UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

Case No. IPR2019-00122
U.S. Patent No. 8,992,486

PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

EXHIBIT LIST

Exhibit #	Description
2001	Press Release, "Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products", Feb. 13, 2013 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=122834
2002	Press Release, "Mylan Commences Phase III Clinical Trials for its Generic Version of Advair Diskus® and Insulin Analog to Lantus®", Sept. 16, 2014 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=123251
2003	Press Release, "Mylan and Biocon Present Clinical Data on Insulin Glargine at the American Diabetes Association's 77th Scientific Sessions", June 10, 2017 (PR Newswire), available at http://newsroom.mylan.com/2017-06-10-Mylan-and-Biocon-Present-Clinical-Data-on-Insulin-Glargine-at-the-American-Diabetes-Associations-77th-Scientific-Sessions
2004	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.*, C.A. No. 1-16-cv-00812-RGA (D. Del), Dkt. No. 1
2005	Stipulation and Proposed Order, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.*, Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb 5, 2018), Dkt. No. 45
2006	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1
2007	Excerpts from Defendants' Invalidity Contentions, dated Jan. 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2008	Mylan GMBH's Exhibit E to Invalidity Contentions, dated Jan. 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2009	Excerpts from Mylan GMBH's Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

Exhibit #	Description
2010	Mylan GMBH's Exhibit E to Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2011	Aug. 13, 2018 Service of Sanofi's Responses to Mylan's Amended Contentions, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2012	MP4 file of Sanofi's Patented Pen animation
2013	Excerpts from McGraw Hill Dictionary of Scientific and Technical Terms (Sixth edition, McGraw-Hill 2003), p. 972 and 1873
2014	Excerpts from Merriam-Webster's Collegiate Dictionary (10th edition, Merriam-Webster, Inc. 2001), p. 538
2015	The New Oxford American Dictionary (Oxford University Press 2001), p. 789-90
2016	Transcript, Conference Call for Case IPR2018-01675, -1676, and -1678 (P.T.A.B. Jan. 15, 2019)
2017	Excerpts from Transcript, Conference Call dated Aug. 2, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.) (confidentiality designation removed)
2018	Report of the Local Patent Rules Committee, Explanatory Notes for 2016 Amendments
2019	Defendants' Opposition to Plaintiffs' Motion to Stay dated Nov. 22, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 44
2020	Joint Proposed Discovery Plan dated Dec. 14, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2021	Letter from A. Calmann to Judge Waldor dated Apr. 24, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.), Dkt. No. 90
2022	Motion to Expedite Defendants' Motion Requesting an Expedited Scheduling Conference dated Nov. 22, 2017 , *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 46
2023	Initial Planning Meeting Report and Discovery Proposals dated Dec. 22, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 61

Exhibit #	Description
2024	Transcript of Motion / Scheduling Conference dated Jan. 3, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 64
2025	Transcript, Conference Call for Case IPR2018-01675, -01676, -01678, -01680 (P.T.A.B. Feb. 5, 2019)
2026-2099	*Reserved*
2100	Leinsing Deposition Exhibit 2100: Thomas van der Burg, *Injection Force of SoloSTAR® Compared with Other Disposable Insulin Pen Devices at Constant Volume Flow Rates*, J. of Diabetes Sci. and Tech., Vol. 5, Issue 1, 150-155 (Jan. 2001)
2101	Leinsing Deposition Exhibit 2101: Estelle Davis, et. al., *An evaluation of prefilled insulin pens: a focuse on the Next Generation FlexPen®*, Med. Devices: Evidence & Research, 41-50 (2010:3)
2102	Leinsing Deposition Exhibit 2102: Hand drawings
2103	Leinsing Deposition Exhibit 2103: Annotations of Figures 6-15 of Burroughs
2104	Leinsing Deposition Exhibit 2104: Annotations of Figures 5-8 of the 486 Patent
2105	Leinsing Deposition Exhibit 2105: Hand drawings
2106	Leinsing Deposition exhibit 2106: Annotations of Figures 11 and 12 of Giambattista
2107	Declaration of Alexander Slocum, Ph.D.
2108	Curriculum Vitae of Alexander Slocum, Ph.D.
2109	Declaration of Henry R. Grabowski, Ph.D.
2110	Curriculum Vitae of Henry R. Grabowski, Ph.D.
2111	Declaration of Dr. Robin S. Goland
2112	Curriculum Vitae of Dr. Robin S. Goland
2113	Bradley M. Wright et al., *A Review Of Insulin Pen Devices And Use In The Elderly Diabetic Population*, 3 Clinical Medicine Insights: Endocrinology & Diabetes 54-63 (2010)
2114	Teresa L. Pearson, *A-Practical-Review-of-Insulin-Pen-Devices*, EMJ Diabet., 58-64 (2014:2)
2115	Arthritis & Diabetes, *What do diabetes and arthritis have in common? Plenty.*, https://www.arthritis.org/living-with-arthritis/comorbidities/diabetes-and-arthritis/

Exhibit #	Description
2116	Andreas Bode, *Development of the SoloSTAR insulin pen device design verification and validation*, 6 Expert Opinion on Drug Delivery 103-112 (2008)
2117	Sanofi's Patented Pen animation
2118	John Carter, *Usability, Participant Acceptance, and Safety of a Prefilled Insulin Injection Device in a 3-Month Observational Survey in Everyday Clinical Practice in Australia, J. Diabetes Sci & Tech., Vol. 3, Issue 6, 1425-1438 (Nov. 2009)*
2119	Sherwyn Schwartz, *Correct Use of a New Reusable Insulin Injection Pen by Patients with Diabetes: A Design Validation Study*, 4 J. Diabetes Sci. and Tech. 1229-1235 (2010)
2120	*Reserved*
2121	DBA Design Effectiveness Awards 2009
2122	SoloSTAR Disposable Pen Injector (The Grand Prix Oct. 22, 2009)
2123	Arnd Friedrichs et al., *Dose Accuracy and Injection Force of Different Insulin Glargine Pens*, 7 J. Diabetes Sci. and Tech. 1346-1353 (2013)
2124	Stacey A. Seggelke et al., *Effect of Glargine Insulin Delivery Method (Pen Device Versus Vial/Syringe) on Glycemic Control and Patient Preferences in Patients with Type 1 and Type 2 Diabetes*, 20 ENDOCRINE PRACTICE, 536, 536, 538–539 (2014)
2125	Julia Pfutzner et al., *Evaluation of Dexterity in Insulin-Treated Patients with Type 1 and Type 2 Diabetes Mellitus*, 5 J. Diabetes Sci. and Tech. 158-165 (2011)
2126	Jerome S. Fischer et al., *United States Patient Preference and Usability for the New Disposable Insulin Device Solostar® versus Other Disposable Pens*, 2 JOURNAL OF DIABETES SCIENCE AND TECHNOLOGY 1157-1160 (2008)
2127	U.S. Provisional Patent Application 60/073820
2128	Samita Garg et al., *Insulin glargine and glulisine SoloSTAR pens for the treatment of diabetes*, 5 Expert Rev. Med. Devices 113-123 (2008)
2129	Nicolae Hancu et al., *A Pan-European and Canadian Prospective Survey to Evaluate Patient Satisfaction with the SoloSTAR Insulin Injection Device in Type 1 and Type 2 Diabetes*, 5 J. Diabetes Sci. and Tech. 1224-1234 (2011)

Exhibit #	Description
2130	Norbert Hermanns, Bernhard Kulzer & Thomas Haak, *Dosing Accuracy with a Novel Pen Device (SoloSTAR) as Performed by Patients with Diabetes in a Clinical Setting*, 10 Diabetes Tech. & Threapeutics 322-327 (2008)
2131	ISO 11608-1, Pen-injectors for medical use (1st Ed. Dec. 15, 2000)
2132	Meike Krzywon et al., *Study on the Dosing Accuracy of Commonly Used Disposable Insulin Pens*, 14 Diabetes Tech. & Therapeutics 804-809 (2012)
2133	Lantus SoloSTAR Pen Guide
2134	Arlan L. Rosenbloom, *Limitation of Finger Joint Mobility in Diabetes Mellitus*, 3 J. Diabetic Complications 77-87 (1989)
2135	Douglas Merritt et al., *Dose Accuracy and Injection Force of Disposable Pens Delivering Pramlintide for the Treatment of Diabetes*, 4 J. Diabetes Sci. and Tech. 1438-1446 (2010)
2136	Novo Nordisk Form 6-K (Feb. 9, 2009)
2137	Novo Nordisk History
2138	W. Schady et al, *Observations on Severe Ulnar Neuropathy in Diabetes*, 12 J Diabetes and Its Complications 128-132 (1998)
2139	Alfred Penfornis & Kristian Horvat, *Dose Accuracy Compariosn Between SoloSTAR and FlexPen at Three Different Dose Levels*, 10 Diabetes Tech. & Therapeutics 359-362 (2008)
2140	Riccardo Perfetti, *Reusable and Disposable Insulin Pens for the Treatment of Diabetes: Understanding the Global Differences in User Preference and an Evaluation of Inpatient Insulin Pen Use*, 12 Diabetes Tech. & Therapeutics 79-85 (2010)
2141	John Shelmet et al., *Preference and resource utilization in elderly patients: InnoLet versus vial/syringe*, 63 Diabetes Res. and Clinical Prac. 27-35 (2004)
2142	*Prix Galien USA Announces 2009 Final Candidates* (Prix Galien USA, August 7, 2009)
2143	Thomas Haak et al., *Comparison of Usability and Patient Preference for the New Disposable Insulin Device SoloStar Versus FlexPen, Lilly Disposable Pen, and a Prototype Pen: An Open-Label Study*, 29 CLINICAL THERAPEUTICS, 650-660 (2007)
2144	Alastair Clarke & Geralyn Spollett, *Dose accuracy and injection force dynamics of a novel disposable insulin pen*, 4 EXPERT OPINION ON DRUG DELIVERY 165-174 (2007)

Exhibit #	Description
2145	US Lantus SoloSTAR Launch Book, 2007, PTX-0705, Document bates stamped SANOFI_00232909-45
2146	Lantus COMPASS Study Report (Nov. 29, 2007), PTX-0739, Document bates stamped SANOFI3_90330807-1025
2147	Steenfeldt-Jensen 5th Embodiment Animation
2148	Steenfeldt-Jensen 1st Embodiment Animation
2149	Steenfeldt-Jensen 2nd Embodiment Animation
2150	Steenfeldt-Jensen 5th Embodiment Thread and Slot Animation
2151	Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Animation
2152	Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Collar Friction Animation
2153	International Patent Application WO999038554A1
2154	*Reserved*
2155	*Reserved*
2156	*Reserved*
2157	*Reserved*
2158	Geralyn Spollett, *Insulin Devices, Addressing Barriers to Insulin Therapy With the Ideal Pen, 957-967 (The Diabetes EDUCATOR)*
2159	Serpil Savas et al., *The effects of the diabetes related soft tissue hand lesions and the reduced hand strength on functional disability of hand in type 2 diabetic patients*, 77 Diabetes Res. and Clinical Prac. 77-83 (2007)
2160	Jean-Louis Selam, *Evolution of Diabetes Insulin Delivery Devices*, 4 J. Diabetes Sci. and Tech. 505-513 (2010)
2161	SoloSTAR Principles of Operation, PTX-0553, Document bates stamped SANOFI_00406383-94
2162	Sanofi Patent Drive Sleeve and Piston Rod Animation
2163	Deposition of Karl R. Leinsing, dated June 3, 2019 for IPR2018-01675, -01676, -01678, -01680
2164	Deposition of Karl R. Leinsing, dated June 4, 2019 for IPR2018-01675, -01676, -01678, -01680
2165	Opinion and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.*, Civil Action No. 17-9105-SRC-SLW (D.N.J. May 9, 2019), Dkt. No. 319

Exhibit #	Description
2166	Memorandum and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Merck*, No. 16-812-RGA (D. Del. Jan. 12, 2018), Dkt. No. 192
2167	Giambattista Animation (1)
2168	Giambattista Animation (2)
2169	U.S. Patent No. 4,648,872
2170	U.S. Patent No. 4,747,824
2171	U.S. Patent No. 6,248,093
2172	Karl R. Leinsing Declaration in *Hologic, Inc. v. Minerva Surgical, Inc., No. 15-1031* (D. Del. Jan. 26, 2018), Dkt. No. 309
2173	Bruce A. Perkins, David Olaleye & Vera Bril, *Carpal Tunnel Syndrome in Patients With Diabetic Polyneuropathy*, 25 Diabetes Care 565-569 (2002)
2174	Jefferson Becker et al., *An evaluation of gender, obesity, age and diabetes mellitus as risk factors for carpal tunnel syndrome*, 113 Clinical Neurophysiology 1429-1434 (2002)
2175	A. Pfutzner et al., *Prefilled insulin device with reduced injection force: patient perception and accuracy*, 24 Current Med. Res. and Opinion 2545-2549 (2008)
2176	Ercan Cetinus et al., *Hand grip strength in patients with type 2 diabetes mellitus*, Diabetes Res. and Clinical Prac. 1-9 (2005)
2177	Ragnhild I. Cederlund et al., *Hand disorders, hand function, and activities of daily living in elderly men with type 2 diabetes*, 23 J. Diabetes and Its Complications 32-99 (2009)
2178	Shubha Gundmi et al., *Hand dysfunction in type 2 diabetes mellitus: Systematic review with meta-analysis*, 61 Annals of Physical and Rehabilitation Med. 99-104 (2018)
2179	Joule J. Li et al., *Muscle grip strength predicts incident type 2 diabetes: Population-based cohort study*, 65 Metabolism Clinical and Experimental 883-892 (2016)
2180	Considering Insulin Pens for Routine Hospital Use - Consider This... (ISMP article), https://www.ismp.org/resources/considering-insulin-pens-routine-hospital-use-consider
2181	Trigger Finger Overview (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/trigger-finger/symptoms-causes/syc-20365100

Exhibit #	Description
2182	Bone and joint problems associated with diabetes (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes/art-20049314
2183	Peripheral Neuropathy (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/peripheral-neuropathy/symptoms-causes/syc-20352061
2184	Charles E. Buban, *A pen that seeks to improve diabetes care*, INQUIRER.NET (2008), Document Bates stamped SANOFI_00006282-84
2185	"*Sanofi-aventis' SoloSTAR(R) Insulin Pen for Lantus and Apidra Receives the Prestigious GOOD DESIGN Award"*, (PR Newswire Feb. 14), Document Bates stamped SANOFI_00006299-301
2186	Select Injectable Insulin Drugs Approved by the FDA in the U.S.
2187	U.S. Dollar Sales of Lantus SoloSTAR
2188	U.S. New Prescriptions of Lantus SoloSTAR
2189	U.S. Total Prescriptions of Lantus SoloSTAR
2190	U.S. Share of Sales by Drugs in the Lantus Franchise
2191	Formulary Placement of Long-Acting Insulin Pen Products: Commercial Plans
2192	Formulary Placement of Long-Acting Insulin Pen Products: Medicare Plans
2193	Formulary Placement of Long-Acting Insulin Pen Products: Medicaid Plans
2194	Formulary Placement of Long-Acting Insulin Pen Products in Healthcare Exchanges
2195	U.S. Share of Long-Acting Pens Among All Pens
2196	U.S. Dollar Sales of Long-Acting Pens
2197	U.S. New Prescriptions of Long-Acting Pens
2198	U.S. Total Prescriptions of Long-Acting Pens
2199	U.S. Share of Long-Acting Pen Products
2200	Yuzu Sato et al., *Clinical Aspects of physical exercise for diabetes/metabolic syndrome*, 77S Diabetes Research and Clinical Practice S87 (2007)
2201	2007 Good Design Award from The Chicago Athenaeum: Museum of Architecture and Design
2202	*Reserved*

Exhibit #	Description
2203	U.S. Total Marketing Expenditure of Long Acting Insulin Franchises
2204	U.S. Total Marketing Expenditures of Long-Acting Insulin Pens
2205	U.S. Marketing-to-Sales Ratios of Select Injectable Insulin Drugs
2206	Møller First Embodiment Animation
2207	Møller Second Embodiment Animation
2208	Press Release, *Lantus / Apdira SoloSTAR help to improve patient satisfaction* (June 27, 2011), Document bates stamped SANOFI_00179886-88
2209	Henry Grabowski, John Vernon & Joseph A. DiMasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 Pharmacoeconomics 15 (2002)
2210	Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 N. Engl. J. Med. 673 (2007)
2211	Collar Friction Model Demonstrator Animation
2212	Excerpts from Ernest Rabinowicz, Friction And Wear of Materials, 2nd Edition, 68-70 (John Wiley & Sons, Inc. 1995)
2213	*Reserved*
2214	Excerpts from Alexander H. Slocum, *Precision Machine Design*, 706-709 (Prentice-Hall, Inc. 1992)
2215	Collar Friction Model Demonstration 1
2216	Collar Friction Model Demonstration 2
2217	Collar Friction Model Demonstration 3
2218	SoloSTAR Dial Inject Video

I. INTRODUCTION

Petitioner's single obviousness ground fails to render the challenged claims obvious because the sole prior art reference fails to disclose or render obvious multiple limitations of the challenged claims.

First, Petitioner admits that its prior art reference, U.S. Patent No. 6,221,046 ("Burroughs"), does not disclose the required "helical groove" on a dose dial sleeve in a pen-type injector. Petition at 28. Despite acknowledging these shortcomings in Burroughs, Petitioner proposes a modification to the reference that Petitioner's own expert rejected at his deposition. Indeed, Petitioner's expert proposes a ***different*** modification to Burroughs in his declaration that Petitioner did not raise in the Petition. Moreover, Petitioner fails to offer any reason to modify the Burroughs' disclosure (whether according to Petitioner's unsupported modification, or according to Mr. Leinsing's modification) to include a helical groove.

Second, Burroughs does not disclose a tubular clutch, as required by the challenged claims. Petitioner relies on Burroughs' injection button 32 for the tubular clutch limitation, but Burroughs' button does not meet the proper construction of "tubular clutch" -- a component that can operate to reversibly lock two components in rotation -- because it does not reversibly lock Burroughs' dial and Burroughs' housing ***in rotation***, and also does not reversibly ***lock*** Burroughs' dial to Burroughs' nut.

Third, secondary indicia of non-obviousness support the conclusion that the challenged claims of the 486 Patent are patentable over Burroughs. Specifically, the 486 Patent addressed a long-felt, but unmet need in the insulin pen injector industry – the need for an injection pen with reduced injection force. The commercial embodiment of the 486 Patent, Sanofi's LANTUS® SoloSTAR®[1], was met with critical acclaim and overwhelming commercial success that is directly attributable to the improvements claimed in the 486 Patent.

For these reasons, as detailed further below, Patent Owner respectfully requests that the Board find all challenged claims of the 486 Patent to be patentable over the asserted grounds of invalidity.

II. THE 486 PATENT

The 486 Patent is directed to a pen-type injector for medications such as insulin and insulin glargine. Ex. 1003, 1:20-24. Such injectors are regularly used by patients without formal medical training, such as diabetic patients who manage their condition through self-treatment. *Id*., 1:25-29. The 486 Patent teaches that pen injectors should meet several criteria, including being robust in construction while

[1] LANTUS® is the commercial name for Sanofi's insulin glargine formulation, and LANTUS® SoloSTAR® is the commercial name for LANTUS® packaged in the SoloSTAR® pen injector.

being easy to manipulate and understand by the user, who in many cases may be physically infirm and have impaired vision. *Id*., 1:30-35.

The figures below, from the 486 Patent, depict an embodiment of an improved injection pen that meets these requirements. An animation of the embodiment's operation has been submitted as Ex. 2012.

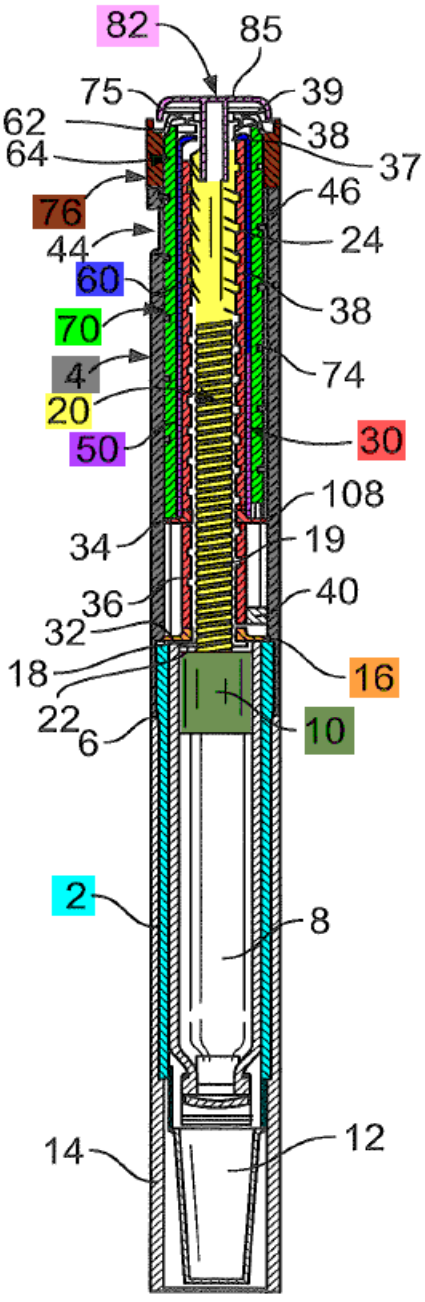


FIG. 1

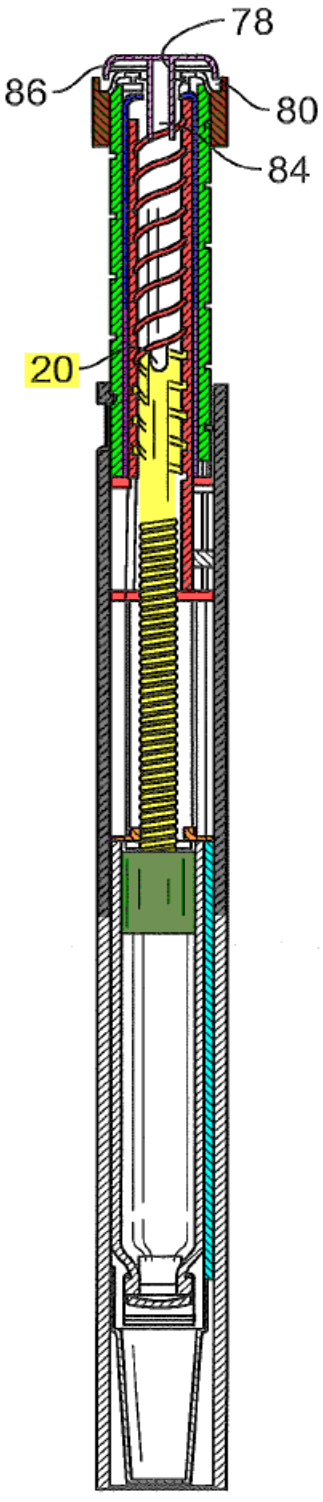


FIG. 2

Ex. 1003, Figs. 1 and 2 (highlighted).

The injection pen of the above shown embodiment comprises a cartridge retaining part 2 (light blue), an internally threaded main housing 4 (grey), a medicament cartridge 8, a cartridge piston 10 (dark green), an insert 16 (orange), a piston rod 20 (yellow), a drive sleeve 30 (red), a clicker 50 (purple), and clutch 60 (dark blue), an externally-grooved dose dial sleeve 70 (light green), a dose dial grip 76 (brown), and a button 82 (pink). The injection pen includes a window 44 in the main housing 4 that indicates the selected dosage to the user.

As seen in the embodiment below, the dose value is selected by rotating the dial grip portion 76 (brown) of a dose dial sleeve 70 (light green), which winds out of the main housing 4 (grey) on a helical path defined by a threaded engagement between a helical groove on the surface of the dose dial sleeve and a helical rib 46 inside the housing. *Id.*, 5:50-6:3; Figs. 9-10.

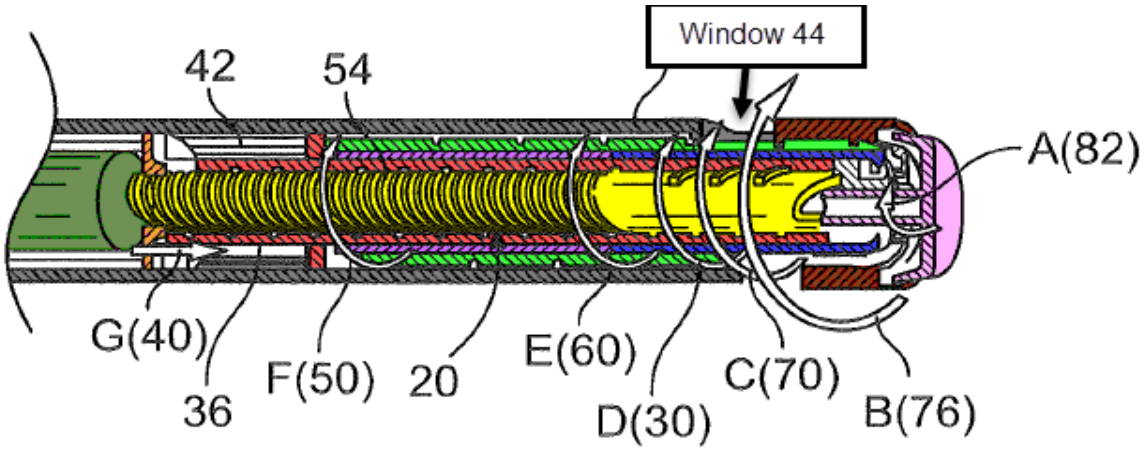


FIG. 9

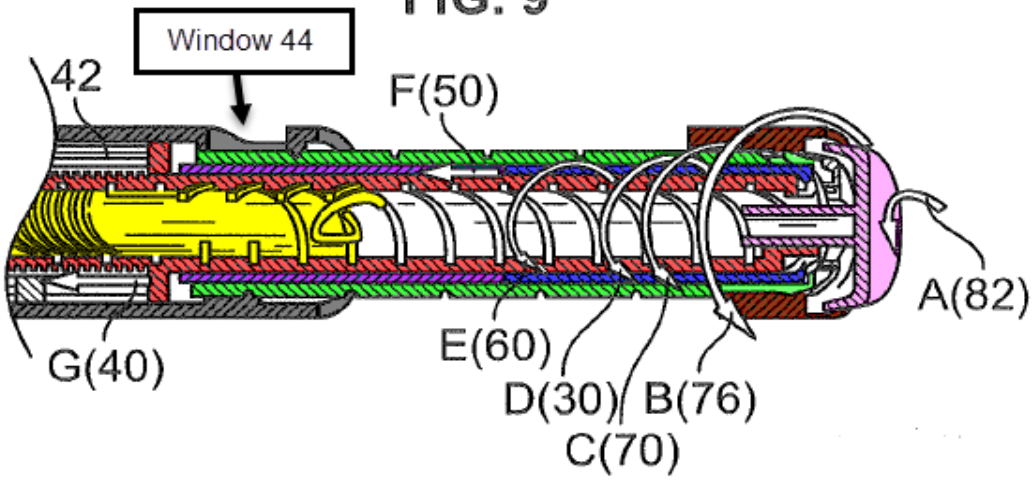


FIG. 10

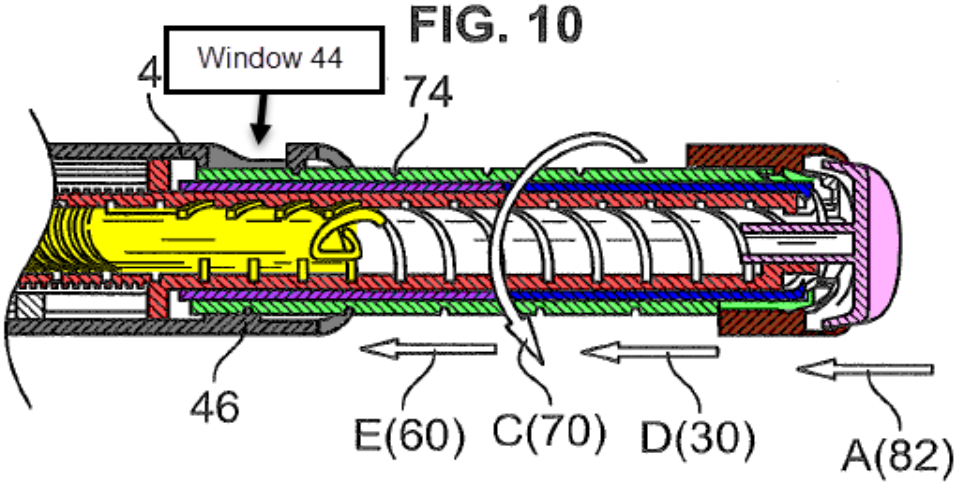


FIG. 11

Ex. 1003, Figs. 9 – 11 (highlighted and annotated).

Dose markings (numbers) printed on an external surface of the dose dial sleeve 70 indicate the dosage. *Id*., 5:17-21. In this embodiment, a clicker 50 detents the dose dial sleeve relative to the housing at each fixed dosage unit and provides audible feedback (*e.g.*, one click for every unit dialed) to assist in dose selection. *Id*., 4:33-44, 5:54-60.

Once the correct dose is selected, the user delivers a dose by pressing the dose button 82 (pink) with his or her finger or thumb, as shown in Figure 11. *Id.*, 6:28-29. This user action returns the dose dial sleeve into the housing and delivers the dose by causing the drive sleeve 30 (red) to move toward the distal end of the pen, as indicated by the arrow D in Figure 11. This in turn causes a piston rod 20 (yellow) to advance a piston 10 (dark green) into the cartridge to dispense the stored medication. *Id.*, 6:45-47. During this dose-injection process the dose button and drive sleeve are not rotationally coupled to the dose dial sleeve, allowing the dose dial sleeve to rotate back into the housing along the path defined by the helical groove (arrow C in Figure 11), while the dose button and drive sleeve travel on an axial path without rotating (arrows A and D in Figure 11). *Id.*, 6:28-35; Fig. 11.

Once the dose is administered, the dose dial sleeve returns to the starting or "zero dose" position and is prevented from rotating further into the device. *Id.*, 6:48-52. The user then releases the dose button, which returns the internal mechanism of the device into the dose dialing state. *Id.*, 6:40-44.

III. LEVEL OF ORDINARY SKILL IN THE ART

The correct level of ordinary skill is defined by a person who understands the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further understands the basics of device design and manufacturing. That person will have a bachelor's degree in mechanical engineering or an equivalent degree. Ex. 2107, ¶ 102. Patent Owner's proposed level of ordinary skill reflects the educational level of workers in the field and the sophistication of the technology. *Id*.; *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *see* M.P.E.P. 2141.03.

Patent Owner does not believe Petitioner's proposed level of ordinary skill should be adopted because the level of ordinary skill proposed by the Petitioner is inconsistent across IPR Nos. 2018-01670, -01675, -01676, -01678, -01679, -01680, -01682, -01684, and 2019-00122. For example, in IPRs 2018-01684, -01682, -01680, and -01670 Petitioner's proposed level of ordinary skill does not require any years of experience, whereas in other petitions, Petitioner states that a POSA would have had "design experience," "approximately three years of experience in medical-device design," or "three-year's experience" depending on the petition. *See* IPR2018-01675, Paper 2 at 14; IPR2018-01676, Paper 2 at 14. Petitioner provides no reasoning for the inconsistency. Moreover, Mr. Leinsing testified that three years

of experience is not required. Therefore, Patent Owner's proposed level of ordinary skill should be accepted. Regardless, the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below.

IV. CLAIM CONSTRUCTION

The Petitioner alleges that "[t]he ground presented below relies on the ordinary and customary meaning." Petition at 16. Yet the Petition does not articulate what the plain and ordinary meaning is for any terms, and rather proffers means-plus-function limitations for the "tubular clutch," "clicker," and "insert" limitations. *Id*. at 15-16. Petitioner also states that, "Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable," and proceeds to list constructions from a preliminary claim construction disclosure in the District Court case (Ex. 1019). Petition at 13. It is unclear, however, whether Petitioner has adopted the preliminary claim constructions from the District Court case for purposes of the Petition. In any event, for purposes of this proceeding, Patent Owner believes it is only necessary to address the construction of the term "tubular clutch."

Patent Owner additionally addresses the "clicker" and "insert" only to dispute that they should be construed as a means-plus-function limitations.

A. "tubular clutch" (claim 1)

Petitioner's Construction	Patent Owner's Construction
Means-plus-function Function: during dose setting, it clutch[es], i.e., coupling and decoupling a movable component from another component, or it operates to reversibly lock two components in rotation. Corresponding Structure: component 60 in Figures 1, 5-11 of the 486 Patent	a tubular component that can operate to reversibly lock two components in rotation

For the reasons discussed below, the Board should construe "tubular clutch" to mean "a tubular component that can operate to reversibly lock two components in rotation."

1. "tubular clutch" is not a means-plus-function term.

Petitioner asserts that the term "tubular clutch" is a means-plus-function limitation having the following alternative recited functions: "during dose setting, it 'clutch[es], i.e., coupling and decoupling a movable component from another component,' or, during dose setting, it 'operates to reversibly lock two components in rotation.'" Petition at 15. In the related District of New Jersey litigation between

the parties[2], the court rejected Petitioner's contention that "clutch" is a means-plus-function limitation, finding that Petitioner had not demonstrated "that 'clutch' fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." Ex. 2165 at 12. Likewise, the Petition in this proceeding does not include any support to overcome the presumption against applying means-plus-function. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Indeed, the Petition includes *no* analysis whatsoever of whether a POSA would have understood the term "tubular clutch," which clearly does not include the word "means," to recite sufficiently definite structure or to recite function without reciting sufficient structure for performing the claimed function. Accordingly, Petitioner fails to overcome the presumption that "tubular clutch" is not a means-plus-function limitation, and Petitioner's contention that "tubular clutch" is means-plus-function should be rejected.

2. The plain and ordinary meaning of "tubular clutch" is "a tubular component that can operate to reversibly lock two components in rotation."

In the related district court litigation, the Court further considered the plain and ordinary meaning for the term "clutch," and determined that the ordinary

[2] All defendants involved in the District of New Jersey litigation are real parties-in-interest or privies of Petitioner.

meaning of clutch is "a component that can operate to reversibly lock two components in rotation." Ex. 2165 at 13. Patent Owner agrees that the plain and ordinary meaning of the term "clutch" is "a component that can operate to reversibly lock two components in rotation." Petitioner's proposed construction also requires the function of reversibly locking two components in rotation. Thus, there is *no* dispute that "tubular clutch" should be construed to require "a tubular component that can operate to reversibly lock two components in rotation." Because this construction is the plain and ordinary meaning of the term, as the District of New Jersey found, it is also the correct construction under the broadest reasonable interpretation standard.

While Petitioner also proposed that a "tubular clutch" is a structure that "during dose setting, 'it clutch[es], i.e., coupling and decoupling a movable component from another component,'" Petition at 15, the District of New Jersey rejected this position for at least two reasons. First, the District of New Jersey rejected "during dose setting," determining that it cannot be part of the ordinary meaning of "clutch." Ex. 2165 at 13. Second, the New Jersey district court expressly considered and rejected, as inconsistent with the plain and ordinary meaning, claim construction proposals that would have required a structure that "couples and decouples" two components rather than reversibly locking two components in rotation. Ex. 2165 at 10-11.

As discussed below in Section VI.B.1, Burroughs does not disclose or render obvious a tubular component that can operate to reversibly lock two components in rotation, and therefore properly construing the term "tubular clutch" according to its plain and ordinary meaning, as discussed above, is dispositive of Petitioner's validity challenge.

B. "clicker" (claim 14), and "insert" (claim 38)

Petitioner asserts that the terms "clicker" and "insert," which are not written in means-plus-function format, may be means-plus-function limitations. *See* Petition at 15-16. Petitioner is incorrect, and has not included any support to overcome the presumption against applying means-plus-function. *See Williamson*, 792 F.3d at 1349. The District of New Jersey has also held that the term "clicker" is not a means-plus-function limitation. *See* Ex. 2165 at 20-23. Specifically, the District of New Jersey determined that as to "clicker," the defendants (who are all real parties-in-interest or privies of the Petitioner) "do not even address, much less satisfy," the standard for overcoming the presumption against applying means-plus-function, and further acknowledged that the claims provided "many details about the structure of the clicker" and that the specification "offers a very detailed description of the structure of an exemplary clicker." *Id*. at 21-22. As to "insert," the District of New Jersey found that in the course of their argument, the defendants conceded that the structure is disclosed in the specification. *Id*. at 23-24.

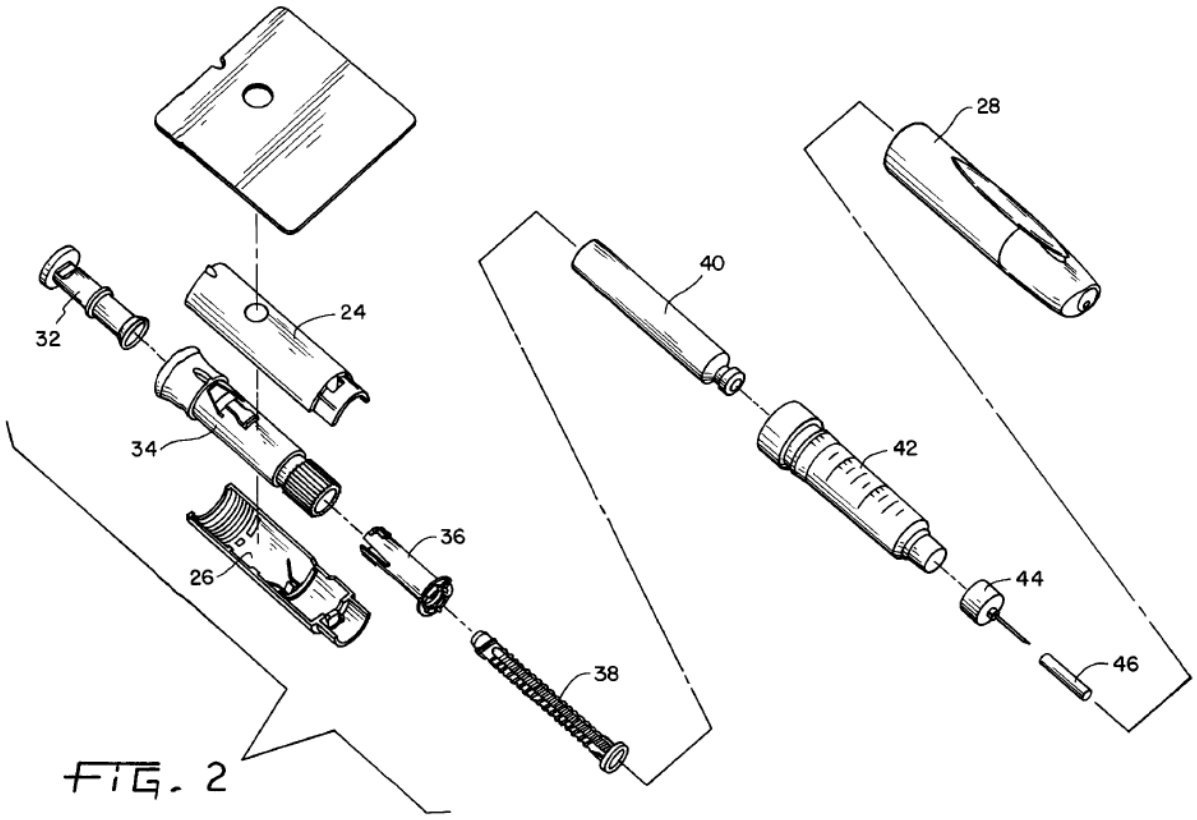
V. THE PRIOR ART

A. Burroughs

Burroughs is directed to a multi-use medication dispensing pen. Ex. 1013, Abstract. Burroughs was disclosed to the Examiner during prosecution of the 486 Patent, and is cited on the face of the 486 Patent. Ex. 1003, p. 2; Ex. 1008, p. 1.

According to Burroughs, patients such as diabetics conventionally used syringes to inject themselves with liquid medication solutions, such as insulin. *Id*., 1:18-24. Patients, however, had difficulty controlling the syringe as well as the quantity of drug injected. *Id*., 1:24-25. Burroughs further explained that injector pens were developed to permit diabetics to measure and administer more accurate and controlled dosages. *Id*., 1:26-29. *See* Ex. 2107, ¶ 129.

The main components of Burroughs' injector pen are shown in Figure 2.



Ex. 1013, Fig. 2.

The main housing is comprised of a first part 24 and a second part 26. Ex. 1013, 7:16-26. A cap 28 attaches to the distal end of the housing. *Id*., 7:27-30. The main housing contains a dial mechanism 34, into the proximal end of which a button 32 is inserted. *Id*., 7:31-33. A nut 36 interfaces with the distal end of the dial mechanism 34, and a drive stem in the form of a leadscrew 38 is inserted into the distal mechanism 34 through the nut 36. *Id*. A medication cartridge 40 is inserted into distal body 42, which has a needle 44 and a needle cover 46. *Id*., 7:34-35. Ex. 2107, ¶ 131.

To use Burroughs' injector pen, a user first sets the injection dose. This requires initially turning the dial mechanism 34 to the zero position, which is indicated to the user by a clicking sound generated when splines 152 (shown in Figure 8) of the dial mechanism 34 engage with finger 170 (shown in Figure 5) of the second housing part 26. *Id*., 9:47-64. This same engagement also creates a tangible vibration in the device. *Id*., 9:64-66. A protrusion 153 in the first housing part 24 also aligns with protrusion 88 (shown in Figure 7) of the dial mechanism to provide a visual indication of the zero position. *Id*., 9:66-10:4. Ex. 2107, ¶ 132.

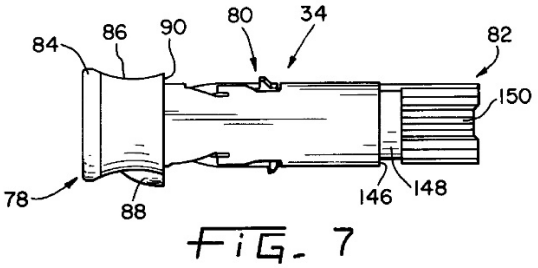


FIG. 7

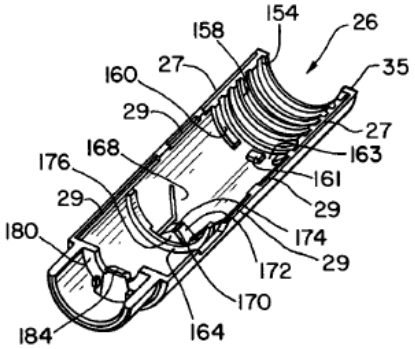


FIG. 5

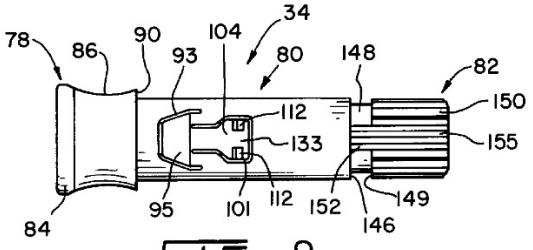


FIG. 8

Ex. 1013, Fig. 5, 7, and 8.

From the zero position, the user retracts the dial mechanism 34 a predetermined distance to place it into the dose-setting position. *Id*., 10:15-18. From

this position, the user sets the desired dosage by rotating the dial mechanism 34. *Id*., 10:42-52.

Dial mechanism 34 has threads 110 and 112 on its outer surface, which move within a groove 158 on the inner surface of housing parts 24 and 26 to guide and restrict the rotational movement of the dial mechanism. *Id*., 10:28-38, 10:60-63. The groove 158 is sized such that when the dial mechanism reaches the predetermined maximum dosage, the threads 110 and 112 will reach the proximal end of the groove. *Id*., 10:63-65. A ledge at the end of the groove prevents the dial mechanism from turning past this maximum dosage. *Id*., 10:65-11:1. Ex. 2107, ¶ 133.

Once the desired dosage is set, the user can dispense the dose by pressing button 32, which causes the button and dial mechanism to move forward until the dial mechanism reaches the end-of-injection position. *Id*., 11:13-23. At this position, a click finger 97 located on the surface of the dial mechanism 34 engages with groove 154 on the inner surface of the housing parts 24 and 26 (shown in Figures 3 and 5), providing an audible "click" sound to indicate that the entire dosage has been injected. *Id*., 11:23-26. Additionally, an end-of-injection stop feature prevents the dial mechanism 34 and nut 36 from moving past the end-of-injection position by engaging raised surface 199 of the nut 36 (shown in Figures 10 and 11)

with ledges 178 and 180 in the housing parts 24 and 26 (shown in Figures 3 and 5). Ex. 2107, ¶ 136.

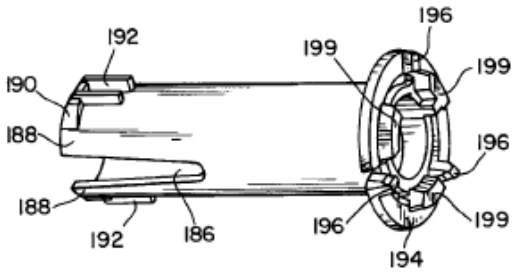


FIG. 10

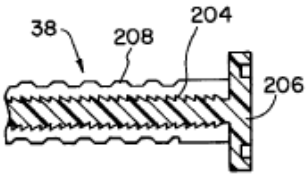


FIG. 13

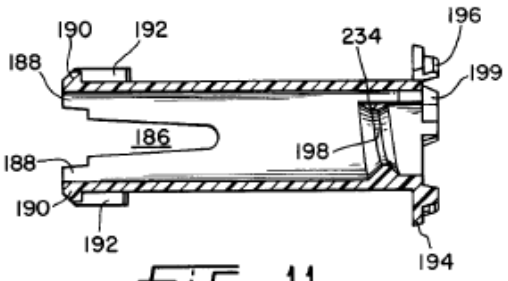


FIG. 11

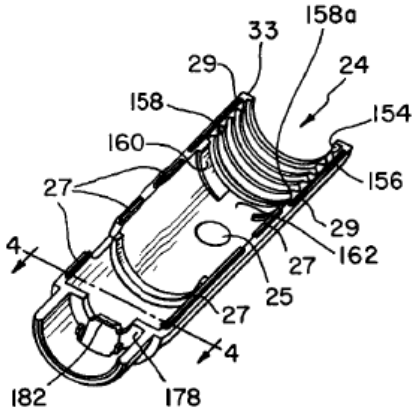


FIG. 3

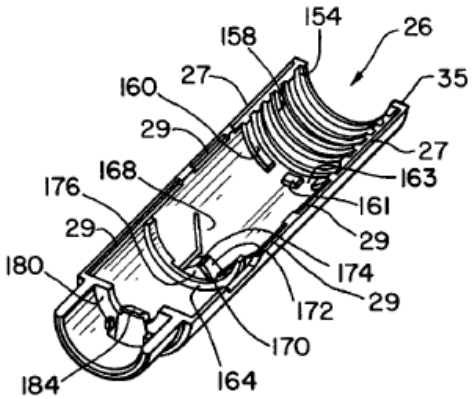
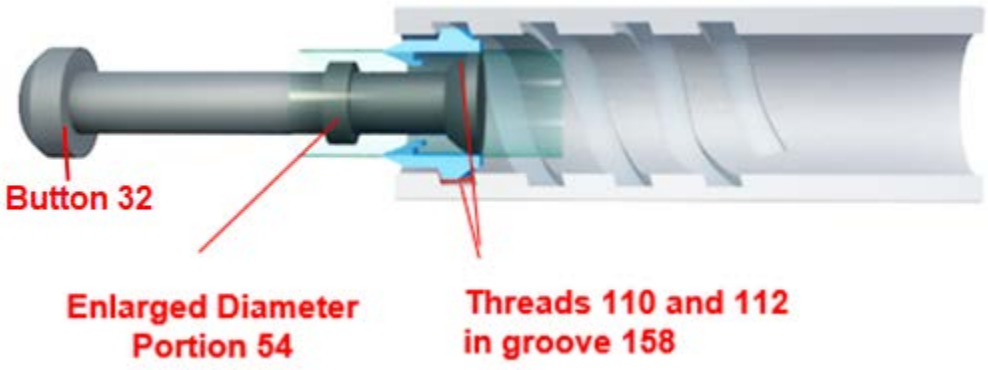


FIG. 5

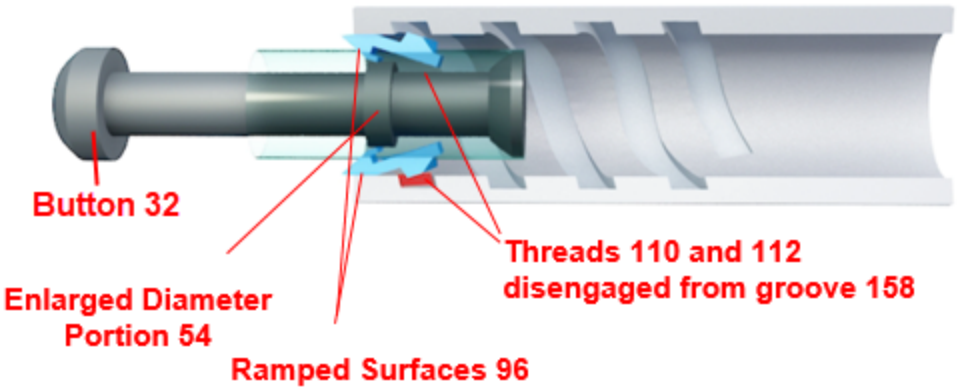
Ex. 1013, Fig. 3, 5, 10, 11, and 13.

Importantly, Burroughs discloses that a key advantage of its injector pen over prior art designs is a "dosage lockout mechanism" that prevents inadvertent delivery

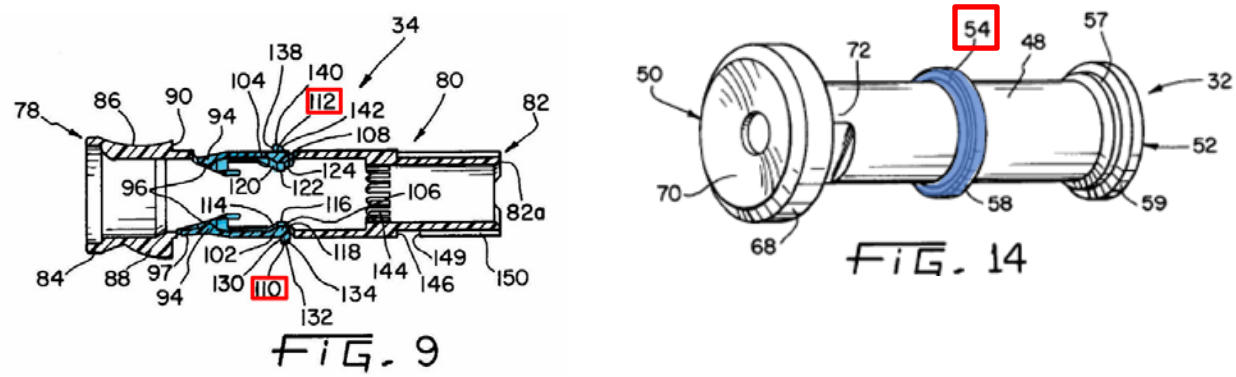
of medication. *Id*., 4:29-31. Specifically, the threads 110 and 112 on the dial mechanism 34 are forced into the groove 158 in housing parts 24 and 26 during dose-setting by the button surface 57, thereby preventing the dial mechanism 34 from moving axially forward and dispensing the dialed dosage. *Id*., 11:1-6. An illustration of this is depicted in the figure below.



In order to "unlock" the dial mechanism 34 to allow a dose to be dispensed, the threads 110 and 112 must be retracted from groove 158. *Id*., 11:5-6. This occurs only when the user depresses the button 32, which moves the button 32 axially forward, bringing enlarged diameter portion 54 into contact with the ramped surfaces 96 of legs 102 and 104. *Id*., 7:47-52; 8:25-30. Legs 102 and 104 are driven downward, which retracts threads 110 and 112 from groove 158. Ex. 2107, ¶¶ 134-135.



As shown in Figure 9 below, the threads 110 and 112 are positioned on distal end of legs 102 and 104, each of which has a ramped surface 96. Fig. 9, below depicts a side view of the legs 102 and 104 and threads 110 and 112. Fig. 14 depicts enlarged diameter portion 54.



Ex. 1013, Fig. 9 and 14 (highlighted).

Once the user has injected the dose, he or she releases the button. When this happens, the elastic bias from ramped surfaces 96 forces the button back towards the proximal end of the device and causes the threads 110 and 112 to re-engage with groove 158. *Id.*, 11:57-65.

VI. THE CHALLENGED CLAIMS ARE PATENTABLE

A. Burroughs Does Not Disclose Or Render Obvious A Dose Dial Sleeve That Comprises "A Helical Groove Configured To Engage A Threading Provided By Said Main Housing"

Petitioner has failed to meet its burden of showing that Burroughs, in view of the knowledge of a POSA, discloses or renders obvious all of the elements of the challenged claims. In particular, Burroughs does not disclose a dose dial sleeve that comprises a "helical groove configured to engage a threading provided by said main housing," and Petitioner fails to prove that such a helical groove would have been obvious. Because challenged claims 2-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 all depend from claim 1, this failure is dispositive of Petitioner's entire challenge.

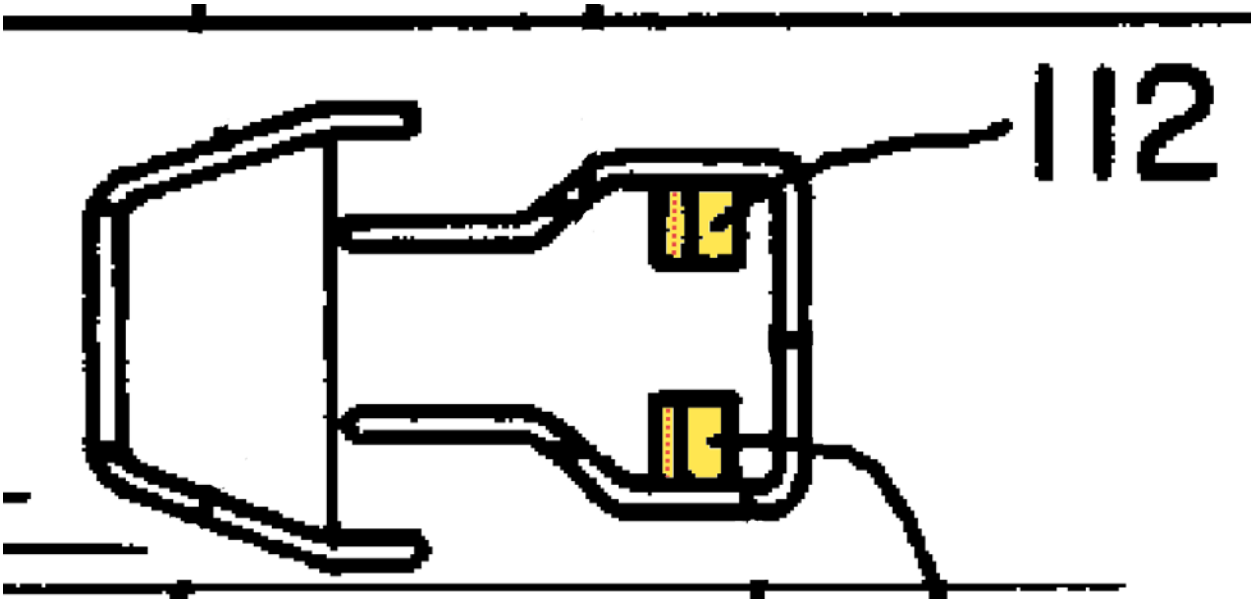
1. Petitioner and Mr. Leinsing Propose Two Different, Conflicting Modifications to Burroughs.

Before discussing the specific reasons why Burroughs does not disclose or render obvious that the dose dial sleeve comprises a "helical groove configured to engage a threading provided by said main housing," further explanation of Petitioner's and Mr. Leinsing's proposed modifications to Burroughs – which are inconsistent with one another – is necessary.

a) Petitioner's Proposed Modification

Petitioner proposes a convoluted modification to Burroughs in which a groove would be cut ***into the existing threads 110 and 112***, creating "[g]rooved threading" which subsequently engages with a thread on the inner surface of the housing.

Petition at 38-40; Ex. 2107, ¶ 170. Specifically, what Petitioner proposes is retaining the existing threads 110 and 112 on the dial mechanism, but modifying those threads 110 and 112 to be slotted – "[a] POSA thus would have understood that a ***protruding u-shaped groove*** would operate in the same manner and provide the same function as the depicted ribs." Petition at 39; Ex. 2107, ¶ 170. Petitioner argues that making threads 110 and 112 "u-shaped" results in discrete "protruding helical grooves" or "grooved threading." Petition at 39. These discrete, grooved threads would then mate with a helical thread on the inner surface of Burroughs' housing. The figures below, which are cutaways from Figures 7 and 8 of Burroughs, illustrate how Petitioner proposes to add a slot to the threads 110 and 112; the yellow highlights illustrate the existing discrete, protruding threads 110, 112 in Burroughs, and the dashed redlines illustrate Petitioner's proposed "grooves." Ex. 2107, ¶ 170.



Ex. 1013, Figs. 7 and 8 (excerpted and annotated)

Importantly, Petitioner's modification is plainly ***not*** a simple reversal or "swapping" of the features disclosed in Burroughs. A reversal of the features results in a spiral groove across the outer surface of the dial mechanism 34 and two discrete, protruding threads 110 and 112 at fixed points of the inner surface of Burroughs' housing. Ex. 2107, ¶ 172. As shown above, this is not Petitioner's proposed modification. Indeed, Petitioner's expert Mr. Leinsing, when asked in his deposition whether he was proposing putting groove 158 on the dial and threads 110 and 112 on the housing, expressly testified that "you're not swapping the threads around." Ex. 2163 at 194:15-20.

A POSA would have recognized (and Petitioner apparently does, too) that a reversal of the features of Burroughs would not have worked without a significant

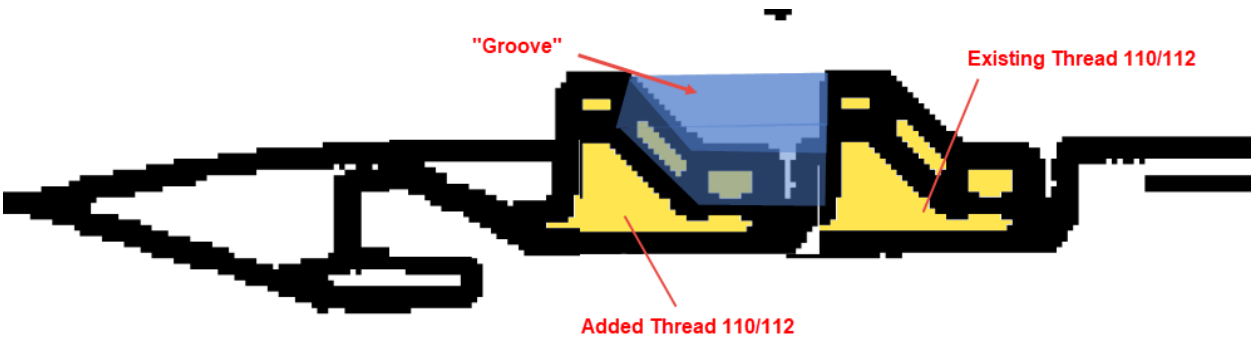
redesign to the entire pen mechanism , because, as discussed in Section V, Burroughs relies on having the protruding threads 110 and 112 on the dial mechanism 34 so that the threads can disengage from the helical groove 158 when the user pushes the injector button. Ex. 1013, 8:15-20, 11:6-12; Ex. 2107, ¶ 172. If the features were reversed so that the threads were located on the inside of the housing and the helical groove wrapped circumferentially around the outer surface of the dial mechanism 34, nothing would happen when the enlarged diameter portion 54 of the button 32 presses against the ramped surfaces 96 of the legs 102 and 104, because the downward projecting threads on the interior of the housing would prevent the dial from advancing axially. Ex. 2107, ¶ 172. As a result, no dosage would be dispensed even when the button 32 is pressed. *Id*.

For the reasons discussed below, Petitioner's proposed modification fails to render obvious the required helical groove provided along an outer surface of said dose dial sleeve, because a POSA would not have been motivated to attempt Petitioner's proposed modification, which increases the complexity of Burroughs' device without providing any cognizable benefit or solving any problems.

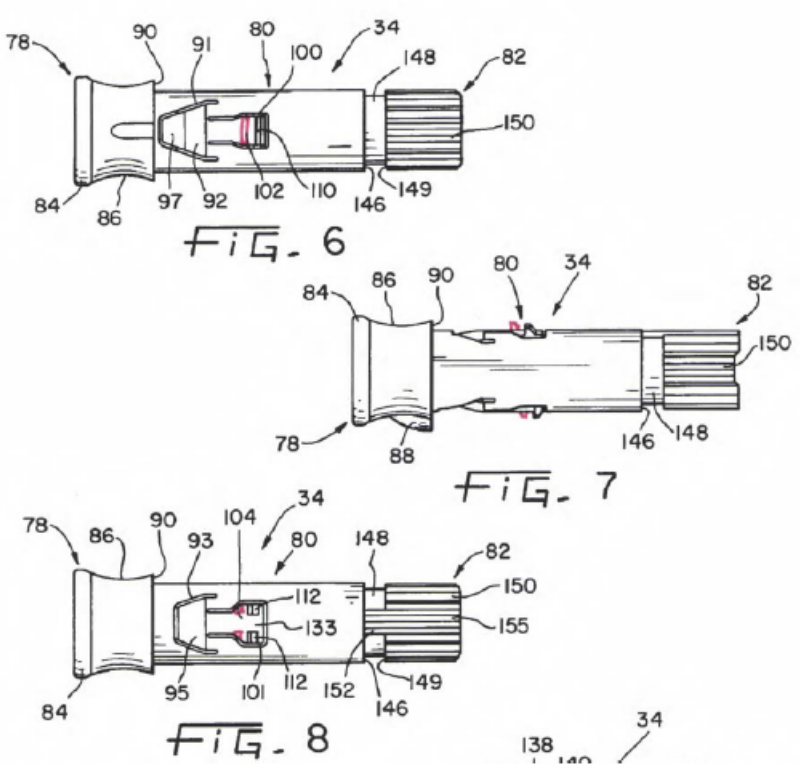
b) Mr. Leinsing's Proposed Modification

Separately, Petitioner's declarant Mr. Leinsing proposes a *different* modification to Burroughs. Ex. 2107, ¶ 171. Rather than modifying the existing threads 110 and 112 to have a "u-shape", Mr. Leinsing proposes "add[ing] another

helical rib next to the existing one, such that the threads 110, 112 form a 'helical groove' that engages a threading provided by the housing." Ex. 1011, ¶ 166; Ex. 2107, ¶ 171. In other words, Mr. Leinsing's proposal is to place an ***additional*** thread behind Burroughs' existing threads 110 and 112, such that the space ***between*** the threads forms a helical groove. Ex. 2107, ¶ 171. This "groove" then engages with the existing "walls" of the helical groove 158, with each thread 110, 112 fitting into a consecutive turn of the helical groove 158. *Id*. An approximate illustration of this proposed modification is shown below, along with Mr. Leinsing's annotation of Burroughs' figures to illustrate his proposed modification:



Ex. 1013, Fig. 7 (modified and annotated)



Ex. 1013, Figs. 6-8 (annotated by Mr. Leinsing and excerpted); Ex. 2103 (excerpted)

As can be seen in the figures above, in this modification, discrete threads 110 and 112 ***are not*** "u-shaped" threads or "grooved threading" as proposed in the Petition. *See* Petition at 39. Thus, Mr. Leinsing's proposed modification is a separate and different modification than the one in the Petition. Nowhere does the Petition suggest duplicating threads 110, 112 and then offsetting those new threads to create a helical grove that mates with the "wall" of the groove on the housing 22.

For the reasons discussed below, a POSA would not have been motivated to try Mr. Leinsing's proposed modification, which increases the likelihood that the

injection pen as modified would not properly function and subjects the internal components of the pen to undesirable increased stress during use.

2. Burroughs Does Not Disclose A Helical Groove Provided Along An Outer Surface Of Said Dose Dial Sleeve

Petitioner admits that Burroughs does not disclose a helical groove on the dose dial sleeve. Petition at 28. Thus, there is no dispute that Burroughs fails to disclose this limitation.

3. Petitioner Fails To Meet Its Burden Of Showing That Burroughs In View Of The Knowledge Of A POSA Renders Obvious That The Dose Dial Sleeve Comprises A Helical Groove

As discussed above, Petitioner and Mr. Leinsing propose two different modifications to Burroughs: Petitioner proposes adding grooves to each of Burroughs' threads 110, 112, (*i.e.* making threads 110, 112 "u-shaped") while Mr. Leinsing proposes duplicating threads 110, 112 and offsetting those duplicated threads from threads 110, 112 to create a groove in the space between the threads. Ex. 2107, ¶¶ 170-171. Petitioner's modification is advanced solely in the Petition, and Mr. Leinsing's modification is advanced solely in Mr. Leinsing's declaration. Further, Mr. Leinsing testified in his deposition that he is *not* opining that it would have been obvious to adapt threads 110, 112 to be u-shaped by cutting a groove into them. Ex. 2163, 193:22-194:11. Thus, Petitioner's expert has distanced himself from the very modification that the Petition advances, and the Petition's proposed

modification is therefore nothing more than attorney argument, unsupported by any record evidence in this proceeding. *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017). Petitioner has therefore failed to meet its burden of presenting evidence to demonstrate that Petitioner's proposed modification would have been obvious to a POSA.

Mr. Leinsing's proposed modification, conversely, is not presented in the Petition. Nowhere does the Petition suggest duplicating threads 110, 112 and then offsetting those new threads to create a helical grove that mate with the "wall" of the groove on the housing 22. Petitioner has therefore failed to even argue that Mr. Leinsing's proposed modification would have been obvious to a POSA. Because Petitioner failed to present Mr. Leinsing's proposed modification as an argument in the Petition, Petitioner should be precluded from raising the argument in Reply or at the oral hearing in this proceeding. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("Unlike district court litigation – where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material – the expedited nature of

IPRs bring with it an obligation for petitioners to make their case in their petition to institute.")[3].

Accordingly, Petitioner has failed to meet its burden of proof with respect to both Petitioner's proposed modification to Burroughs and Mr. Leinsing's proposed modification to Burroughs.

4. Petitioner Does Not Establish A Reason To Modify Burroughs' Threads To Include A Groove, As Suggested In The Petition

With respect to Petitioner's proposed modification, Petitioner fails to establish a reason to modify Burroughs to include a groove in each of the threads 110 and 112 and a corresponding thread in the inner surface of the housing parts 24 and 26 to engage with those grooves. It is the Petitioner's burden to show "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (internal citation and

[3] Even if Petitioner had incorporated Mr. Leinsing's opinion by reference, which it did not do, this would not have corrected this failing in the Petition because the Board's regulations are clear that arguments "must not be incorporated by reference from one document into another document." 37 C.F.R. § 42.6(a)(3).

quotations omitted). The Petition does not even purport to set forth a motivation, asserting only that such a modification would have been "interchangeable" with the structure disclosed in Burroughs and that the modified elements would have still performed the same functions. Petition at 38-40.

As discussed in Section VI.A.1, Petitioner is not simply swapping or reversing threads 110 and 112 with the helical groove 158 in the housing (which would not work for the reasons discussed in Section VI.A). Ex. 2107, ¶ 172. Instead, Petitioner is modifying threads 110 and 112 to be u-shaped (*i.e.*, a u-shaped channel is cut in each of the protrusions) such that the u-shape mates with the "wall" of the existing groove in the housing 22. Ex. 2107, ¶ 170. As a practical matter, this would not work because threads 110, 112 are sized for the grooves in the housing. Ex. 2107, ¶ 176. Any u-shaped groove in threads 110, 112 would necessarily be too narrow to accommodate the "wall" of the groove on the housing. *Id*. Petitioner does not suggest enlarging threads 110, 112 to accommodate appropriately sized u-shape grooves, but even had Petitioner done so, this would likewise not work because enlarging threads 110, 112 requires significant changes elsewhere in the device because the threads are currently sized to interface with the button for dosing and injecting. *Id*. A POSA would not have been motivated to attempt a modification that renders Burroughs inoperable for its intended purpose. *See Plas-Pak Indus. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758-60 (Fed. Cir. 2015) ("However,

combinations that change the 'basic principles under which the [prior art] was designed to operate,' or that render the prior art 'inoperable for its intended purpose,' may fail to support a conclusion of obviousness.") (internal citations omitted); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.").

Indeed, Professor Slocum explains that modifying Burroughs' threads as Petitioner proposes would have greatly complicated the process of manufacturing Burroughs' injector pen. and risked malfunctions during normal usage. Ex. 2107, ¶ 177. For example, Petitioner's proposed modification would have required a POSA to make highly precise cuts into Burroughs' threads 110 and 112, which are themselves no more than a few millimeters wide. *Id*. Similarly, because the threads 110 and 112 are themselves so narrow, the groove added to each thread would need to be even narrower, requiring an equally narrow thread in the housing to engage with the groove. *Id*. Using such a narrow thread would greatly increase the likelihood that when force is applied to the thread-groove interface (for example, during dose setting or injection), the thread would break or otherwise "skip" free of the groove, causing the injector pen to malfunction. *Id*.

In the face of this evidence that the modification would have made Burroughs' injector unreliable or even inoperable, Petitioner must show that it would have been obvious to add a groove to each of the threads 110, 112 and that these "u-shaped" grooves would engage with the "wall" of the groove on housing 22. The Petition does not even purport to set forth a rationale for this convoluted modification, asserting only that such a modification would have been "interchangeable" with the structure disclosed in Burroughs and that the modified elements would have still performed the same functions. Petition at 38-40; Ex. 2107, ¶ 178.

As the Federal Circuit has cautioned, merely asserting that a particular placement of elements was a "design choice" does not make it obvious. *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n. 4 (Fed. Cir. 2018) (citing *Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016)). Rather, Petitioner must show "why a person of ordinary skill in the art would have selected these components for combination in the manner claimed." *Id*. (internal quotation marks omitted). It is insufficient to show that a POSA *could have* made the proposed combination. *Belden Inc. v. Berk-Tek LLC,* 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.") (emphasis in original). Rather, Petitioner must show "why a person of ordinary skill in the art *would have selected*

these components for combination in the manner claimed." *Polaris Indus*., 882 F.3d at 1069 n. 4 (emphasis added; internal quotation marks omitted).

Here, Petitioner makes no such showing with respect to Petitioner's proposed modification to Burroughs. Ex. 2107, ¶ 178. The Petition identifies neither any problem that would be solved by the proposed modification, nor any other improvement to Burroughs' device that would have resulted from the proposed modification. *Id*. Petitioner provides no explanation as to why a POSA would have been motivated to increase the complexity of manufacturing Burroughs' injector pen by requiring further removal or addition of material from threads 110 and 112 in order to form a u-shaped groove in each thread, only to provide a structure that, according to the Petition, would simply perform the same function as the structure already disclosed in Burroughs. Petition at 39; Ex. 2107, ¶ 178. Nor does Petitioner explain why a POSA would have found it acceptable to introduce additional failure points into the device, as discussed by Professor Slocum. Ex. 2107, ¶ 178. Indeed, even Petitioner's declarant, Mr. Leinsing, testified in his deposition that he is not of the opinion that Petitioner's proposed modification would have been obvious to a POSA. Ex. 2163 at 193:22-194:11; Ex. 2107, ¶ 179. The only justifications relied upon to support Petitioner's "u-shaped" modification are conclusory statements by Petitioner's attorneys and Petitioner's expert (who admitted in deposition that Petitioner's proposed modification makes no sense – Ex. 2163 at 193:22-194:11)

that the modification would have been "functionally equivalent," "largely interchangeable," and "would not change the function or the principle of operation of the mechanism." Petition at 39. This is clearly insufficient to provide a POSA with a reason to make the modification proposed in the Petition.

Thus, Ground 1 fails because Petitioner has failed to establish a reason for the proposed modification to Burroughs.

5. Petitioner Does Not Establish A Reason For A POSA To Attempt Mr. Leinsing's Proposed Modification

As discussed above, Mr. Leinsing's proposed modification is not set forth in the Petition, and therefore should be rejected for that reason alone. Even if it were in the Petition, however, Petitioner fails to establish a reason for a POSA to attempt the modification.

a) Petitioner Offers No Rationale For The Proposed Modification

Both the Petition and Mr. Leinsing's declaration state only that rib-to-groove threaded connections were known in the art, that the relative placement of the ribs and grooves was "largely interchangeable" and "routine variations," and that a POSA would have understood that positioning the threads 110, 112 as proposed by Mr. Leinsing to form two parallel ribs would have preserved the rotational operability of the components in Burroughs' injector pen. Ex. 1011, ¶¶ 168-171; *see also* Petition at 39-40. But these assertions do no more than establish that a POSA

could have performed the proposed modification. As noted above, the relevant inquiry for obviousness is not merely whether a POSITA could have made the proposed combination, but instead whether they would have had a reason or rationale to do so. *Belden*, 805 F.3d at 1073. None of Petitioner's or Mr. Leinsing's assertions establishes that a POSA would have been motivated or inclined to make the proposed combination, and therefore Petitioner has failed to meet its burden of showing a rationale for making Mr. Leinsing's proposed modification.

b) A POSA Would Have Been Deterred From Making Mr. Leinsing's Proposed Modification

Moreover, as Professor Slocum explains, there are express reasons why a POSA would not have made Mr. Leinsing's proposed modification. Placing an additional thread in front of or behind Burroughs' existing threads 110 and 112 would have required detrimental changes to the design of the legs 102 and 104 on which the threads sit, which, as discussed in Section V, are what allow the threads 110 and 112 to disengage from the helical groove 158 during dose injection. Ex. 2107, ¶ 181

In Burroughs' existing design, the legs 102 and 104 need only pivot inward far enough for a single thread to disengage from a single turn of the helical groove 158. Ex. 2107, ¶ 184. In Mr. Leinsing's proposed modification, in which two threads are positioned on each leg, the legs must pivot inward far enough for *two* threads to simultaneously disengage from two consecutive turns of the helical

groove. *Id*. If the legs only pivoted far enough for a single thread (*i.e.*, the more distal thread) to disengage from its engagement with the helical groove, then the remaining thread would continue to prevent the dial mechanism from moving axially, which would in turn prevent the pen from dispensing a dialed dose. *Id*.

Alternatively, the force exerted against the injection button by the user would eventually cause the remaining thread to "skip" out of the helical groove, resulting in a jerky and potentially dangerous movement of the dial 34. *Id*. Even if a dose could be fully dispensed in this manner, the operation would be highly sub-par and undesirable. *Id*.

While Mr. Leinsing asserted in his deposition that his proposed modification did not require any changes aside from adding the additional threads, Professor Slocum explains that a POSA would have been deterred from simply adding another set of threads with no other changes. Ex. 2107, ¶ 185. Specifically, a POSA would have understood that in order for the legs 102 and 104 to pivot far enough to allow the additional threads to disengage from the helical groove without further modifications, the legs 102 and 104 would have been subjected to 30 to 40 percent greater force and stress during the injection process. Ex. 2107, ¶¶ 186-187. This increased stress would have caused the legs to wear out faster, decreasing the lifespan of the injector. *Id*., ¶ 188. A decrease in lifespan is especially undesirable

for Burroughs' device, which is expressly intended to be a multi-use device. *Id*.; Ex. 1013, Abstract.

While it would have been possible to reduce the stress on the legs 102 and 104 by changing their dimensions, a POSA likewise would have been deterred from attempting this additional modification. Ex. 2107, ¶ 189. As an initial matter, neither Petitioner nor Mr. Leinsing have asserted such a change as part of their obviousness theory; indeed, as noted above, Mr. Leinsing testified that his proposed modification requires no changes other than adding the additional set of threads behind the existing threads 110 and 112. Ex. 2163, 195:14-25. Thus, Petitioner has not even advanced this argument in this proceeding. Regardless, as Professor Slocum explains, a POSA would have understood that making the necessary changes to the dimensions of legs 102 and 104 would have also required increasing the internal diameter of the pen injector by at least 10 percent in order to accommodate the modified legs when they pivot inward during injection. Ex. 2107, ¶¶ 190-191. A POSA would have recognized this to be undesirable because a wider injector pen is more difficult to grasp and manipulate, especially for diabetic patients who frequently suffer from hand and wrist conditions associated with diabetes that decrease their grip strength and dexterity. *Id*. Increasing the internal diameter also increases the cost of the injector, since it would require more material to manufacture, and makes the device heavier and therefore less portable.

Additionally, regardless of whether the legs 102 and 104 are changed, Mr. Leinsing's modification would have increased the injection force required for a user to dispense a dose. Ex. 2107, ¶ 192. As Professor Slocum explains, because legs 102 and 104 must pivot further in order for the additional threads proposed by Mr. Leinsing to clear the helical groove 158 during dose injection, a greater amount of the injection button 32's available travel must be allotted to engaging the ramped surfaces 96 to cause the legs to pivot. *Id*. This leaves less travel available for dispensing the dialed dose, which requires the user to exert a greater amount of force over the same distance (as compared to the unmodified Burroughs injector) to dispense the medication. *Id*. As Professor Slocum explains, the required increase in injection force is on the order of 15%. *Id*. Because diabetic patients' ability to generate force with their thumbs is often diminished by hand and wrist conditions that accompany diabetes, a POSA would have recognized that Mr. Leinsing's proposed modification impairs the usability of Burroughs' pen injector for patients with hand and wrist conditions, and therefore would not have been motivated to attempt the modification. *Id*.

Neither the Petition nor Mr. Leinsing's declaration identifies any benefit from Mr. Leinsing's proposed modification that would have offset these detrimental changes. Ex. 2107, ¶ 193. Accordingly, a POSA would not have had a reason to modify Burroughs' injector pen as proposed by Mr. Leinsing.

B. Burroughs Does Not Disclose Or Render Obvious "A Tubular Clutch Located Adjacent A Distal End of Said Dose Knob, Said Tubular Clutch Operatively Coupled to Said Dose Knob"

Challenged claim 1 requires "a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip." As discussed in Section IV.A, the parties agree that "tubular clutch," whether a means-plus-function limitation or not (it is not), must be able to "operate to reversibly lock two components in rotation." Petitioner relies upon Burroughs' button 32 as purportedly disclosing this limitation. Petition at 34-37. As discussed below in detail, however, Burroughs' button 32 does not "operate to reversibly lock two components in rotation." Petitioner makes no argument that it would have been obvious to modify Burroughs' button 32 to perform this function. Accordingly, Burroughs fails to disclose or render obvious a tubular clutch, under any party's proposed construction.

1. Burroughs' Button 32 Is Not "A Tubular Component That Can Operate To Reversibly Lock Two Components In Rotation."

As set forth in Section IV.A, the proper construction for the term "tubular clutch" is "a tubular component that can operate to reversibly lock two components in rotation." Petitioner has failed to show that Burroughs discloses or renders obvious a "tubular clutch," properly construed, for several reasons.

As an initial matter, Petitioner proposed "operates to reversibly lock two components in rotation" as one of two alternative functions for its means-plus-function argument. Petition at 15. Petitioner also advocated a similar construction in the District of New Jersey litigation. Yet, in its analysis of the "tubular clutch" limitation in the Petition, Petitioner failed to address this alternative construction at all. *See* Petition at 34-37. Accordingly, Petitioner has failed to meet its burden of proving invalidity under the proper construction of "tubular clutch." In view of the construction advocated by the Petitioner in the Petition and at the District Court, the Petitioner should not be given a "do-over" in its forthcoming reply.

While Petitioner asserts that Burroughs' button 32 is a "tubular clutch" because it allegedly "rotationally decouples" the dial mechanism 34 from nut 36 and from the housing 22, the proper construction of "tubular clutch" requires the capability to "reversibly lock two components in rotation," not merely the capability to "rotationally decouple" them. Indeed, the District of New Jersey expressly considered and rejected, as inconsistent with the plain and ordinary meaning, claim construction proposals that would have required a structure that "couples and decouples" two components rather than reversibly locking two components in rotation. Ex. 2165 at 10-11.

The record in this proceeding clearly demonstrates that Burroughs' button 32 does not reversibly lock two components in rotation. Petitioner sets forth two

theories for disclosing a tubular clutch: (1) engagement of the dial mechanism 34 with the housing 22, and (2) engagement of the dial mechanism 34 with the nut 36.

With respect to the engagement between dial mechanism 34 and housing 22, Petitioner discusses how button 32, when pressed for injection, causes dial 34 to disengage from the housing's helical groove 158. Petition at 36-37. This, however, does not demonstrate that the button 32 "reversibly locks" the dial 34 and housing 22 "in rotation." In particular, even when dial 34 is engaged with the housing 22, the two components are not "reversibly locked ***in rotation***." Ex. 2107, ¶ 207. As discussed above in Section V, dial 34 is coupled to the housing by threads 110 and 112, which engage with the housing's helical groove 158. As Burroughs explains, "[u]pon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal direction ***as dial mechanism 34 retracts from housing 22***…." Ex. 1013, 10:34-37. As Professor Slocum explains, this means that the dial mechanism 34 is rotating relative to the housing 22, and therefore dial mechanism 34 and housing 22 are not "reversibly locked in rotation". Ex. 2107, ¶ 207. Thus, Petitioner's first theory does not render the claims invalid because the dial mechanism is never locked rotationally to the housing.

With respect to Petitioner's second theory, the engagement between dial mechanism 34 and nut 36, Petitioner argues that button 32, when pressed for injection, causes splines 144 of dial 34 to disengage from nut 36's splines 192 to

allow the dial 34 to rotate relative to nut 36. In other words, Petitioner argues that the button unlocks the dial from the nut by disengaging their respective splines. Petition at 37. According to Burroughs, however, button 32 never locks the dial to the nut. Ex. 2107, ¶ 208. Rather, the splines 144 and 192 engage to couple the dial to the nut when the user retracts the *dial mechanism* from the zero-dose position during dose setting. Ex. 1013, 8:42-48, 10:15-26; Ex. 2107, ¶ 208. Thus, Petitioner's second theory does not render the claims invalid because button 32 does not reversibly ***lock*** two components in rotation. Ex. 2107, ¶ 208.

2. Burroughs Expressly Discloses A Clutch That Is Not Button 32, Is Not Tubular, And Is Not Located Adjacent To A Distal End Of A Dose Knob

Notably, Burroughs discloses a "clutch" consisting of the combination of splines 144 and teeth 192:

> The clutching device comprises ***a series of splines on the inner cylindrical surface of the dial mechanism which axially engage corresponding splines on the outer surface of the nut***. The splines are engaged with one another by retracting the dial mechanism with respect to the nut after the dial mechanism has been rotated to its zero-dose position.

Ex. 1013, 2:59-65; Ex. 2107, ¶ 209. Splines 144 and teeth 192 reversibly lock two components in rotation – dial mechanism 34 and nut 36. Petitioner, however, cannot point to this clutch as the claimed "clutch" because splines 144 and teeth 192 are not

tubular and they are not located adjacent to a distal end of the proximal portion 78 of the dial mechanism 34 – both of which are required by the claim. Thus splines 144 and teeth 192 are not "a tubular clutch located adjacent a distal end of said dose knob." Ex. 2107, ¶ 209.

* * *

Because Petitioner relies solely on button 32 for the "tubular clutch located adjacent a distal end of said dose dial grip" limitation, and because button 32 does not operate to reversibly lock two components in rotation for the reasons discussed above, Burroughs does not disclose or render obvious a "tubular clutch located adjacent a distal end of said dose knob" under the proper construction of "tubular clutch."

VII. OBJECTIVE INDICIA OF NONOBVIOUSNESS

The PTAB has recognized that "objective evidence of nonobviousness[] may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art." *Lupin Ltd. v. Senju Pharm. Co.*, No. IPR2015-01100, Paper 70 at 20 (P.T.A.B. Sep. 12, 2016) (holding patent nonobvious in view of objective evidence of nonobviousness, despite prior art evidence of obviousness). Objective indicia help "guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966). Objective indicia of

nonobviousness may include long-felt but unresolved need for the invention, commercial success of embodying products, and industry praise, among other factors, which the PTAB must evaluate before reaching an obviousness determination. *Id*. at 35-36; *see also Transocean Offshore Deepwater Drilling Inc. v. Maersk Drilling USA, Inc*., 699 F.3d 1340, 1349-50 (Fed. Cir. 2012) (objective indicia must be considered). The Federal Circuit has held that evidence of objective indicia "may often be the most probative and cogent evidence in the record." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016).

A nexus must exist between the objective indicia and the claimed invention. *WBIP*, 829 F.3d at 1331. The nexus inquiry is directed to the invention as a whole and not to individual limitations. *Id*. at 1330. A nexus is presumed to exist "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *Id*. at 1329. Here, the objective indicia and nexus to the claimed invention confirm the non-obviousness of all challenged claims.

A. The LANTUS® SoloSTAR® Practices Challenged Claim 1 of the 486 Patent

As an initial matter, Sanofi's LANTUS® SoloSTAR®[4] product practices challenged claim 1. Ex. 2107, ¶¶ 513-550. As explained by Dr. Slocum, the inventions in the challenged claims describe a set of components that elegantly work together to provide the user a mechanical device that is easy to use and includes a combination of desirable features and properties, such as (i) low injection force, (ii) short injection stroke length or higher maximum dose per injection, and (iii) a relatively small number of components that decrease the complexity of the device. Ex. 2107, ¶ 650. For example, Dr. Slocum confirms that the claimed components and interfaces, such as the threaded engagements, piston rod, driver, and tubular clutch, are reflected in the LANTUS® SoloSTAR®. Ex. 2107, ¶¶ 513-550.

B. The LANTUS® SoloSTAR® Satisfied Previously Unresolved Needs for Pen Injectors Due To the Inventions in the 486 Patent

As set forth below, due to the contributions of the above features described by Dr. Slocum, the LANTUS® SoloSTAR® satisfied long-felt, but unresolved needs existing in commercially available pen injectors.

[4] LANTUS® is the commercial name for Sanofi's insulin glargine formulation, and LANTUS® SoloSTAR® is the commercial name for LANTUS® packaged in the SoloSTAR® pen injector.

Dr. Robin Goland, a leading endocrinologist and co-director of the Naomi Berrie Diabetes Center at Columbia University, explains that for patients dealing with a lifelong condition that requires daily medication/care, as with diabetes, anything that can be done to reduce the burden of living with such a condition is a huge benefit. Ex. 2111 ¶ 22. For example, people suffering from diabetes experience higher rates of deterioration of fine motor skills that impact hand–eye coordination, balance, and dexterity, among other basic skills. Ex. 2111 ¶ 23. These problems can be especially pronounced with the elderly. *Id.* Moreover, people with diabetes suffer from higher rates of carpal tunnel syndrome (diabetic hand), stiff hand syndrome, shoulder-hand syndrome (reflex dystrophy), and limited joint mobility, the latter of which is especially common with younger patients. Ex. 2111 ¶ 24. Each of these conditions interferes with the patient's basic life activities, in particular, with the ability to administer diabetic medications. Ex. 2111 ¶ 25. Accordingly, diabetic patients need an easy-to-use injection device with a low injection force to reduce the burden on the patient and increase the likelihood of the patient adhering to their prescribed therapy. Ex. 2111 ¶¶ 24-26.

Prior to the launch of LANTUS® SoloSTAR®, there were multiple injection pens on the market for administering insulin or an insulin analog – *e.g.*, Levemir FlexPen and Lantus OptiClik in the long-acting category, and the Humalog KwikPen in the rapid-and intermediate-acting categories, among many others. These injection

pens, however, had numerous shortcomings and design flaws that resulted in significant injection force. A 2007 study, for example, found that FlexPen ranked far below SoloSTAR in injection force. Ex. 2143; *see also* Ex. 2144. The OptiClik likewise had many deficiencies, including a direct drive system that resulted in a high injection force. *See* Ex. 2107, ¶ 646. Numerous other studies confirmed the relatively high injection force of each of the pens on the market at the time of and prior to the launch of SoloSTAR. Ex. 2111 ¶¶ 23-25 (discussing studies); Ex. 2109 ¶¶ 52-55 (discussing studies). As Dr. Goland explains, the high injection force of these prior art pens made the devices difficult to use and thus increased the risk of patients not adhering to their insulin and insulin-analog therapy. Ex. 2111 ¶¶ 33-35.

The LANTUS® SoloSTAR® revolutionized the injection pen market, in large part because the LANTUS® SoloSTAR® was easy to use. *See, e.g.*, Ex. 2142, Press Release, Prix Galien, 2009 (naming DCA as a candidate for the prestigious Best Medical Device for SoloSTAR®). As Dr. Goland explains, "the pen is so easy-to-use because of the low injection force, or the amount of pressure a patient needs to apply to the injection button in order to inject the dose." Ex. 2111 ¶ 33. This is reflected in literature at the time that demonstrates that the LANTUS® SoloSTAR® required a greatly reduced injection force. *See, e.g.*, Ex. 2116 at 7 (explaining the challenge of combining low injection force with the need for a short dial extension

and large dose injections). Moreover, these papers confirm that injection force was a primary concern.

And, as recited in the 486 Patent, the primary intent of the invention is to address these specific problems in the prior art – "The illustrated embodiment . . . helps reduce the overall force required for a user to cause medicinal product to be dispensed."), Ex. 1003, 3:64-67. Indeed, as reflected in a related patent, "Surprisingly it was found that the drive mechanism according to instant invention without having a unidirectional coupling provides a valuable technical alternative for drive mechanisms, wherein reduced force is needed to actuate the mechanism.").[5] Ex. 1005, 1:66-2:3.

The industry extensively recognized SoloSTAR for solving the problem of needing to deliver high doses with a short dial extension and with low injection force. *See, e.g.*, Ex. 2128 (discussing SoloSTAR's unique characteristics that "overcome existing unmet needs," specifically, the short dial extension, larger maximum dose, low injection force, simplicity of use); *see also* Ex. 2117; Ex. 2123 at 6; Ex. 2184 at 2 (containing a statement by endocrinologist Sjoberg Kho of the University of Santo Tomas Hospital that "self-injection can be a barrier to acceptance of insulin therapy.

[5] This description is from the 008 Patent, which is related to the 486 Patent. *See* footnote 2, *infra*.

However, the Lantus® SoloSTAR operates with a low injection force 31 percent less than other insulin pens that allows a gentle injection."); Ex. 2185 at 1 (containing a statement by Denis Raccah, Professor of Endocrinology, University Hospital Sainte Marguerite, France, that, "Insulin injection with SoloSTAR® brings flexibility, satisfaction for the patients, and an opportunity for earlier initiation of insulin therapy which may contribute to better long term glycemic control".)).

Patients likewise expressed a preference for SoloSTAR for its low injection force. *See, e.g.*, Ex. 2143; Ex. 2121 at 2, 9 (finding that 7 out of 10 patients now prefer the lower injection force of SoloSTAR® to competitor products and in 2008 it accounted for "41% of all growth in the global injectable insulin market"); Ex. 2144.

The product has thus satisfied a long-felt but unmet need for an easy-to-use pen that was particularly well suited to administer medication with a low injection force.

C. The Lantus® SoloSTAR® Received Industry Praise for its Patented Features

The nonobviousness of the 486 patent is further demonstrated by the high level of praise and industry recognition that Sanofi and DCA, the design firm with whom Sanofi partnered in creating SoloSTAR®, received for the designs embodied in the SoloSTAR® device. In 2009, for example, SoloSTAR won the Gold, International Export, and Grand Prix awards at the Design Business Association

(DBA) Design Effectiveness Awards. *See* Ex. 2121. The DBA is a design organization based in the UK that is interested in how a design commercially impacts a company's business. The case study of SoloSTAR for the DBA Awards describes the SoloSTAR's inventiveness as "suitably ambitious" and explains that "SoloSTAR® is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough." *Id*. at 3. SoloSTAR also won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design. Ex. 2201. In connection with this award, and as recognition of its inventiveness, the Lantus® SoloSTAR® device was put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design. Ex. 2109 ¶ 73.

Additionally, in 2007, SoloSTAR® won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design. *Id*. The criteria for this award are "quality design of the highest form, function, and aesthetics a standard beyond ordinary consumer products and graphics." *Id*. Christian K. Narkiewicz-Laine, President of the Chicago Athenaeum Museum of Architecture and Design noted that "SoloSTAR represents a design for social good and for humanitarian concerns." *Id*. In connection with this award, the Lantus® and Apidra® SoloSTAR® devices were put into the permanent Design Collection of the Chicago

Athenaeum Museum of Architecture and Design, as recognition of its inventiveness. *Id*.

Finally, at the Prix Galien USA 2009 Award, which "recognize[s] innovative biopharmaceutical drugs and medical technologies" and "is considered the industry's highest accolade for pharmaceutical research and development — equivalent to the Nobel Prize," Sanofi and DCA were both finalists. *Id*. ¶ 74.

In sum, Sanofi and DCA received a high level of acclaim for the design of the SoloSTAR® device.

D. The Commercial Success of the LANTUS® SoloSTAR® Is Attributable to the Inventions in the 486 Patent

The tremendous commercial success of LANTUS® SoloSTAR® is further objective evidence of non-obviousness. The commercial success is demonstrated by the contribution of LANTUS® SoloSTAR® to the growth of the LANTUS® franchise overall, and by the strong performance of LANTUS® SoloSTAR® when compared to other long-acting insulin and insulin analog pens.[6]

As explained by Dr. Grabowski, LANTUS® SoloSTAR® has enjoyed fast and long-sustained growth in terms of dollar sales, new prescriptions, and total

[6] Although Patent Owner's commercial success evidence focuses on the long-acting insulin and insulin-analog market in which LANTUS® SoloSTAR® competes, the

prescriptions. *Id*. ¶ 12. The commercial success of LANTUS® SoloSTAR® is also demonstrated by the overall levels and shares of dollar sales, new prescriptions, and total prescriptions, as well as the profitability and formulary placement achieved by LANTUS® SoloSTAR®. *Id*. This success is notable because sales and prescriptions for LANTUS® SoloSTAR® remained strong despite the entry of several competing long-acting insulin and insulin analog drugs (all in pen form) starting in 2015. *Id*. Furthermore, the LANTUS® SoloSTAR® achieved the highest level of sales among long-acting insulin and insulin analog pens even though it launched after several other long-acting insulin and insulin analog pens, including the Levemir® FlexPen® (the commercial embodiment of Steenfeldt-Jensen), which was the first long-acting insulin or insulin analog product available in a disposable pen. *Id*.

The success of LANTUS® SoloSTAR® is further evidenced by its substantial growth relative to LANTUS® OptiClik®, which is an older pen injector product that included the same insulin glargine formulation as LANTUS® SoloSTAR®. *Id*. ¶ 12. For example, new prescriptions of LANTUS® OptiClik® totaled 461 thousand in the third year after its launch, and total prescriptions amounted to 1.2 million by this time. By comparison, new prescriptions of LANTUS® SoloSTAR® (using the exact

---

device satisfied long-felt needs left unresolved by inferior injection pen devices in other markets, such as the rapid-acting and intermediate acting markets.

same insulin formula) totaled 1.6 million in the third year after its launch, and total prescriptions amounted to 3.9 million by this time. *Id*. at ¶ 37.

As explained by Prof. Slocum and Dr. Grabowski, the features of the device disclosed and claimed in the 486 Patent and used in LANTUS® SoloSTAR® contributed to its commercial success. Ex. 2109 ¶ 53; Ex. 2107 ¶¶ 513-550. For example, there was a long-felt but unfulfilled need for an easy-to-use pen device with low injection force. As explained in the supporting declaration of Dr. Goland, the SoloSTAR® device satisfied that need and drove patient adoption. Additionally, as explained in the supporting declaration of Dr. Grabowski, the SoloSTAR® device won numerous design awards, and achieved significant industry praise. Finally, as explained above and in the supporting declaration of Prof. Slocum, the SoloSTAR® device embodies the challenged claims of the 486 patent. Thus, there is a nexus between the claimed invention in the 486 patent and the commercial success of LANTUS® SoloSTAR®.

To the extent Petitioner argues that Patent Owner's evidence of commercial success is not due to the claimed invention, but rather, to factors beyond the claimed invention such as, *e.g.*, marketing, such arguments should be rejected. In particular, Dr. Grabowski analyzed marketing expenditures for long-acting insulin products and determined that sales of LANTUS® SoloSTAR® exceeded sales for other well-marketed long-acting insulin products despite the fact that total marketing

expenditures for LANTUS® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products. Ex. 2109 ¶¶ 16, 64-69. Patent Owner's marketing of LANTUS® SoloSTAR® therefore does not explain the commercial success of LANTUS® SoloSTAR®.

Moreover, to the extent Petitioner argues that Patent Owner's evidence of commercial success is due to alleged "blocking patents" covering the glargine molecule that is used in the production of the active ingredient in Lantus®, any such argument would be misplaced. First, the law does not mandate across-the-board-discounting of commercial success simply because other patents cover components of the product. Rather, the PTAB is directed to weigh the evidence on a case-by-case basis, in light of the specific commercial success argument being made. *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1339 (Fed. Cir. 2018), *pet. for cert filed*, No. 18-1280 (U.S. Apr. 8, 2019) (noting that while a blocking patent "can be evidence that can discount the significance of evidence that nobody but the blocking patent's owners or licensees arrived at, developed, and marketed the invention covered by the later patent," the "magnitude of the diminution … is a fact-specific inquiry").

Second, as described above, the success of Lantus® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because Lantus® OptiClik® used the exact same Lantus® formulation and failed to achieve the success of

SoloSTAR®. Thus, the success of SoloSTAR® must be attributable at least in part to its unique design covered by the 486 patent.

Third, Sanofi's earlier patents on the insulin glargine molecule did not prevent others from entering the market for non-glargine, long-acting insulin products and competing with Lantus® SoloSTAR®. As explained above, numerous other competitive pen devices existed prior to Lantus SoloSTAR®. The Levemir FlexPen, for example, was a disposable pen device that delivered long-acting insulin. Sanofi's patents on the insulin glargine molecule do not cover the Levemir formulation and, indeed, did not prevent competition between those devices. The tremendous success of Lantus® SoloSTAR®, as compared to pens with long-acting insulins that failed to address the long-felt but unfilled need for a low injection force device, therefore shares a strong nexus with the claimed invention.

Thus, the commercial success of LANTUS® SoloSTAR®, which is covered by claim 1 of the 486 Patent, confirms the nonobviousness of the 486 Patent.

VIII. CONCLUSION

For the reasons set forth above, Patent Owner respectfully requests that the Board confirm the patentability of challenged claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40.

Dated: June 25, 2019

Respectfully submitted,

/Elizabeth Stotland Weiswasser/

Elizabeth Stotland Weiswasser
Reg. No. 55,721
Anish R. Desai
Reg. No. 73,760
Sudip K. Kundu
Reg. No. 74,193
Kathryn M. Kantha
Reg. No. 70,371
Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Phone: 212-310-8000
elizabeth.weiswasser@weil.com
anish.desai@weil.com
sudip.kundu@weil.com
kathryn.kantha@weil.com

Adrian C. Percer
Reg. No. 46,986
Brian C. Chang
Reg. No. 74,301
Weil, Gotshal & Manges LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Phone: 650-802-3124
adrian.percer@weil.com
brian.chang@weil.com

William S. Ansley
Reg. No. 67,828
Matthew D. Sieger
Reg. No. 76,051
Weil, Gotshal & Manges LLP
2001 M Street NW, Ste. 600
Washington, D.C. 20036
Phone: 202-682-7000
sutton.ansley@weil.com

matthew.sieger@weil.com

Sanofi.IPR.Service@weil.com

CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 10,764 words (excluding the table of contents, the table of authorities, mandatory notices under 37 CFR § 42.8, the certificate of service, certificate of compliance, and appendix of exhibits), as calculated by the "Word Count" feature of Microsoft Word 2016, the word processing program used to create it.

2. The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: June 25, 2019

Respectfully submitted,

/*Elizabeth Stotland Weiswasser*/

Elizabeth Stotland Weiswasser
Reg. No. 55,721
Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Phone: 212-310-8000
elizabeth.weiswasser@weil.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 25, 2019, the foregoing Patent Owner's Response and accompanying exhibits were served via electronic mail upon the following:

Richard Torczon
Wesley Derryberry
Tasha Thomas
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, 5th Floor
Washington, D.C. 20006
rtorczon@wsgr.com
wderryberry@wsgr.com
tthomas@wsgr.com

Douglas H. Carsten
Jeffrey W. Guise
Arthur Dykhuis
Elham F. Steiner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130
dcarsten@wsgr.com
jguise@wsgr.com
adykhuis@wsgr.com
esteiner@wsgr.com

Lorelei Westin
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
lwestin@wsgr.com

Franklin Chu
WILSON SONSINI GOODRICH & ROSATI
701 Fifth Avenue, Suite 5100
Seattle, WA 98104
ychu@wsgr.com

Nicole W. Stafford
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas, IV Fifth Floor
Austin, TX 78746
nstafford@wsgr.com

/Timothy J. Andersen/
Timothy J. Andersen
Case Manager
Weil, Gotshal & Manges LLP
2001 M Street, NW, Suite 600
Washington, DC 20036
timothy.andersen@weil.com