IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Diaz et al.	
U.S. Patent No.:	11,649,287	Attorney Docket No.: 52261-00013IP1
Issue Date:	May 16, 2023	
Appl. Serial No.:	17/465,096	
Filing Date:	September 2, 2021	
Title:	CHECKPOINT BLOCKADE AND MICROSATELLITE INSTABILITY	

DECLARATION OF BRIAN J. SEGERS

I currently hold the opinions expressed in this declaration. However, my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare 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.

Dated: 1/22/2024 By: _____

Brian J. Segers

JHU 2191
Merck Sharp v. Johns Hopkins
IPR2024-00647
MERCK EX1270
Merck Sharp & Dohme LLC v. The Johns Hopkins University
IPR2024-00624

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I, Brian J. Segers, under penalty of perjury, declare as follows:

I. INTRODUCTION

A. Qualifications

1. My name is Brian J. Segers. I am a Managing Director with Coherent Economics. Coherent Economics is an economic consulting firm specializing in complex economic issues in litigation and business consulting. My Curriculum Vitae contains my prior testifying experience, including a complete record of my testimony over the last four years and is attached as Appendix A.

2. I received my M.S. in economics from Texas A&M in 2002. During my time at Texas A&M, I taught undergraduate Microeconomics. I joined Coherent Economics in 2022. I have consulted on many economic matters since beginning my career in 2002.

3. As a consultant, I have worked on a variety of matters involving intellectual property, antitrust issues, and contract disputes, among other issues. Many of these matters involved the determination of damages in several contexts, including patent infringement, theft of trade secrets, trademark infringement, breach of contract, and breach of fiduciary duty. Many of these matters also include valuations as well as calculations of patent infringement damages in the form of both reasonable royalties and lost profits. I have experience involving a variety of industries including pharmaceuticals, health insurance, medical equipment,

hospitals, and retail sales. In the pharmaceutical context, I have provided testimony regarding patent damages and trade secret damages. I have testified in Federal Court regarding commercial success, and I have provided economic consulting services to a variety of pharmaceutical clients dealing with commercial success, valuations of certain drug properties, lost profits, and reasonable royalties. I have offered economic consulting services regarding intellectual property issues disputes involving cancer treatment drugs. I have offered expert testimony regarding damages, valuations, and intellectual property issues. I have testified in Federal Court and in arbitration proceedings. Appendix 1 contains a list of my testimony and recent consulting work.

B. Assignment

4. The above-referenced matter relates to the patentability of U.S. Patent 11,649,287 ('287 patent) owned by The Johns Hopkins University ("JHU"). I understand Merck filed a petition with the Patent Office challenging the patentability of all claims of the '287 patent under various grounds, including obviousness.

5. Coherent Economics, LCC was retained by Fish & Richardson P.C. ("Counsel") on behalf of Patent Owner JHU in the above referenced matter to provide analysis of the commercial success of the use of Merck's branded cancer drug KEYTRUDA® for the treatment of microsatellite instability-high or mismatch

repair deficient colorectal cancer (CRC), which I understand practices the invention claimed in the ’287 patent at issue in this dispute before the Patent Office.

6. My project team and I have been engaged for this assignment at the standard hourly billing rates of the individuals assigned plus expenses. My hourly billing rate is $675 per hour. The hourly billing rates of other individuals working on this engagement range from $300 to $500 per hour. The amount of our fees is not contingent on the opinions expressed herein or on the outcome of this matter.

7. My opinions are based on information available to me as of the date of this report. I, and the professionals working under my direction, have relied on and examined documents produced by Merck along with publicly available information, either in whole or in part. I have reviewed Dr. Richard Goldberg’s declaration in support of JHU’s Patent Owner response, and I am relying on Dr. Goldberg’s analysis regarding the nexus of the method of using KEYTRUDA® with the ’287 patent claims. I previously spoke with Dr. Goldberg in connection with JHU’s ’393 patent IPR Patent Owner Response regarding the nexus of the ’393 patent to the objective indicia, including commercial success. For this analysis, I had no further questions for nexus in relation to the ’287 patent.

II. SUMMARY OF OPINIONS

8. I understand that the U.S. Food and Drug Administration (FDA) approved KEYTRUDA® (pembrolizumab) 100 mg / 4 mL for injection and

intravenous use on May 23, 2017 for the treatment of patients with unresectable or metastatic solid tumors that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).[1] Specifically, the FDA granted accelerated approval for treatment of patients with MSI-H or dMMR solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options (i.e. "last line treatment") and patients with MSI-H or dMMR colorectal cancer that progressed following treatment with certain chemotherapy drugs (i.e. "second-line treatment"). KEYTRUDA® is a type of immunotherapy that works by blocking the PD-1 pathway to help prevent cancer cells from hiding.[2] Merck first began selling KEYTRUDA® after its initial FDA approval in September 2014.[3]

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[1] "FDA approved first cancer treatment for any solid tumor with a specific genetic feature," FDA, May 23, 2017, available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-cancer-treatment-any-solid-tumor-specific-genetic-feature (accessed 9/5/2024). EX2004

[2] "HOW DOES KEYTRUDA WORK?" KEYTRUDA, available at https://www.keytruda.com/how-does-keytruda-work/#how-keytruda-works (accessed 9/5/2024). EX2192

[3] Merck 2014 SEC Form 10-K, dated February 27, 2015, p. 48. EX2193; AEO Document 11 (Merck Sales Data) (EX2187); "The FDA approved KEYTRUDA® to be 'indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor'." *See* EX1055.

9. KEYTRUDA®'s use in treating MSI-H or dMMR colorectal cancer is commercially successful because:

- its sales and profits have been substantial and growing since launch,
- its number of patients undergoing treatment has been substantial and growing since launch,
- [redacted]

10. KEYTRUDA®'s commercial success in treating MSI-H or dMMR colorectal cancer is due to the claimed invention, and Merck's marketing efforts and KEYTRUDA®'s price are not responsible for the commercial success of KEYTRUDA® in treating MSI-H or dMMR colorectal cancer.

III. BACKGROUND

A. Parties

11. Merck Sharp & Dohme LLC is a wholly-owned subsidiary of Merck & Co., Inc (collectively "Merck").[4] Merck Sharp & Dohme LLC was founded in 1891 and is based on Rahway, New Jersey.[5] Merck manufactures and distributes vaccines, prescription products, oncology products, consumer products, animal health

[4] Merck 2023 SEC Form 10-K, dated February 26, 2024, at Exhibit 10.30 p. 1 and Exhibit 21 p. 11. EX2194.

[5] Merck Sharp & Dohme LLC Private Company Profile at S&P Capital IQ. EX2195.

products, and biologic therapies for customers worldwide.[6] Merck's leading pharmaceutical product, KEYTRUDA®, accounted for about 42 percent of total worldwide Merck sales in 2023.[7]

12. The Johns Hopkins University ("JHU") is a private university founded in 1876 and based in Baltimore, Maryland.[8] JHU is the first research university of the United States.[9] Twenty-nine people associated with JHU as a faculty member, fellow, resident, or graduate have received a Nobel Prize, including 17 recipients of the Nobel Prize in Physiology or Medicine.[10]

B. Challenged Patent

13. I understand that my assignment is to evaluate the commercial success related to the '287 patent.[11]

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[6] Merck Sharp & Dohme LLC Private Company Profile at S&P Capital IQ. EX2195.

[7] Merck 2023 SEC Form 10-K, dated February 26, 2024, at p. 1. EX2194.

[8] Johns Hopkins University Educational Institution Profile at S&P Capital IQ. EX2196.

[9] "Research and Faculty" Johns Hopkins University, available at https://www.jhu.edu/research/ (accessed 10/2/2024). EX2197.

[10] "Nobel Prize Winners" Johns Hopkins University, available at https://www.jhu.edu/research/milestones/nobel-prize-winners/ (accessed 10/2/2024). EX2198.

[11] Patent No. US 11,649,287. EX1001.

14. The Johns Hopkins University submitted the initial patent application for the ’287 patent on November 13, 2014 and the patent issued on May 16, 2023.[12] I understand that the patent application was based on the results of a Phase-2 clinical study called “Study of MK-3475 in Patients with Microsatellite Unstable (MSI) Tumors (Cohorts A, B, C)”, which was conducted between September 2013 and August 2019.[13] Initial results were published May 30, 2015.[14] The clinical study was sponsored by Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins with collaborator Merck and Principal Investigator Dung Le, MD.[15]

C. MSI-H/dMMR Cancer and MSI-H/dMMR Colorectal Cancer

15. I understand that DNA mismatch repair (MMR) is a system that corrects errors that occur during DNA replication.[16] Cells that become deficient in

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[12] Patent No. US 11,649,287. EX1001.

[13] “Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C).” EX1005

[14] *See* T. Le et al. “PD-1 Blockade in Tumors with Mismatch-Repair Deficiency,” *N Engl J Med (*June 25, 2015): 372(26):2509-20. EX1031.

[15] “Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C).” EX1005

[16] “IS KEYTRUDA RIGHT FOR YOU?” KEYTRUDA, available at https://www.keytruda.com/msi-h/treatment-options/ (accessed 9/10/2024) (EX2199); Maria Lorenzi et al. “Epidemiology of Microsatellite Instability High (MSI-H) and Deficient Mismatch Repair (dMMR) in Solid Tumors: A Structured Literature Review,” *Hindawi Journal of Oncology* (2020) p.1. EX2200.

mismatch repair (dMMR) have difficulty in repairing mistakes in DNA.[17] Defects in MMR in regions of simple repetitive DNA sequences known as microsatellites can lead to microsatellite instability-high (MSI-H) cancer cells, which can be found in many cancer types.[18]

16. I understand that MSI-H or dMMR is more common in earlier stages of cancer than in advanced (stage IV) tumors. According to a study, approximately 10 percent of stage I to stage III cancers and 5 percent of stage IV cancers exhibit dMMR across 11 tumor types, including colorectal.[19] However, MSI-H or dMMR is detected in about 15 percent of all colorectal cancers.[20] As of 2023, there are 152,810

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[17] "IS KEYTRUDA RIGHT FOR YOU?" KEYTRUDA, available at https://www.keytruda.com/msi-h/treatment-options/ (accessed 9/10/2024) (EX2199); Maria Lorenzi et al. "Epidemiology of Microsatellite Instability High (MSI-H) and Deficient Mismatch Repair (dMMR) in Solid Tumors: A Structured Literature Review," *Hindawi Journal of Oncology* (2020) p.1. EX2200.

[18] "IS KEYTRUDA RIGHT FOR YOU?" KEYTRUDA, available at https://www.keytruda.com/msi-h/treatment-options/ (accessed 9/10/2024) (EX2199); Maria Lorenzi et al. "Epidemiology of Microsatellite Instability High (MSI-H) and Deficient Mismatch Repair (dMMR) in Solid Tumors: A Structured Literature Review," *Hindawi Journal of Oncology* (2020) p.1. EX2200.

[19] Dung T. Le et al. "Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade," *Science* 357, 409–413 (2017). EX2118

[20] "Microsatellite Instability Biomarker (MSI-H)," Colorectal Cancer Alliance, 18 Jan. 2024, available at colorectalcancer.org/treatment/types-treatment/why-biomarkers-matter/types-biomarkers/microsatellite-instability (accessed 10/2/2024) (EX2230); C. Richard et. al "Microsatellite Instability in Colorectal Cancer Boland," *Gastroenterology* Volume 138, Issue 6, 2073 - 2087.e3 (2010) p. 2073. EX2201.

estimated new CRC cases in the United States.[21] CRC makes up around 7.6 percent of all cancer cases.[22]

D. KEYTRUDA®

17. KEYTRUDA® received initial U.S. approval from the FDA on September 4, 2014 and launched in the United States in September 2014.[23] I understand that KEYTRUDA® is a prescription medicine and a type of immunotherapy that works by blocking the PD-1 pathway to help prevent cancer

[21] Siegel, Rebecca L et al. "Cancer statistics, 2024." *CA: a cancer journal for clinicians* vol. 74,1 (2024): 12-49. EX2202.

[22] Siegel, Rebecca L et al. "Cancer statistics, 2024." *CA: a cancer journal for clinicians* vol. 74,1 (2024): 12-49. EX2202.

[23] Merck 2014 SEC Form 10-K, dated February 27, 2015, p. 48 (EX2193); AEO Document 11 (Merck Sales Data) (EX2187); "The FDA approved KEYTRUDA® to be 'indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor'." *See* EX1055.

cells from hiding.[24] It is the first anti-PD-1 therapy approved in the United States.[25] It is administrated via intravenous infusion over 30 minutes.[26]

18. On May 23, 2017, the FDA approved KEYTRUDA® for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having a MSI-H or dMMR biomarker, covering 1) patients with solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options and 2) patients with colorectal cancer that has progressed following treatment with certain chemotherapy drugs (fluoropyrimidine, oxaliplatin, and irinotecan).[27] I understand that this was the first

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[24] "HOW DOES KEYTRUDA WORK?" KEYTRUDA, available at https://www.keytruda.com/how-does-keytruda-work/#how-keytruda-works (accessed 9/5/2024). EX2192.

[25] Merck 2014 SEC Form 10-K, dated February 27, 2015, p.13. EX2193. Since then, two more have been approved. *See* "Immune Checkpoint Inhibitors and Their Side Effects," American Cancer Society, available at https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/immune-checkpoint-inhibitors.html (accessed 10/3/2024). EX2203.

[26] "HOW KEYTRUDA IS GIVEN," KEYTRUDA, available at https://www.keytruda.com/taking-keytruda/ (accessed 9/5/2024). EX2204.

[27] "FDA approves first cancer treatment for any solid tumor with a specific genetic feature," FDA, May 23, 2017, (accessed 9/5/2024) (EX2004); Approval Letter, FDA, May 23, 2017, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/125514Orig1s014ltr.pdf (accessed 10/3/2024). EX2205.

time the agency approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.[28]

19. On June 29, 2020, FDA approved KEYTRUDA® as monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer.[29]

20. Initially, KEYTRUDA® was approved for the MSI-H indication using the Accelerated Approval pathway.[30] Recently, FDA has granted full approval to KEYTRUDA® for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.[31]

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[28] FDA approved first cancer treatment for any solid tumor with a specific genetic feature," FDA, May 23, 2017. EX2004

[29] Supplemental Approval Letter, FDA, June 29, 2020, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125514Orig1s084ltr.pdf (accessed 10/3/2024). EX2205.

[30] "FDA approves first cancer treatment for any solid tumor with a specific genetic feature," FDA, May 23, 2017, available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-cancer-treatment-any-solid-tumor-specific-genetic-feature (accessed 9/5/2024). EX2004.

[31] "FDA Converts to Full Approval Indication for KEYTRUDA® (pembrolizumab) for Certain Adult and Pediatric Patients With Advanced Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors" Merck, March 29, 2023. EX2026.

21. For MSI-H or dMMR cancer and MSI-H or dMMR CRC in adults, KEYTRUDA® is administered either 200 mg every three weeks or 400 mg every six weeks. For MSI-H or dMMR cancer in children, it is administered 2 mg/kg (up to 200 mg) every three weeks.[32]

IV. COMMERCIAL SUCCESS OF KEYTRUDA®'S USE AS A TREATMENT OF MSI-H OR DMMR COLORECTAL CANCER

22. Economically, commercial success is an indicator of non-obviousness because it suggests a demand that was not met by pre-existing products. That is to say, the fact that a product can generate meaningful sales and capture market share is an indication that the product offers characteristics or features that are valued by consumers and not found in other products. Many indicators show that KEYTRUDA®'s use in treating MSI-H or dMMR CRC has been commercially successful.

A. Sales

23. I understand that substantial and growing sales are an indicator of commercial success. Based on such a measure, KEYTRUDA®'s use in treating MSI-H or dMMR CRC is a commercial success. Since its FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or

[32] KEYTRUDA® Prescribing Information (August 2024). EX2207.

dMMR solid tumors, KEYTRUDA®'s sales in both net revenue and units have been large and consistently growing.

24. KEYTRUDA®'s U.S. sales have grown consistently since its initial launch in September 2014. Appendix 2 shows that U.S. sales of KEYTRUDA® grew from [redacted] in 2015 to [redacted] in 2017 to [redacted] in 2023. Appendix 3 shows that KEYTRUDA® has become an increasingly important product to Merck every year. In 2023, KEYTRUDA®'s U.S. sales represented more than 50 percent of Merck's total U.S. sales.

25. In particular, KEYTRUDA®'s U.S. sales experienced rapid growth since 2017 when it received FDA approval for several new indications, including approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors in May 2017. Appendix 4 shows that U.S. sales of KEYTRUDA® grew from [redacted] in 2017 Q1 to [redacted] in 2023 Q4. Over that time, KEYTRUDA® went from accounting for 8.6 percent of Merck's U.S. sales to accounting for 56.0 percent.[33]

[33] *See* Appendix 4; Merck 2018 Q1 SEC Form 10-Q, dated May 8, 2018, p. 29 (EX2247); Merck 2023 Q1 SEC Form 10-Q, dated May 5, 2023, p. 25 (EX2248); Merck 2023 Q2 SEC Form 10-Q, dated August 7, 2023, p. 27 (EX2249); Merck 2023 Q3 SEC Form 10-Q, dated November 3, 2023, p. 29 (EX2250); Merck 2023 SEC Form 10-K, dated February 26, 2024, p. 124 (EX2194).

26. Appendix 4 shows that the timing of KEYTRUDA®'s FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors coincides with an apparent inflection point in KEYTRUDA®'s sales trajectory. KEYTRUDA® earned [redacted] in net sales in the four quarters following FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors (2017 Q2 through 2018 Q1) than it had in the four quarters prior, for a growth of [redacted]. By comparison, KEYTRUDA® sales grew by only [redacted] in the four quarters prior to FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors (2016 Q2 though 2017 Q1), a growth rate of [redacted]. This increase in the rate of growth several years after launch is notable, as typically growth rates are highest in the years immediately following launch.

27. Sales of KEYTRUDA® for treatment of MSI-H or dMMR cancers specifically has also experienced consistent and rapid growth since its FDA approval for that indication. Merck management noted in each quarter from 2018 Q2 to 2019 Q1, that all MSI-H indications accounted for about 5 percent of KEYTRUDA® U.S. sales, meaning that KEYTRUDA® quarterly sales for MSI-H grew from $48 million

to $64 million over those four quarters.[34] More specifically, monthly sales of KEYTRUDA® for the treatment of MSI-H or dMMR CRC accounted for between [redacted] U.S. sales from its FDA approval for the treatment of MSI-H or dMMR CRC through January 2024.[35] Appendix 5 shows KEYTRUDA®'s sales for MSI-H or dMMR CRC indications [redacted]. Through the end of 2023, KEYTRUDA®'s sales for MSI-H or dMMR CRC indications [redacted].

28. KEYTRUDA®'s sales for MSI-H or dMMR CRC have been strong compared to competitor products in the market. The only other drugs approved to treat MSI-H or dMMR colorectal cancer specifically are ipilimumab (YERVOY®) and nivolumab (OPDIVO®).[36] In addition, dostarlimab-gxly (JEMPERLI) has a

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[34] Merck & Co., Inc., Q2 2018 Earnings Call, dated July 27, 2018 (EX2208); Merck & Co., Inc., Q3 2018 Earnings Call, dated October 25, 2018 (EX2209); Merck & Co., Inc., Q4 2018 Earnings Call, dated February 01, 2019 (EX2210); Merck & Co., Inc., Q1 2019 Earnings Call, dated April 30, 2019 (EX2211).

[35] AEO Document 12 (IQVIA Patient Data) (EX2188). This data provides [redacted]. I assume that the percentage of total sales attributable to MSI-H or dMMR CRC is equal to the percentage of total patients that are MSI-H or dMMR CRC patients. [redacted] I understand from my discussion with Dr. Goldberg that all KEYTRUDA® CRC patients are likely to be MSI-H/dMMR CRC patients so I count all CRC patients as MSI-H or dMMR CRC patients.

[36] *See* "List of Targeted Therapy Drugs Approved for Specific Types of Cancer," National Cancer Institute, available at https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/approved-drug-list (accessed 10/3/2024) (EX2212). Of the 13 drugs listed under "Targeted therapy approved for colorectal

tissue-agnostic approval for dMMR recurrent or advanced solid tumors.[37] According to Bristol-Myers Squibb, MSI-H or dMMR CRC indications accounted for no more than—and likely less than—5 percent of OPDIVO® and YERVOY® U.S. sales in 2018 and 2019.[38] Appendix 6 compares sales of JEMPERLI and an estimate of

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cancer", only ipilimumab (YERVOY®) and nivolumab (OPDIVO®), aside from KEYTRUDA®, are approved to treat MSI-H or dMMR colorectal cancer. OPDIVO® received FDA approval for the treatment of patients 12 years of age and older with MSI-H or dMMR metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan in August 2017. YERVOY® received FDA approval for use in combination with OPDIVO® for this indication in July 2018. *See* Bristol-Myers Squibb Company 2017 SEC Form10-K, dated February 13, 2018, p. 30 (EX2240) and Bristol-Myers Squibb Company 2018 SEC Form 10-K, dated February 25, 2019, p. 30 (EX2241).

[37] On August 17, 2021, the FDA granted accelerated approval to GlaxoSmithKline LLC's JEMPERLI for adult patients with dMMR recurrent or advanced solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. *See* "FDA grants accelerated approval to dostarlimab-gxly for dMMR advanced solid tumors," FDA, August 17, 2021, available at https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-advanced-solid-tumors (accessed 1/9/2025) (EX2283). I understand from my discussion with Dr. Goldberg that no other drug was approved by the FDA for MSI-H or dMMR cancer indications as of the end of 2023.

[38] Bristol-Myers Squibb Company, Q2 2018 Earnings Call, dated July 26, 2018. (EX2213) "in regard to the business mix, let me start with the U.S. and then Chris will cover international. Across our I-O franchise, our lung business is about 35%. So that's kind of diminished a little bit, and that's because our melanoma and renal business are increasing in light of some of the launches such as adjuvant in melanoma and also in renal. And what's interesting here is that, if you look at Opdivo and Yervoy together, you're looking at about 35% of our mix is melanoma so in line with our lung mix is. And about 20% for renal, 5% for head and neck, and a little bit of all others in the bottom 5, 10 parts." *See also* Bristol-Myers

OPDIVO® and YERVOY® sales for MSI-H or dMMR CRC indications to those of KEYTRUDA® from 2017 to 2023. KEYTRUDA®'s sales growth rates for the treatment of MSI-H or dMMR CRC have been [redacted] JEMPERLI's sales in its first two full years after approval for MSI-H or dMMR cancers, 2022 and 2023, were much less than KEYTRUDA®'s sales for MSI-H or dMMR cancers in its first 2 years after approval for the indication, 2018 and 2019. In fact, KEYTRUDA®'s sales for MSI-H or dMMR cancers in its first full year after approval for the indication were greater than those of JEMPERLI in its second full year after approval for the indication.

29. KEYTRUDA®'s consistently growing sales for the treatment of MSI-H or dMMR CRC, both in absolute terms and relative to competing products, are a clear indicator of its commercial success.

30. In economic terms, an invention is a commercial success if the invention generates an economic profit and adds value to the enterprise. KEYTRUDA®'s substantial revenue and growth within the MSI-H or dMMR CRC

Squibb Company, Q3 2018 Earnings Call, dated October 25, 2018 (EX2214) and Bristol-Myers Squibb Company, Q1 2019 Earnings Call, dated April 25, 2019 (EX2215), mentioning similar percentages for lung, melanoma, and renal and not mentioning MSI-H or colorectal cancer.

[39] To be conservative, I have counted all JEMPERLI sales as dMMR CRC sales in this comparison.

population is an indicator that the ’287 patent has generated an economic profit. Merck’s financial statements support the conclusion that the ’287 patent has generated substantial economic profit and value. According to Merck’s SEC filings, Merck’s operating profit margins as measured by “Sales” less “Cost of sales,” “Selling, general and administrative,” and “Research and development” as a percent of “Sales” was 16.9 percent in 2017, 21.1 percent in 2018, 26.1 percent in 2019, 17.7 percent in 2020, 27.1 percent in 2021, 30.8 percent in 2022, and 4.9 percent in 2023.[40] Even using these operating profit percentages for Merck as a whole, Merck’s profits on sales of KEYTRUDA® for treatment of MSI-H or dMMR colorectal

[40] This is a conservative measure relative to EBITDA margin as these expense categories include depreciation and amortization. Merck 2017 SEC Form 10-K, dated February 27, 2018, p. 70 (EX2216); Merck 2018 SEC Form 10-K, dated February 27, 2019, p. 68 (EX2217); Merck 2019 SEC Form 10-K, dated February 26, 2020, p. 70 (EX2218); Merck 2020 SEC Form 10-K, dated February 25, 2021, p. 79 (EX2219); Merck 2021 SEC Form 10-K, dated February 25, 2022, p. 79 (EX2220); Merck 2022 SEC Form 10-K, dated February 24, 2023, p. 71 (EX2221); Merck 2023 SEC Form 10-K, dated February 26, 2024, p. 71 (EX2194). Merck used different expense categories in its 2017 SEC Form 10-K, but restated 2017 expenses using the categories listed above in its 2018 SEC Form 10-K. I rely on the 2018 SEC Form 10-K for 2017 sales and expenses in this calculation. Merck’s profit margin was reduced in 2023 due in part to three acquisitions in 2023 that resulted in a combined $11.6 billion charges to Research and development expenses in 2023, which make this a further conservative measure of KEYTRUDA® profit margin as these large expenses are unlikely to be related to KEYTRUDA®. Merck 2023 SEC Form 10-K, dated February 26, 2024, pp. 81-82 (EX2194).

cancer are substantial, [redacted] It is likely that these profits will continue for some time as the ’287 patent does not expire until at least November 12, 2035.[42] Such large profits are a clear indication that the ’287 patent has created economic value and if the invention were obvious others would have had an incentive to undertake the same research as the Patent Owner.

B. Number of Patients Under Treatment

31. The number of patients under treatment with KEYTRUDA® for MSI-H or dMMR CRC has increased consistently since KEYTRUDA®’s FDA approval to treat MSI-H or dMMR colorectal cancer. Appendix 7 shows the trend in total patients under treatment for MSI-H or dMMR CRC with KEYTRUDA® from 2017 to 2023. For MSI-H or dMMR CRC specifically, on average there were [redacted] with KEYTRUDA® per month in 2017. By 2023, that number had

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[41] *See* Appendix 5. [redacted].

[42] November 12, 2035 is 20 years after the initial application was filed on November 12, 2015. Patent No. US 11,649,287 (EX1001).

[redacted]. The [redacted] relying on KEYTRUDA® for treatment each year is evidence of its commercial success.

32. Perhaps more tellingly than the total number of patients under treatment per month is the number of new patients using KEYTRUDA® each month. Appendix 8 shows the trend in new patients under treatment for MSI-H or dMMR CRC with KEYTRUDA® each month from 2017 to 2023. In 2017, the year of its approval for MSI-H or dMMR CRC, KEYTRUDA® [redacted] MSI-H or dMMR CRC patients per month. That number [redacted] The fact that [redacted] are being treated with KEYTRUDA® each year is further evidence of its commercial success.

C. Market Share

33. Other measures of commercial success are a growing share of sales (or prescriptions) or a maintenance of market share with a price premium. The market share penetration that KEYTRUDA® has achieved so far since its approval to treat MSI-H or dMMR colorectal cancer is further evidence of its commercial success.

34. As discussed above, there are only two other drugs approved to treat MSI-H or dMMR colorectal cancer, OPDIVO® and YERVOY®, and one other drug which can be used to treat dMMR colorectal cancer through a tissue-agnostic approval, JEMPERLI. Therefore, the total market for drugs specifically targeted to

treat MSI-H or dMMR colorectal cancer is defined by the sales of KEYTRUDA®, OPDIVO®, YERVOY®, and JEMPERLI for the indication of MSI-H or dMMR colorectal cancer. Appendix 9 shows the respective market shares of KEYTRUDA®, OPDIVO®, YERVOY®, and JEMPERLI in each year from 2017 through 2023. In 2017, KEYTRUDA® and OPDIVO® were approved as second-line treatments for MSI-H or dMMR colorectal cancer. In that year, KEYTRUDA®'s share of sales for treatment of MSI-H or dMMR colorectal cancer was at least [redacted]. By 2019, following YERVOY®'s approval in combination with OPDIVO® in 2018, KEYTRUDA®'s share of sales was about [redacted]. Following KEYTRUDA®'s approval as a first-line treatment for MSI-H or dMMR CRC in 2020, its market share continued to [redacted] in 2020 to about [redacted] in 2022, [redacted] from 2021 to 2023. This gain in market share and eventually dominant market share compared to its competitors is evidence of the commercial success of KEYTRUDA®'s use as a treatment for MSI-H or dMMR CRC.

35. More broadly, an increasing share of new cases of MSI-H or dMMR CRC are treated using KEYTRUDA® each year. There were between 135,000 and 155,000 new cases of colorectal cancer each year in the U.S. from 2017 to 2023.[43]

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[43] Siegel, Rebecca L et al. "Cancer Statistics, 2017." *CA: a cancer journal for clinicians* vol. 67,1 (2017): 7-30 (EX2223); Siegel, Rebecca L et al. "Cancer

Approximately 15 percent of all colorectal cancer are MSI-H or dMMR, meaning that there were between 20,000 and 24,000 new cases of MSI-H or dMMR CRC each year in the U.S. from 2017 to 2023.[44] Appendix 10 shows that while in 2018 KEYTRUDA® was used [redacted], that percentage increased [redacted] by 2023. Appendix 10 also compares this share to KEYTRUDA®'s share of other indications it is approved to treat. In 2018 and 2019, Merck management noted that non-small cell lung cancer (NSCLC), melanoma, and bladder cancer consistently accounted for significant shares of KEYTRUDA®'s overall sales. Appendix 10 shows that KEYTRUDA® has [redacted] than it has for those three indications. [redacted] than it has been in the bladder cancer and melanoma indication and has [redacted] of the NSCLC indication. The fact that

statistics, 2018." *CA: a cancer journal for clinicians* vol. 68,1 (2018): 7-30 (EX2224); Siegel, Rebecca L et al. "Cancer statistics, 2019." *CA: a cancer journal for clinicians* vol. 69,1 (2019): 7-34 (EX2225); Siegel, Rebecca L et al. "Cancer statistics, 2020." *CA: a cancer journal for clinicians* vol. 70,1 (2020): 7-30 (EX2226); Siegel, Rebecca L et al. "Cancer Statistics, 2021." *CA: a cancer journal for clinicians* vol. 71,1 (2021): 7-33 (EX2227); Siegel, Rebecca L et al. "Cancer statistics, 2022." *CA: a cancer journal for clinicians* vol. 72,1 (2022): 7-33 (EX2228); Siegel, Rebecca L et al. "Cancer statistics, 2023." *CA: a cancer journal for clinicians* vol. 73,1 (2023): 17-48 (EX2229).

[44] "Microsatellite Instability Biomarker (MSI-H)," Colorectal Cancer Alliance, available at colorectalcancer.org/treatment/types-treatment/why-biomarkers-matter/types-biomarkers/microsatellite-instability (accessed 10/3/2024). EX2230.

treatment for MSI-H or dMMR CRC is one of the indications where KEYTRUDA® [redacted] is evidence of the commercial success of KEYTRUDA®'s use as a treatment for MSI-H or dMMR CRC. KEYTRUDA®'s success relative to its competitors within the MSI-H or dMMR CRC indication is another clear indication that the '287 patent has created economic value and that if the invention were obvious others would have had an incentive to undertake the same research as the Patent Owner.

V. COMMERCIAL SUCCESS OF KEYTRUDA®'S USE AS A TREATMENT FOR MSI-H OR DMMR COLORECTAL CANCER IS DUE TO CLAIMED INVENTIONS

A. KEYTRUDA®'s Use as a Treatment for MSI-H or dMMR Colorectal Cancer Embodies the Challenged Claims

36. I understand from Dr. Goldberg that the challenged claims allow for the use of KEYTRUDA® as a treatment for MSI-H or dMMR colorectal cancer. I further understand from counsel that the independent claims of the '287 patent cover all uses of KEYTRUDA® as a treatment for MSI-H or dMMR colorectal cancer, regardless of whether it is as a first-line, second-line, or last-line therapy. Therefore, use of KEYTRUDA® as a treatment for MSI-H or dMMR colorectal cancer embodies the challenged claims.

B. There is a Nexus Between the Commercial Success of KEYTRUDA®'s Use for the Treatment of MSI-H or dMMR CRC and the Claimed Inventions

37. My analysis considers the commercial success of KEYTRUDA®'s use for the treatment of MSI-H or dMMR CRC. I understand from Dr. Goldberg that such a use is not possible without practicing the invention claimed in the '287 Patent. As such, none of the sales and profits generated and patients treated which I have presented as evidence of commercial success would be possible without the claimed invention.

VI. COMMERCIAL SUCCESS OF KEYTRUDA®'S USE AS A TREATMENT FOR MSI-H OR DMMR COLORECTAL CANCER IS NOT DUE TO OTHER FACTORS

A. Commercial Success is Not Due to Merck's Marketing or Promotional Efforts

38. I understand that if the commercial success of a product is due to factors such as marketing and advertising expenditures, and not due to the benefits of the patented invention, such marketing and advertising may undermine the understanding that the patented invention drives commercial success.

39. As an economic matter, the mere fact that a product is promoted would not indicate that the commercial success of a product is unrelated to its patented use. Indeed, if promotion consisted predominantly of providing information about a product's patented use with which physicians and consumers could make informed choices, then any increase in sales related to such a promotional campaign would be

attributable to the value consumers (or their physicians) place on benefits of those product characteristics through use of the product, and not on the mere fact that a promotional campaign had been undertaken. The inventions claimed in the '287 patent allowed KEYTRUDA® to become the first cancer drug to be approved for tissue-agnostic treatment of solid tumors and was a novel treatment for MSI-H or dMMR CRC patients who had failed numerous prior therapies. As such, immediately following that approval Merck's marketing and promotional efforts were focused on educating health professionals to "increase awareness for MSI testing and the value of KEYTRUDA® across tumor types."[45]

40. I have seen no evidence that Merck significantly increased its marketing and promotional efforts following the FDA approval for treatment of MSI-H or dMMR cancers in 2017. At a very high level, Merck's advertising and promotion expenses increased slightly in 2017 to $2.2 billion from $2.1 billion in 2016, representing an increase in advertising spend as a percent of revenue from 5.28 percent to 5.48 percent.[46] To the extent that increase is attributable to increased marketing of KEYTRUDA® for treatment of MSI-H or dMMR CRC, it is likely given Merck management's statement above that such an increase took the form of increased education about MSI-H and testing for MSI-H—i.e., uses related to the

[45] Merck Q2 2017 Earnings Call, dated July 28, 2017. EX2231.

[46] Merck 2018 SEC Form 10-K, dated February 27, 2019, pp. 68, 76. EX2217.

’287 Patent. Furthermore, Merck’s advertising and promotion expenses decreased in 2018 and 2019 to 4.97 percent and 4.48 percent of total revenue, respectively, despite the continuing growth in sales of KEYTRUDA® for treatment of MSI-H or dMMR CRC, indicating that KEYTRUDA®’s increasing sales are not correlated with increased marketing and promotional efforts.[47] I have seen no evidence that Merck’s advertising of KEYTRUDA® for treatment of MSI-H or dMMR CRC is persuasive in nature as opposed to educational. For example, KEYTRUDA®’s website says that KEYTRUDA® may be right for a patient suffering advanced MSI-H/dMMR colorectal cancer when “cancer has spread or cannot be removed by surgery (advanced colon or rectal cancer), and has been shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).”[48]

41. I am unaware of the extent to which Merck engaged in any direct-to-consumer advertising of KEYTRUDA®. Regardless of the extent, there is evidence that direct-to-consumer advertising is not particularly effective at causing cancer patients to ultimately receive the advertised drug. One study in a survey of cancer patients showed that 17 percent of patients who saw cancer-related direct-to-

[47] Merck 2019 SEC Form 10-K, dated February 26, 2020, pp. 70, 77. EX2218

[48] “IS KEYTRUDA RIGHT FOR YOU,” KEYTRUDA, available at https://www.keytruda.com/msi-h-dmmr-colorectal-cancer/treatment-options/ (accessed 10/3/2024). EX2199.

consumer advertising had a discussion with their doctor about the advertised product and ultimately only 3 percent received the advertised medication.[49]

B. Commercial Success is Not Due to KEYTRUDA®'s Pricing

42. I understand that a potentially relevant factor in an analysis of commercial success in patent litigation is the degree to which that success is driven by the patented features as opposed to price or pricing strategy. Economic theory suggests that if price were the driving factor for KEYTRUDA®'s success, it should be priced lower than its closest potential substitutes. As noted above, OPDIVO® and YERVOY® are the only other drugs approved by the FDA to treat MSI-H or dMMR colorectal cancer. Although out-of-pocket prices to patients vary depending on insurance coverage, the full list prices of KEYTRUDA® and OPDIVO® are very similar when controlling for dose frequency. Although dosing frequency can vary by patient for both KEYTRUDA® and OPDIVO®, as of the filing of this declaration the full list price over a 6-week period regardless of dosing frequency is $23,138 for KEYTRUDA® and $22,905 for OPDIVO®.[50] This one percent difference in price

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[49] Gregory A. Abel et al., Cancer-Related Direct-to-Consumer Advertising: Awareness, Perceptions, and Reported Impact Among Patients Undergoing Active Cancer Treatment. JCO 27, 4182-4187(2009). EX2232.

[50] *See* Cost Information and Financial Help With KEYTRUDA® (pembrolizumab), available at https://www.keytruda.com/financial-support/ (accessed 9/17/2024) (EX2233) and Pricing Information for OPDIVO® and OPDIVO®+ YERVOY®, available at

between products is unlikely to be the driver of the large and growing difference in sales, prescriptions, growth, and market share between KEYTRUDA® and OPDIVO®. The price of OPDIVO® + YERVOY® varies based on patient weight and cancer type but can range from $25,677 to $46,060 per dose for four doses before the patient switches to OPDIVO®-only dosing.[51] Although KEYTRUDA® can have a significantly lower list price than OPDIVO® + YERVOY®, this price difference is a direct result of the fact that, unlike YERVOY®, KEYTRUDA® is an effective single-agent treatment for MSI-H or dMMR colorectal cancer, which I understand is a benefit of the claimed inventions of the '287 Patent.

43. While out-of-pocket costs vary widely for patients with commercial insurance, Medicare, or Medicaid coverage, the pricing information available on KEYTRUDA®'s and OPDIVO®'s websites do not indicate that KEYTRUDA® is regularly available at a lower price than OPDIVO®. For example, OPDIVO®'s website tells patients with commercial insurance simply that they "could pay as little as $0 per medication per infusion with the BMS Oncology Co-pay Assistance

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https://www.bmspricinginformation.com/opdivo (accessed 9/17/2024) (EX2234; EX2235).

[51] *See* Pricing Information for OPDIVO® and OPDIVO®+ YERVOY®, available at https://www.bmspricinginformation.com/opdivo (accessed 9/17/2024) (EX2234; EX2235); YERVOY® U.S. Prescribing Information, available at https://packageinserts.bms.com/pi/pi_yervoy.pdf, (accessed 9/17/2024). EX2236.

Program."[52] In comparison, KEYTRUDA®'s website states that "65% of patients paid no out-of-pocket costs for KEYTRUDA. For those patients who did have out-of-pocket costs, approximately 80% of patients paid between $0.01 and $300 per infusion, after satisfying their deductible."[53] For patients with Medicaid, OPDIVO® says patients "could pay $0–$20 per infusion (depending on state plan)" whereas KEYTRUDA® says "[f]or most people on Medicaid, patient out-of-pocket costs for prescription medicines like KEYTRUDA range from $4 to $8 per infusion."[54] For Medicare patients, the OPDIVO® site says "you may pay 0-20% of the medication list price," or roughly $0 to $1,527 per infusion every two weeks.[55] KEYTRUDA®'s site says that "38% of patients [with a Medicare Advantage plan] paid no out-of-pocket costs for KEYTRUDA" and that for those who did pay, "approximately 80%

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[52] "Pricing Information for OPDIVO® and OPDIVO®+ YERVOY®, available at https://www.bmspricinginformation.com/opdivo (accessed 9/17/2024) (EX2234; EX2235).

[53]Cost Information and Financial Help With KEYTRUDA® (pembrolizumab), available at https://www.keytruda.com/financial-support/ (accessed 9/17/2024) EX2233.

[54] Cost Information and Financial Help With KEYTRUDA® (pembrolizumab), available at https://www.keytruda.com/financial-support/ (accessed 9/17/2024) (EX2233); Pricing Information for OPDIVO® and OPDIVO®+ YERVOY®, available at https://www.bmspricinginformation.com/opdivo (accessed 9/17/2024) (EX2234;EX2235).

[55] Pricing Information for OPDIVO® and OPDIVO®+ YERVOY®, available at https://www.bmspricinginformation.com/opdivo (accessed 9/17/2024) EX2234; EX2235.

of patients paid between $0.01 and $925 per infusion [every three weeks], after satisfying their deductible."[56] For traditional Medicare patients "approximately 80% of patients paid between $1,300 and $2,100 per infusion [every three weeks], after satisfying their deductible."[57]

44. An analysis conducted by GlobalData comparing market trends for KEYTRUDA® and OPDIVO® ten years after their initial U.S. launches determined that KEYTRUDA®'s "price per strength unit" at launch in the U.S. was nearly twice as high as that of OPDIVO®, at $43.16 to OPDIVO®'s $23.98.[58] The analysis estimates that since then KEYTRUDA® and OPDIVO® have experienced similar price increases over time, at 31 percent and 33 percent respectively.[59]

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[56] Cost Information and Financial Help With KEYTRUDA® (pembrolizumab), available at https://www.keytruda.com/financial-support/ (accessed 9/17/2024) EX2233.

[57] Cost Information and Financial Help With KEYTRUDA® (pembrolizumab), available at https://www.keytruda.com/financial-support/ (accessed 9/17/2024) EX2233.

[58] Watt, Alex. "Keytruda and Opdivo: A Decade Review." Pharmaceutical Technology, 30 Sept. 2024, EX2237.

[59] Watt, Alex. "Keytruda and Opdivo: A Decade Review." Pharmaceutical Technology, 30 Sept. 2024, EX2237.

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Expert Testimony, Affidavits, and Reports

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Joseph Allen, Steven Ayers, Ashley Hurlburt, Rory Kevin Gates, James Howard, DeMarcus Morrow, Rodney Waller, Keith Arcement, Frederick Bell, Genaro Cruz Gomez, Sam Ybarra, Michael Carter, and James Park, on behalf of themselves and all others similarly situated v. John Bel Edwards in his official capacity as Governor of the State of Louisiana, Zita Jackson Andrus, Chris L. Bowman, Flozell Daniels Jr., Thomas D. Davenport Jr., Patrick J. Fanning, W. Ross Foote, Katherine E. Gilmer, Michael C. Ginart Jr., Frank Holthaus, Donald W. North, and Moses Junior Williams, in their official capacities as members of the Louisiana Public Defender Board; and James T. Dixon, Jr., in his official capacity as the Louisiana State Public Defender, 19th Judicial District Court, East Baton Rouge Parish, State of Louisiana, Docket No. C655079, Expert Report on behalf of Plaintiffs regarding risk of constructive denial of counsel faced by Plaintiffs as well as the lack of economic rationale for the current state wide public defense funding system.

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- *Dexon Computer, Inc. v. Cisco Systems, Inc. and CDW Corporation,* USDC for the Eastern District of Texas, Texarkana Division, Case No. 5:22-CV-53, on behalf of Dexon Computer regarding alleged monopolization claims involving the sale of routers and switches and licensed software.
- *Ningde Amperex Technology Limited v. Zhuhai CosMX Battery Co., Ltd.* USDC for the Eastern District of Texas, Marshall Division, Civil Action No. 2:22-CV-232 on behalf of CosMX Battery regarding alleged monopolization claims involving the assertion of allegedly baseless patents and no poach agreements.
- *Genesys Telecommunications Laboratories, Inc. v. Talkdesk, Inc., Michael Strahan, Mark Hertel, and Ralph Manno*, USDC for the Southern District of Indiana, Indianapolis Division, C.A. No. 1:19-CV-00695-TWP-DML on behalf of Talkdesk regarding alleged trade secret misappropriation and corporate raiding. Provided an assessment of economic damages, including lost profits, reasonable royalty, and unjust enrichment.
- *Novartis Pharma AG v. Amgen, Inc.,* USDC for the Southern District of New York, C.A. No. 1:19-CV-2993. On behalf of Novartis. Economic analysis of the materiality of an alleged breach of contract regarding commercialization and marketing of the anti-migraine drug, Aimovig.
- *Continental Resources, Inc. v. Hiland Partners Holdings LLC*, State of Oklahoma, In the District Court in and for Garfield County, Case No. CJ-2017-310-03. On behalf of Continental Resources. Calculated economic lost profits associated with Hiland's alleged breach of multiple long term gas purchase agreements.
- *Bio-Rad Laboratories, Inc., The University of Chicago, Lawrence Livermore National Security, LLC, and President and Fellows of Harvard College v. Stilla Technologies, Inc., and Stilla Technologies*, USDC for the District of Massachusetts, C.A. No. 1:19-cv-11587 on behalf of Stilla regarding alleged patent infringement damages and evaluation of a reasonable royalty for various digital PCR testing patents.
- *First Quality Tissue, LLC v. Irving Consumer Products Limited and Irving Consumer Products, Inc.,* USDC for the District of Delaware, C.A. No. 19-cv-00428 on behalf of First Quality regarding alleged patent infringement damages and evaluation of a reasonable royalty.
- *Magellan Crude Oil Pipeline Company, L.P. v. Enterprise Crude Oil LLC,* for the 101st Judicial District, Dallas County, Texas on behalf of Defendant Enterprise regarding alleged breach of contract, damages, and alleged lost tariffs from a crude oil distribution and pipeline agreement.

- *OGD Equipment Co. d/b/a Overhead Garage Door, LLC v. Overhead Door Corporation and Overhead Door Company of Lubbock, Inc.*, USDC for the Eastern District of Texas, Sherman Division, CA No. 4:17-cv-00898-ALM-KPJ, on behalf of Defendant Overhead Door Corp. regarding alleged anticompetitive harm and damages from restrictions on the use of branded tradenames in competitor's Google AdWords purchases. Also evaluated trademark counterclaims of Defendants.
- *Sanofi-Aventis U.S. LLC v. Mylan Inc. and Mylan Specialty, L.P.,* USDC for the District of New Jersey, on behalf of Sanofi regarding Mylan's counterclaim allegations of false advertising and Lanham Act violations.
- *Duke University, Allergan Sales, LLC, and Allergan, Inc. v. Sandoz Inc.,* USDC for the District of Colorado, CA No. 18-cv-00997-MSK-KLM, on behalf of Allergan regarding Allergan's lost profits and patent infringement damages. Also an evaluation of the commercial success of the drug, Latisse®.
- *Vantage Deepwater Drilling Company and Vantage Deepwater Drilling, Inc. v. Petrobras America Inc. and Petroleo Brasileiro S.A. – Petrobras*, ICDR American Arbitration Association, Case No. 01-15-0004-8503 on behalf of Respondants regarding damages related to an alleged breach of a drilling services agreement.
- *Sunoco Partners Marketing & Terminals L.P.,* v. *Powder Springs Logistics, LLC, and Magellan Midstream Partners, L.P.*, USDC District of Delaware, CA No. 17-1390-NA on behalf of Defendants regarding damages claims of patent infringement and irreparable harm.
- *Archer and White Sales, Inc.*, v. *Henry Schein, Inc., Danaher Corporation, Instrumentarium Dental, Inc., Dental Equipment, LLC, Kavo Dental Technologies, LLC, and Dental Imaging Technologies Corporation*, USDC Eastern District of Texas, Marshall Division, CA No. 2:12-CV-00572-JRG on behalf of Defendants regarding antitrust liability involving an alleged group boycott of distributors and dental supply manufacturers.
- Economic Analysis of the Competitive Effects of New Hospitals in Southern Lee County, Florida, on behalf of hospital client seeking a certificate of need for a new hospital and opposing a competing certificate of need for an existing hospital.
- *Gerresheimer Glas GmbH and West Pharmaceutical Services Inc., v. Biocorp Production SA,* USDC Middle District of Florida, Orlando Division on behalf of Plaintiffs regarding economic harm from potential at-risk launch and patent infringement by Defendant.
- *OrthoAccel Technologies, Inc. v. Propel Orthodontics, L.L.C.*, US District Court for the Eastern District of Texas, Sherman Division, Case No. 4:16-cv-350-ALM on behalf of Defendant regarding evaluation of damages related to alleged false claims and disparagement and evaluation of antitrust counter-claims.
- *Radiosurgical Center of Memphis, L.P., d/b/a Memphis Regional Gamma Knife Center v. Methodist Healthcare-Memphis Hospitals and The West Clinic, P.C., d/b/a West Cancer Center Co.*, US District Court for the Western District of Tennessee, Case No. 2:15-cv-02709-JTF on behalf of Plaintiff regarding evaluation of alleged antitrust damages resulting from an alleged boycott.

- *Allergan, Inc. v. Teva Pharmaceuticals, USA, Inc., et.al.* US District Court for the Eastern District of Texas, Marshall Division, Case No. 2:15-cv-1455-WCB on behalf of Plaintiff regarding an evaluation of commercial success for the drug, Restasis®.
- *Adrienne Moore, On Behalf Of Herself And All Others Similarly Situated v. Apple Inc.*, US District Court for the Northern District of California, San Jose Division on behalf of Apple regarding class certification issues regarding allegedly lost iMessages.
- *In Re Korean Ramen Antitrust Litigation,* U.S. District Court for the Northern District of California, San Francisco Division, Case No. 3:13-cv-04115-WHO on behalf of Defendants Nongshim Co., Ltd., Nongshim America, Inc., Ottogi Co. Ltd and Ottogi America, Inc. responding in opposition to direct purchasers and indirect purchasers motions for Class Certification relating to the sales of Korean ramen products in the United States.
- *XimpleWare Corp. v. Versata Software, Inc. f/k/a Trilogy Software, Inc.; Trilogy Development Group, Inc.; Ameriprise Financial Services, Inc.; Aurea Software, Inc. a/k/a Aurea, Inc.,* USDC C13-05160SI on behalf of Versata Software, Inc., Aurea Software, Inc. and Trilogy Development Group, Inc. regarding alleged copyright infringement damages experienced by plaintiff.
- *SD3, LLC, and Sawstop, LLC, v. Black & Decker (U.S.), Inc., et al.,* U.S. Disctrict Court for the Eastern District of Virginia, Case No. 1:14-cv-00191 on behalf of Defendants regarding allegations of a group boycott of the license or adoption of Sawstop's active injury mitigation technology.
- *Comcast Cable Communications, LLC, et al. v. Sprint Communications Company L.P., et al.,* U.S. District Court for the Eastern District of Pennsylvania Case No. 2:12-cv-0859-JD on behalf of Sprint regarding the purported damages from alleged patent infringement.
- *Al-Daiwa, Ltd. v. Apparent, Inc., et al.,* US District Court for the Northern District of California Case No. CV13-04156(VC) on behalf of Al-Daiwa regarding damages due to an alleged breach of contract.
- *Nippon Steel & Sumitomo Metal Corporation v. POSCO and POSCO America Corporation*, US District Court for the District of New Jersey on behalf of Nippon regarding reasonable royalty damages due to defendants' alleged patent infringement.
- *Church & Dwight Co. v. SPD Swiss Precision Diagnostics GmbH, et al.,* US District Court for the S.D. of New York Case No. 14 Civ. 00585 (AJN) on behalf of defendant SPD Swiss Precision regarding damages arising out of defendant's alleged false advertising.
- *BetterMouse Company, LLC v. SteelSeries North America Corp.,* US District Court for the Eastern District of Texas Marshall Division, Case No. 2:14-cv-00198-JRG on behalf of defendant regarding alleged reasonable royalty damages due to defendant's alleged patent infringement.
- *Sprint Communications Company L.P., et al. v. Comcast Cable Communications LLC, et al.,* US District Court for the Eastern District of Pennsylvania Case No. 2:12-cv-00859-JD on behalf of Sprint regarding reasonable royalty damages experienced by Sprint due to Comcast's alleged infringement of Sprint's patents.

- *DPWN Holdings USA Inc. (DHL)*, Provided consulting for DHL regarding DHL's claims of air cargo price fixing against various airlines.
- *David v. Signal International, LLC*, On behalf of Plaintiffs: Economic analysis of Signal's financial and economic incentives to participate in a human trafficking, forced labor, and fraud scheme involving H-2B guest workers of Indian nationality.
- *Charlene Eike, Shirley Fisher, Jordan Pitler and Alan Raymond, on behalf of themselves and all others similarly situated, v. Allergan, Inc.; Allergan USA, Inc.; Allergan Sales, LLC; Alcon Research Laboratories, Inc.; Alcon Research, LTD.; Falcon Pharmaceuticals, Ltd.; Sandoz, Inc.; Bausch and Lomb Incorporated; Pfizer Inc., Merck & Co., Inc.; Merck, Sharp & Dohme Corp., and Prasco, LLC*. On behalf of Defendants. Provided economic analysis of class damages regarding allegations of product wasting from oversized droppers.
- *MM Steel, LP, v. Reliance Steel & Aluminum Co., Chapel Steel Corp., American Alloy Steel, Inc., Arthur J. Moore, JSW Steel (USA) Inc., Nucor Corp., and SSAB Enterprises, LLC D/B/A SSAB Americas*. On behalf of Defendants: Provided an economic analysis of antitrust damages regarding allegations of a group boycott in the steel plate industry.
- *12th Man Foundation*, Provided litigation consulting for the 12th Man Foundation regarding endowed Texas A&M football season ticket holder lawsuits.
- *Allergan, Inc., v. Sandoz Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., Hi-Tech Pharmacal Co. Inc., Watson Laboratories, Inc., Actavis, Inc., and Watson Pharma, Inc.* On behalf of Allergan: Provided an economic analysis of commercial success regarding the ophthalmic drug Lumigan.
- *OSI Pharmaceuticals, Inc., Pfizer Inc. and Genentech, Inc., v. Teva Pharmaceuticals USA Inc. and Mylan Pharmaceuticals, Inc.* On behalf of Defendants: Provided an economic analysis of commercial success regarding the cancer drug Tarceva.
- *Alcoa, Inc., vs. Luminant Generation Company LLC, et al.*, On behalf of Alcoa: Antitrust damages associated with Luminant's alleged manipulation of the Texas ERCOT wholesale electricity market.
- *Freedom Medical, Inc., vs. Premier, Inc. and Premier Purchasing Partners, L.P.*, On behalf of defendant Premier: antitrust liability and damages regarding GPO contracting practices in the medical equipment rental industry.
- *John Ivan Sutter, M.D., et. al. vs. Horizon Blue Cross Blue Shield of New Jersey*, On behalf of defendant Horizon, analyzing damages regarding New Jersey prompt pay statutes

PAPERS AND PUBLICATIONS

"Refusal to Deal Under FDA Imposed Risk Evaluation and Mitigation Strategies (REMS): Economic Considerations." With Brian Segers, *CPI Antitrust Chronicle,* Competition Policy International, April 2014.

PRESENTATIONS

Panelist at a seminar titled “Addressing the Risks of Class Certification,” hosted by NERA on August 24, 2016, Palo Alto, CA. Mr. Segers discussed economic tools, including surveys and regression techniques, which can be used in defending or undercutting certification.

APPENDIX 2

(in millions)

[redacted]

APPENDIX 3

[redacted]

APPENDIX 4

[redacted]

APPENDIX 5

[redacted]

APPENDIX 6

[redacted]

APPENDIX 7

[redacted]

APPENDIX 8

[redacted]

APPENDIX 9

[redacted]

APPENDIX 10

[redacted]