade Commission Issues." Continuing Legal Education Program for Duane Morris (Boston), October 2012 (co-presenter).

"Recent Developments In Intellectual Property Damages," 16th Annual Intellectual Property Institute: Crucial Insight and Update on Patent, Trademark and Copyright Law, Washington State Bar Association, March 2011 (panelist).

"Ongoing Royalties," 2010 IP Damages Institute, CalCPA Education Foundation, November 2010 (panelist).

"Valuation of Early-Stage Intellectual Property," BVR/Morningstar Summit on Best Practices in Valuing Intellectual Property, September 2010 (panelist).

"An Overview of Patent Reform and Recent Cases: Promoting Innovation?" Continuing Education Program for Attorneys, Houston Bar Association, Corporate Counsel Section, December 13, 2007 (co-panelist).

"Selecting an Expert and Getting the Most From Your Relationship," Continuing Education Program for Attorneys, Association of Corporate Counsel, October 18, 2007 (co-presenter).

"Working with Your Damages Expert Throughout the Litigation Life Cycle." Houston Bar Association, March 22, 2007 (presenter).

Lectured and/or participated in classroom lectures at Baylor University (BEST Honors Business Program), University of Maryland at College Park (Smith School of Business) and the University of Houston (Blakely Advocacy Institute).

Planning committee, 2005 Advanced Patent Law Institute, Austin, TX.

Program advisory committee, Electric Power 2005, Chicago, IL.

"Economics of Power Applications." Electric Power 2003, Houston, TX, March 2003 (co-chair).

"Comparison of US and European Energy Markets." PowerGen Europe, Milan, Italy, June 2002.

Affiliations and certifications

University of Maryland, Dingman Center for Entrepreneurship (Advisory Committee)

World Intellectual Property Organization (Advisory Committee)

American Society of Appraisers (Accredited Senior Appraiser in Business Valuation; served on the Board of Directors of Houston Chapter)

Licensing Executives Society (Certified Licensing Professional)

Association for Corporate Growth (Member)

American Intellectual Property Law Association (Member)

The Sedona Conference Working Group Series (Member)

University of Texas Advanced Patent Law Institute (Faculty and Planning Member)

Professional history

2024–Present	*Vice President, Intellectual Property Practice,* Charles River Associates
2007–2024	Kroll (formerly Duff & Phelps)
	Managing Director, Global Intellectual Property Advisory Services Leader and Service Line Leader, Expert Services (Americas), 2008–2024
	Senior Director, 2008
	Director, 2007–2008
2002–2005	CRA International (formerly InteCap)
	Principal, 2005–2006
	Director, 2002–2005
2001	*Manager, Global Financial Strategies,* KPMG
1995–2002	Wartsila Corporation
	Director, Business Development WDFS, 2001–2002
	Director of Finance, WDFS, 2000–2001
	Controller and Treasurer, Wartsila Power Development, 1999–2000
	Controller, Wartsila Netherlands, 1998–1999
	Controller and Manager of Finance, Wartsila North America, 1995–1998
1993–1995	C.W. Amos & Company
	Consulting Supervisor, 1995
	Senior Consultant, 1993–1994
1990–1991	*Consultant,* Andersen Consulting (now Accenture)

Attachment B

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EXPERT TESTIMONY
PRIOR FOUR YEARS

United States District Court, District of Delaware
TQ Delta, LLC v. Comcast Cable Communications LLC*, CoxCom LLC*, Cox Communications Inc.*, Time Warner Cable Inc.*, Time Warner Cable Enterprises*, Verizon Services Corp.* (Case Nos. 1:15-cv-00611, 1:15-cv-00612, 1:15-cv-00615, 1:15-cv-00616)
Deposition, Reports

United States District Court, Eastern District of Texas, Marshall Division
Motorola Solutions, Inc.* v. STA Group LLC, et al. (Case No. 2:23-cv-00030)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Touchstream Technologies, Inc. v. Charter Communications, Inc.*, Charter Communications Operating, LLC*, Spectrum Management Holding Company, LLC*, Time Warner Cable Enterprises, LLC*, Spectrum Gulf Coast, LLC*, Charter Communications, LLC* (Case No. 2:23-cv-0059)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Advanced Coding Technologies LLC v. Samsung Electronics Co. Ltd.*, Samsung Electronics America, Inc.* (Case No. 2:22-cv-00499)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Motorola Solutions, Inc.* v. STA Group LLC, et al. (Case No. 2:22-cv-00381)
Deposition, Report

United States District Court, Eastern District of Michigan, Southern Division
Neo Wireless, LLC v. Nissan North America Inc.*, Nissan Motor Acceptance Corporation a/k/a Nissan Motor Acceptance Company LLC*, Toyota Motor Corporation*, Toyota Motor North America, Inc.*, Toyota Motor Sales, U.S.A., Inc.*, Toyota Motor Engineering & Manufacturing North America, Inc.*, Toyota Motor Credit Corporation* (Case Nos. 2:22-MD-03034, 2:22-cv-11405 and 2:22-cv-11406)
Deposition, Reports

District Court, 71st Judicial District, Harrison County, Texas
The State of Texas v. Meta Platforms, Inc. f/k/a Facebook, Inc.* (Case No. 22-0121)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
General Access Solutions, Ltd. v. Cellco Partnership d/b/a Verizon Wireless*, Verizon Services Corp.*, Verizon Business Global LLC*, Verizon Business Network Services LLC*, Verizon Corporate Services Group Inc.*, Verizon Data Services LLC*, Verizon Online LLC* (Case No. 2:22-cv-00394)
Deposition, Report

United States District Court, Southern District of New York, Foley Square
Fujifilm North America Corporation*, Fujifilm Corporation* v. Polaroid IP B.V., et al. (Case No. 1:17-cv-08796)
Deposition, Report

United States District Court, Western District of Texas, Waco Division
Sable Networks, Inc., et al. v. Cloudflare, Inc.* (Case No. 6:21-cv-00261)
Trial, Deposition, Report

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United States District Court, Eastern District of Texas, Marshall Division
Element Capital Commercial Company PTE. LTD v. BOE Technology Group Co., Ltd*, Motorola (Wuhan) Mobility Technologies Communication Co., Ltd.* (Case No. 2:22-cv-00118)
Deposition, Report

United States District Court, Western District of Texas, Waco Division
Viasat, Inc. v. Kioxia Corporation*, Kioxia America, Inc.* (Case No. 6:21-cv-01231)
Deposition, Report

United States District Court, District of Delaware
C.R. Bard, Inc., et al. v. AngioDynamics, Inc.* (Case No. 1:20-cv-01544)
Deposition, Report

United States District Court, Eastern District of Virginia, Norfolk Division
Centripetal Networks, LLC v. Palo Alto Networks, Inc.* (Case No. 2:21-cv-00137)
Trial, Deposition, Reports

United States District Court, District of Delaware
3G Licensing, et al. v. HTC Corporation* (Case No. 1:17-cv-00083)
Trial, Reports

United States District Court, Western District of Texas, Austin Division
RFCyber Corp. v. Apple, Inc.* (Case No. 1:23-cv-00661)
Deposition, Report

United States District Court, Eastern District of Delaware, Wilmington
Fundamental Innovation Systems International LLC v. Anker Innovations Ltd.*, Fantasia Trading LLC d/b/a AnkerDirect* (Case No. 1:21-cv-00339)
Deposition, Reports

United States International Trade Commission
Certain Integrated Circuits, Components Thereof, and Products Containing Same (Inv. No. 337-TA-1350)
Realtek Semiconductor Corp. (Complainant) v. Advanced Micro Devices, Inc.* (Respondent)
Hearing, Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Magema Technology LLC* v. Phillips 66, et al. (Case Nos. 4:20-cv-02444)
Trial, Reports

United States District Court, Western District Texas, Waco Division
AlmondNet, Inc., et al. v. Amazon.com, Inc.*, Amazon.com Services LLC*, Amazon Web Services, Inc.* (Case 6:21-cv-00898)
Trial, Deposition, Report

United States District Court, Western District of Texas, Waco Division
EcoFactor, Inc. v. Resideo Technologies, Inc.* (Case No. 6:22-cv-00069)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Alacritech, Inc. v. Tier 3, et al., Wistron Corporation, et al., Dell Inc.* (Case Nos. 2:16-cv-00693, 2:16-cv-00692, 2:16-cv-00695)
Depositions, Reports

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United States District Court, Western District of Texas, Waco Division
WSOU Investments, LLC d/b/a Brazos Licensing and Development v. Google LLC* (Case Nos. 6:20-cv-00572, 6:20-cv-00580 and 6:20-cv-00585)
Deposition, Reports

United States District Court, Northern District of Texas, Dallas Division
Helmerich & Payne International Drilling Co.*, Helmerich & Payne Technologies, LLC*, Motive Drilling Technologies, Inc.* v. Nabors Drilling Technologies USA, Inc. (Case No. 3:20-cv-03126)
Trial, Deposition, Reports

United States District Court, Western District of Texas, Waco Division
Vervain, LLC v. Western Digital Corporation*, Western Digital Technologies, Inc.* (Case No. 6:21-cv-00488)
Deposition, Report

United States District Court, Central District of California, Los Angeles Division
S10 Entertainment & Media LLC v. Samsung Electronics Co., Ltd.*, Samsung Electronics America, Inc.* (Case No. 2:21-cv-02442)
Trial, Deposition, Reports

United States District Court, District of Minnesota
Fair Isaac Corporation v. Federal Insurance Company*, ACE American Insurance Company* (Case No. 0:16-cv-01054)
Trial, Deposition, Report

United States District Court, Northern District of California, San Francisco Division
Google LLC* v. Sonos, Inc. (Case No. 3:20-cv-06754 related to Case No. 3:21-cv-07559)
Trial, Deposition, Reports

United States District Court, Central District of California, Southern Division
Open Text Corporation, et al. v. Hyland Software, Inc.*, Hyland UK Operations Limited (f/k/a Alfresco Software, Ltd.)* (Case Nos. 8:20-cv-02116; 8:20-cv-02123; 2:21-cv-09099; 2:21-cv-09101; 2:21-cv-09191)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Collision Communications, Inc. v. Nokia Corporation*, Nokia Solutions and Networks Oy*, Nokia of America Corporation* (Case Nos. 2:21-cv-00308 and 2:21-cv-00327)
Deposition, Reports

United States District Court, Western District of Texas, Waco Division
Proxense, LLC v. Samsung Electronics, Co., Ltd.*, Samsung Electronics America, Inc.* (Case No. 6:21-cv-00210)
Deposition, Report

United States District Court, Southern District of Texas, Houston Division
Mexichem Amanco Holding, S.A. de C.V. v. The Chemours Company*, The Chemours Company FC, LLC* (Case No. 4:20-cv-01960)
Deposition, Reports

United States District Court, Southern District of Indiana, Indianapolis Division
Knauf Insulation, Inc., et al. v. Johns Manville Corporation*, Johns Manville, Inc.* (Case No. 1 :15-cv-00111)
Deposition, Reports

District Court, Tarrant County, Texas, 17th Judicial District
Cardone Industries, Inc.* v. Joel Farina, et al. (Case No. 017-271617-14)
Hearing, Depositions, Reports

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United States District Court, District of Massachusetts
NeuralMagic, Inc. v. Meta Platforms, Inc.*, Aleksandar Zlateski* (Case No. 1:20-cv-10444)
Deposition, Report

International Centre for Dispute Resolution
Solution Technology Incorporated v. DXC Technology Company* (Case No. 01-20-0014-9648)
Hearing, Report

United States District Court, District of Delaware, Wilmington
Fundamental Innovation Systems International LLC v. Lenovo (United States), Inc.*, Lenovo Holding Company Inc.*, Lenovo Group Ltd.*, Motorola Mobility LLC* (Case No. 1:20-cv-00551)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Fundamental Innovation Systems International LLC v. TCT Mobile (US), Inc.*, TCT Mobile (US) Holdings, Inc.*, Huizhou TCL Mobile Communications Co. Ltd.*, TCL Communication, Inc.* (Case No. 1:20-cv-00552)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Aqua Connect, Inc., et al. v. Teamviewer US, LLC* (Case No. 1:18-cv-01572)
Trial, Deposition, Report

United States District Court, Southern District of Texas, Houston Division
Abaco Drilling Technologies LLC v. PV Fluid Products, Inc.*, et al. (Case No. 4:20-cv-01946)
Deposition, Report

United States International Trade Commission
Certain Laptops, Desktops, Servers, Mobile Phones, Tablets, and Components Thereof (Inv. No. 337-TA-1280)
Sonrai Memory Limited (Complainant) v. Amazon.com, Inc.*, Dell Technologies Inc.*, EMC Corporation*, Lenovo Group Ltd.*, Lenovo (United States) Inc.*, Motorola Mobility LLC*, LG Electronics Inc.*, LG Electronics USA, Inc.*, Samsung Electronics Co., Ltd.*, Samsung Electronics America, Inc.*
Deposition, Report

United States District Court, District of Delaware, Wilmington
Innovative Memory Systems, Inc. v. Micron Technology, Inc.* (Case No. 1:14-cv-01480)
Deposition, Report

United States International Trade Commission
Certain Residential Premises Security Monitoring and Automation Control Panels, and Components Thereof (Inv. No. 337-TA-1273)
ADT LLC*, The ADT Security Corporation* (Complainants) v. Vivint, Inc. (Respondents)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
KAIFI LLC v. Verizon Communications Inc.*, Cellco Partnership d/b/a Verizon Wireless*, Verizon Services Corp.*, Verizon Enterprise Solutions LLC*, Verizon Business Global LLC*, Verizon Business Network Services, LLC*, Verizon Corporate Services Group Inc.*, Verizon Data Services, LLC*, Verizon Media Inc.* and Verizon Online, LLC* (Case No. 2:20-cv-00280)
Deposition, Report

United States District Court, Central District of California, Western Division, Los Angeles
Honda Trading America Corporation v. BASF Corporation* (Case No. 2:20-cv-04375)
Deposition, Report

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United States District Court, Western District of Texas, Waco Division
Godo Kaisha IP Bridge 1 v. Micron Technology, Inc.*, Micron Semiconductor Products, Inc.*, Micron Technology Texas, LLC* (Case No. 6:20-cv-00178)
Deposition, Report

United States District Court, Northern District of Alabama
Karl Storz Endoscopy-America, Inc. v. Steris Instrument Management Services, Inc.* (Case No. 2:12-cv-02716)
Deposition, Report

United States District Court, Western District of Texas, Waco Division
Daedalus Blue LLC v. SZ DJI Technology Co., Ltd.*, DJI Europe B.V.* (Case No. 6:20-cv-00073)
Deposition, Report

United States District Court, Western District of Texas, Waco Division
Huawei Technologies Co. Ltd., et al. v. Verizon Communications Inc.*, Cellco Partnership d/b/a Verizon Wireless, Inc.*, Verizon Business Network Services LLC* (Case No. 6:20-cv-00090)
Deposition, Report

United States District Court, Western District of Virginia, Lynchburg Division
Crown Packaging Technology, Inc., et al. v. Belvac Production Machinery, Inc.* (Case No. 6:18-cv-00070)
Deposition, Report

Canada, Federal Court
Paid Search Engine Tools, LLC v. Google Canada Corporation*, Google LLC*, Alphabet Inc.* (Court File No. T-40-18)
Trial, Report

United States District Court, Western District of Texas, Austin Division
Fintiv, Inc. v. Apple Inc.* (Case No. 1 :19-cv-01238)
Deposition, Reports

United States District Court, Western Division of Washington, Seattle
Treehouse Avatar LLC v. Valve Corporation* (Case 2:17-cv-01860)
Deposition, Report

United States District Court, Eastern District of Virginia, Alexandria Division
In Re: Capital One Consumer Data Security Breach Litigation (MDL No. 1:19md2915)
Deposition, Report

United States International Trade Commission
Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof (Inv. No. 337-TA-1207)
Novartis Pharma AG*, Novartis Technology LLC*, Novartis Pharmaceuticals Corporation* (Complainant) v. Regeneron Pharmaceuticals Inc. (Respondents)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Gree, Inc. v. Supercell Oy* (Case No. 2:20-cv-00113)
Deposition, Report

United States International Trade Commission
Certain Filament Light-Emitting Diodes and Products Containing Same (II) (Inv. No. 337-TA-1220)
The Regents of the University of California (Complainant) v. Feit Electric Company, Inc.*, Home Depot Product Authority, LLC*, Home Depot U.S.A., Inc.*, The Home Depot, Inc.*, IKEA Supply AG*, IKEA U.S. Retail LLC*, IKEA of Sweden AB*, Savant Systems, Inc.*, Savant Technologies, LLC d/b/a GE Lighting*, General Electric Company*, Satco Products, Inc.* (Respondents)
Hearing, Deposition, Report

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United States District Court, Western District of Texas, Austin Division
Freshub, Inc., et al. v. Amazon.com, Inc.*, Amazon Digital Devices, LLC*, Prime Now, LLC*, Whole Foods Market Services, Inc.* (Case No. 1:19-cv-00885)
Trial, Deposition, Report

United States District Court, Northern District of California, San Francisco Division
Proofpoint, Inc., et al. v. Vade Secure, Inc.*, Vade Secure SASU*, Olivier Lemarie* (Case No. 3:19-cv-04238)
Trial, Deposition, Report

United States International Trade Commission
Certain Light-emitting Diode Products, Fixtures, and Components Thereof (Inv. No. 337-TA-1213)
IDEAL Industries Lighting LLC d/b/a Cree Lighting* (Complainant) v. RAB Lighting Inc. (Respondent)
Hearing, Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Huawei Technologies Co. Ltd. v. Verizon Communications, Inc.*, Verizon Business Network Services, Inc.*, Verizon Enterprise Solutions, LLC*, Cellco Partnership d.b.a. Verizon Wireless, Inc.*, Verizon Data Services LLC*, Verizon Business Global, LLC*, Verizon Services Corp.* (Case No. 2:20-cv-00030)
Deposition, Report

United States International Trade Commission
Certain Non-invasive Aesthetic Body-contouring Devices, Components Thereof, and Methods of Using the Same (Inv. No. 337-TA-1219)
BTL Industries, Inc. (Complainant) v. Allergan Limited*, Allergan USA, Inc.*, Allergan, Inc.*, Zeltiq Aesthetics, Inc.*, Zeltiq Ireland Unlimited Company*, Zimmer MedizinSysteme GmbH* (Respondents)
Witness Statement, Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Gree, Inc. v. Supercell Oy* (Case No. 2:20-cv-00413)
Deposition, Report

United States District Court, Eastern District of Virginia, Alexandria Division
Maglula, Ltd. v. Amazon.com, Inc.*, Amazon.com Services, Inc.* (Case No. 1:19-cv-01570)
Deposition, Reports

United States District Court, Northern District of California, Oakland Division
Droplets, Inc. v. Verizon Media and Altaba, Inc. f/k/a Yahoo!, Inc.* (Case No. 4:12-cv-03733)
Trial, Deposition, Report

United States District Court, Southern District of New York, Foley Square
General Electric Company* v. APR Energy plc (Case No. 1:19-cv-03472)
Deposition, Report

Canada, Federal Court
Bauer Hockey Ltd. v. Sport Maska Inc. dba CCM Hockey* (Case No. T-311-12)
Trial, Reports

United States International Trade Commission
Certain Synthetic Roofing Underlayment Products and Components Thereof (Inv. No. 337-TA-1202)
Kirsch Research and Development, LLC (Complainant) v. Atlas Roofing Corporation*, CertainTeed LLC*, DuPont De Nemours, Inc.*, E.I. du Pont De Nemours and Company*, Epilay, Inc.*, GAF Materials LLC*, Owens Corning*, Owens Corning Roofing & Asphalt, LLC*, InterWrap Corp.*, System Components Corporation*, TAMKO Building Products, LLC* (Respondents)
Deposition, Report

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United States District Court, Northern District of California, San Francisco Division
Healthplan Services, Inc.*, HPH-TH Holdings, Inc.* v. California Physicians' Service, Inc. d/b/a Blue Shield of California (Case No. 3:18-cv-3730)
Depositions, Reports, Declaration

United States District Court, Eastern District of Texas, Marshall Division
Gree, Inc. v. Supercell Oy* (Case No. 2:19-cv-00237, 2:19-cv-00310 and 2:19-cv-00311)
Trial, Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Gree, Inc. v. Supercell Oy* (Case No. 2:19-cv-00200)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Shopify, Inc.*, Shopify (USA), Inc.* v. Express Mobile, Inc. (Case No. 1:19-cv-00439)
Deposition, Reports

United States District Court, Eastern District of Texas, Marshall Division
Joe Andrew Salazar v. HTC Corporation*, HTC America, Inc.*, AT&T Mobility LLC*, Sprint/United Management Company*, T-Mobile USA, Inc.*, Cellco Partnership d/b/a Verizon Wireless* (Case No. 2:20-cv-00004)
Trial, Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Oyster Optics, LLC v. Infinera Corporation*, Coriant North America, LLC*, Coriant Operations, Inc.*, Coriant (USA) Inc.* (Case No. 2:19-cv-00257)
Depositions, Reports

United States District Court, Western District of Texas, Austin Division
CliniComp International, Inc. v. Athenahealth, Inc.* (Case No. 1:18-cv-00425)
Deposition, Report

American Arbitration Association
MLB Advanced Media, L.P. v. StubHub, Inc.* (Arbitration No. 01-19-0001-6947)
Deposition, Reports

Canada, Federal Court
Rovi Guides, Inc., et al. v. BCE Inc.*, Bell Canada*, Bell Aliant Regional Communications Inc.*, Bell MTS Inc.*, Northerntel, L.P.* (Court File No. T-113-18)
Trial, Report

Canada, Federal Court
Rovi Guides, Inc., et al. v. Telus Corporation*, Telus Communications Inc.*, Telus Communications Company* (Court File No. T-206-18)
Trial, Report

United States District Court, Central District of California, Southern Division – Santa Ana
Polaris Powerled Technologies, LLC v. Vizio, Inc.* (Case No. 8:18-cv-01571)
Deposition, Report

United States District Court, Eastern District of Texas, Marshall Division
Gree, Inc. v. Supercell Oy* (Case No. 2:19-cv-00070 and 2:19-cv-00071)
Trial, Deposition, Report

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United States District Court, District of Delaware, Wilmington
Sprint Communications Company LP v. Mediacom Communications Corp.* (Case No. 1:17-cv-01736)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Sprint Communications Company LP v. WideOpenWest, Inc.*, WideOpenWest Networks, Inc.*, WideOpenWest Finance, LLC*, WideOpenWest Georgia, LLC*, Knology of Alabama, Inc.*, Knology of Florida, LLC*, Knology of Georgia, Inc.*, Knology of South Carolina, Inc.*, Knology of Tennessee, Inc.*, Knology of Kansas, Inc.*, Anne Arundel Broadband, LLC* (Case No. 1:18-cv-00361)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Sprint Communications Company LP v. Atlantic Broadband Finance, LLC*, Atlantic Broadband (CT), LLC*, Atlantic Broadband (Delmar), LLC*, Atlantic Braodband (Miami), LLC*, Atlantic Broadband (NH-ME), LLC*, Atlantic Broadband (Penn), LLC*, Atlantic Broadband (SC), LLC* (Case No. 1:18-cv-00362)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Sprint Communications Company LP v. Grande Networks, LLC*, Radiate Holdings, L.P.*, RCN Telecom Services LLC*, Wavedivision Holdings, LLC* (Case No. 1:18-cv-00363)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Data Engine Technologies LLC v. Google Inc.* (Case No. 1:14-cv-01115)
Deposition, Reports

United States International Trade Commission
Certain Filament Light-Emitting Diodes and Products (Inv. No. 337-TA-1172)
UC Regents of the University of California (Complainant) v. Amazon.com, Inc.*, Amazon.com Services, Inc.*, Target Corporation Inc.*, IKEA Distribution Services, Inc.*, IKEA North America Services LLC*, IKEA of Sweden AB*, IKEA Supply AG*, Walmart Inc.* (Respondents)
Hearing, Witness Statement, Deposition, Report

United States District Court, Eastern District of Texas, Sherman Division
Innovation Sciences, LLC, et al. v. Resideo Technologies, Inc.* (Case No. 4:18-cv-00475)
Deposition, Report

United States District Court, District of Delaware, Wilmington
Align Technology, Inc.* v. 3Shape A/S, et al. (Case No. 1:17-cv-01646)
Deposition, Report

United States International Trade Commission
Certain Touch-Controlled Mobile Devices and Components Thereof (Inv. No. 337-TA-1162)
Neodron Ltd. (Complainant) v. Amazon.com, Inc.*, Dell Technologies Inc.*, HP Inc.*, Microsoft Corporation*, Lenovo Group Ltd.*, Lenovo (United States) Inc.*, Motorola Mobility LLC*, Samsung Electronics Co., Ltd.*, Samsung Electronics America, Inc.* (Respondents)
Witness Statement, Deposition, Report

United States District Court, Northern District of Illinois, Chicago
ClearOne Inc.* v. Shure Incorporated (Case No. 1:17-cv-03078)
Deposition, Reports

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United States District Court, District of Delaware, Wilmington
Chanbond, LLC v. Atlantic Broadband Group, LLC*, Bright House Networks, LLC*, Cable One Inc.*, Cablevision Systems Corp.*, Cequel Communications Holdings I, LLC*, Cequel Communications, LLC d/b/a Suddenlink Communications*, Charter Communications, Inc.*, Comcast Cable Communications, LLC*, Comcast Corporation*, Cox Communications, Inc.*, CSC Holdings, LLC d.b.a. Optimum-Cablevision*, Mediacom Communications Corp.*, RCN Telecom Services, LLC*, Spectrum Management Holding Company, LLC f.k.a. Time Warner Cable, Inc.*, Time Warner Cable Enterprises, LLC*, WaveDivision Holdings, LLC*, WideOpen West Finance, LLC* (Case 1:15-cv-00842 through 1:15-cv-00854)
Deposition, Reports

United States District Court, Eastern District of Texas, Tyler Division
VirnetX, Inc., et al. v. Apple, Inc.* (Case No. 6:12-cv-00855)
Trials, Depositions, Reports

Client/party denoted with *

Attachment C

Attachment C
Documents Cited

Exhibit	Document
1001	U.S. Patent No. 10,702,600 and U.S. Patent No. 10,933,127
1024	"The messenger RNA pioneers everyone ignored," Bloomberg, Nov. 23, 2021, https://www.bloomberg.com/news/newsletters/2021-11-23/the-messenger-rna-pioneers-everyone-ignored (last accessed August 24, 2023)
1025	"Katalin Karikó and Drew Weissman awarded Horwitz Prize for pioneering research on COVID-19 vaccines," Columbia University Irving Medical Center, Aug. 16, 2021, https://www.cuimc.columbia.edu/news/horwitz-priz 2021 (last accessed August 24, 2023)
1026	Patent Sublicense Agreement Between Cellscript, LLC and ModernaTx, Inc.
1102	"Moderna Science & Technology Day," Moderna presentation, May 17, 2022 (accessed: https://s29.q4cdn.com/435878511/files/doc_presentations/2022/05/Science-Day-2022-Master-Slides-FINAL-(05.17_7am).pdf)
1124	Nobel Prize, Discoveries concerning nucleoside base modifications that enabled the development of effective mRNA vaccines against COVID-19 (2023) (accessed: https://www.nobelprize.org/prizes/medicine/2023/advanced information/)
1127	"U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted for Individuals Aged 18 and Over," Novavax press release, July 13, 2022 (accessed: https://ir.novavax.com/press-releases/2022 07-13-U-S-FDA-Grants-Emergency-Use-Authorization-for-Novavax-COVID-19-Vaccine,-Adjuvanted-for-Individuals-Aged-18-and-Over)
1133	Sahin, U., Kariko, K., and Türeci, O. "mRNA-based therapeutics —developing a new class of drugs" Nature Reviews Drug Discovery, 13, 759–780 (2014) (accessed: https://doi.org/10.1038/nrd4278)
1157	Deposition of James E. Malackowski, July 22, 2024, and Errata Sheet, Aug. 27, 2024
1166	"COVID-19 Timeline," CDC website (accessed: https://www.cdc.gov/museum/timeline/covid19.html)
1167	"After nearly $1B in research funding, Moderna takes $1.5B coronavirus vaccine order from U.S." Fierce Pharma, August 12, 2020 (accessed: https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-modern takes-1-5b-coronavirus-vaccine-order-from-u-s)
1168	"The biotech targeting personalized medicine, CNBC, May 13, 2015 (accessed: https://www.cnbc.com/2015/05/12/moderna-therapeutics-is-trying-to-cure-disease-with-mrna-drugs.html)
1169	"Our History," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/history.html)
1170	"Collaboration to Develop mRNA Vaccines Expands," CureVac press release, August 4, 2015 (accessed: https://www.curevac.com/en/collaboration-to-develop-mrna-vaccines-expands/)
1171	"COVID-19 Commercialization," HHS website (accessed: https://www.hhs.gov/coronavirus/commercialization/index.html)
1172	"Inside the $250 million effort to convince Americans the coronavirus vaccines are safe," CBS News, December 23, 2020 (accessed: https://www.cbsnews.com/news/covid-vaccine-safety-250-million-dollar-marketing-campaign/)
1173	Moderna Form 8-K, March 16, 2020
1174	"WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," WHO website, March 11, 2020 (accessed: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)
1175	"Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study," Moderna website, February 24, 2020 (accessed: https://investors.modernatx.com/news/news-details/2020/Moderna-Ships-mRNA-Vaccine-Against-Novel-Coronavirus-mRNA-1273-for-Phase-1-Study/default.aspx)
1176	"Operation Warp Speed Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges," GAO website, February 5, 2021 (accessed: https://www.gao.gov/assets/gao-21-319.pdf)
1177	"Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNA-1273) Against COVID-19," Moderna website, July 26, 2020 (accessed: https://web.archive.org/web/20200726212828/https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase/)
1178	"FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine," FDA website, December 18, 2020 (accessed: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid)
1179	"Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax," Moderna website, January 31, 2022 (accessed: https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx)
1180	"Welcome to our investor page," BioNTech website (accessed: https://investors.biontech.de/)
1181	"Vision & Mission," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/who-we-are/vision-and-mission.html)
1182	"The Husband-and-Wife Team Behind the Leading Vaccine to Solve Covid-19," The New York Times, November 10, 2020 (accessed: https://www.nytimes.com/2020/11/10/business/biontech-covid-vaccine.html)
1183	"Pfizer and BioNTech to Co-develop Potential COVID-19 Vaccine," BioNTech press release, March 17, 2020 (accessed: https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-co-develop-potential-covid-19-vaccine)
1184	Pfizer Form 10-K for the year ended December 31, 2023
1185	"About," Pfizer website (accessed: https://www.pfizer.com/about/history)
1186	"Science," Pfizer website (accessed: https://www.pfizer.com/science)
1187	"Ongoing Vaccine Research and Development at Pfizer," Pfizer website (accessed: https://www.pfizer.com/science/vaccines/research)
1188	"How will Pfizer maintain vaccine integrity during distribution?" Pfizer website (accessed: https://www.pfizer.com/science/coronavirus/vaccine/manufacturing-and-distribution)
1189	"Working to Make COVID-19 Vaccines Accessible to Everyone, Everywhere," Pfizer website (accessed: https://www.pfizer.com/science/coronavirus/vaccine/working-to-reach-everyone-everywhere)
1190	"A vaccine is Pfizer's best-selling drug," Axios website, February 5, 2019 (accessed: https://www.axios.com/2019/02/05/pfizer-vaccine-prevnar-top-selling-drug)

Attachment C
Documents Cited

Exhibit	Document
1191	"Top selling vaccines in pharmaceutical history," Proclinical website, December 9, 2016 (accessed: https://www.proclinical.com/blogs/2016-9/top-selling-vaccines-in-pharmaceutical-history)
1192	"BioNTech Signs Collaboration Agreement with Pfizer to Develop mRNA-based Vaccines for Prevention of Influenza," Pfizer press release, August 16, 2018 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/biontech-signs-collaboration-agreement-pfizer-develop-mrna)
1193	"FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine," FDA press release, December 11, 2020 (accessed: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)
1194	"FDA grants full approval to Pfizer-BioNTech's Covid shot, clearing path to more vaccine mandates," CNBC, August 23, 2021 (accessed: https://www.cnbc.com/2021/08/23/fda-pfizer-biontech-covid-vaccine-wins-full-approval-clearing-path-to-mandates.html)
1195	"U.S. Department of Health and Human Services, Explaining Operation Warp Speed," (accessed: https://www.nihb.org/covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf)
1196	"The U.S. has already invested billions in potential coronavirus vaccines. Here's where the deals stand," CNBC, August 14, 2020 (accessed: https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potentia coronavirus-vaccines-heres-where-the-deals-stand.html)
1197	"Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021 (accessed https://crsreports.congress.gov/product/pdf/IN/IN11560/7)
1198	CNN, Facts First (accessed: https://www.cnn.com/factsfirst/politics/factcheck_565aa63a-4c46-4eea-9586-093253d1bdf3)
1199	"The U.S. Government's Role in Domestic and Global COVID-19 Vaccine Supply and Distribution: Frequently Asked Questions," Congressional Research Service, February 17, 2022 (accessed: https://crsreports.congress.gov/product/pdf/IF/IF12013)
1200	"Johnson & Johnson Updates U.S. COVID-19 Vaccine Fact Sheet," Johnson & Johnson press release, May 5, 2022 (accessed: https://www.jnj.com/johnson-johnson-updates-u-s-covid-19-vaccine-fact-sheet)
1201	"From zero to 500 million: America's vaccination effort in 4 charts," NBC News, December 30, 2021 (accessed: https://www.nbcnews.com/news/all/zero-500-million-america-s-vaccination-effort-4-charts-n1286773)
1202	"Daily COVID-19 vaccine doses administered," Our World in Data, March 9, 2023 (accessed: https://ourworldindata.org/grapher/daily-covid-19-vaccination-doses?tab=chart&country=~USA)
1203	"Household Pulse Survey Shows Many Don't Trust COVID Vaccine, Worry About Side Effects," United States Census Bureau, December 28, 2021 (accessed: https://www.census.gov/library/stories/2021/12/who-are-the-adults-not-vaccinated-against-covid.html)
1204	"Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine," FDA website, April 13, 2021 (accessed:https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine)
1205	"Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals," FDA News Release, May 5, 2022 (accessed: https://web.archive.org/web/20220505225458/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals)
1206	"Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices," CDC website, January 21, 2022 (accessed: https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm)
1207	"What You Need to Know About the Novavax Protein-Based Vaccine," Johns Hopkins, July 14, 2022 (accessed: https://publichealth.jhu.edu/2022/what-you-need-to-know-about-the-novavax-protein-based-vaccine)
1208	"What is the Novavax vaccine, and why does the world need another type of COVID-19 vaccine?" Gavi, February 14, 2022 (accessed: https://www.gavi.org/vaccineswork/what-novavax-vaccine-and-why-does-world-need-another-type-covid-19-vaccine)
1209	"Tracking Coronavirus Vaccinations Around the World," The New York Times, March 13, 2023 (accessed: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html)
1210	"Covid vaccine rates in the U.S. are slumping — and it will be a challenge to boost them," CNBC, November 30, 2023 (accessed: https://www.cnbc.com/2023/11/30/us-covid-shot-rates-are-low-and-it-will-be-a-challenge-to-boost-them.html)
1211	"WHO chief declares end to COVID-19 as a global health emergency," UN News, May 5, 2023 (accessed: https://news.un.org/en/story/2023/05/1136367)
1212	"CDC COVID-19 Vaccination Program Provider Requirements and Support: 10/6/2023 Update," CDC website, October 6, 2023 (accessed: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html)
1213	"HHS Launches Bridge Access Program to Safeguard Free COVID-19 Vaccination for Uninsured and Underinsured Adults," CDC Newsroom Releases, September 14, 2023 (accessed: https://www.cdc.gov/media/releases/2023/p0914-uninsured-vaccination.html)
1214	"FACT SHEET: How Are COVID-19 Vaccines Covered by Insurance?" Covid-19 Vaccine Education and Equity Project, September 2023 (accessed: https://covidvaccineproject.org/wp-content/uploads/2023/09/CVEEP_Youre-Covered_Coverage-Overview_0923.pdf)
1215	"BioNTech Announces Fourth Quarter and Full Year 2023 Financial Results and Corporate Update," BioNTech press release, March 20, 2024 (accessed: https://investors.biontech.de/system/files-encrypted/nasdaq_kms/assets/2024/03/20/8-02-08/BNTX%20Q4%202023%20Press%20Release_EN_post-issuance%20update.pdf)
1216	"BioNTech Announces Fourth Quarter and Full Year 2022 Financial Results and Corporate Update," BioNTech press release, March 27, 2023 (accessed: https://investors.biontech.de/node/14871/pdf)
1217	"BioNTech Announces Fourth Quarter and Full Year 2021 Financial Results and Corporate Update," BioNTech press release, March 30, 2022 (accessed: https://investors.biontech.de/node/11911/pdf)
1218	"Moderna Covid vaccine sales plunge by two-thirds in 2023, but meet company's $6 billion forecast," CNBC, January 8, 2024 (accessed: https://www.cnbc.com/2024/01/08/moderna-covid-vaccine-sales-plunge-in-2023-but-meet-company-forecast.html)
1219	"Patents," Moderna website, October 8, 2020 (accessed: https://web.archive.org/web/20201008145751/https://www.modernatx.com/patents)
1220	"Patents," Moderna website, December 1, 2021 (accessed: https://web.archive.org/web/20211201193750/https://www.modernatx.com/patents)

Attachment C
Documents Cited

Exhibit	Document
1221	"Patents," Moderna website, December 5, 2022 (accessed: https://web.archive.org/web/20221205004929/https://www.modernatx.com/patents)
1222	"Patents," Moderna website, March 8, 2023 (accessed: https://web.archive.org/web/20230308131232/https://www.modernatx.com/patents)
1223	"Patents," Moderna website, December 9, 2023 (accessed: https://web.archive.org/web/20231209004401/https://www.modernatx.com/en-US/patents)
1224	"Why Did The World Shut Down For COVID-19 But Not Ebola, SARS Or Swine Flu?" ABC News, April 14, 2020 (accessed: https://fivethirtyeight.com/features/why-did-the-world-shut-down-for-covid-19-but-not-ebola-sars-or-swine-flu/)
1225	Bishai, D. et al, Handbook of Applied Health Economics In Vaccines, Oxford University Press, 2023
1226	"Landmark moment as first NHS patient receives COVID-19 vaccination," NHS England, December 8, 2020 (accessed: https://www.england.nhs.uk/2020/12/landmark-moment-as-first-nhs-patient-receives-covid-19-vaccination/)
1227	Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. A global database of COVID-19 vaccinations. Nat Hum Behav (2021) (accessed: https://ourworldindata.org/covid-vaccinations)
1228	"2020 Final Death Statistics: COVID-19 as an Underlying Cause of Death vs. Contributing Cause," National Center for Health Statistics, January 7, 2022 (accessed: https://www.cdc.gov/nchs/pressroom/podcasts/2022/20220107/20220107.htm#print)
1229	"Provisional Mortality Data — United States, 2021," CDC website, April 29, 2022 (accessed: https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e1.htm)
1230	"COVID-19 hospitalizations," Our World in Data, (accessed: https://ourworldindata.org/covid-hospitalizations)
1231	"US death rate dropped 6% in 2023, with Covid-19 falling to 10th leading cause of death, CDC says," CNN, August 8, 2024 (accessed: https://www.cnn.com/2024/08/08/health/us-death-rate-2023-cdc/index.html)
1232	"FDA authorized Novavax COVID-19 vaccine for emergency use in US," ABC News, July 13, 2022 (accessed: https://abcnews.go.com/Health/fda-authorizes-novavax-covid-19-vaccine-emergency-us/story?id=86769988)
1233	"Novavax Says U.S. Will Pause Funding for Production of Its Vaccine," The New York Times, August 8, 2021 (accessed: https://www.nytimes.com/2021/08/06/us/politics/novavax-coronavirus-vaccine.html)
1234	"AstraZeneca's COVID-19 vaccine authorised for emergency supply in the UK," AstraZeneca press release, December 30, 2020 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2020/astrazenecas-covid-19-vaccine-authorised-in-uk.html#)
1235	"Vaxzevria receives full marketing authorisation in the EU for the prevention of COVID-19," AstraZeneca, November 1, 2022 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2022/vaxzevria-receives-fu marketing-authorisation-in-the-eu-for-the-prevention-of-covid-19.html)
1236	"Press Briefing by White House COVID-19 Response Team and Public Health Officials, April 27, 2021 (accessed: https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/27/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-32/)
1237	"AZD1222 US Phase III primary analysis confirms safety and efficacy," AstraZeneca, March 25, 2021 (accessed: https://www.astrazeneca.com/media-centre/press-releases/2021/azd1222-us-phase-iii-primary-analysis-confirms-safety-and-efficacy.html)
1238	"Is Novavax a Buy Now?" The Motley Fool, March 4, 2024 (accessed: https://www.fool.com/investing/2024/03/04/is-novavax-a-buy-now/)
1239	"Novavax's COVID-19 Shot Just in Time, Optimism Surrounds As Demand Picks Up Momentum," Business Insider, October 4, 2023, (accessed: https://markets.businessinsider.com/news/stocks/novavax-s-covid-19-shot-jus in-time-optimism-surrounds-as-demand-picks-up-momentum-1032679259)
1240	"This was mRNA's breakout year," ACS Publications website, December 6, 2021 (accessed: https://pubs.acs.org/doi/10.1021/cen-09944-cover2)
1241	Lalani, Hussain S., et al. "US public investment in development of mRNA covid-19 vaccines: retrospective cohort study." British Medical Journal, 380: e073747, March 1, 2023 (accessed: https://doi.org/10.1136/bmj-2022-073747 and https://doi.org/10.1136/bmj.p587)
1242	Moderna LinkedIn post (accessed: https://www.linkedin.com/posts/modernatx_breaking-news-the-nobel-assembly-at-karolinska-activity-7114610548184334336-NP4y?utm_source=share&utm_medium=member_desktop)
1243	"How researchers unlocked mRNA: Learn about mRNA research history," Moderna website, video transcript (accessed: https://www.modernatx.com/en-US/power-of-mrna/about-mrna#how-researchers-unlocked-mrna)
1244	"A Nobel for Modified mRNA," American Association for the Advancement of Science, October 2, 2023 (accessed: https://www.science.org/content/blog-post/nobel-modified-mrna)
1245	"Moderna Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Updates," Moderna press release, February 23, 2023 (accessed: https://investors.modernatx.com/news/news-details/2023/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2022-Financial-Results-and-Provides-Business-Updates/default.aspx)
1246	NIH Technology Transfer Annual Report for the year ended December 31, 2021 (accessed: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/FY2021%20NIH%20Technology%20Transfer%20Annual%20Report.pdf)
1247	Moderna Form 10-K for the year ended December 31, 2018
1248	"Acuitas Therapeutics Non-Confidential Presentation," Acuitas website, November 11, 2018 (accessed: https://acuitastx.com/wp-content/uploads/2018/11/Acuitas-non-confidential-overview_Nov_2018.pdf)
1249	"Our Journey," Acuitas website (accessed: https://acuitastx.com/company/our-journey/)
1250	AICPA Accounting & Valuation Guide, updated as of May 1, 2013
1251	"First Quarter 2020: Corporate update and financial results," BioNTech website, May 12, 2020, slide 5 (accessed: https://investors.biontech.de/static-files/7700eaa3-12b1-43e1-855e-d7c08856b9b8)
1254	"A Guide to Valuation of the Assembled Workforce Intangible Asset," American Bankruptcy Institute website, October 1, 2006 (accessed: https://www.abi.org/abi-journal/a-guide-to-valuation-of-the-assembled-workforce-intangible-asset)

Attachment C
Documents Cited

Exhibit	Document
1255	"Leveraging 13 Years of Investment in mRNA Innovation for Future Pandemic Preparedness," Moderna website (accessed: https://www.modernatx.com/en-US/media-center/all-media/blogs/leveraging-13-years-of-investmer in-mrna)
1256	"How the Moderna Covid-19 mRNA vaccine was made so quickly," CNBC website, July 3, 2021 (accessed: https://www.cnbc.com/2021/07/03/how-moderna-made-its-mrna-covid-vaccine-so-quickly-noubar-afeyan.html)
1257	"How Moderna is racing to a coronavirus vaccine," MIT Sloan website, April 3, 2020 (accessed: https://mitsloan.mit.edu/ideas-made-to-matter/how-moderna-racing-to-a-coronavirus-vaccine)
1258	"The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine: From the Pharmaceutical Scientists' Perspective," NIH website, September 18, 2022 (accessed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9482796/)
1259	Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief," Industry Week, January 31, 2023 (accessed: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-mrna-manufacturing-code-with-pfizers-supply-chain-chief)
1260	"The power of mRNA," Moderna website (accessed: https://www.modernatx.com/en-US/power-of-mrna/modernas-mrna-platform)
1261	"Updated vaccines. Consistent storage," Moderna website (accessed: https://spikevax.com/healthcare-provider-guide/helpful-vaccine-resource-tools)
1262	"Shot of a Lifetime: How Two Pfizer Manufacturing Plants Upscaled to Produce the COVID-19 Vaccine in Record Time," Pfizer website (accessed: https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_two_pfizer_manufacturing_plants_upscaled_to_produce_the_covid_19_vaccine_in_record_time)
1263	"None of us were ready" to manufacture genetic vaccines for a billion people," MIT Technology Review, December 17, 2020 (accessed: https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability stephane-bancel-ceo/)
1264	"Here's Why COVID-19 Vaccines Like Pfizer's Need to be Kept So Cold," Science News, November 20, 2020 (accessed: https://www.sciencenews.org/article/coronavirus-covid-19-why-vaccines-cold-freeze-pfizer-moderna
1265	"Accelerating Digital Technology for the COVID-19 Vaccine Rollout," Pfizer website, March 2022 (accessed: https://www.pfizer.com/news/behind-the-science/accelerating-digital-technology-covid-19-vaccine-rollout)
1266	United Airlines Begins Pfizer COVID-19 Vaccine Charter Flights," Airline Geeks website, November 28, 2020 (accessed: https://airlinegeeks.com/2020/11/28/united-airlines-begins-pfizer-charter-flights/)
1267	Update on our COVID-19 vaccine," BioNTech website, December 22, 2020 (accessed: https://investors.biontech.de/static-files/3193fc38-2158-45df-a19c-b9e294db3f11)
1268	"Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints," Pfizer website, November 18, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine)
1269	"Pfizer Wins 2022 Supply Chain Award," Gartner (accessed: https://www.gartner.com/en/supply-chain/trends/supply-chain-award-winner-2022-pfizer)
1270	"Pfizer and BioNTech Achieve First Authorization in the World for a Vaccine to Combat COVID-19," Pfizer website, December 2, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-achieve-first-authorization-world)
1271	"Moderna struggling to supply promised doses of Covid vaccine," The Guardian, April 16, 2021 (accessed: https://www.theguardian.com/world/2021/apr/16/moderna-struggling-to-supply-promised-doses-of-covid-vaccine)
1272	Moderna Form 10-K for the year ended December 31, 2022
1273	FDA, Current Good Manufacturing Practices (CGMP) Regulations (accessed: https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmpregulations)
1274	"What Is the Network Effect?" Wharton University of Pennsylvania, January 17, 2023 (accessed: https://online.wharton.upenn.edu/blog/what-is-the-network-effect/)
1275	Pfizer's Form 10-K for the year ended December 31, 2020
1276	"Number of COVID-19 vaccine doses administered in the United States as of April 26, 2023, by vaccine manufacturer," Statista, April 2023 (accessed: https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/)
1277	"Fourth Quarter 2021 Earnings Teleconference," Pfizer website, February 8, 2022 (accessed: https://s28.q4cdn.com/781576035/files/doc_financials/2021/q4/Q4-2021-Earnings-Charts-FINAL.pdf)
1278	Druedahl, Louise C et al., "Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships," Vaccine vol. 39,42, September 2021, 6291-6295, doi:10.1016/j.vaccine.2021.08.101
1279	"Collaborators," BioNTech website (accessed: https://www.biontech.com/int/en/home/about/collaborators.html)
1280	"Pfizer and BioNTech Announce Collaboration With Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America," Pfizer website, August 26, 2021 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-brazils)
1281	"As COVID vaccine patent dispute drags on, Moderna forks over $400M to NIH," ARS Technica, February 24, 2023 (accessed: https://arstechnica.com/science/2023/02/moderna-forks-over-400m-to-nih-amid-dispute-over-covid-vaccine-ip/)
1282	"What happened to the AstraZeneca vaccine? Now rare in rich countries, it's still saving lives around the world," The Conversation, May 23, 2022 (accessed: https://theconversation.com/what-happened-to-the-astrazeneca-vaccine-now-rare-in-rich-countries-its-still-saving-lives-around-the-world-181791)
1283	Vaxzevria (previously COVID-19 Vaccine AstraZeneca)," European Medicines Agency (accessed: https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca).
1284	"VidPrevtyn Beta," Very Well Health, European Medicines Agency (accessed: https://www.ema.europa.eu/en/medicines/human/EPAR/vidprevtyn-beta)
1285	"Coronavirus vaccine trial begun by drug firms GSK and Sanofi," BBC, September 3, 2020 (accessed: https://www.bbc.com/news/business-54009633)
1286	"Fast-forward: Will the speed of COVID-19 vaccine development reset industry norms?" McKinsey & Company, May 13, 2021 (accessed: https://www.mckinsey.com/industries/life-sciences/our-insights/fast-forward-will-th speed-of-covid-19-vaccine-development-reset-industry-norms)
1287	"Emergency Use Authorization for Vaccines Explained," FDA website, November 20, 2020 (accessed: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)

Attachment C
Documents Cited

Exhibit	Document
1288	"FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine," FDA website, February 27, 2021 (accessed: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine)
1289	"Oxford / AstraZeneca vaccine reaches two billion dose milestone," University of Oxford website, November 16, 2021 (accessed: https://www.ox.ac.uk/news/2021-11-16-oxford-astrazeneca-vaccine-reaches-two-billion-dose milestone)
1290	"A Guide to Global COVID-19 Vaccine Efforts," Council on Foreign Relations, December 5, 2022 (accessed: https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts)
1291	"Trump signs $8.3 billion emergency coronavirus spending package," CNBC News, March 6, 2020 (accessed: https://www.cnbc.com/2020/03/06/trump-signs-8point3-billion-emergency-coronavirus-spending-package.html)
1292	"Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2," Pfizer press release, July 22, 2020 (accessed: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government)
1293	"The Covid Vaccine Is Free, but Not Everyone Believes That," The New York Times, June 1, 2021 (accessed: https://www.nytimes.com/2021/06/01/upshot/covid-vaccine-hesitancy-cost.html)
1294	"Commercialization of COVID-19 Vaccines, Treatments, and Tests: Implications for Access and Coverage," KFF, February 6, 2024 (accessed: https://www.kff.org/coronavirus-covid-19/issue-brief/commercialization-of-cov 19-vaccines-treatments-and-tests-implications-for-access-and-coverage/)
1295	"COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured," HRSA, January 1, 2024 (accessed: https://www.hrsa.gov/provider-relief/about/covid-uninsured-claim)
1296	"Government Warns Doctors and Insurers: Don't Bill for Covid Vaccines," The New York Times, June 9, 2021 (accessed: https://www.nytimes.com/2021/06/09/upshot/covid-vaccines-government-warning-bills.html)
1297	"Incentives for COVID-19 Vaccination: Food, Cash, & Other Perks," GoodRx Health, June 24, 2021 (accessed: https://www.goodrx.com/health-topic/vaccines/covid-19-vaccination-incentives)
1298	"LA Has Imposed One of the US's Strictest Vaccine Mandates. Will It Prevent a Covid Surge?" The Guardian, November 13, 2021 (accessed: https://www.theguardian.com/us-news/2021/nov/13/los-angeles-vaccine-mandat covid-surge)
1299	"Here Are The U.S. Cities Where You Need A Covid Vaccine To Dine In A Restaurant," Forbes, December 22, 2021 (accessed: https://www.forbes.com/sites/carlieporterfield/2021/12/22/here-are-the-us-cities-where-you-need-a-covid-vaccine-to-dine-in-a-restaurant/)
1300	"Key to NYC': Indoor vaccine mandate begins on Tuesday," ABC 7 News, August 16, 2021 (accessed: https://abc7ny.com/nyc-vaccine-pass-proof-of-vaccination-key-to-mandate/10954428/)
1301	"NYC Slaps 14 Businesses With $1,000 Fines for Violating Vaccine Mandate," Eater, October 12, 2021 (accessed: https://ny.eater.com/2021/10/12/22722297/nyc-business-vaccine-mandate-violations-fines)
1302	"Moderna vs Pfizer: Is it OK to mix and match the updated COVID-19 booster shots?" Los Angeles Times, September 23, 2022 (accessed: https://www.latimes.com/california/story/2022-09-23/moderna-vs-pfizer-is-it-ok-to-mix-and-match-the-updated-covid-19-booster-shots)
1303	"Covid-19: Biden tells states to offer $100 vaccine incentive as cases rise," BBC, July 30, 2021 (accessed: https://www.bbc.com/news/world-us-canada-58020090)
1304	Moderna Form 10-Q for the quarterly period ended June 30, 3024
2012	Complaint for Patent Infringement, ModernaTX, Inc. et al v. Pfizer Inc. et al, Case No. 1:22-cv-11378, August 26, 2022
2012	Complaint, ModernaTX, Inc. et al. v. Pfizer Inc et al., C.A. No. 22- 11378, Dkt. No. 1 (D. Mass, Aug. 26, 2022)
2034	"Patents," Moderna website (accessed: https://www.modernatx.com/en-US/patents)
2034	Moderna, Inc., Patents, https://www.modernatx.com/patents
2121	BioNTech Form 20-F for the year ended December 31, 2023
2125	Moderna Form 10-K for the year ended December 31, 2023
2126	"Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus," Moderna website, March 16, 2020 (accessed: https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-First-Participant-Dosed-in-NIH-led-Phase-1-Study-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx)
2126	Moderna, Moderna Announces First Participant Dosed in NIH-Led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (Mar. 16, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna- Announces-First-Participant-Dosed-in-NIH-led-Phase-1-Study-of- mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx
2197	Declaration of James E. Malackowski, May 29, 2024
2200	Declaration of Philip Krause, M.D., May 28, 2024
2229	"Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine," FDA press release, January 31, 2022 (accessed: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine)
	35 U.S.C. § 103
	Asyst Technologies, Inc. v. Emtrak, Inc., 544 F.3d 1310, 1316 (Fed. Cir. 2008)
	Campbell Soup Company v. Gamon Plus, Inc., 10 F.4th 1268, 1275-76 (Fed. Cir. 2021)
	Decision Granting Institution of Inter Partes Review and Granting the Parties' Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01358
	Decision Granting Institution of Inter Partes Review and Granting the Parties' Respective Motions to Seal Granting Request to Enter Protective Order, Case No. IPR2023-01359
	Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1393 (Fed. Cir. 1988)

Attachment C
Documents Cited

Exhibit	Document
	Ericsson, Inc. v. D-Link Systems, Inc., 773 F.3d 1201, 1226 (Fed Cir. 2014)
	Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019)
	Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC, 618 F.3d 1294, 1304 (Fed. Cir. 2010)
	In re DBC, 545 F.3d 1373, 1384 (Fed. Cir. 2008)
	In re Huai-Hung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011)
	In re Hubbell Inc., 644 Fed. App'x 1004, 1008 (Fed. Cir. 2016)
	In re Kluter, 92 F.2d 906, 908 (CCPA 1937)
	In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990)
	KSR Intern. Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007)
	Media Technologies Licensing, LLC v. Upper Deck Co., 596 F.3d 1334, 1339 (Fed. Cir. 2010)
	Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1376, 1377 (Fed. Cir. 2005)
	Novartis AG v. Torrent Pharmaceuticals Limited, 853 F.3d 1316, 1330-1331 (Fed. Cir. 2017)
	Order Granting in Part and Denying in Part Motions to Exclude Expert Testimony, Denying Motion to Bifurcate Trial, Denying Motion for Preclusive Sanctions in the matter of Mformation Techs., Inc. v. Research in Motion et al., 5:08-cv-04990-JW (N.D. Cal. 2012)
	Oren Techs., LLC v. Proppant Express Invs. LLC, No. 2019-1778, 2021 WL 3120819, at *6–7 (Fed. Cir. July 23, 2021)
	Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006)
	Patent Owner's Preliminary Response, Case No. IPR2023-01358, December 8, 2023
	Patent Owner's Preliminary Response, Case No. IPR2023-01359, May 31, 2024
	Power Integrations, Inc. v. Fairchild Semiconductor International, Inc., 894 F.3d 1258 (Fed. Cir. 2018)
	Prometheus Labs., Inc. v. Roxane Laboratories, Inc., 805 F.3d 1092, 1101-02 (Fed. Cir. 2015)
	Purdue Pharma L.P. v. Epic Pharma, LLC, 811 F.3d 1345, 1354 (Fed. Cir. 2016)
	Ritchie v. Vast Resources, Inc., 563 F.3d 1334, 1336 (Fed. Cir. 2009)
	Riverwood Intern. Corp. v. Mead Corp., 212 F.3d 1365, 1367 (Fed. Cir. 2000)
	S. Alabama Med. Sci. Found. v. Gnosis S.P.A., 808 F.3d 823, 827 (Fed. Cir. 2015)
	TalexMedical, LLC v. Becon Med. Ltd., No. 2021-2069, 2022 WL 2898934, at *9–10 (Fed. Cir. July 22, 2022)
	Textile Mach. Works v. Louis Hirsch Textile Mach., 87 F.2d 702, 704 (2d Cir. 1937)
	Tokai Corp., et al. v. Easton Enterprises, Inc., 632 F.3d 1358, 1369-1370 (Fed. Cir. 2011)
	Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1318 (Fed. Cir. 2011)
	VirnetX, Inc. v. Cisco Sys., 767 F.3d 1308 (Fed. Cir. 2014)
	WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1329, 1337 (Fed. Cir. 2016)
	WesternGeco LLC v. ION Geophysical Corporation, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018)
	Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010)