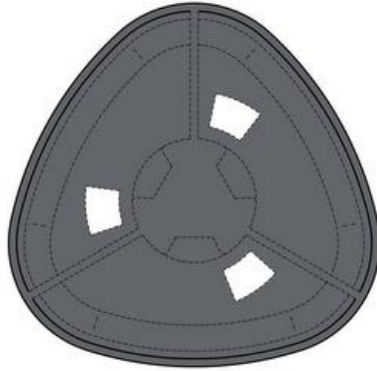


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



**TRADEMARK:**

**SERIAL NO.:** 87/838,079

**FILING DATE:** March 16, 2018

**APPLICANT:** Eli Lilly and Company

**EXAMINING ATTORNEY:** Dominic Ferraiuolo

**LAW OFFICE:** 102

**RESPONSE TO OFFICE ACTION**

Applicant Eli Lilly and Company (“Lilly”) submits this response to the Office Action issued on June 15, 2018, concerning the above-referenced application.

**I. Identification of Goods and Specimen Requirement**

In response to the Examining Attorney’s request, Lilly hereby deletes Class 10 from its application and maintains the original identification of goods in Class 5, *i.e.*, “Pharmaceutical preparations for the treatment of diabetes.”

In view of the deletion of Class 10, Lilly respectfully submits that the specimen of record (a photograph showing the mark as it appears on the automatic injector device containing a pharmaceutical preparation for the treatment of diabetes) is sufficient for the remaining Class 5 goods.

## **II. Lilly's Mark Has Acquired Distinctiveness Under Section 2(f)**

Lilly's applied-for mark (the "Mark") has acquired distinctiveness for pharmaceutical preparations for the treatment of diabetes under Section 2(f) of the Trademark Act. Therefore, this mark is entitled to registration on the Principal Register.

In support of its Section 2(f) claim, Applicant submits the declarations of Kevin Duffy, Tori Brown, and Jaime Valtierra, attached hereto, including substantial evidence demonstrating that the Mark has acquired distinctiveness.

Lilly has used the Mark for nearly five years in connection with a pharmaceutical preparation for the treatment of diabetes that is marketed under the brand name Trulicity (the "Treatment"), which is one of the leading diabetes treatments in the United States. In fact, the Treatment has helped millions of Americans manage their diabetes care and continues Lilly's long and pioneering work in the diabetes field. The Mark consists of a three-dimensional trilobular-shaped base cap, in a specific Pantone shade of the color gray, used with the automatic injector device that delivers the Treatment. Since 2014, the Mark has become widely recognized by customers and prospective customers as an identifier of Lilly and its Treatment. Additionally, the Mark's design and color make it unique and, therefore, the Mark stands out in the pharmaceutical industry for this type of product.

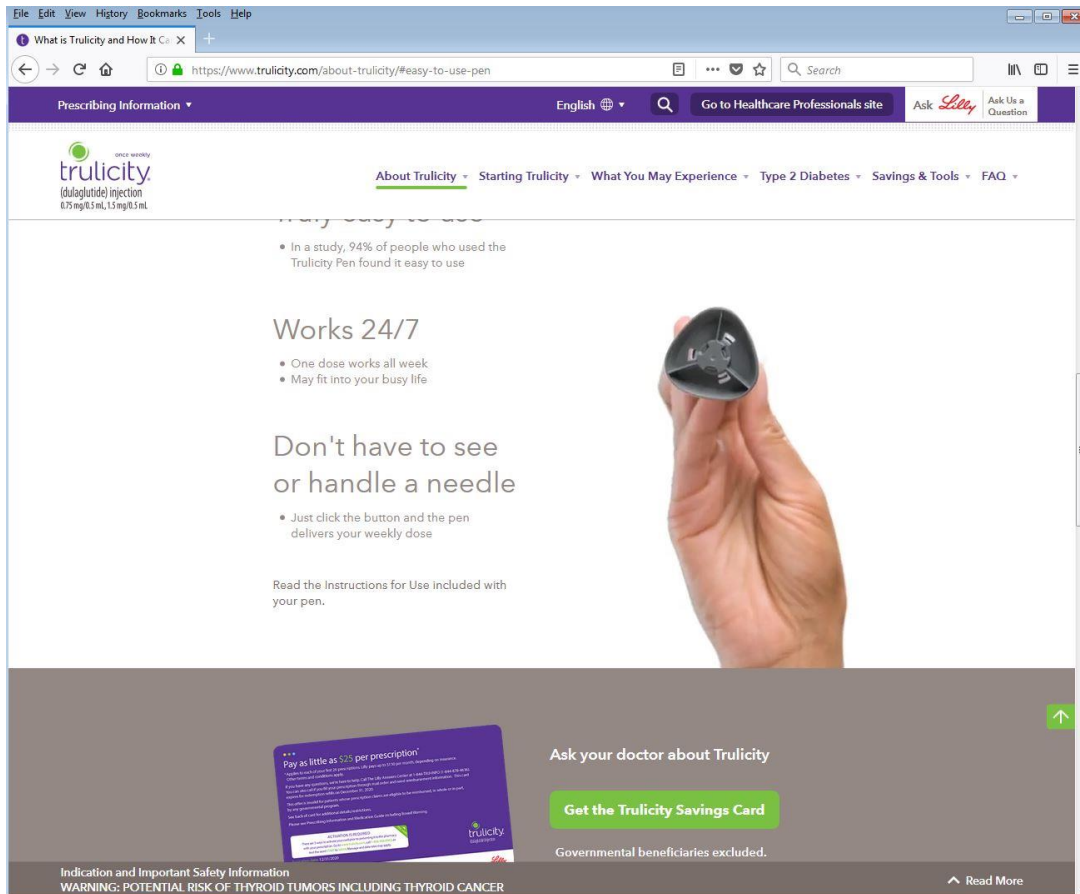
As noted below and detailed in the attached declarations, the evidence of acquired distinctiveness includes, among other things:

- that Lilly has emphasized and continues to emphasize the Mark in implicit look-for advertising and promotions;
- Lilly's sales, advertising and marketing of the Treatment;
- the efforts of Lilly's sales force, which have brought attention to the Mark;

- Lilly’s promotion of the Treatment at conferences, which also has brought attention to the Mark;
- unsolicited media coverage for the Treatment;
- unsolicited customer reaction to the Mark;
- that the Mark has helped the Treatment to stand out in the marketplace; and
- Lilly’s exclusive use of the Mark.

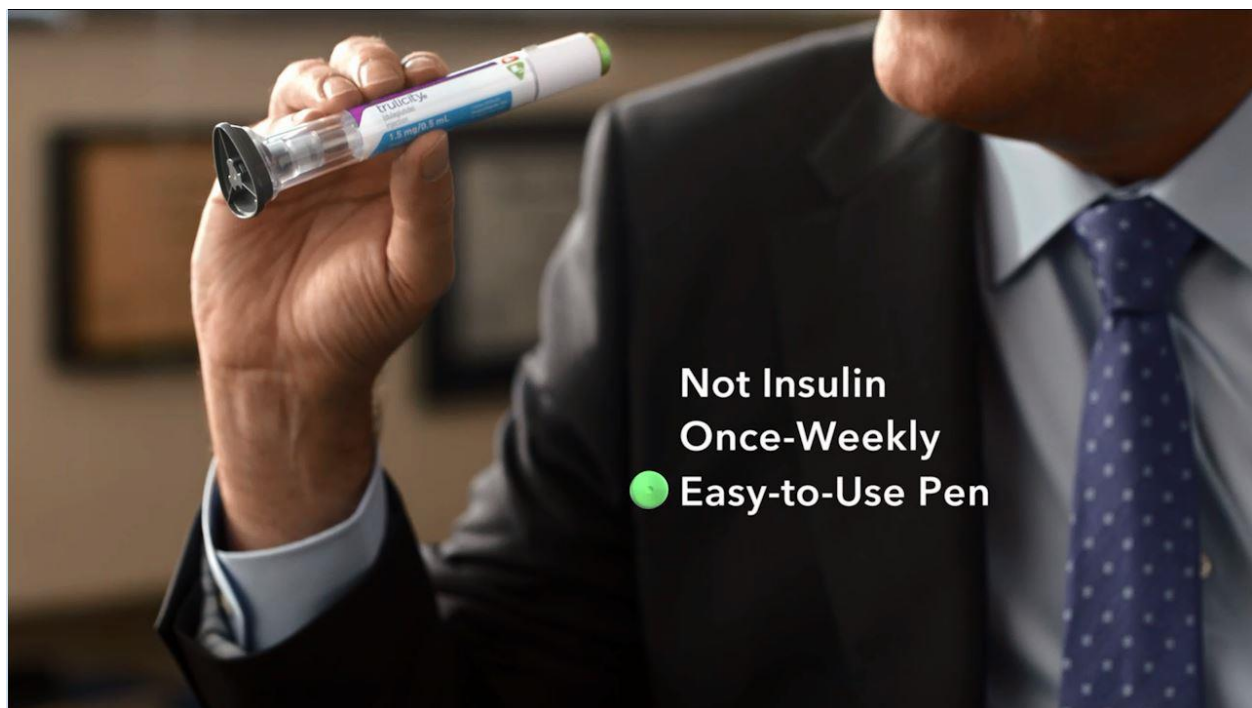
**A. Lilly’s Emphasis on the Mark in Advertising and Promotions**

Lilly’s implicit look-for advertising and promotion of the Treatment has consistently focused and continues to focus the attention of customers and prospective customers on the Mark, including both its design and color. For example, Lilly prominently features the Mark on its website:



Declaration of Tori Brown in Support of Response to June 15, 2018, Office Action (“Brown Decl.”) at ¶ 6.

The Mark has also been featured in Lilly’s television advertisements since 2015. Below are screen shots from three separate advertisements for the Treatment that have aired in the United States in 2017 and 2018. These advertisements aired on all four major networks, as well as some of the most popular cable networks, including during popular television shows, such as CBS Sunday Morning and NFL football games, which have a large number of viewers.





Brown Decl. at ¶ 7.

Lilly's significant television and website advertising highlighting the Mark has helped the Mark to acquire distinctiveness. *See, e.g., Yamaha Int'l Corp. v. Hoshino Gakki Co., Ltd.*, 840

F.2d 1572, 1583 (Fed. Cir. 1988) (affirming the Board’s finding of acquired distinctiveness that was based in part on advertising that included images of the trade dress); *Seabrook Foods, Inc. v. Bar-Well Foods, Ltd.*, 568 F.2d 1342, 1345 n.8 (C.C.P.A. 1977) (finding that advertising emphasizing the design portion of the applied-for mark to potential consumers was persuasive evidence of acquired distinctiveness); *In re Cabot Corp.*, 15 U.S.P.Q.2d 1224 (T.T.A.B. 1990) (finding acquired distinctiveness of a package using a blue and white color scheme, as the applicant used advertising highlighting the colors).

**B. Lilly’s Sales Have Helped to Establish the Distinctiveness of the Mark**

Since Lilly launched the Treatment featuring the Mark in the United States in 2014, the Treatment has been used by millions of Americans. Brown Decl. at ¶ 9. More than 9 million prescriptions have been filled for the Treatment. *Id.* Moreover, sales of the Treatment in the U.S. have increased every year, including more than \$200 million in 2015; more than \$700 million in 2016; more than \$1.5 billion in 2017; and, in 2018, are expected to exceed 2017 sales. Overall, Lilly’s sales of the Treatment in connection with the Mark total in excess of \$4 billion. *Id.* at ¶ 8.

Currently, sales of Lilly’s Treatment comprise approximately 44 percent of the GLP-1 class of products in the United States. *Id.* at ¶ 10. Since May 2018 and up until today, it has been the market-leading type 2 diabetes treatment of its kind in the United States. *Id.* Indeed, it is projected to be the top-selling diabetes drug in the world by 2024. *Id.* at ¶ 11.

The sales of the Treatment reinforce that the Mark has acquired distinctiveness. *See In re Uncle Sam Chem. Co.*, 229 U.S.P.Q. 233, 235 (T.T.A.B. 1986) (finding Section 2(f) claim of acquired distinctiveness of its mark persuasive where applicant had submitted declaration showing increased sales figures); *In re Cartier N.V.*, 2010 WL 3164745, at \*3 (T.T.A.B. July 30, 2010) (reversing refusal to register and finding that evidence of substantial sales and national advertisements of the watch subject to the trade dress application supported the Section 2(f)

claim) (non-precedential opinion attached to this filing); *Selchow & Righter Co. v. Decipher, Inc.*, 598 F. Supp. 1489, 1496 (E.D. Va. 1984) (sale of 14 million units over a two-year period supported finding that trade dress had acquired secondary meaning).

**C. Lilly's Advertising and Promotion of the Treatment Reinforces the Distinctiveness of the Mark**

Since June 2014, Lilly has spent tens of millions of dollars advertising the Treatment in the United States. Brown Decl. at ¶ 12.<sup>1</sup> This advertising has included national television advertising on all four major networks, as well as some of the most popular cable networks (such as the advertisements shown above), the Internet, and major print advertising campaigns. *Id.* at ¶ 13. For example, in 2017 the Treatment was one of the top 10 most advertised pharmaceutical products in the United States. *Id.* at ¶ 14. Further, Lilly has advertised the Treatment in magazines such as *Good Housekeeping*, *Reader's Digest* and *Woman's Day*. *Id.* at ¶ 16. Lilly's social media marketing for the Treatment includes an active Facebook page with video advertising depicting the Treatment, including images of the Mark. *Id.* at ¶ 15. Additionally, Lilly developed a mobile application that promoted the Treatment by showing visual depictions of it, including the Mark. *Id.* at ¶ 17.

Lilly's promotional activities for the Treatment have extended beyond television, print, and Internet advertising. For example, for several years Lilly has made presentations about the Treatment, including displaying the Mark, at prominent conferences in the U.S. related to diabetes, which are attended by tens of thousands of physicians and other health care professionals. *Id.* at ¶ 23. At these conferences (which often provide an opportunity for companies such as Lilly to have an exhibit booth), attendees interact with a promotional version

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<sup>1</sup> A further breakdown of the advertising spend for the Treatment would reveal confidential information and, therefore, it is not identified here. *See* TMEP § 814.

of the Treatment, which bears the Mark. *Id.* These conferences include the annual American Diabetes Association Scientific Sessions meeting, as well as the American Association of Clinical Endocrinologists' national annual meeting and regional conferences. *Id.*

Lilly also attends other conferences related to health care. For example, at the 2016 Barclays Global Healthcare Conference in Miami Beach, Florida, Lilly's then CFO Derica Rice was interviewed about the Treatment and other topics. *Id.* at ¶ 24.

Further, Lilly has a large team of sales representatives working across the country to educate physicians about the Treatment. Lilly employs approximately 1,300 sales representatives in the United States who have made approximately 9.98 million in-person visits to physician offices since 2014. *Id.* at ¶ 18-19. At such visits, they demonstrate and describe the Treatment to physicians, physician's assistants, nurse practitioners, and other members of the office, who then interact with a promotional version of the Treatment, which features the Mark. *Id.* at ¶ 19. Lilly's sales representatives have provided more than 600,000 of these promotional devices to physician's offices, drawing considerable attention to the Mark. *Id.* at ¶ 20. Once this promotional device is left at the office, it can be used by a physician, nurse, or the physician's medical staff to inform patients about the Treatment, who then also see the Mark. *Id.* at ¶ 21.

In addition to the promotional version of the Treatment, the sales representatives leave behind patient education brochures. *Id.* at ¶ 22. Lilly has printed more than 2 million of these brochures in both English and Spanish. *Id.*

Lilly's advertising and promotional efforts provide strong support for its Section 2(f) claim. *See, e.g. In re Rolled Alloys, Inc.*, 2014 WL 2967635, at \*7 (T.T.A.B. June 3, 2014) (applicant's advertising expenditures of more than \$2 million over a five-year period support the Board's finding of acquired distinctiveness and reversal of the refusal to register) (non-



precedential opinion attached to this filing); *In re Carl Walther GmbH*, 2010 WL 4502071, at \*4 (T.T.A.B. Oct. 26, 2010) (advertising expenditures of approximately \$920,000 over a four-year period support applicant's acquired distinctiveness claim and reversal of the refusal to register) (non-precedential opinion attached to this filing).

**D. Significant Unsolicited Media Coverage for the Treatment**

Lilly's Treatment has garnered substantial unsolicited media coverage. In fact, the FDA's approval and Lilly's introduction of Trulicity was reported by major newspapers such as *The New York Times* and *Boston Globe*, as well as publications focused on diabetes such as *Diabetes Week* and *diaTribe*. Brown Decl. at ¶¶ 25, 26. Since its launch in 2014, the Treatment has received significant additional unsolicited media coverage, as it has been covered in over one hundred articles published in just the U.S. in a variety of pharmaceutical industry, financial, and general interest publications. *See* Declaration of Jaime Valtierra in Support of Response to June 15, 2018, Office Action at ¶¶ 2, 3.

**E. Unsolicited Customer Videos of the Treatment Emphasizing the Mark**

In addition to traditional news sources, users of the Treatment have posted numerous videos on YouTube describing the Treatment. These videos have generated nearly 60,000 views of the Mark and highlight its unique design and color. Brown Decl. at ¶ 27; *See* Declaration of Kevin Duffy ("Duffy Decl.") in Support of Response to June 15, 2018, Office Action at ¶ 4.

**F. The Mark is Unique and Stands Out in the Competitive Landscape**

Lilly is aware of no third parties using a design and color similar to the Mark in the U.S. *See* Duffy Decl. at ¶¶ 6–9. In fact, Lilly adopted the Mark, in part, so that the Treatment would have an innovative design that is distinct from the devices of other pharmaceutical companies. *Id.* at ¶ 2. Lilly made these efforts so that customers and potential customers, as well as the rest

of the public, would be able to immediately recognize it as coming from a single source. *Id.* at ¶¶ 2, 3.

Of note, Lilly carefully selected the color of the Mark, Pantone 10 C Cool Gray, to distinguish the product from others in the field. *Id.* at ¶ 4. This unique color is one of myriad shades of gray available for plastics coloring; for example, the Pantone website includes 53 shades of the color gray, one of which is the color in the Mark, Pantone 10 C Cool Gray. *Id.*

Below is an image of directly competing products:<sup>2</sup>



*Id.* at ¶ 7. As shown above, Lilly’s Treatment — and in particular the Mark — is easily distinguishable from these other devices. *Id.*

Furthermore, the Mark is unique and readily identifiable even among a broad range of pharmaceutical products sold in similar fashion, *i.e.*, in auto-injector devices. Below is a photograph showing auto-injector devices for various other pharmaceutical products in the United States:

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<sup>2</sup> From left to right, the products in this photo are: Novartis’ Tanzeum, Novo Nordisk’s Ozempic, AstraZeneca’s Bydureon Pen, Lilly’s Trulicity Treatment, AstraZeneca’s Byetta, Novo Nordisk’s Victoza, and AstraZeneca’s Bydureon BCise.



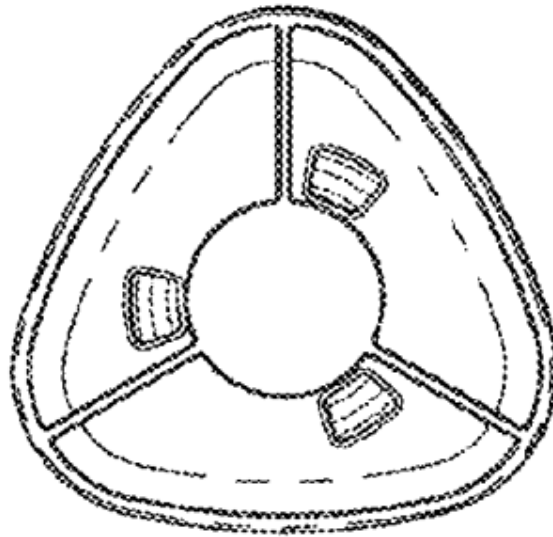
*Id.* at ¶ 8.<sup>3</sup> Again, Lilly's Mark easily stands out from the rest and was designed with this unique character in mind. *Id.*

Lilly's exclusive use of the Mark, and the fact that injectable pens for diabetes treatments are distinguishable by their designs, is a significant factor in showing that the Mark has acquired distinctiveness. For example, in the case *In re Black & Decker Corp.*, 81 U.S.P.Q.2d 1841 (T.T.A.B. 2006), the Board found that it was industry practice for key head designs to be used as source designators. *Id.* at 1844. As a result, the fact that the applicant's key head design was unlike the key head designs used by other manufacturers (even with no "look-for" advertising for the design) was a significant factor in its reversal of the Examining Attorney's refusal to register. *Id.* at 1844–45.

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<sup>3</sup> From left to right, the products in this photo are: Mylan's EpiPen (for allergic reactions), Novartis' Cosentyx (for psoriasis and arthritis), AbbVie's Humira Pen (for psoriasis, arthritis and Crohn's), Lilly's Trulicity Treatment, Janssen Biotech's Simponi (for arthritis and colitis), Immunex's Enbrel (for psoriasis and arthritis), and EMD Serono's Rebif Rebidose (for multiple sclerosis).

Furthermore, Lilly’s exclusive use of its Mark is supported and protected by its United States design patent (Patent No. D739,011), which includes the following figure:



See Exhibit 1.<sup>4</sup>

### **III. Conclusion**

As discussed above, and as detailed in the attached declarations, Lilly’s Mark has acquired distinctiveness as an identifier of source. Therefore, the Mark is registrable on the Principal Register pursuant to Section 2(f) of the Trademark Act.

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<sup>4</sup> Courts have found that a design patent can support a finding of acquired distinctiveness. *See, e.g., govino, LLC v. WhitePoles LLC*, Case No. 4:16-cv-06981-JSW (KAW), 2017 WL 6442187, at \*6 (N.D. Cal. Nov. 3, 2017), *report and recommendation adopted*, 2017 WL 6442188 (N.D. Cal. Nov. 3, 2017) (“Importantly, govino enjoys comprehensive design patent coverage that permits govino to exclude others from making, using, selling, etc. glasses including the govino Trade Dress. . . . Thus, the Court finds that govino’s use in commerce has been substantially exclusive and continuous over the last nine years and serves as prima facie evidence under section 1052(f) and relevant case law that the govino Trade Dress has acquired distinctiveness through secondary meaning, and is, thus, enforceable as a trademark.”) (unpublished opinion attached to this filing); *Beaumont Prods., Inc. v. Clean Control Corp.*, Case No. 1:09-CV-3325-CAP, 2010 WL 11508002, at \*2 (N.D. Ga. Oct. 7, 2010) (unpublished opinion attached to this filing).

Lilly respectfully requests that the Examining Attorney find that the Mark has acquired distinctiveness and approve the Mark for publication in the *Official Gazette*.

Respectfully submitted,

PATTISHALL, McAULIFFE, NEWBURY,  
HILLIARD & GERALDSON LLP

Dated: December 17, 2018

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