UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner

_____

Case IPR2021-00816
Patent 9,220,631

_____

DECLARATION OF JAMES E. MALACKOWSKI, IN SUPPORT OF PATENT OWNER RESPONSE

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I. INTRODUCTION

1. I, James E. Malackowski, have been retained by Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp. (collectively, "Patent Owner" or "Novartis") as an independent expert witness in the above-captioned *inter partes* review ("IPR"), in which Petitioner Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron") has requested that the U.S. Patent and Trademark Office cancel as unpatentable all claims of U.S. Patent No. 9,220,631 ("the '631 Patent"). This declaration sets forth my opinions based on the materials I have considered and my knowledge, education, skills, training, and experience.

2. I provide this declaration to provide my opinions regarding certain secondary considerations of non-obviousness concerning the '631 Patent, specifically commercial success and licensing. In order to perform this evaluation, I have reviewed certain accounting, financial, marketing, licensing, and other business data and related information in connection with this litigation.

II. QUALIFICATIONS AND COMPENSATION

3. I am the Co-Founder and Chief Executive Officer of Ocean Tomo, LLC, the Intellectual Capital Merchant Banc™ firm providing industry leading financial products and services related to intellectual property including financial expert testimony, valuation, strategy consulting, patent analytics, investment

management, and transaction brokerage. Ocean Tomo assists clients – corporations, law firms, governments and institutional investors – in realizing Intellectual Capital Equity® value broadly defined. Subsidiaries of Ocean Tomo include Ocean Tomo Investments Group, LLC, a registered broker dealer, and Ocean Tomo International (HK) Ltd.

4. I am a founding and continuous member of the IP Hall of Fame Academy. I have been recognized annually since 2007 by leading industry publications as one of the "World's Leading IP Strategists." Significantly, I have been listed among "50 Under 45" by IP Law & Business™; included in the National Law Journal's inaugural list of 50 Intellectual Property Trailblazers & Pioneers; and named as one of "The Most Influential People in IP" by Managing Intellectual Property™. I was named as 1 of 50 individuals, companies and institutions that framed the first 50 issues of IAM Magazine as well as 1 of 60 leading global Economics Expert Witnesses by the same publication in 2014. In 2011, I was selected by the World Economic Forum as one of less than twenty members of the Network of Global Agenda Councils to focus on questions of IP policy. In 2013, I was inducted into the Chicago Area Entrepreneurship Hall of Fame by the Institute for Entrepreneurial Studies at the University of Illinois at Chicago College of Business Administration. In 2018, I joined the Standards Development Organization Board of the Licensing Executives Society (USA &

Canada), Inc. governing voluntary consensus-based professional practices that are guided in their development by the American National Standards Institute's (ANSI's) Essential Requirements. LES standards are designed to encourage and teach consensus practices in many of the business process aspects of intellectual capital management.

5. On more than fifty occasions, I have served as an expert in U.S. Federal Court, U.S. Bankruptcy Court, State Court, the Ontario Superior Court of Justice, and global arbitrations on questions relating to intellectual property economics, including the subject of valuation, reasonable royalty, lost profits, price erosion, commercial success, corrective advertising, creditor allocations, Hatch-Waxman Act market exclusivity, business significance of licensing terms including RAND obligations, venture financing, and equities of a potential injunction. My experience extends to matters of general business valuation and commercial disputes, both domestic and foreign. I have publicly addressed policy issues affecting international trade and have provided expert opinions concerning antidumping and countervailing duties imposed by the U.S. Department of Commerce as well as testimony on domestic industry, bond, and remedies before the International Trade Commission.

6. I have substantial experience as a Board Director for leading technology corporations and research organizations as well as companies with

critical brand management issues. I am Past President of The Licensing Executives Society International, Inc. as well as its largest chapter, LES USA & Canada, Inc. Today, I focus my not-for-profit efforts with organizations leveraging science and innovation for the benefit of children, including those located in lesser developed countries. I am a Director of the Stanley Manne Children's Research Institute and have served since 2002 as a Trustee or Director of the National Inventors Hall of Fame, Inc., an organization providing summer enrichment programs for more than 160,000 students annually.

7. I am a frequent speaker on emerging technology markets and related financial measures. I have addressed mass media audiences including Bloomberg Morning Call, Bloomberg Evening Market Pulse, Bloomberg Final Word, CNBC Closing Bell, CNBC On the Money, CNBC Street Signs, CNBC World Wide Exchange, CBS News Radio, and Fox Business National Television as well as other recognized news-based internet video channels. I am a judge on behalf of the Illinois Technology Association's CityLIGHTS™ Innovation Awards program, 1st Source Faculty Commercialization Awards, and have also appeared as a judge on PBS's Everyday Edisons.

8. As an inventor, I have more than twenty issued U.S. patents. I am a frequent instructor for graduate studies on IP management and markets and a Summa Cum Laude graduate of the University of Notre Dame majoring in

accountancy and philosophy. I am Certified/Accredited in Financial Forensics, Business Valuation, and Blockchain Fundamentals. I am a Certified Licensing Professional and a Registered Certified Public Accountant in the State of Illinois.

9. My curriculum vitae is provided as Appendix 1, and provides further information about my experience, expertise, and presentations.

10. My payment is not contingent upon my testimony or outcome of this investigation. I have no personal interest in the outcome of this investigation.

III. SUMMARY OF OPINIONS

11. In my opinion, the antibody drug product Lucentis (active ingredient ranibizumab) is an anti-vascular endothelial growth factor ("anti-VEGF") treatment sold in a pre-filled syringe ("PFS") presentation incorporating the claimed inventions of the '631 Patent that has been commercially successful. The commercial success of the Lucentis PFS is demonstrated by significant sales in the relevant market, rapid conversion of sales from vial to PFS presentation, the reversal from declining sales to increasing sales, and positive effects on market share. Additionally, it is my opinion that a nexus exists between the technology of the claimed inventions and the commercial success of the Lucentis PFS, which incorporates the patented technologies.

12. The claimed inventions of the ’631 Patent have also been licensed by third-parties. Additionally, it is my opinion that a nexus exists between the technology of the claimed inventions and the licenses entered into by third-parties.

13. As a result, these secondary considerations of non-obviousness tend to indicate that the ’631 Patent is not obvious.

IV. INDUSTRY BACKGROUND

A. Treatments for Wet AMD

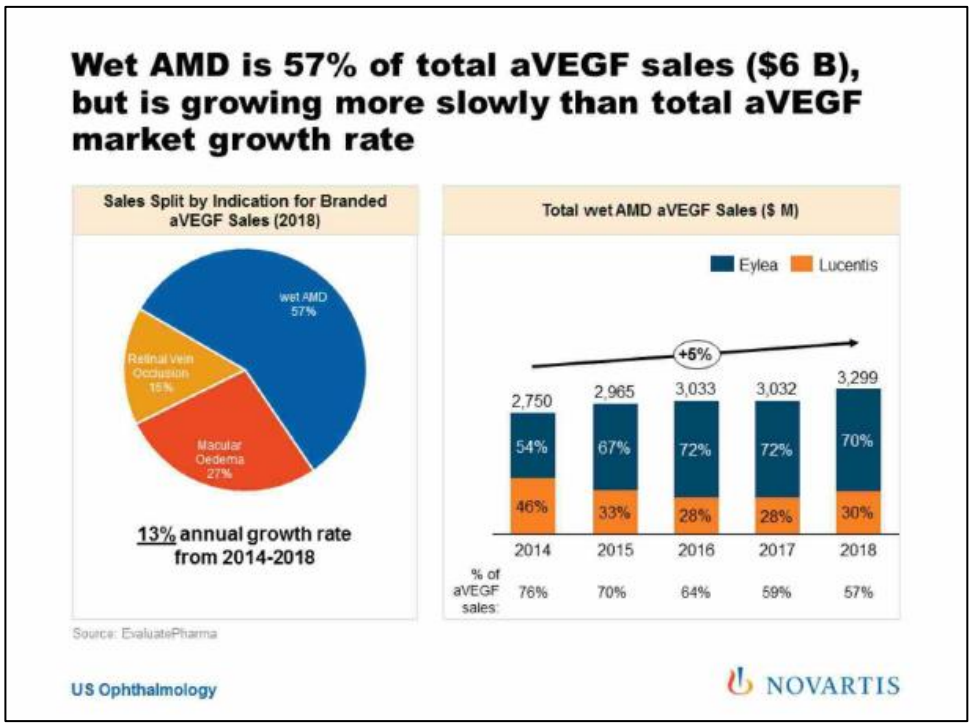
14. Wet age-related macular degeneration (“wet AMD”) is an eye disease that occurs when a protein called vascular endothelial growth factor (“VEGF”) impacts blood vessels in the back of the eye, causing vision loss.[1]

15. Currently, the most common and effective clinical treatment for wet AMD is anti-VEGF therapy, which is periodic intravitreal injection of an anti-

[1] Exhibit 2277 (“Treatments for Wet AMD (Advanced Neovascular AMD),” *National Eye Institute*, https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration/treatments-wet-amd-advanced-neovascular-amd); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶¶ 43-45).

VEGF drug.[2] There are several products in the anti-VEGF market for wet AMD, including Genentech's Avastin (bevacizumab), Genentech's Lucentis (ranibizumab), Regeneron's Eylea (aflibercept), and Novartis's Beovu (brolucizumab), among others, as discussed in the following sections.

Figure 1: Wet AMD Anti-VEGF Market[3]



[2] Exhibit 2258 ("Macular Degeneration Treatments," *American Macular Degeneration*, https://www.macular.org/treatments).

[3] Exhibit 2172 (NOVITC(US)00718202-335 at 205).

i. Avastin

16. Avastin (bevacizumab), manufactured by Genentech, is a VEGF inhibitor indicated for the treatment of metastatic colorectal cancer, glioblastoma, and several other types of cancer and is sold as a single-dose vial.[4]

17. Avastin is sometimes used "off-label" in patients with wet AMD.[5] Avastin received its first FDA approval on February 26, 2004, for treatment for metastatic colorectal cancer.[6]

[4] Exhibit 2259 ("Highlights of Prescribing Information – Avastin," *Genentech*, https://www.gene.com/download/pdf/avastin_prescribing.pdf.)

[5] Exhibit 2260 ("Comparison of Anti VEGF Treatments for Wet AMD," *American Academy of Ophthalmology*, February 3, 2020, https://www.aao.org/eye-health/diseases/avastin-eylea-lucentis-difference); Exhibit 2261 ("Age-Related Macular Degeneration: Facts & Figures," *BrightFocus Foundation*, https://www.brightfocus.org/macular/article/age-related-macular-facts-figures).

[6] Exhibit 2262 ("FDA Approves Avastin," *Drugs*.com, February 2004, https://www.drugs.com/newdrugs/avastin-approved-metastatic-colorectal-cancer-21.html).

ii. Lucentis

18. Lucentis (ranibizumab), manufactured by Genentech, is a VEGF inhibitor indicated for the treatment of patients with wet AMD, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization and is sold as a single-dose vial or a single-dose PFS.[7]

19. Lucentis is made by Genentech in collaboration with Novartis.[8] In June 2003, Genentech entered into an agreement with Novartis, under which Novartis licensed the exclusive right to develop and market Lucentis outside of North America for indications related to diseases of the eye.[9] Novartis paid an upfront milestone payment and R&D related fees during the development of the

[7] Exhibit 2125 ("Highlights of Prescribing Information – Lucentis," *Genentech*, https://www.gene.com/download/pdf/lucentis_prescribing.pdf).

[8] Exhibit 2264 ("Investor Update," *Roche*, March 22, 2018, https://www.roche.com/investors/updates/inv-update-2018-03-22.htm).

[9] Exhibit 2265.007 (Genentech, Inc. 10-K for the year ended December 31, 2003, p. 6, https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k_2003.htm); Exhibit 2123 (NOVITC(CH)00007283-394).

drug, and continues to pay royalties on net sales of Lucentis products outside of North America, which Genentech manufactures and supplies to Novartis.[10]

20. Lucentis received FDA approval for treatment of wet AMD on June 30, 2006.[11] The FDA approved the Lucentis 0.5 mg PFS as a new method of administering the medicine on October 14, 2016.[12] Genentech's first sales of the Lucentis PFS began in January 2017.[13] On March 21, 2018, the FDA approved the

[10] Exhibit 2265.007 (Genentech, Inc. 10-K for the year ended December 31, 2003, p. 6, https://www.sec.gov/Archives/edgar/data/318771/000031877104000002/dna-10k_2003.htm); Exhibit 2123 (NOVITC(CH)00007283-394).

[11] Exhibit 2266 ("FDA Approves Lucentis (ranibizumab) for the Treatment of Wet Age-Related Macular Degeneration," *Drugs.com,* June 30, 2006, https://www.drugs.com/newdrugs/fda-approves-lucentis-ranibizumab-wet-age-related-macular-degeneration-327.html).

[12] Exhibit 2116 ("FDA Approves Genentech's Lucentis (ranibizumab) Prefilled Syringe," *Drugs.com,* October 14, 2016, https://www.drugs.com/newdrugs/fda-approves-genentech-s-lucentis-ranibizumab-prefilled-syringe-4444.html); Exhibit 2166.009 (NOVITC(US)00389194-205 at 202).

[13] Exhibit 2099 (GENEITC_1207-0000030).

Lucentis 0.3 mg PFS.[14] As of March 2018, PFS options were approved for all Lucentis indications.[15]

iii. Eylea

21. Eylea (aflibercept), manufactured by Regeneron, is a VEGF inhibitor indicated for treatment of patients with wet AMD, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy and is sold as a single-dose vial or a single-dose PFS.[16]

[14] Exhibit 2117 ("FDA Approves Lucentis (ranibizumab injection) 0.3 mg Prefilled Syringe for Diabetic Macular Edema and Diabetic Retinopathy," *Genentech*, March 21, 2018, https://www.gene.com/media/press-releases/14708/2018-03-21/fda-approves-genentechs-lucentis-ranibiz).

[15] Exhibit 2267 ("FDA Approves Lucentis (ranibizumab injection) 0.3 mg Prefilled Syringe for Diabetic Macular Edema and Diabetic Retinopathy," *Roche*, March 22, 2018, https://www.roche.com/investors/updates/inv-update-2018-03-22.htm).

[16] Exhibit 2197 ("Highlights of Prescribing Information – Eylea," *Regeneron*, https://www.regeneron.com/sites/default/files/EYLEA_FPI.pdf).

22. Eylea received FDA approval in a vial presentation on November 18, 2011, for treatment of wet AMD.[17] The FDA approved an Eylea 2.0 mg PFS on August 13, 2019.[18]

B. Market Transition from Vials to Prefilled Syringes

23. Intravitreal injections of anti-VEGF medications play an increasingly important role in the treatment of several retinal vascular diseases.[19] Initially, anti-

[17] Exhibit 2269 ("FDA Approves Eylea," *Drugs.com*, November 18, 2011, https://www.drugs.com/newdrugs/fda-approves-eylea-wet-age-related-macular-degeneration-2955.html).

[18] Exhibit 2270 ("FDA Approves Eylea® (aflibercept) Injection Prefilled Syringe," *Regeneron*, August 13, 2019, https://investor.regeneron.com/news-releases/news-release-details/fda-approves-eylear-aflibercept-injection-prefilled-syringe).

[19] Exhibit 2018 ("Prefilled syringes for intravitreal drug delivery," *National Center for Biotechnology Information*, April 23, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6485318/); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶ 81).

VEGF medications came in vials that had to be drawn up by the physician into a syringe for administration.[20]

24. A prefilled syringe, or PFS, is packaged in a single use, sealed sterile tray, which allows physicians to eliminate a number of steps in the preparation and administration of the anti-VEGF injection.[21] The use of prefilled syringes offers certain advantages over vials including reduced injection time, possible reduced risk of endophthalmitis, reduction in intraocular air bubble and silicone oil droplets, and improved precision in the volume and dose of the intravitreal drug administered.[22] Chris Simms, then the vice president of the U.S. Ophthalmics

[20] Exhibit 2018 ("Prefilled syringes for intravitreal drug delivery," *National Center for Biotechnology Information*, April 23, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6485318/).

[21] Exhibit 2018 ("Prefilled syringes for intravitreal drug delivery," *National Center for Biotechnology Information*, April 23, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6485318/); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶ 88).

[22] Exhibit 2018 ("Prefilled syringes for intravitreal drug delivery," *National Center for Biotechnology Information*, April 23, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6485318/); Exhibit 2271

franchise at Novartis, testified that the PFS is easier to use than the vial and requires fewer steps to prepare the drug for administration.[23] Mr. Simms also stated that the prefilled syringe is preferable over the vial format for customers.[24]

25. Since 2012, there have been three FDA approvals for PFS as a new method of administering anti-VEGF medicines: Genentech's Lucentis 0.5 mg PFS in October 2016, Genentech's Lucentis 0.3 mg PFS in March 2018, and Regeneron's Eylea 2.0 mg PFS in August 2019.[25]

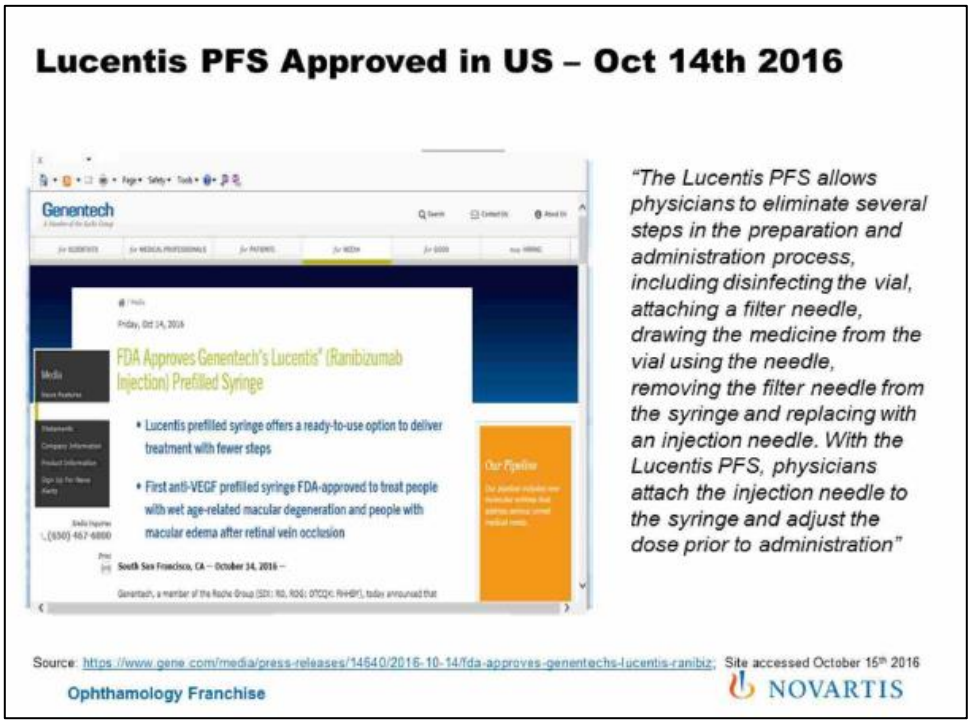
("Prefilled Syringe Delivery of Intravitreal Anti-VEGF Medications," *RetinalPhysician.com*, March 1, 2019, https://www.retinalphysician.com/issues/2019/march-2019/prefilled-syringe-delivery-of-intravitreal-anti-ve); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶ 105 n. 68).

[23] Exhibit 2272.011-.012 (Deposition of Christopher Simms, December 4, 2020, pp. 73-74).

[24] Exhibit 2272.010 (Deposition of Christopher Simms, December 4, 2020, p. 26).

[25] Exhibit 2015 ("FDA Approves Genentech's Lucentis (ranibizumab) Prefilled Syringe," *Drugs.com*, October 14, 2016, https://www.drugs.com/newdrugs/fda-approves-genentech-s-lucentis-ranibizumab-prefilled-syringe-4444.html); Exhibit 2267 ("FDA Approves Lucentis (ranibizumab injection) 0.3 mg Prefilled Syringe

Figure 2: Benefits of Lucentis PFS[26]



for Diabetic Macular Edema and Diabetic Retinopathy," *Roche*, March 22, 2018, https://www.roche.com/investors/updates/inv-update-2018-03-22.htm); Exhibit 2270 ("FDA Approves Eylea® (aflibercept) Injection Prefilled Syringe," Regeneron, August 13, 2019, https://investor.regeneron.com/news-releases/news-release-details/fda-approves-eylear-aflibercept-injection-prefilled-syringe).

[26] Exhibit 2166.009 (NOVITC(US)00389194-205 at 202).

V. THE ’631 PATENT

26. The ’631 Patent, titled “Syringe,” issued on December 29, 2015.[27] The application for the ’631 Patent was filed on January 25, 2013. The abstract of the patent reads as follows:

> *The present invention relates to a syringe, particularly to a small volume syringe such as a syringe suitable for ophthalmic injections.*

27. I understand that Mr. Karl R. Leinsing, expert witness for Novartis regarding syringe design, has opined that the ’631 Patent is directed to the invention of a terminally-sterilized small-volume PFS for intravitreal injection of a VEGF antagonist, which includes low levels of silicone oil while maintaining low injection forces.[28] The ’631 Patent also enabled terminal sterilization of a PFS suitable for intravitreal injection through improvements to prior art syringe designs.[29]

28. The ’631 Patent has a single independent claim and twenty-five dependent claims. Independent claim 1 reads as follows:[30]

[27] Exhibit 1001.001 (U.S. Patent No. 9,220,631, p. 1).

[28] Exhibit 2001 (Declaration of Karl R. Leinsing, PE, ¶ 23).

[29] Exhibit 2001 (Declaration of Karl R. Leinsing, PE, ¶ 26).

[30] Exhibit 1001 at 19:2-13 (U.S. Patent No. 9,220,631, c. 19:2-13).

1. A pre-filled, terminally sterilized syringe for intravitreal injection, the syringe comprising a glass body forming a barrel, a stopper and a plunger and containing an ophthalmic solution which comprises a VEGF-antagonist, wherein:

(a) the syringe has a nominal maximum fill volume of between about 0.5 ml and about 1 ml,

(b) the syringe barrel comprises from about 1 μg to 100 ug silicone oil,

(c) the VEGF antagonist solution comprises no more than 2 particles >50 μm in diameter per ml and wherein the syringe has a stopper break loose force of less than about 11N.

29. In describing the background art and the need that the invention addressed, the '631 Patent provides the following:[31]

Many medicaments are delivered to a patient in a syringe from which the user can dispense the medicament. If medicament is delivered to a patient in a syringe it is often to enable the patient, or a caregiver, to inject the medicament. It is important for patient safety and medicament integrity that the syringe and the contents of that syringe are sufficiently sterile to

[31] Exhibit 1001 at 1:11-43 (U.S. Patent No. 9,220,631, c. 1:11-43).

avoid infection, or other, risks for patients. Sterilisation can be achieved by terminal sterilisation in which the assembled product, typically already in its associated packaging, is sterilised using heat or a sterilising gas.

For small volume syringes, for example those for injections into the eye in which it is intended that about 0.1 ml or less of liquid is to be injected the sterilisation can pose difficulties that are not necessarily associated with larger syringes. Changes in pressure, internal or external to the syringe, can cause parts of the syringe to move unpredictably, which may alter sealing characteristics and potentially compromise sterility. Incorrect handling of the syringe can also pose risks to product sterility.

Furthermore, certain therapeutics such as biologic molecules are particularly sensitive to sterilisation, be it cold gas sterilisation, thermal sterilisation, or irradiation. Thus, a careful balancing act is required to ensure that while a suitable level of sterilisation is carried out, the syringe remains suitably sealed, such that the therapeutic is not compromised. Of course, the syringe must also remain easy to use, in that the force required to depress the plunger to administer the medicament must not be too high.

There is therefore a need for a new syringe construct which provides a robust seal for its content, but which maintains ease of use.

30. In generally describing the invention, the '631 Patent states:[32]

The present invention provides a pre-filled syringe, the syringe comprising a body, a stopper and a plunger, the body comprising an outlet at an outlet end and the stopper being arranged within the body such that a front surface of the stopper and the body define a variable volume chamber from which a fluid can be expelled though the outlet, the plunger comprising a plunger contact surface at a first end and a rod extending between the plunger contact surface and a rear portion, the plunger contact surface arranged to contact the stopper, such that the plunger can be used to force the stopper towards the outlet end of the body, reducing the volume of the variable volume chamber, characterised in that the fluid comprises an ophthalmic solution. In one embodiment, the ophthalmic solution comprises a VEGF-antagonist.

In one embodiment, the syringe is suitable for ophthalmic injections, more particularly intravitreal injections, and as such has a suitably small volume. The syringe may also be silicone oil free, or substantially silicone oil free, or may comprise a low level of silicone oil as lubricant. In one

[32] Exhibit 1001 at 1:47-68 (U.S. Patent No. 9,220,631, c. 1:47-68).

embodiment, despite the low silicone oil level, the stopper break loose and slide force is less than 20N.

VI. LEGAL PRINCIPLES

31. I am not an attorney and I will offer no opinions on the law. I have, however, been instructed by Counsel regarding the following legal principles related to my opinions. Based on these instructions, I have developed and applied the following understandings in arriving at the opinions and conclusions in this Declaration. The legal principles I have employed are set out below.

32. I understand the determination of whether or not an invention is obvious is a legal conclusion based on underlying factual inquiries including objective indicia of non-obviousness. Objective indicia of non-obviousness are sometimes referred to as "secondary considerations of non-obviousness." I understand that it is not permissible to use hindsight in determining whether or not a patent was obvious as of the relevant date, and that a judge will consider the existence of secondary considerations of non-obviousness, in order to mitigate the possible impact of hindsight in an obviousness analysis. Two examples of secondary considerations of non-obviousness include: 1) the commercial success of products incorporating the claimed technology and 2) licensing.

33. I have been asked to evaluate the commercial success of the Lucentis PFS, a product incorporating the '631 Patent. I understand that commercial

success may be established by looking to the patented products of a patentee or licensee, as well as infringing products. Further, I understand that commercial success is relevant regardless of whether it takes place within the United States. Finally, I understand that independently, licenses granted under a patent, including those resulting from settlement of litigation, can also support a finding of non-obviousness.

34. In evaluating the commercial success of a patented product for the purposes of considering non-obviousness, I understand that courts often look to a standard of "significant sales in a relevant market." While there may not be a strict quantitative test to determine what constitutes "significant sales in a relevant market," I understand that commercial success should be shown in a market context rather than simply a recounting of a company's sales.

35. I also understand courts have indicated that, in order to demonstrate commercial success, the patentee must show a factually sufficient connection, or nexus, between the patented invention and the product's commercial success. In demonstrating nexus, the patentee is not necessarily required to demonstrate that its claimed inventions are "solely responsible" for commercial success of its products. Additionally, I understand that nexus is presumed to exist if the commercially successful product is coextensive with the invention disclosed and claimed in the patent.

VII. SECONDARY CONSIDERATIONS SUPPORTING THE NON-OBVIOUSNESS OF THE '631 PATENT

A. Commercial Success

36. As discussed above, I understand that commercial success may be established by looking to the patented products of a patentee or licensee, as well as infringing products. I also understand that Regeneron's expert witness, Mr. Horst Koller, concludes that "the evidence does not show a nexus between the alleged commercial success of Lucentis PFS and the claims in the '631 Patent."[33] I disagree with Mr. Koller's conclusion for the reasons that follow.

37. I understand that the first product sold in the U.S. that practices the '631 Patent was the Lucentis PFS, sold by Genentech, a licensee to the '631

[33] Exhibit 1003.197 (Declaration of Horst Koller, April 16, 2021, p. 192).

Patent.[34] The FDA approved the Lucentis PFS on October 14, 2016,[35] while Genentech's first sales of the Lucentis PFS began in January 2017.[36]

38. As seen in the following figure, by early 2018, Novartis recognized that Lucentis PFS "[redacted]" in total Lucentis sales twelve months after launch.[37]

[34] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶¶ 117 n. 14, 167); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶¶ 51-54).

[35] Exhibit 2015 ("FDA Approves Genentech's Lucentis (ranibizumab) Prefilled Syringe," *Drugs.com*, October 14, 2016, https://www.drugs.com/newdrugs/fda-approves-genentech-s-lucentis-ranibizumab-prefilled-syringe-4444.html).

[36] Exhibit 2099 (GENEITC_1207-0000030).

[37] Exhibit 2170 (NOVITC(US)00507243).

Figure 3: Lucentis Sales Impact from PFS Launch[38]

39. This positive impact on sales is even more apparent when Lucentis' longer sales trends are considered. Lucentis vial sales had generally increased from 2010 through 2014,[39] apart from a decrease in 2012 "due to the entry of a competitor drug to treat wAMD and CRVO."[40] I understand this new competitor to be Regeneron's Eylea, which received FDA approval on November 18, 2011,

[38] Exhibit 2170 (NOVITC(US)00507243).

[39] Appendix 2.1.

[40] Exhibit 2274 ("Finance Report for 2012," *Roche*, p. 14, https://www.roche.com/dam/jcr:13c45df4-9cf6-4545-a23d-874d398aa788/en/fb12e.pdf).

for treatment of wet AMD.[41] Beginning in 2015 Lucentis vial sales began to decline. In 2015, Roche attributed this decline to "strong competition."[42] In 2016, Roche again attributed the continuing decline in Lucentis sales to "competitive pressure."[43] However, in 2017, Lucentis sales "increased by 1% in the US, mainly driven by the launch of prefilled syringes" and growth in new indications.[44] In 2018, Lucentis sales generated more substantial growth when "Lucentis sales increased by 18% due to the ongoing rollout of prefilled syringes, with increased

[41] Exhibit 2269 ("FDA Approves Eylea," *Drugs.com*, November 18, 2011, https://www.drugs.com/newdrugs/fda-approves-eylea-wet-age-related-macular-degeneration-2955.html).

[42] Exhibit 2275 ("Finance Report for 2015," *Roche*, pp. 5, 13, https://www.roche.com/dam/jcr:74af99eb-b51a-4f13-88b2-aacaf9f53c0c/en/fb15e.pdf).

[43] Exhibit 2161 ("Finance Report for 2016," *Roche*, pp. 5, 13, https://www.roche.com/dam/jcr:6ddcec16-c658-48b2-82b5-4ed426c14ac8/en/fb16e.pdf).

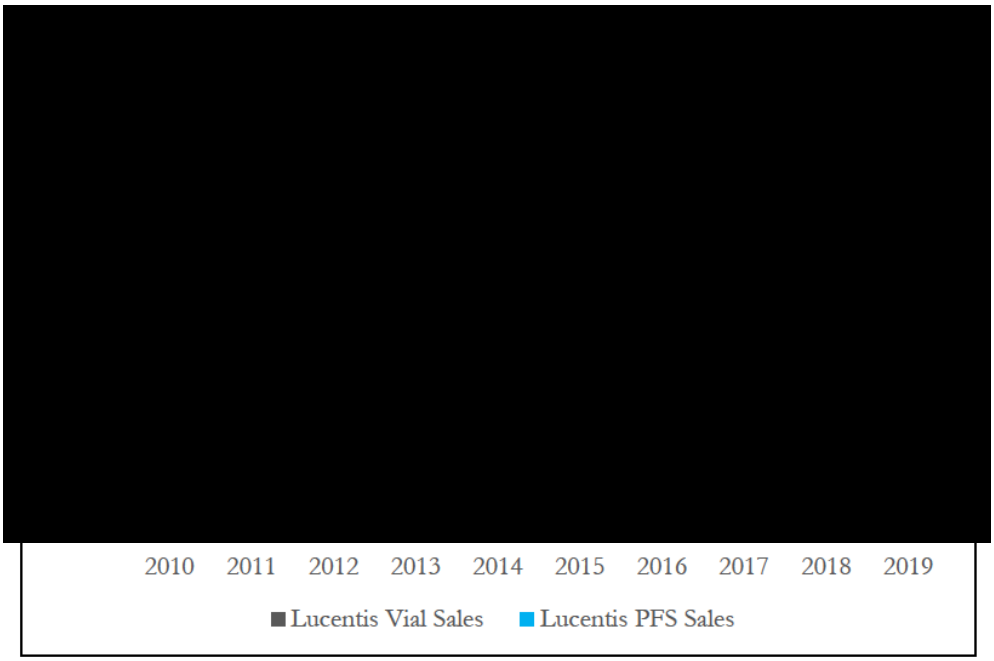
[44] Exhibit 2276 ("Finance Report for 2017," *Roche*, p. 15, https://www.roche.com/dam/jcr:b70415c0-954f-4a2a-a0e2-47f94bd280e0/en/fb17e.pdf).

market share in all approved indications."[45] In 2019, the growth trend continued as "sales grew 8% driven by increased market share across all indications and the ongoing rollout of prefilled syringes."[46] As seen in the figure below, Genentech's launch of the Lucentis PFS enabled it to transition from declining annual sales to increasing annual sales.

[45] Exhibit 2162 ("Finance Report for 2018," *Roche*, p. 15, https://www.roche.com/dam/jcr:933329c4-4564-4b17-a29b-246ac7e617d5/en/fb18e.pdf); Exhibit 2167 (NOVITC(US)00394737-792 at 750).

[46] Exhibit 2163 ("Finance Report for 2019," *Roche*, p. 15, https://www.roche.com/dam/jcr:1e6cfce4-2333-4ed6-b98a-f6b62809221d/en/fb19e.pdf).

Figure 4: Genentech U.S. Lucentis Sales, 2010 - 2019[47]



40. Additionally, as seen in the figure above, Lucentis PFS quickly replaced Lucentis vial sales, thereby both replacing the vial product and generating more sales revenue than had been previously realized with the vial product.[48] By September 2020, [redacted].[49]

41. As seen in the following figures, various Novartis internal models of the wet AMD market in the United States indicate that starting in 2017, with the

[47] Appendix 2.1.

[48] Appendix 2.1.

[49] Exhibit 2099 (GENEITC_1207-0000030).

launch of the Lucentis PFS, the patient share of Lucentis ended a multi-year decline to stabilize or increase, depending on the model.

Figure 5: Lucentis Wet AMD Patient Share Stabilizes, 2010 – 2019[50]

[50] Exhibit 2169 (NOVITC(US)00395565, tab "USA_wAMD"). Patient share data starting around cell F1127.

Figure 6: Lucentis Wet AMD Patient Share Increases, 2010 – 2019[51]

42. Similarly, Novartis internal documents indicate that the launch of Lucentis PFS "helped differentiate Lucentis thereby minimizing [market share] erosion due to competition," as seen in the following figure.[52]

[51] Exhibit 2168 (NOVITC(US)00395564, tab "USA_wAMD"). Patient share data starting around cell F1127.

[52] Exhibit 2166.007 (NOVITC(US)00389194-205 at 200).

Figure 7: Impact of Lucentis PFS Launch on Market Share Erosion in Europe[53]

43. The demand for the Lucentis drug molecule itself cannot explain this commercial success, because Lucentis is the *same molecule* as a PFS relative to a vial. In other words, the increase in demand for Lucentis PFS versus the Lucentis vial is not attributable to the drug molecule, because the molecule is unchanged in the PFS and vial.[54]

[53] Exhibit 2166.007 (NOVITC(US)00389194-205 at 200).

[54] Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶ 57).

44. Regarding nexus, I understand that Lucentis PFS practices the ’631 Patent.[55] Additionally, I understand that “[t]he ’631 patent is directed to the invention of a terminally-sterilized small-volume pre-filled syringe (“PFS”) for intravitreal injection of a VEGF antagonist, which includes low levels of silicone oil while maintaining low injection forces.”[56] The ’631 patent also enabled terminal sterilization of a PFS suitable for intravitreal injection through improvements to prior art syringe designs.[57] I understand that the ’631 Patent is critical to the Lucentis PFS and that, along with any patents protecting the active pharmacological ingredients for each product, would be among the most important contributions to the success of the products.[58]

B. Licensing

45. As discussed above, I understand that independently, licenses granted under a patent can also support a finding of non-obviousness.

[55] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶¶ 166-285).

[56] Exhibit 2001 (Declaration of Karl Leinsing, PE, ¶ 23).

[57] Exhibit 2001 (Declaration of Karl Leinsing, PE, ¶ 26).

[58] Exhibit 2204 (Declaration of Andrew F. Calman, Ph.D., ¶ 112).

46. I understand that the first product sold in the U.S. that practices the ’631 Patent was the Lucentis PFS, sold by Genentech, a licensee to the ’631 Patent.[59]

47. I have reviewed the declarations of Novartis’s experts Karl Leinsing and Michael Miller, which describe Genentech’s failed attempt to develop its own Lucentis PFS.[60] I understand that, prior to licensing the ’631 Patent from Novartis, Genentech put forth considerable continuous efforts toward the development of a PFS presentation for Lucentis, over the course of at least six or seven years, but opted to first launch Lucentis in a vial form and never successfully developed a PFS, due to technical challenges.[61]

[59] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶¶ 117 n. 14, 167); Exhibit 2204 (Declaration of Andrew Calman, Ph.D., ¶¶ 51-54).

[60] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, pp. 91–94, 102-106); Exhibit 2203.0035-0038 (Declaration of Michael Miller, Ph.D., pp. 32-35).

[61] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶¶ 156-158); Exhibit 2203.0035-0038 (Declaration of Michael Miller, Ph.D., pp. 32-35).

48. After failure to develop its own Lucentis PFS, Genentech was able to obtain FDA approval for, and bring to the United States market, a Lucentis PFS in 2016, but only after licensing the '631 Patent.[62]

49. David Overcashier, principal engineer and senior manager at Genentech, testified that the Lucentis PFS presentation that is on the market was

[62] Exhibit 2116 ("FDA Approves Genentech's Lucentis® (Ranibizumab Injection) Prefilled Syringe," *Genentech*, October 14, 2016, https://www.gene.com/media/press-releases/14640/2016-10-14/fda-approves-genentechs-lucentis-ranibiz). *See also* Exhibit 2123 (NOVITC(CH)00007283-394); Exhibit 2124 (NOVITC(CH)00008409-414); Exhibit 2121 (NOVITC(CH)00005765-787); Exhibit 2119 (NOVITC(CH)00003455-526); Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶ 167). The license to Genentech included two groups of patents, indicted by "Novartis Reference" numbers "PAT055157" and "PAT055146." One of the patent applications listed under Novartis Reference PAT055157 is "Filing Number" 13/750352, filed January 25, 2013, which is the application that issued as the '631 patent. *See* Exhibit 2121 (NOVITC(CH)00005765-787) at Exhibit D ("PFS Patents"); Exhibit 1001 (U.S. Patent No. 9,220,631); Exhibit 2206.0019-0020 (Declaration of Juergen Sigg, Ph.D., pp. 18-19).

[redacted].[63]

50. Regarding nexus, I understand that Karl Leinsing has opined that the Lucentis PFS practices and is co-extensive with the claimed invention of the ’631 Patent.[64] Additionally, I understand that “[t]he ’631 patent is directed to the invention of a terminally-sterilized small-volume PFS for intravitreal injection of a VEGF antagonist, which includes low levels of silicone oil while maintaining low injection forces. The ’631 patent also enabled terminal sterilization of a PFS suitable for intravitreal injection through improvements to prior art syringe designs.”[65] I understand that the Lucentis PFS is co-extensive with certain claims of the ’631 Patent.[66]

51. As a result, there is a clear nexus between the ’631 Patent and the license between Novartis and Genentech, as the license would be required for Genentech to practice the ’631 Patent, which is embodied by the Lucentis PFS. Without the benefit of the license to the ’631 Patent, Genentech would be unable to

[63] Exhibit 2194 (Deposition of David Overcashier, December 9, 2020, pp. 33-34).

[64] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, pp. 107-147).

[65] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, ¶ 26).

[66] Exhibit 2201 (Supplemental Declaration of Karl Leinsing, PE, pp. 107-147).

practice the ’631 Patent and would thus be unable to manufacture and sell the Lucentis PFS, thereby foregoing the significant economic benefits of the commercially successful product, discussed above.

52. I am also aware that in January 2009 Novartis entered into a Development Agreement with Vetter Pharma International GmbH (“Vetter”) for work relating to the Lucentis PFS.[67] Per the Development Agreement, Vetter “may grant worldwide, non-exclusive, royalty-free, fully paid-up and non-transferable sub-licenses to any Existing Vetter Customers under the Novartis Ophthalmology PFS IP[.]”[68] I also understand that Bayer HealthCare AG (“Bayer”) is an Existing Vetter Customer,[69] and that Vetter has granted a sublicense to the Novartis patent family PAT055157, including all present and future applications, to Bayer, for Eylea PFS outside of the U.S.[70] It is my understanding that the ’631 Patent is a member of the Novartis patent family PAT055157.[71] Accordingly, Bayer’s

[67] Exhibit 2132 (NOVITC(CH)00170859-895).

[68] Exhibit 2133 (NOVITC(CH)00170896-909, § 2.3(b)).

[69] Exhibit 2134 (NOVITC(CH)00170915-033, § 2.2(d)(v)).

[70] Exhibit 2146 (NOVITC(CH)01863785-788).

[71] *See* Exhibit 1001 (U.S. Patent No. 9,220,631) (identifying foreign application priority data to EP 12174860); Exhibit 2146 (NOVITC(CH)01863785-788)

sublicense to Novartis's PFS technology specifically for Eylea PFS is additional evidence that supports a finding of non-obviousness.

VIII. DECLARATION

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

Dated: January 18, 2022 By: _____
James E. Malackowski

("[T]he Novartis Patent Family IP licensed by Novartis to Vetter Pharma International GmbH with the right to sublicense to Existing Vetter Customers consists of the Novartis patent family PAT055157…claiming priority from EP 12174860.2…, and includes all present and future applications, patents[.]").

Appendix 1

OCEAN TOMO®
INTELLECTUAL CAPITAL EQUITY®

January 18, 2022

JAMES E. MALACKOWSKI
CURRICULUM VITAE

James E. Malackowski is the Co-Founder and Chief Executive Officer of Ocean Tomo, LLC. Established in 2003, Ocean Tomo provides Financial Expert, Management Consulting, and Advisory services related to intellectual property (IP) and other intangible assets; corporate accounting investigations; regulatory and reporting obligations; solvency and restructuring; and contractual or competition disputes. Practice offerings address economic damage calculations and testimony; accounting investigations and financial forensics; technology and intangible asset valuation; strategy and risk management consulting; mergers and acquisitions; debt and equity private placement; and IP brokerage. Ocean Tomo assists clients – corporations, law firms, governments and institutional investors – in realizing Intellectual Capital Equity® value broadly defined. Subsidiaries of Ocean Tomo include Ocean Tomo Investments Group, LLC, a registered broker dealer, and Ocean Tomo International (HK) Ltd.

Mr. Malackowski is a founding and continuous member of the IP Hall of Fame Academy. He has been recognized annually since 2007 by leading industry publications as one of the 'World's Leading IP Strategists'. Significantly, Mr. Malackowski is listed among "50 Under 45" by *IP Law & Business*™; included in the *National Law Journal's* inaugural list of 50 Intellectual Property Trailblazers & Pioneers; and, named as one of "The Most Influential People in IP" by *Managing Intellectual Property*™. Mr. Malackowski was named as1 of 50 individuals, companies and institutions that framed the first 50 issues of *IAM Magazine* as well as 1 of 60 leading global Economics Expert Witnesses by the same publication in 2014. In 2011 Mr. Malackowski was selected by the World Economic Forum as one of less than twenty members of the Network of Global Agenda Councils to focus on questions of IP policy. In 2013 he was inducted into the Chicago Area Entrepreneurship Hall of Fame by the Institute for Entrepreneurial Studies at the University of Illinois at Chicago College of Business Administration. In 2018, Mr. Malackowski joined the Standards Development Organization Board of the Licensing Executives Society (USA & Canada), Inc. governing voluntary consensus-based professional practices that are guided in their development by the American National Standards Institute's (ANSI's) Essential Requirements. LES standards are designed to encourage and teach consensus practices in many of the business process aspects of intellectual capital management.

On more than fifty occasions, Mr. Malackowski has served as an expert in U.S. Federal Court, U.S. Bankruptcy Court, State Court, Court of Chancery, the Ontario Superior Court of Justice and global arbitrations on questions relating to intellectual property economics including the subject of valuation, reasonable royalty, lost profits, price erosion, commercial success, corrective advertising, creditor allocations, Hatch Waxman Act market exclusivity, business significance of licensing terms including RAND obligations, venture financing including expected risk / return, and equities of a potential injunction. Mr. Malackowski's experience extends to matters of general business valuation and commercial disputes, both domestic and foreign. Mr. Malackowski has publicly addressed policy issues affecting international trade and has provided expert opinions concerning antidumping and countervailing duties imposed by the U.S. Department of Commerce as well as testimony on domestic industry, bond, and remedies before the International Trade Commission.

Mr. Malackowski has substantial experience as a Board Director for leading technology corporations and research organizations as well as companies with critical brand management issues. He is Past President of The Licensing Executives Society International, Inc., with oversight for more than ten thousand members in thirty-two countries. Mr. Malackowski focuses his non-for-profit efforts with organizations leveraging

science and innovation for the benefit of children and students, including those located in lesser developed countries. He has served since 2002 as a Trustee or Director of the National Inventors Hall of Fame, Inc., an organization providing summer enrichment programs for more than 100,000 students annually. For more than ten years Mr. Malackowski served as a Director of Chicago's Stanley Manne Children's Research Institute, advancing the organization's agenda to measure and report the impact of its pediatric research. He currently services on the Advisory Board of the Pritzker School of Molecular Engineering at the University of Chicago.

Mr. Malackowski is a frequent speaker on emerging technology markets and related financial measures. He has addressed mass media audiences including Bloomberg Morning Call, Bloomberg Evening Market Pulse, Bloomberg Final Word, CNBC Closing Bell, CNBC On the Money, CNBC Street Signs, CNBC World Wide Exchange, CBS News Radio and Fox Business National Television as well as other recognized news-based internet video channels. Mr. Malackowski is a current or past judge for the Illinois Technology Association's CityLIGHTS™ Innovation Awards program, the University of Notre Dame McCloskey Venture Competition, 1st Source Faculty Commercialization Awards, and PBS's *Everyday Edisons*.

As an inventor, Mr. Malackowski has more than twenty issued U.S. patents. He is a frequent instructor for graduate studies on IP management and markets and a Summa Cum Laude graduate of the University of Notre Dame majoring in accountancy and philosophy. Mr. Malackowski is Certified/Accredited in Financial Forensics, Business Valuation and Blockchain Fundamentals. He is a Certified Licensing Professional and a Registered Certified Public Accountant in the State of Illinois. Mr. Malackowski has been certified to receive United States Sensitive Security Information (SSI) as governed by Title 49 Code of Federal Regulations.

EMPLOYMENT HISTORY

Co-Founder and Chief Executive Officer, *Ocean Tomo, LLC,* July 1, 2003 to present. Mr. Malackowski is responsible for all aspects of the firm's merchant banking practice. Mr. Malackowski was the Chairman and majority owner of Ocean Tomo, LLC until its sale to Bow River Capital in April of 2020.

President and Chief Executive Officer, *IP Equity Management, LLC,* doing business as Duff & Phelps Capital Partners, March 1, 2002 to June 30, 2003. The firm's intellectual property structured finance efforts were consolidated with Ocean Tomo on July 1, 2003.

Principal and Founder, *VIGIC Services, LLC*, July 1, 2000 to February 28, 2002. Mr. Malackowski identified and evaluated intellectual capital based private equity investment opportunities and served as an advisor to four completed transactions.

Principal and co-Founder, *IPC Group LLC*, August 1, 1988 – June 30, 2000. Mr. Malackowski also held the offices of President and CEO and was a Board member / chairman of the firm. Along with four co-founders, Mr. Malackowski grew IPC Group to become the largest professional services firm specializing in intellectual property valuation and strategy consulting. IPC Group was sold in 1999 later changing its name to InteCap.

Executive Consultant, *Peterson & Co. Consulting*, Chicago, June 3, 1985 – July 30, 1988. Mr. Malackowski began with Peterson as a Staff Consultant and was the firm's quickest promotion to both Senior Consultant and Executive

Consultant. Mr. Malackowski helped to establish the firm's intellectual property litigation and valuation practice. Peterson & Co. was sold to Saatchi & Saatchi PLC in 1988.

NON-PROFIT AND ASSOCIATION EXPERIENCE

Mr. Malackowski has been active in The Licensing Executives Society (LES) locally, nationally and internationally. LES is the premiere global professional association of technology transfer and intellectual asset management professionals with more than 9,000 members in more than 32 countries.

Mr. Malackowski is Past President of the Licensing Executives Society International, LLC, where his experience included the following positions:

- Director, LES Standards Development Organization (2018 – present)
- Chair, Past President's Council (2012 – 2013)
- President and Member of the Board (2011 - 2012)
- President Elect and Member of the Board (2010 - 2011)
- Secretary and Member of the Board (2007 - 2010)
- Member and Permanent Alternate, Board of Delegates (1992 - 2005)
- Past Chair, Membership, Investment, Education, Long-range Planning and Global Technology Impact Forum Committees.

Mr. Malackowski's term as President of LESI has been recognized for creation of the LESI Global Technology Impact Forum and concurrent Invent For Humanity™ Technology Transfer Exchange Fair; formalizing the National Presidents' Council; establishing the position of a permanent Executive Director; and, restructuring the leadership of LESI committees utilizing a Chair, Past Chair, Chair Elect ladder combined with functional responsibilities for committee Vice Chairs. This later organizational stamp is based largely on Mr. Malackowski's experience as President of LES USA & Canada described below where he led a restructuring of the Board from a regional to a functional focus for each officer and Trustee. As with his tenure at his national Society discussed below, Mr. Malackowski led a financial turn-around returning LESI to positive cash flow following its' only two years of loss.

Mr. Malackowski is also Past President of The Licensing Executives Society (USA and Canada), Inc. where he held numerous offices in the organization including:

- President and Member of the Board (2001 – 2002)
- International Vice President and Member of the Board (2000)
- Treasurer and Member of the Board (1996 -- 1999)
- Trustee and Member of the Board (1992 – 1996)
- Chair, Annual Meeting in Miami Beach (1998) and the Summer Meeting in Chicago (1997)

Mr. Malackowski presided over a restructuring of the LES USA & Canada Board and a financial turn-around returning the organization to positive cash flow following its only two years of loss to such date. Mr. Malackowski is the

youngest President to hold office at LES USA & Canada as well as at LES International.

In 2007, Mr. Malackowski was the Founding Chair of the Board of Governors for what is now Certified Licensing Professionals, Inc., administrator of the Certified Licensing Professional (CLP) program for professionals in the fields of licensing, business development and commercialization of intellectual property. More than 1,000 individuals involved in patenting, marketing, valuation, IP law, negotiation, and intellectual asset management have earned the CLP certification. CLP, Inc. is a 501(c)(6) organization whose mission is to elevate the licensing profession through knowledge and standards.

In 2018 Mr. Malackowski joined the Standards Development Organization Board of LES USA & Canada. LES standards are voluntary consensus-based professional practices that are guided in their development by the "American National Standards Institute's (ANSI's) Essential Requirements." ANSI is the unique accrediting agency in the United States for voluntary consensus standards development organizations. LES is an accredited ANSI Standards Developer and as such guarantees its constituents that its standards will be developed in a fair, balanced, consensus-based, due process driven way. LES standards are designed to encourage and teach consensus practices in many of the business process aspects of intellectual capital management and, where appropriate, offer enterprises the opportunity to differentiate themselves based on their use of these consensus professional practices, through certification of conformance to those standards.

Mr. Malackowski extends significant time to non-profit activities directed towards a further understanding of the economic importance of innovation and intellectual property, in both the United States and developing economies. These efforts include:

- Founding Board Member and member of the Executive Committee, United Stages Intellectual Property Alliance (USIPA), (2020 -)
- Judge, University of Notre Dame McCloskey Venture Competition (2019 -)
- Advisory Board, University of Chicago, Pritzker School of Molecular Engineering (2018 -)
- Judge, Illinois Technology Association, CityLIGHTS™ Innovation Awards (2013 -)
- Member, World Economic Forum Network of Global Agenda Councils (2011 - 2012)
- Director, International Intellectual Property Institute, Washington D.C., (2002 - 2007)
- Resident Advisor, U.S. Information Agency, (1999)
- Resident Advisor, U.S. Department of Commerce Commercial Law and Development Program (1997)
- Founder and Chairman, The Center for Applied Innovation, Inc. (2004 -)

In addition to his University instruction described herein, Mr. Malackowski focuses his non-for-profit efforts with those organizations leveraging science and innovation for the benefit of children.

- Director, Children's Research Fund (2013); Co-Chair Annual Fund Campaign (2013)
- Director, National Inventors Hall of Fame, Inc. (NIHF) including service as a Member, Trustee or Director of related subsidiaries and Board Committees (2001 - 2019). The NIHF provides summer enrichment programs for more than 160,000 students annually including Camp Invention™ for kids in grades 1-6 (and their parents and teachers); Collegiate Inventors Competition™ for college students (and their mentors); and, Club Invention™ for kids in grades 1-6 (and their parents and teachers). NIHF provides more than 20,000 camp scholarships annually for children in financial need.
- President's Council, Chicago Museum of Science and Industry (2005 - 2011) including participation on the Education Advisory Committee (2007 - 2009) and the Alternative Revenue Committee (2008 - 2011)
- Director, Stanley Manne Children's Research Institute (2009 - 2020) including Chair of the Board's Technology Transfer Committee (2014 - 2020) and the Strategic Planning Resources Committee (2011 - 2012). Mr. Malackowski is recognized for initiating the development of a program to measure and track innovation metrics relevant to the Institute.

Mr. Malackowski was the Founder of the Center for Applied Innovation, a Chicago based non-for-profit with both local and international programs. CAI was created to manage education, public policy outreach and related economic activity around applied technology and intellectual property (IP) rights in the State of Illinois and around the world.

- CAI created and patented the first commoditized contract for technology licensing, the Unit License Right™. This innovation has been licensed to the Chicago-based Intellectual Property Exchange International.
- Under Mr. Malackowski's continued leadership as Chairman, CAI organizes the Invent for Humanity™ Technology Transfer Exchange Fair (InventforHumanity.org) launched in January, 2012, in Geneva, Switzerland. Invent for Humanity showcases field-ready, sustainable innovations, known as "appropriate technologies", leveraging the experience of licensing professionals to match and structure the actual transfer of such technology to meet recognized needs of emerging market economies.

Mr. Malackowski's association and non-profit activities are informed in part by his participation in the Harvard Business School Executive Education Program on Governing for Nonprofit Excellence, November 2000. Mr. Malackowski's Board service is informed by his participation at the Rock Center Corporate Governance Directors College for Venture-Backed Company Directors, Stanford University, March 2016.

RELATED OFFICES

Berg, LLC, Member, Council of Advisors, Senior Advisor, Intellectual Property Licensing & Innovation (2012 - 2015)

The Copyright Hub, LLC d/b/a 3Discovered, Founder. The company was formed as a collaborative venture between Ocean Tomo, LLC and Liberty Advisor Group in 2013. 3Discovered is a current portfolio company of US-based venture capital firm AITV. Mr. Malackowski served as Chairman of the company through September 2016. (2103 – 2106)

Curious Networks, Inc., Director, (1999 - 2000), Co-Chair of the Board's Strategic Partnership Committee. Mr. Malackowski led the company's first and second round of venture funding.

ewireless, Inc. (f/k/a JEMAN Holdings, Inc. d/b/a Cellular Linking), Director, (1995-1999, 2000-2002)

Ford Global Technologies, Inc., Ford Motor Company, Director (1997 - 2001). Mr. Malackowski advised Ford Motor Company on the original business strategy which led to the formation of FGTI. FGTI was the largest known technology management company in the United States during Mr. Malackowski's term.

Infocast, Corporation (OTC BB: IFCC.OB), Director (2001-2002). Member of the Audit and Compensation Committees. Mr. Malackowski led the transition of the company's senior management team and continued U.S. based funding efforts.

Insignis, Inc., Director (2000 - 2002) Mr. Malackowski led the company's first round of venture funding. Insignis is a Chicago based provider of institutional financial data services.

The Intellectual Property Coin Group, Inc., Chairman and Co-Founder (2018 -). The company is a planned Ethereum based blockchain platform and related cryptocurrency designed to facilitate IP based transactions. See www.IPcoinGroup.com.

The Intellectual Property Exchange International, Inc. Mr. Malackowski was the founder of the company guiding initial product development of IPXI and recruitment of executive management. In 2011, IPXI was funded by an industry consortium including the Chicago Board Options Exchange. Mr. Malackowski was the Chair or Co-Chair of the Exchange from inception to February 26, 2015.

JEMAN Technologies, Inc., Founder. (1995 – 1999). Mr. Malackowski led the company's efforts to develop new technologies related to wireless direct response services. JEMAN was sold to ewireless, Inc. in 1999 as part of a venture transaction funded by Bedrock Capital Partners and Tredegar Investments.

Silent-Yachts, GmbH. Member, Advisory Board (2021 -). Mr. Malackowski provides general business advice to both the company's chief executive as well as its U.S. distributor of solar-electric catamarans. Silent-Yachts is located in Magdalensberg, Kärnten, Austria.

Solutionary, Inc., Director (2000 - 2013). Arranged and advised on Solutionary's asset acquisition of S3Networks effective August 31, 2001 and

sale to strategic buyer in 2013. Member of the Board's Compensation Committee.

Sendle, Pty, Advisor (2012 - 2015). See www.Sendle.com.

EDUCATION AND CERTIFICATION

University of Notre Dame, B.B.A., Bachelor of Business Administration with majors in Accountancy and Philosophy. Graduated Summa Cum Laude, 1985.

Registered Certified Public Accountant, State of Illinois Certificate Number 41,187 issued January 16, 1986; License No. 239.007831; Expires September 24, 2022.

Certified Licensing Professional, Certificate Number 1606 issued July 1, 2008; Recertification through November 29, 2022.

Certified in Financial Forensics, CFF™, American Institute of Certified Public Accountants, Certificate Number 391 issued July 31, 2008; Expires July 31, 2022.

Accredited in Business Valuation, ABV™, American Institute of Certified Public Accountants, Certificate Number 4278 issued May 31, 2014; Expires July 31, 2022.

Accredited in Blockchain Fundamentals for Accounting and Finance Professionals, American Institute of Certified Public Accountants, Certificate Number 15860970, 2018 - 2020.

UNIVERSITY INSTRUCTION

John Marshall Law School, Intellectual Property Damages (1992 - 1994)

DePaul University, Intellectual Property Entrepreneurial Finance (2003)

The George Washington University Law School, Intellectual Property Management (2004)

The University of Chicago Graduate School of Business:

- Intellectual Property Investment (2004 - 2006)
- Entrepreneurial Discovery, MBA Course 34705, Adjunct Professors Mark Tebbe and Brian Coe (Fall 2014 - 2015)

Indiana University Kelly School of Business, Intellectual Property Finance (2005)

University of Notre Dame, Mendoza College of Business, Adjunct Instructor:

- MBA Interterm Intensives, Intellectual Property Based Market Transactions, Valuation and Trading (Fall 2006, Fall 2008)

- MBA Executive Program, Course MBAE 70639, Intellectual Property, (Spring Semester 2008)
- MBA Program, Litigation Support and Valuation (Spring 2009)
- Notre Dame Law School, Advanced Trial Advocacy, LAW 75713-10 (Spring 2017)
- Member, Venture Builder Community Advisory Board (2019 -)

University of California at Berkeley Haas School of Business, Innovation Markets (2008)

Chicago-Kent College of Law, Adjunct Professor of Law, IP Financial Markets and Legal Principles (Fall 2008)

Rutgers Professional Science Master's Program, Fundamentals of Intellectual Property (Summer 2011)

Northwestern University Kellogg School of Management, Adjunct Instructor:

- MGMT 441, Intellectual Property Management, Clinical Professor James G. Conley (Fall 2012, Spring 2013 - 2017)
- DSGN 460, Innovation in Context, McCormick Engineering School (Spring 2017)

University of Texas McCombs School of Business, MBA Course: Open Innovation, Professor Sirkka Jarvenpaa (Spring 2013)

University of Arizona, James E. Rogers College of Law, Advisor, Intellectual Property & Entrepreneurship Clinic (2017 -)

- IP Valuation (Spring 2017)
- IP Valuation for Commercial Transactions (Spring 2019)

University of Southern California, Lloyd Greif Center for Entrepreneurial Studies at the Marshall School of Business, Entrepreneurs Guide to Intellectual Property, Professor Luke L. Dauchot, JFF 322 (Fall 2017)

MEMBERSHIPS

American Institute of Certified Public Accountants, Member 01182237 (1985 -)
The Economic Club of Chicago (1990 - 2019)
The Licensing Executives Society (1988 -)
Young Presidents' Organization ("YPO" / "YPO Gold" Chicago Chapter, 2006 – 2017) (Mid-America U.S. At Large Chapter, 2019 - 2021)

RECOGNITION AND AWARDS

Individually, Mr. Malackowski has been recognized for his expertise as well as his work in developing markets for intellectual property transfer including:

- *EY Entrepreneur Of The Year*®, Regional Semifinalist (2019 and 2020)
- "IAM Global Leaders", *IAM Magazine* (2020)

- "IAM Patent 1000: The World's Leading Patent Professionals", *IAM Magazine* (2015-2021)
- Named to the *National Law Journal's* inaugural list of 50 Intellectual Property Trailblazers & Pioneers. (August 2014)
- Named as 1 of 60 leading global Economics Expert Witnesses in the *IAM Patent 1000, IAM Magazine.* Selection based on interviews by IAM researchers with more than 100 patent litigators. (May 2014)
- Inductee, Chicago Area Entrepreneurship Hall of Fame as selected by the Institute for Entrepreneurial Studies at the University of Illinois at Chicago College of Business Administration, (2013; 28th Year of Program)
- Named as 1 of 50 Individuals, Companies and Institutions that Framed the First 50 Issues of *IAM Magazine*, November / December 2011.
- "IP Personalities of 2008", *IAM blog* by Joff Wild, Editor
- "IAM Strategy 300: The World's Leading IP Strategists", *IAM Magazine* (2012-2021); formally presented and included as "World's 250 Leading IP Strategists", *IAM Magazine* (2009-2011)
- "50 Under 45", *IP Law & Business*™ (2008)
- "The Most Influential People in IP", *Managing Intellectual Property*™ (2007)
- Member, IP Hall of Fame Academy (2007-)

Ocean Tomo as a firm has been likewise recognized for its accomplishments including:

- Ocean Tomo was chosen as the exclusive U.S. representative for the 2016 Healthcare & Pharma Leading Expert Awards by *Global Health & Pharma Magazine*.
- Ocean Tomo was recognized as a member of the *2015 Inc.5000*® list of fastest-growing private companies in America.
- Ocean Tomo was honored in 2011 with the "Best of Chicago Award in Investment Advisory Services" by the U.S. Commerce Association (USCA).
- In addition to Mr. Malackowski, Ocean Tomo as a firm was named as 1 of 50 Individuals, Companies and Institutions that Framed the First 50 Issues of *IAM Magazine*, November / December 2011 and the only firm other than Microsoft (2 of 50 mentions) to be recognized multiple times (5 of 50 mentions).
- The firm's Chicago office was presented the *2011 Alfred P. Sloan Awards for Business Excellence in Workplace Flexibility* after having been finalist for scoring in the top 20% of all firm's measured nationally.
- Ocean Tomo was recognized in 2010 by Corporate Voices for Working Families for its work-life balance as part of the National Workplace Flexibility Campaign published by *USA Today*.
- Ocean Tomo was recognized as a juried Finalist for the Illinois Technology Association 2010 CityLIGHTS Award for raising the stature of the Illinois technology industry.
- Selected as case study organization for Haas School of Business, University of California, Berkeley (2009)
- Selected as case study organization for Harvard Business School MBA Program (2008)

- Ocean Tomo was named one of 20 small and mid-sized firms recognized as the "Best Places to Work in Illinois" by Best Companies Group in a competition sponsored by the Illinois Chamber of Commerce and the Illinois State Council Society for Human Resource (2007)
- Ocean Tomo Auctions received the 2006 Chicago Innovation Award for most innovative new product or service introduced between January 1, 2005, and July 31, 2006, that uniquely satisfied unmet needs in the marketplace. The award was presented by Kuczmarski & Associates and the *Chicago Sun-Times*.
- Ocean Tomo Auctions was awarded the Department of Commerce Technology Administration & National Knowledge & Intellectual Property Management 2006 Innovator of the Year Award.
- Ocean Tomo was recognized as a "Top Ten IP Newsmakers of 2006" by *IP Law & Business*, Almanac 2006.

Numerous authors and graduate business programs have written case studies about Ocean Tomo and its affiliates including:

- Piscione, Deborah Perry, The Risk Factor, Copyright 2014.
- Houle, David, Entering the Shift Age, Copyright 2013.
- Kuczmarski, Thomas D., Dan Miller and Luke Tanen, Innovating Chicago-Style: How Local Innovators Are Building The National Economy, Copyright 2012.
- Houle, David, The Shift Age, Copyright 2007.
- Chesbrough, Henry, Open Business Models: How to Thrive in the New Innovation Landscape, Copyright 2006.
- Harvard Business School Case Study
- University of California Business School Case Study

RELATED U.S. SPEECHES AND PUBLICATIONS

"The Determination of a Reasonable Royalty: Hypothetical Negotiation v. A General License Agreement", The Licensing Executives Society, Chicago Chapter, December 8, 1987.

"The Business Economics of Technology Development", The Licensing Executives Society, New England Chapter, February 9, 1988.

"The Importance of Protecting Intellectual Property Through Corporate Transition", Licensing Executives Society, National Meeting, October 18, 1989, Moderator.

"Valuation of Intellectual Property Rights", The Chicago Bar Association, March 6, 1990.

"Dispute Resolution -- There Are Alternatives!", Licensing Executives Society, National Meeting, October 22, 1990.

"How to Value a License", Adding to the Bottomline Through Licensing, LES / John Marshall Law School, November 1, 1990.

"An Advanced Discussion on Licensing and Patent Damages", Licensing Executives Society, National Meeting, October 28, 1992.

"An Advanced Discussion on Patent Damages", Licensing Executives Society, National Meeting, October 18, 1993.

Royalty Provisions in Technology License Agreements, Technology Transfers, American Conference Institute, November 15 & 16, 1993.

"Commercializing Technology and the Intellectual Property Quality Management Imperative", Technology Transfer, American Conference Institute, June 20 & 21, 1994.

"How to Accurately Value Software", The Software Protection and Litigation Institute, July 28 & 29, 1994.

"IP Damages Advanced Case Studies", Licensing Executives Society, National Meeting, October 19, 1994.

"Preparation and Presentation of Damages by Outside Consultants", AIPLA Mid-Winter Meeting, February 1, 1995

"Damages Discovery - An Expert's Perspective", Intellectual Property Law Association, New York, December 15, 1995.

"Pre-Litigation Damages Techniques: Patents and More", The Intellectual Property Strategist, March, 1996.

"Corporate Exposures to Copyright, Patent, Trademark, and Trade Secret Claims", Digital Bullets - Digital Shields: A Financial Perspective, American Conference Institute, New York, March 5, 1996.

"IP Management and Taxation - How companies are proactively managing IP assets to maximize shareholder value, including measuring contribution of IP protection to corporate value", American Bar Association, Virginia, April 11, 1996.

"Effectively Select & Use Experts in Trademark & Copyright Cases", AIPLA Spring Meeting, Boston, May 1, 1996.

"The Industry-University Interface: Mechanisms For Technology Transfer", 1996 AUTM Central Region / Licensing Executives Society Chicago Chapter, Chicago, July 21, 1996.

"Valuing Health Care Technologies", Licensing Executives Society Winter Meeting, South Carolina, March 13, 1997.

"Creative Marketing & Packaging - How to Differentiate Yourself in a Competitive Market", CTIA Annual Meeting, Atlanta, February 23, 1998.

"Intellectual Property Valuation: The Latest Techniques from Boardroom and Courtroom", Patent Law Association of South Florida Annual Meeting, Fort Lauderdale, October 22, 1998.

"The Aftermath of *Rite-Hite v. Kelly*", 16th Judicial Conference of the U.S. Court of Appeals for the Federal Circuit, Washington D.C., April 6, 1999.

"Expert Admissibility After Daubert", Wisconsin Academy of Trial Lawyers, Milwaukee, December 3, 1999.

"Intellectual Property Strategic Planning: a Corporate Perspective", Research Directors Association of Chicago, Winter Meeting, January 10, 2000.

"Intellectual Property Asset Management: Linking IP and Corporate Strategy", 44th Annual Conference on Developments in Intellectual Property Law, John Marshall Law School, Chicago, February 25, 2000.

"Boost Your Client's Intellectual Capital IQ: Get Top Management Involved", Corporate Legal Times, October 2000, p. 104.

"Strategic and Financial Opportunities for Privately Held and Public Middle Market Companies: Building Shareholder Value", The Standard Club, Chicago, October 5, 2000.

"Commercializing Intellectual Capital Through Venture Funding", LESI Expanded Board of Directors Meeting and Seminar, Delray Beach, Florida, January 26, 2001; LES Chicago Meeting, May 10, 2001.

"New Paths to Growth: Joint Ventures and Accessing Equity Capital", Panel Presentation and Discussion, LaSalle Street Project Economic Summit, Chicago, May 10, 2001.

ViewPoints, The Newsletter of the Licensing Executives Society (U.S.A. and Canada), Inc., President's Column: Vol. VIII No. 5, Nov. / Dec. 2001, "President Changes the Way LES Does Business"; Vol. VIV No. 1, Jan. / Feb. 2002, "It's Time To Count Our Intellectual Assets"; Vol. VIV No. 2; Vol. VIV No. 3, May / June 2002, "Mid-Year Review"; Vol. VIV No. 4, July / August 2002, "Ethical Issues Related To Intellectual Property".

"Venture Investment Grounded In Intellectual Capital", From Ideas To Assets: Investing Wisely in Intellectual Property, Edited by Bruce Berman, John Wiley & Sons, Inc., 2002.

"Current Issues in Accounting for Intangibles", Congressional Economic Leadership Institute, Panel Presentation and Discussion with Steven H. Wallman, Former Commissioner, United States Securities and Exchange Commission, Washington, DC, May 1, 2002.

"Intellectual Capital Based Corporate Carve-outs: Strategy, Structure and Funding", James E. Malackowski and Suzanne Harrison, The LESI Guide to Licensing Best Practices, Edited by Robert Goldscheider, John Wiley & Sons, Inc., 2002.

"Intellectual Property Finance: Securitization to Venture Capital", American Bar Association Intellectual Property Law Conference, Philadelphia, June 28, 2002.

"The IIPI Roundtable: The New Emphasis on Patent Value – Opportunities and Challenges", Washington DC, July 22, 2002.

"Moving Technology from University to Marketplace: Business Creation and the Venture Capital Community, Licensing Executives Society Annual Conference, Chicago, September 24, 2002.

"Presidents' Forum on Intellectual Property: A Leadership Discussion with The Licensing Executives Society, the American Intellectual Property Law Association, the Association of University Technology Managers, the Intellectual Property Owners Association, The National Inventors Hall of Fame, and BIO", Licensing Executives Society Annual Conference, Chicago, September 24, 2002.

"Extracting Value From Your Intellectual Asset Portfolio: Ensuring ROI from IP and Technology Assets", World Research Group, November 22, 2002, Chicago, Illinois.

"Licensing", American Intellectual Property Law Association 2003 Mid-Winter Institute, Marco Island, Florida, January 22 – 25, 2003.

"Cashing in on Chicago: A Closer Look at Liquidity in the Heartland", The Executives' Club of Chicago, Panel Discussion, February 11, 2003.

Conference Chair and Speaker, "Optimizing Valuation & Value Realization of your IP/Intellectual Assets", World Research Group, Las Vegas, February 27-28, 2003.

Live Webcast, "Turning Your Intellectual Property into Cash", Ernst & Young Business Insights, April 28, 2003.

Intermediate PDS Workshop: Application of Private Equity and Leveraged Finance Investing to Intellectual Property, LES / AUTM Summer Meeting, Philadelphia, May 8, 2003.

World Research Group, Advanced Intellectual Property Structured Finance, Conference Co-Chair Person, New York City, June 29-30, 2003.

The Conference Board, The 2003 Conference on Intellectual Asset Management & Value Reporting, "Application of Private Equity and Leveraged Finance Investing to Intellectual Property", Chicago, June 4, 2003.

Intellectual Property and Information Technology for Investment Funds, "Intellectual Capital Equity Management", Panel Discussion Sponsored by Schulte Roth & Zabel, New York City, June 18, 2003.

Chicago Capital Access Forum III, "Private Investors: The Case for Domestic Emerging Market Investments", Panel Discussion, Chicago, June 26, 2003.

Pension Consultants' Forum, "Extracting Value from Private Equity Investing", World Research Group, Chicago, July 22, 2003.

Midwest Intellectual Property Institute, "Intellectual Capital Equity Management", Minneapolis, September 19, 2003.

"Intellectual Asset Strategies", Add-On Seminar at the 2003 Licensing Executives Society Annual Meeting, San Diego, September 25, 2003.

"Leveraging Intellectual Property", Keynote Speaker, Thomson Financial Thought Leadership Forum, New York, October 8, 2003.

"Beyond Licensing: Innovative Techniques for Extracting Value", Advanced Forum on Licensing Intellectual Property, San Francisco, December 9, 2003.

Intellectual Asset Management, *Column: IP Merchant Banker*, Douglas R. Elliott & James E. Malackowski, Issue 01, "Challenges of the Fifth Epoch", July / August 2003; Issue 02, "What the Market Fortells", September / October 2003; Issue 03, "Economics, Ethos and Intellectual Ethics", December / January 2004; Issue 04, "Patent Predictions – facts or fictions?", February / March 2004; "Wealth management in the age of patents", June / July 2004; "Patent pools – the 80% solution", August / September 2004.

"Intellectual Capital Equity Management: IP as an Asset Class", Minnesota State Bar Association Continuing Legal Education, Minneapolis, January 15-16, 2004.

"Understanding the Motivations Behind an IP Structured Finance Transaction", "Analyzing the Anatomy of A Patent-Based Structured Finance Transaction", World Research Group, New York, January 21-22, 2004.

"Managing Your Intellectual Property", Investment Banking for Women / Minority Owned Business Enterprises, Annual Forum, Conference Co-Chairperson, Chicago, March 3-5, 2004.

"Private Equity: Investor Capital for Mature Businesses", Dream*Makers* Forum 2004, Santa Barbara, California, March 7 – 10, 2004.

"IP Finance: Convergence of IP Valuation and Value Creation", World Research Group 2nd Annual Strategies and Solutions for Optimizing IP Valuation & Value Creation, Chicago, March 23 – 24, 2004.

"Leveraging the Value of Intellectual Property", Creating, Managing & Valuing an Intellectual Property Portfolio, Vedder Price Conference Series, Chicago, April 28, 2004.

"Federal Circuit Damages Decision Emphasizes the Importance of Sound Economic Models", IP Review, McDermott Will & Emery, with Robert M. Hess, Spring 2004.

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"Intellectual Property Financing and Securitization: Conclusions and Future Implications for Financing the IP Market", New York, New York, July 21, 2004.

"Emerging Financial Concepts in IP Asset Management", Mining Patent Portfolios, Seattle, Washington, September 13, 2004.

"Intellectual Property Investment", National Institutes of Health, Commercialization Assistance Program, Larta Institute, Chicago, November 12, 2004.

"Using Intellectual Property to Grow", The Beacon, Chicagoland Entrepreneurial Center, Volume 3, Issue 4, December 10, 2004.

"Techniques for Assessing the Value of Your IP Portfolio", The Wall Street Transcript Intellectual Property Conference, New York, January 27, 2005.

"The Tipping Point: Assessing Major Challenges and Growth Opportunities in IP Finance", Moderator, The 3rd Annual Advancing IP Structured Finance World Research Group Conference", New York, February 3, 2005.

"Commerce One IP Auction", Optimizing IP Valuation and Value Creation, World Research Group Conference, Miami, March 30-31, 2005.

"Intellectual Capital Equity Management: IP As An Asset Class", Minnesota Continuing Legal Education Conference, Minneapolis, May 12, 2005.

"Techniques for Evaluating IP Potential", Life for After Rembrandts, Law Seminars International, Chicago, Illinois, August 4, 2005.

Keynote Address, 2nd Annual Intellectual Property Financing and Securitization Summit, New York, September 26, 2005.

"The Power of Intellectual Property in Private Equity Deals", Association for Corporate Growth and The Licensing Executives Society Connecticut Chapters, Greenwich, Connecticut, October 6, 2005.

"Maximizing the Value of Distressed Debt Backed by Intellectual Property", Financial Research Associates Distressed Debt Summit 2005, New York, October 7, 2005.

"To Sell or Not to Sell", Licensing in the Boardroom 2005, a supplement to *Intellectual Asset Management* magazine, 2005.

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"Risky Business: Overlooking Patents as Financial Assets", Making Innovation Pay, Edited by Bruce Berman, Published by John Wiley & Sons, Inc., 2006.

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"Generating Revenue From Your Inventions", IIR 2nd Annual Summit on IP Rights for Financial Services, New York, April 25-26, 2006.

"A Behind the Scenes Look at the Patent Bazaar: How Companies and Industry Are Buying and Selling Patents", Innovators in IP Litigation, IP Law & Business, San Jose, California, May 17, 2006.

"Patent Markets and Their Impact to R&D Strategy", Industrial Research Institute Annual Meeting, May 21-24, 2006, Colorado.

USC Gould School of Law 2006 Intellectual Property Institute; Featured Speaker, "A Final Word"; Panelist, "Patent Trolls: The Good, the Bad and the Ugly"; May 23, 2006, Los Angeles.

"Patent Auctions: Past, Present & Future", The 50th Annual Conference on Developments in Intellectual Property Law, John Marshall Law School Center for Intellectual Property Law, May 25-26, 2006, Chicago. Speech published as "The Intellectual Property Marketplace: Past, Present and Future", 5 J. Marshall Rev. of Intell. Prop. L. 605, (2006)

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Innovative Structures for Acquiring Intellectual Property: The Benefits, Challenges and Process, LSI Law Seminars International, Program Co-Chair, July 17, 2006, Chicago.

"Licensing and Intellectual Property", Chicago Regional Independent Inventor's Conference, Presented by the United States Patent and Trademark Office, Northwestern University School of Law, and the National Inventors Hall of Fame Foundation, July 28-29, 2006, Chicago.

"Reinventing the IP Marketplace – The Exclusive Ocean Tomo Patent Auction Case Study", IP Licensing Summit: Practical Strategies to Maximize Revenue in Today's Challenging Intellectual Property Marketplace, August 21-23, 2006, New York.

"Unlocking the Value of Intellectual Property Rights", Conference of the International Bar Association, September 20, 2006, Chicago.

"This Too Shall Pass", Americas IP Focus 2006, Managing Intellectual Property Rights, Copyright, Euromoney Institutional Investor, PLC, 2006.

"Developing Markets for Intellectual Assets and Technology", 21st Annual Intellectual Assets and Technology Law Institute, October 5 & 6, 2006, Irving, Texas.

"Patent Damages" and "Patent Reform Efforts: An Update and Review", The Sedona Conference Patent Litigation VII, October 12-13, 2006, Sedona, Arizona.

"Patent Auctions", 44th Annual Intellectual Property Law Conference, The Center for American and International Law, November 9-10, 2006, Plano, Texas.

"The Future of Developing IP Markets", 3rd Annual Monetization of Intellectual Property & Intangible Assets, Strategic Research Institute, November 16-17, 2006, Boston.

"The IP Transactional Landscape", Economics of IP Based Transactions, National Knowledge & Intellectual Property Management Taskforce Series Program, November 29-30, 2006, Washington, D.C.

Keynote Presentation, The Business of Intellectual Property Conference, Tech Council of Maryland, Rockville, Maryland, January 10, 2007.

Luncheon Speaker, Corporate Intellectual Property Roundtable, Georgia State University College of Law, Atlanta, January 24, 2007.

"Patent Markets", American Intellectual Property Law Association, 2007 Mid-Winter Institute, New Orleans, January 24-27, 2007.

"Assessing the Real Value of Your IP Portfolio" and "Growing IP Impact on Public and Semi-Public Markets", The 5th Annual Summit on Monetizing, Financing & Securitizing IP, New York, January 30-31, 2007.

"Ocean's 300", Moderator, World Intellectual Property Review 2007, pp. 16-20.

"The Intellectual Property Marketplace: Emerging Transaction and Investment Vehicles", Co-author with Cardoza, Gray and Conroy, *The Licensing Journal*, Aspen Publishers, Vol. 27, No. 2, pages 1 - 11, February 2007.

"The Importance of Emerging Intellectual Property Market Opportunities to the City of Chicago", Keynote Speaker, Notre Dame Club of Chicago Meeting, Chicago, March 8, 2007.

"The Intellectual Property Marketplace", Harvard Business School Club of New York, New York, April 12, 2007.

Keynote Address, BRICs & Mortar: Technological Drivers in Booming Economies of Brazil, Russia, India and China, Northwestern University Journal

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"Innovation Measurement: The Economic Impact of Patent Value", Co-author with Barney, Cardoza, Walker and Gray, Submission to United States Department of Commerce Economics and Statistics Administration, Pursuant to Notice in the Federal Register, Vol. 72, No. 71, 18627, May 11, 2007.

"Objective Patent Valuation", Business Meeting, Association of Corporate Patent Counsel, Newport, Rhode Island, June 27, 2007.

"Intellectual Property Exchange Chicago", a two day symposium presented by The National Knowledge & Intellectual Property Management Taskforce and The Center for Applied Innovation, Moderator and Speaker, July 17 – 18, 2007, Chicago.

"Start-up Stories: Tales from the Front Line", TiE Midwest, August 1, 2007, Chicago.

Keynote Address, Notre Dame Financial Executives Alumni Conference, September 21, 2007, South Bend, Indiana.

"The Birth of an IP Marketplace", Missouri Bar Association Seminar, November 2, 2007, St. Louis, Missouri.

"Market Forces and IP", The Giles S. Rich American Inn of Court, Howard University, January 17, 2008.

"Market for Technology: Challenges and Opportunities", Panel Discussion on Impediments to Technology Markets, Duke University's Fuqua School of Business, February 20, 2008.

"IP Markets – An Intangible Walk Down Wall Street", Keynote Address, Securities Industry and Financial Markets Association, March 11, 2008, New York.

"Patent Valuation, Is there One or Many?", Mini-Plenary Session of the High Tech Sector, The Licensing Executives Society International Annual Meeting, May 7, 2008, Chicago.

"What is Patent Quality – A Merchant Banc's Perspective", with Jonathan A. Barney, *les Nouvelles*, June 2008, p. 123 – 134.

"Intangibles in the Firm and Financial Markets", *Intangible Assets: Measuring and Enhancing Their Contribution to Corporate Value and Economic Growth*, The National Academies, Washington DC, June 23, 2008.

"Developing IP Markets: Opportunity for the Financial Services Industry", Keynote Address, The 5th Annual Patents & The Financial Services Industry Symposium, New York, July 29, 2008.

"New Trends in Monetizing IP Rights: Trolls, Licensing and Securitization", *Managing Intellectual Property* Webinar, September 3, 2008.

"Magnificent Mile – Shopping for the Ideal IP Expert", DRI Intellectual Property Litigation Seminar, September 4-5, 2008, Chicago.

From Assets to Profits: Competing for IP Value and Return, Contributing Author, Edited by Bruce Berman, John Wiley & Sons, November 2008.

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"Helping Companies in a Down Economy: Strategic Planning for Identifying and Valuing Your IP", American Bar Association Annual Meeting, Chicago, July 31, 2009.

"Managing IP During Uncertain Times", NanoBusiness Alliance Conference, Chicago, September 8, 2010.

National Economic Framework for Intellectual Property Based Commerce, A Research Report by the National Knowledge & Intellectual Property Management Taskforce, Net Worth Press, 2009.

"The Role of IP in Tough Economic Times and How to Use it to Your Advantage: Corporate Recovery and Restructuring", Licensing Executives Society Annual Meeting, San Francisco, October 19, 2009.

"Global IP Market Development", 11th Annual Utah IP Summit, Salt Lake City, February 13, 2010.

"Law, Economics, Business and Policy Implications for Innovation and Competition of Diverse Business Models for Using Patents", Stanford University Hoover Institution Annual Conference, Stanford, California, June 25, 2010.

"Establishing an Objective Value of IP", IPO Annual Meeting, Atlanta, September 14, 2010.

"Intellectual Property and the Marketplace: Hot Topics Impacting the Role of Patents, Trademarks and Copyrights in Today's Business World", Vedder Price Illinois Continuing Legal Education Forum, Chicago, October 6, 2010.

"IP Essentials for the Chief Executive Officer", Illinois Technology Association, Chairman's Dinner Keynote Speaker, Chicago, October 20, 2010.

"Valuation of IP in Emerging Market Platforms", 2010 IP Damages Institute, CalCPA Education Foundation, Los Angeles, November 8, 2010.

"Shifting Sands: What is Discoverable and Admissible for Damages, Willfulness and Other Purposes", Intellectual Property Owners Association CLE Roundtable, Washington, DC, March 21, 2011.

"Intellectual Property: From Asset to Asset Class", Intellectual Property Strategies for the 21st Century Corporation, Bryer, Lebson & Asbell Editors, John Wiley & Sons, Inc., 2011.

"The Next Big Think in Monetizing IP: A Natural Progression to Exchange-Traded Units", Ian D. McClure co-author, *LANDSLIDE*, A Publication of the ABA Section of Intellectual Property Law, Volume 3, Number 5, May/June 2011, pp. 32-37.

"Risk Management Strategies to Defend Against Patent Trolls and the New Trend in Patent Royalty Trusts", 2011 Congress on Patent Strategies for the Financial Services Industry, New York, September 19-20, 2011.

"Patent Quality and its Impact on Valuation", Licensing Executives Society United States and Canada, Inc., Annual Meeting, San Diego, October 17, 2011.

Introduction, "LESI Global Technology Impact Forum (GTIF) Creates Tech Transfer Platform", *les Nouvelles*, Journal of the Licensing Executives Society International, Volume XLVII No. 2, June 2012.

Panelist, "IP Monetization", McDermott Will & Emery 2012 Intellectual Property Symposium, Chicago, June 14, 2012.

Keynote Address, Northwestern Law Fifth Annual Conference on Entrepreneurship and Innovation, Chicago, June 14, 2012.

"IP Market Development", 38th Annual Intellectual Property Law Summer Institute, Sponsored by the Intellectual Property Law Section of the State Bar of Michigan, Traverse City, Michigan, July 21, 2012.

"An Investors' Perspective on IP", CenterForce IP Strategy Summit, New York City, New York, November 13, 2012.

"Investing in IP", DealFlow Media Webinar, January 10, 2013.

"Evolving IP Marketplace", American Intellectual Property Law Association, Mid-Winter Meeting, Tampa, Florida, February 1, 2013. Includes paper:

New Emphasis on the Analytical Approach of Apportionment In Determination of a Reasonable Royalty by James E. Malackowski, Justin Lewis and Robert Mazur.

"An Inventor's Walk Down Wall Street", PatCon 3 at Illinois Institute of Technology Chicago-Kent School of Law, Chicago, April 12, 2013.

Report on Judge Rader Comments at the 2013 LESI Annual Conference, LES Global News, Vol. XLVIII No. 2, June 2013.

"Strategic Insights", Plenary Panel Discussion, IPBC 2013, IP Business Congress, Boston, June 9, 2013.

"IP and Antitrust", Panel Discussion, McDermott 2013 IP Symposium, June 13, 2013, Chicago.

IP Investments and Markets Presented by the Center for Applied Innovation, Panelist on IP Marketplace, Chicago, June 25-26, 2013.

Capturing Innovation, Irish Entrepreneurs: An Affiliate Group of the Notre Dame Club of Chicago, Chicago, September 5, 2013.

Preventing the Napsterization of 3D Printing: Areas for Industry Collaboration and Transparency, Inside 3D Printing Conference and Expo, San Jose, California, September 18, 2013.

The Latest Thinking about Non-Practicing Entities, 2013 AIPLA Annual Meeting, Washington, DC, October 25, 2013.

Challenges and Opportunities in Asia, Think Asia, Think Hong Kong: IP, Technology & China/U.S. Opportunities, The Hong Kong Business Association of the Midwest, Chicago, November 19, 2013.

Rationalizing Remedies, The 2013 Patent Institute presented by Cravath Swain & Moore, New York, December 5, 2013.

Special Address: Looking to the Future of the Intellectual Property Marketplace – Where Will We Be in 2020?, Best Practices in Patent Monetization, Law Seminars International, San Francisco, March 6-7, 2014.

Reinventing Finance: Funding Innovation Beyond Silicon Valley, Forbes Reinventing America Summit, Chicago, March 27-28, 2014.

IP Pricing – Current Issues for Markets and Courts, Georgia State University / Licensing Executives Society Joint Meeting, Atlanta, May 28, 2014.

The Growing Global 3DP IP Market & How Much Is At Stake, 3D Printing Politics, Washington D.C., September 17, 2014.

The Changing Role of the Expert, 2014 IP Institute presented by the Engleberg Center on Innovation Law & Policy at New York University and Cravath, Swaine & Moore, LLP, New York, December 4, 2104.

"Intellectual Property Exchange", Dallas Chapter Meeting of the Licensing Executives Society (USA & Canada), Inc., Dallas, January 22, 2015.

"Actavis, Valuation, and Fairness Opinions", 2015 Generic Pharmaceutical Association Annual Meeting, Miami, February 9-11, 2015.

Patent Damages Roundtable, USC Gould School of Law 2015 Intellectual Property Institute, Los Angeles, March 23, 2015.

"Intellectual Property Impact on M&A", Transaction Advisors Midwest Symposium, Chicago, September 17, 2015

"The Changing Landscape of Patent Value and Patent Risks", 2016 Berkeley Law / Cleary Gottlieb M&A-IP-Antitrust Conference, Berkeley Center for Law, Business and the Economy, San Francisco, January 29, 2016.

"Damages Experts on Evidence and Gatekeeping", The University of Texas School of Law Conference on Patent Damages, Austin, Texas, June 9-10, 2016.

"Investing In Innovation: Global Trends In Innovation and Sustainability", CFA Society of Chicago, Chicago, September 28, 2016.

IP Remedies Roundtable and Workshop, USC Gould School of Law 2017 Intellectual Property Institute, Los Angeles, March 20, 2017.

"Economic Tools Used for Damages Estimation", Panel Discussion, Intellectual Property Owners Association, Chicago, June 7, 2017.

"Quantitative Approaches to Determining FRAND Royalties", Intellectual Property Owners Association Annual Meeting, San Francisco, September 18, 2017.

"The Intersection of Intellectual Property, Blockchain and Cryptocurrency", Licensing Executives Society International Annual Conference, San Diego, April 30, 2018 – May 1, 2018.

"Best Practices and Useful Tools for Assessing the Value of Your Company's IP", American Intellectual Property Law Association 2018 Spring Meeting, May 15 - 17, 2018.

"Practical Blockchain", IDEA Week Innovation Festival, South Bend, Indiana, April 8, 2019.

"Blockchain Primer," Introductory Remarks by Hon. Kara F. Stoll, The Giles S. Rich American Inn of Court, Washington D.C., February 11, 2020.

Managing Your Intellectual Property, LESI Business Briefings, Series Co-author, May 2020.

"IP Transaction Ecosystem: An Update on Market Activity", LES USA & Canada, Inc., Greater Washington D.C. Chapter, September 9, 2021.

"Judicial Perspectives on Using Damages Specialty Experts", Intellectual Property Law Association of Chicago, Litigation Committee, September 15, 2021

"Global Patent Issues", Plenary Panel, University of Illinois Chicago 65th Annual IP Law Conference, UIC School of Law, Chicago, November 4, 2021.

INTERNATIONAL SPEECHES AND PUBLICATIONS

"Taxation Issues when Licensing with the U.S.", Licensing Executives Society International, South Africa Conference, January 28, 1996.

"Intellectual Property Damages: Advanced Case Studies", Licensing Executives Society Annual Meeting, Puerto Rico, September 30, 1996.

"License Agreement Royalty Audits: Untapped Riches Or Fool's Gold?", Licensing Executives Society Annual Meeting, Puerto Rico, October 1, 1996

"Valuation of IPR", Conference on Appeals Related to Intellectual Property, Bucharest, Romania, November 20, 1997.

"Avaliacao e Contabilizacao de Propriedade Intellectual – Metodologia e Aspectos Fiscais", XIX Seminario Nacional de Propriedade Intellectual, Rio de Janeiro, Brazil, August 16, 1999.

"Avaliacao e Contabilizacao de Propriedade Intelectual", Conferencia pela Consulate General of the United States of America, Sao Paolo, Brazil, August 18, 1999.

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"Due Diligence in an Intellectual Capital Focused Investment", LES Annual Conference Add-on Session, Toronto, September 14, 2000.

"What's New in Intellectual Property Asset Management", Panel Discussion, 8th Annual Intellectual Property Law Institute, State Bar of Georgia, Puerto Vallarta Mexico, November 15, 2002.

"Les brevets en tant qu'actifs economiques: comment les exploiter au mieux" and "Brevets et financement: couvrir les couts, trouver des investisseurs", Un

System Du Brevet Competitif Pour L'Europe, sponsored by the European Patent Office, Brussels, May 3-4, 2006.

"What is Patent Quality?", Co-author with Jonathan A. Barney, Paper Presented to the Colloquium on a Comprehensive Approach to Patent Quality, Federation Internationale Des Conseils En propriete Industrielle, Amsterdam, June 8-9, 2007.

"Fostering Innovation with Seed Money and Venture Capital", Licensing Executives Society International Annual Conference, Zurich, June 19, 2007.

"Legal Problems Arising from Auctioning of IPR", Bi-Annual International Forum, Association Internationale Pour La Protection De La Propriete Intellectuelle, October 6, 2007.

"IP Auctions", Plenary Address, The Licensing Executives Society Annual Meeting, October 16, 2007, Vancouver, Canada.

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Verinata Health, Inc. v. Ariosa Diagnostics, Inc.
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United States District Court for the Central District of California
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United States District Court for the Eastern District of Texas
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ZiiLabs Inc., Ltd. v. Samsung Electronics Co. Ltd (and related Samsung parties) and Apple Inc.
Case No. 2:14-cv-00203
United States District Court for the Eastern District of Texas Marshall Division
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In the Matter of Certain Robotic Floor Cleaning Devices and Components Thereof
Case No. 337-TA-1252
On behalf of the Respondents SharkNinja Operating LLC, SharkNinja Management LLC, SharkNinja Management Company, SharkNinja Sales Company, SharkNinja Hong Kong Co. Ltd., and EP Midco LLC
United States International Trade Commission
Deposition Testimony

PATENTS

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Appendix 2

Regeneron Pharmaceuticals, Inc., v. Novartis Pharma AG, et al.

SUMMARY OF LUCENTIS ANNUAL SALES IN CHF, 2010 - 2019 [1]

Appendix 2.1

(millions CHF)	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
Lucentis Product Sales	1,458	1,523	1,481	1,689	1,701	1,520	1,406	1,414	1,659	1,826
[2] % Change at Constant Exchange Rates		23%	-8%	15%	2%	-15%	-10%	1%	18%	8%
[3] Lucentis PFS Gross Sales as % of Total										
Lucentis Vial Sales										
Lucentis PFS Sales										

Notes:

[1] Exhibit 2273 ("Finance Report for 2011," Roche, p. 10, https://www.roche.com/dam/jcr:76319099-c4c4-4608-9977-ec25c6ca2a2c/en/fb11e.pdf);
Exhibit 2274 ("Finance Report for 2012," Roche, p. 11, https://www.roche.com/dam/jcr:13c45df4-9cf6-4545-a23d-874d398aa788/en/fb12e.pdf);
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Exhibit 2162 ("Finance Report for 2014," Roche, p. 12, https://www.roche.com/dam/jcr:9d9091a6-dfcc-4d57-8017-4a4cb5fa224c/en/fb14e.pdf);
Exhibit 2275 ("Finance Report for 2015," Roche, p. 11, https://www.roche.com/dam/jcr:74af99eb-b51a-4f13-88b2-aacaf9f53c0c/en/fb15e.pdf);
Exhibit 2161 ("Finance Report for 2016," Roche, p. 11, https://www.roche.com/dam/jcr:6ddcec16-c658-48b2-82b5-4ed426c14ac8/en/fb16e.pdf);
Exhibit 2276 ("Finance Report for 2017," Roche, p. 11, https://www.roche.com/dam/jcr:b70415c0-954f-4a2a-a0e2-47f94bd280e0/en/fb17e.pdf);
Exhibit 2016 ("Finance Report for 2018," Roche, p. 12, https://www.roche.com/dam/jcr:933329c4-4564-4b17-a29b-246ac7e617d5/en/fb18e.pdf);
Exhibit 2163 ("Finance Report for 2019," Roche, p. 12, https://www.roche.com/dam/jcr:1e6cfce4-2333-4ed6-b98a-f6b62809221d/en/fb19e.pdf).

[2] Roche financial reports provide the percentage change based on a constant exchange rate. The percentage changes at constant exchange rates are calculated using simulations by reconsolidating both the current and prior year results at constant exchange rates (the average rates for the current and prior year).

[3] Appendix 2.2.

Regeneron Pharmaceuticals, Inc., v. Novartis Pharma AG, et al.

SUMMARY OF LUCENTIS ANNUAL GROSS SALES IN USD, 2017 - 2019

Appendix 2.2

(millions USD)	[redacted]
Lucentis Vial Gross Sales	
Lucentis PFS Gross Sales	
Total Lucentis Gross Sales	
Lucentis PFS Gross Sales as % of Total	

Notes:

[1] Exhibit 2099 (GENEITC_1207-0000030).