

DECLARATION OF JOHN C. JAROSZ



**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JANSSEN BIOTECH, INC.,

Plaintiff,

v.

AMGEN, INC.,

Defendant.

Civil Action No. 22-cv-01549-UNA

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MARCH 1, 2023**

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I. INTRODUCTION

A. Assignment

1. I was retained by Counsel for Janssen Biotech, Inc. (“Janssen” or “Plaintiff”) to provide expert economic analysis and possible testimony concerning irreparable harm, balance of hardships, and public interest related to Janssen’s motion for a preliminary injunction prohibiting launch by Amgen, Inc. (“Amgen” or “Defendant”) of a biosimilar copy of Janssen’s biologic drug STELARA[®] (ustekinumab) (“STELARA[®]”).

2. I understand from Counsel that Amgen’s imminent launch of ABP 654 will infringe on certain Janssen patents, including U.S. Patent Nos. 9,217,168 (the “’168 patent”) and 9,217,810 (the “’810 patent”) (collectively, the “Manufacturing Patents”). I understand that the ’810 patent is the later-to-issue of the Manufacturing Patents and expires on March 14, 2033.

B. Qualifications

3. I am a Managing Principal of Analysis Group, Inc. (“AG”) and Director of the firm’s Washington, DC office. AG is an economic, financial, strategy, and health care consulting firm with offices in Beijing, China; Boston, MA; Brussels, Belgium; Chicago, IL; Dallas, TX; Denver, CO; London, UK; Los Angeles, CA; Menlo Park, CA; Montreal, Quebec; New York, NY; Paris, France; San Francisco, CA; and Washington, DC. AG provides research and analysis in a variety of business, litigation, and regulatory settings.

4. I received my B.A. in Economics and Organizational Communications, *summa cum laude*, from Creighton University in Omaha, NE. Thereafter, I was a fellowship student in the Ph.D. program in Economics at Washington University in St. Louis, MO. I completed most of the degree

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requirements but left before finishing my Ph.D. degree. I ultimately was awarded an M.A. in Economics. I worked for some period after that and then enrolled in law school at the University of Wisconsin in Madison, WI. From there, I received a J.D., concentrating on courses covering the intersection of law and economics. I am a member of the State Bar of Wisconsin but have been on inactive status for the past 37 years.

5. My resume, which describes all my testimony, publications, and presentations, is attached as Tab 1. I have spent my entire professional career as a practicing economist. Almost all of my work has involved evaluating the economics of intellectual property (“IP”) protection. The bulk of that work has dealt with issues of damages estimation; commercial success; fair, reasonable, and non-discriminatory (“FRAND”) compliance; injunctive relief; and antitrust violations. I have testified at trial or arbitration in over 100 such matters.

6. Among other things, I have published articles in academic and professional journals, edited a treatise on IP licensing, given presentations and speeches to a wide variety of groups, and taught classes at various graduate schools.

7. Though I have been engaged in a wide range of industries, the largest amount of my work has been in pharmaceutical settings, where I have been involved in scores of matters. Those matters often deal with patient, physician, and payer decision-making, as well as supplier actions and reactions to competitive conditions.

C. Evidence Considered

8. In undertaking my study, I have considered information from a variety of sources, which are identified in the footnotes of this declaration and/or in the attached Tab 2. I also have relied upon my professional judgment and expertise, gathered in many years of evaluating

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economic issues associated with the alleged infringement or misappropriation of intellectual property rights. My analysis and opinions in this declaration are based on the information available to me as of the date of this declaration. I may modify or supplement my opinions, if necessary and allowed, based on review and analysis of information provided to me after the filing of this declaration.

D. Compensation

9. AG has billed Janssen for my work and that of my colleagues who assisted me with preparation of this declaration, all of whom worked under my direction and supervision. My hourly billing rate for the time spent evaluating the issues, producing this declaration, and any testimony I may give is \$990. The hourly billing rates of my colleagues who assisted me with preparation of this declaration range from \$250 to \$750. Neither my compensation nor that of the people who worked with me is contingent upon my findings, the testimony I may give, or the outcome of this litigation.

E. Summary of Conclusions

10. Based upon review and analysis of the evidence that I have examined to date, it is my opinion that Janssen will likely be irreparably harmed if Amgen is allowed to launch ABP 654 prematurely. It would be exceedingly difficult, if not impossible, to fully quantify with a reasonable degree of certainty all of the harm to Janssen's STELARA[®] business; immunotherapy business; research and development activities; and industry goodwill/reputation.

11. Furthermore, it is my opinion that the balance of hardships in this matter weighs in favor of Janssen if Amgen's ABP 654 is permitted to launch prematurely. The likely losses to Janssen will be immediate, severe, and likely irreparable. In contrast, enjoining Amgen's premature

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launch of ABP 654 until a full trial on the merits would simply delay Amgen’s ability to compete in the marketplace with this product. While STELARA[®] is probably the most important product in Janssen’s portfolio, and has been for years, ABP 654 is just one of many products in Amgen’s portfolio, and one that has yet to contribute to any Amgen success in the marketplace.

12. Finally, it is my opinion that the public interest would, on balance, be served through a finding in favor of Janssen and the issuance of the requested preliminary injunction. Not only would such a finding confirm the merits of a strong patent protection system and the innovation incentives it creates, but it would also not disrupt (and likely would ensure) uninterrupted access to, and support for, STELARA[®].

II. BACKGROUND

A. Parties

1. Janssen

13. Janssen is a Pennsylvania corporation with its principal place of business in Horsham, Pennsylvania.¹

14. Janssen is a subsidiary of Johnson & Johnson (“J&J”).² Janssen focuses on developing, manufacturing, and marketing therapies in six areas: cardiovascular and metabolism; immunology; infectious diseases and vaccines; neuroscience; oncology; and pulmonary hypertension.³

¹ Complaint, *Janssen Biotech, Inc., v. Amgen, Inc.*, United States District Court for the District of Delaware, Case No. 1:22-cv-01549-MN, Dkt. No. 1 (November 29, 2022) (“Complaint”), ¶ 10.

² “About Us,” Janssen, available at <https://www.janssen.com/about>, accessed December 30, 2022.

³ “About Us,” Janssen, available at <https://www.janssen.com/about>, accessed December 30, 2022.

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2. Amgen

15. Amgen is a Delaware corporation with a principal place of business in Thousand Oaks, California.⁴

16. Amgen is a “biopharmaceutical company in the business of developing, manufacturing, marketing, and selling both biologic and biosimilar drugs, including the proposed biosimilar ABP 654.”⁵

B. Patents at Issue

17. I understand from Counsel that Janssen’s Manufacturing Patents cover novel methods of producing a preparation of a recombinant antibody, such as ustekinumab, targeting a certain reference standard.

C. Products at Issue

1. STELARA® (Janssen)

18. STELARA® is a “fully human monoclonal antibody that selectively targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23).”⁶ Ustekinumab is the active ingredient in STELARA®.⁷

⁴ Complaint, ¶ 11.

⁵ Complaint, ¶ 12.

⁶ “STELARA (Ustekinumab) Receives FDA Approval for Treatment for Moderate to Severe Plaque Psoriasis with Four-Times-A-Year Maintenance Dosing,” Johnson & Johnson, September 25, 2009, available at <https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/stelara-tm-ustekinumab-receives-fda-approval-treatment-moderate>, accessed December 30, 2022.

⁷ “STELARA (Ustekinumab) Receives FDA Approval for Treatment for Moderate to Severe Plaque Psoriasis with Four-Times-A-Year Maintenance Dosing,” Johnson & Johnson, September 25, 2009, available at <https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/stelara-tm-ustekinumab-receives-fda-approval-treatment-moderate>, accessed December 30, 2022.

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19. STELARA[®] was first approved by the U.S. Food and Drug Administration (“FDA”) on September 25, 2009, for the treatment of adults with moderate to severe plaque psoriasis (“PSO”) “who are candidates for phototherapy or systemic therapy.”⁸

20. Since 2009, STELARA[®] has been approved for several other indications. Currently, in addition to its PSO indication, STELARA[®] has been approved to treat adult patients and pediatric patients six years and older with active psoriatic arthritis (“PSA”); adult patients with moderately to severely active Crohn’s disease (“CD”); and adult patients with moderately to severely active ulcerative colitis (“UC”).⁹

21. Since its launch in 2009, STELARA[®] has generated substantial and growing revenue.¹⁰ In fiscal year 2021, STELARA[®]’s worldwide revenues exceeded \$9 billion, with U.S. revenues accounting for about \$6 billion (or approximately 65 percent of worldwide revenues), as summarized in J&J’s annual reports.¹¹

22. STELARA[®] is currently Janssen’s most successful pharmaceutical product.¹² Its worldwide revenues accounted for 17.5 percent of Janssen’s total worldwide revenues for the fiscal year 2021.¹³

⁸ “STELARA (Ustekinumab) Receives FDA Approval for Treatment for Moderate to Severe Plaque Psoriasis with Four-Times-A-Year Maintenance Dosing,” Johnson & Johnson, September 25, 2009, available at <https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/stelara-tm-ustekinumab-receives-fda-approval-treatment-moderate>, accessed December 30, 2022.

⁹ STELARA[®] Label, Drugs@FDA, 2022, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125261s161lbl.pdf.

¹⁰ See Tab 6.

¹¹ More precisely, worldwide STELARA[®] sales in fiscal year 2021 were \$9.134 billion. U.S. STELARA[®] sales in the same fiscal year were \$5.938 billion. See Tab 6.

¹² Exhibit B60 (Johnson & Johnson 2021 Annual Report), at p. 3.

¹³ Tab 6.

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2. ABP 654 (Amgen)

27. On November 11, 2020, Amgen initiated a Phase 3 study evaluating the efficacy and safety of ABP 654 compared with STELARA® in adult patients with moderate to severe plaque psoriasis.²²

28. On April 18, 2022, Amgen announced that its Phase 3 study “demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA.”²³

29. Currently, Amgen is conducting a Phase 3 study to investigate interchangeability of ABP 654 for STELARA® for the treatment of moderate to severe plaque psoriasis; this study is expected to be completed on March 9, 2023.²⁴

²⁰ Tab 4.

²¹ Tab 5. [REDACTED]

²² Complaint, Exhibit C, at p. 3.

²³ Complaint, Exhibit B, at p. 1. *See also* Complaint, Exhibit D, at p. 41 (“Preliminary results from a Phase 3 study evaluating the efficacy and safety compared to STELARA® in adult patients with moderate to severe plaque psoriasis met the primary efficacy endpoint.”)

²⁴ Complaint, Exhibit E, at pp. 3-4. *See also* Complaint, Exhibit F, at p. 40 (“A Phase 3 study to support an interchangeability designation in the U.S. is ongoing.”) A biosimilar is a “biologic drug that is ‘highly similar to a reference (originator) product, and for which there are no clinically meaningful differences between the two products in safety, purity, and potency.’” A biosimilar that is designated as “interchangeable” with the reference biologic “may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product,” enabling “pharmacy-mediated substitution, where state laws allow.” “To meet the additional designation of interchangeability in the US..., ‘an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient.’ Moreover, ‘if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.” *See* Exhibit B28 (Alvarez, D.F., G. Wolbink, C. Cronenberger, J. Orazem, and J. Kay, “Interchangeability of Biosimilars: What Level of Clinical

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30. On or before [REDACTED], Amgen submitted an Abbreviated Biologic License Application (“aBLA”) to the FDA seeking approval to market in the U.S. its biosimilar copy of STELARA[®].²⁵

31. On November 7, 2022, Amgen provided to Janssen its 180-day notice of commercial marketing.²⁶ I understand that this notice signals Amgen’s intent to begin selling its infringing biosimilar product as soon thereafter as it receives FDA approval to do so.²⁷ Moreover, I understand that Amgen has informed Janssen it intends to market ABP 654 for all indications and patient groups for which STELARA[®] is approved.²⁸

32. I understand that Amgen could gain FDA approval for ABP 654 in the second or third quarter of 2023.²⁹

D. STELARA[®] Competitive Landscape

33. To date, [REDACTED]
[REDACTED]
[REDACTED]

Evidence Is Needed to Support the Interchangeability Designation in the United States?” *BioDrugs*, Vol. 34, 2020, pp. 723-732), at pp. 723-724.

²⁵ Complaint, ¶ 24.

²⁶ Complaint, ¶ 28, Exhibit A.

²⁷ Complaint, ¶ 29, Exhibit A (Amgen “intends to be ready to commence commercial marketing upon receiving FDA approval”).

²⁸ Complaint, ¶ 29, Exhibit A (“Amgen intends to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the STELARA[®] drug products.”).

²⁹ See Complaint, ¶ 31.

³⁰ Exhibit B5, at [REDACTED]

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[REDACTED]

34. Though branded biologics comprise the vast bulk of treatments for PSO, PSA, CD, and UC, small molecule therapies and biosimilars have entered each of these segments in recent years. For example, Pfizer’s XELJANZ[®] (tofacitinib) (“XELJANZ[®]”) and three biosimilar versions of Janssen’s REMICADE[®] (infliximab)—INFLECTRA[®], RENFLEXIS[®], and AVSOLA[®]—have each been prescribed for these indications as well.³⁴ Amgen’s Humira biosimilar also just launched in January 2023.³⁵ [REDACTED]

35. In recent years, across indications, health insurance providers and pharmacy benefit managers (“PBMs”), which are third-party organizations that work on behalf of health insurance providers, increasingly have employed a step therapy strategy, requiring patients to initiate

³¹ [REDACTED]

³² Exhibit B5, at [REDACTED]

³³ Exhibit B5, at [REDACTED]

³⁴ Exhibit B5, at [REDACTED]
Stewart, J., “How Many Biosimilars Have Been Approved in the United States?” Drugs.com, December 23, 2022, available at <https://www.drugs.com/medical-answers/many-biosimilars-approved-united-states-3463281/>, accessed December 19, 2022.

³⁵ “Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States,” Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023.

³⁶ See, e.g., Exhibit B19, at p. 31.

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[REDACTED]

treatment with a chosen, often less expensive drug and allowing them to access later “lines” of therapy only if the “first line” drug becomes ineffective or is deemed inappropriate, as a tool to reduce pharmaceutical treatment costs.³⁷ While PBMs/insurers have a clear incentive to “step” patients through less expensive treatments, physicians, on the other hand, often contend that certain more expensive therapies, such as biologics, merit early line use when their efficacy and/or safety benefits clearly outweigh those of traditional first line treatments.³⁸

36. STELARA[®] has achieved first-line (“1L”) access in over 90 percent of commercial plans for each of the four indications discussed above, with 94 percent 1L access in PSO, 92 percent 1L access in PSA, 93 percent 1L access in CD, and 90 percent 1L access in UC.³⁹ As such, for the majority of commercially insured patients with these conditions, access to STELARA[®] is not contingent on the patient first trying another medication.

37. As noted above, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

38. However, [REDACTED]
[REDACTED]

³⁷ Chung, A., J. MacEwan, and D.P. Goldman, “Does A ‘One-Size-Fits-All’ Formulary Policy Make Sense?” *Health Affairs*, June 2, 2016, available at <https://www.healthaffairs.org/doi/10.1377/forefront.20160602.055116/full/>, accessed February 10, 2023.

³⁸ Exhibit B36 (Hagland, M., “Step Therapy and Biologics: No Easy Answers,” *Biotechnology Healthcare*, Vol. 3, No. 6, 2006), pp. 32-40.

³⁹ Exhibit B9, at p. 9.

⁴⁰ Tabs 4-5.

⁴¹ Tab 4.

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1. Physicians

39. Moderate to severe PSO and PSA typically are treated by dermatologists and rheumatologists.⁴³ Moderate to severe CD and UC typically are treated by gastroenterologists (“GIs”), though patient care teams may also include specialists in hepatology, colon and rectal surgery, and radiology.⁴⁴

40. Since its launch in 2009, doctors have prescribed STELARA® to tens of thousands of PSO, PSA, CD, and UC patients.⁴⁵ STELARA®’s anti-IL-12/anti-IL-23 approach has been particularly useful for patients who fail treatment with other classes of drugs.⁴⁶

⁴² Exhibit B7, at pp. 6-7. . See also “Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States,” Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023.

⁴³ “Your Care Team,” National Psoriasis Foundation, available at <https://www.psoriasis.org/your-care-team/>, accessed February 10, 2023.

⁴⁴ “Ulcerative Colitis,” Mayo Clinic, available at <https://www.mayoclinic.org/diseases-conditions/ulcerative-colitis/care-at-mayo-clinic/mac-20353335>, accessed February 13, 2023; “Crohn’s Disease,” Mayo Clinic, available at <https://www.mayoclinic.org/diseases-conditions/crohns-disease/care-at-mayo-clinic/mac-20353314>, accessed February 10, 2023.

⁴⁵ .

⁴⁶ See, e.g., Exhibit B43 (Kashani, A., and D.A. Schwartz, “The Expanding Role of Anti-IL-12 and/or Anti-IL-23 Antibodies in the Treatment of Inflammatory Bowel Disease,” *Gastroenterology & Hepatology*, Vol. 15, No. 5, 2019, pp. 255-265).

⁴⁷ See, e.g., Exhibit B24, at pp. 24, 57; Exhibit B20, at p. 8.

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41. [REDACTED]

[REDACTED]

[REDACTED].⁴⁸

42. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].⁴⁹

2. PBMs and Payors

43. Health insurance providers typically provide plans with medical benefits (*i.e.*, coverage for healthcare provider-rendered services, including administration of certain medications in a healthcare setting under clinical supervision, such as infusion or injection) and/or pharmacy benefits (*i.e.*, coverage for certain medications that can be self-administered, such as oral medications and autoinjectors).⁵⁰ As noted above, PBMs are third-party organizations that work on behalf of health insurance providers and employers (payors) to administer pharmacy benefit plans, negotiating with manufacturers and determining patient access to medications.⁵¹

⁴⁸ [REDACTED]

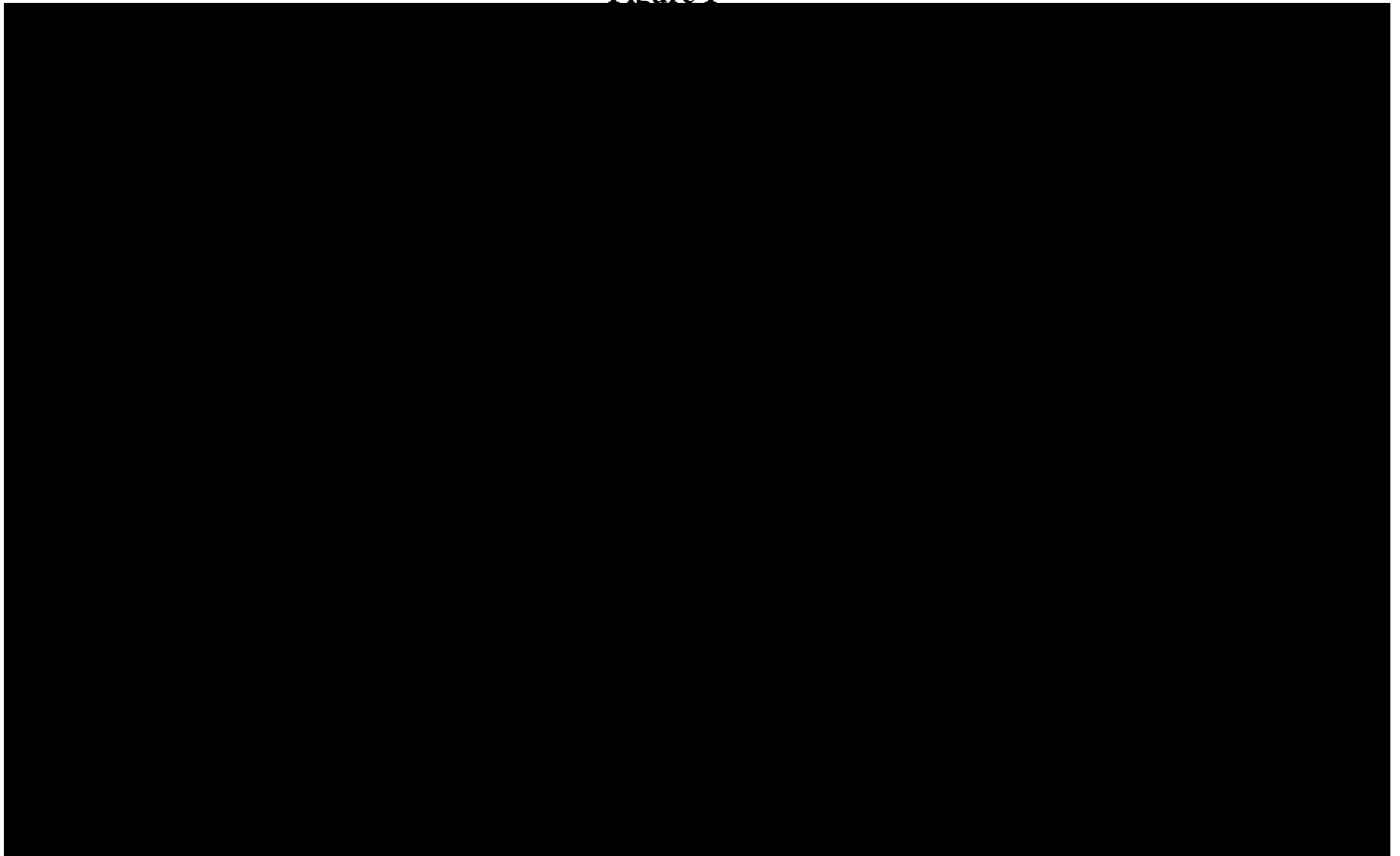
⁴⁹ Exhibit B14, at [REDACTED]

⁵⁰ See Exhibit B27, at p. 84.

⁵¹ “Pharmacy Benefit Managers,” NAIC, April 11, 2022, available at <https://content.naic.org/cipr-topics/pharmacy-benefit-managers>, accessed February 10, 2023.

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Figure 1⁵⁸



46. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].⁶⁰

⁵⁸ Exhibit B10, at p. 4.

⁵⁹ [REDACTED]; “340B Drug Pricing Program Overview,” 340bHealth, available at <https://www.340bhealth.org/members/340b-program/overview/>, accessed January 13, 2023.

⁶⁰ “340B Drug Pricing Program Overview,” 340bHealth, available at <https://www.340bhealth.org/members/340b-program/overview/>, accessed January 13, 2023.

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3. Pharmacies

47. Biologic and biosimilar medications typically are dispensed in a hospital setting, provider office, or through pharmacies that specialize in managing complex and high-cost medications for chronic and rare conditions.⁶¹ [REDACTED]

[REDACTED].⁶² Because most currently available biosimilars have been administered in hospitals or physician clinics, these biosimilars primarily have been covered under a medical benefit of patients' plans.⁶³ As such, pharmacies and PBMs, which are involved in the distribution of drugs covered under a pharmacy benefit of patients' plans, have had limited exposure to biosimilar management to date.⁶⁴ However, this is expected to change dramatically given the recent launch in November 2021 of long-acting insulin SEMGLEE[®], a biosimilar copy of LANTUS[®] (insulin glargine) ("Lantus") and the launch of Humira and potentially STELARA[®] biosimilars beginning in 2023.⁶⁵ In short, pharmacies and PBMs soon will become much more involved in the distribution of biosimilars.

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁶⁶ In fact, as discussed in the

⁶¹ "Specialty Pharmacy," American Pharmacists Association, available at <https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty>, accessed February 10, 2023.

⁶² Exhibit B8, at p. 9.

⁶³ Exhibit B25, at p. 50.

⁶⁴ Exhibit B25, at p. 50.

⁶⁵ Exhibit B27, at p. 75; Exhibit B25, at pp. 50-51.

⁶⁶ Exhibit B1, at pp. 4, 22.

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following section, biosimilars that have obtained the interchangeability designation from the FDA can be substituted for the reference biologic product by the pharmacist without consulting the physician that prescribed the treatment.⁶⁷

E. Biosimilar Competitive Landscape

49. Biologic therapies currently represent the fastest growing segment of pharmaceutical research and development (“R&D”).⁶⁸ Many recently-developed biologics are antibody-based therapies designed to reduce inflammation by precisely targeting certain inflammatory proteins in the body, sparing side effects that are associated with treatments that affect the whole body.⁶⁹ While biologics currently account for 2 percent of prescriptions in the U.S., these therapies represent 37 percent of net drug spending.⁷⁰

50. As noted above, a biosimilar is a chemical compound that is highly similar but not identical to an approved biologic product (called “reference biologic” or “reference product”).⁷¹ As of the end of 2022, 41 biosimilars had been approved in the U.S., and 24 had launched since 2015.⁷²

51. Again, as noted above, I understand that biosimilars that have been designated to be “interchangeable” may be substituted for their respective reference products at the discretion of

⁶⁷ See Exhibit B28 (Alvarez, D.F., G. Wolbink, C. Cronenberger, J. Orazem, and J. Kay, “Interchangeability of Biosimilars: What Level of Clinical Evidence Is Needed to Support the Interchangeability Designation in the United States?” *BioDrugs*, Vol. 34, 2020, pp. 723-732), at pp. 723-724.

⁶⁸ Exhibit B26, at p. 2.

⁶⁹ See, e.g., Rosenthal, I.M., and S.R. Rosenthal, “Fact Sheet: News from the IBD Help Center,” Crohn’s and Colitis Foundation, available at <https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/biologic-therapy.pdf>, at p. 1.

⁷⁰ Exhibit B26, at p. 2.

⁷¹ Exhibit B25, at p. 5; Exhibit B28 (Alvarez, D.F., G. Wolbink, C. Cronenberger, J. Orazem, and J. Kay, “Interchangeability of Biosimilars: What Level of Clinical Evidence Is Needed to Support the Interchangeability Designation in the United States?” *BioDrugs*, Vol. 34, 2020, pp. 723-732), at pp. 723-724.

⁷² Tab 3. See also Exhibit B27, at p. 6.

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[REDACTED]

53. As I explain below, biosimilar entry, across therapeutic areas, usually has an immediate impact on the reference biologic therapy’s sales. This impact is often severe, though past experiences of biologic therapies suggest that the precise path of the impact can vary widely from one treatment to another.

1. Immediacy of Impacts

54. In the U.S., the increase in biosimilar uptake has been especially apparent over the last three years. Biosimilars launched in the last 3 years have gained an average volume share of 75 percent within their respective therapeutic areas.⁸⁰ This increase in biosimilar uptake has been particularly evident with more recent biosimilar launches, such as those of AVASTIN® (bevacizumab) (“Avastin”) and RITUXAN® (rituximab) (“Rituxan”).⁸¹

55. Most biosimilars have achieved rapid increases in volume share within months following launch, with most holding at least 20 percent share by the end of the first year following entry.⁸²

56. Even for biologic therapies that are reimbursed through the plans’ medical benefit, insurers are often able to steer patients towards the biosimilars. [REDACTED]

[REDACTED]

[REDACTED]

⁸⁰ Exhibit B27, at p. 14.

⁸¹ Exhibit B27, at p. 14.

⁸² Exhibit B25, at p. 16.

⁸³ [REDACTED]

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2. Severity of Impacts

57. Biosimilars historically have launched at a wholesale acquisition cost (“WAC”) that is anywhere from 10 to 57 percent lower than that of the reference product.⁸⁵ WAC, or list price, is “the price paid by a wholesaler for drugs purchased from the wholesaler’s supplier, typically the manufacturer of the drug.”⁸⁶ WAC is almost always higher than the price that “the end customer or pharmacy pays the wholesaler for the drug.”⁸⁷ It is also much higher than the net price the pharmaceutical manufacturer receives for the drug: WAC does not account for rebates that the payors receive from the manufacturer when they reimburse for patients’ use of the drug or other discounts manufacturers offer on the drug.⁸⁸ In contrast to WAC, average sales price (“ASP”) refers to a quarterly weighted average of sales to U.S. non-government purchasers net of all eligible discounts.⁸⁹ This generally leads to ASP being related to, but ultimately lower than, WAC.

⁸⁴ Exhibit B1, at p. 21.

⁸⁵ Exhibit B27, at p. 12. *See also* Exhibit B25, at p. 6, suggesting that biosimilars are expected to be priced “15% to 30% lower than their reference products.”

⁸⁶ Devenport, B., “Key Government Pricing Terms,” Prescription Analytics, August 2022, available at <https://prescriptionanalytics.com/white-papers/key-terms-in-pharmaceutical-government-pricing/>, at p. 2. *See also* Exhibit B44 (Mattingly, J., “Understanding Drug Pricing,” U.S. Pharmacist, Vol. 37, No. 6, 2012, pp. 40-45).

⁸⁷ Devenport, B., “Key Government Pricing Terms,” Prescription Analytics, August 2022, available at <https://prescriptionanalytics.com/white-papers/key-terms-in-pharmaceutical-government-pricing/>, at p. 2.

⁸⁸ Devenport, B., “Key Government Pricing Terms,” Prescription Analytics, August 2022, available at <https://prescriptionanalytics.com/white-papers/key-terms-in-pharmaceutical-government-pricing/>, at p. 2; “Transferability of Economic Studies: Is There a Generally Accepted Alternative Price Benchmark to the WAC Price?” ISPOR, available at https://www.ispor.org/docs/default-source/presentations/1058.pdf?sfvrsn=ae6fa2a1_1, at p. 7.

⁸⁹ ASP is used by Medicare to determine reimbursement rates for drugs covered under Medicare Part B (*i.e.*, injectables or drugs that are physician-administered). Devenport, B., “Key Government Pricing Terms,” Prescription Analytics, August 2022, available at <https://prescriptionanalytics.com/white-papers/key-terms-in->

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[REDACTED]

Biosimilar launches have generally resulted in markedly lower observed ASPs for the reference biologics. Based on Amgen’s 2022 Biosimilar Trends Report, reference biologic product ASPs have decreased at a compound annual rate of anywhere from 4 to 21 percent since the launch of the first biosimilar in the class.⁹⁰

58. [REDACTED]

[REDACTED]

[REDACTED]⁹¹ According to Cardinal Health’s 2022 Biosimilar Report, the recent launch of the first biosimilar version of Humira—the “all-time top-selling [autoimmune] drug in the world”—on January 31, 2023, and the subsequent launches that are expected later in 2023, will likely have a “dramatic” impact “for all immunology therapies in the class” (*e.g.*, STELARA®).⁹² Janssen’s internal documents [REDACTED]

[REDACTED]⁹³

3. Varying Nature of Impacts

59. While the impact of biosimilar entry can be immediate and severe, the precise path of the impact can and does vary widely from one treatment to another. For example, in Q2 2022, three years after its first biosimilar launched, branded Avastin held only 18 percent share in the

pharmaceutical-government-pricing/, accessed at p. 3. *See also* Exhibit B44 (Mattingly, J., “Understanding Drug Pricing,” U.S. Pharmacist, Vol. 37, No. 6, 2012, pp. 40-45).

⁹⁰ Exhibit B27, at p. 13.

⁹¹ Exhibit B17, at p. 9. *See also* Exhibit B15, at pp. 48, 53.

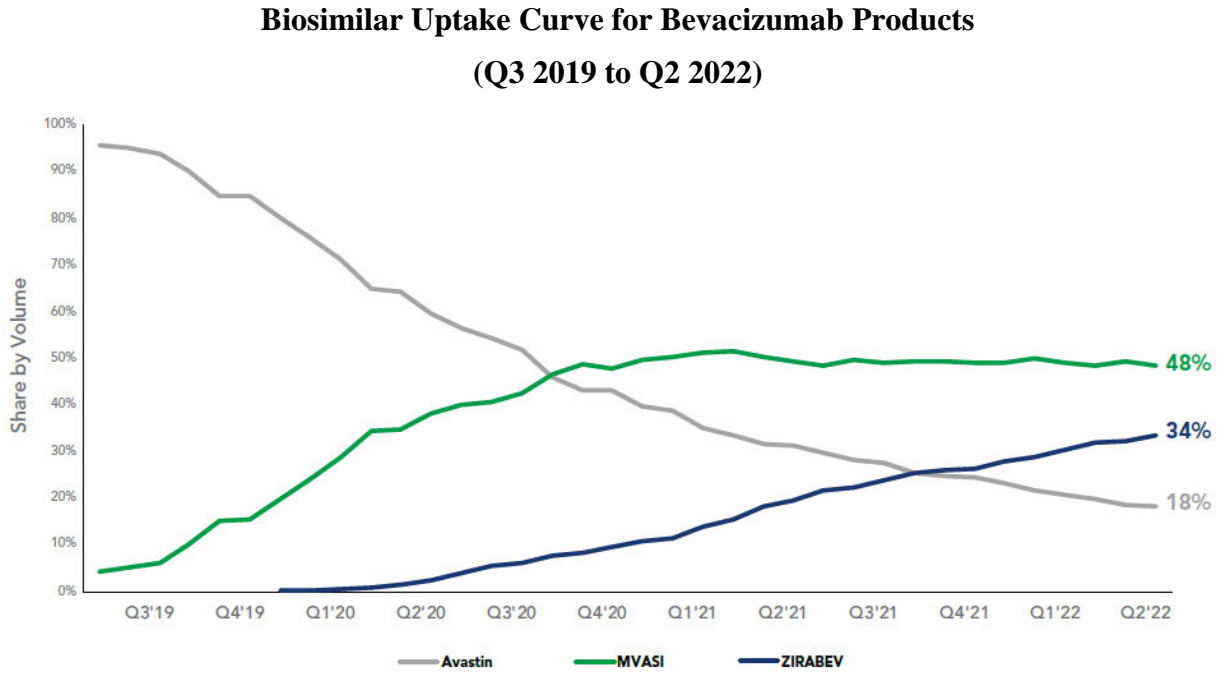
⁹² Exhibit B25, at p. 58; Exhibit B1, at p. 5; “Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States,” Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023. *See also* Exhibit B27, at p. 25.

⁹³ Exhibit B15, at pp. 48, 53.

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bevacizumab segment, illustrating a rapid decline in share triggered by biosimilar entry, as shown in Figure 2 below.

Figure 2⁹⁴



60. By contrast, Rituxan had retained 36 percent share in the rituximab segment in Q2 2022, approximately three years since its first biosimilar launch (*see* Figure 3 below). Thus, while all reference biologics experience declines in volume share following biosimilar entry, the magnitude of this decline has varied across reference products.⁹⁵

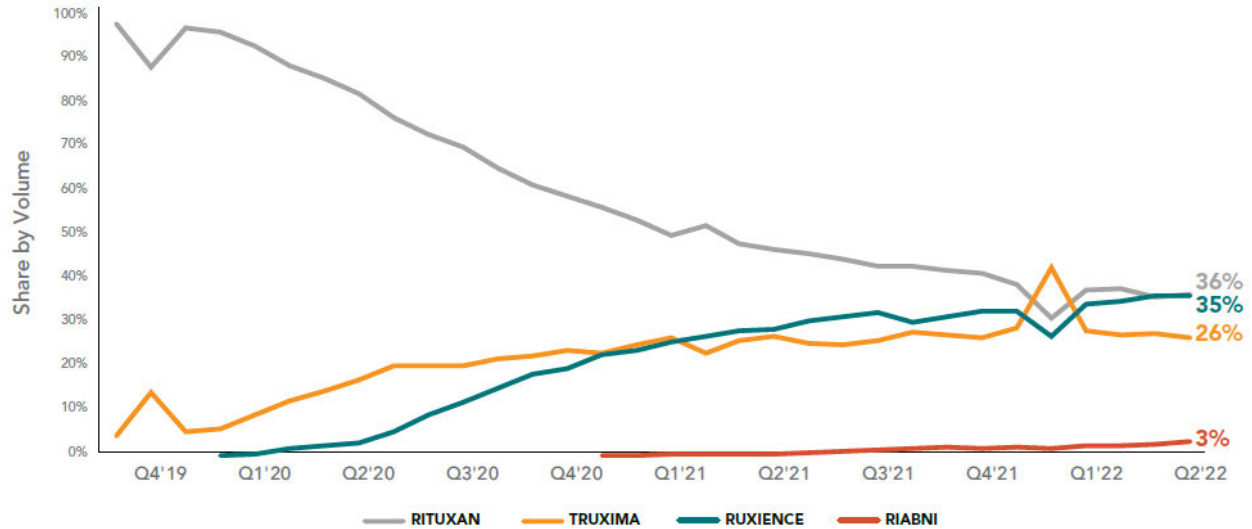
⁹⁴ Exhibit B27, at p. 39.

⁹⁵ Exhibit B27, at pp. 35-65.

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Figure 3⁹⁶

**Biosimilar Uptake Curve for Rituximab Products
(Q4 2019 to Q2 2022)**



61. Similarly, with the exception of NEUPOGEN[®] (filgrastim) (“Neupogen”), all reference biologics experienced ASP erosion following biosimilar entry. However, as with volume share, the magnitude of the ASP decline has varied across products and therapeutic areas.⁹⁷ For example, Rituxan has been able to minimize price erosion, having experienced a decline of only 11 percent in ASP by Q3 2022 from first biosimilar rituximab product launch in Q4 2019, even though its biosimilars had reached ASP discounts of 50 to 56 percent relative to the pre-biosimilar-entry Rituxan ASP over the same period (*see* Figure 4 below).

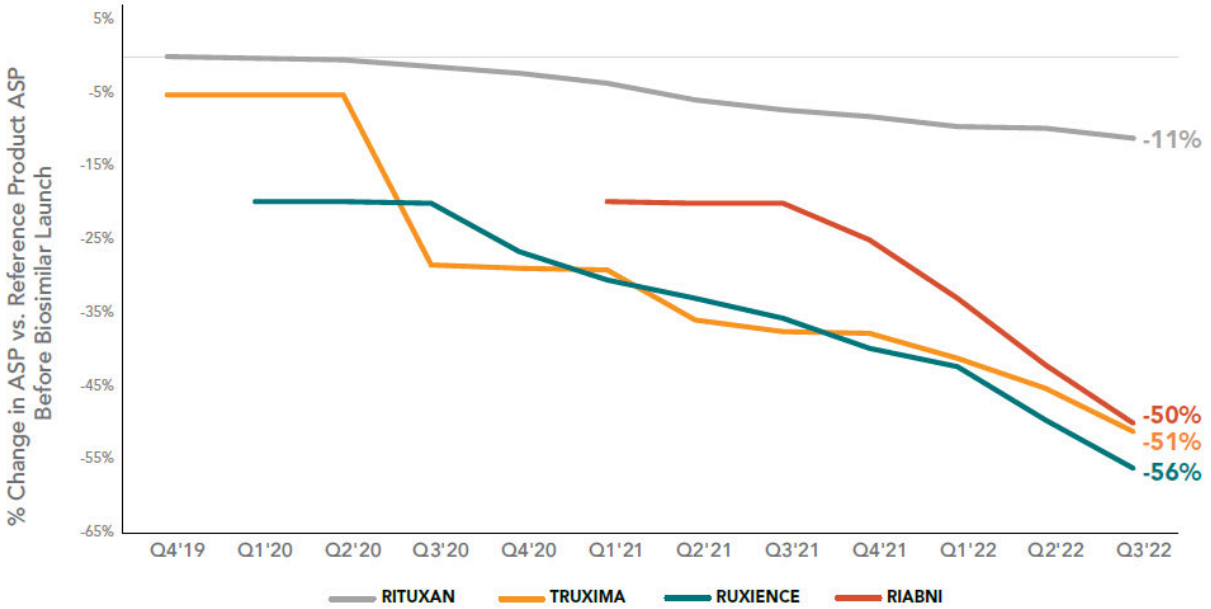
⁹⁶ Exhibit B27, at p. 44.

⁹⁷ Exhibit B27, at p. 13.

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Figure 4⁹⁸

ASP of Rituximab Products Following Biosimilars' Launches
(Q4 2019 to Q3 2022)



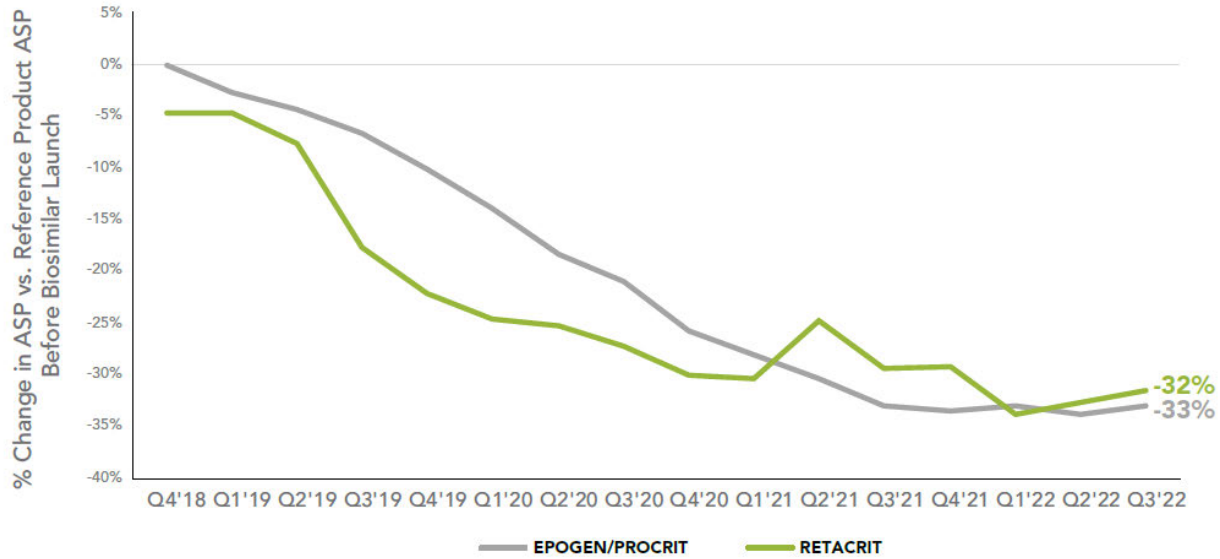
62. By contrast, over an approximately four-year period following biosimilar entry, the branded EPOGEN[®] (epoetin alfa) (“Epogen”) ASP had plummeted to 33 percent lower than the ASP of Epogen before the biosimilar launch (*see* Figure 5 below).

⁹⁸ Exhibit B27, at p. 43.

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Figure 5⁹⁹

**ASP of Epoetin Alfa Products Following Biosimilar’s Launch
(Q4 2018 to Q3 2022)**



F. Immunotherapy Competitive Landscape

63. Prominent branded biologics that treat immunologic diseases have only just started experiencing or are expected to experience biosimilar entry for the first time in 2023 and 2024, including ten Humira biosimilars that are expected to launch in 2023, with Amgen’s Humira biosimilar having already launched.¹⁰⁰

64. Notable differences in marketplace conditions and product features suggest that the impacts of Humira and STELARA[®] biosimilar launches on their reference biologics will differ

⁹⁹ Exhibit B27, at p. 58.

¹⁰⁰ Exhibit B7, at p. 6; Exhibit B1, at p. 47; “Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States,” Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023.

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Over time, economic analysis, in conjunction with a wide array of court opinions, suggests that there is a reasonable and workable test to determine whether there is irreparable harm in patent cases. That test suggests an evaluation of five factors:

- **Existence of harm**—is there likely to be harm?¹⁰⁵
- **Preservation of status quo**—will lack of an injunction unreasonably disrupt the status quo that existed immediately prior to the commencement of infringement?¹⁰⁶
- **Causal nexus**—does the harm flow from the infringement?¹⁰⁷
- **Quantifiability**—can all of the likely harm to the patent owner be quantified with a reasonable degree of economic certainty?¹⁰⁸ and
- **Collectability**—are there any impediments to the patent holder’s recovery of payment for that harm?¹⁰⁹

67. I will address each of these factors below.

1. Existence of Harm

a. Harm to Janssen

68. Amgen’s premature launch of ABP 654 will harm Janssen’s STELARA® franchise.

The losses Janssen will likely suffer include some combination of (1) a substantial decline in the

¹⁰⁵ See also, *LEGO v. ZURU Inc.*, 799 Fed. Appx. 823, 834, 836 (Fed. Cir. 2020); *Palmer v. Connecticut Railway & Lighting Co.*, 311 U.S. 544, 561 (1941); *Story Parchment Co. v. Patterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931).

¹⁰⁶ See, e.g., *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987). *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 1231 (Fed. Cir. 1985). *Continental Service Group, Inc. v. United States*, 722 Fed. Appx. 986 (2018).

¹⁰⁷ See, e.g., *Apple Inc. v. Samsung Electronics Co., Ltd.*, 678 F. 3d 1314, 1324 (Fed. Cir. 2012).

¹⁰⁸ See, e.g., *LEGO v. ZURU Inc.*, 799 Fed. Appx. 823, 833 (Fed. Cir. 2020); *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 703 (Fed. Cir. 2008).

¹⁰⁹ See, e.g., *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011).

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[REDACTED]

units of STELARA[®] sold, (2) a substantial reduction in STELARA[®]'s net price or ASP (e.g., through increases in provider discounts, payor rebates), and (3) a disruption of the on-going adoption process for STELARA[®]. As a result, STELARA[®] revenues are likely to be immediately and severely reduced, and the future performance of STELARA[®] is likely to be adversely affected.

69. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

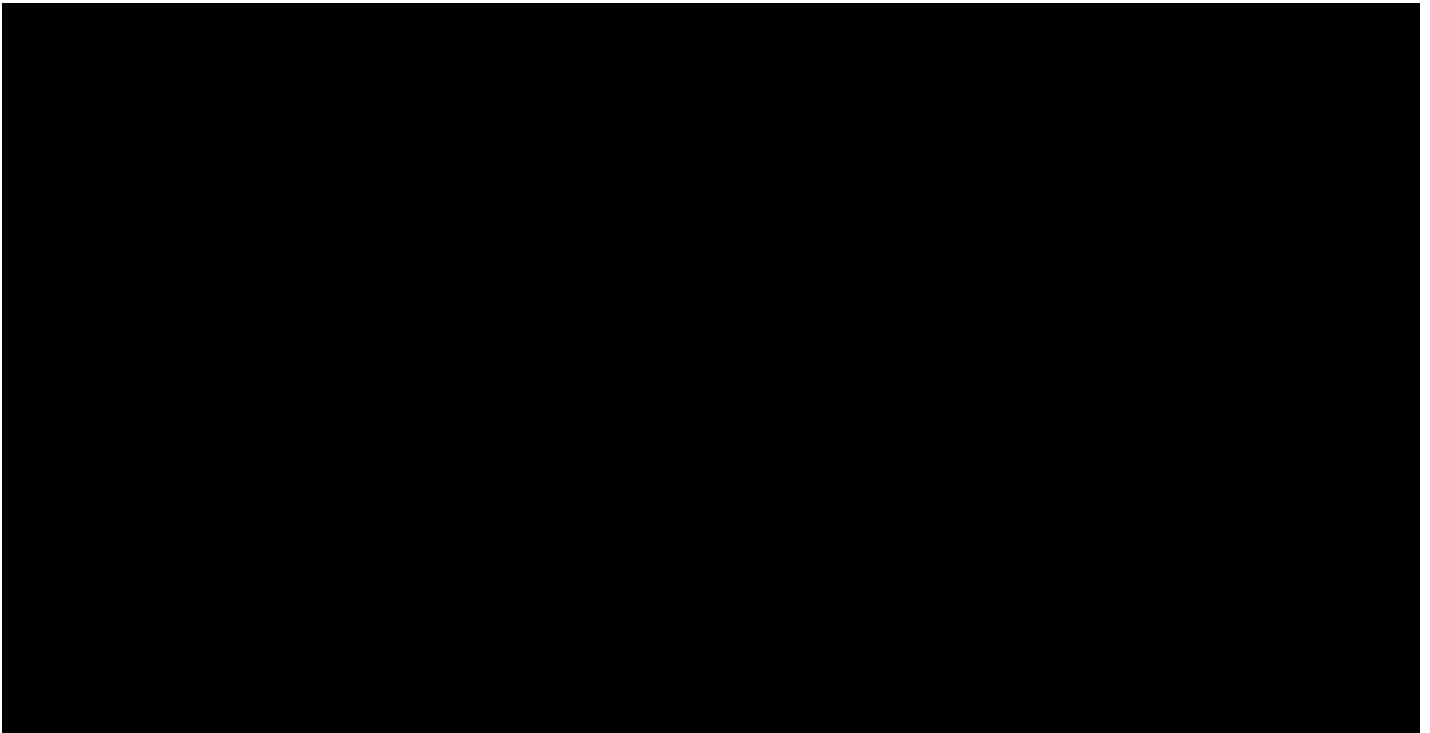
110

[REDACTED]

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Figure 6

111



70. Across indications and therapies, the impact of a biosimilar launch on a reference biologic has varied. [REDACTED] across all indications and therapies, reference biologics experiencing biosimilar competition have suffered considerable volume share and/or net price declines following initial biosimilar entry, resulting in reduced net revenues. For example, within the first year following initial biosimilar launch, share of volume of HERCEPTIN[®] (trastuzumab) (“Herceptin”) within the molecule declined by roughly 50 percent.¹¹² Considerable declines in volume are not surprising if payors discontinue covering the reference biologic in favor of the biosimilar products.¹¹³ Likewise, the launch of biosimilar products, which

¹¹¹ Exhibit B15, at p. 10.

¹¹² Exhibit B27, at p. 35.

¹¹³ Within approximately three years of the launch of Rituxan biosimilar copies, three of the largest PBMs have stopped covering the originator Rituxan biologic in favor of one of its biosimilars. In under three years after the

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[REDACTED]

are typically offered at a discount to the reference product,¹¹⁴ would be expected to increase pressure on the reference biologic manufacturer to offer additional price concessions for its product. For example, the average sales price for Epogen declined to about 90 percent of its average sales price before biosimilar launch (*i.e.*, 10 percent discount) after about one year following initial biosimilar launch and approximately 75 percent of its average sales price before biosimilar launch (*i.e.*, 25 percent discount) after about two years following the initial biosimilar launch.¹¹⁵

71. [REDACTED]

[REDACTED]

[REDACTED] At this point, it is unclear if any [REDACTED] would infringe one or more of Janssen's patents protecting STELARA[®], including the Manufacturing Patents, and would be precluded from launch on that basis. To the extent these additional biosimilar ustekinumab products are precluded from launch in light of Janssen's Manufacturing Patents or any other Janssen patents covering STELARA[®], Amgen's infringing launch of ABP 654 would likely considerably impact Janssen's STELARA[®] unit sales and revenues, as discussed above. However, Amgen's

first biosimilar launch, Rituxan's share by volume declined to about 36 percent of the rituximab products. Exhibit B27, at pp. 44, 78.

¹¹⁴ See, e.g., Exhibit B25, at p. 6.

¹¹⁵ Exhibit B27, at p. 58.

¹¹⁶ Exhibit B7, at p. 7 [REDACTED]

[REDACTED]

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infringing launch is still likely to result in harm to Janssen even if ABP 654 is not the only STELARA[®] biosimilar that becomes available in the marketplace.

72. In fact, Amgen’s own 2022 Biosimilar Trends Report suggests that the “entry of additional biosimilars is expected to lead to greater price declines across all products within the class.”¹¹⁷ While the report does not provide specific estimates of the incremental impact of each additional entrant and the observed impact of additional entrants has varied across products, some examples illustrate the extent of potential harm from additional entry on the reference biologic. For instance, Neulasta’s average sales price began declining particularly quickly in response to entry from third and fourth biosimilar pegfilgrastim products, with discounts from pre-entry ASP increasing from about 5 percent at the time of the third biosimilar launch to approximately 25 percent by the time of the fourth biosimilar launch.¹¹⁸ This suggests that more biosimilars could lead to deeper discounts and a greater reduction in average sales price of the reference biologic.

73. Further, [REDACTED] [REDACTED] le.¹¹⁹ As such, the availability of an additional biosimilar would likely further increase the pressure PBMs will exert on Janssen, demanding ever-increasing rebates in return for keeping STELARA[®] on formulary and maintaining patient access. It may also increase the risk of STELARA[®]’s exclusion from formularies.¹²⁰ Given that [REDACTED] [REDACTED]

¹¹⁷ Exhibit B27, at p. 25.

¹¹⁸ Exhibit B27, at p. 49.

¹¹⁹ See, e.g., [REDACTED]

¹²⁰ See, e.g., Exhibit B27, at p. 78.

¹²¹ Exhibit B10, at p. 7. See also Exhibit B25, at pp. 49, 54, suggesting that there is a strong correlation between biosimilar adoption and increases in payor coverage.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

74. Importantly, many, if not all, of these harms are likely to be long-lasting. As discussed in more detail below, payors and PBMs that would have reduced or eliminated STELARA[®]'s reimbursement coverage on their formularies following Amgen's biosimilar launch and/or required price concessions from Janssen to maintain some level of coverage, would be reluctant to restore STELARA[®]'s levels of coverage and/or price to those they would have provided had Amgen's biosimilar not been launched prematurely.¹²⁴

75. Further, to the extent Amgen's premature launch of ABP 654 would result in a reduction in the promotion of STELARA[®] to physicians and other stakeholders,¹²⁵ this would likely further impact STELARA[®]'s sales.

76. The launch of the first Humira biosimilar in January 2023, followed by nine additional Humira biosimilars later in the year, will further complicate the competitive dynamics for STELARA[®].¹²⁶ Given that Humira is indicated for the treatment of the same indications as STELARA[®] (*i.e.*, PSO, PSA, CD, and UC), among others, the availability of adalimumab

¹²² Exhibit B1, at p. 22.

¹²³ *See, e.g.*, Exhibit B1, at p. 8.

¹²⁴ Smith Declaration, at p. 10

¹²⁵ *See, e.g.*, Guha, R., and M. Salgado, "Economics of Irreparable Harm in Pharma Patent Litigation," Law360, November 18, 2013, available at <https://www.law360.com/articles/489198/economics-of-irreparable-harm-in-pharma-patent-litigation>, accessed January 25, 2023.

¹²⁶ [REDACTED] "Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States," Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023.

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██████████

biosimilars, which are also approved for these uses and may offer cost advantages to payors, is likely to increase marketplace pressure on STELARA[®] across all indications.¹²⁷ According to the Cardinal Health’s 2022 Biosimilars Report, the impact of Humira biosimilar entry on the “rheumatology and immunology market as a whole could be dramatic—not just for Humira but for all immunology therapies in the class, including Janssen’s Stelara.”¹²⁸ ██████████

██████████⁹ In this environment, adding a premature launch of ABP 654 will complicate competitive dynamics in the marketplace in ways that cannot be fully identifiable, let alone undone.

77. ██████████

██████████

78. Moreover, ██████████ ██████████

██████████

██████████

██████████

██████████

¹²⁷ See, e.g., Exhibit B25, at p. 58.

¹²⁸ Exhibit B25, at p. 58.

¹²⁹ See, e.g., Exhibit B9, at pp. 21, 23.

¹³⁰ See, e.g., Exhibit B9, at p. 25; Smith Declaration, at p. 11.

¹³¹ Exhibit B9, at p. 25. See also Exhibit B1, ██████████

¹³² See Tab 8. See also Tab 7; Exhibit B9, at p. 15.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

79. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The premature launch of ABP 654 will also curtail Janssen’s ability to educate physicians and patients about the benefits of STELARA® for the treatment of UC – recognizing that Amgen’s ABP 654 product would be able to free-ride on such educational efforts and siphon off much of the benefit from them.¹³⁹ As STELARA® has only recently been approved for the treatment of UC, the reduction in marketing and education efforts by Janssen may further stunt STELARA®’s sales.

b. Other Harm to Janssen

¹³³ See Tab 4.

¹³⁴ Exhibit B1, at p. 4. See also Tab 5, [REDACTED]

¹³⁵ Exhibit B1, at p. 8.

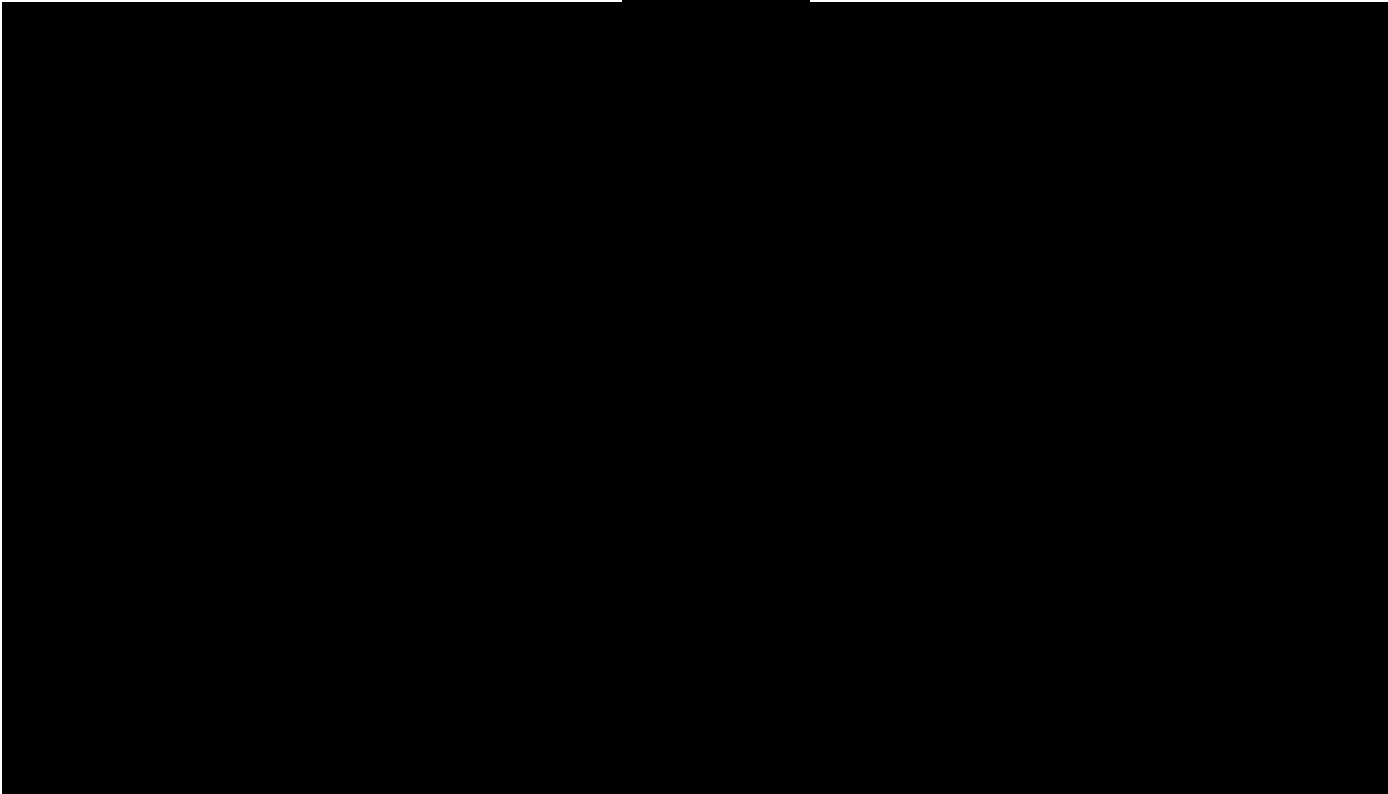
¹³⁶ Exhibit B1, at p. 4; Smith Declaration, at pp. 9-10. See also Exhibit B25, at p. 49 [REDACTED]

¹³⁷ Exhibit B12, at pp. 7, 16. See also Exhibit B9, at p. 9.

¹³⁸ Exhibit B1, at p. 22.

¹³⁹ See, e.g., Exhibit B32 (Cameron, L.J., “Preliminary Injunctions in Pharmaceutical Litigation: The Economics of Irreparable Harm,” Discussion Paper, 2011), at p. 5.

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82. Given this importance, allowing Amgen to prematurely launch ABP 654 despite the potential infringement of the Manufacturing Patents would represent a significant threat of harm to Janssen. The general nature of this threat – a likely substantial decline in sales volumes combined with a material drop in prices resulting in a potentially significant loss of revenue for Janssen – is described above.

83. In the present case, this threat is particularly acute because Amgen has shown itself to have a notable ability to undermine and erode the performance of branded biologics with its biosimilar entry. [REDACTED]

[REDACTED]

¹⁴¹ Exhibit B10, at p. 12.

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[REDACTED]

[REDACTED]

[REDACTED]

(ii) Immunotherapy Business

84. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

85. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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86. [REDACTED]

[REDACTED]

87. [REDACTED]

[REDACTED]

¹⁴⁷ Exhibit B10, at 2.

¹⁴⁸ Smith Declaration, at pp. 7-8.

¹⁴⁹ *See, e.g.*, Exhibit B10, at p. 6; Smith Declaration, at p. 7.

¹⁵⁰ Smith Declaration, at p. 4.

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[REDACTED]

88. [REDACTED]

[REDACTED]

¹⁵¹ Smith Declaration, at pp. 7-8.

¹⁵² See, e.g., Exhibit B10, at p. 6; Smith Declaration, at pp. 10-11.

¹⁵³ See, e.g., Exhibit B10, at p. 6; Smith Declaration, at pp. 10-12.

¹⁵⁴ Exhibit B9, at p. 9.

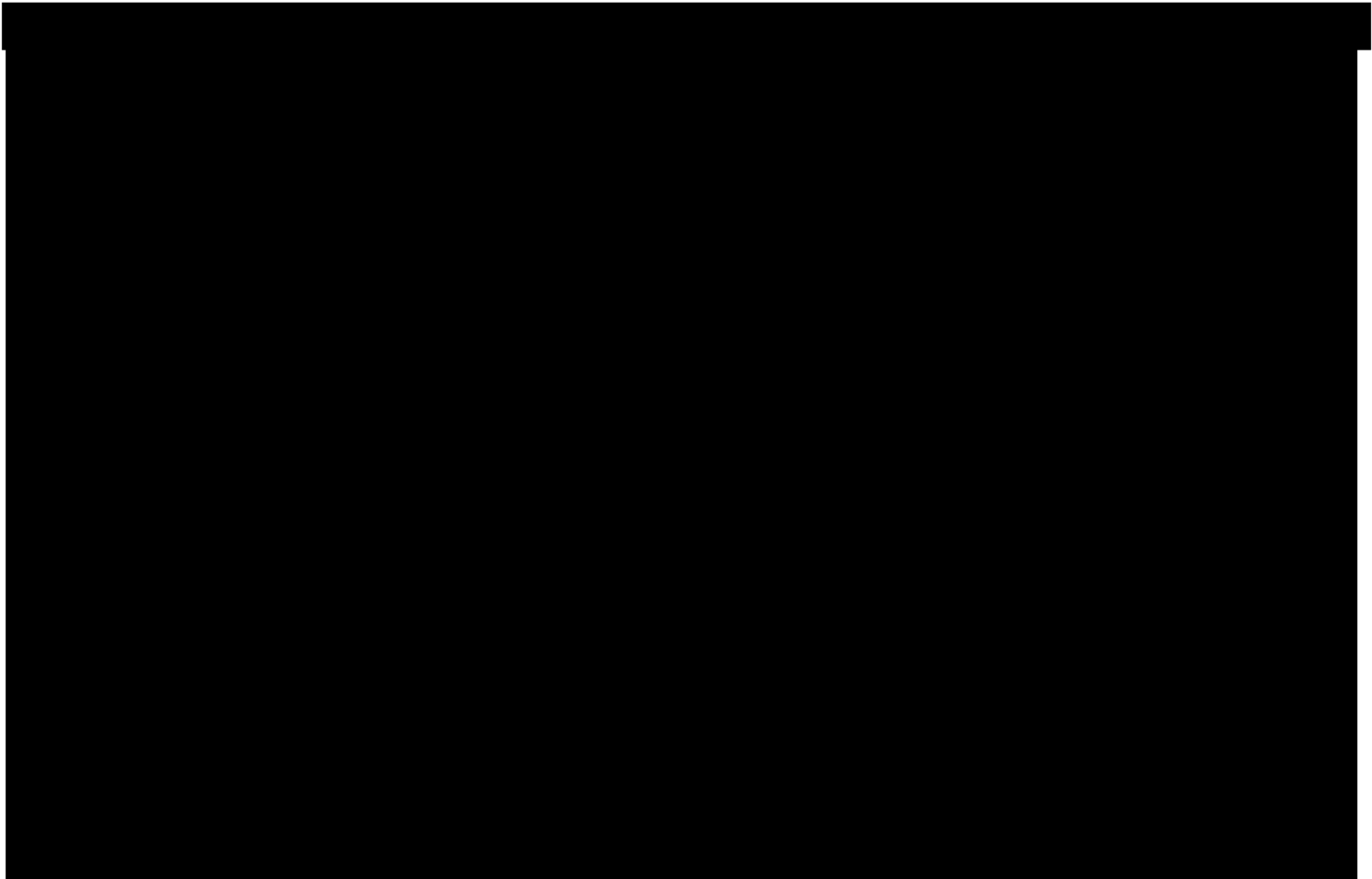
¹⁵⁵ Exhibit B10, at p. 12. See also Exhibit B9, at p. 9 [REDACTED]

¹⁵⁶ Exhibit B21, at p. 3.

¹⁵⁷ Exhibit B17, at p. 9.

¹⁵⁸ Exhibit B17, at p. 5.

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89. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁵⁹ Exhibit B16, at p. 6.

¹⁶⁰ Exhibit B6, at p. 4 [REDACTED]

¹⁶¹ *See, e.g.*, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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(iii) R&D Activities

90. Amgen's premature launch of ABP 654 will impair Janssen's/J&J's future R&D activities in several ways.

91. First, to the extent that Janssen/J&J experiences revenue losses because of an ABP 654 launch, Janssen's/J&J's R&D activities can be expected to fall due to the reduction in available resources to fund R&D.¹⁶²

92. I understand that Janssen/J&J is currently developing and investigating a variety of potential therapies for patients with unmet needs.¹⁶³ These efforts include research on new potential drugs, research on new indications for drugs already available in the marketplace, funding of clinical trials, and more.¹⁶⁴

93. As discussed above, STELARA[®] revenues account for a large portion of both Janssen's and J&J's overall revenues and are, therefore, a substantial contributor to the R&D budget.¹⁶⁵ A material reduction in corporate revenues will lead to a material reduction in corporate R&D.

94. Further, one cannot predict *which* R&D projects will be shelved or abandoned due to reduced STELARA[®] revenue in the face of Amgen's infringing launch, let alone which ones might have succeeded and provided benefits to patients that might not have other options. But it is

¹⁶² Smith Declaration, at p. 13.

¹⁶³ See, e.g., Exhibit B60 (Johnson & Johnson 2021 Annual Report), at p. 2; "R&D at Janssen," Janssen, available at <https://www.janssen.com/belgium/rd-janssen>, accessed January 23, 2023.

¹⁶⁴ See, e.g., Exhibit B60 (Johnson & Johnson 2021 Annual Report), at p. 2; "R&D at Janssen," Janssen, available at <https://www.janssen.com/belgium/rd-janssen>, accessed January 23, 2023; "Selected Pharmaceuticals in Development as of October 19, 2022," Johnson & Johnson, available at <https://jnj-content-lab.brightspotcdn.com/ab/20/742dee48444881a2df80fc6ef070/jnj-pipeline-3q2022-1.pdf>, accessed January 23, 2023; "Research in Clinical Practice," Janssen, available at <https://www.janssen.com/belgium/research-clinical-practice>, accessed January 23, 2023.

¹⁶⁵ See, e.g., Exhibit B60 (Johnson & Johnson 2021 Annual Report), at p. 2; Smith Declaration, at pp. 12-13.

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[REDACTED]

inevitable that some projects that are currently in progress and/or under consideration will be abandoned because of a material reduction in STELARA[®]-generated resources.

95. In addition, Amgen's premature launch of ABP 654 can be expected to adversely affect Janssen's/J&J's R&D spending by discouraging future efforts to pursue new and innovative uses for existing drugs to the detriment of Janssen/J&J and the patients that might have benefited from such investments.

(iv) Industry Reputation/Goodwill

96. Amgen's premature launch of ABP 654 can be expected to harm Janssen's reputation in the marketplace with physicians, patients, and payors/PBMs.

97. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁶⁶ Exhibit B1, at p. 34.
¹⁶⁷ Smith Declaration, at pp. 8-9.
¹⁶⁸ Smith Declaration, at pp. 9-10.
¹⁶⁹ See Section III.B.4.b.iv.

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98. In [REDACTED]

[REDACTED]¹⁷⁰ The premature launch of ABP 654 can be expected to reduce Janssen’s promotional activities for STELARA[®] (*i.e.*, physician detailing and direct-to-consumer (“DTC”) advertising) and make existing promotional activities less effective. This is because the reduction in STELARA[®] revenues will result in fewer resources available for promotion and because ABP 654 will be able to free-ride on Janssen’s promotional efforts concerning ustekinumab.¹⁷¹ The premature curtailment of these promotional efforts for STELARA[®] will limit Janssen’s ability to build and reinforce its reputation in the manner it otherwise would without the premature ABP 654 launch.

99. In short, Janssen will experience harm to its reputation and goodwill in the marketplace if Amgen is allowed to prematurely launch ABP 654.

2. Preservation of Status Quo

100. In this matter, entry of the requested injunctive relief will preserve the status quo, whereby there is no Amgen biosimilar to STELARA[®]. If Amgen ultimately prevails on the merits of the infringement case, Amgen later will be able to offer ABP 654 as soon as the infringement issues are resolved.

¹⁷⁰ See, e.g., Exhibit B13, at pp. 2, 6.

¹⁷¹ See, e.g., Exhibit B32 (Cameron, L.J., “Preliminary Injunctions in Pharmaceutical Litigation: The Economics of Irreparable Harm,” Discussion Paper, 2011), at p. 5; Guha, R., and M. Salgado, “Economics of Irreparable Harm in Pharma Patent Litigation,” Law360, November 18, 2013, available at <https://www.law360.com/articles/489198/economics-of-irreparable-harm-in-pharma-patent-litigation>, accessed January 25, 2023.

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3. Causal Nexus

101. Amgen's premature launch of ABP 654 would authorize and encourage Amgen's product to be substituted for STELARA[®]. It is this substitution that is the basis for harms outlined above. And each of the Manufacturing Patents is presumably used in the manufacture of ABP 654. This is not a case of a patent covering a small part of a multi-component product. I understand that the Manufacturing Patents here cover the process to make the entire end product.

102. If Janssen were to prevail in obtaining the requested relief here, Amgen's ABP 654 would not be able to compete with STELARA[®], which can be expected to (at least to some extent) protect STELARA[®]'s competitive position in the marketplace.

103. There is a strong causal nexus that "relates the alleged harm to the alleged infringement."¹⁷²

4. Quantifiability

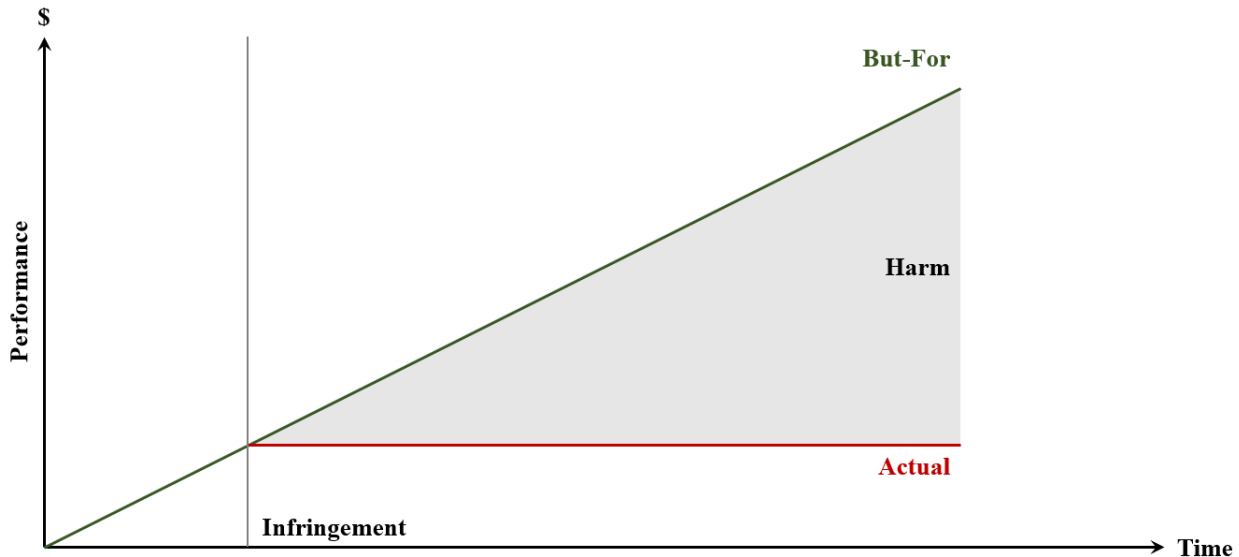
104. Generally, the quantification of economic harm in a case like this involves a comparison of the alleged injured party's (here, Janssen's) condition in the world *without* improper entry (by Amgen) and the injured party's condition in the world *with* improper entry. Any diminishment in the injured company's condition between those worlds represents the injured company's harm attributable to the allegedly unlawful action, holding other things constant. This is illustrated in Figure 10 below.

¹⁷² *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374-75 (Fed. Cir. 2012).

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Figure 10

Illustration of Harm



a. Obstacles

105. To be awarded monetary damages for any harm that is incurred, the harm caused by an infringer's actions must be quantifiable (*i.e.*, reducible to a monetary value) with a reasonable degree of certainty such that the magnitude of harm can be adequately measured and paid. If such a calculation cannot be made for *all* of the harm suffered by the injured party because of the infringing activity, then the injured party will not be able to receive adequate monetary compensation for that harm. In that case, issuance of an injunction may be appropriate.¹⁷³

106. Whether an injured party's harm is considered "irreparable" depends on the facts of each case.¹⁷⁴ Examples of types of harm that have been found by patent courts to be irreparable

¹⁷³ *Automated Merchandising Sys., Inc. v. Crane Co.*, 357 F. App'x. 297, 300-301 (Fed. Cir. 2009).

¹⁷⁴ The Court of Appeals for the Federal Circuit noted in *Celsis In Vitro, Inc. v. Cellzdirect, Inc.* 664 F.3d 922, 930 (Fed. Cir. 2012), that "[p]rice erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm," and upheld a district court's granting of a preliminary

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include loss of sales, price erosion, loss of market share, loss of business opportunities, and loss of goodwill.¹⁷⁵

107. For a variety of reasons, harm suffered by an injured company may not be fully compensable with monetary damages. One possible impediment is that there may be too much uncertainty to estimate how the injured party would have performed in a world where the improper entry had not occurred (the green line above). That is, though there will be, at the point of trial, developed evidence as to STELARA[®]'s performance in the actual world (*i.e.*, with the premature launch of ABP 654) (the red line above), there may be substantial uncertainty as to how well STELARA[®] would have performed absent Amgen's premature launch of ABP 654. Significant uncertainty may be found to exist where sales of the technology or technologies in question are new and / or growing at a rapid, but unpredictable rate, where there have been recent shocks (like adverse macroeconomic events or a pandemic) impacting the marketplace, or where there has been new competitive entry. This is illustrated in Figure 11 below, where the dashed green lines illustrate a range of possibilities.

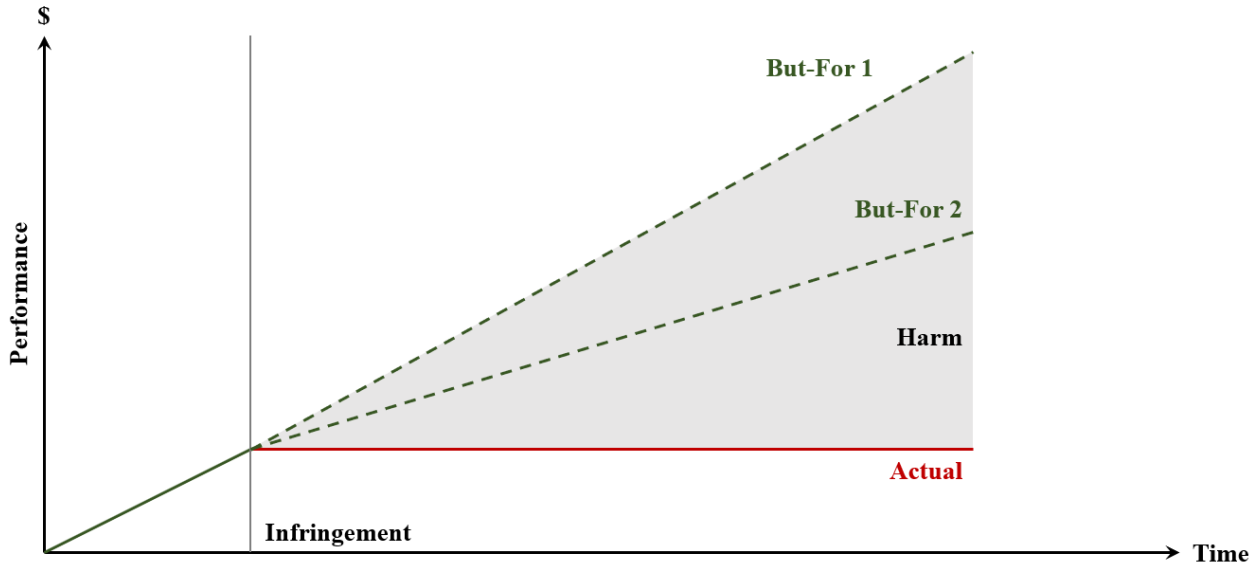
injunction. In doing so, the Court quoted the following explanation from the district court: “[t]here is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer.” *Celsis In Vitro, Inc. v. Cellzdirect, Inc.* 664 F.3d 922, 930 (Fed. Cir. 2012).

¹⁷⁵ *Celsis In Vitro, Inc. v. Cellzdirect, Inc.* 664 F.3d 922, 930 (Fed. Cir. 2012). See also *Canon, Inc. v. GCC Int'l Ltd.*, 263 F. App'x. 57, 62 (Fed. Cir. 2008); *Systemation, Inc. v. Engel Indus., Inc.*, 1999 U.S. App. LEXIS 3849, at *7, *15 (Fed. Cir. 1999); *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1990).

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Figure 11

Illustration of Hard-to-Quantify Harm



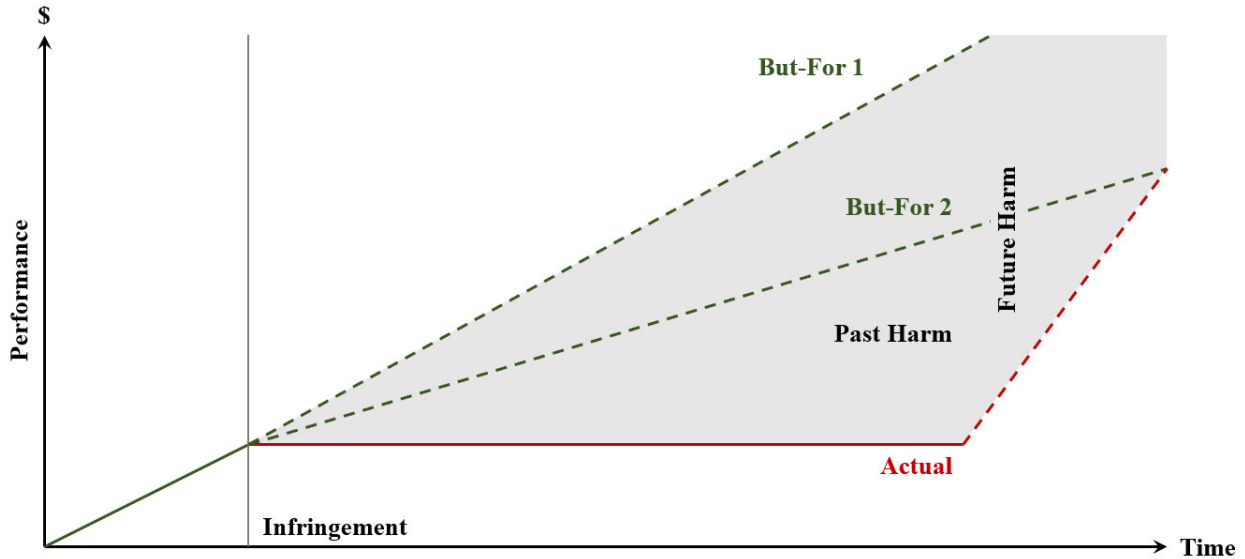
108. Another complication is associated with estimating harm due only to the infringer's actions. In a rapidly changing marketplace, one with substantial new entry, including infringing entry, it often is exceptionally difficult to estimate the impacts associated with only one entrant's (the infringer's) actions as distinct from the impacts of other competitors.

109. Further complicating any ability to quantify harm with a reasonable degree of certainty is that a biosimilar launch will introduce distortions in the marketplace that are likely to alter the long-term development of the STELARA[®] marketplace in unpredictable, and potentially irreversible, ways. For example, a biosimilar launch may lead to long-lasting (or even permanent) distortions in pricing (*i.e.*, price erosion) and marketplace share. Because the distortions caused by a biosimilar launch are irreversible, or virtually so, the full magnitude of the harm may become incalculable (*e.g.*, due to future uncertainty) or uncollectible (*e.g.*, if open-ended future losses exceed the new entrant). This is illustrated in Figure 12 below, where the dashed line illustrates one possibility.

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Figure 12

Illustration of Hard-to-Quantify Past and Future Harm



110. Further, harm may not be compensable if it is not a harm that is typically included in monetary damages awards. Some forms of harm are difficult, if not impossible, to quantify, such as damage to R&D programs, reputation, loss of goodwill, or the loss of potential (but unknown) business opportunities.

b. Harms to Janssen

111. As discussed above, the premature launch of Amgen's ABP 654 will likely cause significant harm to the STELARA[®] franchise. However, the circumstances and conditions surrounding the Amgen premature launch will make full quantification of these damages to a reasonable degree of certainty, even at a future trial, exceedingly difficult, if not impossible. As discussed above, even if other biosimilar copies of STELARA[®] are permitted to launch, Amgen's infringing launch of ABP 654 will still likely harm Janssen, but the proportional uncertainty

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surrounding the magnitude of the incremental harm from Amgen's launch would likely be even greater.

112. The significant uncertainty surrounding Amgen ABP 654's impact would preclude Janssen from obtaining full compensation for the harm it would suffer from Amgen's infringing launch through a subsequent court award of damages. Although actual STELARA[®] revenues and profits will be known as of the point of a merits trial, it will be exceedingly difficult, and likely impossible, to estimate what the revenues and profits would have been absent Amgen's infringement up to the point of trial (the but-for performance line). Among the reasons are the uncertainties of biosimilar impacts generally, and uncertainties in the STELARA[®] marketplace specifically. Moreover, STELARA[®] losses are likely to continue well beyond the point of trial. As I explain below, it is unclear whether Janssen could ever be fully compensated for these short-term and long-term harms.

(i) Uncertain Biosimilar Landscape

113. The difficulty in estimating the impact of biosimilar entry on the revenues of any particular biologic product is reflected in the wide range of impacts observed for nine biologic drugs that have experienced biosimilar entry prior to 2023.¹⁷⁶ Specifically, originator biologics have suffered volume share losses from less than 5 percent to as high as 50 percent one year following initial biosimilar entry.¹⁷⁷ In particular, [REDACTED]

¹⁷⁶ See Tab 3. Amgen's launch of Amjevita (Humira biosimilar) on January 31, 2023, would bring the count of biologic drugs that have experienced biosimilar entry to ten. See "Amjevita (Adalimumab-Atto), First Biosimilar to Humira, Now Available in the United States," Amgen, January 31, 2023, available at <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>, accessed February 10, 2023.

¹⁷⁷ Exhibit B25, at p. 16; Exhibit B1, at p. 46.

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[REDACTED]

[REDACTED].¹⁷⁸

114. Similarly, in its 2022 Biosimilar Trends Report, Amgen reported that over time, the various originator biologics sustained compound annual rates of decline of between 4 and 21 percent (*see* Figure 13).¹⁷⁹ The brand biologic drug Neulasta showed a price decline in the first four years of biosimilar entry of approximately 60 percent.¹⁸⁰ On the other hand, the brand biologic Neupogen showed a price increase of approximately 4 percent in its first four years of biosimilar entry.¹⁸¹ The high variability combined with the relatively small number of biologic drugs that have thus far been subject to biosimilar entry, with very few of them managed by PBMs, as STELARA[®] is, adds to the uncertainty in terms of calculating a biosimilar impact estimate for STELARA[®].

¹⁷⁸ Exhibit B1, at p. 41.

¹⁷⁹ Exhibit B27, at p. 13.

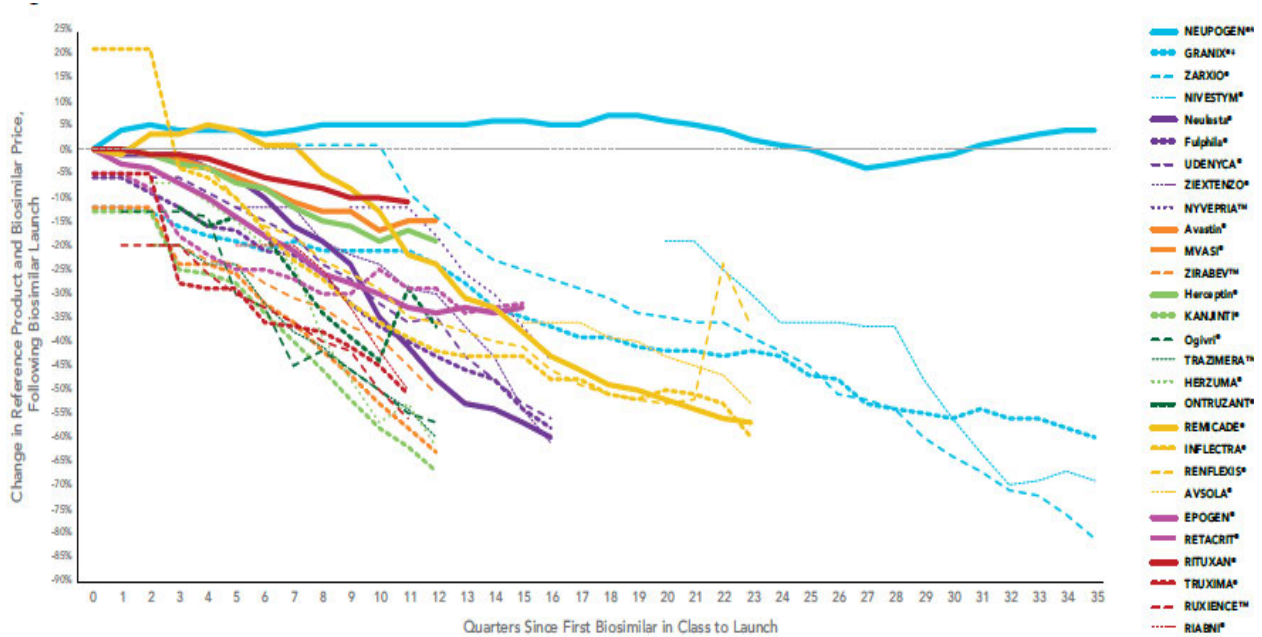
¹⁸⁰ Exhibit B27, at p. 49.

¹⁸¹ Exhibit B27, at p. 54.

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Figure 13¹⁸²

Cumulative Percent Price Changes for Originator Biologics and Biosimilars After Entry



(ii) Uncertain STELARA® Marketplace

115. Quantifying the full magnitude of STELARA®’s lost revenues that would result from an Amgen ABP 654 biosimilar launch that infringes Janssen’s Manufacturing Patents would be exceedingly difficult, if not impossible, due to significant uncertainties in the STELARA® marketplace that would complicate such quantification. I discuss certain of the more salient of these uncertainties below, namely, the factors specific to the STELARA® marketplace that indicate the impacts of biosimilar entry will differ for STELARA® as compared with previous biosimilar entry experience, and otherwise will make estimation of the STELARA® impact more complex such that the full extent of STELARA®’s losses could not be determined with reasonable certainty.

¹⁸² Exhibit B27, at p. 13. This represents percentage changes in “Average Selling Prices,” which reflect most manufacturer discounts and rebates.

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(a) Other Biosimilar Competition

116. [REDACTED]

[REDACTED]

[REDACTED] To the extent one or more of these competitors launch, either “at-risk” or not, their marketplace presence will significantly complicate disentangling the incremental impact of Amgen’s ABP 654 premature launch. That is, it would be exceedingly difficult, if not impossible, to disentangle the impact on STELARA[®] sales of Amgen’s premature launch from that of other STELARA[®] biosimilars.

(b) Limited Immunotherapy Biosimilars

117. Most biologics that have experienced biosimilar entry thus far are not autoimmune drugs like STELARA[®].¹⁸⁶ They treat other health conditions (*e.g.*, neutropenia in cancer patients, in the case of Neupogen and Neulasta¹⁸⁷), [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹⁸⁸

¹⁸³ Exhibit B7, at p. 7.

¹⁸⁴ Exhibit B7, at p. 7. [REDACTED]

¹⁸⁵ Exhibit B7, at p. 7.

¹⁸⁶ Tab 3.

¹⁸⁷ See Neupogen Label, Drugs@FDA, 2021, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103353s51971b1.pdf; Neulasta Label, Drugs@FDA, 2021, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125031s2031b1.pdf.

¹⁸⁸ See, *e.g.*, Exhibit B1, at pp. 4, 21.

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(c) Pharmacy Benefit Reimbursement

118. STELARA[®] generally is sold through pharmacies to patients for self-administration.¹⁸⁹ Consequently, it is typically covered under the plans' pharmacy benefit.¹⁹⁰ In contrast, as discussed above, most biologics that previously have experienced biosimilar entry are sold to institutions for physician administration, and thus, are covered under the plans' medical benefit.¹⁹¹ Coverage under the pharmacy benefit will give PBMs greater ability to manage patient utilization of STELARA[®] biosimilars than was typically possible for earlier biosimilars covered under the medical benefit, which lacks the visibility, cost-control strategies, and oversight of the pharmacy benefit.¹⁹² In addition, of the three large PBMs, accounting for approximately 75 percent of all U.S. prescriptions, each operates its own large specialty pharmacy that provides the PBM with an even greater level of control.¹⁹³

¹⁸⁹ Exhibit B27, at p. 75.

¹⁹⁰ Exhibit B27, at p. 75. *See also* Exhibit B25, at p. 50.

¹⁹¹ Exhibit B27, at p. 29. The biologic diabetes product, Lantus, for which biosimilars recently launched in Q4 2021 (*see* Tab 3), is sold through pharmacies and reimbursed under the pharmacy benefit. Exhibit B25, at p. 10.

¹⁹² *See, e.g.*, Seymore, B., "Challenges of Channel Management for Specialty: Medical Benefit or Pharmacy Benefit," *Pharmacy Times*, July 10, 2020, available at <https://www.pharmacytimes.com/view/challenges-of-channel-management-for-specialty-medical-benefit-or-pharmacy-benefit>, accessed February 8, 2023. *See also*, Exhibit B1, at p. 21.

¹⁹³ Boutross, L., G. Poblete, and S. Sangwan, "Pharmacy Benefit Is a Whole New Ball Game for Biosimilars," ZS Associates, January 12, 2022, available at <https://www.zs.com/insights/pharmacy-benefit-is-a-whole-new-ball-game-for-biosimilars>, accessed February 8, 2023. *See also* Exhibit B8, at p. 9; Exhibit B1, at p. 22; Exhibit B9, at p. 8.

¹⁹⁴ Exhibit B1, at p. 21.

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[REDACTED]**(d) ABP 654 Interchangeability**

119. As noted above, with STELARA[®] being dispensed by pharmacies, Amgen is seeking FDA approval for ABP 654 as being “interchangeable” with STELARA[®],¹⁹⁵ which would allow *pharmacists* to fill physician prescriptions written for brand STELARA[®] with Amgen’s biosimilar.¹⁹⁶ As of December 2022, only two of the previous biologic brands experiencing biosimilar entry, the diabetes drugs Lantus and LUCENTIS[®] (ranibizumab) (“Lucentis”), have faced a biosimilar product that the FDA approved for interchangeability, beginning in July 2021 and August 2022, respectively.¹⁹⁷ Thus, the degree to which Amgen’s prospective approval of its ABP 654 biosimilar for interchangeability would increase its substitutability for brand STELARA[®] would be difficult to estimate, even after the fact at a damages trial, given the very limited marketplace presence of interchangeable biosimilars to this point. The uncertainty of interchangeability’s impact is reflected in Janssen planning documents.¹⁹⁸

(e) STELARA[®]’s Use for UC

120. Identifying the full effects of an infringing ABP 654 launch would be particularly difficult due to STELARA[®]’s relatively recent entry into the UC marketplace. As noted above, STELARA[®] was approved for the treatment of UC in October 2019. [REDACTED]

¹⁹⁵ Exhibit B1, at p. 3; Exhibit B7, at p. 7.

¹⁹⁶ See Exhibit B28 (Alvarez, D.F., G. Wolbink, C. Cronenberger, J. Orazem, and J. Kay, “Interchangeability of Biosimilars: What Level of Clinical Evidence Is Needed to Support the Interchangeability Designation in the United States?” *BioDrugs*, Vol. 34, 2020, pp. 723-732), at pp. 723-724; Exhibit B25, at p. 64. Amgen is expected to secure interchangeability in mid-2024 for its STELARA[®] biosimilar which will be offered in a “patient-friendly” injection device, suggesting that it is likely to be covered under the pharmacy benefit plan. Exhibit B1, at p. 4.

¹⁹⁷ Exhibit B25, at p. 10; Exhibit B27, at p. 8; FDA Database of Licensed Biological Products (“Purple Book”), December 2022, available at <https://purplebooksearch.fda.gov/files/2022/purplebook-search-december-data-download.xlsx>. See also Tab 3.

¹⁹⁸ See, e.g., Exhibit B9, at p. 11 [REDACTED] See also Exhibit B9, at p. 17; Exhibit B8, at p. 23.

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[REDACTED]

121. As discussed above, the premature launch of Amgen’s ABP 654 will negatively impact Janssen’s ability to continue to grow its volume share in UC. Given that UC has been key to STELARA®’s recent growth, a reduction in marketing and education efforts will not only impact STELARA®’s sales, but will also complicate the estimation, even at a later damages trial, of how well STELARA® would have performed if there had been no ABP 654 premature launch (*i.e.*, complicate the estimation of STELARA®’s but-for world sales).

(iii) Competing Biosimilar Launches

122. Further complicating the impact that Amgen’s premature biosimilar entry would have on STELARA® revenues is the recent launch of an Amgen biosimilar for the brand drug Humira in January 2023, and the launch of several other Humira biosimilars expected to begin in mid-2023.²⁰³ It is expected that “[t]he impact [of Humira biosimilar entry] on the rheumatology and

¹⁹⁹ Exhibit B21, at p. 17.

²⁰⁰ Exhibit B9, at p. 15.

²⁰¹ Exhibit B1, at p. 4. *See also* Tab 5, [REDACTED]

²⁰² Tabs 5, 7-8.

²⁰³ [REDACTED]

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immunology market as a whole could be dramatic – not just for Humira but for all immunology therapies in the class, including Janssen’s Stelara (ustekinumab) and Genentech’s Actemra (tocilizumab), which are also anticipated to face biosimilar competition over the next few years.”²⁰⁴

123. Humira biosimilar entry is expected to impact STELARA[®] revenues for multiple reasons. First, Humira also is an autoimmune biologic that is approved for treating the same conditions as STELARA[®].²⁰⁵ Second, Humira is the largest-selling autoimmune drug,²⁰⁶ registering net sales of \$20.7 billion worldwide in 2021, of which \$17.3 billion was generated in the U.S.,²⁰⁷ which magnifies the autoimmune marketplace impact of biosimilar entry for the product. Third, Humira, like STELARA[®], is generally sold through pharmacies to patients for self-administration, and thus, will be one of the first biologics to face biosimilar entry that is covered under insurance plans’ pharmacy benefit.²⁰⁸ As discussed above, coverage under the pharmacy benefit will give PBMs greater ability to manage patient utilization of Humira biosimilars than typically was possible for biologics with biosimilar competition.

124. [REDACTED]

²⁰⁴ Exhibit B25, at p. 58.

²⁰⁵ Tab 3; STELARA[®] Label, Drugs@FDA, 2022, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125261s1611bl.pdf.

²⁰⁶ Exhibit B27, at p. 24, Table 1.

²⁰⁷ Exhibit B47 (AbbVie 2021 SEC Form 10-K), p. 38. In fact, Humira was the world’s second-largest-selling drug of any kind in 2021, after having been the world’s top-selling drug in 2020 and a number of years before. Dunleavy, K., “The Top 20 Drugs by Worldwide Sales in 2021,” FiercePharma, May 31, 2022, available at <https://www.fiercepharma.com/special-reports/top-20-drugs-worldwide-sales-2021>, accessed January 26, 2023. The drug’s net U.S. sales reported through Q3 2022 are pacing ahead of U.S. sales reported for the same period in 2021. *See* Exhibit B48 (AbbVie 3Q 2022 SEC Form 10-Q), at p. 23.

²⁰⁸ Exhibit B27, at p. 75.

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[REDACTED]

125. As a result, it would be exceedingly difficult, even at a later damages trial, to distinguish the incremental impact on STELARA® revenues of Amgen’s premature ABP 654 launch from the impact of the nearly concurrent launches of biosimilars for Humira.

(iv) Potential Long-Lasting Effects

126. Even absent the difficulties identified above that would preclude a reasonably certain estimation of Janssen’s total harm up to the time of a patent trial and award of damages, such an award would likely still fail to compensate Janssen fully. That is because of harm Janssen would continue to incur after the award of damages and (presumed) withdrawal of Amgen’s infringing biosimilar from the marketplace. Such future harm can be anticipated largely because the sale of Amgen’s biosimilar would fundamentally alter customers’ willingness to purchase and reimburse STELARA® rather than its biosimilars, and to do so at the prices they would have paid had Amgen not launched.

²⁰⁹ Exhibit B1, at p. 42.

²¹⁰ Exhibit B4, at p. 3; Smith Declaration, at pp. 9-10.

²¹¹ Exhibit B9, at pp. 21, 23.

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127. Specifically, as discussed above with respect to harm from Amgen's biosimilar launch, pharmacies may substitute the biosimilar to fill STELARA[®] prescriptions and cease stocking STELARA[®] while Amgen prematurely markets its biosimilar.²¹² If pharmacies grow accustomed to this substitution and stocking practice and other biosimilars besides Amgen become available in the marketplace, pharmacies may decide to continue stocking biosimilars instead of STELARA[®] even if Amgen's infringing ABP 654 biosimilar was later removed.

128. In addition, PBMs and insurers that would have reduced or eliminated STELARA[®]'s reimbursement coverage on their formularies following Amgen's premature biosimilar launch, and/or required lower prices from Janssen to maintain some level of coverage, would be reluctant or outright refuse to restore the coverage and price of STELARA[®] to the same levels had Amgen's biosimilar not launched prematurely. In particular, Janssen's ability to negotiate favorable formulary positioning and favorable prices with PBMs and other insurers would not be fully restored following the removal of Amgen's biosimilar after a merits trial had Amgen's ABP 654 not prematurely launched in the first place. The coverage and price expectations underlying the parties' negotiations would have become anchored at the lower levels reflecting Amgen's biosimilar presence in the marketplace (albeit based on illegitimate competition if the Amgen launch was found unlawful), which would impede Janssen's post-trial ability to negotiate STELARA[®]'s coverage and prices back to the levels that would have prevailed had Amgen's biosimilar not launched.²¹³ The anticipated adoption of "biosimilar first" policies by PBMs in the near future would complicate reliable estimation of STELARA[®] lost revenue damages further by

²¹² Smith Declaration, at p. 11.

²¹³ This is true whether or not Amgen is the only biosimilar entrant. Each entrant impacts the marketplace, though the full impact of each is exceedingly difficult, if not impossible, to estimate with a reasonable degree of certainty.

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requiring a determination of the degree to which PBMs would or would not have withheld STELARA[®] formulary coverage to the same degree if Amgen had not launched.

129. The “anchoring” impediment to restoring STELARA[®] coverage and prices to “but-for world” levels is supported by economic theory showing that parties tend to maintain their negotiating positions around outcomes that previously have been reached.²¹⁴ In particular, purchasers (*e.g.*, PBMs) typically place more negative value on a loss (*e.g.*, a price increase) relative to *a priori* conditions than they place positive value on a gain (*e.g.*, a price decrease) of equal magnitude.²¹⁵ In short, prices are sticky upward; they tend to move down fairly quickly, but only move up with substantial effort.²¹⁶

130. Further, even if Janssen prevails during the merits trial, it is unlikely that Janssen can be fully compensated for any post-trial harms. Specifically, if Amgen’s infringing biosimilar is removed from the marketplace, there will be no “infringing” sales after the trial that can be used as a basis for the calculation of an on-going royalty. It is unclear, therefore, how Janssen could be compensated for future harms.

c. Other Janssen Harms

²¹⁴ See Exhibit B38 (Kahneman, D., and A. Tversky, “Judgment under Uncertainty: Heuristics and Biases,” *Science*, Vol. 185, 1974, pp. 1124-1131); Exhibit B40 (Kahneman, D., J. Knetsch, and R. Thaler, “Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias,” *Journal of Economic Perspectives*, Vol. 5, No. 1, 1991, pp. 193-206); Exhibit B41 (Kahneman, D., “Reference Points, Anchors, Norms, and Mixed Feelings,” *Organizational Behavior and Human Decision Processes*, Vol. 51, 1992, pp. 296-312); Exhibit B29 (Ames, D.R., and M. Mason, “Tandem Anchoring: Informational and Politeness Effects of Range Offers in Social Exchange,” *Journal of Personality and Social Psychology*, Vol. 108, No. 2, 2015, pp. 254-274).

²¹⁵ See Exhibit B39 (Kahneman, D., and A. Tversky, “Prospect Theory: An Analysis of Decision Under Risk,” *Econometrica*, Vol. 47, 1979, pp. 263-292); Exhibit B42 (Kalwani, M.U., C.K. Yim, H.J. Rinne, and Y. Sugita, “A Price Expectations Model of Customer Brand Choice,” *Journal of Marketing Research*, Vol. 27, 1990, pp. 251-262).

²¹⁶ See also Smith Declaration, at p. 10.

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[REDACTED]

134. The impact Amgen’s infringing launch will have on Janssen’s negotiations with PBMs for future products is also exceptionally difficult, if not impossible, to quantify. [REDACTED]

135. Quantifying the full impact of Amgen’s infringing launch on the sales [REDACTED] to a sufficient degree of economic certainty will be exceptionally difficult, if not impossible.

(ii) R&D

136. Pharmaceutical companies typically rely heavily on profits generated from current product sales (*i.e.*, “retained earnings”) to fund investment for the research, development, and launch of new products, or research and development for product improvements.²²² Losing a substantial portion of STELARA® revenues due to an infringing launch of ABP 654 will

²²⁰ Exhibit B1, at p. 5.

²²¹ Smith Declaration, at p. 10.

²²² Pharmaceutical companies’ heavy reliance on retained earnings is generally attributed to the primarily intangible nature of pharmaceutical assets, which are relatively illiquid and have significantly diminished value with which to compensate debt holders in case of default. The risky nature of pharmaceutical R&D creates information asymmetries between borrowers and lenders regarding the likely success of the borrowers’ R&D investments, which raises the cost of lending because of the difficulty in monitoring the borrowers’ incentive to accept additional risk that will be disproportionately borne by the lender in case of project failure. Exhibit B37 (Harrington, S.E., “Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms,” in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, 2012), at pp. 2-4, 35-36; Exhibit B31 (Brealey, R.A., S.C. Meyers, and F. Allen, *Principles of Corporate Finance*, Tenth Edition, McGraw-Hill/Irwin, 2011), at pp. 2-3, 8, 457-463, 716-717.

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[REDACTED]

dramatically reduce the funds available for Janssen/J&J to fund these investments. Tab 6 shows that STELARA[®] U.S. revenues were approximately \$6 billion in FY 2021, representing over 20 percent of Janssen U.S. sales and over 12 percent of J&J's U.S. sales.²²³ Consequently, any material loss of STELARA[®] sales due to a failure to grant a preliminary injunction in this proceeding can be expected to limit the resources available to Janssen/J&J to support the R&D investment activities. As discussed above, the inability to fund some or all of the R&D investments due to the erosion of STELARA[®] sales based on an infringing launch of ABP 654 would result in substantial harm.

137. As discussed above, one cannot predict which R&D projects will be shelved or abandoned due to reduced STELARA[®] revenue in the face of Amgen's infringing launch, let alone which ones might have succeeded and provided benefits to patients that might not have other options. It is estimated that only 5 out of every 5,000 to 10,000 discovered compounds will reach the stage of clinical investigation (*i.e.*, clinical trials with humans) and only one such compound will eventually be approved by the FDA, as shown in Figure 14 below. Even in later stages of clinical investigation (*e.g.*, Phase 2 and Phase 3) when compounds have already undergone rigorous testing and consumed significant resources, regulatory approval remains far from certain. While over the period 2012 to 2021 Janssen/J&J sponsored a total of 247 Phase 2 and Phase 3 clinical trials to investigate new applications for novel and approved pharmaceutical compounds, Janssen/J&J secured a total of 68 FDA approvals during this period, producing a ratio of new approvals to contemporary Phase 2 and 3 clinical trials of approximately 28 percent.²²⁴

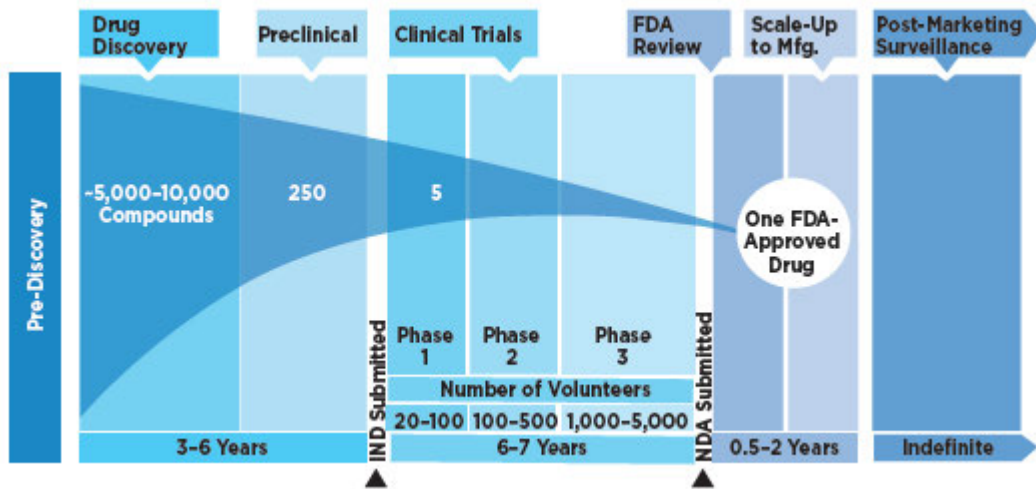
²²³ Tab 6.

²²⁴ A search for U.S. Phase 2 and 3 clinical trials that were sponsored by Janssen and were started between January 1, 2012, and January 1, 2022, was conducted on clinicaltrials.gov. Of the 250 search results, 247 results were deemed to be related to the study of a drug's efficacy or safety. Three results (*i.e.*, NCT01988961,

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Figure 14²²⁵

A Typical Timeline for Drug Discovery



NCT02462473, and NCT02641028 trials) were non-drug related clinical trials and were excluded from analysis. A similar search for clinical trials sponsored by Johnson & Johnson resulted in identification of clinical trials for products sponsored by Johnson and Johnson Consumer and Personal Products Worldwide, Johnson and Johnson Consumer, Inc., Johnson & Johnson Vision Care, Inc., or McNeil Consumer Healthcare (e.g., over-the-counter pain relievers, contact lenses, etc.). These results were excluded from analysis. See “Find a Study – Search Results Janssen Sponsor,” U.S. National Library of Medicine, available at https://clinicaltrials.gov/ct2/results?cond=&term=&type=Intr&rslt=&age_v=&gndr=&intr=&titles=&outc=&sp ons=janssen&lead=janssen&id=&cntry=US&state=&city=&dist=&locn=&phase=1&phase=2&rsub=&strd_s=01%2F01%2F2012&strd_e=01%2F01%2F2022&prcd_s=&prcd_e=&sfpd_s=&sfpd_e=&rfpd_s=&rfpd_e=&lupd_s=&lupd_e=&sort=#, accessed February 16, 2023; “Find a Study – Search Results J&J Sponsor,” U.S. National Library of Medicine, available at https://clinicaltrials.gov/ct2/results?cond=&term=&spons=johnson+and+johnson&lead=johnson+and+johnson&strd_s=01%2F01%2F2012&strd_e=01%2F01%2F2022&cntry=US&state=&city=&dist=&Search=Search&ty pe=Intr&phase=1&phase=2, accessed February 19, 2023. Approvals were counted based on mentions of original or supplemental FDA approval of drugs in Johnson & Johnson’s Form 10-Ks and distinct approvals were confirmed using information on Drugs.com. See Exhibit B53 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2012), p. 6; Exhibit B51 (Johnson & Johnson Form 10-K for the fiscal year ended December 29, 2013), p. 6; Exhibit B50 (Johnson & Johnson Form 10-K for the fiscal year ended December 28, 2014), p. 6; Exhibit B57 (Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2016), p. 14; Exhibit B56 (Johnson & Johnson Form 10-K for the fiscal year ended January 1, 2017), p. 19; Exhibit B55 (Johnson & Johnson Form 10-K for the fiscal year ended December 31, 2017), p. 20; Exhibit B54 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2018), p. 21; Exhibit B52 (Johnson & Johnson Form 10-K for the fiscal year ended December 29, 2019), p. 22; Exhibit B58 (Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2021), p. 24; Exhibit B59 (Johnson & Johnson Form 10-K for the fiscal year ended January 2, 2022), p. 26.

²²⁵ Exhibit B33 (“Complexity in Action,” National Academies of Sciences, Engineering, and Medicine, in *Making Medicines Affordable: A National Imperative*, 2018, eds. Augustine, Norman R., Madhavan, Guru, and Nass, Sharyl J., Washington, DC: *The National Academies Press*, 2018), at p. 37.

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138. Academic research similarly suggests that the overall probability of clinical success is relatively low.²²⁶ Thus, it is difficult to predict whether any shelved project as a result of a reduction in revenue would have been terminated anyway because the drug would have failed to reach its efficacy target or was found to be unsafe or would have become a blockbuster medicine, like STELARA[®]. This uncertainty is also reflected in the variation of the estimated returns to R&D. For example, the most recent iteration of Deloitte’s annual industry report titled “Measuring the Return on Pharmaceutical Innovation” estimates that return on late-stage pipeline investment has varied from as low as 1.2 percent (2022) to as high as 7.2 percent (2014) over the past decade.²²⁷ Previous research similarly has estimated variable and heavily skewed distributions of returns to R&D investment over time. An analysis of return on R&D investment in the pharmaceutical industry from 1970-1994 found a range of 7 percent to 11.5 percent mean internal rate of return (“IRR”), with the top decile accounting for 46 to 54 percent of returns.²²⁸ Additional research has found that average economic profits of novel active substances had fallen significantly from \$725 million in the late 1990s to negative \$25.7 million by the late 2000s.²²⁹

139. The harm to R&D may be even harder to quantify than the harm to such metrics as volumes or profits. This is because R&D has potentially long-term benefits, like future sales, that can be difficult to measure. Given the significance of STELARA[®] to Janssen’s/J&J’s business,

²²⁶ For example, a 2016 study by DiMasi et al., which examined “the dataset of 1442 self-originated compounds of top 50 pharmaceutical firms,” has found that the likelihood that a drug that enters clinical testing will eventually be approved by the FDA is only about 11.83 percent. *See* Exhibit B34 (DiMasi, J.A., H.G. Grabowski, and R.W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics*, 2016), at p. 23.

²²⁷ Exhibit B46 (“Seize the Digital Momentum: Measuring the Return from Pharmaceutical Innovation 2022,” Deloitte Centre for Health Solutions, January 2023), at p. 8.

²²⁸ Exhibit B35 (Grabowski, H., J. Vernon, and J.A. DiMasi, “Returns on Research and Development for 1990s New Drug Introductions,” *Pharmacoeconomics*, Vol. 20, No. 3, 2002, pp. 11-29).

²²⁹ Exhibit B30 (Berndt, E.R., D. Nass, M. Kleinrock, and M. Aitken, “Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations,” *Health Affairs*, Vol. 34, No. 2, 2015, pp. 245-252).

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Amgen's infringing launch will likely impact Janssen's/J&J's R&D activities and their ability to benefit from such activities in the long run. The value of R&D, separate from the out-of-pocket investments in R&D activities, is rarely undertaken as the full value of certain R&D activities may not become apparent until many years later.²³⁰ As a result, it can be difficult to measure the harm associated with even one forgone R&D project.²³¹

(iii) Reputation/Goodwill

140. As discussed above, the premature launch of ABP 654 will likely adversely affect Janssen's reputation and goodwill in the marketplace by reducing the visibility of STELARA[®] among physicians and patients, particularly among physicians and patients who deal with gastrointestinal problems, as well as undermining Janssen's negotiating position with PBMs.

141. It is often difficult to quantify harm to goodwill from patent infringement because there are rarely adequate measures for the types of things that contribute to or reflect goodwill. Further, while measures of goodwill may exist at the corporate level, these values are rarely attached to specific products. Because quantifying goodwill in general is far from straightforward,

²³⁰ For example, azidothymidine ("AZT") was initially discovered in the early 1960s in an attempt to find a compound that could inhibit cancer cell growth. Early testing of the drug revealed that it was ineffective against cancer and the research was stopped. However, by early 1984, when the scientists had established that AIDS patients were infected with a retrovirus, Burroughs Wellcome Company began testing a variety of compounds in an attempt to find a compound that could be effective against AIDS. This research led to identification of AZT as a drug that could potentially be effective against AIDS. In 1987, and more than 20 years since the discovery of the compound, AZT became the first antiretroviral drug to be approved for the treatment of AIDS by the FDA. *See* "A Failure Led to Drug against AIDS," *The New York Times*, September 20, 1986, available at <https://www.nytimes.com/1986/09/20/us/a-failure-led-to-drug-againstaids.html>, accessed February 13, 2023; "The History of FDA's Role in Preventing the Spread of HIV/AIDS," FDA, March 14, 2019, available at <https://www.fda.gov/about-fda/fda-historyexhibits/history-fdas-role-preventing-spread-hivaids>, accessed February 13, 2023.

²³¹ *See, e.g.*, Guha, R., and M. Salgado, "Economics of Irreparable Harm in Pharma Patent Litigation," *Law360*, November 18, 2013, available at <https://www.law360.com/articles/489198/economics-of-irreparable-harm-in-pharma-patent-litigation>, accessed January 25, 2023; Exhibit B32 (Cameron, L.J., "Preliminary Injunctions in Pharmaceutical Litigation: The Economics of Irreparable Harm," Discussion Paper, 2011), at p. 4.

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quantifying the diminution in value of goodwill/reputation as a result of an infringement can be exceptionally difficult.²³²

5. Collectability

142. Given Amgen's size and resources (net income of almost \$5.9 billion in FY 2021²³³), collectability of a damages award following a merits trial is unlikely to be an issue.

143. In sum, while collectability of damages is unlikely to be problematic in this case, the harm to Janssen's STELARA[®] business, immunotherapy business, R&D, and industry goodwill/reputation from Amgen's premature launch of ABP 654 in the absence of a preliminary injunction will be exceedingly difficult, if not impossible, to fully quantify with a reasonable degree of certainty. The launch of ABP 654 will also disrupt the status quo.

C. Balance of Hardships

144. My analysis here compares (1) the extent of harm that is likely to be suffered by Janssen in the event that injunctive relief is not issued, but should have been, with (2) the extent of harm that is likely to be suffered by Amgen in the event that injunctive relief is issued, but should not have been.

1. Janssen

145. As discussed above, Janssen is likely to suffer immediate, severe, and likely irreparable harm in the event that injunctive relief is not issued, but should have been.

²³² See, e.g., Exhibit B32 (Cameron, L.J., "Preliminary Injunctions in Pharmaceutical Litigation: The Economics of Irreparable Harm," Discussion Paper, 2011), at pp. 6-7.

²³³ Exhibit B49 (Amgen 2021 Annual Report), at p. F-4.

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146. As discussed above, the strategic and economic importance of STELARA® to Janssen is clear. [REDACTED]”²³⁴ Based on Janssen’s reported sales in its annual reports, STELARA® has generated total worldwide revenues of over \$43 billion through FY 2021.²³⁵

147. Moreover, it was the best-selling product for all of J&J in FY 2021,²³⁶ accounting for approximately 12.6 percent (approximately \$6 billion) of J&J’s total U.S. sales revenue and approximately 9.7 percent (approximately \$9 billion) of J&J’s total worldwide revenue in FY 2021.²³⁷ [REDACTED]

148. In these circumstances, allowing Amgen to prematurely introduce ABP 654 into the marketplace in the face of an ultimate finding of infringement of the Manufacturing Patents would put a substantial portion of Janssen’s business at risk.

149. Further, the launch of ABP 654 would adversely affect the formulary positioning for STELARA® and, consequently, [REDACTED].²³⁹

150. Taken together, this evidence indicates that a failure to grant a preliminary injunction to Janssen in this proceeding will cause Janssen substantial harm.

²³⁴ Exhibit B10, at p. 12.

²³⁵ Tab 6.

²³⁶ Exhibit B60 (Johnson & Johnson 2021 Annual Report), at p. 3.

²³⁷ See Tab 6.

²³⁸ Exhibit B10, at p. 12; Exhibit B16, at p. 6.

²³⁹ Exhibit B1, at pp. 2-3, 5, 12, 34.

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2. Amgen

151. In contrast, the potential harm to Amgen if a preliminary injunction were issued and the asserted patents were ultimately found not to have been infringed is substantially lower compared with the harm to Janssen.

152. In the event that an ultimately unjustified preliminary injunction issued that prevented ABP 654 from prematurely launching until the infringement issues are resolved, Amgen would face a delay in marketing ABP 654, which may involve launching into a marketplace with more competitors (*e.g.*, other biosimilars for competing biologics, including, perhaps, STELARA®). Nevertheless, Amgen is likely to be able to reap substantial benefits from marketing of this biosimilar as soon as the infringement issues are resolved. Given that ABP 654 is not yet a driver of Amgen revenues, this delay is unlikely to have material adverse long-term effects on Amgen's business. In fact, Amgen's worldwide total revenues were approximately \$26 billion in FY 2021.²⁴⁰ As emphasized in Amgen's 2021 Annual Report, Amgen's revenue is mainly driven by sales of its "innovative medicines" (*i.e.*, branded therapies).²⁴¹ Only approximately \$2 billion of Amgen's 2021 total revenue was attributable to its portfolio of five biosimilars – and Amgen aspired to doubling this figure with the launch of multiple biosimilars (including for STELARA®) by the end of the decade.²⁴² In these circumstances, the significance of ABP 654 to Amgen's overall

²⁴⁰ Exhibit B49 (Amgen 2021 Annual Report), at p. 2.

²⁴¹ Exhibit B49 (Amgen 2021 Annual Report), at p. 2. When asked which products in Amgen's pipeline are expected to be the biggest contributors in the Business Review Day Q&A in 2022, an Amgen executive indicated that they were "[e]xpecting Lumakras and Tezspire to be significant contributors. In the oncology portfolio, Amgen continues to be very bullish on bemarituzumab and solid tumor BiTE. AMG 451 from I&I targeting atopic dermatitis will come later." Exhibit B62 ("Business Review Day Follow-Up: Bullish Long-Term Expectations Appear Optimistic," BMO Capital Markets Analyst Report, February 8, 2022), at p. 8.

²⁴² Exhibit B49 (Amgen 2021 Annual Report), at pp. 2, 6-7. Some analysts argue that "Amgen will need to launch multiple biosimilars over the next several years in order to reach their guidance of doubling 2021 biosimilar revenues by 2030 due to price instability for biosimilars," and instead forecast "flat biosimilar sales." Exhibit

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revenues is likely to be considerably less than the significance of STELARA® to Janssen's revenues and profits. That is, harm to Amgen is less significant than the harm that will be faced by Janssen if no preliminary injunction were to issue and (at least one of) the Manufacturing Patents is ultimately found to be infringed by ABP 654.

3. Net Balance

153. If Amgen is permitted to prematurely launch ABP 654, Janssen will face substantial losses in STELARA® revenues, and likely much more, that could not only permanently stunt the potential for this important drug, but also impair Janssen's business as a whole. As a result, Janssen could experience adverse short-term and long-run effects on its operations.

154. In contrast, enjoining Amgen from prematurely launching ABP 654 would not have a substantial effect on its business. Rather, it would temporarily delay Amgen's benefits from sales of ABP 654. Moreover, Janssen would likely be required to post a bond to ensure Amgen could obtain compensation for any delayed entry should it ultimately prevail in the patent litigation.

155. The balance of hardships is, therefore, weighted toward Janssen.

D. Public Interest

156. The last factor that I have been asked to examine is the impact of the requested relief on the public interest. That is, I have been asked to assess whether the requested relief will run counter to the public interest or, alternatively, whether it would serve it.

B62 ("Business Review Day Follow-Up: Bullish Long-Term Expectations Appear Optimistic," BMO Capital Markets Analyst Report, February 8, 2022), at p. 3.

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157. As in most patent infringement cases, the question of public interest involves balancing the merits of a system that promotes vigorous competition versus one that provides strong protection for patented innovations. Competition is the “organizing principle for most of the U.S. economy” and can stimulate innovation by encouraging the creation of new or better products and lower-cost production processes.²⁴³ On the other hand, the patent system, by granting market exclusivity for a limited time, allows innovators to receive economic returns that compensate them for the significant risk of pioneering new technologies and incorporating them in products. Both of these goals have substantial merit. The assessment of the public interest in any given case depends on how these competing interests compare based on the specific facts of the case.

158. Given the circumstances of this case, the public interest would best be served by granting a preliminary injunction because the benefits to the public of protecting Janssen’s patent rights outweigh the incremental benefits to competition that might arise from the denial of a preliminary injunction here.

159. As explained above, the marketplace in which STELARA[®] competes is in flux, and ABP 654 is only one of a number of biosimilar entrants that are expected to compete generally with STELARA[®]. On the other hand, given the considerable risks and costs associated with developing pharmaceutical products, as well as the amount of time it takes to develop a product, patent protection may be particularly important in the pharmaceutical industry to maintain incentives for product development and other innovation.²⁴⁴ As the literature suggests, any innovator that

²⁴³ “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,” United States Federal Trade Commission, 2003, available at <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>, at p. 1.

²⁴⁴ See, e.g., Exhibit B33 (“Complexity in Action,” National Academies of Sciences, Engineering, and Medicine, in *Making Medicines Affordable: A National Imperative*, 2018, eds. Augustine, Norman R., Madhavan, Guru, and

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[REDACTED]

anticipates a rapid erosion of its profits below its original costs due to imitation of the invention by others will not invest in the innovation in the first place.²⁴⁵ Further, here, the patent protection provided to Janssen has provided incentive for it to extend the application of STELARA® to several indications, from PSO to PSA to CD to UC. Without the protection provided by the patents, Janssen, like any other pharmaceutical company, would have reduced incentives to innovate and expand to serve unmet needs. In these circumstances, the benefits of protecting Janssen’s patent right is likely to outweigh the loss of incremental competitiveness that might be associated with denying a preliminary injunction here.

160. In contrast, the incremental competitive benefits that might arise from the denial of a preliminary injunction here appear to be limited. In the absence of a preliminary injunction, Amgen would be permitted to launch its ABP 654. But such a preliminary injunction may only delay Amgen’s ability to market its ustekinumab biosimilar (*i.e.*, if Amgen ultimately prevails at the merits trial). To the extent other ustekinumab biosimilar products in development do not infringe

Nass, Sharyl J., Washington, DC: *The National Academies Press*, 2018), at pp. 33-37 (“Each step of the biopharmaceutical research and development process has a high failure rate even before a drug gets to the point where it is ready for regulatory review.”), Figure 2-1 (suggesting that the entire process from discovery to approval may take as long as 15 years); Exhibit B34 (DiMasi, J.A., H.G. Grabowski, and R.W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics*, 2016), at p. 20 (finding that the estimated average out-of-pocket cost per approved new compound is \$1.4 billion (in 2013 dollars) and the total capitalized pre-approval cost is \$2.6 billion (in 2013 dollars)).

²⁴⁵ See, e.g., Exhibit B45 (Rockett, K., “Property Rights and Invention,” in the *Handbook of the Economics of Innovation*, Bronwyn H. Hall and Nathan Rosenberg, eds., Vol. 1, 2010, pp. 315-380), at p. 328 (“Is a system granting exclusive rights to innovators necessary to generate a reward or disclosure? Let no intellectual property right exist. Further, as soon as an innovative product is sold or used let a variety of individuals become familiar with the invention, creating the seeds for imitation. If the innovation generates profits, potential imitators are attracted to the innovation to produce their own versions of it. This process creates a variety of suppliers of the innovative product or process, driving down its price and so the profits of the original innovator. If this process is quick or very cheap, then very little surplus is captured by the initial innovator. Indeed, if the cost of developing the innovation in the first place was privately borne, the rapid imitation can reduce the benefits from innovating below the original cost. Any innovator anticipating this process will not invest in the innovation in the first place. In essence, the innovator contributes to a common pool of knowledge when she creates and practices an innovation. This positive externality, if it is not captured by the inventor, generates a private under incentive to innovate. The patent resolves this problem by making the embodiment of the innovation—in other words, the ‘object’ that is actually traded in the marketplace—a private good even though the underlying knowledge remains a public good.”).

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the Manufacturing Patents and are able to launch by Q4 2023, even if Amgen's ABP 654 does not, the public would not be denied of the competitive benefits associated with such biosimilar launches.

IV. CONCLUSION

161. Based upon review and analysis of the evidence that I have examined to date, it is my opinion that Janssen will likely be irreparably harmed if Amgen is allowed to launch ABP 654 prematurely. It would be exceedingly difficult, if not impossible, to fully quantify with a reasonable degree of certainty all of the harm to Janssen's STELARA[®] business; immunotherapy business; research and development activities; and industry goodwill/reputation.

162. Furthermore, it is my opinion that the balance of hardships in this matter weighs in favor of Janssen if Amgen's ABP 654 is permitted to launch prematurely. The likely losses to Janssen will be immediate, severe, and likely irreparable. In contrast, enjoining Amgen's premature launch of ABP 654 until a full trial on the merits would simply delay Amgen's ability to compete in the marketplace with this product. While STELARA[®] is probably the most important product in Janssen's portfolio, and has been for years, ABP 654 is just one of many products in Amgen's portfolio, and one that has yet to contribute to any Amgen success in the marketplace.

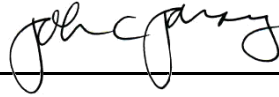
163. Finally, it is my opinion that the public interest would, on balance, be served through a finding in favor of Janssen and the issuance of the requested preliminary injunction. Not only would such a finding confirm the merits of a strong patent protection system and the innovation incentives it creates, but it would also not disrupt (and likely would ensure) uninterrupted access to, and support for, STELARA[®].

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██████████

I declare under penalty of perjury that to the best of my knowledge, information, and belief, the foregoing statements are true and correct.

Signed on March 1, 2023

A handwritten signature in cursive script, appearing to read "John C. Jarosz", is written over a solid horizontal line.

John C. Jarosz

TAB 1

JOHN C. JAROSZ
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John Jarosz, a Managing Principal of Analysis Group, Inc., specializes in applied microeconomics and industrial organization. He has performed research, given economic testimony, and provided strategy consultation in intellectual property, licensing, and commercial damages matters, including:

- evaluation of damages in patent, copyright, trade secret, trademark, and unfair competition cases (including lost profits, reasonable royalties, price erosion, unjust enrichment, accelerated market entry, and prejudgment interest);
- evaluation of injunctive relief and commercial success in a variety of intellectual property cases;
- strategy consultation regarding the nature and value of technology, methods to share technology, and reasonable compensation terms;
- analysis of compliance with FRAND/RAND commitments; and
- general commercial damages testimony in a variety of cases and across numerous industries.

Mr. Jarosz has been recognized for many years as among the top economic experts for IP matters by *Intellectual Asset Management* (IAM) in the IAM Patent 1000, which identifies leading patent professionals around the globe.

Prior to joining Analysis Group, Mr. Jarosz was a Director with Putnam, Hayes & Bartlett, Inc. Before that, he was a Senior Analyst with Richard J. Barber Associates, a Section Supervisor with Mutual of Omaha Insurance, and a Research Analyst with the Center for the Study of American Business.

EDUCATION

J.D.	University of Wisconsin
M.A. & Ph.D. candidate	Economics, Washington University, St. Louis
B.A., <i>Summa Cum Laude</i>	Economics and Organizational Communication, Creighton University

TAB 1

PROFESSIONAL ASSOCIATIONS/MEMBERSHIPS

- American Economic Association
- American Law and Economics Association
- American Bar Association (Sections: Intellectual Property, Antitrust and Litigation)
- State Bar of Wisconsin (Section: Intellectual Property)
- American Intellectual Property Law Association (Sections: Federal Litigation, Licensing, Trade Secrets and Antitrust)
- Licensing Executives Society
 - Former Chair, Valuation and Taxation Committee
 - Former Member, Certified Licensing Professional Exam Writing Team
- Former Advisory Board - *The IP Litigator*
- Former Columnist (Damage Awards) - *The IP Litigator*
- Omicron Delta Epsilon (International Honor Society in Economics)
- Association of University Technology Managers
- Certified Licensing Professional
- Intellectual Property Owners Association (Committee: Damages and Injunctions)
- 2011 Presidential Rank Review Board
- Referee, Journal of Forensic Economics
- The Sedona Conference (Sections: Best Practices in Patent Litigation, Patent Damages and Remedies)
- IAM Patent 1000 (2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021): The World's Leading Patent Practitioners - Economic Experts
- IP Law360: Voices of the Bar

TESTIMONIAL EXPERIENCE

Patent Cases – Damages

- **Collision Communications, Inc. v. Nokia Corporation, Nokia Solutions and Networks OY, and Nokia of American Corporation**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:21-cv-00308)
Deposition testimony and expert reports: reasonable royalty damages involving patents directed to mobile telecommunication technologies.
- **Collision Communications, Inc. v. Telefonaktiebolaget LM Ericsson and Ericsson Inc.**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:21-cv-00327)
Deposition testimony and expert report: reasonable royalty damages involving patents directed to mobile telecommunication technologies.

TAB 1

- **Panasonic Corporation v. Getac Technology Corporation and Getac, Inc.**
United States District Court, Central District of California (Case No. 8:19-cv-01118-DOC-DFM)
 Trial and deposition testimony and expert reports: monopolization/attempted monopolization counterclaim and design patent damages directed to market for rugged 2-in-1 portable computers.
- **Carnegie Institution of Washington and M7D Corporation v. Pure Grown Diamonds, Inc. and IIA Technologies PTE. Ltd d/b/a IIA Technologies**
United States District Court, Southern District of New York (Case No. 1:20-cv-00189-JSR)
 Deposition testimony and expert report: reasonable royalty damages covering patents directed to methods and apparatus used for producing lab-grown diamonds.
- **Carnegie Institution of Washington and M7D Corporation v. Fenix Diamonds LLC**
United States District Court, Southern District of New York (Case No. 1:20-cv-00200-JSR)
 Deposition testimony and expert report: reasonable royalty damages covering patents directed to methods and apparatus used for producing lab-grown diamonds.
- **BASF Plant Science, LP v. Commonwealth Scientific and Industrial Research Organisation; and Commonwealth Scientific and Industrial Research Organisation, Grains Research and Development, Corp., and Nuseed Pty Ltd. v. BASF Plant Science, LP and Cargill, Inc.**
United States District Court, Eastern District of Virginia (Case No. 17-cv-503-HCM)
 Trial and deposition testimony and expert report: reasonable royalty damages and injunctive relief covering patents directed to the production of plant-derived omega-3 oils.
- **Riddell, Inc. v. Kranos Corporation, d/b/a Schutt Sports**
United States District Court, Northern District of Illinois (Case No. 1:16-cv-04496)
 Trial testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents covering football helmet technology.
- **Cedars-Sinai Medical Center v. Quest Diagnostics Inc. and Quest Diagnostics Nichols Institute**
United States District Court, Central District of California, Western Division (Case No. 17-cv-5169-GW-FFM)
 Deposition testimony and expert report: damages associated with alleged misappropriation of trade secrets, breach of contract, and patent infringement involving diagnostic testing for irritable bowel syndrome (IBS).
- **Roche Diagnostics Corporation v. Meso Scale Diagnostics, LLC and Meso Scale Diagnostics, LLC v. Roche Diagnostics Corporation and BioVeris Corporation**
United States District Court, District of Delaware (Case No. 17-189 (LPS)(CJB))
 Trial and deposition testimony and expert report: reasonable royalty damages related to alleged patent infringement involving electrochemiluminescent detection technology used in immunoassay kits.
- **Kranos IP Corporation, Kranos IP II Corporation, and Kranos Corporation d/b/a Schutt Sports v. Riddell, Inc.**
United States District Court, Northern District of Illinois (Case No. 1:17-cv-06802)
 Deposition testimony and expert report: reasonable royalty damages and prejudgment interest involving patents covering football helmet technology.
- **Nichia Corporation v. Vizio, Inc.**
United States District Court, Central District of California (Case No. 8:16-cv-00545)
 Deposition testimony and expert report: reasonable royalty damages and commercial success involving patents directed to light emitting diodes (LEDs).
- **Syngenta Crop Protection, LLC v. Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited**
United States District Court, Middle District of North Carolina (Case No. 1:15-cv-274)
 Trial and deposition testimony and expert report: damages and prejudgment interest related to alleged patent and copyright infringement involving crop fungicide.

TAB 1

- **Integra Lifesciences Corporation, Integra Lifesciences Sales, LLC, Confluent Surgical, Inc., and Incept, LLC v. Hyperbranch Medical Technology, Inc.**
United States District Court, District of Delaware (Case No. 15-cv-00819)
 Trial and deposition testimony and expert reports: lost profits, price erosion, reasonable royalty, prejudgment interest, preliminary relief, and commercial success involving patents directed to cranial and spinal dural repair sealants.
- **Blue Spike, LLC v. Toshiba America, Inc., and Toshiba Corporation**
United States District Court, Eastern District of Texas, Tyler Division (Case No. 6:16-CV-430-RWS-JDL)
 Damages hearing and early expert report: damages related to alleged patent infringement involving address space layout randomization (ASLR) technology.
- **Audio MPEG, Inc., U.S. Philips Corporation, TDF SAS, and Institut Für Rundfunktechnik GmbH v. Dell, Inc.**
United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 1:15-CV-1674 AJT/TCB)
 Deposition testimony and expert report: analysis of patent pool compliance with FRAND commitments and determination of FRAND-compliant royalties involving patents directed to the transmission and storage of digital audio files.
- **Koninklijke Philips Electronics N.V. and Philips Electronics North America Corporation v. ZOLL Medical Corporation**
United States District Court, District of Massachusetts (Case No. 1:10-cv-11041)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty damages, and prejudgment interest related to alleged patent infringement involving external defibrillators.
- **Erfindergemeinschaft UroPep GbR v. Eli Lilly and Company and Brookshire Brothers, Inc.**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:15-cv-1202-WCB)
 Trial and deposition testimony and expert report: reasonable royalty damages related to alleged patent infringement directed to phosphodiesterase (PDE) V inhibitor(s) indicated for the treatment of benign prostatic hyperplasia.
- **Koninklijke Philips Electronics N.V. and Philips Electronics North America Corporation v. ZOLL Lifecor Corporation**
United States District Court, Western District of Pennsylvania (Case No. 2:2012-cv-01369)
 Deposition testimony and expert report: damages related to alleged patent infringement involving wearable defibrillators.
- **Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co., et al.; Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co. v. Luminara Worldwide, LLC, et al. ; and Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd and Central Garden and Pet Co., et al.**
United States District Court, District of Minnesota (Case Nos. 14-cv-03103 (SRN/FLN) and 15-cv-03028 (SRN/FLN))
 Deposition testimony and expert reports: damages associated with alleged patent infringement and breach of contract, and unjust enrichment associated with breach of non-disclosure agreement and use of trade secrets, related to flameless candle technology and distribution.
- **MobileMedia Ideas LLC v. Apple, Inc.**
United States District Court, District of Delaware (Case No. 10-258-SLR)
 Trial and deposition testimony and expert report: reasonable royalty involving patents directed to incoming call, playlist, and location detection features used in smartphones, tablets, and portable media players.

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- **MAZ Encryption Technologies LLC v. Blackberry Corporation**
United States District Court, District of Delaware (Case No. 1:13-cv-00304-LPS)
 Deposition testimony and expert report: reasonable royalty involving a patent directed to encryption/decryption methods used in smartphone and tablet operating systems.
- **BroadSoft, Inc. v. Callwave Communications, LLC**
United States District Court, District of Delaware (Case No. 13-cv-0711-RGA)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to telecommunications call processing.
- **Advanced Video Technologies, LLC v. Blackberry, LTD. and Blackberry Corporation**
United States District Court, Southern District of New York (Case No. 1:11-cv-06604-CM-RLE)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to video compression and decompression.
- **Drone Technologies, Inc. v. Parrot S.A. and Parrot, Inc.**
United States District Court, Western District of Pennsylvania (Case No. 2:14-cv-0111)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to drone technology.
- **Bayer CropScience AG and Bayer CropScience NV v. Dow AgroSciences LLC, Mycogen Plant Science Inc., Agrigenetics, Inc. d/b/a Mycogen Seeds LLC, and PhytoGen Seed Company, LLC**
International Chamber of Commerce (Case No. 18892/VRO/AGF)
 Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and patent infringement involving genetically modified seed.
- **CertusView Technologies, LLC v. S & N Locating Services LLC and S & N Communications, Inc.**
United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:13-cv-346 (MSD/LRL))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to creation of electronic sketches for utility location purposes.
- **Ecolab USA Inc. and Kleantech Systems, LLC v. Diversey, Inc.**
United States District Court, District of Minnesota (Civil Action No. 12-cv-1984 (SRN/JJG))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving products covering the monitoring of hospital cleaning.
- **Everlight Electronics Co. Ltd., and Emcore Corporation v. Nichia Corporation and Nichia America Corporation v. Everlight Americas, Inc.**
United States District Court, Eastern District of Michigan, Southern Division (Case No. 4:12-cv-11758 GAD-MKM)
 Trial and deposition testimony, expert report and declaration: commercial success, lost profits, reasonable royalty, and prejudgment interest involving patents directed to LEDs.
- **Source Search Technologies, LLC v. Kayak.com, Inc.**
United States District Court, District of New Jersey (Case No. 2:11-cv-03388-FSH-MAH)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online exchanges.
- **Universal Electronics, Inc. v. Universal Remote Control, Inc.**
United States District Court, Central District of California, Southern Division (Case No. SACV12-329AG (JPRx))
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to universal remotes.

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- **Prowess, Inc. v. RaySearch Laboratories AB, et al.**
United States District Court, District of Maryland (Case No. 11 CV 1357 (WDQ))
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to treatment planning software for radiation therapy.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**
United States District Court, Southern District of New York (Case No. 1:12-cv-09002-JSR)
 Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.
- **comScore, Inc. v. Moat, Inc.**
United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:12CV695-HCM/DEM, Lead Case 2:12CV351-HCM/DEM)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to online analytics.
- **Impulse Technology Ltd. v. Microsoft Corporation, Electronic Arts, Inc., Ubisoft Holdings, Inc., and Konami Digital Entertainment Inc.**
United States District Court, District of Delaware (Case No. 11-586-RGA-CJB)
 Deposition testimony and expert report: reasonable royalty involving patents directed to video game motion detection functionalities.
- **LendingTree, LLC v. Zillow, Inc., NexTag, Inc., and Adchemy, Inc.**
United States District Court, Western District of North Carolina, Charlotte Division (Case No. 3:10-cv-439-FDW-DCK)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to internet loan matching systems.
- **Network Protection Sciences, LLC v. Fortinet, Inc.**
United States District Court, Northern District of California (Case No. 3:12-cv-01106-WHA)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to network security systems.
- **Shurtape Technologies, LLC and Shurtech Brands, LLC v. 3M Company**
United States District Court, Western District of North Carolina (Case No. 5:11-cv-00017)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to painter's tape.
- **Abbott Biotechnology Ltd. and AbbVie, Inc. v. Centocor Ortho Biothech, Inc.**
United States District Court, District of Massachusetts (Case No. 09-40089-FDS)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to the treatment of rheumatoid arthritis.
- **Wi-LAN Inc. v. Alcatel-Lucent USA Inc.; Telefonaktiebolaget LM Ericsson; Ericsson Inc.; Sony Mobile Communications AB; Sony Mobile Communications (USA) Inc.; HTC Corporation; HTC America, Inc.; Exede Inc.; LG Electronics, Inc.; LG Electronics Mobilecomm U.S.A., Inc.; and LG Electronics U.S.A., Inc.**
United States District Court, Eastern District of Texas (Case No. 6:10-CV-521-LED)
 Trial and deposition testimony, affidavit, and expert report: reasonable royalty and prejudgment interest involving patents directed to wireless telecommunication systems.

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- **Epos Technologies Ltd.; Dane-Elec S.A.; Dane-Elec Memory S.A.; and Dane-Elec Corporation USA v. Pegasus Technologies Ltd. and Luidia, Inc.**
United States District Court, District of Columbia (Case No. 07-cv-00416-WMN)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to digital pen products.
- **Life Technologies Corporation; Applied Biosystems, LLC; Institute for Protein Research; Alexander Chetverin; Helena Chetverina; and William Hone v. Illumina, Inc. and Solexa, Inc.**
United States District Court, Southern District of California (Case No. 3:11-cv-00703)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to DNA amplification and sequencing technology.
- **TomTom, Inc. v. Michael Adolph**
United States District Court, Eastern District of Virginia (Case No. 1:12-cv-528)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to automotive navigation systems.
- **Carl B. Collins and Farzin Davanloo v. Nissan North America, Inc. and Nissan Motor Co., Ltd.**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:11-cv-00428-JRG)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to automotive engines.
- **I.E.E. International Electronics & Engineering, S.A. and IEE Sensing, Inc. v. TK Holdings, Inc.**
United States District Court, Eastern District of Michigan (Case No. 2:10-cv-13487)
 Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to capacitive sensing used in automotive seats.
- **St. Clair Intellectual Property Consultants, Inc. v. Acer, Inc., et al.; Microsoft Corporation v. St. Clair Intellectual Property Consultants, Inc.**
United States District Court, District of Delaware (Case No. 09-354-JJF; 09-704-JJF; and 10-282-LPS)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to power management, bus configuration and card slot technology in laptops and desktops.
- **CardioFocus, Inc. v. Xintec Corporation (d/b/a Convergent Laser Technologies); Trimedyn, Inc.; and Cardiogenesis Corporation**
United States District Court, District of Massachusetts (Case No. 1:08-cv-10285 NMG)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to laser devices used for the treatment of advanced coronary artery disease.
- **Avocent Redmond Corp. v. Raritan Americas, Inc.**
United States District Court, Southern District of New York (Case No. 10-cv-6100 (PKC)(JLC))
 Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to software and hardware products and technologies that provide connectivity and centralized management of IT infrastructure through KVM switches.
- **Frontline Placement Technologies, Inc. v. CRS, Inc.**
United States District Court, Eastern District of Pennsylvania (Case No. 2:07-CV-2457)
 Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to automated substitute fulfillment software.

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- **Novozymes A/S and Novozymes North America, Inc. v. Danisco A/S; Genecor International Wisconsin, Inc.; Danisco US Inc.; and Danisco USA Inc.**
United States District Court, Western District of Wisconsin (Case No. 10-CV-251)
 Trial and deposition testimony and expert report and expert declaration: lost profits, reasonable royalty, prejudgment interest and irreparable harm involving a patent directed to alpha-amylases used for fuel ethanol.
- **Triangle Software, LLC v. Garmin International, Inc.; Garmin USA, Inc.; TomTom, Inc.; and Volkswagen Group of America, Inc.**
United States District Court, Eastern District of Virginia, Alexandria Division (Case No. 1:10-CV-01457-CMH-TCB)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to providing personal navigation device functionality.
- **Northeastern University and JARG Corporation v. Google, Inc.**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:07-cv-486(CE))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to internet index and search technology.
- **Bissell Homecare, Inc. v. Dyson, Inc.**
United States District Court, Western District of Michigan (Case No. 1:08-cv-724)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to vacuum cleaner collection and discharge.
- **Toshiba Corporation v. Imation Corp.; Moser Baer India Ltd; Glyphics Media, Inc.; Ritek Corp.; Advanced Media, Inc.; CMC Magnetics Corp.; Hotan Corp.; and Khypermedia Corp.**
United States District Court, Western District of Wisconsin (Case No. 3:09-cv-00305-slc)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to DVDs.
- **Affinity Labs of Texas, LLC. v. BMW North America, LLC, et al.**
United States District Court, Eastern District of Texas, Lufkin Division (Case No. 9:08-CV-00164-RC)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to connecting a portable audio player to an automobile sound system.
- **Regents of the University of Minnesota v. AGA Medical Corp.**
United States District Court, District of Minnesota (Case No. 0:07-cv-04732 (PJS/RLE))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to septal occlusion devices.
- **Ethicon Endo-Surgery, Inc. v. Hologic Inc. and Suros Surgical Systems, Inc.**
United States District Court, Southern District of Ohio, Western Division (Case No. 07-cv-00834)
 Trial and deposition testimony and expert report: lost profits and reasonable royalty involving patents directed to biopsy equipment and methods, and the biopsy of soft tissue.
- **Humanscale Corp. v. CompX International, Inc. and CompX Waterloo**
United States District Court, Eastern District of Virginia, Richmond Division (Case No. 3:09-CV-86-JRS)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to keyboard support mechanisms.
- **Carl Zeiss Vision GMBH and Carl Zeiss Vision International GMBH v. Signet Armorlite, Inc.**
United States District Court, Southern District of California (Case No. 09-CV-0657-DMS (POR))
 Trial testimony and deposition testimony and expert report: lost profits, reasonable royalty, and lost licensing fees involving a patent directed to progressive eyeglass lenses.

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- **ShopNTown LLC v. Landmark Media Enterprises, LLC**
United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:08CV564)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to rental matching systems over the internet.
- **Cerner Corp. v. Visicu, Inc.**
United States District Court, Western District of Missouri, Western Division (Case No. 04-1033-CV-W-GAF)
 Trial and deposition testimony and expert report: lost profits and reasonable royalty involving patents directed to electronic ICU monitoring systems.
- **Sanofi-Aventis Canada Inc.; Schering Corp.; and Sanofi-Aventis Deutschland GmbH v. Apotex/Novopharm Limited**
Federal Court of Canada (Case No. T-1161-07/T-161-07)
 Trial testimony and expert report: lost profits and reasonable royalty involving a patent directed to hypertension treatment.
- **C2 Communications Technologies, Inc. v. Qwest Communications Corp; Global Crossing Telecommunications, Inc.; and Level 3 Communications, LLC**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2-06CV-241 TJW)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to carrying PSTN calls via Voice over Internet Protocol (VoIP).
- **Siemens AG v. Seagate Technology**
United States District Court, Central District of California, Southern Division (Case No. SA CV 06-788 JVS (ANx))
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to hard disk drive technology.
- **Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.**
United States District Court, District of Delaware (Case No. 07-190-SLR)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to medical scanner technology.
- **Aventis Pharma, S.A. v. Baxter Healthcare Corp.**
Arbitration
 Arbitration hearing and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to hemophilia treatment.
- **Every Penny Counts, Inc. v. Bank of America Corp. and Bank of America, N.A.**
United States District Court, Middle District of Florida, Fort Myers Division (Case No. 2:07-CV-42-FTM-29SPC)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to the Keep the Change debit card program.
- **DEKALB Genetics Corp. v. Syngenta Seeds, Inc.; Golden Harvest Seeds, Inc.; Sommer Bros. Seed Co.; JR Robinson Seeds, Inc.; and Garst Seed Co.**
United States District Court, Eastern District of Missouri (Case No. 4:06CV01191MLM)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to genetically modified corn.
- **International Flora Technologies, Ltd. v. Clarins U.S.A.**
United States District Court, District of Arizona (Case No. 2:06-CV-01371-ROS)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to skin care products.

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- **Howmedica Osteonics Corp. v. Zimmer, Inc.; Centerpulse Orthpedics, Inc. (formerly known as Sulzer Orthopedics, Inc.); and Smith & Nephew, Inc.**
United States District Court, District of New Jersey (Case No. 05-0897 (WHW))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to hip implant technology.
- **Elan Pharma International, Ltd. v. Abraxis Bioscience, Inc.**
United States District Court, District of Delaware (Case No. 06-438-GMS)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to nanotechnology drug delivery.
- **Mobile Micromedia Solutions LLC v. Nissan North America, Inc.**
United States District Court, Eastern District of Texas, Texarkana Division (Case No. 505-CV-230)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automotive entertainment systems.
- **Nichia Corp. v. Seoul Semiconductor, Ltd. and Seoul Semiconductor, Inc.**
United States District Court, Northern District of California (Case No. 3:06-CV-00162-MMC (JCS))
 Trial and deposition testimony and expert report: reasonable royalty, unjust enrichment, and prejudgment interest involving patents directed to light emitting diodes (LEDs).
- **NetRatings, Inc. v. WebSideStory, Inc.**
United States District Court, Southern District of New York (Case No. 06-CV-878(LTS)(AJP))
 Deposition testimony and expert report: reasonable royalty involving technology directed to internet audience measurement and analysis.
- **Ernest K. Manders, M.D. v. McGhan Medical Corp.**
United States District Court, Western District of Pennsylvania (Case No. 02-CV-1341)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to implantable tissue expanders.
- **Source Search Technologies, LLC v. LendingTree, Inc.; IAC/InterActiveCorp; and ServiceMagic, Inc.**
United States District Court, District of New Jersey (Case No. 2:04-CV-4420)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online exchanges.
- **The Boeing Co. v. The United States**
United States Court of Federal Claims (Case No. 00-705 C)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to a process for aging aluminum lithium alloys used for space shuttle external tanks.
- **Bridgestone Sports Co., Ltd. and Bridgestone Golf, Inc. v. Acushnet Co.**
United States District Court, District of Delaware (Case No. 05-132-(JJF))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to cores, intermediate layers and covers of golf balls.
- **Dyson Technology Ltd. and Dyson, Inc. v. Maytag Corp.**
United States District Court, District of Delaware (Case No. 05-434-GMS)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to upright cyclonic vacuum cleaners.

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- **Verizon Services Corp. and Verizon Laboratories, Inc. v. Vonage Holdings Corp. and Vonage America, Inc.**
United States District Court, Eastern District of Virginia (Case No. 1:06CV682)
 Trial and deposition testimony and expert report: permanent injunction, lost profits, and reasonable royalty involving patents directed to Voice over Internet Protocol (VoIP) platforms.
- **Hitachi, LTD v. BorgWarner, Inc.**
United States District Court, District of Delaware (Case No. 05-048-SLR)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automotive cam shaft technology.
- **Innogenetics N.V. v. Abbott Laboratories**
United States District Court, Western District of Wisconsin (Case No. 05-C-0575-C)
 Trial and deposition testimony and expert report: reasonable royalty involving a patent directed to HCV genotyping.
- **O2 Micro International v. Monolithic Power Systems, Inc.**
United States District Court, Northern District of California (Case No. 04-02000 CW; 06-02929 CW)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to AC to DC power converter circuits used for backlights.
- **Solvay Solexis, Inc. v. 3M Co.; 3M Innovative Properties Co.; and Dyneon LLC**
United States District Court, District of New Jersey (Case No. 04-06162 (FSH/PS))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to low temperature fluoroelastomers.
- **Target Technology Co., LLC v. Williams Advanced Materials, Inc., et al.**
United States District Court, Central District of California (Case No. SACV04-1083 DOC (MLGx))
 Deposition testimony and expert report: reasonable royalty and design-around alternatives involving a patent directed to silver alloy sputtering targets for DVDs.
- **Metrologic Instruments, Inc. v. Symbol Technologies, Inc.**
United States District Court, District of New Jersey (Case No. 03cv2912 (HAA))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to bar code scanners.
- **Eaton Corp. v. ZF Meritor, LLC**
United States District Court, Eastern District of Michigan (Case No. 03-74844)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to truck clutches and transmissions.
- **Meritor Transmission Corp. v. Eaton Corp.**
United States District Court, Western District of North Carolina (Case No. 1:04-CV-178)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to truck transmissions.
- **Monsanto Co. v. Syngenta Seeds, Inc.**
United States District Court, District of Delaware (Case No. 04-305-SLR)
 Deposition testimony and expert report: reasonable royalty involving patents directed to genetically modified corn seed.
- **Indiana Mills & Manufacturing, Inc. v. Dorel Industries, Inc.**
United States District Court, Southern District of Indiana (Case No. 1:04-CV-1102)
 Deposition testimony and expert report: damages and profits associated with alleged contract breach and patent infringement involving technology directed to automobile child restraint systems.

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- **Paice LLC v. Toyota Motor Corp.**
United States District Court, Eastern District of Texas, Marshall Division (Case No. 2-04CV-211) (DF)
 Deposition testimony and expert report: reasonable royalty involving patents directed to hybrid-electric powertrain systems.
- **GTECH Corp. v. Scientific Games International**
United States District Court, District of Delaware (Case No. 04-0138)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to a system and method for distributing lottery tickets.
- **WEDECO UV Technologies, Inc. v. Calgon Carbon Corp.**
United States District Court, District of New Jersey (Case No. 01-924)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to treatment of potable water with UV light.
- **Khyber Technologies Corp. v. Casio, Inc; Everex Systems, Inc.; Hewlett-Packard Co.; and Hewlett-Packard Singapore PTE. LTD.**
United States District Court, District of Massachusetts (Case No. 99-CV-12468-GAO)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to audio playback for portable electronic devices.
- **Air Liquide America, L.P. v. P.H. Glatfelter Co.**
United States District Court, Middle District of Pennsylvania (Case No. 1:CV-04-0646)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to the use of ozone bleaching of pulp.
- **Gary J. Colassi v. Cybex International, Inc.**
United States District Court, District of Massachusetts (Case No. 02-668-JEL/JGL)
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to treadmill support decks.
- **Medinol Ltd. v. Guidant Corp. and Advanced Cardiovascular Systems, Inc.**
United States District Court, Southern District of New York (Case No. 03 Civ.2604 (SAS))
 Deposition testimony and expert report: reasonable royalty analysis and prejudgment interest involving patents directed to connectors for coronary and peripheral stents.
- **Donner, Inc. v. American Honda Motor Co.; McDavid Plano-Acura, L.P.; and The Beaumont Co.**
United States District Court, Eastern District of Texas, Texarkana Division (Case No. F:03-CV-253)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automobile entertainment systems.
- **Nonin Medical, Inc. v. BCI, Inc.**
United States District Court, District of Minnesota, Fourth Division (Case No. 02-668-JEL/JGL)
 Deposition testimony and expert report: reasonable royalty, lost profits, and prejudgment interest involving patents directed to finger clip pulse oximeters.
- **Stryker Trauma S.A. and Howmedica Osteonics Corp. v. Synthes (USA)**
United States District Court, District of New Jersey (Case No. 01-CV 3879 (DMC))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to snap-fit external fixation systems.

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- **Michael Foods, Inc. and North Carolina State University v. Rose Acre Farms, Inc.**
United States District Court, Eastern District of North Carolina, Western Division (Case No. 5:02-CV-477-H(3))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to extended shelf life eggs.
- **Waters Technologies Corp.; Waters Investments, Ltd.; Micromass UK Ltd.; and Micromass, Inc. v. Applera Corp.**
United States District Court, District of Delaware (Case No. 02-1285-GMS)
 Deposition testimony and expert report: lost profits, price erosion, reasonable royalty, and prejudgment interest involving a patent directed to mass spectrometer ionization sources.
- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**
United States District Court, Western District of Tennessee (Case No. 01-2373 GV)
 Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Matsushita Electric Industrial Co. Ltd. v. Cinram International, Inc.**
United States District Court, District of Delaware (Case No. 01-882-SLR)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents directed to aspects of bonding substrates together to form optical discs, such as DVDs.
- **Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp. and Schering Corp.**
United States District Court, District of New Jersey (Case No. 96-CV-04047)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, price erosion, and prejudgment interest involving a patent directed to porcine vaccine (PRRS) products.
- **Arris International and Randall A. Holliday v. John Mezzalingua and Associates, Inc. d/b/a PPC**
United States District Court, District of Colorado (Case No. 01-WM-2061)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to coaxial cable connectors.
- **Promega Corp. v. Applera Corp.; and Lifecodes Corp., and its Subsidiaries Cellmark Diagnostics, Inc.; and Genomics International Corp.**
United States District Court, Western District of Wisconsin (Case No. 01-C-0244-C)
 Deposition testimony and expert report: lost profit rate, reasonable royalty, and prejudgment interest involving a patent directed to DNA sequencing technology.
- **Alcon Laboratories, Inc. and Alcon Manufacturing, Ltd. v. Pharmacia Corp.; Pharmacia & Upjohn Co.; and The Trustees of Columbia University in the City of New York**
United States District Court, Southern District of New York (Case No. 01-Civ.2989 (WHP))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to compositions for treatment of glaucoma.
- **Pharmacia Corp.; Pharmacia AB; Pharmacia Enterprises S.A.; and Pharmacia & Upjohn Co. v. Alcon Laboratories, Inc.**
United States District Court, Southern District of New York (Case No. 01-070-SLR)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to compositions for treatment of glaucoma.
- **Takata Corp. v. AlliedSignal, Inc. and Breed Technologies, Inc.**
United States District Court, District of Delaware (Case No. 98-94-MMS)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents and trade secrets directed to seatbelt retractors.

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- **Chiron Corp. v. Genentech, Inc.**
United States District Court, Eastern District of California (Case No. S-00-1252 WBS GGH)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to the active ingredient in an anti-cancer drug.
- **Greene, Tweed of Delaware, Inc. v. DuPont Dow Elastomers, LLC**
United States District Court, Eastern District of Pennsylvania (Case No. 00-CV-3058)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent covering perfluorelastomeric seals used in semiconductor fabrication applications.
- **Streck Laboratories v. Beckman Coulter, Inc.**
United States District Court, District of Nebraska (Case No. 8:99CV473)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents covering hematology testing equipment.
- **Adobe Systems Inc. v. Macromedia, Inc.**
United States District Court, District of Delaware (Case No. 00-743-JJF)
 Trial and deposition testimony and expert report: reasonable royalty involving patents covering computer video and audio software.
- **Dictaphone Corp. v. Nice Systems, Ltd.**
United States District Court, District of Connecticut (Case No. 3:00-CV-1143)
 Deposition testimony and expert report: lost profits, price/margin erosion, reasonable royalty, and prejudgment interest involving patents covering digital logger systems.
- **Metrollogic Instruments, Inc. v. PSC, Inc.**
United States District Court, District of New Jersey (Case No. 99-CV-04876)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents covering bar code scanning equipment.
- **Genzyme Corp. v. Atrium Medical Corp.**
United States District Court, District of Delaware (Case No. 00-958-RRM)
 Trial testimony and expert report: lost profits and price/margin erosion involving patents covering chest drainage systems.
- **Norian Corp. v. Stryker Corp.**
United States District Court, Northern District of California (Case No. C-01-0016 (WHA))
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent covering bone cement.
- **John Mezzalingua Associates, Inc., d/b/a PPC v. Antec Corp.**
United States District Court, Middle District of Florida (Case No. 3:01-CV-482-J-25 HTS)
 Deposition testimony and expert report: disgorgement of profits involving a design patent covering a coaxial cable connection.
- **Rockwell Automation Technologies, LLC v. Spectra-Physics Lasers, Inc. and Opto Power Corp.**
United States District Court, District of Delaware (Case No. 00-589-GMS)
 Deposition testimony and expert report: reasonable royalty involving a patent covering a process for producing semiconductor epitaxial films.
- **Tanashin Denk Co., Ltd. v. Thomson Consumer Electronics, Inc.**
United States District Court, Southern Division of Indiana (Case No. IP 99-836-C Y/G)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents covering cassette tape drives.

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- **Medtronic Sofamor Danek, Inc. et al. v. Osteotech**
United States District Court, Western Division of Tennessee (Case No. 99-2656-GV)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents covering the instruments and method of inserting a spinal inter-body fusion device.
- **Heimann Systems GmbH v. American Science and Engineering, Inc.**
United States District Court, District of Connecticut (Case No. 00 CV 10276 (WGY))
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to mobile X-ray examining apparatus.
- **Omega Engineering, Inc. v. Cole-Parmer Instrument Co.; Davis Instrument Manufacturing Co., Inc.; Dwyer Instruments, Inc.; and Raytek Corp.**
United States District Court, District of Connecticut (Case Nos. 3:98 CV 00733 (JCH); 3:98 CV 02052 (JCH); and 3:98 CV 02276 (JCH))
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents and alleged unfair competitive practices directed to portable infrared thermometers.
- **Particle Measuring Systems, Inc. v. Rion Co., Ltd.**
United States District Court, District of Colorado (Case No. 99-WM-1433)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a device and method for optically detecting particles in fluid.
- **The University of Colorado Foundation Inc., et al. v. American Cyanamid Co.**
United States District Court, District of Colorado (Case No. 93-K-1657)
 Trial and deposition testimony and expert report: measure and amount of prejudgment interest in a patent infringement, fraud and unjust enrichment case covering prenatal vitamin formulations.
- **Gleason Works v. Oerlikon Geartec AG and Liebherr-America, Inc.**
United States District Court, Western District of New York (Case No. 98-CV-6275 L)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to bevel gear-cutting machines.
- **Amersham Pharmacia v. PE Corp.**
United States District Court, Northern District of California (Case No. C 97-04203-TEH)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a method of using energy transfer reagents in a DNA sequencing system.
- **Ziarno v. The American Red Cross, et al.**
United States District Court, Northern District of Illinois (Case No. 99 CIV 3430)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online/internet fundraising.
- **Applied Medical Resources Corp. v. Core Dynamics, Inc.**
United States District Court, Central District of California (Case No. SACV 99-748-DOC (ANx))
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to surgical trocars.
- **Bell Communications Research, Inc. v. Fore Systems, Inc.**
United States District Court, District of Delaware (Case No. 98-586 JJF)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents directed to telecommunications technology (ATM over SONET networks).

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- **Newell Operating Co. (EZ Painter Co.) v. Linzer Products Corp.**
United States District Court, Eastern District of Wisconsin (Case No. 98-C-0864)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to a method for manufacturing polypropylene paint roller covers.
- **Dow Chemical Co. v. Sumitomo Chemical Co., Ltd. and Sumitomo Chemical America, Inc.**
United States District Court, Eastern District of Michigan (Case No. 96-10330-BC)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to a method for manufacturing cresol epoxy novalac resins used in integrated circuit encapsulation.
- **Insight Development Corp. v. Hewlett-Packard Co.**
United States District Court, Northern District of California (Case No. C 98 3349 CW)
 Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc. and Centre National De La Recherche Scientifique**
United States District Court, Southern District of New York (Case No. 95 Civ. 8833)
 Deposition testimony and expert report: reasonable royalty covering a patent directed to semi-synthetic processes for manufacturing an anti-cancer drug.
- **Pactiv Corp. v. S.C. Johnson & Son, Inc.**
United States District Court, Northern District of Illinois (Case No. 98 C 2679)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to zipper closure mechanisms for home storage bags.
- **Dr. Harry Gaus v. Conair Corp.**
United States District Court, Southern District of New York (Case No. 94-5693 (KTD) (FM))
 Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to hazard prevention devices used with electrical hair dryers.
- **Neogen Corp. v. Vicam, L.P., et al.**
United States District Court, Middle District of Florida (Case No. 97-405-CIV-T-23B)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent and a variety of tort claims directed to aflatoxin testing equipment.
- **Surety v. Entrust**
United States District Court, Eastern District of Virginia (Case No. 99-203-A)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent directed to digital time stamping.
- **Sofamor Danek Holdings, Inc., et al. v. United States Surgical Corp., et al.**
United States District Court, Western District of Tennessee (Case No. 98-2369 GA)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent covering the method of inserting a spinal inter-body fusion device.
- **Molten Metal Equipment Innovation, Inc. v. Metallulics**
United States District Court, Northern District of Ohio (1:97-CV2244)
 Trial testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent directed to submersible molten metal pumps.
- **AcroMed Corp. v. Sofamor Danek Group, Inc.**
United States District Court, Northern District of Ohio (Case No. 1:93-CV01184)
 Trial and deposition testimony and expert report: lost profits and prejudgment interest involving patents directed to spinal implant devices.

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- **BIC Corp. v. Thai Merry Co., Ltd.**
United States District Court, Central District of California (Case No. 98 CIV. 2113 (DLC))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to disposable cigarette lighters.
- **Syncsort Inc. v. Michael Wagner; Cambridge Algorithm; ICF Kaiser Intl. Inc., et al.**
United States District Court, Northern District of Georgia (Case No. 1:93-CV-2247-JEC)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to data sorting software.
- **Shell Oil Co. v. ICI Americas, Inc. and P.E.T Processors, LLC**
United States District Court, Eastern District of Louisiana (Case No. 97-3526 Section “K”)
 Deposition testimony and expert report: lost profits and reasonable royalty involving a patent directed to a process to manufacture solid stated polyethylene naphthalene.
- **Pall Corp. v. Hemasure Inc. and Lydall, Inc.**
United States District Court, Eastern District of New York (Case No. CV-96-436 (TCP/ETB), Case No. 96-5620 (LDW/VVP))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to prestorage leukodepletion devices.
- **Mentor H/S, Inc. v. Medical Device Alliance, Inc.; Lysonix, Inc.; and Misonix, Inc.**
United States District Court, Central District of California (Case No. CV97-2431 WDK (BQRx))
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to ultrasonic liposuction.
- **Hyundai Electronics Industries Co., Ltd. v. NEC Corp. and NEC Electronics, Inc.**
United States District Court, Eastern District of Virginia (Case No. 97-2030A, Case No. 97-2031A, Case No. 98-118-A)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to semiconductor technology.
- **Hitachi, LTD. v. Samsung Display Devices Co., LTD.; Samsung Display Devices, Inc.; Samsung Electronics Co., LTD.; Samsung Electronics America, Inc.; and Office Depot, Inc.**
United States District Court, Eastern District of Virginia (Case No. 97-1988-A)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to various aspects of cathode ray tubes.
- **Stairmaster Sports/Medical Products, a Limited Partnership v. Groupe Procycle, Inc. and Procycle USA, Inc.**
United States District Court, District of Delaware (Case No. 97-396 MMS)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to stair climbing fitness equipment.
- **Angelo Mongiello’s Children, LLC v. Pizza Hut, Inc.**
United States District Court, Eastern District of New York (Case No. 95 CV 4601)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to a method for forming pizza shells.
- **BTG v. Magellan Corp.; BTG v. Trimble Navigation**
United States District Court, Eastern District of Pennsylvania (Case No. 96-CV-7551/Case No. 96-CV-5084 (HB))
 Deposition testimony and expert reports: reasonable royalty, prejudgment interest, value of inventory on hand, preparation and investments made and business commenced (as of patent reissuance) involving a patent directed to secret or secure communications technology employed in global positioning system products.

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- **Micro Chemical, Inc. v. Lextron, Inc.**
United States District Court, District of Colorado (Case No. 88-Z-499)
 Trial and deposition testimony and expert report: lost profits, price erosion, reasonable royalty, and prejudgment interest involving a patent directed to feed additive weigh/mix dispensing machines.
- **Thai Merry Co., Ltd.; Honson Marketing Group, Inc.; and Calico Brands, Inc. v. BIC Corp.**
United States District Court, Central District of California (Case No. 96-5256 WJR (BQRx))
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to child-resistant disposable cigarette lighters.
- **Radco, Inc. v. Shell Oil Co.; Foster Wheeler USA Corp.; Lyondell-Citgo Refining Co., LLC; Petro-Chem Development Co. Inc.; and Marathon Oil Co.**
United States District Court, Northern District of Oklahoma (Case No. 93-C 1102)
 Deposition testimony and expert report: reasonable royalty involving a patent directed to coker heater refinery equipment.
- **Beloit Corp. v. Valmet Corp., et al.**
United States District Court, Western District of Wisconsin (Case No. 96-C-0087-C)
 Trial testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to the dryer section of paper making machines.
- **Burke, Inc. v. Everest & Jennings, Inc. et al./Burke, Inc. v. Invacare Corp.**
United States District Court, California Central District (Case No. 89-2613 (KMW)/Case No. 90-787 (KMW))
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest over a patent directed to three wheel motorized scooter technology.
- **Bauer Inc. v. Rollerblade, Inc.**
United States District Court, Eastern District of Virginia (Case No. 96-952-A)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a hybrid stitched and molded skate boot design.
- **Mettler - Toledo A.G. v. Denver Instrument Co., et al.**
United States District Court, Eastern District of Virginia (Case No. 95-1055-A)
 Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to analytical and precision balances.
- **Bristol-Myers Squibb Co. v. Abbott Laboratories**
United States District Court, Southern District of Indiana (Case No. EV 94-56-C)
 Trial and deposition testimony and expert report: reasonable royalty involving a patent directed to a guiding device used in enteral delivery set assemblies.
- **Crown Equipment Corp. v. The Raymond Corp.**
United States District Court, Northern District of Ohio (Case No. 3:93CV7356)
 Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to lift truck technology.
- **Mitsubishi Kasei Corp.; and Mitsubishi Kasei America, Inc. v. Virgle Hedgcoth; and Mertec Licensing Technology**
United States District Court, Northern District of California (Case No. 94-1971 SAW (JSB))
 Deposition testimony and expert report: reasonable royalty involving a patent directed to sputtered rigid disks used in personal computers.
- **Travelers Express Co. Inc. v. The Standard Register Co.**
United States District Court, District of Minnesota (Case No. 4-93-436)
 Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse, and prejudgment interest involving patents directed to money order dispensers.

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- **Dow Chemical Co. v. The United States**
Court of Federal Claims (Case No. 19-83C)
 Trial and deposition testimony: measure and amount of delay compensation in an eminent domain case over the taking of a patent directed to the back - filling of abandoned coal mines.

Patent Cases – Injunctive Relief

- **Biogen International GmbH and Biogen MA, Inc. v. Amneal Pharmaceuticals LLC**
United States District Court, District of Delaware (Cases 17-cv-823-LPS (Consolidated); 17-cv-00875-UNA (Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd.); 17-cv-00847 (Shilpa Medicare Limited); 17-cv-00954-UNA and 19-cv-00333-UNA (Zyodus Pharmaceuticals USA, Inc.); 17-cv-00824-UNA (Aurobindo Pharma USA, Inc. and Aurobindo Pharma USA LLC); 17-cv-00825-UNA and 19-cv-00211-UNA (Hetero USA, Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited); 17-cv-00845-UNA (MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.); and 17-cv-00827-UNA and 17-cv-00874-UNA (Prinston Pharmaceutical, Inc. and Sandoz, Inc.))
 Trial and deposition testimony and expert report: commercial success and injunctive relief covering patents directed to oral medication for the treatment of multiple sclerosis.
- **Biogen International GmbH and Biogen MA, Inc. v. Mylan Pharmaceuticals, Inc.**
United States District Court, Northern District of West Virginia (Case No. 17-cv-00116-IMK)
 Deposition testimony and expert report: commercial success and injunctive relief covering patents directed to oral medication for the treatment of multiple sclerosis.
- **BASF Plant Science, LP v. Commonwealth Scientific and Industrial Research Organisation; and Commonwealth Scientific and Industrial Research Organisation, Grains Research and Development, Corp., and Nuseed Pty Ltd. v. BASF Plant Science, LP and Cargill, Inc.**
United States District Court, Eastern District of Virginia (Case No. 17-cv-503-HCM)
 Trial and deposition testimony and expert report: reasonable royalty damages and injunctive relief covering patents directed to the production of plant-derived omega-3 oils.
- **Fresenius Kabi USA, LLC v. Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC**
United States District Court, District of New Jersey (Case No. 15-03654-KM-MAH)
 Deposition testimony and expert declarations: antitrust liability and damages; commercial success and preliminary injunctive relief involving patents directed to injectable drug treatment of myxedema coma.
- **Dominion Resources, Inc., and Virginia Electric and Power Company v. Alstom Grid, Inc.**
United States District Court, Eastern District of Pennsylvania
 Trial and deposition testimony and expert report: permanent injunction involving patents directed to a system and process that dynamically samples smart meters in order to achieve voltage optimization.
- **Integra Lifesciences Corporation, Integra Lifesciences Sales, LLC, Confluent Surgical, Inc., and Incept, LLC v. Hyperbranch Medical Technology, Inc.**
United States District Court, District of Delaware (Case No. 15-cv-00819)
 Trial and deposition testimony and expert reports: lost profits, price erosion, reasonable royalty, prejudgment interest, preliminary relief, and commercial success involving patents directed to cranial and spinal dural repair sealants.
- **Antares Pharma, Inc. v. Medac Pharma, Inc., Medac GmbH, Becton Dickinson France S.A.S., and Becton, Dickinson and Company**
United States District Court, District of Delaware (C.A. No. 14-270-SLR)
 Deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving patents directed to methotrexate autoinjector products.

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- **Delavau, LLC v. J.M. Huber Corporation and J.M. Huber Micropowders Inc.**
United States District Court, District of New Jersey (Case No. 12-05378 (ES)(SCM))
 Deposition testimony and expert declaration: preliminary injunctive relief involving patents directed to dietary calcium supplements.
- **Dyson Technology Limited and Dyson, Inc. v. Cornucopia Products, LLC**
United States District Court, District of Arizona (Case No. 2:12-cv-00924-ROS)
 Hearing testimony and expert declaration: irreparable harm involving patents directed to bladeless fans.
- **Novozymes A/S and Novozymes North America, Inc. v. Danisco A/S; Genecor International Wisconsin, Inc.; Danisco US Inc.; and Danisco USA Inc.**
United States District Court, Western District of Wisconsin (Case No. 10-CV-251)
 Trial and deposition testimony and expert report and expert declaration: lost profits, reasonable royalty, prejudgment interest and irreparable harm involving a patent directed to alpha-amylases used for fuel ethanol.
- **LifeWatch Services, Inc. and Card Guard Scientific Survival, LTD. v. Medicomp, Inc. and United Therapeutics Corp.**
United States District Court, Middle District of Florida, Orlando Division (Case No. 6:09-cv-1909-Orl-31DAB)
 Hearing and deposition testimony and expert declaration: preliminary injunctive relief involving patents directed to ambulatory arrhythmia monitoring solutions.
- **Verizon Services Corp. and Verizon Laboratories, Inc. v. Vonage Holdings Corp. and Vonage America, Inc.**
United States District Court, Eastern District of Virginia (Case No. 1:06CV682)
 Trial and deposition testimony and expert report: permanent injunction, lost profits and reasonable royalty involving patents directed to Voice over Internet Protocol (VoIP) platforms.
- **Riverwood International Corp. v. MeadWestvaco Corp.**
United States District Court, Northern District of Georgia (Case No. 1:03-CV-1672 (TWT))
 Deposition testimony and expert report: irreparable harm involving a patent directed to 2x6 beverage cartons.

Patent Cases – Commercial Success

- **Slayback Pharma LLC v. Eye Therapies LLC, Bausch & Lomb, Inc., and Bausch & Lomb Ireland Limited**
The United States Patent and Trademark Office (Case No. IPR2022-00142)
 Deposition testimony and expert reports: commercial success covering patents directed to eye drops for the treatment of eye redness.

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- **Otsuka Pharmaceutical Co., Ltd. Inc. and H. Lundbeck A/S v. Ajanta Pharma Ltd.; Alembic Pharmaceuticals Ltd.; Alembic Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals Company GmbH; Raks Pharma Pvt. Ltd.; Apotex, Inc.; Apotex Corp.; Apotex Pharmachem, Inc.; Signa S.A. de C.V.; Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.; Hetero Labs Ltd.; Hetero Labs Ltd. Unit-V; Hetero USA, Inc.; Hetero Drugs Ltd.; Honour Lab Ltd.; Lupin Limited; Lupin Pharmaceuticals, Inc.; Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc.; MSN Laboratories Pvt. Ltd.; MSN Pharmaceuticals, Inc.; Optimus Pharma Pvt. Ltd.; Prinston Pharmaceutical, Inc.; Sandoz, Inc.; Teva Pharmaceuticals USA, Inc.; Zenara Pharma Private Ltd.; Biophore India Pharmaceuticals Private Ltd.; Zydus Pharmaceuticals (USA), Inc.; and Cadila Healthcare Ltd.**
United States District Court, District of Delaware (Case No. 19-1938-LPS)
 Deposition testimony and expert reports: commercial success covering patents directed to the treatment of major depressive disorder and schizophrenia.
- **Bial - Portela & CA S.A., Bial - Holding, S.A., and Sunovion Pharmaceuticals Inc. v. Alkem Laboratories Limited and S&B Pharma, Inc.; Bial - Portela & CA S.A., Bial - Holding, S.A., and Sunovion Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp.; Bial - Portela & CA S.A., Bial - Holding, S.A., and Sunovion Pharmaceuticals Inc. v. Jubilant Life Sciences Limited, Jubilant Pharma Limited, Jubilant Generics Limited, Jubilant Life Sciences (USA) Inc., Jubilant Cadista Pharmaceuticals Inc., and Jubilant Pharmova Limited**
United States District Court, District of Delaware (Case Nos. 20-786-CFC-CJB; 20-785-CFC-CJB; 20-783-CFC-CJB)
 Trial and deposition testimony and expert report: commercial success involving patents directed to the treatment of partial-onset seizures.
- **Genzyme Corporation and The Regents of the University of Michigan v. Apotex, Inc., Apotex Corp., Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., and Aizant Drug Research Solutions Private Ltd.**
United States District Court, District of Delaware (Case No. 1:18-cv-01795 (CFC))
 Deposition testimony and expert report: commercial success involving patents directed to the treatment of Gaucher disease.
- **Baxalta Incorporated, Baxalta US Inc., and Nektar Therapeutics v. Bayer Healthcare LLC**
United States District Court, District of Delaware (Case No. 17-1316-RGA)
 Deposition testimony and expert report: commercial success involving patents directed to the treatment of hemophilia.
- **Biogen International GmbH and Biogen MA, Inc. v. Amneal Pharmaceuticals LLC**
United States District Court, District of Delaware (Cases 17-cv-823-LPS (Consolidated); 17-cv-00875-UNA (Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd.); 17-cv-00847 (Shilpa Medicare Limited); 17-cv-00954-UNA and 19-cv-00333-UNA (Zydus Pharmaceuticals USA, Inc.); 17-cv-00824-UNA (Aurobindo Pharma USA, Inc. and Aurobindo Pharma USA LLC); 17-cv-00825-UNA and 19-cv-00211-UNA (Hetero USA, Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited); 17-cv-00845-UNA (MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.); and 17-cv-00827-UNA and 17-cv-00874-UNA (Prinston Pharmaceutical, Inc. and Sandoz, Inc.))
 Trial and deposition testimony and expert report: commercial success and injunctive relief covering patents directed to oral medication for the treatment of multiple sclerosis.
- **Biogen International GmbH and Biogen MA, Inc. v. Mylan Pharmaceuticals, Inc.**
United States District Court, Northern District of West Virginia (Case No. 17-cv-00116-IMK)
 Deposition testimony and expert report: commercial success and injunctive relief covering patents directed to oral medication for the treatment of multiple sclerosis.

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- **Mylan Pharmaceuticals, Inc. v. Biogen MA, Inc.**
The United States Patent and Trademark Office (Case No. IPR2018-01403)
 Deposition testimony and expert report: commercial success covering patents directed to oral medication for the treatment of multiple sclerosis.
- **Teva Pharmaceuticals International GmbH, Cephalon, Inc., and Eagle Pharmaceuticals, Inc. v. Apotex, Inc., Apotex Corp., Fresenius Kabi USA, LLC, Mylan Laboratories Ltd., and Slayback Pharma Limited Liability Company**
United States District Court, District of Delaware (Case No. 17-cv-1154-CFC)
 Trial and deposition testimony and expert report: commercial success covering patents directed to an injectable chemotherapy drug for the treatment of blood cancer.
- **Astellas Pharma, Inc., Astellas US LLC, Astellas Pharma US, Inc., Medivation LLC, Medivation Prostate Therapeutics LLC, Pfizer, Inc., and The Regents of the University of California v. Actavis Laboratories FL, Inc., Actavis LLC, Apotex, Inc., Apotex Corp., Zydus Pharmaceuticals (USA), Inc., Cadila Healthcare Limited, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., and West-Ward Pharmaceuticals International Limited**
United States District Court, District of Delaware (Case No. 16-cv-1120)
 Deposition testimony and expert report: commercial success involving patents directed to the treatment of prostate cancer.
- **Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Progenics Pharmaceuticals, Inc., and Wyeth LLC v. Actavis Laboratories FL, Inc.**
United States District Court, District of New Jersey (Case No. 2:16-cv-09038 (SRC)(CLW))
 Deposition testimony and expert report: commercial success covering patents directed to an oral treatment of opioid-induced constipation (OIC) indications.
- **Nichia Corporation v. Vizio, Inc.**
United States District Court, Central District of California (Case No. 8:16-cv-00545)
 Deposition testimony and expert report: reasonable royalty damages and commercial success involving patents directed to light emitting diodes (LEDs).
- **Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Progenics Pharmaceuticals, Inc., and Wyeth LLC v. Mylan Pharmaceuticals, Inc., Mylan Laboratories Ltd., Mylan, Inc., and Actavis LLC**
United States District Court, District of New Jersey (Case No. 2:15-08180 (SRC)(CLW))
 Deposition testimony and expert report: commercial success covering patents directed to an intravenous treatment of opioid induced constipation (OIC) indications.
- **Eli Lilly and Company v. Teva Pharmaceuticals USA, Inc.**
United States District Court, Southern District of Indiana, Indianapolis Division (Case No. 16-cv-596)
 Deposition testimony and expert report: commercial success covering a patent directed to treatment of postmenopausal osteoporosis.
- **Integra Lifesciences Corporation, Integra Lifesciences Sales, LLC, Confluent Surgical, Inc., and Incept, LLC v. Hyperbranch Medical Technology, Inc.**
United States District Court, District of Delaware (Case No. 15-cv-00819)
 Trial and deposition testimony and expert reports: lost profits, price erosion, reasonable royalty, prejudgment interest, preliminary relief, and commercial success involving patents directed to cranial and spinal dural repair sealants.
- **VIVUS, Inc. v. Actavis Laboratories FL, Inc.**
United States District Court, District of New Jersey (Case No. 14-cv-3786-SRC-CLW; 15-cv-1636-SRC-CLW; and 15-CV-02693-SRC-CLW)
 Deposition testimony and expert reports: commercial success involving patents directed to an immediate release/extended release combination drug used for chronic weight management.

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- **Fresenius Kabi USA, LLC v. Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC**
United States District Court, District of New Jersey (Case No. 15-03654-KM-MAH)
 Deposition testimony and expert declarations: antitrust liability and damages; commercial success and preliminary injunctive relief involving patents directed to injectable drug treatment of myxedema coma.
- **In the Matter of Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (Sony Corporation, Sony Corporation of America, and Sony Electronics, Inc. (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1012)
 Trial and deposition testimony and expert report: economic evaluation of FRAND, commercial success, bond, remedy, domestic industry, and public interest issues involving patents directed to certain magnetic data storage tapes and cartridges.
- **Noven Pharmaceuticals, Inc. v. Actavis Laboratories UT, Inc.**
United States District Court, District of Delaware (Case No. 15-249 (LPS))
 Trial and deposition testimony and expert report: commercial success involving patents directed to an estrogen therapy patch.
- **Sebela International, Ltd. v. Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc.; Sebela International Ltd. v. Prinston Pharmaceutical, Inc., Solco Healthcare U.S., LLC, and Huahai US, Inc.**
United States District Court, District of New Jersey (Case No. 14-cv-06414 (CCC-JBC) and 14-cv-07400 (CCC-JBC); consolidated with Case No. 15-cv-05308)
 Trial and deposition testimony and expert report: commercial success involving patents directed to a non-hormonal product indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.
- **Meda Pharmaceuticals, Inc. and Cipla, Ltd. v. Apotex, Inc. and Apotex Corp.**
United States District Court, District of Delaware (Case No. 14-1453-LPS)
 Trial and deposition testimony and expert declaration: commercial success involving patents directed to a combination formulation drug used to treat seasonal allergic rhinitis.
- **Arctic Cat, Inc., v. Polaris Industries, Inc.**
The United States Patent and Trademark Office (Cases IPR2015-01781; IPR2015-01783)
 Deposition testimony and expert declaration: commercial success involving patents directed to side-by-side all-terrain vehicles.
- **Innopharma Inc., Mylan Pharmaceuticals, Inc., et al. v. Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp.**
The United States Patent and Trademark Office (Case Nos. IPR2015-00902 and IPR2015-00903)
 Deposition testimony and expert declaration: commercial success involving patents directed to nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat post-cataract surgery inflammation and pain.
- **Lupin Ltd. and Lupin Pharmaceuticals, Inc. v. Senju Pharmaceutical Co., Ltd.**
The United States Patent and Trademark Office (Case Nos. IPR2015-01097; IPR2015-01105; IPR2015-01099; and IPR2015-01100)
 Deposition testimony and expert declaration: commercial success involving patents directed to nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat post-cataract surgery inflammation and pain.

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- **Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp. v. Innopharma Inc., Lupin Pharmaceuticals, Inc., et al.**
United States District Court, District of New Jersey (Case Nos. 14-cv-00667-JBS-KMW; 14-cv-04149-JBS-KMW; 14-cv-05144-JBS-KMW; 15-cv-00335-JBS-KMW; 14-cv-06893-JBS-KMW; and 15-cv-03240-JBS-KMW)
 Deposition testimony and expert declaration: commercial success involving patents directed to nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat post-cataract surgery inflammation and pain.
- **Arctic Cat, Inc., v. Polaris Industries, Inc.**
The United States Patent and Trademark Office (Case IPR2014-01427)
 Deposition testimony and expert declaration: commercial success involving patents directed to side-by-side all-terrain vehicles.
- **Intendis GmbH, Intraseriv GmbH & Co. KG and Bayer Healthcare Pharmaceuticals Inc., v. Glenmark Generics Ltd. and Glenmark Generics Inc., USA.**
United States District Court, District of Delaware (Case No. 13-cv-421-SLR)
 Trial and deposition testimony and expert report: commercial success involving a patent directed to the treatment of certain skin diseases.
- **Everlight Electronics Co. Ltd., and Emcore Corporation v. Nichia Corporation and Nichia America Corporation v. Everlight Americas, Inc.**
United States District Court, Eastern District of Michigan, Southern Division (Case No. 4:12-cv-11758 GAD-MKM)
 Trial and deposition testimony, expert report and declaration: commercial success, lost profits, reasonable royalty, and prejudgment interest involving patents directed to LEDs.
- **Bayer Healthcare Pharmaceuticals, Inc. and Dow Pharmaceutical Sciences, Inc. v. River's Edge Pharmaceuticals, LLC, Teresina Holdings, LLC, Medical Products Laboratories, Inc. and Stayma Consulting Services, LLC**
United States District Court, Northern District of Georgia, Atlanta Division (Case No. 11-cv-01634-RLV)
 Deposition testimony and expert report: commercial success involving a patent directed to the treatment of certain skin diseases.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**
United States District Court, Southern District of New York (Case No. 1:12-cv-09002-JSR)
 Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.
- **Ferring, B.V. v. Watson Laboratories, Inc. – Florida, Apotex Inc., and Apotex Corp.**
United States District Court, District of Nevada (Case Nos. 3:11-cv-00481-RCJ-VPC, 3:11-cv-00485-RCJ-VPC, 3:11-cv-00853-RCJ-VPC, 3:11-cv-00854-RCJ-VPC, 2:12-cv-01935-RCJ-VPC, and 2:12-cv-01941-RCJ-VPC)
 Deposition testimony and expert report: commercial success involving patents directed to the treatment of menorrhagia.
- **Medicis Pharmaceutical Corporation; Dow Pharmaceutical Sciences, Inc.; and Alyzan, Inc. v. Actavis Mid Atlantic LLC**
United States District Court, District of Delaware (Case No. 11-CV-409)
 Deposition testimony and expert report: commercial success involving a patent directed to delivery vehicles for treatment of dermatological disorders.

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- **Galderma Laboratories, L.P.; Galderma S.A.; and Galderma Research & Development, S.N.C. v. Tolmar Inc.; and Actavia Mid Atlantic LLC**
United States District Court, District of Delaware (Case No. 10-cv-45 (LPS))
 Trial and deposition testimony and expert report: commercial success involving a patent directed to treatment of dermatological disorders.
- **Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA, Inc.; Apotex Corp. and Apotex Inc.; Par Pharmaceutical, Inc.; and Par Pharmaceutical Companies, Inc.**
United States District Court, District of Delaware (Case Nos. 09-286-SLR/09-304-SLR/09-305-SLR-MPT)
 Trial and deposition testimony and expert report: commercial success covering patents directed to treatment of HDL cholesterol and hypertriglyceridemia.
- **Eli Lilly and Company v. Wockhardt Limited and Wockhardt USA, Inc.**
United States District Court, District of Indiana, Indianapolis Division (Case No. 1:08-cv-1547-WTL-TAB)
 Deposition testimony and expert report: commercial success covering a patent directed to treatment of depression, anxiety and pain.
- **Acorda Therapeutics, Inc. v. Apotex Inc. and Apotex Corp.**
United States District Court, District of New Jersey (Case No. 2:07-cv-04937-JAG-MCA)
 Trial and deposition testimony and expert report: commercial success covering a patent directed to treatment of spasticity.
- **Medeva Pharma Suisse A.G. and Procter & Gamble Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.**
United States District Court, District of New Jersey (Case No. 3:07-CV-05165-FLW-TJB)
 Deposition testimony and expert report: commercial success involving a patent directed to treatment of ulcerative colitis.
- **Otsuka Pharmaceutical Co, Ltd., Inc., et al. v. Sandoz, Inc., et al.**
United States District Court, District of New Jersey (Case No. 07-cv-01000)
 Trial and deposition testimony and expert report: commercial success covering a patent directed to the active ingredient of an atypical antipsychotic drug.
- **Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd v. Novopharm Ltd.**
Federal Court of Canada (Case No. T-2175-04)
 Trial testimony (written) and affidavit: commercial success covering a patent directed to the active ingredient of an anti-infective drug.
- **Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd v. The Minister of Health; and Apotex Inc.**
Federal Court of Canada (Case No. T-1508-05)
 Deposition testimony and expert report: commercial success interest involving a patent directed to an anti-infective drug.
- **Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories**
United States District Court, Northern District of West Virginia (Case No. 1:02CV32)
 Trial and deposition testimony and expert report: commercial success covering a patent directed to the active ingredient of an anti-infective drug.
- **Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.**
United States District Court, Southern District of Florida (Case No. 98-7164)
 Trial and deposition testimony and expert report: commercial success covering a patent directed to controlled release dosing of a nonsteroid anti-inflammatory drug.

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Patent Cases – Other

- **MPEG LA, LLC v. Toshiba American Information Systems, Inc.**
Supreme Court of the State of New York, County of New York (Index No. 162716/2015)
 Deposition testimony and expert report: contract transfer and patent misuse involving patents directed to digital television standards.
- **Fresenius Kabi USA, LLC v. Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC**
United States District Court, District of New Jersey (Case No. 15-03654-KM-MAH)
 Deposition testimony and expert declarations: antitrust liability and damages; commercial success and preliminary injunctive relief involving patents directed to injectable drug treatment of myxedema coma.
- **Travelers Express Co. Inc. v. The Standard Register Co.**
United States District Court, District of Minnesota (Case No. 4-93-436)
 Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse and prejudgment interest involving patents directed to money order dispensers.

Trade Secret Cases

- **J.S.T. Corporation v. Robert Bosch LLC, f/k/a Robert Bosch Corporation, Robert Bosch GmbH, and Bosch Automotive Products (Suzhou) Co., Ltd.**
United States District Court, Eastern District of Michigan, Southern Division (Case No. 2:15-cv-13842-AC-EAS)
 Deposition testimony and expert reports: lost profits, unjust enrichment, disgorgement of profits, reasonable royalty, and prejudgment interest associated with alleged misappropriation of trade secrets and breach of contract in case involving automotive electrical connectors.
- **Modoral Brands, Inc. v. Swedish Match North America LLC, Pinkerton Tobacco Co., LP, NYZ AB, and Helix Innovations GmbH**
United States District Court, Central District of California (Case No. 2:21-cv-05013-SB-MRWx)
 Deposition testimony and expert report: unjust enrichment associated with alleged misappropriation of trade secrets involving nicotine pouches.
- **Swedish Match North America LLC, Pinkerton Tobacco Co., LP, and NYZ AB v. Kretek International, Inc. and Dryft Sciences LLC**
United States District Court, Central District of California (Case No. 2:20-cv-08729-SB-MRWx)
 Deposition testimony and expert report: unjust enrichment associated with alleged misappropriation of trade secrets involving nicotine pouches.
- **Life Spine, Inc. v. Aegis Spine, Inc.**
United States District Court, Northern District of Illinois, Eastern Division (Case No. 19-cv-7092)
 Deposition testimony and expert report: damages associated with lost profits, improper gains, withheld inventory, and prejudgment interest associated with alleged breaches of contract, breach of fiduciary duty, fraudulent inducement, and misappropriation of trade secrets in case involving implant devices used for the treatment of degenerative disc disease.
- **Colony Grill Development, LLC and Fairfield Colony, LLC v. Colony Grill, Inc. and Colony Grill of Stamford, LLC v. Paul Coniglio, Kenneth M. Martin, Cody L. Lee, and Christopher Drury**
United States District Court, District of Connecticut (Case No. 3:20-cv-00213)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged breach of contract, trademark infringement, unfair competition and unfair trade practices, theft of trade secrets, and breach of good faith and fair dealing in case involving pizza restaurants.

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- **CODA Development s.r.o., CODA Innovations s.r.o., and Frantisek Hrabal v. The Goodyear Tire & Rubber Company, Robert Benedict, and Robert Losey**
United States District Court, Northern District of Ohio, Eastern Division (Case No. 5:15-cv-01572-SL)
 Trial and deposition testimony and expert report: damages and profits associated with alleged misappropriation of trade secrets involving self-inflating tires.
- **FMC Corporation v. Syngenta Crop Protection, AG; Syngenta Crop Protection, AG v. FMC Corporation**
American Arbitration Association (Case Nos. 01-19-0002-4192 and 01-19-0002-4208)
 Arbitration hearing and deposition testimony and expert report: injunctive relief and damages related to alleged misappropriation of trade secrets and breach of contract involving crop herbicides.
- **JELD-WEN, Inc. v. John Ambruz and Global Strategic Partners LLC**
American Arbitration Association (Case No. 01-17-0007-0838)
 Hearing and deposition testimony and expert report: damages and reasonable royalty associated with alleged misappropriation of trade secrets and breach of contract involving the production of molded door skins.
- **NCR Corporation v. Pendum LLC and Burroughs, Inc.**
United States District Court, Northern District of Georgia (Case No. 16-cv-04114-SCJ)
 Deposition testimony and expert report: damages associated with lost profits, price erosion, unjust enrichment, and economic effects and harm associated with alleged misappropriation of trade secrets, copyright infringement, trademark infringement, breach of contract, and tortious interference with current and prospective business relations in case involving the servicing of automatic teller machines (ATMs).
- **Cedars-Sinai Medical Center v. Quest Diagnostics Inc. and Quest Diagnostics Nichols Institute**
United States District Court, Central District of California, Western Division (Case No. 17-cv-5169-GW-FFM)
 Deposition testimony and expert report: damages associated with alleged misappropriation of trade secrets, breach of contract, and patent infringement involving diagnostic testing for irritable bowel syndrome (IBS).
- **Steves and Sons, Inc. v. JELD-WEN, Inc.**
United States District Court, Eastern District of Virginia, Richmond Division (Case No. 16-cv-00545-REP)
 Trial and deposition testimony and expert report: damages, profits, and reasonable royalty associated with alleged misappropriation of trade secrets and tortious interference with employment contracts and severance agreements involving the production of molded door skins.
- **Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co., et al.; Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co. v. Luminara Worldwide, LLC, et al. ; and Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd and Central Garden and Pet Co., et al.**
United States District Court, District of Minnesota (Case Nos. 14-cv-03103 (SRN/FLN) and 15-cv-03028 (SRN/FLN))
 Deposition testimony and expert reports: damages associated with alleged patent infringement and breach of contract, and unjust enrichment associated with breach of non-disclosure agreement and use of trade secrets, related to flameless candle technology and distribution.

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- **Red Online Marketing Group LP, d/b/a 50onRED v. Revizer Ltd., d/b/a Ad Force Technologies, Ltd., and Revizer Technologies, Ltd.**
United States District Court, Eastern District of Pennsylvania (Case No. 14-1353)
 Deposition testimony and expert report: damages associated with alleged misappropriation of trade secrets, breach of contract, and unfair competition (Lanham Act violations) involving internet monetization products.
- **Thomas C. Sisoian v. International Business Machines Corporation (IBM)**
United States District Court, Western District of Texas, Austin Division (Case No. A-14-CA-565-SS)
 Deposition testimony and expert report: unjust revenues and profits involving misappropriation of trade secrets over developing, implementing, and integrating complex telecommunication information systems.
- **In the Matter of Certain Sulfentrazone, Sulfentrazone Compositions, and Processes for Making Sulfentrazone (FMC (Complainant))**
United States International Trade Commission (Investigation No. 337-TA-914)
 Trial and deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving a patent directed to a crop herbicide.
- **In the Matter of Certain Opaque Polymers (Organik Kimya (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-883)
 Deposition testimony and expert report: injury, independent economic valuation, and bond involving trade secrets used in the production of opaque polymers.
- **MacDermid, Inc. v. Cookson Group, plc, Cookson Electronics, Enthone, Inc., and David North**
United States Superior Court, Judicial District of Waterbury (Case No. x10-cv-09-5014518-d)
 Deposition testimony and expert report: royalty and prejudgment interest involving the misappropriation of trade secrets directed to chemicals, materials, and technical services used in a possible corporate acquisition.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**
United States District Court, Southern District of New York (Case No. 1:12-cv-09002-JSR)
 Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.
- **E. I. du Pont de Nemours and Company v. Kolon Industries, Inc. and Kolon USA, Inc.**
United States District Court, Eastern District of Virginia, Richmond Division (Case No. 3:09CV58)
 Trial and deposition testimony and expert report: unjust enrichment involving misappropriation of trade secrets directed to aramid fiber production.
- **CA, Inc.; Computer Associates Think, Inc.; Platinum Technology International, Inc.; and Platinum Technology IP, Inc., v. Rocket Software, Inc.**
United States District Court, Eastern District of New York (Case No. 07-CV-1476 (ADS)(MLO)
 Deposition testimony and expert report: lost profits, unjust enrichment, price erosion and prejudgment interest involving copyrights and trade secrets related to DB2 software tools.
- **Sensormatic Electronics Corp. v. The TAG Co. US LLC; Phenix Label Co.; Dennis Gadoniex**
United States District Court, Southern District of Florida (Case No. 06-81105-Civ-Hurley/Hopkins)
 Trial and deposition testimony and expert report: unjust enrichment involving misappropriation of trade secrets directed to loss prevention systems.
- **Cogent Systems, Inc. v. Northrop Grumman Corp.**
California Superior Court, County of Los Angeles, Central District (Case No. BC332199)
 Deposition testimony and expert report: reasonable royalty involving misappropriation of trade secrets directed to fingerprint identification technology.

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- **Geomatrix, LLC and David A. Potts v. Infiltration Systems, Inc.**
Connecticut Superior Court, District of Middlesex at Middletown (Case No. MMX-CV-05-4004477 S)
 Deposition testimony and expert disclosure: reasonable royalty involving misappropriation of trade secrets directed to leach field and septic tank technology.
- **McMahon Marketing v. Toyota Motor Sales**
California Superior Court, County of Los Angeles (Case No. BC317277)
 Deposition testimony: damages and profits associated with trade secrets directed to a luxury hotel and automotive partnership.
- **Christopher Karol and Karol Designs, LLC v. Burton Corp.**
United States District Court, District of Vermont (Case No. 1:01-CV-178)
 Deposition testimony and expert report: reasonable royalty and disgorgement of profits involving trade secrets and an NDA directed to snowboard boot and binding technology.
- **Takata Corp. v. AlliedSignal, Inc. and Breed Technologies, Inc.**
United States District Court, District of Delaware (Case No. 98-94-MMS)
 Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents and trade secrets directed to seatbelt retractors.
- **Trimless-Flashless Design, Inc. v. Augat, Inc.; Thomas & Betts Corp.; and Tyco International, Ltd.**
United States District Court, Eastern District of Virginia (Case No. CA00-245-A)
 Trial and deposition testimony and expert report: damages and profits associated with alleged breach of contract and misappropriation of trade secrets involving metallized particle interconnects used to connect microprocessors with mother boards.
- **Insight Development Corp. v. Hewlett-Packard Co.**
United States District Court, Northern District of California (Case No. C 98 3349 CW)
 Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **DSC Communications Corp. v. DGI Technologies, Inc.**
United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)
 Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.
- **Wayne State University; Lumigen Inc.; and A. Paul Schapp v. Irena Bronstein and Tropix Inc.**
State of Michigan Circuit Court, County of Wayne and Court of Claims (Case No. 88-804-627 CK/Case No. 88-11871CM)
 Deposition testimony and expert report: unjust enrichment and lost profits involving trade secrets directed to chemiluminescence (medical detection) technology.

Trademark Cases

- **Colony Grill Development, LLC and Fairfield Colony, LLC v. Colony Grill, Inc. and Colony Grill of Stamford, LLC v. Paul Coniglio, Kenneth M. Martin, Cody L. Lee, and Christopher Drury**
United States District Court, District of Connecticut (Case No. 3:20-cv-00213)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged breach of contract, trademark infringement, unfair competition and unfair trade practices, theft of trade secrets, and breach of good faith and fair dealing in case involving pizza restaurants.

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- **Constellation Brands U.S. Operations, Inc. v. The Vineyard House LLC**
United States District Court, Northern District of California - Oakland (Case No. 3:20-cv-00238)
 Trial testimony and expert report: disgorgement of profits associated with alleged trademark infringement, false association, designation of origin, and advertising, and violations of the Lanham Act and other similar state statutes, involving alleged mislabeling of wine.
- **NCR Corporation v. Pendum LLC and Burroughs, Inc.**
United States District Court, Northern District of Georgia (Case No. 16-cv-04114-SCJ)
 Deposition testimony and expert report: damages associated with lost profits, price erosion, unjust enrichment, and economic effects and harm associated with alleged misappropriation of trade secrets, copyright infringement, trademark infringement, breach of contract, and tortious interference with current and prospective business relations in case involving the servicing of automatic teller machines (ATMs).
- **Katherine Dines v. Toys “R” Us-Delaware, Inc.**
United States District Court, District of Colorado (Case No. 12-cv-2279-PAB-KMT)
 Deposition testimony and expert report: profits and prejudgment interest associated with trademark infringement involving a line of stuffed animal toys.
- **The Coryn Group II, LLC v. O.C. Seacrets, Inc.**
United States District Court, District of Maryland, Northern Division (Case No. 08-cv-02764-WDQ)
 Trial testimony and expert report: profits and damages involving the use of “Secrets” trademark in the leisure resort business.
- **YSL Beauté v. Oscar de la Renta, Ltd.**
American Arbitration Association (Case No. 13 133 01389 08)
 Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and trademark infringement involving cosmetics, fragrances and beauty products.
- **Fishman Transducers, Inc. v. Stephen Paul d/b/a “Esteban” Daystar Productions and HSN Interactive LLC**
United States District Court, District of Massachusetts (Case No. 07-CA-10071 RCL)
 Trial and deposition testimony and expert report: damages and profits associated with a trademark directed to guitar transducers.
- **ISP.NET, LLC d/b/a IQuest Internet v. Qwest Communications International, Inc.**
United States District Court, Southern District of Indiana, Indianapolis Division (Case No. IP01-0480 C B/S)
 Deposition testimony and expert report: reasonable royalty, disgorgement of profits and prejudgment interest involving a trademark directed to internet service provision.
- **Fuel Clothing Co., Inc. v. Safari Shirt Co. d/b/a Fuel Clothing Co., Inc.**
United States District Court, Western District of Washington at Tacoma (Case No. CO5 5366 KJB)
 Deposition testimony and expert report: economic harm involving a trademark directed to sports apparel logos.
- **Alpha International, Inc. v. General Foam Plastics Corp.**
United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))
 Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.
- **Fuel TV, Inc. v. Fuel Clothing Co., Inc.**
United States District Court, Central District of California, Western Division (Case No. CV03-8248-ABC-VBKx)
 Deposition testimony and expert report: economic harm involving infringement of trademark used in extreme sports applications.

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- **AutoNation, Inc. v. Acme Commercial Corp., et al. (CarMax)**
United States District Court, Southern District of Florida (Case No. 96-6141)
 Trial and deposition testimony and expert report: reasonable royalty associated with trademark infringement and unfair competition in the auto superstore business.

Copyright Cases

- **ICC Evaluation Service, LLC and International Code Council, Inc. v. International Association of Plumbing and Mechanical Officials, Inc. and IAPMO Evaluation Service, LLC**
United States District Court, District of Columbia (Case No. 1:16-cv-54-EGS-DAR)
 Deposition testimony and expert report: lost profits, unjust enrichment, fair use, and irreparable harm associated with alleged copyright infringement involving compliance and evaluation reports for building products and systems.
- **NCR Corporation v. Pendum LLC and Burroughs, Inc.**
United States District Court, Northern District of Georgia (Case No. 16-cv-04114-SCJ)
 Deposition testimony and expert report: damages associated with lost profits, price erosion, unjust enrichment, and economic effects and harm associated with alleged misappropriation of trade secrets, copyright infringement, trademark infringement, breach of contract, and tortious interference with current and prospective business relations in case involving the servicing of automatic teller machines (ATMs).
- **Syngenta Crop Protection, LLC v. Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited**
United States District Court, Middle District of North Carolina (Case No. 1:15-cv-274)
 Trial and deposition testimony and expert report: damages and prejudgment interest related to alleged patent and copyright infringement involving crop fungicide.
- **American Society for Testing and Materials d/b/a ASTM International; National Fire Protection Association, Inc.; and American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc. v. Public.Resource.org, Inc.**
United States District Court, District of Columbia (Case No. 13-cv-01215-TSC)
 Deposition testimony and expert report: harm and public interest involving copyrights and trademarks covering standards incorporated by reference into law.
- **Complex Systems, Inc. v. ABN AMRO Bank N.V.**
United States District Court, Southern District of New York (Case No. 08-cv-7497)
 Deposition testimony and expert report: revenues and profits involving copyrighted trade finance software.
- **Shepard Fairey and Obey Giant Art, Inc. v. The Associated Press v. Shepard Fairey; Obey Giant Art, Inc.; Obey Giant LLC; Studio Number One, Inc.; and One 3 Two, Inc.**
United States District Court, Southern District of New York (Case No. 09-01123(AKH))
 Deposition testimony and expert report: fair use, damages and profits involving copyrighted photograph of President Obama.
- **CA, Inc.; Computer Associates Think, Inc.; Platinum Technology International, Inc.; and Platinum Technology IP, Inc., v. Rocket Software, Inc.**
United States District Court, Eastern District of New York (Case No. 07-CV-1476 (ADS)(MLO)
 Deposition testimony and expert report: lost profits, unjust enrichment, price erosion and prejudgment interest involving copyrights and trade secrets related to DB2 software tools.

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- **Alpha International, Inc. v. General Foam Plastics Corp.**
United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))
 Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.
- **Insight Development Corp. v. Hewlett-Packard Co.**
United States District Court, Northern District of California (Case No. C 98 3349 CW)
 Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **First National Bank of Omaha v. Three Dimensions Systems Products, Inc.**
United States District Court, District of Nebraska (Case No. 8:98CV569)
 Trial and deposition testimony and expert report: damages and profits associated with an alleged contract breach and copyright infringement involving financial services software.
- **Leslie Atkins v. Benson J. Fischer, et al.**
United States District Court, District of Columbia (Case No. 1:98CV00800)
 Deposition testimony and expert report: damages and profits associated with copyright infringement covering beer label and packaging designs.
- **Wrench LLC v. Taco Bell Corp.**
United States District Court, Southern District of Michigan (Case No. 1:98-CV-45)
 Trial and deposition testimony and expert report: unjust enrichment and actual damages involving chihuahua promotional campaign.
- **DSC Communications Corp. v. DGI Technologies, Inc.**
United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)
 Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.

Breach of Contract Cases

- **J.S.T. Corporation v. Robert Bosch LLC, f/k/a Robert Bosch Corporation, Robert Bosch GmbH, and Bosch Automotive Products (Suzhou) Co., Ltd.**
United States District Court, Eastern District of Michigan, Southern Division (Case No. 2:15-cv-13842-AC-EAS)
 Deposition testimony and expert reports: lost profits, unjust enrichment, disgorgement of profits, reasonable royalty, and prejudgment interest associated with alleged misappropriation of trade secrets and breach of contract in case involving automotive electrical connectors.
- **Life Spine, Inc. v. Aegis Spine, Inc.**
United States District Court, Northern District of Illinois, Eastern Division (Case No. 19-cv-7092)
 Deposition testimony and expert report: damages associated with lost profits, improper gains, withheld inventory, and prejudgment interest associated with alleged breaches of contract, breach of fiduciary duty, fraudulent inducement, and misappropriation of trade secrets in case involving implant devices used for the treatment of degenerative disc disease.
- **FMC Corporation v. Syngenta Crop Protection, AG; Syngenta Crop Protection, AG v. FMC Corporation**
American Arbitration Association (Case Nos. 01-19-0002-4192 and 01-19-0002-4208)
 Arbitration hearing and expert report: valuation and license terms for co-development project covering crop herbicides.

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- **LG Display Co. v. Sharp Corporation**
Singapore International Arbitration Centre (SIAC Arbitration No. 435/19/JTA)
 Trial testimony and expert reports: damages associated with the alleged breach of contract involving licenses and releases related to liquid-crystal display (LCD) and organic light-emitting diode (OLED) display technologies.
- **Colony Grill Development, LLC and Fairfield Colony, LLC v. Colony Grill, Inc. and Colony Grill of Stamford, LLC v. Paul Coniglio, Kenneth M. Martin, Cody L. Lee, and Christopher Drury**
United States District Court, District of Connecticut (Case No. 3:20-cv-00213)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged breach of contract, trademark infringement, unfair competition and unfair trade practices, theft of trade secrets, and breach of good faith and fair dealing in case involving pizza restaurants.
- **FMC Corporation v. Syngenta Crop Protection, AG; Syngenta Crop Protection, AG v. FMC Corporation**
American Arbitration Association (Case Nos. 01-19-0002-4192 and 01-19-0002-4208)
 Arbitration hearing and deposition testimony and expert report: injunctive relief and damages related to alleged misappropriation of trade secrets and breach of contract involving crop herbicides.
- **In re: Windstream Holdings, Inc., et al. (Debtors); Windstream Holdings, Inc., et al. v. Charter Communications, Inc. and Charter Communications Operating, LLC**
United States Bankruptcy Court, Southern District of New York (Chapter 11, Case No. 19-22312 (RDD); Adv. Pro. No. 19-08246 (RDD))
 Trial and deposition testimony and expert report: lost profits and increased costs associated with alleged violations of the Lanham Act and other similar state statutes, breach of contract, violation of the Bankruptcy Code’s automatic stay, and equitable subordination involving alleged false advertising campaign.
- **JELD-WEN, Inc. v. John Ambruz and Global Strategic Partners LLC**
American Arbitration Association (Case No. 01-17-0007-0838)
 Hearing and deposition testimony and expert report: damages and reasonable royalty associated with alleged misappropriation of trade secrets and breach of contract involving the production of molded door skins.
- **NCR Corporation v. Pendum LLC and Burroughs, Inc.**
United States District Court, Northern District of Georgia (Case No. 16-cv-04114-SCJ)
 Deposition testimony and expert report: damages associated with lost profits, price erosion, unjust enrichment, and economic effects and harm associated with alleged misappropriation of trade secrets, copyright infringement, trademark infringement, breach of contract, and tortious interference with current and prospective business relations in case involving the servicing of automatic teller machines (ATMs).
- **MPEG LA, LLC v. Toshiba American Information Systems, Inc.**
Supreme Court of the State of New York, County of New York (Index No. 162716/2015)
 Deposition testimony and expert report: contract transfer and patent misuse involving patents directed to digital television standards.
- **Cedars-Sinai Medical Center v. Quest Diagnostics Inc. and Quest Diagnostics Nichols Institute**
United States District Court, Central District of California, Western Division (Case No. 17-cv-5169-GW-FFM)
 Deposition testimony and expert report: damages associated with alleged misappropriation of trade secrets, breach of contract, and patent infringement involving diagnostic testing for irritable bowel syndrome (IBS).

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- **Western Enterprises, Inc. v. Buckeye Rubber & Packaging Co.; Freudenberg-NOK General Partnership, a/k/a Freudenberg-NOK Sealing Technologies, Inc.; and International Seal Company, Inc.** *Court of Common Pleas, Cuyahoga County, Ohio (Case No. 16-869179)*
 Deposition testimony and expert report: damages associated with alleged breaches of contract, duty to indemnify, and negligence related to portable oxygen systems.
- **Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co., et al.; Shenzhen Liown Electronics Co., Ltd, Central Garden and Pet Co. v. Luminara Worldwide, LLC, et al. ; and Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd and Central Garden and Pet Co., et al.**
United States District Court, District of Minnesota (Case Nos. 14-cv-03103 (SRN/FLN) and 15-cv-03028 (SRN/FLN))
 Deposition testimony and expert reports: damages associated with alleged patent infringement and breach of contract, and unjust enrichment associated with breach of non-disclosure agreement and use of trade secrets, related to flameless candle technology and distribution.
- **Red Online Marketing Group LP, d/b/a 50onRED v. Revizer Ltd., d/b/a Ad Force Technologies, Ltd., and Revizer Technologies, Ltd.**
United States District Court, Eastern District of Pennsylvania (Case No. 14-1353)
 Deposition testimony and expert report: damages associated with alleged misappropriation of trade secrets, breach of contract, and unfair competition (Lanham Act violations) involving internet monetization products.
- **Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd.**
State of Minnesota District Court, County of Hennepin Fourth Judicial District (Case No. 27-CV-14-16085)
 Deposition testimony and expert report: damages associated with alleged breaches of contract and duty of good faith and fair dealing related to agreements to manufacture flameless candles.
- **ABS Holdings, Ltd. and ABS Global, Ltd. v. KT Corporation and KTSAT Corporation**
International Court of Arbitration of the International Chamber of Commerce
 Arbitration hearing testimony and expert declaration: damages associated with alleged breaches of contract involving the sale and on-going operations of a satellite.
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International Chamber of Commerce (Case No. 18892/VRO /AGF)
 Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and patent infringement involving genetically modified seed.
- **Immunomedics Inc. v. Nycomed GmnH (n/k/a Takeda GmbH), Takeda Pharmaceutical Company Limited, and Takeda Pharmaceuticals International, Inc.**
International Center for Dispute Resolution
 Arbitration hearing testimony and expert report: diminution of value associated with the delayed/failed development of a monoclonal antibody drug to treat various autoimmune diseases.
- **Avocent Redmond Corp. v. Raritan Americas, Inc.**
United States District Court, Southern District of New York (Case No. 10-cv-6100 (PKC)(JLC))
 Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to software and hardware products and technologies that provide connectivity and centralized management of IT infrastructure through KVM switches.

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- **General Assurance of America, Inc. v. Overby-Seawell Company**
United States District Court, Eastern District of Virginia, Alexandria Division (Case No. 1:11CV483)
 Deposition testimony and expert report: damages and profits associated with obligations arising from a contract involving specialized insurance products.
- **Frontline Placement Technologies, Inc. v. CRS, Inc.**
United States District Court, Eastern District of Pennsylvania (Case No. 2:07-CV-2457)
 Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to automated substitute fulfillment software.
- **Amkor Technology, Inc. v. Tessera, Inc.**
International Chamber of Commerce, International Court of Arbitration (Case No. 166531/VRO)
 Arbitration hearing and deposition testimony and expert report: royalty payments due under a contract directed to semiconductor packaging technology.
- **Max-Planck-Gesellschaft zur Förderung der Wissenschaften E. V.; Max-Planck-Innovation GmbH; and Alnylam Pharmaceuticals, Inc. v. Whitehead Institute for Biomedical Research; Massachusetts Institute of Technology; and the Board of Trustees of the University of Massachusetts**
United States District Court, District of Massachusetts (Case No. 2009-11116-PBS)
 Deposition testimony and expert report: damages and profits associated with contracts covering the transfer and sharing of RNAi technology.
- **YSL Beauté v. Oscar de la Renta, Ltd.**
American Arbitration Association (Case No. 13 133 01389 08)
 Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and trademark infringement involving cosmetics, fragrances, and beauty products.
- **IMTEC Imaging LLC v. CyberMed, Inc.**
JAMS Arbitration (Reference No. 1410005418)
 Arbitration hearing and deposition testimony and expert report: lost profits and development costs associated with the alleged breach of a contract involving a software license agreement directed to cone beam computed tomography machines used in dental applications.
- **Biosynexus, Inc. v. Glaxo Group Limited and MedImmune, Inc.**
New York Supreme Court, County of New York (Case No. 604485/05)
 Deposition testimony and expert report: diminution of value associated with the delayed/failed development of a pediatric anti-infective drug.
- **Indiana Mills & Manufacturing, Inc. v. Dorel Industries, Inc.**
United States District Court, Southern District of Indiana (Case No. 1:04-CV-1102)
 Deposition testimony and expert report: damages and profits associated with alleged contract breach and patent infringement involving technology directed to automobile child restraint systems.
- **ETEX Corp. v. Medtronic, Inc.; Medtronic International Limited; and Medtronic Sofamor Danek, Inc.**
CPR Institute for Dispute Resolution
 Arbitration hearing and deposition testimony and expert report: lost revenues and profits associated with alleged contractual breaches and antitrust violations involving spinal implant materials.
- **Audiotext International, Ltd. and New Media Group, Inc. v. Sprint Communications Co., L.P.**
United States District Court, Eastern District of Pennsylvania (Case No. 03-CV-2110)
 Deposition testimony and expert report: non-delivery damages involving contracts covering resale of telecommunications services.

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- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**
United States District Court, Western District of Tennessee (Case No. 01-2373 GV)
 Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Honeywell International, Inc. and GEM Microelectronic Materials LLC v. Air Products and Chemicals, Inc. and Ashland, Inc.**
Delaware Chancery Court, County of New Castle (Case No. 20434-NC)
 Trial and deposition testimony and expert report: lost profits associated with alleged contractual breach and tortious interference as well as irreparable harm inquiry involving a strategic alliance to provide electronic chemicals, gases and services to the semiconductor industry.
- **Christopher Karol; and Karol Designs, LLC v. Burton Corp.**
United States District Court, District of Vermont (Case No. 1:01-CV-178)
 Deposition testimony and expert report: reasonable royalty and disgorgement of profits involving trade secrets and an NDA directed to snowboard boot and binding technology.
- **Interactive Return Service, Inc. v. Virginia Polytechnic Institute and State University, et al.**
Circuit Court for the City of Richmond (Case No. LM-870-3)
 Deposition testimony: lost profits and lost licensing fees involving contracts to develop interactive/return path communications.
- **City of Hope National Medical Center v. Genentech, Inc.**
Superior Court, State of California, County of Los Angeles (Case No. BC215152)
 Deposition testimony and expert report: damages associated with alleged breach of contract involving license fees for use of recombinant DNA technology.
- **Igen International, Inc. v. Roche Diagnostics GmbH**
United States District Court, Southern Division of Maryland (Case No. PJM 97-3461)
 Trial and deposition testimony and expert report: damages and profits associated with an alleged breach of contract involving electrochemiluminescent detection technology used in DNA probe and immunoassay kits.
- **Trimless-Flashless Design, Inc. v. Augat, Inc.; Thomas & Betts Corp.; Tyco International, Ltd.**
United States District Court, Eastern District of Virginia (Case No. CA00-245-A)
 Trial and deposition testimony and expert report: damages and profits associated with alleged breach of contract and misappropriation of trade secrets involving metallized particle interconnects used to connect microprocessors with mother boards.
- **New Industries Co. (Sudan) Ltd. v. PepsiCo, Inc.**
American Arbitration Association (Case No. 50 T 114 00001 95)
 Arbitration hearing testimony and expert report: damages and profits associated with breaches of PepsiCo franchise agreement.
- **Insight Development Corp. v. Hewlett-Packard Co.**
United States District Court, Northern District of California (Case No. C 98 3349 CW)
 Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **First National Bank of Omaha v. Three Dimensions Systems Products, Inc.**
United States District Court, District of Nebraska (Case No. 8:98CV569)
 Trial and deposition testimony and expert report: damages and profits associated with an alleged contract breach and copyright infringement involving financial services software.

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- **Computer Aid v. Hewlett-Packard**
United States District Court, Eastern District of Pennsylvania (Case No. (C-96-3085 (MHP))
 Deposition testimony and expert report: appropriate discount rate and prejudgment interest rate involving a failed software development contract.
- **Wrench LLC v. Taco Bell Corp.**
United States District Court, Southern District of Michigan (Case No. 1:98-CV-45)
 Trial and deposition testimony and expert report: unjust enrichment and actual damages involving chihuahua promotional campaign.
- **Kabushiki Kaisha Izumi Seiko Seiskusho v. Windmere Corp. et al.**
United States District Court, Southern District of Florida (Case No. 94-0803-CIV-MOORE)
 Deposition testimony and expert declaration: lost revenues and lost profits in a breach of contract, fraud and antitrust case involving rotary shavers.

Antitrust Cases

- **Panasonic Corporation v. Getac Technology Corporation and Getac, Inc.**
United States District Court, Central District of California (Case No. 8:19-cv-01118-DOC-DFM)
 Deposition testimony and expert reports: monopolization/attempted monopolization counterclaim and design patent damages directed to market for rugged 2-in-1 portable computers.
- **Rambus Inc., v. Micron Technology, Inc.**
California Superior Court, County of San Francisco (Case No. 04-431105)
 Deposition testimony and expert report: lost revenues and profits associated with alleged antitrust violations related to DRAM technology.
- **ETEX Corp. v. Medtronic, Inc.; Medtronic International Limited; and Medtronic Sofamor Danek, Inc.**
CPR Institute for Dispute Resolution
 Arbitration hearing and deposition testimony and expert report: lost revenues and profits associated with alleged contractual breaches and antitrust violations involving spinal implant materials.
- **Kabushiki Kaisha Izumi Seiko Seiskusho v. Windmere Corp. et al.**
United States District Court, Southern District of Florida (Case No. 94-0803-CIV-MOORE)
 Deposition testimony and expert declaration: lost revenues and lost profits in a breach of contract, fraud and antitrust case involving rotary shavers.
- **DSC Communications Corp. v. DGI Technologies, Inc.**
United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)
 Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.
- **Travelers Express Co. Inc. v. The Standard Register Co.**
United States District Court, District of Minnesota (Case No. 4-93-436)
 Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse and prejudgment interest involving patents directed to money order dispensers.

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General Tort Cases

- **Life Spine, Inc. v. Aegis Spine, Inc.**
United States District Court, Northern District of Illinois, Eastern Division (Case No. 19-cv-7092)
 Deposition testimony and expert report: damages associated with lost profits, improper gains, withheld inventory, and prejudgment interest associated with alleged breaches of contract, breach of fiduciary duty, fraudulent inducement, and misappropriation of trade secrets in case involving implant devices used for the treatment of degenerative disc disease.
- **Diamond Resorts U.S. Collection Development, LLC and Diamond Resorts Hawaii Collection Development, LLC v. Pandora Marketing, LLC d/b/a Timeshare Compliance; Intermarketing Media, LLC d/b/a Resort Advisory Group; Slattery, Sobel & Decamp, LLC; Del Mar Law Group, LLP; Carlsbad Law Group, LLP; JL “Sean” Slattery, Esq.; Unlock Legal, APLC; Miranda Dempsey, APLC d/b/a McCroskey Legal; and Miranda McCroskey, Esq.**
United States District Court, Central District of California (Case No. 2:20-cv-05486-DSF-ADS)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged tortious interference, civil conspiracy, and violations of the Lanham Act and other similar state statutes in case involving timeshare exit services.
- **Colony Grill Development, LLC and Fairfield Colony, LLC v. Colony Grill, Inc. and Colony Grill of Stamford, LLC v. Paul Coniglio, Kenneth M. Martin, Cody L. Lee, and Christopher Drury**
United States District Court, District of Connecticut (Case No. 3:20-cv-00213)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged breach of contract, trademark infringement, unfair competition and unfair trade practices, theft of trade secrets, and breach of good faith and fair dealing in case involving pizza restaurants.
- **Diamond Resorts U.S. Collection Development, LLC and Diamond Resorts Hawaii Collection Development, LLC v. US Consumer Attorneys, P.A., Henry Portner, Esq., Robert Sussman, Pluto Marketing Inc., 1Planetmedia Inc, Newton Group Transfers, LLC, The Newton Group, ESA LLC, Interval Broker Direct, LLC, Newton Group Exit, LLC, and DC Capital Law Firm, LLP**
United States District Court, Southern District of Florida - Fort Pierce Division (Case No. 9:18-cv-80311)
 Deposition testimony and expert report: damages and disgorgement of profits associated with alleged tortious interference, civil conspiracy, and violations of the Lanham Act and other similar state statutes in case involving timeshare exit services.
- **Constellation Brands U.S. Operations, Inc. v. The Vineyard House LLC**
United States District Court, Northern District of California - Oakland (Case No. 3:20-cv-00238)
 Trial testimony and expert report: disgorgement of profits associated with alleged trademark infringement, false association, designation of origin, and advertising, and violations of the Lanham Act and other similar state statutes, involving alleged mislabeling of wine.
- **In re: Windstream Holdings, Inc., et al. (Debtors); Windstream Holdings, Inc., et al. v. Charter Communications, Inc. and Charter Communications Operating, LLC**
United States Bankruptcy Court, Southern District of New York (Chapter 11, Case No. 19-22312 (RDD); Adv. Pro. No. 19-08246 (RDD))
 Trial and deposition testimony and expert report: lost profits and increased costs associated with alleged violations of the Lanham Act and other similar state statutes, breach of contract, violation of the Bankruptcy Code’s automatic stay, and equitable subordination involving alleged false advertising campaign.

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- **NCR Corporation v. Pendum LLC and Burroughs, Inc.**
United States District Court, Northern District of Georgia (Case No. 16-cv-04114-SCJ)
 Deposition testimony and expert report: damages associated with lost profits, price erosion, unjust enrichment, and economic effects and harm associated with alleged misappropriation of trade secrets, copyright infringement, trademark infringement, breach of contract, and tortious interference with current and prospective business relations in case involving the servicing of automatic teller machines (ATMs).
- **Western Enterprises, Inc. v. Buckeye Rubber & Packaging Co.; Freudenberg-NOK General Partnership, a/k/a Freudenberg-NOK Sealing Technologies, Inc.; and International Seal Company, Inc.** *Court of Common Pleas, Cuyahoga County, Ohio (Case No. 16-869179)*
 Deposition testimony and expert report: damages associated with alleged breaches of contract, duty to indemnify, and negligence related to portable oxygen systems.
- **General Assurance of America, Inc. v. Overby-Seawell Company**
United States District Court, Eastern District of Virginia, Alexandria Division (Case No. 1:11CV483)
 Deposition testimony and expert report: damages and profits associated with obligations arising from a contract involving specialized insurance products.
- **The Osage Tribe of Indians of Oklahoma v. The United States of America**
United States Court of Federal Claims (Case No. 99-550 L (into which is consolidated No. 00-169L))
 Deposition testimony and expert declaration: present value interest from unpaid oil royalties.
- **Biosynexus, Inc. v. Glaxo Group Limited; and MedImmune, Inc.**
New York Supreme Court, County of New York (Case No. 604485/05)
 Deposition testimony and expert report: diminution of value associated with the delayed/failed development of a pediatric anti-infective drug.
- **Bavarian Nordic A/S and Anton Mayr v. Acambis, Inc.**
United States District Court, District of Delaware (Case No. 05-614-SLR)
 Deposition testimony and expert report: unjust enrichment and value of property associated with tortious conversion, unfair trade practices and unfair competition involving proprietary technology directed to vaccines.
- **Alpha International, Inc. v. General Foam Plastics Corp.**
United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))
 Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.
- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**
United States District Court, Western District of Tennessee (Case No. 01-2373 GV)
 Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Honeywell International, Inc. and GEM Microelectronic Materials LLC v. Air Products and Chemicals, Inc. and Ashland, Inc.**
Delaware Chancery Court, County of New Castle (Case No. 20434-NC)
 Trial and deposition testimony and expert report: lost profits associated with alleged contractual breach and tortious interference as well as irreparable harm inquiry involving a strategic alliance to provide electronic chemicals, gases and services to the semiconductor industry.
- **Interactive Return Service, Inc. v. Virginia Polytechnic Institute and State University, et al.**
Circuit Court for the City of Richmond (Case No. LM-870-3)
 Deposition testimony: lost profits and lost licensing fees involving contracts to develop interactive/return path communications.

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- **Omega Engineering, Inc. v. Cole-Parmer Instrument Co.; Davis Instrument Manufacturing Co., Inc.; Dwyer Instruments, Inc.; and Raytek Corp.**
United States District Court, District of Connecticut (Case Nos. 3:98 CV 00733 (JCH), 3:98 CV 02052 (JCH) and 3:98 CV 02276 (JCH))
 Trial and deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents and alleged unfair competitive practices directed to portable infrared thermometers.
- **The University of Colorado Foundation Inc., et al. v. American Cyanamid Co.**
United States District Court, District of Colorado (Case No. 93-K-1657)
 Trial and deposition testimony and expert report: measure and amount of prejudgment interest in a patent infringement, fraud and unjust enrichment case covering prenatal vitamin formulations.
- **Hunter Group, Incorporated v. Susan Smith, et al.**
United States District Court, District of Maryland (Case No. 97-2218)
 Trial and deposition testimony and expert report: lost enterprise value and lost profits associated with improper solicitation of enterprise resource planning software trainers.
- **William Aramony v. United Way of America et al.**
United States District Court, Southern District of New York (Case No. 96 Civ. 3962 (SAS))
 Trial testimony and expert report: lost contributions and out-of-pocket losses surrounding the departure of United Way of America president.
- **Fox v. Fox**
State of Virginia, Circuit Court, Arlington County (Chancery No. 96-80)
 Trial testimony (proffered) and expert report: prospective valuation of a patent portfolio involving lasers used for lithotripsy and angioplasty.
- **AutoNation, Inc. v. Acme Commercial Corp., et al. (CarMax)**
United States District Court, Southern District of Florida (Case No. 96-6141)
 Trial and deposition testimony and expert report: reasonable royalty associated with trademark infringement and unfair competition in the auto superstore business.

International Trade Cases

- **In the Matter of Certain Integrated Circuits, Chipsets, and Electronic Devices, and Products Containing Same (NXP Semiconductors N.V. and NXP USA, Inc. (Complainants))**
United States International Trade Commission (Investigation No. 337-TA-1287)
 Deposition testimony and expert report: economic evaluation of domestic industry, bond, and the amount and economic significance of inventory of the accused products in case involving patents directed to integrated circuits, chipsets, and electronic devices.
- **In the Matter of Certain High-Density Fiber Optic Equipment and Components Thereof (Panduit Corp. (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-1194)
 Trial and deposition testimony and expert reports: civil penalty associated with compliance with GEO and CDO involving patents directed to certain high-density fiber optic equipment.
- **In the Matter of Certain Electrical Connectors and Cages, Components Thereof, and Products Containing the Same (Amphenol Corporation (Complainant))**
United States International Trade Commission (Investigation No. 337-TA-1241)
 Trial and deposition testimony and expert report: economic evaluation of domestic industry, remedy, and bond in case involving patents directed to electrical connectors and cages.

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- **In the Matter of Certain Lithium-Ion Battery Cells, Battery Modules, Battery Packs, Components Thereof, and Products Containing the Same (SK Innovation Co., Ltd and SK Battery America, Inc. (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1181)
 Trial and deposition testimony and expert report: economic evaluation of domestic industry and bond issues involving patents directed to lithium-ion batteries.
- **In the Matter of Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (Sony Corporation, Sony Corporation of America, and Sony Electronics, Inc. (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1012E)
 Deposition testimony and expert report: civil penalty associated with compliance with CDOs involving patents directed to certain magnetic data storage tapes and cartridges.
- **In the Matter of Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II) (Sony Corporation, Sony Storage Media Solutions Corporation, Sony Storage Media Manufacturing Corporation, Sony DADC US, Inc., and Sony Latin America (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1076)
 Trial and deposition testimony and expert report: domestic industry, bond, and public interest issues involving patents directed to certain magnetic data storage tapes and cartridges.
- **In the Matter of Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (Sony Corporation, Sony Corporation of America, and Sony Electronics, Inc. (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1012)
 Trial and deposition testimony and expert report: economic evaluation of FRAND, commercial success, bond, remedy, domestic industry, and public interest issues involving patents directed to certain magnetic data storage tapes and cartridges.
- **In the Matter of Certain 3G Mobile Handsets and Components Thereof (Nokia (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-613)
 Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation and economic evaluation of hold-up and reverse hold-up.
- **In the Matter of Certain Sulfentrazone, Sulfentrazone Compositions, and Processes for Making Sulfentrazone (FMC (Complainant))**
United States International Trade Commission (Investigation No. 337-TA-914)
 Trial and deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving a patent directed to a crop herbicide.
- **In the Matter of Certain Opaque Polymers (Organik Kimya (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-883)
 Deposition testimony and expert report: injury, independent economic valuation, and bond involving trade secrets used in the production of opaque polymers.
- **In the Matter of Certain Wireless Devices with 3G and/or 4G Capabilities and Components Thereof (Nokia (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-868)
 Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation, and economic evaluation of hold-up and reverse hold-up.
- **In the Matter of Certain Wireless Devices with 3G Capabilities and Components Thereof (Nokia (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-800)
 Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation.

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- **In the Matter of Certain Computing Devices with Associated Instruction Sets and Software (VIA Technologies, Inc., Centaur Technology, IP-First LLC (Complainants))**
United States International Trade Commission (Investigation No. 337-TA-812)
Trial and deposition testimony and expert report: economic evaluation of domestic industry issues associated with importation of certain computing devices.
- **In the Matter of Certain Modified Vaccinia Ankara (“MVA”) Viruses and Vaccines and Pharmaceutical Compositions Based Thereon (Bavarian Nordic A/S (Complainant))**
United States International Trade Commission (Investigation No. 337-TA-550)
Deposition testimony and expert report: domestic industry and injury involving patents and proprietary technology directed to vaccines.

Malpractice Cases

- **TattleTale Portable Alarm Systems, Inc. v. Calfee, Halter & Griswold LLP, et al.**
United States District Court, Southern District of Ohio, Eastern Division (Case No. 2:10-CV-226)
Deposition testimony and expert report: lost royalties associated with a law firm’s negligence in handling a patent directed to portable alarm systems.
- **Timothy Robinson and Whorl, LLC v. Cohen Mohr, LLP; Dan Duval; Perkins Coie, LLP; Perkins Coie, L.P.C.; Perkins Coie, D.C.P.C.; and Perkins Coie, California, P.C.**
State of Virginia, Circuit Court of Fairfax County (Case No. CL-2009-080)
Deposition testimony and expert report: lost value and prejudgment interest involving allegations of law firm’s negligence in securing an interest in intellectual property directed to biometric payment technology.
- **Frank Robertson and Cayvon, Inc. v. Nexsen Pruet Jacobs & Pollard, LLP**
South Carolina Common Pleas Court, Fifth Judicial Circuit, Richland (Case No. 2004-CP-40-5531)
Deposition testimony: lost profits associated with a law firm’s negligence in handling a patent directed to commercial nut-cracking machines.
- **Anodyne Corp. v. Klaas, Law, O’Meara & Malkin**
State of Colorado District Court, City and County of Denver (Case No. 97-CV-7129)
Trial testimony and expert report: lost licensing income and prejudgment interest associated with a law firm’s negligence in filing a patent application directed to wrappable flashlights.

FRAND Cases

- **Audio MPEG, Inc., U.S. Philips Corporation, TDF SAS, and Institut Für Rundfunktechnik GmbH v. Dell, Inc.**
United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 1:15-CV-1674 AJT/TCB)
Deposition testimony and expert report: analysis of patent pool compliance with FRAND commitments and determination of FRAND-compliant royalties involving patents directed to the transmission and storage of digital audio files.
- **In the Matter of Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (Sony Corporation, Sony Corporation of America, and Sony Electronics, Inc. (Respondents))**
United States International Trade Commission (Investigation No. 337-TA-1012)
Trial and deposition testimony and expert report: economic evaluation of FRAND, commercial success, bond, remedy, domestic industry, and public interest issues involving patents directed to certain magnetic data storage tapes and cartridges.

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- **In the Matter of Certain 3G Mobile Handsets and Components Thereof (Nokia (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-613)
 Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation and economic evaluation of hold-up and reverse hold-up.
- **In the Matter of Certain Wireless Devices with 3G and/or 4G Capabilities and Components Thereof (Nokia (Respondent))**
United States International Trade Commission (Investigation No. 337-TA-868)
 Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation, and economic evaluation of hold-up and reverse hold-up.
- **In the Matter of Certain Wireless Devices with 3G Capabilities and Components Thereof (Nokia (Respondent))**
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- “The CAFC and its Patent Damages Awards,” in 1 *The University of Baltimore Intellectual Property Law Journal* 17 (1992).
- “Pre-tax Versus After-tax Patent Damages: Do the Courts Have It Right?” in 74 *Journal of the Patent and Trademark Office Society* 938 (December 1992). Also in 7 *Managing Intellectual Property* 17 (March, 1993).
- “Taxes and Lost Profits,” in 7 *Commercial Damages Reporter*, 177 (Iss. 6, Sept. 1992).
- “Considering Taxes in the Computation of Lost Business Profits,” in 25 *Creighton L.R.* 41 (1991).

TAB 1

SPEECHES/COURSES/PRESENTATIONS

- “Litigating Patent and Trade Secret Remedies,” Co-Chair, Certified Patent Valuation Analyst 2023 Virtual Summit, January 2023.
- “Prejudgment Interest: W.D. Texas Got it Right in the *VLSI v. Intel* Patent Suit,” *les Nouvelles Live!* Highlights from the September 2022 Edition, Licensing Executives Society International, October 2022 (with Joseph Maloney).
- “WG9/10 Panel: Unique Problems and Opportunities Posed by Global Patent Litigation - Part 1 (Unified Patent Court & Global SEP/FRAND),” The Sedona Conference WG9 and WG10 Joint Annual Meeting, November 2021 (with Juliane Buchinski, Patricio Delgado, Benjamin Grzimek, Haifeng Huang, Frances Marshall, Jim Oliva, Hon. Prathiba Singh, Richard Stark, and Laura Whiting).
- “Problems with Irreparable Harm in Preliminary Injunction Patent Cases,” IPO Damages & Injunction Committee Meeting, August 2021.
- “Irreparable Harm in Patent Preliminary Injunction Cases,” Intellectual Property Scholars Conference, August 2021 and August 2022 (with Jorge Contreras).
- “Understanding the Buying Process,” Patent Transactions, IAM Market, April 2021 (with Heath Hoglund, Joseph Kucera, Ami Patel Shah, Changhae Park, and Kent Richardson).
- “Remedies,” Guest Lecturer, Georgetown University Law Center, April 2012, April 2013, April 2014, April 2015, April 2016, April 2017, April 2018, April 2019, April 2020, April 2021, and April 2022 (with John Taurman).
- “Impacts of Coronavirus and Major Business Disruption on Remedies in IP Cases,” IPO Chat Channel Webinar, June 2020 (with Douglas Frank, Lucy Wheatley, and Jenna Pellecchia).
- “Irreparable Harm in Patent Cases,” IPO Damages & Injunctions Committee Meeting, May 2020 (with Natalie Gonzales and Syed Fareed).
- “Patents, Innovation and Value,” Guest Lecturer, University of Pennsylvania Law School, February 2019 (with David Abrams).
- “*Sprint v. Time Warner Cable*: Admissibility of Past Jury Verdicts in Damages Estimation,” Intellectual Property Owners Association Damages and Injunctions Committee Monthly Call, December 2018 (with Mark Finkelstein).
- “Entire Market Value Rule: *Finjan v. Exmark v. Power Integrations*,” 2018 Patent Damages Symposium, The Licensing Executive Society (Washington DC Chapter), September 2018 (with Stephen Crenshaw, Jennifer Vanderhart, Jeff Stec, and Stephen Holzen).
- “2018 Daubert Guideposts in Reasonable Royalty Estimation,” Daubert Motion and Patent Challenges in the 2018 Landscape: Significant Trends and Updates, The Knowledge Group, September 2018 (with James Donohue).
- “*TCL v. Ericsson*: Non-Discrimination,” *TCL v. Ericsson FRAND Decision*: Legal Implications, The Knowledge Group, September 2018 (with Alan Cox, Stephen Korniczky, and Mario Lopez).

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- “Apportionment in Reasonable Royalty Cases,” Reasonable Royalty Damages, Apportionment and Expert Opinions in Light of *Exmark* Case, The Knowledge Group, May 2018 (with Matthew Lynde, Russell Mangum III, and Joel Wacek).
- “Apportionment in Reasonable Royalty Cases,” Apportionment in Patent Damages: What you Need to Know and Do, The Knowledge Group, March 2018 (with Daniel McGavock and John Scalf).
- “Post-Trial Remedies,” What Is My Intellectual Property Worth: Issues That Make a Difference Inside and Outside the Courtroom, Inaugural IP Conference on Issues that Make A Difference, University of Arizona James E. Rogers College of Law, March 2018 (with Timothy Sendek).
- “Design Patent Damages Before *Apple v. Samsung*,” Design Patent Damages: Hot Buttons in 2017 and Beyond, The Knowledge Group, July 2017 (with Barry Bell and Jeffery Stec).
- “Early Consideration of Patent Damages,” The Sedona Conference Webinar, June 2017 (with Hon. John Love, Melissa Finocchio, and Andrea Weiss Jeffries).
- “Permanent Injunctive Relief,” Recent Developments in Damages and Injunctions Law, IPO Damages & Injunctions Committee Conference, June 2017 (with Sarah Burstein, Mark Halligan, David Nelson, and Jenna Pellecchia).
- “U.S. Patent Landscape,” The European Patent Market – The Next Wave for Business? International In-House Counsel Journal 5th Annual Conference, March 2017 (with Anders Arvidsson, Mark Houghton, and Bruce Girvan).
- “The Conference on Patent Damages,” University of Texas School of Law, February 2017 (with David Abrams, Elizabeth Bailey, James Kearl, Shirley Webster, and Michael Risch).
- “2016 Patent Damages Daubert Opinions,” The Evolving Landscape in the Calculation of Patent Damages – Reasonable Royalties, The Knowledge Group, February 2017 (with Barry Bell, James McGovern, and Jeffery Stec).
- “Commercial Success at the PTAB: 2016 Update,” Strafford Publications CLE Webinar, September 2016 (with Michael Flibbert and Maureen Queler).
- “Economic Perspectives on Recent Patent Damages Rulings,” Silicon Valley Intellectual Property Law Association, May 2016 (with Michael Chapman).
- “Recent Developments in Reasonable Royalty Damages,” Intellectual Property Owners Association Patent Damages Summit, May 2016 (with Charles Barquist, Douglas Melamed, Joseph Shear, and Karen Vogel Weil).
- “The Rise of the ‘Footprint’ Approach in Reasonable Royalty Damages: What’s New in 2016,” The Knowledge Group, February 2016 (with Lisa Cameron, Thomas Dunlap, Kevin Goldman, and Michael Padden).
- “Patent Infringement Reasonable Royalty Damages: Apportion the Increment?” Asian Pacific American Bar Association of Silicon Valley, November 2015 (with William Rooklidge, Michael Chapman, and Richard Eichmann).
- “Patent Enforcement,” Guest Lecturer, George Washington University Law School, September 2015 (with Chuck Donohoe), September 2016.

TAB 1

- “Commercial Success at the PTAB,” Strafford Publications CLE Webinar, August 2015 (with Michael Flibbert and Maureen Queler).
- “Patent Damages Developments in the US,” International Intellectual Property Law Association Global IP Summit, July 2015 (with Iain Connor and Ronald Courtney).
- “WG9 Panel: Development of a Preliminary Compensatory Damages Contentions (PCDCs) Process, Including the Drafting of Local Patent Damages Rules,” The Sedona Conference WG9 and WG10 Joint Midyear Meeting, May 2015 (with Marta Beckwith, Cathy Bissoon, Melissa Finocchio, Andrea Weiss Jeffries, and James Morando).
- “Commercial Success at the PTAB,” IPO Chat Channel Webinar, March 2015 (with Michael Flibbert and Pradeep Chintagunta).
- “WG9 Panel: Commentary on Development of Local Patent Rules for the Exchange of Preliminary Compensatory Damages Contentions (PCDCs),” The Sedona Conference All-Voices Meeting, November 2014 (with Marta Beckwith, Cathy Ann Bencivengo, John Desmarais, and Melissa Finocchio).
- “Patent Damages: How to Build a Case Now,” IPO Chat Channel Webinar, October 2014 (with Paul Grewal and Gary Hoffman).
- “WG9 Commentary on Patent Damages and Remedies,” The Sedona Conference Webinar, October 2014 (with Gary Hoffman, Michael Brody, Rachel Krevans, and William Rooklidge).
- “Economic Testimony in IP Litigation,” Inside Counsel Spotlight, August 2014.
- “The Evolution of License Comparability in the Estimation of Reasonable Royalty Damages,” West Legal Education Center Webinar, July 2013 (with Carla Mulhern).
- “Georgia-Pacific and the Hypothetical Negotiation: Is the Tail Wagging the Dog?” Licensing Executives Society Washington DC Chapter Meeting, May 2012 (with Michael Chapman).
- “Early Evaluation of Damages in Patent Trials,” IPO Chat Channel Webinar, February 2012 (with Peter Armenio and Rachel Krevans).
- “Evolving IP Value: Recent Developments in Damages and Licensing,” Top IP Retreat 2011, September 2011 (with Michael Wagner).
- “Intellectual Property Valuation,” WIPO Summer School on Intellectual Property, USPTO, August 2011 (with Daria Killebrew).
- “Patent Infringement: Calculating Royalty Damages in a Post-Uniloc World,” Strafford Publications Webinar, March 2011 (with Paul Michel, George Pappas, and Carla Mulhern).
- “Uniloc v. Microsoft: The Decision and Its Impact on IP Valuation,” Licensing Executives Society Hot Topic Webinar, January 2011 (with Michael Lasinski, Justin Nelson, and Mohan Rao).
- “Patent Reform Update,” The District of Columbia Bar, January 2011 (with Paul Michel, Cheryl Miller, and Jason Everett).
- “Reasonable Royalties and Apportionment of Value,” CalCPA Education Foundation, IP Damages Institute 2010, November 2010 (with Michael Wagner, Karen Vogel Weil, and William Rooklidge).

TAB 1

- “What is a Trademark Worth?,” Stifel Retail Summer School at Columbia Business School, August 2010.
- “Economics of False Patent Marking,” BNA Webinar and Audioconferences, Recent Developments in the Law and Economics of False Patent Marking, July 2010 (with Anthony Roth and John Browning).
- “Economic Implications of Patent Reform,” Georgetown University McDonough School of Business, Center for Business and Public Policy; McKool Smith; and Analysis Group, Patent Reform 2010: What Shape Will it Finally Take?, June 2010 (with Paul Michel, Bernard Cassidy and Brian Riopelle).
- “Patent Auctions: How Far Have We Come?,” Licensing Executives Society Annual Meeting (Workshop 3-U), October 2009 (with Robin Heider).
- “Creating a Bullet-Proof Damages Case from Day One,” Minnesota’s CLE’s First Litigation Advocacy Institute: Winning Before Trial, June 2009.
- “Permanent Injunction: An Economist’s Perspective,” Strategies for Managing Intellectual Property Litigation Summit, February 2007.
- “Providing Effective Royalty Testimony,” Licensing Executives Society / Association of University Technology Managers Spring Meeting, May 2006 (with Carla Mulhern and Lisa Pirozzolo).
- “Intellectual Property Damages From An Economist’s Perspective,” The District of Columbia Bar, Trade Secrets Section, November 2005 (with Carla Mulhern, Abram Hoffman and Michael Morin).
- “Valuation and Taxation Roundtable Discussion -- Hands on Application of Valuation Tools,” Licensing Executives Society Winter Meeting, February 2005 (with Serge-Alain Wandji).
- “Valuation and Pricing of IP,” Association of University Technology Managers Annual Meeting (Educational Track ED1), February 2005 (with Ashley Stevens, Jennifer Hartt and Andrew Maslow); Licensing Executives Society DC Chapter Meeting, February 2005.
- “Ingredients of a Damages Study,” Law Seminars International, Calculating and Proving Patent Damages, October 2004.
- “Current Topics in Technology Valuation,” Association of University Technology Managers Annual Meeting (Educational Track ED1), March 2004.
- “Creative Thinking on Remedies,” Law Seminars International, Trademarks Transactions and Litigation Workshop, July 2003.
- “Industry Royalty Rates and Profitability: An Empirical Test of the 25% Rule,” Licensing Executives Society Annual Meeting (Workshop 3-L), October 2001 (with Carla Mulhern and Robert Vigil).
- “Patent vs. Trade Secret Protection after 18-Month Publication and Festo--Monetary Relief,” Licensing Executives Society Annual Meeting (Workshop 2-M), October 2001 (with Griffith Price, Jr., John Williamson and Robert Payne).
- “The Design-Around Defense in Lost Profits Litigation,” Patent Lawyers Club of Washington, May 2000.

TAB 1

- “Use of the 25% Rule in Valuing Intellectual Property,” Center for Continuing Education, Santa Clara, California, December 1999.
- “Extracting Value from Intellectual Assets: Valuation,” INTX Seminar -- On the Frontier of Intellectual Asset Management: The Strategic Management of Intellectual Assets, November 1999.
- “Internet Patents – Monetary Remedies,” American Intellectual Property Law Association Mid-winter Meeting – IP Law in Cyberspace, February 1999 (with R. Jeffrey Malinak).
- “Industry Royalty Rates and Profitability: An Empirical Test of the 25% Rule,” Licensing Executives Society Annual Meeting (Workshop 3-11), October 1998 (with Carla Mulhern).
- “Royalty Rates and Awards with Patent Infringement Cases: 1916-1996,” Licensing Executives Society Annual Meeting (Workshop G3), November 1997.
- “Valuation of Technology,” Technology Transfer Society Annual Meeting, July 1997.
- “The Valuation and Licensing of Intellectual Property,” Launchspace, December 1996 (with Robert Goldscheider).
- “Quantifying and Valuing Royalties for Intellectual Property,” The 5th Intellectual Property Institute for Corporate Counsel, May 1996.
- “Taxes and Damages,” CPA/Lawyer Relations Committee, DC Institute of CPAs -Legal and Financial Implications of Damages in Litigation, October 1995.
- “Estimating Lost Profits in Commercial Litigation,” Maryland Association of Certified Public Accountants, Litigation Support Service Conferences, May 1995.
- “Damages in Patent and Trademark Infringement,” Joint American Society of Appraisers and Canadian Institute of Chartered Business Valuators meeting, November 1994.

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B25	2022 Biosimilars Report: The U.S. Journey and Path Ahead
B26	JAMA Network, Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland (December 2, 2022)

TAB 2

Exhibit Number	Document Label
B27	AMGEN 2022 Biosimilar Trends Report
B28	Alvarez, D.F., G. Wolbink, C. Cronenberger, J. Orazem, and J. Kay, “Interchangeability of Biosimilars: What Level of Clinical Evidence Is Needed to Support the Interchangeability Designation in the United States?” <i>BioDrugs</i> , Vol. 34, 2020, pp. 723-732.
B29	Ames, D.R., and M. Mason, “Tandem Anchoring: Informational and Politeness Effects of Range Offers in Social Exchange,” <i>Journal of Personality and Social Psychology</i> , Vol. 108, No. 2, 2015, pp. 254-274.
B30	Berndt, E.R., D. Nass, M. Kleinrock, and M. Aitken, “Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations,” <i>Health Affairs</i> , Vol. 34, No. 2, 2015, pp. 245-252.
B31	Brealey, R.A., S.C. Meyers, and F. Allen, <i>Principles of Corporate Finance</i> , Tenth Edition, McGraw-Hill/Irwin, 2011.
B32	Cameron, L.J., “Preliminary Injunctions in Pharmaceutical Litigation: The Economics of Irreparable Harm,” Discussion Paper, 2011.
B33	“Complexity in Action,” National Academies of Sciences, Engineering, and Medicine, in <i>Making Medicines Affordable: A National Imperative</i> , 2018, eds. Augustine, Norman R., Madhavan, Guru, and Nass, Sharyl J., Washington, DC: <i>The National Academies Press</i> , 2018.
B34	DiMasi, J.A., H.G. Grabowski, and R.W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” <i>Journal of Health Economics</i> , 2016.
B35	Grabowski, H., J. Vernon, and J.A. DiMasi, “Returns on Research and Development for 1990s New Drug Introductions,” <i>Pharmacoeconomics</i> , Vol. 20, No. 3, 2002, pp. 11-29.
B36	Hagland, M., “Step Therapy and Biologics: No Easy Answers,” <i>Biotechnology Healthcare</i> , Vol. 3, No. 6, 2006.
B37	Harrington, S.E., “Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms,” in <i>The Oxford Handbook of the Economics of the Biopharmaceutical Industry</i> , 2012.
B38	Kahneman, D., and A. Tversky, “Judgment under Uncertainty: Heuristics and Biases,” <i>Science</i> , Vol. 185, 1974, pp. 1124-1131.
B39	Kahneman, D., and A. Tversky, “Prospect Theory: An Analysis of Decision Under Risk,” <i>Econometrica</i> , Vol. 47, 1979, pp. 263-292.
B40	Kahneman, D., J. Knetsch, and R. Thaler, “Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias,” <i>Journal of Economic Perspectives</i> , Vol. 5, No. 1, 1991, pp. 193-206.

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TAB 2

Exhibit Number	Document Label
B41	Kahneman, D., "Reference Points, Anchors, Norms, and Mixed Feelings," <i>Organizational Behavior and Human Decision Processes</i> , Vol. 51, 1992, pp. 296-312.
B42	Kalwani, M.U., C.K. Yim, H.J. Rinne, and Y. Sugita, "A Price Expectations Model of Customer Brand Choice," <i>Journal of Marketing Research</i> , Vol. 27, 1990, pp. 251-262.
B43	Kashani, A., and D.A. Schwartz, "The Expanding Role of Anti-IL-12 and/or Anti-IL-23 Antibodies in the Treatment of Inflammatory Bowel Disease," <i>Gastroenterology & Hepatology</i> , Vol. 15, No. 5, 2019, pp. 255-265.
B44	Mattingly, J., "Understanding Drug Pricing," <i>U.S. Pharmacist</i> , Vol. 37, No. 6, 2012, pp. 40-45.
B45	Rockett, K., "Property Rights and Invention," in the Handbook of the Economics of Innovation, Bronwyn H. Hall and Nathan Rosenberg, eds., Vol. 1, 2010, pp. 315-380.
B46	"Seize the Digital Momentum: Measuring the Return from Pharmaceutical Innovation 2022," Deloitte Centre for Health Solutions, January 2023.
B47	AbbVie 2021 SEC Form 10-K.
B48	AbbVie 3Q 2022 SEC Form 10-Q.
B49	Amgen 2021 Annual Report.
B50	Johnson & Johnson Form 10-K for the fiscal year ended December 28, 2014.
B51	Johnson & Johnson Form 10-K for the fiscal year ended December 29, 2013.
B52	Johnson & Johnson Form 10-K for the fiscal year ended December 29, 2019.
B53	Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2012.
B54	Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2018.
B55	Johnson & Johnson Form 10-K for the fiscal year ended December 31, 2017.
B56	Johnson & Johnson Form 10-K for the fiscal year ended January 1, 2017.
B57	Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2016.
B58	Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2021.
B59	Johnson & Johnson Form 10-K for the fiscal year ended January 2, 2022.
B60	Johnson & Johnson 2021 Annual Report.
B62	"Business Review Day Follow-Up: Bullish Long-Term Expectations Appear Optimistic," BMO Capital Markets Analyst Report, February 8, 2022.

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TAB 3

U.S. FDA APPROVED BIOSIMILARS
AS OF DECEMBER 31, 2022

Biologic			Biosimilar(s)				
Brand Name	Indication(s)	Method of Administration	Brand Name	Indication(s)	U.S. FDA Approval Date	U.S. Launch Date	Interchangeability
[A]	[B]	[C]	[D]	[E]	[F]	[G]	[H]
[1] Avastin (bevacizumab)	Metastatic colorectal cancer; non-squamous non-small cell lung cancer; glioblastoma; metastatic renal cell carcinoma; cervical cancer; epithelial ovarian, fallopian tube, or primary peritoneal cancer; hepatocellular carcinoma	Intravenous infusion	Vegzelma	Same as reference biologic, except for hepatocellular carcinoma	9/27/2022	n/a	No
[2]			Alymsys	Same as reference biologic, except for hepatocellular carcinoma	4/13/2022	n/a	No
[3]			Zirabev	Same as reference biologic, except for hepatocellular carcinoma	6/27/2019	2020 Q1	No
[4]			Mvasi	Same as reference biologic, except for hepatocellular carcinoma	9/14/2017	2019 Q3	No
[5] Enbrel (etanercept)	Rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; polyarticular juvenile idiopathic arthritis; plaque psoriasis	Subcutaneous injection	Eticovo	Same as reference biologic	4/25/2019	n/a	No
[6]			Erelzi	Same as reference biologic	8/30/2016	n/a	No
[7] Epogen/Procrit (epoetin alfa)	Anemia (nephrology/oncology supportive therapy)	Subcutaneous/intravenous injection	Retacrit	Same as reference biologic	5/15/2018	2018 Q4	No
[8] Herceptin (trastuzumab)	HER2 overexpressing breast cancer; HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma	Intravenous infusion	Kanjinti	Same as reference biologic	6/13/2019	2019 Q3	No
[9]			Trazimera	Same as reference biologic	3/11/2019	2020 Q2	No
[10]			Ontruzant	Same as reference biologic	1/18/2019	2020 Q2	No
[11]			Herzuma	Same as reference biologic	12/14/2018	2020 Q2	No
[12]			Ogivri	Same as reference biologic	12/1/2017	2019 Q4	No

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Brand Name	Indication(s)	Method of Administration	Brand Name	Indication(s)	U.S. FDA Approval Date	U.S. Launch Date	Interchangeability
[A]	[B]	[C]	[D]	[E]	[F]	[G]	[H]
[13] Humira (adalimumab)	Rheumatoid arthritis; juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; crohn's disease;	Subcutaneous injection	Idacio	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	12/13/2022	n/a	No
[14]	ulcerative colitis; plaque psoriasis; hidradenitis suppurativa; uveitis		Yusimry	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	12/17/2021	n/a	No
[15]			Hulio	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	7/6/2020	n/a	No
[16]			Abrilada	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	11/15/2019	n/a	No
[17]			Hadlima	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	7/23/2019	n/a	No
[18]			Hyrimoz	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	10/30/2018	n/a	No
[19]			Cyltezo	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	8/25/2017	n/a	Yes
[20]			Amjevita	Same as reference biologic, except for: hidradenitis suppurativa; uveitis	9/23/2016	n/a	No
[21] Lantus (insulin glargine)	Improve glycemic control in patients with diabetes mellitus	Subcutaneous injection	Rezvoglar	Same as reference biologic	12/17/2021	n/a	Yes
[22]			Semglee	Same as reference biologic, except for type 2 child diabetics	7/28/2021	2021 Q4	Yes
[23] Lucentis (ranibizumab)	Neovascular (wet) macular degeneration; macular edema following retinal vein occlusion; diabetic macular edema; diabetic retinopathy; myopic choroidal neovascularization	Ophthalmic intravitreal injection	Cimerli	Same as reference biologic	8/2/2022	2022 Q3	Yes
[24]			Byooviz	Same as reference biologic, except for: diabetic macular edema; diabetic retinopathy	9/17/2021	2022 Q3	No

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Brand Name	Indication(s)	Method of Administration	Brand Name	Indication(s)	U.S. FDA Approval Date	U.S. Launch Date	Interchangeability
[A]	[B]	[C]	[D]	[E]	[F]	[G]	[H]
[25] Neulasta (pegfilgrastim)	Oncology supportive therapy	Subcutaneous injection	Stimufend	Only for neutropenia in response to anti-cancer drugs	9/1/2022	n/a	No
[26]			Flyntra	Only for neutropenia in response to anti-cancer drugs	5/26/2022	n/a	No
[27]			Nyvepria	Only for neutropenia in response to anti-cancer drugs	6/10/2020	2020 Q4	No
[28]			Ziextenzo	Only for neutropenia in response to anti-cancer drugs	11/4/2019	2019 Q4	No
[29]			Udenyca	Same as reference biologic	11/2/2018	2019 Q1	No
[30]			Fulphila	Only for neutropenia in response to anti-cancer drugs	6/4/2018	2018 Q3	No
[31] Neupogen (filgrastim)	Oncology supportive therapy	Subcutaneous or intravenous injection	Releuko	Same as reference biologic, except for acute radiation syndrome and mobilizing autologous hematopoietic progenitor cells	2/25/2022	n/a	No
[32]			Nivestym	Same as reference biologic, except for acute radiation syndrome	7/20/2018	2018 Q4	No
[33]			Zarxio	Same as reference biologic, except for acute radiation syndrome	3/6/2015	2015 Q3	No
[34]			Granix	Only for severe neutropenia in response to anti-cancer drugs	8/30/2012	2013 Q4	No
[35] Remicade (infliximab)	Crohn's disease; ulcerative colitis; rheumatoid arthritis; ankylosing spondylitis; psoriatic arthritis; plaque psoriasis	Intravenous infusion	Avsola	Same as reference biologic	12/6/2019	2020 Q3	No
[36]			Ixifi	Same as reference biologic	12/13/2017	n/a	No
[37]			Renflexis	Same as reference biologic	4/21/2017	2017 Q3	No
[38]			Inflectra	Same as reference biologic	4/5/2016	2016 Q4	No

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Brand Name	Indication(s)	Method of Administration	Brand Name	Indication(s)	U.S. FDA Approval Date	U.S. Launch Date	Interchangeability
[A]	[B]	[C]	[D]	[E]	[F]	[G]	[H]
[39] Rituxan (rituximab)	Non-hodgkin's lymphoma, mature B-cell NHL and mature B-cell acute leukemia; chronic lymphocytic leukemia; rheumatoid arthritis; granulomatosis with polyangiitis; microscopic polyangiitis; pemphigus vulgaris	Intravenous injection	Riabni	Same as reference biologic, except for: B-cell acute leukemia; pemphigus vulgaris	12/17/2020	2021 Q1	No
[40]			Ruxience	Same as reference biologic, except for: B-cell acute leukemia; pemphigus vulgaris	7/23/2019	2020 Q1	No
[41]			Truxima	Same as reference biologic, except for: B-cell acute leukemia; pemphigus vulgaris	11/28/2018	2019 Q4	No

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AS OF DECEMBER 31, 2022

Notes & Sources:

- [A],[D],[F],[H] From Stewart, J., "How Many Biosimilars Have Been Approved in the United States?" Drugs.com, December 23, 2022, available at <https://www.drugs.com/medical-answers/many-biosimilars-approved-united-states-3463281/>, accessed December 19, 2022.
- [B],[E] All indications are updated to the most recent label as of December 26, 2022.
- [G] From Exhibit B27, at p. 11.
- [1]-[4][B]-[C] From Avastin (bevacizumab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125085s225lbl.pdf.
- [1][E] From Vegzelma FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761268Orig1s000Correctedlbl.pdf.
- [2][E] From Alymsys FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761231s000lbl.pdf.
- [3][E] From Zirabev FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761099s006lbl.pdf.
- [4][E] From Mvasi FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761028s008lbl.pdf.
- [5]-[6][B]-[C] From Enbrel (etanercept) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103795s5591lbl.pdf.
- [5][E] From Eticovo FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761066s000lbl.pdf.
- [6][E] From Erelzi FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761042s018lbl.pdf.
- [7][B]-[C] From Exhibit B27, at p. 56.
- [7][E] From Retacrit FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125545s005lbl.pdf.
- [8]-[12][B]-[C] From Herceptin (trastuzumab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103792s5345lbl.pdf.
- [8][E] From Kanjinti FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761073Orig1s000lbl.pdf.
- [9][E] From Trazimera FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761081s000lbl.pdf.
- [10][E] From Ontuzant FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761100Orig1s005Llbl.pdf.
- [11][E] From Herzuma FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761091s001s002lbl.pdf.
- [12][E] From Ogivri FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761074s004lbl.pdf.
- [13] From Idacio FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761255s000lbl.pdf.
- [13][F] From "Idacio FDA Approval History," Drugs.com, available at <https://www.drugs.com/history/idacio.html>, accessed January 17, 2023.
- [14]-[20][B]-[C] From Humira (adalimumab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125057s417lbl.pdf.
- [14]-[20][G] Humira biosimilars are expected to launch in 2023. See "Humira Biosimilar Landscape Overview," CardinalHealth, available at <https://www.cardinalhealth.com/en/product-solutions/pharmaceutical-products/biosimilars/humira-biosimilar-landscape-overview.html>, accessed February 17, 2023.

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TAB 3

**U.S. FDA APPROVED BIOSIMILARS
AS OF DECEMBER 31, 2022**

Notes & Sources (continued):

- [14][E] From Yusimry FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761216s000lbl.pdf
- [15][E] From Hulio FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761154s002lbl.pdf.
- [16][E] From Abrilada FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761118s006lbl.pdf.
- [17][E] From Hadlima FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761059s005lbl.pdf.
- [18][E] From Hyrimoz FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761071s010s012lbl.pdf.
- [19][E] From Cyltezo FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761058s008lbl.pdf.
- [20][E] From Amjevita FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761024s010lbl.pdf.
- [21]-[22][B]-[C] From Lantus (insulin glargine) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021081s076lbl.pdf.
- [21][E] From Rezvoglar FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021081s076lbl.pdf.
- [22][E] From Semglee FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210605s000lbl.pdf.
- [23]-[24][B]-[C] From Lucentis (ranibizumab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf.
- [23][E] From Cimerli FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761165s000lbl.pdf.
- [23][G] From “Coherus to Launch Cimerli (ranibizumab-eqrn) in the United States on October 3, 2022,” Coherus Biosciences, September 19, 2022, available at <https://investors.coherus.com/news-releases/news-release-details/coherus-launch-cimerlitm-ranibizumab-eqrn-united-states-october>, accessed December 26, 2022.
- [24][E] From Byooviz FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761202s004lbl.pdf.
- [24][G] From “Biogen and Samsung Bioepis’ Byooviz launches in USA,” The Pharma Letter, March 6, 2022, available at <https://www.thepharmaletter.com/article/biogen-and-samsung-bioepis-byooviz-launches-in-usa>, accessed February 16, 2023.
- [25]-[30][B]-[C] From Neulasta (pegfilgrastim) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125031s203lbl.pdf. Neulasta is indicated to decrease incidence of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs and increase survival in patients acutely exposed to myelosuppressive doses of radiation.
- [25][E] From Stimufend FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761173Orig1s000correctedlbl.pdf.
- [26][E] From Flynetra FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761084s000lbl.pdf.
- [27][E] From Nyvepria FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761111s004lbl.pdf.

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TAB 3

**U.S. FDA APPROVED BIOSIMILARS
AS OF DECEMBER 31, 2022**

Notes & Sources (continued):

- [28][E] From Ziextenzo FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761045s0061bl.pdf.
- [29][E] From Udenyca FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761039s0141bl.pdf.
- [30][E] From Fulphila FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761075s0121bl.pdf.
- [31]-[34][B]-[C] From Neupogen (filgrastim) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/103353s51841bl.pdf.
Neupogen is indicated to treat neutropenia that is caused by cancer medicines. See “Filgrastim (Injection Route),” Mayo Clinic, available at <https://www.mayoclinic.org/drugs-supplements/filgrastim-injection-route/description/drg-20071547>, accessed December 20, 2022.
- [31][E] From Releuko FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761082s0031bl.pdf.
- [32][E] From Nivestym FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125294s0351bl.pdf.
- [33][E] From Zarxio FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761080s0071bl.pdf.
- [34] Granix is not a biosimilar. It was approved under a stand-alone Biologics License Application, which was submitted to the FDA before the enactment of the biosimilar approval pathway.
See Exhibit B27, at p. 11.
- [34][E] From Granix FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125553s0231bl.pdf.
- [34][F] From “Granix FDA Approval History,” Drugs.com, available at <https://www.drugs.com/history/granix.html>, accessed December 28, 2022.
- [35]-[38][B]-[C] From Remicade (infliximab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103772s54011bl.pdf.
- [35][E] From Avsola FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761086s0011bl.pdf.
- [36][E] From Ixifi FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761072s0061bl.pdf.
- [37][E] From Renflexis FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761054Orig1s0291bl.pdf.
- [38][E] From Inflectra FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s0001bl.pdf.
- [39]-[41][B]-[C] From Rituxan (rituximab) FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103705s54671bl.pdf.
- [39][E] From Riabni FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761140s0011bl.pdf.
- [40][E] From Ruxience FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761103s0051bl.pdf.
- [41][E] From Truxima FDA Label, found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761088s0181bl.pdf.

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TAB 5

TOTAL U.S. STELARA REVENUE AND UNITS BY INDICATION

Q1 2017 – Q3 2022

Notes & Sources:

Revenue in \$ millions.

Units from Exhibit B22, at [REDACTED]

Revenue from Exhibit B22, at [REDACTED]

Data collapsed to quarterly level.

Revenue in reported dollars. Calculated as mg of drug sold × WAC \$ (Wholesale Acquisition Cost).

Percentages calculated as a % of [8].

Stelara units include 45MG, 45MG LIV, 90MG, and 130MG units.

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TAB 6

**U.S. AND WORLDWIDE STELARA SALES
AS A PERCENT OF JOHNSON & JOHNSON AND JANSSEN TOTAL SALES
BASED ON DATA FROM JOHNSON & JOHNSON ANNUAL REPORTS AND INTERNAL SALES RECORDS
FY 2010 – FY 2021**

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
	[A]	[B]	[C]	[D]	[E]	[F]	[G]	[H]	[I]	[J]	[K]	[L]
[1] Stelara U.S. Sales	████	████	████	████	████	████	\$2,263	\$2,767	\$3,469	\$4,346	\$5,240	\$5,938
[2] As a % of Janssen US Sales	1.9%	3.6%	5.1%	6.9%	7.7%	9.1%	11.2%	12.9%	14.9%	18.2%	20.4%	21.2%
[3] As a % of J&J US Sales	0.8%	1.5%	2.1%	3.0%	3.8%	4.7%	6.0%	6.9%	8.3%	10.3%	12.1%	12.6%
[4] Stelara OUS Sales	\$150	\$295	\$397	\$547	\$738	\$797	\$969	\$1,244	\$1,687	\$2,015	\$2,467	\$3,196
[5] As a % of Janssen OUS Sales	1.5%	2.5%	3.1%	3.9%	5.0%	6.1%	7.3%	8.4%	9.7%	11.0%	12.4%	13.2%
[6] As a % of J&J OUS Sales	0.5%	0.8%	1.1%	1.4%	1.9%	2.3%	2.8%	3.4%	4.2%	5.0%	6.3%	6.9%
[7] Stelara WW Sales	\$393	\$738	\$1,025	\$1,504	\$2,072	\$2,474	\$3,232	\$4,011	\$5,156	\$6,361	\$7,707	\$9,134
[8] As a % of Janssen WW Sales	1.8%	3.0%	4.0%	5.3%	6.4%	7.9%	9.7%	11.1%	12.7%	15.1%	16.9%	17.5%
[9] As a % of J&J WW Sales	0.6%	1.1%	1.5%	2.1%	2.8%	3.5%	4.5%	5.2%	6.3%	7.8%	9.3%	9.7%

Notes & Sources:

Sales in \$ millions.

Total worldwide sales for Stelara from fiscal year 2010 – fiscal year 2021 = \$43.8 billion.

[1][A]-[F] From Exhibit B23.

[1],[4],[7][G]-[I] From Exhibit B54 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2018), at p. 74.

[1],[4],[7][J]-[L] From Exhibit B59 (Johnson & Johnson Form 10-K for the fiscal year ended January 2, 2022), at p. 78.

[2],[5],[8][A]-[C] From Exhibit B53 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2012), at p. 48.

[2],[5],[8][D] From Exhibit B57 (Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2016), at p. 61.

[2],[5],[8][E]-[G] From Exhibit B56 (Johnson & Johnson Form 10-K for the fiscal year ended January 1, 2017), at p. 67.

[2],[5],[8][H]-[I] From Exhibit B54 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2018), at p. 76.

[2],[5],[8][J]-[L] From Exhibit B59 (Johnson & Johnson Form 10-K for the fiscal year ended January 2, 2022), at p. 80.

[3],[6],[9][A]-[G] From Exhibit B56 (Johnson & Johnson Form 10-K for the fiscal year ended January 1, 2017), at p. 13.

[3],[6],[9][H]-[I] From Exhibit B54 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2018), at p. 15.

[3],[6],[9][J]-[L] From Exhibit B59 (Johnson & Johnson Form 10-K for the fiscal year ended January 2, 2022), at p. 82.

[7][A]-[C] From Exhibit B53 (Johnson & Johnson Form 10-K for the fiscal year ended December 30, 2012), at p. 5.

[7][D]-[F] From Exhibit B57 (Johnson & Johnson Form 10-K for the fiscal year ended January 3, 2016), at p. 12.

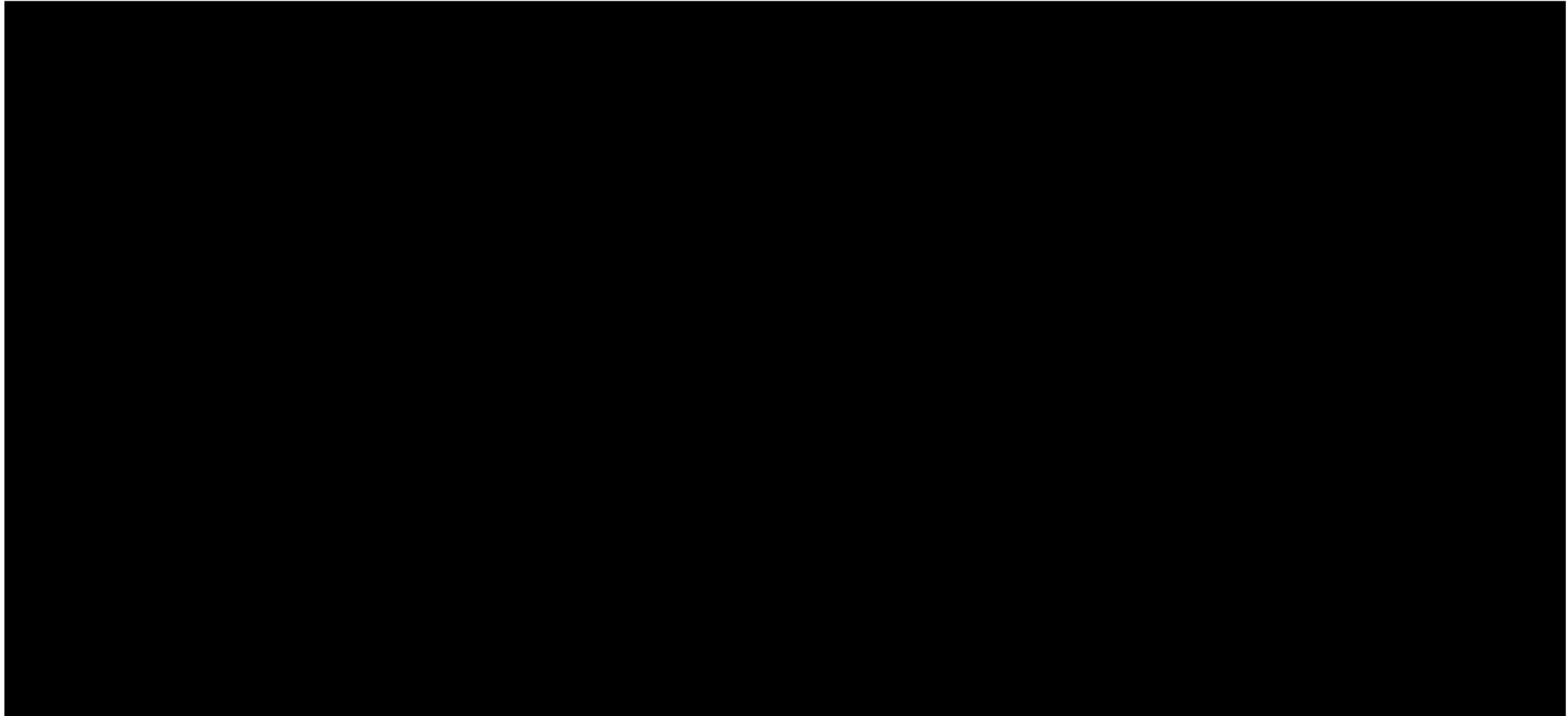
[4] = [7] - [1]

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TAB 7

PERCENT OF U.S. STELARA UNITS USED FOR THE TREATMENT OF ULCERATIVE COLITIS

Q1 2017 – Q3 2022



Notes & Sources:

From Exhibit B22, at [REDACTED]
Data collapsed to quarterly levels.

Stelara was approved by the FDA for treatment of adults with moderately to severely active ulcerative colitis on October 21, 2019.

See "Janssen Announces U.S. FDA Approval of STELARA® (Ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative," Johnson & Johnson, October 21, 2019, available at <https://www.jnj.com/janssen-announces-u-s-fda-approval-of-stelara-ustekinumab-for-the-treatment-of-adults-with-moderately-to-severely-active-ulcerative>, accessed December 31, 2022.

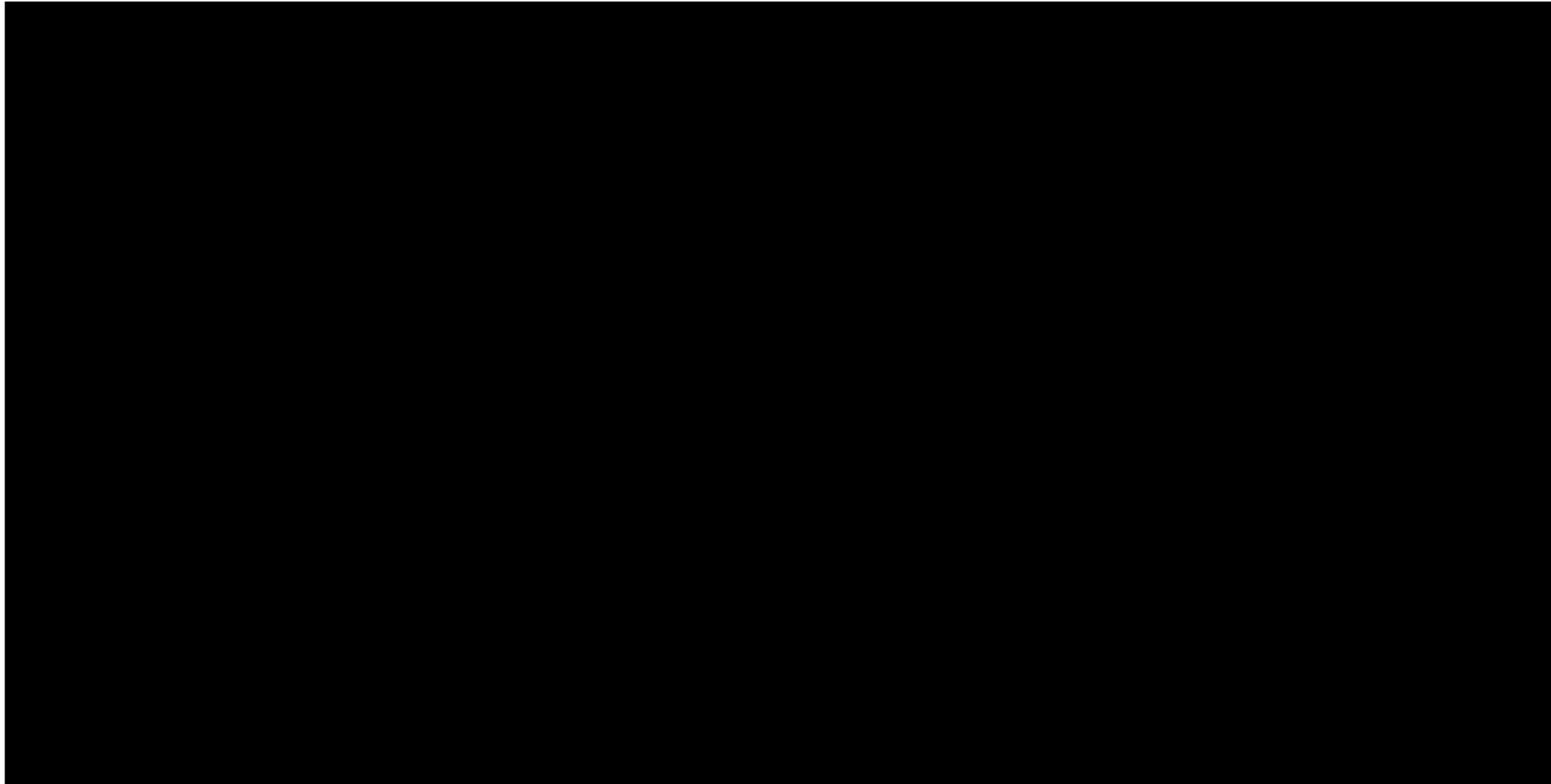
Stelara units include 45MG, 45MG LIV, 90MG, and 130MG units. Indications include rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, and "Other." Ankylosing spondylitis and rheumatoid arthritis are not FDA approved indications for Stelara.

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TAB 8

**PERCENT OF TOTAL U.S. STELARA REVENUES ASSOCIATED WITH UNITS
USED FOR THE TREATMENT OF ULCERATIVE COLITIS**

Q1 2017 – Q3 2022



Notes & Sources:

From Exhibit B22, at [REDACTED]
Revenue in reported dollars. Calculated as mg of drug sold \times WAC \$ (Wholesale Acquisition Cost).

Data collapsed to quarterly levels.

Stelara was approved by the FDA for treatment of adults with moderately to severely active ulcerative colitis on October 21, 2019.

See "Janssen Announces U.S. FDA Approval of STELARA® (Ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative," Johnson & Johnson, October 21, 2019, available at <https://www.jnj.com/janssen-announces-u-s-fda-approval-of-stelara-ustekinumab-for-the-treatment-of-adults-with-moderately-to-severely-active-ulcerative>, accessed December 31, 2022.

Stelara revenues used in the analysis include those associated with 45MG, 45MG LIV, 90MG, and 130MG units. Indications include rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, and "Other." Ankylosing spondylitis and rheumatoid arthritis are not FDA approved indications for Stelara.