

PUBLIC VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., DR. REDDY'S
LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD.
Petitioner,

v.

NOVO NORDISK A/S
Patent Owner.

Case IPR2023-00724¹
Patent 10,335,462

DECLARATION OF DEFOREST MCDUFF, Ph.D.

¹ IPR2024-00009 (Dr. Reddy's Laboratories) has been joined with this proceeding.

I, DeForest McDuff, Ph.D., declare as follows:

I. Introduction

A. Qualifications

1. I am an economist at Insight Economics with more than 15 years of experience in economic consulting, research, and education. I provide economic expertise as a consultant and expert witness in many areas, including economic harm (lost profits, actual harm, unjust enrichment, reasonable royalty, loss of value), intellectual property (patents, trademarks, trade secrets, copyright), antitrust (monopolization, price discrimination, tying, price fixing), competition (economic harm, market definition, unfair competition, false advertising), valuation, financial analysis, and other areas.

2. I have significant experience evaluating the economics of the pharmaceuticals industry. I have provided expert analysis and consulting in more than 75 cases involving pharmaceuticals and related products, including analysis of economic damages, competition, economic harm, secondary considerations, and other issues. I have evaluated a number of pharmaceutical product launches, both in a litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical topics as well.

3. I am an Assistant Teaching Professor in the Department of Economics at the University of North Carolina at Chapel Hill. I earned a Ph.D. in Economics

from Princeton University, where I received a National Science Foundation Graduate Research Fellowship for academic research in financial economics and applied microeconomics. I graduated summa cum laude with a B.A. in Economics and a B.S. in Mathematics from the University of Maryland. My curriculum vitae contains more details on my education, experience, and testimony.

B. Scope of Work

4. In connection with my work on this matter, Insight Economics has been retained by Perkins Coie LLP on behalf of Mylan Pharmaceuticals, Inc. (“Mylan” or “Petitioner”).² For this declaration, I was asked to evaluate and respond to the Expert Declaration of Christopher A. Vellturo submitted on January 17, 2024 (“Vellturo Declaration”) regarding the alleged commercial success of Ozempic, commercialized by Novo Nordisk A/S (“Novo Nordisk” or “Patent Owner”). Specifically, I have been asked to evaluate the Vellturo Declaration’s claims of commercial success as they relate to U.S. Patent No. 10,335,462 (“the ’462 Patent” or “patent-in-suit”).³ This declaration is a statement of my opinions and the basis and reasons for those opinions.

² Insight Economics is being compensated at a rate of \$950 per hour for my work and at lower rates for time spent by others on my team. The compensation of Insight Economics does not depend on the substance of my testimony or the outcome of this matter.

³ EX2300: Vellturo Declaration.

II. Background

A. Novo Nordisk

5. Novo Nordisk is a global healthcare company headquartered in Denmark.⁴ Novo Nordisk discovers and develops medicines for diabetes, obesity, rare diseases, cardiovascular disease, and emerging therapy areas.⁵ Novo Nordisk A/S is the Danish parent company of the Novo Nordisk group of companies.⁶

B. Type 2 diabetes

6. Type 2 diabetes is a disease related to improper function of how the body utilizes insulin and metabolizes sugar.⁷ Type 2 diabetes results in a build-up of sugar in the bloodstream and can cause heart disease, stroke, vision loss, kidney disease, sensory loss, amputation, and other life-threatening conditions.⁸ Treatment for Type 2 diabetes includes healthy eating, regular exercise, blood sugar monitoring, and a variety of medicine options: alpha-glucosidase inhibitors, biguanides, bile acid sequestrants, DPP-4 inhibitors, GLP-1 agonists, meglitinides, SGLT2 inhibitors, sulfonylureas, thiazolidinediones, and insulin.⁹

⁴ EX1177: Novo Nordisk, Annual Report 2023, at 6.

⁵ EX1177: Novo Nordisk, Annual Report 2023, at 6.

⁶ EX1177: Novo Nordisk, Annual Report 2023, at 81.

⁷ EX1181: Medline Plus, “Type 2 diabetes,” 2/10/2023, <https://medlineplus.gov/ency/article/000313.htm>.

⁸ EX1181: Medline Plus, “Type 2 diabetes,” 2/10/2023, <https://medlineplus.gov/ency/article/000313.htm>.

⁹ EX1181: Medline Plus, “Type 2 diabetes,” 2/10/2023, <https://medlineplus.gov/ency/article/000313.htm>.

C. Ozempic

7. Ozempic is a glucagon-like peptide (GLP-1) receptor agonist manufactured by Novo Nordisk A/S and marketed in the U.S. by Novo Nordisk Inc.¹⁰ Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.¹¹ Ozempic was approved by the FDA on December 5, 2017¹² and launched in the U.S. in February 2018.¹³ Ozempic injections are available in single-patient-use pens that deliver 0.25 mg with a strength of 2 mg / 3 mL (0.68 mg/mL), 0.5 mg with a strength 2 mg / 3 mL (0.68

¹⁰ EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 1 and 25.

¹¹ EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 1.

¹² EX2106: FDA, Ozempic NDA 209637 Approval Letter, 12/5/2017, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf.

¹³ EX2494: Novo Nordisk, “Company announcement Financial report for the period 1 January 2018 to 21 March 2018,” 5/2/2018, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/quarterly_financial_reports/2018/20180502_Financial%20statement_Q1%202018_UK.pdf, at 8.

mg/mL), 1 mg with a strength of 4 mg / 3 mL (1.34 mg/mL), and 2 mg with a strength of 8 mg / 3 mL (2.68 mg/mL).¹⁴

D. The '462 Patent

8. U.S. Patent No. 10,335,462, entitled “Use of Long-Acting GLP-1 Peptides,” was filed on July 21, 2017 and issued to Novo Nordisk on July 2, 2019.¹⁵ The '462 Patent claims priority to foreign application EP12174535, dated July 1, 2012.¹⁶ I understand that Novo Nordisk claims that the '462 Patent claims certain methods of treating type 2 diabetes using semaglutide 1.0 mg once weekly.¹⁷ I understand that the use of Ozempic to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease is not claimed by the '462 Patent.¹⁸

¹⁴ EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 1.

¹⁵ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

¹⁶ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

¹⁷ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

EX2300: Vellturo Declaration, ¶ 3.

¹⁸ EX1302: Spiegel Reply Declaration, ¶¶ 50-64, 102, 282, 285, 313.

EX1304: Schwartzbard Reply Declaration, ¶ 41.

III. Commercial Success Framework

9. Commercial success is a secondary consideration that a patent owner may rely upon to support an argument of non-obviousness of a claimed invention. The Federal Circuit has stated that commercial success may be relevant “because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.”¹⁹

10. To be relevant, commercial success requires a nexus to the claimed subject matter. The Federal Circuit has stated: “Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.”²⁰ For products with several features or alleged innovations, a patent owner may “prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention,’”²¹ or “the *degree to which* evidence of secondary considerations tied to a product is attributable to a particular claimed

¹⁹ *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005).

See also: EX1171: McDuff, DeForest, Ryan Andrews, and Matthew Brundage (2017), “Thinking Economically About Commercial Success,” *Landslide* March/April 2017;9(4):37-40.

²⁰ *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1311-1312 (Fed. Cir. 2006).

²¹ *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1378, 1374 (Fed. Cir. 2019).

invention.”²² The Federal Circuit has stated: “‘Where objective indicia result from something other than what is both *claimed* and *novel* in the claim, there is no nexus to the merits of the claimed invention.’”²³

11. Finally, blocking patents provide an additional consideration to whether commercial success is relevant, where the “practice of a later invention would infringe the earlier patent.”²⁴ The Federal Circuit has stated that blocking patents “may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later, ‘blocked’ invention, because of the risk of infringement liability and associated monetary or injunctive remedies.”²⁵ The Federal Circuit has stated that blocking patents “can discount the significance of evidence that nobody but the blocking patent’s owners or licensees

²² *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1378 (Fed. Cir. 2019). Emphasis added.

²³ *Janssen Pharm. v. Teva Pharm. U.S.*, No. 2022-1258 (Fed. Cir. Apr. 1, 2024), at 30.
See also: Novartis AG v. Torrent Pharms. Ltd., 853 F.3d 1316, 1330 (Fed. Cir. 2017), citing *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). “Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.”

²⁴ *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1337 (Fed. Cir. 2018).

²⁵ *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1337 (Fed. Cir. 2018).

arrived at, developed, and marketed the invention covered by the later patent at issue in litigation.”²⁶

12. Economically, for commercial success to be relevant, the product performance must be strong enough and specific enough to the patent at issue so that we can conclude that others would have developed the claimed invention sooner, had it been obvious. If features of a product other than what is both claimed and novel in the claims substantially contribute to demand or if blocking patents would have deterred others even if the patent were obvious, then commercial success can be economically irrelevant for the obviousness inquiry, even if a product overall has been a market success.

IV. Analysis of the Vellturo Declaration

A. Overview

13. Based on my review of the Vellturo Declaration and my assessment of Ozempic as it relates to the '462 Patent, I have reached the following conclusions.

14. The claimed commercial success of Ozempic set forth in the Vellturo Declaration does not support an economic inference of non-obviousness of the '462 Patent, since the claimed dosing is only one of many features of Ozempic. Evidence indicates that factors other than what is both claimed and novel in the

²⁶ *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1339 (Fed. Cir. 2018).

'462 Patent claims, such as the semaglutide compound, other product features, titration regimen, off-label use for obesity among non-type-2-diabetics, Novo Nordisk's established presence in type 2 diabetes, and marketing have contributed substantially to Ozempic's market performance.

15. A corrected assessment indicates only a limited connection between the claimed commercial success and the novel contributions of the claimed subject matter, and correspondingly limited incentives for development by others. Further, blocking patents offer an alternative explanation for why the claimed subject matter was not developed sooner, so that commercial success is economically irrelevant for obviousness of the '462 Patent.

16. My specific assessments of the Vellturo Declaration are summarized as follows and described more fully in the sections that follow:

- a. **Product performance**. While Ozempic has achieved a certain degree of overall product success, the Vellturo Declaration fails to explain how the product sales overall would have motivated others to develop the claimed invention of the '462 Patent specifically.
- b. **Nexus**. The Vellturo Declaration has not shown a nexus to the '462 Patent due to the contribution of factors other than what is both claimed and novel in the claims, other patents covering Ozempic, and no evidence that the claimed success is the “direct result” of the alleged

novel aspects of the claimed subject matter as opposed to other product attributes or features covered by prior art patents.

- c. **Blocking patents**. Regardless of the product performance and nexus, earlier blocking patents and FDA exclusivity make commercial success economically irrelevant for the '462 Patent.

B. Product performance

17. The Vellturo Declaration presents a number of figures on Ozempic's U.S. net sales, prescriptions, and growth derived from Novo Nordisk's public filings and IQVIA market data.²⁷

18. While it is not disputed that Ozempic has achieved a certain level of overall success, figures on Ozempic's overall commercial performance via net sales and prescriptions (and related net sales and prescription market shares) are not necessarily informative on commercial success of the '462 Patent specifically.

19. Others considering whether to develop the claimed subject matter would have considered only the potential returns from developing the novel claimed elements, not the product overall. The Vellturo Declaration acknowledges this to some extent by focusing on 1.0 mg Ozempic sales,²⁸ which I understand are

²⁷ EX2300: Vellturo Declaration, ¶¶ 74-79, Figures 1-2, Appendices D, E-E-4, and F-F-4.

²⁸ EX2300: Vellturo Declaration, ¶¶ 80-87, Appendices G-G-1 and H-H-1.

alleged to fall within the scope of the '462 Patent claims.²⁹ However, even this adjustment does not fully apportion the impact of the '462 Patent on 1.0 mg sales separate and apart from the other factors, as discussed in the nexus section below.

20. Still, the Vellturo Declaration presents an overstated assessment of Ozempic's commercial performance for at least two primary reasons.

i. No analysis of profits, costs, or risk

21. The Vellturo Declaration only provides evidence of Ozempic's U.S. sales, prescriptions, and growth, but provides no analysis of profits, costs, or risk-adjusted returns associated with the claimed subject matter, even though these factors are commonly evaluated for commercial success. For example, the Federal Circuit has identified these variables as relevant to the calculus of incentives for development.³⁰ Yet, these factors are omitted from the Vellturo Declaration.

²⁹ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

³⁰ *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1338-39 (Fed. Cir. 2018). "...a number of variables appear generally relevant to the calculus, including: the costliness of the project; the risk of research failure; the nature of improvements that might arise from the project, and whether such improvements will be entirely covered by the blocking patent; the size of the market opportunities anticipated for such improvements; the costs of arriving at the improvements and getting them to market; the risk of losing the invention race to a blocking-patent owner or licensee; the risk that the blocking-patent owner (making its own economic calculations, perhaps in light of its own other products or research activities) will altogether refuse to grant a license to the improvement or will demand so large a share of profits that the whole project is not worthwhile for the potential innovator—all evaluated in light of other investment opportunities."

22. Viewing overall product net sales and prescriptions after the fact is not a complete analysis of incentives for others to pursue development many years before a product launches. Pharmaceutical development is typically a costly and risky endeavor,³¹ and the Vellturo Declaration provides no assessment for whether cost- and risk-adjusted returns from the claimed subject matter would have provided sufficient incentives to develop the claimed dosing regimen sooner.

ii. Flawed market share analysis

23. The Vellturo Declaration's comparison of Ozempic's relative share and performance versus other type 2 diabetes treatments is overstated and uninformative for several reasons.

24. First, Ozempic's overall market share is not informative on the '462 Patent specifically due to many other factors contributing to Ozempic's market performance, as discussed in Section IV.C below. A more informative market share metric would consider, at most, the market share held by 1.0 mg Ozempic sales,³² which I understand fall within the scope of the '462 Patent claims.³³ Even still, there are other factors contributing to that demand besides the '462 Patent.

³¹ EX1179: National Institutes of Health, "The Pathway from Idea to Regulatory Approval: Examples for Drug Development," 2009, <https://www.ncbi.nlm.nih.gov/books/NBK22930/>.

³² EX2300: Vellturo Declaration, ¶¶ 80-87, Appendices G-G-1.

³³ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

25. Second, the market share of Ozempic sales overall captures significant use of Ozempic for treatments other than type 2 diabetes, such as weight loss among non-type-2-diabetics, that fall outside the scope of the '462 Patent claims. As discussed in Section IV.C below, evidence indicates that a significant and growing fraction of Ozempic prescriptions have been for use other than type 2 diabetes. Adjusting 1.0 mg Ozempic sales to reflect only use among type 2 diabetics would imply a lower market share within the patent scope and lower incentives for development.

26. Finally, the Vellturo Declaration analyzes Ozempic's sales and prescription performance in the context of only GLP-1 agonist, DPP-4 inhibitor, and SGLT2 inhibitor drugs, referred to as MNIADs (modern non-insulin anti-diabetics),³⁴ which is unnecessarily limiting. For example, [REDACTED]

[REDACTED]

[REDACTED]

³⁴ EX2300: Vellturo Declaration, ¶¶ 23, 75-76, 78-79, Appendices E-1, E-3, E-4, F-1, F-3, and F-4.

See also: EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 7:14-8:1 (“Q. So in your declaration, you make a number of comparisons of market share and sales to other drugs, and I believe your – I guess the market – the drugs you’re comparing are the noninsulin diabetic medications, GLP-1 agonist, DPP-4, SGL-2, and others. Is that right? A. It’s very close. I think I have an acronym that I use, [MNIADs], I believe it is. It’s that set of products.”)

³⁵ EX2314: NN-OZEM-004656390, 5/16/2017, at 3.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], so the

Vellturo Declaration’s analysis of Ozempic’s share within that limited subset provides an artificially inflated assessment of Ozempic’s performance.

Additionally, Novo Nordisk’s technical expert, Dr. Robin Goland, testified that insulin was the most commonly used injectable treatment for type 2 diabetes prior to Ozempic being commercially available, further highlighting the Vellturo Declaration’s limited market definition.³⁶

³⁶ EX1140: Robin Goland, Dep. Tr., 4/9/2024, 57:17-22 (“Q. ...Would you agree that GLP-1 receptor agonists were the most commonly used injectable treatments for type 2 diabetes patients who were not meeting their glycemic targets before Ozempic was commercially available? A. No. Insulin was.”)

Figure 1: Novo Nordisk 2017 Market Overview: Volume for US Diabetes Products³⁷



C. Nexus

27. On nexus, the Vellturo Declaration applies a flawed framework and improperly concludes there is a nexus to the '462 Patent. The Vellturo Declaration describes a nexus as “a causal connection... between the characteristics of the patented invention and the marketplace success of the product that incorporates that invention.”³⁸ Yet, the Vellturo Declaration does not specify how much of a causal connection or to what degree a connection is needed, resulting in an ambiguous threshold that is seemingly met by any amount of connection.

³⁷ EX2314: NN-OZEM-004656390, 5/16/2017, at 3.

³⁸ EX2300: Vellturo Declaration, ¶ 71.

28. By contrast, the Federal Circuit has described nexus as the market performance being the ““direct result of the unique characteristics of the claimed invention.””³⁹ Published economic literature also recognizes that “[c]ourts have... generally required a showing that any commercial success be directly linked to demand for the patented feature rather than any other factors.”⁴⁰ Further, the Federal Circuit has held that “[w]here objective indicia result from something other than what is both *claimed* and *novel* in the claim, there is no nexus to the merits of the claimed invention.”⁴¹ The Vellturo Declaration’s nexus analysis does not meet this standard for establishing nexus, as discussed below.

i. Coextensiveness

29. The Vellturo Declaration first concludes a nexus based on coextensiveness, but this analysis is incomplete.

30. The Vellturo Declaration claims that “when the marketed product is an embodiment of the claims and is coextensive with them, there is a presumption

³⁹ *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1374 (Fed. Cir. 2019), citing *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). Emphasis added.

⁴⁰ EX1180: David, Jesse and Stewart, Marion, “Commercial Success: Economic Principles Applied to Patent Litigation,” *Economic Approaches to Intellectual Property: Policy, Litigation, and Management* (Gregory K. Leonard & Lauren J. Stiroh eds., 2005), at 161. Emphasis added.

⁴¹ *Janssen Pharm. v. Teva Pharm. U.S.*, No. 2022-1258 (Fed. Cir. Apr. 1, 2024), at 30.
See also: Novartis AG v. Torrent Pharms. Ltd., 853 F.3d 1316, 1330 (Fed. Cir. 2017), citing *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

of nexus.”⁴² However, Dr. Vellturo testified that he did not independently analyze whether the ’462 Patent was coextensive with Ozempic⁴³ and that he has no opinion regarding whether any of the other Orange Book patents could be coextensive with Ozempic.⁴⁴

31. The Vellturo Declaration primarily cites to the Goland Declaration to claim that “the use of Ozempic’s 1.0 mg dose to treat type 2 diabetes embodies the challenged claims of the ’462 Patent and is an essential part of the product as prescribed.”⁴⁵ Notably, Dr. Goland testified that she had not reviewed any prior art to the ’462 Patent⁴⁶ (including U.S. Patent Nos. 8,129,343 (“the ’343 Patent”) claiming the use of semaglutide to treat type 2 diabetes),⁴⁷ and only reviewed

⁴² EX2300: Vellturo Declaration, ¶ 83.

⁴³ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 11:6-9 and 12:11-18 (“Q. What is your understanding of what it means to be coextensive? A. I’m not a legal expert. It’s just a layperson’s understanding... Q. So you’re getting your understanding that Ozempic is coextensive with the ’462 patent from Dr. Goland. Is that right? A. Yes. Q. And you don’t have an independent opinion on that aside from her understanding? A. I do not.”)

⁴⁴ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 11:16-12:10, 21:15-22:15, and 34:3-13.

⁴⁵ EX2300: Vellturo Declaration, ¶ 83.

⁴⁶ EX1140: Robin Goland, Dep. Tr., 4/9/2024, at 26:1-8 (“Q. And I didn’t see anything in your declaration where you identified what you view as the closest prior art to the ’462 patent. If there is someplace in your declaration where you think you did that, could you point it out to me? A. I do not think those words are exactly in there.”)

⁴⁷ EX1140: Robin Goland, Dep. Tr., 4/9/2024, at 15:10-13 (“Q. ...you didn’t look at any other patents that may or may not cover Ozempic; is that fair to

literature after the priority date of the '462 Patent in forming her opinions.⁴⁸ Dr. Goland also testified that she had not reviewed U.S. Patent 9,764,003 (“the '003 Patent”)⁴⁹, which claims a method for reducing body weight by administering semaglutide once weekly in an amount of at least 0.7 mg and up to 1.6 mg, which includes a 1.0 mg dose.⁵⁰

32. I understand that “the degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies perfect or near perfect correspondence. At the other end lies no or very little correspondence, such as where ‘the patented invention is only a component of a commercially successful machine or process.’ ...Although [the Federal Circuit does] not require the patentee to prove perfect correspondence to meet the

say? A. That is true.”) and at 41:3-5 (“Q. ...I take it, you didn’t look at any other patents other than the '462 patent? A. That is correct.”)

EX1068: U.S. Patent No. 8,129,343, Acylated GLP-1 compounds (filed 3/20/2006, issued 3/6/2012)

⁴⁸ EX1140: Robin Goland, Dep. Tr., 4/9/2024, at 19:14-18 (“Q. Okay. The only references that you list in your appendix are from after what we call the priority date, so after July of 2012; is that fair? A. That is correct.”)

⁴⁹ EX1140: Robin Goland, Dep. Tr., 4/9/2024, at 78:6-17 (“Q. And I take it because you didn’t review any other patents in this case – were you unaware that Novo Nordisk has another patent, what we call the '003 patent, that claims the use of a once-weekly dose of semaglutide, including a 1 milligram dose, for reducing body weight in a subject in need thereof? ...A. I’m not familiar with that patent.”)

⁵⁰ EX2002: U.S. Patent No. 9,764,003, Use of long-acting GLP-1 peptides (filed 6/21/2013, issued 9/19/2017).

coextensiveness requirement, what [it does] require is that the patentee demonstrate that the product is essentially the claimed invention.”⁵¹

33. I understand from the Reply Declaration of Dr. Allen Spiegel submitted on May 21, 2024 (“Spiegel Reply Declaration”) that the claimed subject matter is not coextensive with the product (*i.e.*, Ozempic is not “essentially the claimed invention”).⁵² Indeed, as discussed in Section C.ii below, Ozempic includes significant prior art and/or unclaimed features, including but not limited to the semaglutide compound, titration regimen, device, and other features that contribute to its claimed efficacy and benefits.⁵³ At best, the novel aspects of the ’462 Patent are limited to the 1.0 mg dosing regimen (and even this is disputed). In reaching a conclusion on nexus, the Velturo Declaration largely ignores the contributions of the other dosing regimens and fails to address that the 1.0 mg dosing regimen itself is only one of many components used in combination with other features and prior art technologies.

⁵¹ *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1374 (Fed. Cir. 2019). Emphasis added.

⁵² EX1302: Spiegel Reply Declaration, ¶¶ 229-230.

⁵³ EX1302: Spiegel Reply Declaration, ¶¶ 79, 91, 99, 219-225, 254, 261-270, and FN 5.
EX2069: Ozempic label, 9/2023,
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 3.

34. I understand that in cases where products embody multiple patented inventions, the patentee bears the burden to show that the product's success was due to the invention claimed in the patent asserted in the case.⁵⁴ Here, the Vellturo Declaration's presumption of nexus based on coextensiveness does not address the commercial impact of many prior art and/or unclaimed features, including features covered by two dozen other Ozempic patents listed in the FDA Orange Book (e.g., patents on the compound, device, etc.). See Appendix D-1. For example, Dr. Vellturo testified that he did not analyze whether Ozempic's injection pen feature, covered by several Ozempic Orange Book patents, had an impact on sales.⁵⁵ Dr. Vellturo also testified that he did not address the commercial impact of the availability of the Ozempic 0.25 mg and 0.50 mg quantities.⁵⁶ Similarly, as discussed below, the Vellturo Declaration's presumption of nexus does not account for the contribution to Ozempic's use for weight loss made by the technologies disclosed in the '003 Patent, despite testifying that weight reduction is a significant driver of demand.⁵⁷

⁵⁴ *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1375 (Fed. Cir. 2019), summarizing *Therasense, Inc. v. Becton, Dickinson & Co.* 593 F.3d 1289, 1299 (Fed Cir. 2010).

⁵⁵ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 14:7-11 and 33:7-34:2.

⁵⁶ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 33:20-34:2.

⁵⁷ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019),

35. As such, there is no presumption of nexus based on coextensiveness based on my understanding of how that presumption is applied in commercial success analysis.

ii. Other features and patents

36. The '462 Patent relates to a once-weekly 1.0 mg semaglutide dosing regimen for treatment of type 2 diabetes.⁵⁸ In reaching a conclusion on nexus between the alleged commercial success of Ozempic and the '462 Patent, the Vellturo Declaration does not address other drivers of demand for Ozempic beyond the claimed dosing regimen.⁵⁹

37. As an economic matter, the fact that a product embodies an invention, even one that is purportedly essential, does not establish that the invention directly results in demand. Modern products often embody many inventions that may be considered essential in some sense, but by themselves do not directly result in the product's commercial success. As an analogy, a computer may include a commoditized power cord that is essential for operating the device; however, one

EX2002: U.S. Patent No. 9,764,003, Use of long-acting GLP-1 peptides (filed 6/21/2013, issued 9/19/2017).

EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 25:19-26:1. [REDACTED]

⁵⁸ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

⁵⁹ EX2300: Vellturo Declaration, ¶¶ 71-73, 80-93.

would not reasonably conclude that demand for computers is driven by the presence of a power cord.

38. Here, the claimed 1.0 mg semaglutide dose may be embodied and essential to some portion of demand for Ozempic sales, but the Vellturo Declaration does not show that the alleged commercial success is the ““direct result of the unique characteristics of the claimed invention,”” which I understand to be required for establishing nexus.⁶⁰ Similarly, the Vellturo Declaration does not show that the claimed commercial success is attributable to ““what is both *claimed* and *novel* in the claim.””⁶¹

39. First, the Vellturo Declaration reaches a flawed conclusion regarding the scope of the invention with respect to Ozempic’s overall sales. The Vellturo Declaration quantifies 1.0 mg Ozempic sales and alleges a nexus to the 1.0 mg claim limitations in the ’462 Patent, but then asserts that the mere availability of a 1.0 mg dosing regimen drives demand for Ozempic overall, including other dosing regimens (*e.g.*, 0.5 mg and 2.0 mg doses).⁶² The Vellturo Declaration states: “sales that are 1.0 mg likely serve as lower bound estimates of the percentage of

⁶⁰ *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1374 (Fed. Cir. 2019), citing *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

⁶¹ *Janssen Pharm. v. Teva Pharm. U.S.*, No. 2022-1258 (Fed. Cir. Apr. 1, 2024), at 30.
See also: Novartis AG v. Torrent Pharms. Ltd., 853 F.3d 1316, 1330 (Fed. Cir. 2017), citing *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

⁶² EX2300: Vellturo Declaration, ¶ 87.

prescriptions and sales that would be made under the '462 Patented Inventions.”⁶³

However, if anything, 1.0 mg sales represent an *upper bound* of sales with a nexus to the '462 Patent given that, absent a 1.0 mg dosing regimen, certain of the same patients could have been treated with alternative dosing regimens that do not fall within the scope of the '462 Patent (*e.g.*, by remaining on a 0.5 mg dose, or using 2.0 mg Ozempic as a higher-dose alternative to 1.0 mg Ozempic).⁶⁴

40. More broadly, the Vellturo Declaration claims a nexus to the '462 Patent based on broad claims of efficacy, safety, tolerability, convenience, compliance, and adherence, which are all claimed to have a nexus to the '462 Patent.⁶⁵ However, the Vellturo Declaration fails to recognize other patents covering Ozempic or acknowledge that many of the benefits of efficacy, safety, tolerability and other features are driven substantially by other factors.

41. For example, I understand that the semaglutide compound and related methods of treating type 2 diabetes, which are claimed in prior art patents, rather than the claimed 1.0 mg dose, are responsible for many of the efficacy and safety/tolerability benefits of Ozempic, including the ability to dose Ozempic once weekly.⁶⁶ Indeed, when asked whether “whether the properties of the semaglutide

⁶³ EX2300: Vellturo Declaration, ¶ 87.

⁶⁴ EX1302: Spiegel Reply Declaration, ¶¶ 220-222.

⁶⁵ EX2300: Vellturo Declaration, ¶ 82.

⁶⁶ EX1302: Spiegel Reply Declaration, ¶¶ 226, 254, 289.

molecule itself are what drives sales,” Dr. Vellturo testified that his “understanding is that the therapeutic benefits and profile of Ozempic derive from semaglutide.”⁶⁷

42. As another example, I understand that the 0.25 mg dose of Ozempic is a titration dose.⁶⁸ The Ozempic label states that the “0.25 mg dosage is intended for treatment initiation and is not effective for glycemic control.”⁶⁹ I further understand that the purpose of the 0.25 mg titration dose is to improve tolerability by reducing gastrointestinal side effects.⁷⁰

43. By failing to evaluate the contribution of important prior art like the active ingredient, the titration dose, and treatment of type 2 diabetes, the Vellturo Declaration incorrectly concludes a nexus to the ’462 Patent. Again, the Federal Circuit has stated: “Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.”⁷¹

44. Similarly, the Vellturo Declaration omits any reference to many other Ozempic features unrelated to the claimed 1.0 mg dose. For example, there are *two*

⁶⁷ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 22:16-22.

⁶⁸ EX1302: Spiegel Reply Declaration, ¶¶ 219-220.

⁶⁹ EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 3.

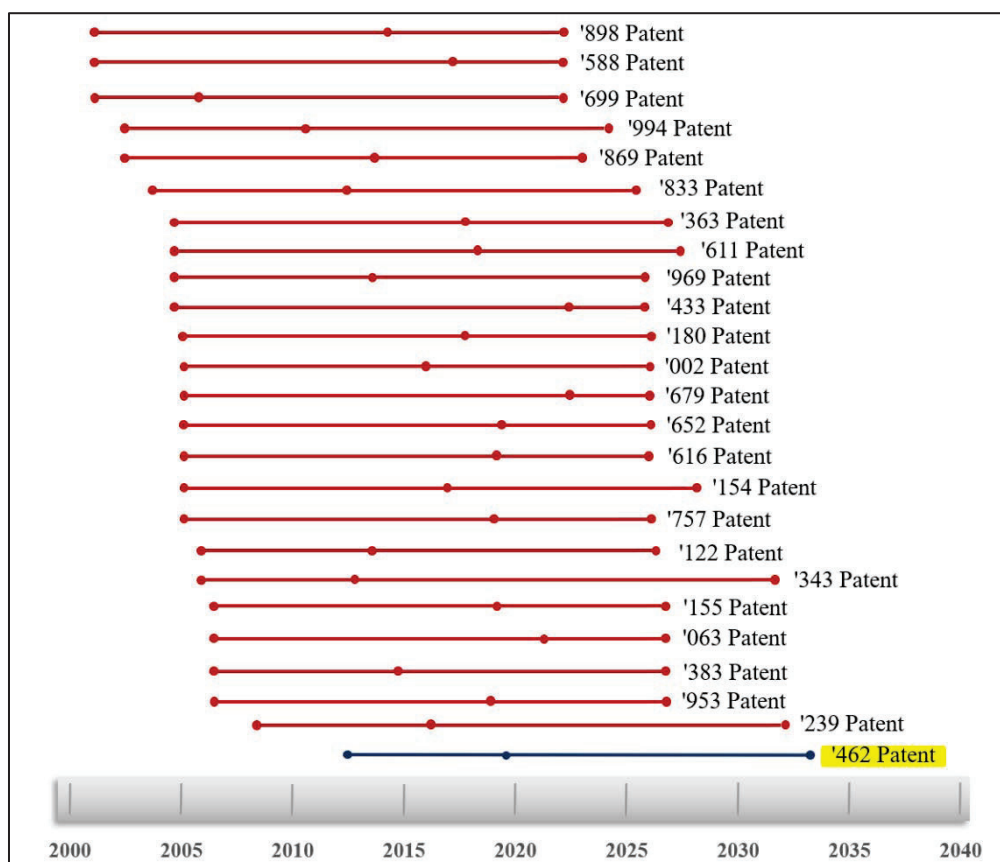
⁷⁰ EX1302: Spiegel Reply Declaration, ¶ 219.

⁷¹ *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1330 (Fed. Cir. 2017), citing *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

dozen other patents listed in the FDA Orange Book as covering Ozempic, as summarized Appendix D-1. I understand that other Ozempic patents listed in the FDA Orange Book cover the compound, device, and other features.⁷² The Vellturo Declaration does not evaluate or address the degree of nexus between any of these other patents and Ozempic,⁷³ instead only finding that the '462 Patent has a nexus, as shown in Figure 2:

⁷² See, for example: EX1167: First Amended Complaint, *Novo Nordisk Inc., et al v. Mylan Pharmaceuticals, Inc.*, 1:22-cv-01040-CFC, 3/21/2023, ¶¶ 11-30, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96, 102, 108, 114, 120, 126, 132, 138, 144, 150, 157, 163, 169, 175, 182, 188.

⁷³ Dr. Vellturo testified he did not analyze whether Ozempic's injection pen feature, covered by several Ozempic Orange Book patents, had an impact on sales and that he did not address the commercial impact of the availability of the Ozempic 0.25 mg and 0.50 mg quantities. See EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 14:7-11 and 33:7-34:2.

Figure 2: Ozempic Patent Timeline⁷⁴

45. Additionally, I understand that the '462 Patent is a continuation of the U.S. Patent 9,764,003 (“the '003 Patent”), which claims a method for reducing body weight by administering semaglutide once weekly in an amount of at least

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Appendix D-2.

On each patent timeline, the first mark represents the U.S. priority date, the second represents the issuance date, and the third represents the expiration date (*e.g.*, for the '898 Patent timeline, the first mark represents the January 2001 U.S. priority date, the second mark represents the March 2014 issuance date, and the third mark represents the January 2022 expiration date of the patent).

0.7 mg and up to 1.6 mg.⁷⁵ However, the Vellturo Declaration does not acknowledge the connection between demand for Ozempic’s weight reduction benefits (including when used off-label, as discussed below) and the weight reduction method using a 1.0 mg once weekly dose of semaglutide that is separately claimed in the ’003 Patent, rather than the ’462 Patent. By failing to account for the fact that a separate Novo Nordisk patent claims the use of 1.0 mg once weekly semaglutide to reduce weight, the Vellturo Declaration is overstating the benefits attributable to the ’462 Patent.

46. Further, I understand that Ozempic’s cardiovascular benefits relate to the subject matter of Novo Nordisk’s U.S. Patent Application No. 16/097,032, which claims a method of reducing the risk of a major adverse cardiovascular event (MACE), comprising administering semaglutide subcutaneously in an effective amount of 0.05-2.0 mg once weekly to a subject with type 2 diabetes and cardiovascular disease.⁷⁶ The Vellturo Declaration does not address this separate patent application, and thus overstates any cardiovascular benefits that it attributes to the ’462 Patent.

⁷⁵ EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019),
EX2002: U.S. Patent No. 9,764,003, Use of long-acting GLP-1 peptides (filed 6/21/2013, issued 9/19/2017).

⁷⁶ EX1296: U.S. Patent Application No. 16/097,032, “Listing of Claims.”
EX1304: Schwartzbard Reply Declaration, ¶ 127.

47. Finally, I understand from Dr. Spiegel that certain Ozempic patients treated using the claimed 1.0 mg dosing regimen could have received treatment using an alternative dosing regimen, such as the existing 0.5 mg or 2 mg regimens depending on the level of glycemic control needed.⁷⁷ The Velturo Declaration therefore overstates the nexus between the '462 Patent and the alleged commercial success represented by sales to patients treated with 1.0 mg Ozempic, since a 1.0 mg dosing regimen may not have been essential for treatment even among certain patients that were prescribed a 1.0 mg dose.

48. Because of these prior art and/or unclaimed patents and features, the Velturo Declaration's analysis of nexus is incomplete. As one author has stated: "Regardless of the vantage point, ...commercial success is only probative of nonobviousness if it is the result of the inventive features as opposed to other factors. If the commercial success is not tied to the inventive features, it cannot be said that innovators would have perceived the potential of the invention for market success, nor can it be said that the commercial success is indicative of inventive ingenuity."⁷⁸ In this sense, the Velturo Declaration has not shown that others would have developed the '462 Patent sooner because it has not proved that the

⁷⁷ EX1302: Spiegel Reply Declaration, ¶¶ 160-162, 220-222.

⁷⁸ EX1210: Walker, Edward (1987), "Objective Evidence of Nonobviousness: The Elusive Nexus Requirement (Part I)," *Journal of the Patent and Trademark Office Society* 1987;69(4):175-196, at 188.

commercial success of Ozempic stems from novel elements of the '462 Patent as opposed to other factors.

iii. Off-label use

49. The Vellturo Declaration is also flawed in its consideration of off-label use of Ozempic that falls outside the scope of the claims of the '462 Patent, specifically its use to reduce weight or treat obesity in people without type 2 diabetes.

50. While Novo Nordisk claims not to have actively promoted Ozempic for treatment of weight loss for non-type-2 diabetics, it has acknowledged that “in the U.S., there is individual doctor experience and then they prescribe medications based on their discretion.”⁷⁹ This practice is known as “off-label” use. For Ozempic, off-label use diminishes the nexus between the claimed commercial success and the '462 Patent for that portion of sales.

51. The Vellturo Declaration correctly acknowledges that “off-label usage of Ozempic to treat obesity (without the presence of type 2 diabetes), to the extent it exists, would not practice the '462 Patented Inventions.”⁸⁰ However, the Vellturo

⁷⁹ EX1190: The Motley Fool, “Novo Nordisk (NVO) Q1 2022 Earnings Call Transcript,” 4/29/2022, <https://www.fool.com/earnings/call-transcripts/2022/04/29/novo-nordisk-nvo-q1-2022-earnings-call-transcript/>.

⁸⁰ EX2300: Vellturo Declaration, ¶ 89.
See also: EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 20:20-21-14.

Declaration finds that “[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] and changes in certain insurance policies.”⁸³

52. The Vellturo Declaration’s conclusion is flawed because it rests on inferential analysis rather than direct evidence of off-label use. In stark contrast to the Vellturo Declaration, Novo Nordisk’s expert Dr. Goland testified that “everyone is familiar with that phenomenon” when shown evidence that market demand for Ozempic “comes from people who don’t have type 2 diabetes but who want to lose weight.”⁸⁴ Indeed, there is substantial additional evidence indicating significant and growing off-label use of Ozempic among non-type-2-diabetics.⁸⁵

⁸¹ EX2300: Vellturo Declaration, ¶ 93.

⁸² EX1206: Wegovy Label, 7/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215256s007lbl.pdf, at 1 and 33.

⁸³ EX2300: Vellturo Declaration, ¶¶ 90-93.

⁸⁴ EX1140: Robin Goland, Dep. Tr., 4/9/2024, at 89:19-90:8.

EX2080: The New Yorker, “The Year of Ozempic,” 12/14/2023.

⁸⁵ EX2518: Han, Sabrina, et al. (2024), “Public Interest in the Off-Label Use of Glucagon-like Peptide 1 Agonists (Ozempic) for Cosmetic Weight Loss: A

53. For example, a Washington Post article found that “while Ozempic has regulatory approval to treat diabetes, the data indicate that many providers prescribed it off-label, meaning for a treatment other than its approved use.”⁸⁶ The article cited a report from Trilliant Health, a healthcare analytics provider, which found the rate of Ozempic uptake is often disproportionate to diabetes prevalence, with an increasing number of unique patients taking Ozempic who had a history of obesity.⁸⁷ According to Trilliant’s chief research officer, “a sizable share” of patients are using diabetes drugs like Ozempic off-label for weight loss.⁸⁸

Google Trends Analysis,” *Aesthetic Surgery Journal* 2024;44(1):60-67, at 60-61 and 63-64.

EX1186: The Washington Post, “Prescriptions for Ozempic and similar drugs have skyrocketed, data shows,” 9/27/2023, <https://www.washingtonpost.com/business/2023/09/27/ozempic-prescriptions-data-analysis/>.

EX1207: USA Today, “These 15 metro areas saw biggest jumps in Ozempic use. They might be where you expect,” 9/27/2023, <https://www.usatoday.com/story/news/health/2023/09/27/ozempic-prescription-jump-varies-across-us/70932858007/>.

⁸⁶ EX1186: The Washington Post, “Prescriptions for Ozempic and similar drugs have skyrocketed, data shows,” 9/27/2023, <https://www.washingtonpost.com/business/2023/09/27/ozempic-prescriptions-data-analysis/>.

⁸⁷ EX1184: Trilliant Health, “2023 Trends Shaping the Health Economy,” 2023, [https://www.trillianthealth.com/hubfs/TH_Annual%20Report_2023.10.25%20\(2\).pdf](https://www.trillianthealth.com/hubfs/TH_Annual%20Report_2023.10.25%20(2).pdf), at 43 and 141-143.

⁸⁸ EX1186: The Washington Post, “Prescriptions for Ozempic and similar drugs have skyrocketed, data shows,” 9/27/2023, <https://www.washingtonpost.com/business/2023/09/27/ozempic-prescriptions-data-analysis/>.

54. Another article from the Washington Post in 2023 noted that certain insurers had recognized significant off-label prescriptions for Ozempic and contacted health care providers, warning that “[n]ationwide shortages have occurred due to the large uptick in off-label prescribing,” and “patients with diabetes often cannot find the medication in stock.”⁸⁹ In one example, a letter from Anthem Blue Cross Blue Shield to one Missouri provider stated that a review by Anthem’s Special Investigations Unit “found that more than 60 percent lacked ‘sufficient evidence’ of diabetes,” while similar language was used in other letters to clinicians in New York and North Carolina.⁹⁰ In this sense, the Vellturro Declaration’s commentary on attempted policy changes by insurers simply reflects the significant extent of off-label use that has occurred and is occurring.

55. Additionally, an analysis by Komodo Health, a provider of patient-level analytics, tracked Ozempic prescriptions in patients with and without diabetes from 2019 through 2022.⁹¹ A comparison of this estimate of Ozempic prescriptions for non-diabetic adults and the total annual Ozempic prescriptions from the

⁸⁹ EX1189: The Washington Post, “Insurers clamping down on doctors who prescribe Ozempic for weight loss,” 6/12/2023, <https://kffhealthnews.org/morning-breakout/insurers-are-warning-doctors-who-prescribe-ozempic-for-weight-loss/>.

⁹⁰ EX1189: The Washington Post, “Insurers clamping down on doctors who prescribe Ozempic for weight loss,” 6/12/2023, <https://kffhealthnews.org/morning-breakout/insurers-are-warning-doctors-who-prescribe-ozempic-for-weight-loss/>.

⁹¹ See Appendix C-1.

Vellturo Declaration indicates off-label use of approximately 10.6% in 2019, 11.8% in 2020, 17.4% in 2021, and 18.3% in 2022 (see Appendix C-1). Data from CNN, Epic Research, and the Health Care Cost Institute indicate historical off-label use in a similar range.⁹²

56. In addition, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].⁹⁴

⁹² EX1176: CNN, “Prescriptions for popular diabetes and weight-loss drugs soared, but access is limited for some patients,” 9/27/2023, <https://www.cnn.com/2023/09/27/health/semaglutide-equitable-access/index.html>.

EX1173: Health Care Cost Institute, “The Share of Ozempic Users with Diabetes has Decreased Over Time, Indicating Increased Off-label Use,” 6/14/2023, <https://healthcostinstitute.org/hcci-originals-dropdown/topics/diabetes-and-insulin/ozempic-users-with-diabetes-have-decreased-over-time-indicating-increased-off-label-use>.

⁹³ EX2326: NN-OZEM-004691816, 11/16/2021, at 24.

⁹⁴ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 21:9-14 and 25:19-26:1. ([REDACTED])



57. While evidence showing use of Ozempic for weight loss does not itself confirm off-label use (as type 2 diabetics may also lose weight), the

[REDACTED]

[REDACTED] and other direct evidence indicates significant off-label use.

58. Ultimately, because off-label use of Ozempic for weight loss among non-type-2-diabetics does not fall within the scope of what is novel about the '462 Patent claims, a third-party developer would not have considered the potential for related sales as an incentive for development, even if the claimed subject matter had been obvious.

⁹⁵ EX2326: NN-OZEM-004691816, 11/16/2021, at 24.

iv. [REDACTED]

59. The Vellturo Declaration claims that Ozempic’s success has not been driven by the success of prior Novo Nordisk type 2 diabetes products.⁹⁶ However, evidence indicates the opposite: that Novo Nordisk’s established presence in the diabetes market facilitated its customer relationships and marketing to transition patients from prior-gen products to Ozempic.

60. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁹⁶ EX2300: Vellturo Declaration, ¶¶ 110-112.

⁹⁷ EX2332: NN-OZEM-004731509, 5/2017, at 19.

[REDACTED]

[REDACTED]

61. As another example, [REDACTED]

[REDACTED]”⁹⁹

[REDACTED]

[REDACTED]

[REDACTED]¹⁰⁰

62. [REDACTED]

[REDACTED]

[REDACTED]

⁹⁸ EX2332: NN-OZEM-004731509, 5/2017, at 19.

⁹⁹ EX2028: NN-OZEM-000020275, 3/2010, at 46-48.

¹⁰⁰ EX1323: NN-OZEM-004426808, 4/15/2010, at 5.

¹⁰¹ EX2308: NN-OZEM-003735283, 7/6/2018, at 1 and 28.

[REDACTED]

[REDACTED].¹⁰²

63. Additionally, the Vellturo Declaration’s own analysis of promotional expenditures shows that [REDACTED]

[REDACTED]

[REDACTED]¹⁰³

64. Together, these factors indicate that Ozempic’s success was driven, at least in part, [REDACTED]. As such, incentives for others to develop the claimed subject matter sooner would have been limited relative to Novo Nordisk’s own incentives and provide an alternative explanation for why the claimed subject matter was not developed sooner.

v. Marketing

65. The Vellturo Declaration claims that Ozempic’s success did not result from high marketing and promotional spend relative to other comparable therapies.¹⁰⁴ However, this analysis is flawed. Evidence indicates that Ozempic has benefited from atypically high marketing and other promotional efforts by Novo Nordisk and third parties, which diminishes the nexus between the claimed subject matter and alleged commercial success.

¹⁰² EX2308: NN-OZEM-003735283, 7/6/2018, at 28.

¹⁰³ EX2300: Vellturo Declaration, Appendix K-2.

¹⁰⁴ EX2300: Vellturo Declaration, ¶¶ 106-109.

66. The Vellturo Declaration bases its conclusion on an analysis of Ozempic’s promotion-to-sales ratio relative to other drugs at similar stages in their lifecycles.¹⁰⁵ [REDACTED]

[REDACTED]

[REDACTED]¹⁰⁶

67. Indeed, the Vellturo Declaration’s own [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]¹⁰⁷ In this sense, Ozempic’s promotional efforts likely explain some of its success, which diminishes the nexus to the ’462 Patent.¹⁰⁸

68. The atypically high marketing and promotional efforts for Ozempic have even received media attention. For example, a 2023 Bloomberg article titled “A Weight-Loss Drug Marketing Bonanza Is Upon Us” found that telemedicine clinics and others prescribing Ozempic for weight loss were investing heavily in marketing, even though Novo Nordisk is limited by law to promoting Ozempic in a

¹⁰⁵ EX2300: Vellturo Declaration, ¶¶ 107-109.

¹⁰⁶ EX2300: Vellturo Declaration, Appendix K-2.

¹⁰⁷ EX2300: Vellturo Declaration, Appendix K-2.

¹⁰⁸ EX2300: Vellturo Declaration, Appendix K-2.

way that is consistent with the label.¹⁰⁹ A 2023 NBC article found that “Online pharmacies, medical spas and diet clinics are running thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy or for their active ingredient... Some consumers are complaining about seeing ads for weight-loss injections everywhere they look: on television, at signs near public transit, on the walls of airports and pretty much every other surface devoted to marketing.”¹¹⁰

69. Moreover, marketing for Ozempic is primarily focused on efficacy (*e.g.*, lowered A1C), reduction in cardiovascular events, and weight loss,¹¹¹ which I understand are attributable in part to the prior art semaglutide compound and methods of using it to treat type 2 diabetes, rather than the novel contributions of

¹⁰⁹ EX1321: Bloomberg, “A Weight-Loss Drug Marketing Bonanza Is Upon Us,” 4/19/2023, <https://www.bloomberg.com/news/newsletters/2023-04-19/ro-is-advertising-wegovy-and-ozempic-on-the-subway-it-s-a-gray-area>. Further, I have not seen any evidence that the marketing messages for Ozempic target or relate to the claimed dosing in the ’462 patent.

¹¹⁰ EX1182: NBC News, “More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook,” 6/15/2023, <https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602>.

¹¹¹ EX2302: NN-OZEM-003176580, 1/2020, at -581-582 and 584.
EX2303: NN-OZEM-003176957, 2/2020, at -957-958.
EX2304: NN-OZEM-003238568, 5/2021, at -568 and 585-594.
EX2328: NN-OZEM-004717717, 6/2021, at -717-720, 722, 724, and 726-728.

the specific 1.0 mg dose claimed in the '462 Patent.¹¹² These factors diminish the nexus between the '462 Patent and alleged commercial success.

vi. Conclusion on nexus

70. Based on the above factors, the Vellturo Declaration has not shown a nexus to the claimed subject matter of the '462 Patent. At a minimum, only the portion of sales falling within the scope of the '462 Patent should be credited, not Ozempic sales or prescriptions overall. More fundamentally, the Vellturo Declaration does not distinguish or apportion the market performance between the novel aspects of the '462 Patent and prior art or unclaimed features, including other patents for Ozempic. Other factors like off-label use, [REDACTED], and Ozempic marketing all diminish claims of nexus as well. Just because there may be *some benefit* of the '462 Patent does not mean it is adequately linked to the alleged commercial success or that others would have developed the claimed subject matter sooner, had it been obvious. The Vellturo Declaration's analysis does not show this one way or the other, or that the market performance is the "direct result" of the novel aspects of the '462 Patent as opposed to other features of the product or features covered by prior art patents.

¹¹² EX1302: Spiegel Reply Declaration, ¶¶ 218-223, 254, 256, 289.
EX1304: Schwartzbard Reply Declaration, ¶ 127.

D. Blocking patents

71. For Ozempic, earlier patents before the '462 Patent provided strong economic disincentives for others to pursue the alleged invention. These blocking patents provide an alternative explanation for why the claimed subject matter was not developed sooner, even if obvious. Accordingly, because of earlier blocking patents, commercial success is economically irrelevant for the '462 Patent.

72. The Vellturo Declaration claims to analyze blocking patents and concludes that “the existence of the '343 and '122 patents would not have significantly diminished the incentives for third-party development of the '462 Patented Inventions.”¹¹³ However, I disagree with the Vellturo Declaration’s assessment of blocking disincentives. Based on the analysis below, at least U.S. Patent Nos. 8,129,343 (“the '343 Patent”), 8,536,122 (“the '122 Patent”), and 8,114,833 (“the '833 Patent”) provided strong disincentives for others to make, develop, and market the '462 Patent, even if obvious, based on the following: (1) scope, (2) timing, (3) exclusivity, (4) FDA exclusivity, and (5) economic deterrence.

¹¹³ EX2300: Vellturo Declaration, ¶ 120, Figure 5.

i. Scope

73. The Vellturo Declaration focuses its blocking patent analysis on the '343 Patent and the '122 Patent,¹¹⁴ which I understand cover the semaglutide compound and related methods of treatment using semaglutide for type 2 diabetes.¹¹⁵ I further understand that at least one other patent also provided blocking disincentives: the '833 Patent, which covers certain pharmaceutical formulations of a GLP-1 agonist (like semaglutide).¹¹⁶

74. I understand that the subject matter related to the '462 Patent overlaps with the subject matter of these blocking patents, such that the '462 Patent could not be practiced and used without use of the technologies claimed by the blocking patents.¹¹⁷ Thus, a hypothetical third-party developer would have considered that there was a risk of infringement liability associated with developing a semaglutide

¹¹⁴ EX2300: Vellturo Declaration, ¶¶ 3, 8, 118-120.
Dr. Vellturo testified that he did not investigate any other patents that may present potential blocking issues.

See EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 28:21-29:3.

¹¹⁵ EX1302: Spiegel Reply Declaration, ¶¶ 65-91, 275-276.

EX1068: U.S. Patent No. 8,129,343, Acylated GLP-1 compounds (filed 3/20/2006, issued 3/6/2012),

EX2488: U.S. Patent No. 8,536,122, Acylated GLP-1 compounds (filed 3/5/2012, issued 9/17/2013).

¹¹⁶ EX1302: Spiegel Reply Declaration, ¶¶ 92-99, 267-268, 277-278.

EX1121: U.S. Patent No. 8,114,833, Propylene glycol-containing peptide formulations which are optimal for production and for use in injection devices (filed 5/17/2006, issued 2/14/2012).

¹¹⁷ EX1302: Spiegel Reply Declaration, ¶¶ 273-278.

dosing regimen technology akin to the claimed subject matter, even if it were obvious at the time.

ii. Timing

75. The Vellturo Declaration largely focuses its blocking patent analysis on the relative timing of the claimed priority date for the '462 Patent versus the U.S. patent issuance dates (or, alternatively, U.S. application publication dates) of the blocking patents, and ultimately concludes that it shows no blocking disincentives.¹¹⁸ However, the Vellturo Declaration's blocking analysis is incorrect. Indeed, an analysis of timing actually shows that there were strong blocking disincentives, for reasons as follows.

76. First, a focus on U.S. patent issuance dates is too restricted. It does not reflect the time when others would have appreciated the disincentives of the blocking patents. Other developers reasonably consider the likelihood that a patent

¹¹⁸ EX2300: Vellturo Declaration, ¶¶ 119-120. Specifically, the Vellturo Declaration states that “the '122 Patent issued on September 17, 2013... after the invention date of the '462 Patent [of no later than July 1, 2012], and therefore would not have disincentivized third-party development of the Patented Inventions,” while “the [March 6, 2012] issuance of the '343 Patent would precede the priority date of the '462 Patent by approximately five months, indicating a small window of time where a third party would be disincentivized from pursuing the '462 Patented Inventions, relative to the large window of time prior to the issuance of the '343 Patented Inventions.” It separately considers the blocking patents' application publication dates relative to an alternative and earlier claimed invention date for at least claims 1-3 of the '462 Patent of “at least as early as March 17, 2010, but in any event no later than May 28, 2010.”

may issue (and, indeed, the patents did eventually issue) and therefore do not pursue development even as a patent is pending. Dr. Vellturo testified that patent applications can present blocking effects.¹¹⁹ Entities engaged in pharmaceutical development are sophisticated and would likely have known of Novo Nordisk's research and patenting efforts related to semaglutide before the blocking patent issuance dates.

77. Similarly, focusing on U.S. application publication dates is too restricted as well. Inventions that publish in a U.S. application may in some cases be filed and become publicly known sooner through the Patent Cooperation Treaty (“PCT”) system. The PCT enables foreign applicants to file a PCT international application, designating the U.S., in their home language in their home patent office and have the application acknowledged as a regular U.S. national filing.¹²⁰ In such cases, a published PCT application listing the U.S. as a designated state would signal to others that the patentee is seeking U.S. patent protection over an

¹¹⁹ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 27:20-28:20. (“Q: ... is it your view that for there to be a blocking issue, a patent needs to have issued? A: That’s quite typically the case. But certainly, there can be matters of degree of publication. But – so it’s not an absolute clear line. Q: So can patent applications potentially present a blocking issue? A: I think that’s too strong a statement. I think it’s a matter of degree. Is it possible that they can have some effect? I think it’s possible.”)

¹²⁰ EX1208: USPTO.gov, “1801 Basic Patent Cooperation Treaty (PCT) Principles [R-07.2022],” 7/2022, <https://www.uspto.gov/web/offices/pac/mpep/s1801.html>.

invention before the U.S. application publication date. In such cases, others (and certainly sophisticated entities engaged in pharmaceutical development) would again reasonably consider the potential that a patent may issue and therefore curtail development prior to the U.S. application publication and issuance dates.

78. For Ozempic, information shows that patent publications and information about Novo Nordisk's development relating to the blocking patents were available dating back to the 2005-2006 timeframe, many years before the claimed priority date(s) for the '462 Patent, as discussed below.

79. '343 and '122 Patent timing. The '343 Patent resulted from a 35 U.S.C. §371 national stage application of International Patent Application PCT/EP2006/060855,¹²¹ which published as WO2006/097537A2 in September 2006 and listed the U.S. as a designated state.¹²² The '122 Patent is a continuation of the '343 Patent.¹²³ Thus, at least as early as September 2006, it was publicly known that Novo Nordisk was seeking U.S. patent protection over the semaglutide inventions that would later issue as the '343 Patent and '122 Patent. This would

¹²¹ EX1068: U.S. Patent No. 8,129,343, Acylated GLP-1 compounds (filed 3/20/2006, issued 3/6/2012).

¹²² EX1015: International Publication Number WO2006/097537A2 (International Publication Date of 9/21/2006).

¹²³ EX2488: U.S. Patent No. 8,536,122, Acylated GLP-1 compounds (filed 3/5/2012, issued 9/17/2013).

have disincentivized development of the claimed subject matter for more than 3 years before March 2010 and more than 5 years before July 2012.

80. '833 Patent timing. The '833 Patent application is a continuation of International Patent Application PCT/DK2004/000792,¹²⁴ which published as WO2005/049061A2 in June 2005 and listed the U.S. as a designated state.¹²⁵ Thus, at least as early as June 2005, it was publicly known that Novo Nordisk was seeking U.S. patent protection over the inventions that would later issue as the '833 Patent. This would have disincentivized development of the claimed subject matter more than 4 years before March 2010 and more than 7 years before July 2012.

81. This timing aligns with other evidence of when Novo Nordisk's research related to semaglutide was becoming publicly known. For example, Novo Nordisk's 2007 annual report disclosed that a once-weekly GLP-1 human analogue for people with type 2 diabetes was being tested in a phase 1 study initiated in 2007, and that Novo Nordisk was building a portfolio of GLP-1 products with the aim of assuming a leadership position.¹²⁶ Specifically, Novo Nordisk started a

¹²⁴ EX1121: U.S. Patent No. 8,114,833, Propylene glycol-containing peptide formulations which are optimal for production and for use in injection devices (filed 5/17/2006, issued 2/14/2012).

EX1209: International Publication Number WO2005/0049061A2 (International Application Number PCT/DK2004/000792 with an International Filing Date of 11/18/2004).

¹²⁵ EX1209: International Publication Number WO2005/0049061A2 (International Publication Date of 6/2/2005).

¹²⁶ EX1178: Novo Nordisk, Annual Report 2007, at 18.

phase 1 trial of subcutaneous doses of semaglutide by at least June 2007.¹²⁷ By February 2009, Novo Nordisk had also published a Phase 2 study protocol regarding treatment with semaglutide in a range of 0.1 mg to 1.6 mg; similarly, an article published in *Nature Reviews Endocrinology* in May 2009 referenced the investigational use of NN9535 (semaglutide) in a 0.1-1.6 mg once weekly dose.¹²⁸ This further indicates that third parties would likely have been aware of Novo Nordisk's semaglutide research and patenting activities well before the claimed priority of the '462 Patent.

82. Ultimately, the Vellturo Declaration's narrow focus on the timing of the U.S. issuance and publication dates of the blocking patents overlooks this important context. Economically, other developers would not have waited for the blocking patents to issue, or for their U.S. applications to be published, before being disincentivized by Novo Nordisk's public pursuit of U.S. patent protection over the blocking inventions with overlapping scope as the '462 Patent. The economic disincentives associated with blocking patents begin with awareness and

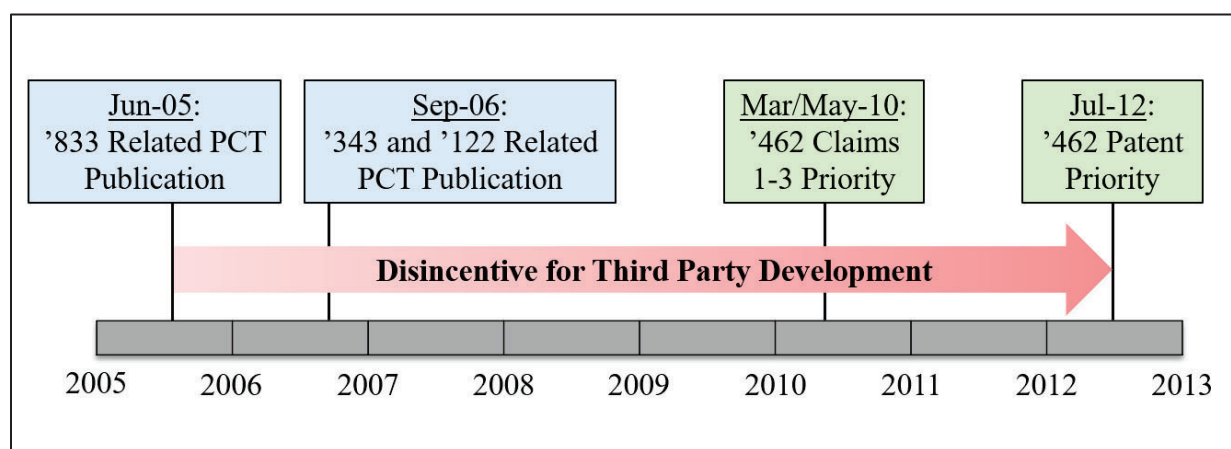
¹²⁷ EX2070: ClinicalTrials.gov, Study Record for NCT03144271, https://clinicaltrials.gov/study/NCT03144271?intr=Semaglutide&start=_2009-12-31&rank=5.

¹²⁸ See also:
EX1013: ClinicalTrials.gov, Study Record for NCT00696657, <https://clinicaltrials.gov/study/NCT00696657>.
EX1012: Lovshin, Julie and Daniel Drucker (2009), "Incretin-based therapies for type 2 diabetes mellitus," *Nature Reviews Endocrinology* 5:262–269, at 263 and 266.

pending intellectual property protection, based on assessment of likely future patent rights.

83. Figure 5 presents a corrected version of the Velturo Declaration's blocking patent considerations timeline, showing a significant period of blocking disincentives prior to the alleged priority date(s) of the '462 Patent:¹²⁹

Figure 5: Corrected Timeline of Blocking Patent Disincentives¹³⁰



¹²⁹ EX2300: Velturo Declaration, ¶¶ 117-120, Figure 5.

¹³⁰ EX1121: U.S. Patent No. 8,114,833, Propylene glycol-containing peptide formulations which are optimal for production and for use in injection devices (filed 5/17/2006, issued 2/14/2012).

EX1209: International Publication Number WO2005/0049061A2 (International Application Number PCT/DK2004/000792 with an International Filing Date of 11/18/2004).

EX1068: U.S. Patent No. 8,129,343, Acylated GLP-1 compounds (filed 3/20/2006, issued 3/6/2012).

EX2488: U.S. Patent No. 8,536,122, Acylated GLP-1 compounds (filed 3/5/2012, issued 9/17/2013).

EX1015: International Publication Number WO2006/097537A2 (International Publication Date of 9/21/2006).

EX2300: Velturo Declaration, ¶¶ 119-120, Footnotes 360 and 363.

84. This timeline highlights the strong blocking disincentives present in the years leading up to the alleged priority of the claimed subject matter. Upon publication of the PCT applications related to the technologies that ultimately issued as the '343, '122, and '833 Patents in 2005 and 2006, third parties would have recognized that Novo Nordisk was seeking U.S. patent protection over the blocking technologies. Novo Nordisk's research activities related to semaglutide were becoming publicly known prior to the alleged priority of the '462 Patent as well. As such, others would not have had an incentive to pursue development of the claimed dosing regimen in that timeframe, which provides an alternative explanation for why it was not developed sooner by others, regardless of the subsequent commercial performance of Ozempic.

iii. Exclusivity

85. Exclusivity of Novo Nordisk's patent use is a third factor indicating strong blocking disincentives here for Ozempic. In theory, one way that third-party development can occur despite blocking patents is if the blocking patents are licensed (out-licensing) or if third parties license patents to the entity with the blocking patents (in-licensing). In this case, I have seen no evidence that Novo Nordisk has out-licensed the blocking patents or in-licensed patents from others for

EX1001: U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).

Ozempic. Dr. Vellturo testified that he is not aware that Novo Nordisk has ever out-licensed any of the Ozempic patents.¹³¹ Instead, Novo Nordisk appears to be the exclusive holder and user of all relevant blocking patents. Further, all of the patents listed in the FDA Orange Book as covering Ozempic are assigned to Novo Nordisk, indicating that Novo Nordisk did not actively in-license patents related to Ozempic (see Appendix D-1). Even if licensing opportunities did exist (and it is not clear that they did), with Novo Nordisk pursuing its own product within the scope of the patents to which it owns, a third-party developer would be highly discouraged by uncertain licensing opportunities and follow-on development by Novo Nordisk on its own product. Thus, exclusivity and Novo Nordisk's own development further supports strong blocking disincentives here.

iv. FDA exclusivity

86. Additionally, Ozempic was granted a five-year New Chemical Entity exclusivity that did not expire until December 2022.¹³² This period of FDA exclusivity enjoyed by Novo Nordisk, but not others, further weighs against an inference of non-obviousness based on alleged commercial success.

87. The FDA grants exclusivity for holders of new drug applications (NDAs) or abbreviated new drug applications (ANDAs) that meet certain statutory

¹³¹ EX1314: Christopher Vellturo, Dep. Tr., 4/24/2024, at 29:8-12.

¹³² EX1166: FDA Orange Book, 2022, at ADA 258-259 of 299.

requirements.¹³³ The length of the exclusivity period may vary depending on which statutory requirements are met.¹³⁴ FDA exclusivity “refers to certain delays and prohibitions on approval of competitor drugs available under the statute that attach upon approval of a drug or of certain supplements”¹³⁵ to provide the holder of an approved new drug protection from competition.¹³⁶

88. The Vellturo Declaration does not consider Ozempic’s exclusivity, which further limits any economic inference that can be drawn from Ozempic’s alleged commercial success. Indeed, courts have held that a product’s commercial

¹³³ EX1175: FDA, “Frequently Asked Questions on Patents on Exclusivity,” https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a (accessed 4/17/2024).

¹³⁴ EX1175: FDA, “Frequently Asked Questions on Patents on Exclusivity,” https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a (accessed 4/17/2024).

¹³⁵ EX1175: FDA, “Frequently Asked Questions on Patents on Exclusivity,” https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a (accessed 4/17/2024).

¹³⁶ EX1174: FDA, “Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity,” 2/11/2016, <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity>.

success evidence may offer “limited probative value” in an obviousness inquiry because of marketing exclusivity granted by the FDA.¹³⁷

v. Economic deterrence

89. Based on the factors described above, the economic deterrence for development by others would have been strong. It is well known in the pharmaceutical industry that follow-on development incentives are substantially reduced by prior patent protection. For example, Correa (2004) states: “When the innovation process is cumulative, strong protection for the first-generation producer limits the scope of second-generation producers, and slows down follow-on innovation.”¹³⁸ Indeed, the Federal Circuit has stated: “Where ‘market entry by others was precluded [due to blocking patents], the inference of non-obviousness

¹³⁷ *Taiho Pharmaceutical Co., Ltd., et al., v. Eugia Pharma Specialties Ltd., et al.*, 2023 WL 5218125, at *20.
See also: Merck & Co. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1377 (Fed. Cir. 2005). “In this case Merck had a right to exclude others from practicing the weekly-dosing of alendronate specified in claims 23 and 37, given (1) another patent covering the administration of alendronate sodium to treat osteoporosis, U.S. Pat. No. 4,621,077 (issued Nov. 4, 1986); and (2) its exclusive statutory right, in conjunction with FDA marketing approvals, to offer Fosamax at any dosage for the next five years... Because market entry by others was precluded on those bases, the inference of non-obviousness of weekly-dosing, from evidence of commercial success, is weak.”

¹³⁸ EX1170: Correa, Carlos (2004), “Ownership of knowledge – the role of patents in pharmaceutical R&D,” *Bulletin of the World Health Organization* 2004;82(10):784-790, at 786.

of [the asserted claims], from evidence of commercial success, is weak.”¹³⁹ This makes sense economically, since companies are deterred from pursuing development that they cannot commercialize without facing patent enforcement. Licensing opportunities for follow-on development can exist, but with limited economic value, significant uncertainty, and thus limited economic incentives overall.

90. For the '462 Patent, Novo Nordisk was in a relatively strong position to develop the claimed subject matter leading up to the alleged priority date (whether or not they are patentable inventions) due to its history with semaglutide, numerous other patents for Ozempic, and presence in the type 2 diabetes space. As a result, other developers faced significant risk of losing the “invention race” for the claimed subject matter and Ozempic, and thus would have disincentivized development.¹⁴⁰

91. In summary, based on the analysis of the economic and factual considerations described above, the blocking patents described herein provided strong economic disincentives for others to pursue the alleged invention and offer an alternative explanation for why the claimed subject matter was not developed

¹³⁹ *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2014), citing *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005).

¹⁴⁰ *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1338-1339 (Fed. Cir. 2018).

sooner. In light of these economic disincentives, there is no economic inference of non-obviousness of the '462 patent from alleged commercial success.

V. Signature

92. I declare that my statements based on my knowledge are true and those based on information and belief I believe to be true. I made all my statements in this declaration with the knowledge that willful false statements and the like are punishable by fine, imprisonment or both pursuant to 18 U.S.C. 1001.

93. I understand that this declaration is to be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.



DeForest McDuff, Ph.D.

May 22, 2024

DeForest McDuff, Ph.D.

May 2024

DeForest McDuff, Ph.D. is a consultant and experienced expert witness in economics, business, damages, competition, and other areas. He provides economic analysis that is relied upon by clients, courts, and government agencies to support sound economic decisions. Dr. McDuff has been named as a nationally recognized economic expert in the IAM Patent 1000. He founded Insight Economics in 2017.

Dr. McDuff provides economic consulting and testimony in many areas, such as:

- Damages: lost profits, reasonable royalty, business impact, loss of value;
- Intellectual property: patents, trademarks, trade secrets, copyrights;
- Antitrust: market definition, restraints on competition, competitive impact;
- Competition: economic harm, unjust enrichment, false advertising;
- Economic analysis: irreparable harm, balance of hardships, class certification;
- Other areas: valuation, financial analysis, labor, employment, and more.

Dr. McDuff's experience includes more than 150 expert reports, 80 depositions, and 30 trials and evidentiary hearings in courts across the country. His experience outside the courtroom includes regulatory analysis, fair market valuation, licensing, negotiation, product launches, strategic analysis, and other topics. He regularly works in the pharmaceutical, medical device, electronic, and software industries, among others.

Dr. McDuff is a teaching professor in the Department of Economics at the University of North Carolina at Chapel Hill. He earned a Ph.D. in Economics from Princeton University, where he received a National Science Foundation Graduate Research Fellowship for his academic research in financial economics and applied microeconomics (awarded to 25 graduate students in economics nationwide each year). Dr. McDuff has published in peer-reviewed academic journals and widely review industry publications. He graduated summa cum laude with bachelor's degrees in economics and mathematics from the University of Maryland.

Dr. McDuff is also the co-founder of Integrity Seminars, a company dedicated to teaching academic integrity to college students since 2006. The company offers the Academic Integrity Seminar, a personalized online educational intervention administered to more than 100 colleges and universities nationwide to promote the importance of social trust and mutual obligation in academic, economic, and personal relationships.

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Insight Economics (www.insighteconomics.com). San Diego, CA and Raleigh, NC. Partner, 2017 to present.

University of North Carolina at Chapel Hill. Chapel Hill, NC. Assistant Teaching Professor, Department of Economics, 2020 to present.

Integrity Seminars (www.integrityseminar.org, formerly Academic Integrity Seminar). Partner, 2006 to present.

Intensity (formerly Quant Economics). San Diego, CA and Boston, MA. Economist from 2009 to 2012, Senior Economist from 2012 to 2013, Vice President from 2013 to 2017, Head of Boston Office from 2015 to 2017.

JPMorgan Chase. New York NY. Trading Analyst, 2006 to 2007.

Princeton University. Princeton NJ. Economic Research Assistant, 2004 to 2006.

Education

Ph.D. in Economics, M.A. in Economics, Princeton University, 2009.

B.A. in Economics, B.S. in Mathematics, University of Maryland, College Park, summa cum laude, 2004.

Professional Memberships

American Economic Association (AEA).

Licensing Executives Society (LES).

Publications

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McDuff, DeForest: "Analyzing Income and Happiness: The Effects of Placing Too Much Emphasis on Income in a Job" (2005), Princeton manuscript.

Awards

IAM Patent 1000: Economic Experts. Awarded to top economic experts nationwide (approximately 100 experts) with expertise in economic patent analysis, 2020-present.

Towbes Teaching Prize for Outstanding Teaching. Awarded to top 4 teaching assistants in the economics department, Princeton University, 2006.

National Science Foundation Graduate Research Fellowship. Awarded to 25 graduate students in economics nationwide each year, Princeton University, 2005-2008.

Princeton University Graduate Research Fellowship. Full tuition fellowship and stipend for graduate research, Princeton University, 2004-2009.

Dillard Prize. Awarded to top undergraduate in economics, University of Maryland at College Park, 2004.

Presentations

“Physician Finances: from Resident to Attending,” Harvard Residency Morning Conference, Boston MA, 2019; Duke University Residency Morning Conference, Durham NC, 2020-present.

“Price Optimization in E-Commerce,” Presenter, Global Big Data Conference, Boston MA, 2016.

“Damages Whirlwind: Navigating Reasonable Royalties in 2015,” Presenter, Boston Patent Law Association, Boston MA, 2015.

“Asset Valuation and Patent Monetization: A Review of Valuation Methods and Transaction Structures,” Presenter, Law Seminars International, San Francisco CA, 2015.

“Jury Trials for At-Risk Generic Launches,” Presenter, Continuing Legal Education, Los Angeles CA, 2015.

“Careers for PhDs in Start-ups,” Panelist, University of California at San Diego, San Diego CA, 2014.

“How to Prove Reasonable Royalty in Patent Damages,” Panelist, The Knowledge Congress, San Diego CA, 2013.

“Careers in Economics and Finance,” Presenter, University of California at San Diego, San Diego CA, 2010.

“Home Price Risk, Local Market Shocks, and Index Hedging,” Presenter, National Bureau of Economic Research, Boston MA, 2008.

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7. Sandoz Inc. v. Amgen Inc. (C.D. Cal., 22-cv-05326-RGK-MAR). Evaluation of false advertising and unfair business competition related to pharmaceutical marketing. Expert report, deposition.
8. Broadcom Corporation and Avago Technologies International Sales PTE. Limited v. Netflix, Inc. (N.D. Cal., 20-cv-04677-JD). Evaluation of reasonable royalty related to video streaming. Expert report, deposition.
9. TwinStrand Biosciences, Inc., University of Washington v. Guardant Health, Inc. (D. Del., 21-1226-GBW-SRF). Evaluation of reasonable royalty related to cancer diagnostic tests. Expert report (x3), expert declaration, deposition, trial testimony.
10. Finjan, Inc. v. ESET, LLC; ESET SPOL. S.R.O (S.D. Cal., 3:17-cv-0183-CAB-BGS). Evaluation of reasonable royalty related to cybersecurity software. Expert report.
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- Reddy's Laboratories, Ltd.; Eugia Pharma Specialties Limited; Fisiopharma SRL; Fresenius Kabi USA, LLC; Gland Pharma Limited; Lek Pharmaceuticals dd; Lifestar Pharma LLC; Lupin Inc.; Lupin Limited; Lupin Pharmaceuticals, Inc.; Mankind Pharma Ltd.; MSN Laboratories Private Limited; MSN Life Sciences Private Ltd.; MSN Pharmaceuticals Inc.; Mylan API US LLC; Mylan Inc.; Mylan Pharmaceuticals Inc.; Sandoz, Inc.; Sun Pharmaceutical Industries Inc.; Sun Pharmaceutical Industries Limited; Teva Pharmaceuticals USA, Inc.; USV Private Limited; Zenara Pharma Ltd.; Zenara Pharma Private Limited; Zydus Lifesciences Limited f/k/a Cadila Healthcare Limited; Zydus Pharmaceuticals (USA) Inc.), (D.N.J., Case No. 2:20-cv-02576). Evaluation of commercial success related to Bridion (sugammadex) for the reversal of neuromuscular blockage. Expert report, deposition.
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 32. Confidential Arbitration, California). Evaluation of breach of contract and business impact related to dentistry medical devices. Expert analysis, deposition, arbitration testimony.
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Appendix B
Materials Considered or Relied Upon

Depositions

Exhibit 1314: Christopher Vellturo, Quantitative Economic Solutions, LLC, Economic Expert, Dep. Tr., Exhibits 1001, 2054, 2300, 2330, 2487, 2528, 4/24/2024.

Exhibit 1140: Robin Goland, Columbia University, Practicing Physician and Technical Expert, Dep. Tr., Exhibits 1001, 1095, 2054, 2072, 2076, 2080, 2081, 2082, 2083, 2084, 2085, 4/9/2024.

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Exhibit 2054: Expert Declaration of Robin S. Goland, M.D. In Support of Patent Owner's Response to Petition for *Inter Partes* Review of U.S. Patent No. 10,335,462, 1/16/2024.

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Exhibit 1304: Reply Declaration of Arthur Z. Schwartzbard, M.D., F.A.C.C., 5/22/2024.

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Exhibit 1204: U.S. Patent No. 10,220,155.

Exhibit 1205: U.S. Patent No. 10,357,616.

Exhibit 1197: U.S. Patent No. 10,376,652.

Exhibit 1198: U.S. Patent No. 11,097,063.

Exhibit 1203: U.S. Patent No. 11,311,679.

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Exhibit 1120: FDA Orange Book, 2018. (excerpts)
Exhibit 1134: FDA Orange Book, 2019. (excerpts)
Exhibit 1135: FDA Orange Book, 2020. (excerpts)

Exhibit 1165: FDA Orange Book, 2021. (excerpts)

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Exhibit 1186: The Washington Post, “Prescriptions for Ozempic and similar drugs have skyrocketed, data shows,” 9/27/2023, <https://www.washingtonpost.com/business/2023/09/27/ozempic-prescriptions-data-analysis/>.

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Exhibit 2304: NN-OZEM-003238568.
Exhibit 2305: NN-OZEM-003242796.
Exhibit 2306: NN-OZEM-003732069.
Exhibit 2307: NN-OZEM-003732120.
Exhibit 2308: NN-OZEM-003735283.
Exhibit 2309: NN-OZEM-003793796.
Exhibit 2310: NN-OZEM-003971783.
Exhibit 2311: NN-OZEM-004055726.
Exhibit 2312: NN-OZEM-004063922.
Exhibit 2313: NN-OZEM-004300946.
Exhibit 2314: NN-OZEM-004656390.
Exhibit 2315: NN-OZEM-004677154.
Exhibit 2316: NN-OZEM-004679316.
Exhibit 2317: NN-OZEM-004680250,
Exhibit 2318: NN-OZEM-004681464,
Exhibit 2320: NN-OZEM-004684107.
Exhibit 2321: NN-OZEM-004684467.
Exhibit 2322: NN-OZEM-004687270.
Exhibit 2323: NN-OZEM-004688496.
Exhibit 2324: NN-OZEM-004690786.
Exhibit 2325: NN-OZEM-004691302.
Exhibit 2326: NN-OZEM-004691816.
Exhibit 2327: NN-OZEM-004701779.
Exhibit 2328: NN-OZEM-004717717.
Exhibit 2329: NN-OZEM-004723449.
Exhibit 2330: NN-OZEM-004723593.
Exhibit 2331: NN-OZEM-004724606.
Exhibit 2332: NN-OZEM-004731509.
Exhibit 2333: NN-OZEM-004741982.
Exhibit 2334: NN-OZEM-004751127.
Exhibit 2028: NN-OZEM-000020275.

Exhibit 1323: NN-OZEM-004426808.

Appendix C-1
Ozempic Off-label Sales Analysis

Source	2019	2020	2021	2022
Off-label Ozempic Prescriptions [A]	230	510	1,200	2,200
Annual Total Ozempic Prescriptions [B]				
Estimated Off-label Prescriptions Share [C]				

Notes and sources:

In thousands.

[A] EX1172: Komodo Health, "Prescriptions for Trendy Diabetes and Weight-Loss Drugs Increased Over 2,000% Since 2019," 2/17/2023, <https://www.komodohealth.com/perspectives/prescriptions-for-trendy-diabetes-and-weight-loss-drugs-increased-over-2000-since-2019>.

EX1185: Track Drugs, "Ozempic Statistics And Trends in 2024," January 2024, <https://trackdrugs.com/ozempic-statistics>.

[B] EX2300: Velturo Declaration, Appendix F.

[C] = [A] ÷ [B]

Appendix D-1
Ozempic FDA Orange Book Patents

U.S. Patent No.	Original Assignee / Applicant	Approximate Priority Date (US)	Patent File Date	Patent Issue Date	Patent Expiration Date	Title	Issuance by FDA Orange Book Edition							
							2017	2018	2019	2020	2021	2022	2023	2024
10,220,155	Novo Nordisk A/S	8/15/2005	7/17/2006	3/5/2019	7/17/2026	Syringe device with a dose limiting mechanism and an additional safety mechanism				x	x	x	x	x
10,335,462 *	Novo Nordisk A/S	8/30/2012	7/21/2017	7/2/2019	6/21/2033	Use of long-acting GLP-1 peptides				x	x	x	x	x
10,357,616	Novo Nordisk A/S	1/27/2005	11/17/2017	7/23/2019	1/20/2026	Injection device with an end of dose feedback mechanism				x	x	x	x	x
10,376,652	Novo Nordisk A/S	1/26/2005	2/24/2017	8/13/2019	1/20/2026	Automatic injection device with a top release mechanism				x	x	x	x	x
11,097,063	Novo Nordisk A/S	8/15/2005	1/17/2019	8/24/2021	7/17/2026	Syringe device with a dose limiting mechanism and an additional safety mechanism						x	x	x
11,311,679	Novo Nordisk A/S	1/26/2005	6/25/2019	4/26/2022	1/20/2026	Automatic injection device with a top release mechanism							x	x
11,446,443	Novo Nordisk A/S	11/9/2004	10/1/2019	9/20/2022	10/20/2025	Injection device with torsion spring and rotatable display							x	x
6,899,699	Novo Nordisk A/S	1/9/2001	1/2/2002	5/31/2005	1/2/2022	Automatic injection device with reset feature	x	x	x	x	x	x		
7,762,994	Novo Nordisk A/S	7/3/2002	7/16/2007	7/27/2010	5/23/2024	Needle mounting system and a method for mounting a needle assembly	x	x	x	x	x	x	x	x
8,114,833	Novo Nordisk A/S	11/24/2003	5/17/2006	2/14/2012	8/13/2025	Propylene glycol-containing peptide formulations which are optimal for production and for use in injection devices	x	x	x	x	x	x	x	x
8,129,343	Novo Nordisk A/S	3/23/2005	3/20/2006	3/6/2012	12/5/2031	Acylated GLP-1 compounds		x	x	x	x	x	x	x
8,536,122	Novo Nordisk A/S	3/23/2005	3/5/2012	9/17/2013	3/20/2026	Acylated GLP-1 compounds	x	x	x	x	x	x	x	x
8,579,869	Novo Nordisk A/S	7/3/2002	2/10/2012	11/12/2013	6/30/2023	Needle mounting system and a method for mounting a needle assembly	x	x	x	x	x	x	x	x
8,672,898	Novo Nordisk A/S	1/9/2001	10/22/2004	3/18/2014	1/2/2022	Automatic injection device with reset feature	x	x	x	x	x	x		
8,684,969	Novo Nordisk A/S	11/9/2004	9/25/2012	4/1/2014	10/20/2025	Injection device with torsion spring and rotatable display	x	x	x	x	x	x	x	x
8,920,383	Novo Nordisk A/S	8/16/2005	7/17/2006	12/30/2014	7/17/2026	Dose mechanism for an injection device for limiting a dose setting corresponding to the amount of medicament left	x	x	x	x	x	x	x	x
9,108,002	Novo Nordisk A/S	1/26/2005	12/15/2011	8/18/2015	1/20/2026	Automatic injection device with a top release mechanism	x	x	x	x	x	x	x	x
9,132,239	Novo Nordisk A/S	10/29/2008	10/21/2009	9/15/2015	2/1/2032	Dial-down mechanism for wind-up pen	x	x	x	x	x	x	x	x
9,457,154	Novo Nordisk A/S	1/27/2005	1/20/2006	10/4/2016	9/27/2027	Injection device with an end of dose feedback mechanism	x	x	x	x	x	x	x	x
9,486,588	Novo Nordisk A/S	1/9/2001	1/30/2014	11/8/2016	1/2/2022	Automatic injection device with reset feature	x	x	x	x	x	x		
9,616,180	Novo Nordisk A/S	1/26/2005	7/13/2015	4/11/2017	1/20/2026	Automatic injection device with a top release mechanism			x	x	x	x	x	x
9,687,611	Novo Nordisk A/S	11/9/2004	1/29/2014	6/27/2017	2/27/2027	Injection device with torsion spring and rotatable display	x	x	x	x	x	x	x	x
9,775,953	Novo Nordisk A/S	8/16/2005	11/21/2014	10/3/2017	7/17/2026	Dose mechanism for an injection device for limiting a dose setting corresponding to the amount of medicament left	x	x	x	x	x	x	x	x
9,861,757	Novo Nordisk A/S	1/27/2005	8/19/2016	1/9/2018	1/20/2026	Injection device with an end of dose feedback mechanism			x	x	x	x	x	x
RE46,363	Novo Nordisk A/S	11/9/2004	11/27/2013	4/11/2017	8/3/2026	Dial-down mechanism for wind-up pen	x	x	x	x	x	x	x	x

Notes and sources:
Ozempic was approved by the FDA on December 5, 2017 and first appeared in the 12th Supplement of the 2017 FDA Orange Book. There are no patents covering Ozempic from 2012 to 2016.
* indicates patent-at-issue.

Patents:
[EX1204](#): U.S. Patent No. 10,220,155, Syringe device with a dose limiting mechanism and an additional safety mechanism (filed 7/17/2006, issued 3/5/2019).
[EX1001](#): U.S. Patent No. 10,335,462, Use of long-acting GLP-1 peptides (filed 7/21/2017, issued 7/2/2019).
[EX1205](#): U.S. Patent No. 10,357,616, Injection device with an end of dose feedback mechanism (filed 11/17/2017, issued 7/23/2019).
[EX1197](#): U.S. Patent No. 10,376,652, Automatic injection device with a top release mechanism (filed 2/24/2017, issued 8/13/2019).
[EX1198](#): U.S. Patent No. 11,097,063, Syringe device with a dose limiting mechanism and an additional safety mechanism (filed 1/17/2019, issued 8/24/2021).
[EX1203](#): U.S. Patent No. 11,311,679, Automatic injection device with a top release mechanism (filed 6/25/2019, issued 4/26/2022).
[EX1202](#): U.S. Patent No. 11,446,443, Injection device with torsion spring and rotatable display (filed 10/1/2019, issued 9/20/2022).
[EX1168](#): U.S. Patent No. 6,899,699, Automatic injection device with reset feature (filed 1/2/2002, issued 5/31/2005).
[EX1183](#): U.S. Patent No. 7,762,994, Needle mounting system and a method for mounting a needle assembly (filed 7/16/2007, issued 7/27/2010).
[EX1121](#): U.S. Patent No. 8,114,833, Propylene glycol-containing peptide formulations which are optimal for production and for use in injection devices (filed 5/17/2006, issued 2/14/2012).
[EX1068](#): U.S. Patent No. 8,129,343, Acylated GLP-1 compounds (filed 3/20/2006, issued 3/6/2012).
[EX2488](#): U.S. Patent No. 8,536,122, Acylated GLP-1 compounds (filed 3/5/2012, issued 9/17/2013).
[EX1187](#): U.S. Patent No. 8,579,869, Needle mounting system and a method for mounting a needle assembly (filed 2/10/2012, issued 11/12/2013).
[EX1193](#): U.S. Patent No. 8,672,898, Automatic injection device with reset feature (filed 10/22/2004, issued 3/18/2014).
[EX1169](#): U.S. Patent No. 8,684,969, Injection device with torsion spring and rotatable display (filed 9/25/2012, issued 4/1/2014).
[EX1194](#): U.S. Patent No. 8,920,383, Dose mechanism for an injection device for limiting a dose setting corresponding to the amount of medicament left (filed 7/17/2006, issued 12/30/2014).
[EX1188](#): U.S. Patent No. 9,108,002, Automatic injection device with a top release mechanism (filed 12/15/2011, issued 8/18/2015).
[EX1192](#): U.S. Patent No. 9,132,239, Dial-down mechanism for wind-up pen (filed 10/21/2009, issued 9/15/2015).
[EX1191](#): U.S. Patent No. 9,457,154, Injection device with an end of dose feedback mechanism (filed 1/20/2006, issued 10/4/2016).
[EX1201](#): U.S. Patent No. 9,486,588, Automatic injection device with reset feature (filed 1/30/2014, issued 11/8/2016).
[EX1196](#): U.S. Patent No. 9,616,180, Automatic injection device with a top release mechanism (filed 7/13/2015, issued 4/11/2017).
[EX1195](#): U.S. Patent No. 9,687,611, Injection device with torsion spring and rotatable display (filed 1/29/2014, issued 6/27/2017).
[EX1200](#): U.S. Patent No. 9,775,953, Dose mechanism for an injection device for limiting a dose setting corresponding to the amount of medicament left (filed 11/21/2014, issued 10/3/2017).
[EX1199](#): U.S. Patent No. 9,861,757, Injection device with an end of dose feedback mechanism (filed 8/19/2016, issued 1/9/2018).
[EX1211](#): U.S. Patent No. RE46,363, Dial-down mechanism for wind-up pen (filed 11/27/2013, issued 4/11/2017).

FDA Orange Books:
[EX1133](#): FDA Orange Book, Supplement 12 December 2017, at A-69.
[EX1120](#): FDA Orange Book, 2018, at ADA 225 of 259.
[EX1134](#): FDA Orange Book, 2019 at ADA 229-230 of 263.
[EX1135](#): FDA Orange Book, 2020, at ADA 242 of 277.
[EX1165](#): FDA Orange Book, 2021, at ADA 258-259 of 297.
[EX1166](#): FDA Orange Book, 2022, at ADA 258-259 of 299.
[EX1293](#): FDA Orange Book, 2023, at ADA 363-365 of 420.
[EX1101](#): FDA Orange Book, 2024, at ADA 374-376 of 442.

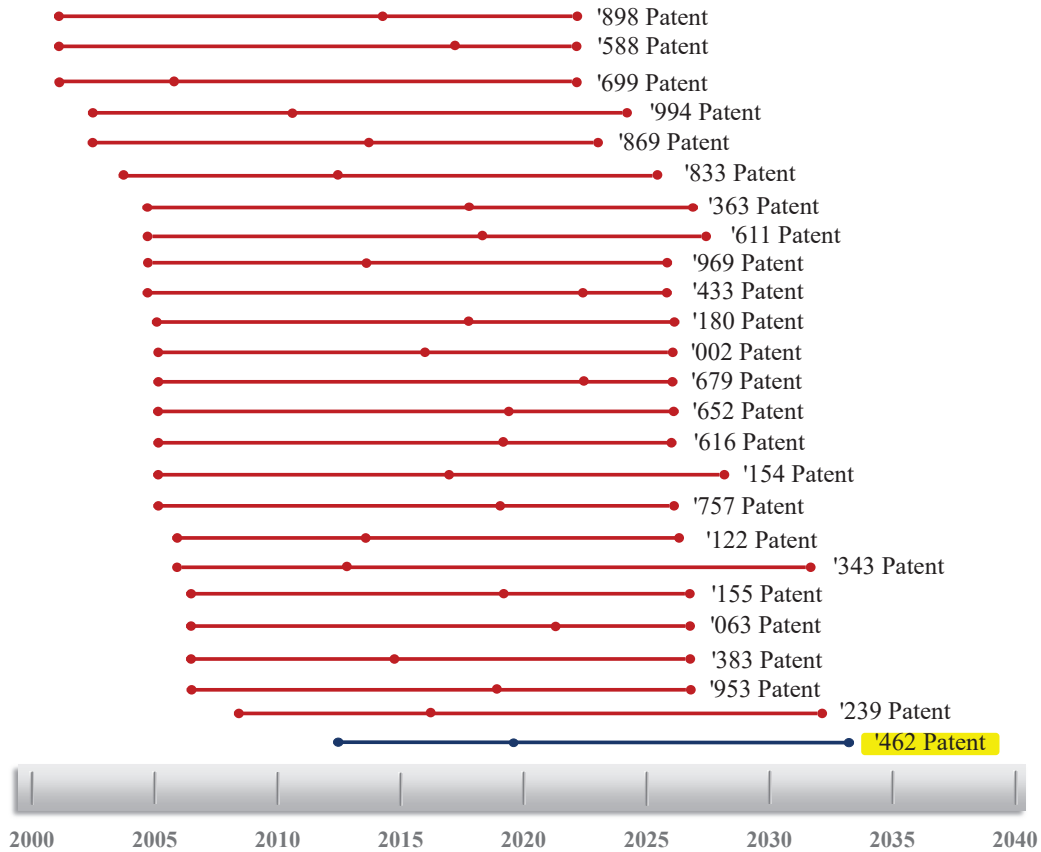
HIGHLY CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

Appendix D-1

PROTECTIVE ORDER MATERIAL

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Appendix D-2
Ozempic Patent Timeline



Notes and sources:
Patent data from Appendix D-1.
From left to right, the circle marks indicate the Approximate U.S. Priority Date, Patent Issue Date, and Patent Expiration Date.

HIGHLY CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

PROTECTIVE ORDER MATERIAL

Appendix D-2

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