IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC. ET AL, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL, Defendants.	2:23-cv-00836-MRH Chief Judge Mark R. Hornak Oral Argument Requested

PLAINTIFFS' RESPONSE IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

From 2001 to 2015, Sanofi held a multi-billion-dollar monopoly over insulin glargine by virtue of a patent protecting its composition. *See* Compl. ¶ 82. That patent expired in 2015, which meant that competitors should have been able to enter the market and increase the availability of lower priced insulin for patients. *See id.* ¶ 93. Instead, Sanofi maintained its monopoly well past the expiration date so it could continue to raise prices, restrict supply, block competition, and accrue billions in profits. It did so through a multi-layered strategy that weaponized the FDA approval process, bought time needed to force the market to adopt a second insulin glargine product, created an exclusionary dual bundle rebating scheme to protect itself from competition while it made the switch to the second product, and punished any customer who tried to make purchases outside of this bundle. These efforts foreclosed Mylan's generic alternative from the market. Patients suffered as a result. The antitrust laws exist to protect consumers and competition from this very avarice, and Sanofi must be held accountable.

In its motion, Sanofi seeks a remedy that the Court cannot provide at this preliminary stage: choose its version of events over Mylan's and decide fact-specific issues in favor of Sanofi. Mylan's non-conclusory allegations, supported with ample evidence from a range of independent third parties, including reports from the U.S. Senate Finance Committee and the U.S. House Committee on Oversight and Government Reform, must be taken as true and sufficiently outline Sanofi's decade-long scheme to thwart generic competition and illegally maintain its monopoly.

STATEMENT OF FACTS

Since its launch in 2001, Sanofi has raked in more than $43.9 billion in net revenue from Lantus, its blockbuster insulin glargine product. *See* Majority Staff Report, Drug Pricing

Investigation, House Committee on Oversight and Reform (Dec. 2021) ("Drug Pricing Rep."),[1] at 28. At first, Sanofi achieved these profits via a patent covering its insulin glargine composition. *See* Compl. ¶ 93. Without competitors, Sanofi could restrict market output and raise prices. The results were staggering: $7.87 billion in gross sales in 2014 *alone*. *See id.* ¶ 94. Millions of Americans resorted to rationing insulin due to exorbitant costs. *See* U.S. Senate Finance Committee, Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug (2021) (hereinafter, "Insulin Rep."), at 14.[2] But, as long as Sanofi's composition patent had not yet expired, insulin glargine was insulated from competition.

Things should have changed in 2015 when Sanofi's patent protecting its insulin glargine composition expired. *See* Compl. ¶¶ 18, 82–85. Generic competitors should have been able to enter the market, increase supply, undercut Sanofi's profit-maximizing prices, and lower prices for patients. *See id.* ¶¶ 18, 80–81. Instead, Sanofi hatched a multifaceted scheme to illegally maintain its monopoly. *See id.* ¶¶ 3–23, 125–26. As detailed in the Complaint, this scheme violated Section 2 of the Sherman Act, Section 3 of the Clayton Act, the New Jersey Antitrust Act, and Pennsylvania common law. *See id*. ¶¶ 232–65. The facts are summarized below.

I. Sanofi Abused The Orange Book and The Hatch-Waxman Act's 30-Month Stay to Delay FDA Approval of Mylan's Generic.

Sanofi continued to monopolize the injectable insulin glargine market by strategically delaying the approval of Mylan's generic[3] alternative ("Semglee™") to Lantus for years. *See* Compl. ¶ 3. To understand how Sanofi accomplished this goal, one must first understand the

[1] The Drug Pricing Report is available at https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf. *See* Compl. ¶ 8 n.3 (incorporating by reference the Drug Pricing Report).

[2] The Insulin Report is available at https:www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. *See id.* ¶ 14 n.8 (incorporating by reference the Insulin Report).

[3] During the lifespan of Sanofi's conduct, the nomenclatures associated with regulatory approvals changed, so Mylan's would-be generic received approval as a drug product and was deemed a biologic. For purposes of this brief, we will use the term "generic."

path of bringing generic alternatives to market. *See generally id.* ¶¶ 43–79.

An applicant seeking FDA approval for a new drug under patent protection may identify patents that claim the drug or a use of the drug that could reasonably be asserted in an infringement action. *See* Compl. ¶¶ 47, 57–58. If FDA approves the new drug, it publishes this patent information in a publication referred to as the "Orange Book." *See id.* ¶¶ 46, 49.

A generic manufacturer seeking to enter the market for a branded drug must provide a certification saying either that their product does not infringe patents listed in the Orange Book or that the listed patents are invalid. *See* Compl. ¶¶ 48, 69–74. The provision of this certification grants the brand manufacturer the right to sue for patent infringement. *See id.* Once a brand manufacturer sues a generic manufacturer for patent infringement, FDA generally may not approve the generic manufacturer's drug application until 30 months pass, or until the court finds the patent invalid or not infringed. *See id.* This means the generic drug will be kept off the market for a lengthy period—i.e., a brand manufacturer like Sanofi gets to keep enjoying its monopoly without any competition.

Brand manufacturers (like Sanofi) looking to extend their monopoly can abuse the Orange Book process by listing invalid patents that were not proper for inclusion. The anticompetitive effects can be compounded by creating a "patent thicket." *See* Compl. ¶ 114. This is accomplished by obtaining multiple patents on aspects of the same product, which forces generic manufacturers to fight through the resulting patent thicket to obtain FDA approval. These regulatory and litigation burdens can significantly deter or delay the approval of generic alternatives.

Here, Sanofi used these overlapping strategies to devastating effect. Sanofi listed a panoply of invalid patents that did not meet the Orange Book criteria to trap Mylan in years of

patent litigation and regulatory approval delays. *See* Compl. ¶¶ 4–7, 95–122. Despite initially asserting over a dozen Orange Book patents against Mylan, not one patent claim survived judicial scrutiny. *See id.* ¶¶ 140–90. Of the invalidity challenges to over 50 claims in Sanofi's asserted patents brought through *inter partes* reviews, *only two* claims survived (neither of which could have excluded Mylan), leaving Sanofi with an abysmal success rate of 4%. *See id.* ¶ 143. But outside of the courtroom, Sanofi prevailed anyway. *See id.* ¶ 141. By entangling Mylan's generic product in a patent thicket, Sanofi was able to prolong its injectable insulin glargine monopoly and, in that competition-free environment, lure doctors and patients to its rebranded product, "Toujeo", which did not face generic competition. *See id.* ¶¶ 3, 141–42, 191–94.

II. Building on Its Regulatory and Patent Abuse, Sanofi Next Coerced the Market to Adopt Toujeo and then Tied Toujeo and Lantus to Exclude Generic Competition.

Sanofi further monopolized the insulin glargine market through a multi-layered rebate tying scheme. Sanofi first released Toujeo, a rebranded, therapeutically indistinguishable version of Lantus, at an exorbitantly high price. *See* Compl. ¶¶ 8–12, 195–98. Although this product did not offer any therapeutic advantage over Lantus, Sanofi introduced and marketed Toujeo as a different product, which meant that Mylan's Semglee could not serve as a generic substitute for Toujeo. *See id.* ¶¶ 195, 197, 199–210. Sanofi then tied rebates offered on Lantus to Toujeo's inclusion as an approved drug for insured patients. *See id.* ¶¶ 14, 201–207. This made Mylan's less expensive, therapeutically identical product unattractive to the pharmacy benefit managers ("PBMs") that help choose which drugs are covered by insurance. *See id.* ¶¶ 8–10.

Insurers—including Medicare Part D—rely on these PBMs to negotiate discounts and rebates for drugs offered to their customers. *See* Compl. ¶ 11. Approved drugs are placed on lists called "formularies" that dictate which drugs an insurance plan will cover. *See* Drug Pricing

Rep. at 31; *see also* Insulin Rep. at 34. Pharmaceutical manufacturers may offer rebates and other discounts to obtain favored (and sometimes exclusive) positions on these formularies. *See* Compl. ¶¶ 11–12, 205; Insulin Report at 8.

Here, Sanofi created a powerful combination with Lantus and Toujeo. *See* Compl. ¶ 3. After leveraging its patent thicket against Mylan to impose a 30-month automatic stay under the Hatch-Waxman Act, Sanofi began coercing patients and doctors to Toujeo by tying Lantus rebates (that PBMs were already receiving) with formulary placement of newly introduced Toujeo. *See id.* ¶¶ 11–14. According to the Drug Pricing Report, this meant that PBMs either listed Toujeo on the formulary or forewent *all* Lantus rebates. *See id.* ¶ 203. Sanofi coupled these strong-arm tactics with a marketing blitz, dedicating millions to market Toujeo. *See id.* ¶¶ 207–09. Sanofi's efforts were successful, and by the time of Mylan's Semglee launch, Toujeo held 22.32% of the insulin glargine market. *See id.* ¶ 18.

Once Mylan batted away all of Sanofi's 18 patents, clearing the way for Mylan's Semglee to compete, Sanofi created yet another obstacle, conditioning Toujeo rebates on maintaining Lantus on formulary at a preferred or exclusive position relative to Semglee. *See* Compl. ¶¶ 6, 204, 209. In so doing, Sanofi leveraged the demand it purposefully manufactured for Toujeo to tie Toujeo and Lantus rebates together and coerce PBMs to exclude Semglee from formularies. *See id.* ¶¶ 3, 210.

This multi-layered scheme prevented Mylan's Semglee product from obtaining any measurable sales until more than a year after it was finally able to enter the market. *See* Compl. ¶ 211. By splitting insulin glargine across two different products, one with established demand (Lantus) and one with patent protection (Toujeo), Sanofi transformed PBMs into a cudgel that substantially foreclosed Mylan. Because Mylan did not have a Toujeo generic, PBMs had no

choice but to place Lantus and Toujeo on preferred or exclusive formulary tiers in order to satisfy the demand Sanofi spent millions to manufacture. *See id.* ¶¶ 201–209. Moreover, tying the Toujeo and Lantus rebates in a dual product bundle made it impossible for Mylan, as a single-product competitor, to compete as a less expensive generic. *See id.* ¶ 13.

ARGUMENT

Throughout its brief, Sanofi mischaracterizes Mylan's claims. Mylan does not allege that Sanofi committed a discrete series of separate anticompetitive acts—improper listing of invalid patents in the Orange Book, sham patent litigation, introducing a product to avoid forthcoming generic entry, and dual product bundling—each with a compartmentalized effect on competition. Rather, Mylan alleges that Sanofi orchestrated a comprehensive plan to maintain a 20-year+ monopoly on injectable insulin glargine beyond its lawful lifespan, and accomplished this plan in phases through interconnected anticompetitive acts. *See* Drug Pricing Rep. at iv. These continuing violations of federal and state antitrust laws reinforced each other for almost a decade, and the scheme was only fully revealed when Congress stepped in to investigate why so many people were unable to afford this drug. *See* Drug Pricing Rep. at 114–15. Antitrust law is fact-bound and turns on "actual market realities," not "formalistic distinctions." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466–467 (1992). Mylan's Complaint provides the "actual market realities" created and perpetuated by Sanofi's illegal conduct. Sanofi's invitation to ignore Mylan's allegations in favor of Sanofi's version of formalistic distinctions is contrary to the law. *See id.*

"The court must take the complaint's [non-conclusory] factual allegations as true," *Martinez v. UPMC Susquehanna*, 986 F.3d 261, 265 (3d Cir. 2021), and must construe the complaint "in the light most favorable to the plaintiff," *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir. 2010). A complaint need only contain "enough facts to state a claim to

relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). But the plausibility standard does not amount to "a probability requirement." *Id*. at 556. Instead, it "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (internal quotations omitted). Thus, even in "antitrust and other complex cases," the plausibility standard carries no "extra bite." *Id*. Indeed, dismissals in antitrust cases "prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Premier Comp Sols. LLC v. UPMC*, 163 F. Supp. 3d 268, 275 (W.D. Pa. 2016).

Under the correct legal standard, the only question is whether Mylan's monopolization and related claims are plausible. They are. Sanofi's motion must thus be denied.

I. Mylan Has Alleged a Plausible Monopolization Claim.

A monopolization claim has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power." *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 147 (3d Cir. 2017). "But to be condemned as exclusionary, a monopolist's anticompetitive conduct must have an anticompetitive effect," which must be caused by the "monopolist's conduct taken as a whole rather than considering each aspect in isolation." *Id.* (quoting *LePage's Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003) (en banc)). Mylan's allegations viewed individually, and taken as a whole, plausibly allege monopolization.

A. Sanofi Willfully Acquired and Maintained Monopoly Power.

A monopolization claim "requires the willful acquisition or maintenance of monopoly power." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007). This willfulness requirement must involve anticompetitive conduct. *Id*. For example, blocking the opportunities of rivals without competing on the merits or in an "unnecessarily restrictive way" may be considered "anticompetitive" conduct. *Id.*

1. Mylan alleged an overall, anticompetitive scheme, not a series of discrete, unconnected, anticompetitive acts.

Sanofi's motion would have the Court believe that Mylan aimlessly alleged a series of discrete, anticompetitive acts bearing no relationship to one another. *See* D.I. 50 at 1. Not so. Mylan clearly alleged that Sanofi engaged in three broad, intertwined, anticompetitive acts collectively designed to extend its monopoly power and to block Mylan from entering the market: (1) the improper Orange Book listings and attendant sham patent litigation; (2) the introduction of Toujeo and manipulation of the market to avoid generic substitution; and (3) the tying of Toujeo rebates to Lantus's preferred formulary placement at the exclusion of Mylan's Semglee. *See* Compl. ¶¶ 3–23. Each of these acts was designed to reinforce the other and cause Mylan—and patients—anticompetitive injury. Mylan properly alleged this overall anticompetitive scheme. Sanofi might prefer to disaggregate individual components of that whole and attack each as alone insufficient (which they are not), but the law expressly prohibits this wholesale restructuring of Mylan's monopolization claim on a motion to dismiss.

Anticompetitive conduct occurs whenever companies attempt to exclude rivals "on some basis other than the merits." *W. Penn Allegheny Health Sys.*, 627 F.3d at 108 (quoting *LePage's*, 324 F.3d at 147). The means of exclusion can vary widely from case to case. *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 622 F. Supp. 3d 22, 59–60 (E.D. Pa. 2022) (hereinafter, "*Suboxone*") (noting anticompetitive conduct "can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties") (citations omitted). The challenged conduct must be scrutinized as a whole "without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962).

One type of monopolization conduct is a continuing, multifaceted anticompetitive scheme. When considering such a scheme, "[t]he relevant inquiry is the anticompetitive effect of [the defendant]'s exclusionary practices considered together." *LePage's*, 324 F.3d at 162. And "the Third Circuit has explicitly recognized that independently lawful conduct—*i.e.*, discount programs, rebates, exclusive dealing contracts—can have an anticompetitive effect that is actionable under antitrust law" when part of a broader course of anticompetitive conduct. *Suboxone*, 622 F. Supp. 3d at 61 (citing *LePage's*, 324 F.3d at 158–59); *see also, e.g.*, *Suboxone*, 967 F.3d 264, 270 (3d Cir. 2020); *Phila. Taxi Ass'n, Inc. v. Uber Techs., Inc.*, 886 F.3d 332, 339 (3d Cir. 2018); *Indivior Inc. v. Alvogen Pine Brook LLC*, 2023 WL 6936749, at *15 n.23 (D.N.J. July 10, 2023).[4]

Accordingly, the question is whether the conduct described in Mylan's Complaint, taken as a whole, plausibly alleges anticompetitive conduct. As outlined below, it does.

2. Mylan's claims based on listing invalid patents and sham litigation are not time-barred.

Sanofi argues that Mylan's claims based on listing invalid patents in the Orange Book and sham litigation are barred by the four-year statute of limitations. D.I. 50 at 21–22. But these events cannot be viewed in a vacuum. Indeed, a monopolization scheme is a "continuing violation," *Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 502 n.15 (1968), making the relevant consideration the "cumulative effect of individual acts." *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 115 (2002). Taken together, Sanofi's continuing anticompetitive

[4] Sanofi says the Supreme Court rejected this style of monopolization claim in *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009). Sanofi is wrong. Numerous courts have explained that *linkLine*'s holding is confined to "price squeezes" and did not reject overall scheme claims. *See, e.g.*, *FTC v. Qualcomm, Inc.*, 2017 WL 2774406, at *18 (N.D. Cal. June 26, 2017) ("*linkLine* did not address allegations of an 'overarching anticompetitive scheme'"); *accord In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009). And the Third Circuit has continued to recognize multifaceted monopolization schemes since *linkLine*. *See, e.g.*, *Suboxone*, 967 F.3d at 270; *Phila. Taxi Ass'n*, 886 F.3d at 339.

conduct harmed Mylan far beyond the statute of limitations in Mylan's causes of action.[5] *See Brenner v. Loc. 514, United Bhd. of Carpenters & Joiners of Am.*, 927 F.2d 1283, 1295 (3d Cir. 1991) (discussing continuing violation doctrine). The proper inquiry focuses on whether affirmative acts were taken as part of a pattern of wrongdoing. *See id.* at 1296. As discussed *supra* at 1–46, Sanofi's years-long practice constituted a series of affirmative acts that wrongfully precluded Mylan from entering the market.[6] *See Brenner*, 927 F.2d at 1295.

Sanofi's monopolistic conduct prevented Mylan from bringing Semglee to market for over five years, with harm continuing into the sixth and seventh years. *See* Compl. ¶¶ 15–16, 123, 209–11, 231. Each one of those years was an integral part of Sanofi's continued scheme to prevent competition and solidify its illegal market position.

Sanofi's Lantus lost patent exclusivity on February 13, 2015. Compl. ¶ 85. From that date forward, in a competitive system, Mylan should have been able to meaningfully compete with Lantus and Toujeo. But Mylan could not. With improper listings in the Orange Book and sham litigation (*see, e.g.*, *id.* ¶¶ 3–6, 140–90), and with dual rebate tying schemes and exclusive dealing (*see, e.g., id.* ¶¶ 8, 11, 14, 195–211), Sanofi successfully blocked Mylan's access to the market.

The timing of when Mylan ascertained the extent of its damages cannot be resolved on a motion to dismiss. *See Suboxone*, 2017 WL 4910673, at *18 (E.D. Pa. Oct. 30, 2017). To prevail on a statute of limitations defense, a plaintiff's untimeliness in initiating the action "must be apparent from the face of the complaint." *W. Penn Allegheny Health Sys.*, 627 F.3d at 105

[5] The Sherman, Clayton, and New Jersey Antitrust Act have a four-year limitations period, and Mylan's claim of tortious inducement of refusal to deal has a two-year limitations period. *See* 15 U.S.C. § 15b; N.J. Stat. § 56:9-14.

[6] Sanofi does not contest that Mylan's claims concerning Sanofi's product-hopping and bundling components of the overall scheme are within the statute of limitations. *Cf.* D.I. 50 at 21–22. As a result, Sanofi has forfeited any arguments to the contrary. *See Laborers' Int'l Union v. Foster Wheeler Corp.*, 26 F.3d 375,398 (3d Cir. 1994).

n.13. Here, it is not. The Complaint makes clear that Mylan did not have full visibility into Sanofi's monopolization scheme until at least 2021, when the Senate Finance Committee's Insulin Report and the Committee on Oversight and Reform's Drug Pricing Report were released. *See* Compl. ¶¶ 8, 11, 203. These reports revealed facts that Mylan did not know and could not have known. These include Sanofi's internal plans to strategically move the market to Toujeo ahead of Mylan's Semglee launch while Mylan was delayed and battling its way through Sanofi's serial petitions, and rebate-tying contracts to exclude Mylan's generic from formularies. *See id.* ¶¶ 203–04. Indeed, "it is hornbook law, in antitrust actions as in others, that even if injury and a cause of action have accrued as of a certain date, future damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative ***or their amount and nature unprovable***." *Meijer, Inc. v. 3M*, 2005 WL 1660188, at *5 (E.D. Pa. July 13, 2005) (citation omitted) (emphasis added). Whether the amount and full nature of Mylan's harm was knowable before 2021 cannot be resolved at this stage. *See Suboxone*, 2017 WL 4910673, at *18. Further, Sanofi's fraudulent concealment of its monopolistic scheme—and Mylan's inability to discover Sanofi's scheme until the 2021 Reports—tolled the statute of limitations. *See In re Elec. Carbon Prods. Antitrust Litig.*, 333 F. Supp. 2d 303, 315–17 (D.N.J. 2004); *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 160, 163 (3d Cir. 2002); *Bethlehem Steel Corp. v. Fischbach & Moore, Inc.*, 641 F. Supp. 271, 272, 275 (E.D. Pa. 1986).

3. Sanofi's sham patent litigation is not immune from antitrust scrutiny.

Sanofi invokes *Noerr-Pennington* immunity and asserts that the sham litigation exception to that doctrine does not apply because Mylan's Complaint does not allege how Sanofi's patent litigation against Mylan was objectively baseless. *See* D.I. 50 at 22–23. But that is not the test. Sanofi ignores the fact—set forth repeatedly in Mylan's Complaint (¶¶ 141, 142, 192)—that this case concerns a pattern of *serial* petitioning. Because of this misconstruction, Sanofi's motion

dwells on the wrong prong. It focuses on arguing—incorrectly—why its patent cases against Mylan were not objectively baseless and entirely fails to address the subjective prong.

Ordinarily, a lawsuit loses its *Noerr-Pennington* immunity if it is both objectively baseless and subjectively motivated by anticompetitive intent. *Pro. Real Estate Invs, Inc. v. Columbia Pictures Indus, Inc.*, 508 U.S. 49, 60–61 (1993) ("*PRE*"); *see also Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179 (3d Cir. 2015). But *serial* petitions are evaluated under the more lenient test from *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972).

Under this test, a conclusion that one or more of a defendant's petitions were meritorious does not automatically preclude a finding that the sham exception applies, and the defendant's subjective motivation must be considered. *See Hanover 3201 Realty*, 806 F.3d at 180. The rationale for this rule is that filing multiple petitions increases the chances that one or more of them will be successful, and therefore not objectively baseless. *Id.* (citing *USS–POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL–CIO*, 31 F.3d 800, 811 (9th Cir. 1994) ("[E]ven a broken clock is right twice a day.")). As a result, when a plaintiff alleges a series of legal proceedings, the defendant cannot defeat a sham petition allegation if some of the petitions turn out to have some objective merit; rather, the proper inquiry asks "whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Hanover 3201 Realty*, 806 F.3d at 180. "In deciding whether there was such a policy of filing petitions with or without regard to merit, a court should perform a holistic review that may include looking at the defendant's filing success—i.e., win-loss percentage—as circumstantial evidence of the defendant's subjective motivations." *Id.*

In *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996), the Federal Circuit recognized that "[e]ach patent asserted raises an independent and distinct cause of action." Sanofi asserted *18* such causes of action against Mylan. *See* Compl. ¶ 145. Sanofi lost again and again (or chose to drop some patents only after receiving the benefit of the attendant 30-month stay). Sanofi could not prove infringement as to a single valid patent. *See id.* ¶¶ 146–90. And of the challenges to over 50 claims in Sanofi's asserted patents brought through *inter partes* reviews, *only two* claims survived (neither of which could have excluded Mylan's product because it did not infringe, as evidenced by Sanofi granting a covenant not to sue), leaving Sanofi with an invalidity success rate of 4%. *Id.* at ¶ 143.

The serial petitioning rule applies here. Although Sanofi initiated only one lawsuit against Mylan, that suit included 18 claims of patent infringement. Compl. ¶ 145. The rationale for applying *California Motors* is the insight that more at-bats mean more chances of "hitting a single in the second inning." *Hanover 3201 Realty*, 806 F.3d at 182. It does not matter whether those additional at-bats occur simultaneously in one voluminous lawsuit or sequentially in multiple lawsuits.[7] Requiring a literal series of lawsuits places form over substance.[8] And, in any event, Sanofi continued to advance its validity arguments in separate *inter partes* review proceedings before the Federal Circuit for several patents. *See, e.g.*, Compl. ¶¶ 5, 143.

Finally, "district courts within this Circuit have routinely prohibited parties from

[7] Indeed, in *California Motor*, the Court stated that it was "a pattern of baseless, repetitive claims," not lawsuits, that could "lead[] the factfinder to conclude that the administrative and judicial processes have been abused." 404 U.S. at 513. *See also Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 414 (3d Cir. 2016) (assuming that "a single claim, separated from an otherwise arguably meritorious suit," could be "so harmful and costly to a defendant that it might impose anticompetitive harm on the defendant in a way that triggers the sham litigation exception to *Noerr–Pennington*.").

[8] *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132 (3d Cir. 2017) is not to the contrary. While the Third Circuit held there that two lawsuits did not amount to a series of petitions, *id.* at 157, both lawsuits at issue asserted only two patent infringement claims apiece. Complaint, *Meijer, Inc. v. Biovail Corp.*, No. 2:08-cv-2431 (E.D. Pa. May 23, 2008), ECF No. 1, at 21–22. That is far fewer than the 18 patents Sanofi asserted here.

invoking the protections of *Noerr-Pennington* at the dismissal stage of a case." *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 394–95 (D.N.J. 2018) (collecting cases). While a court *may* apply *Noerr-Pennington* on a motion to dismiss, "the issue is a fact-intensive one, generally not suitable for resolution at the pleading stage." *Indivior v. Dr. Reddy's Lab'ys S.A.*, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020).[9] Instead, whether litigation is a sham "is generally a question of fact for the jury" unsuitable for resolution on a motion to dismiss. *Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co.*, 760 F.2d 607, 612 n.9 (5th Cir. 1985). That is particularly true here where the issue turns on Sanofi's subjective intent, because "[m]otive is a question of fact that must be decided by the jury, which has the opportunity to hear the explanations of both parties in the courtroom and observe their demeanor." *Monteiro v. City of Elizabeth*, 436 F.3d 397, 405 (3d Cir. 2006).

4. Sanofi's exclusionary formulary practices excluded Mylan's generic product from the market once finally approved.

When addressing a claim that "a rival's sales program violates the antitrust laws, [the court] must consider whether the conduct constitutes an exclusive dealing arrangement or simply a pricing practice." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 408 (3d Cir. 2016). Sanofi's attack on Mylan's exclusive dealing allegations elides this threshold distinction, leading it to assert defenses relevant to pricing practices but irrelevant here (among other errors). In particular, Sanofi overlooks how exclusive dealing arrangements may be "effectuat[ed]" by "bundled rebates." *LePage's Inc. v. 3M*, 324 F.3d at 154 (3d Cir. 2003) (en banc); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 282 (3d Cir. 2012) (recognizing that "bundled rebates [can]

[9] *See also S3 Graphics Co. v. ATI Techs. ULC*, 2014 WL 573358, at *3 (D. Del. Feb. 11, 2014) (resolution of *Noerr-Pennington* immunity "not proper before discovery"); *In re JUUL Labs, Inc. Mktg, Sales Pracs. & Prods. Liab. Litig.*, 2022 WL 1601418, at *19 (N.D. Cal. Apr. 29, 2022) (*Noerr-Pennington* issue "is better determined after the evidence comes in at trial and on post-trial motions").

operate as exclusive dealing arrangements, despite the lack of express exclusivity requirements").[10]

a. Sanofi's rebating practices function as an illegal tie.

One way to "break the competitive mechanism," *ZF Meritor*, 696 F.3d at 285, is by tying different products together for the purpose of bundling rebates across products, foreclosing the market to a competitor who does not "manufacture an equally diverse group of products and who therefore cannot make a comparable offer," *LePage's*, 324 F.3d at 155.[11] Bundling rebates is anticompetitive because it induces "buyers to take increasing amounts or even all of a product in order to take advantage of a discount aggregated across multiple products." *Id.* (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 794, at 83 (Supp. 2002)).[12] By packaging discounts, "the defendant rewards the customer for buying its product B rather than the plaintiff's B, not because defendant's B is better or even cheaper," *id.*, making rebate bundles a form of competition on "some basis other

[10] Sanofi criticizes Mylan for not "alleging the existence of a specific exclusivity agreement." D.I. 50 at 8. But Mylan does not need to plead an express exclusivity clause in Sanofi's PBM contracts, because Mylan does not have to prove such a clause exists. Express exclusivity requirements are not necessary because courts "look past the terms of the contract to ascertain the relationship between the parties and the effect of the agreement 'in the real world.'" *ZF Meritor*, 696 F.3d at 270. Thus, *de facto* exclusive arrangements may be challenged under the antitrust laws. *See Eisai*, 821 F.3d at 403. Here, Sanofi's internal documents, incorporated into the Complaint, demonstrate that, in the real world, tying Lantus and Toujeo together gave Sanofi preferred access and allowed Sanofi to maintain Lantus as the "preferred 1st generation basal insulin." Compl. ¶ 10.

[11] "Bundling is the practice of offering, for a single price, two or more goods or services that could be sold separately." *Eisai*, 821 F.3d at 405 n.32 (quoting *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008)).

[12] The Courts of Appeals disagree as to what makes bundling anticompetitive. Some Circuits consider bundling a form of pricing and will only hold it unlawful if it is predatory, *i.e.*, when the combined discounts applied to a single product in the bundle would render that product priced below cost. *See, e.g.*, *Cascade Health*, 515 F.3d at 902 (applying price-cost test from *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993)). The Third Circuit differs. It analogizes bundling of discounts to the unlawful practice of tying, the practice whereby a party offers "to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier." *Eisai*, 821 F.3d at 405 & n.34 (quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. at 461–62 (1992)). Importantly, the exclusionary nature of tying does not involve below-cost pricing. *ZF Meritor*, 696 F.3d at 278–79. The Third Circuit's bundling test is regarded as less strict and more easily satisfied by plaintiffs. *See Regeneron Pharms., Inc. v. Amgen Inc.*, 2023 WL 1927544, at *6 (D. Del. Feb. 10, 2023), *R&R adopted*, 2023 WL 2587809 (D. Del. Mar. 21, 2023).

than the merits," *LePage's*, 324 F.3d at 147. When "the customer buys the defendant's B in order to receive a greater discount on A, which the plaintiff does not produce," bundling becomes coercive because it punishes disloyal customers. *Id.* Sanofi threatened to punish customers for choosing Semglee over Lantus with not only the loss of a rebate on Lantus but on Toujeo too. Compl. ¶¶ 204, 247.

Sanofi's Lantus-Toujeo bundle was coercive. Despite entering the market at a significantly lower price, Mylan could not make any headway until 2021. There are numerous strategies Sanofi could have deployed to coerce customers into excluding a less expensive product from the formulary—strategies discovery will no doubt reveal. But, at this early stage, Mylan plausibly alleges that its less expensive product could not enter the market because of Sanofi's coercive practices, and that is sufficient to survive a motion to dismiss. *See Castro v. Sanofi Pasteur Inc.*, 2012 WL 12516572, at *9–10 (D.N.J. Aug. 6, 2012) (another challenge to Sanofi's bundled rebates); *3Shape Trios A/S v. Align Tech., Inc.*, 2020 WL 2559777, at *8 (D. Del. May 20, 2020), *R&R adopted*, 2020 WL 6938054 (D. Del. Nov. 25, 2020).

Sanofi insists that its formulary practices can only be found anticompetitive if they fail the price-cost test. *See* D.I. 50 at 6–7. But the price-cost test only applies where a defendant's pricing "is the clearly predominant mechanism of exclusion." *ZF Meritor*, 696 F.3d at 269. Mylan alleges that an exclusivity condition in a contract—not a price—excludes its product, and that Sanofi used bundled rebates, in essence a tie—not a price—to strong-arm customers into accepting that exclusivity term. Thus, the price-cost test is "inapposite," and the rule of reason applies instead. *Suboxone*, 622 F. Supp. 3d at 65–66.[13] "Nothing in the case law suggests, nor

[13] *See also, e.g.*, *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 736–37 (E.D. Pa. 2015) (price-cost test does not apply to exclusive dealing claim where plaintiff never alleged that price was the means of exclusion); *In re Surescripts Antitrust Litig.*, 608 F. Supp. 3d 629, 642 (N.D. Ill. 2022) (Because Plaintiffs

(*continued on the next page*)

would it be sound policy to hold, that above-cost prices render an otherwise unlawful exclusive dealing agreement lawful." *ZF Meritor*, 696 F.3d at 278.

Sanofi's rebate payments do not change that result. The presence of payments is not a talisman that converts any case into a predatory-pricing suit. Payments in the form of bundled discounts may be used by "a dominant supplier" to secure "*de facto* exclusive dealing arrangements." *ZF Meritor*, 696 F.3d at 281. When that is so, the harm is caused "not by the price [but] rather by the condition limiting rivals' sales." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 768b4 (2023) (hereinafter "Areeda & Hovenkamp"). "In these [cases], simply querying whether the fully discounted price is above cost often misses important elements of exclusion." *Id.* And thus, when a brand's practices are challenged on bundling and exclusive-dealing grounds, they may be held illegal "irrespective of below-cost pricing." *ZF Meritor*, 696 F.3d at 281.

Sanofi posits, wrongly, that *Mylan* alleges that Lantus and Toujeo are the same product. *See* D.I. 50 at 5–6. Sanofi then attacks that straw man by arguing that tying Lantus and Toujeo together is therefore not anticompetitive. *See id.* Mylan alleges that Lantus and Toujeo are therapeutically indistinguishable. *See* Compl. ¶¶ 8, 195–97. That is a far cry from alleging that Lantus and Toujeo are the same *products*. They are certainly different products where it counts for purposes of competition—namely, at the pharmacy counter. *See id.* ¶ 81. A prescription for Lantus cannot be filled with Toujeo, nor vice versa, as the drugs contain different levels of insulin glargine. *See id.* ¶ 195.

Moreover, through its own conduct, Sanofi made clear that Lantus and Toujeo should be treated by PBMs as two separate products. Were these not separate products, Sanofi's decision

"[n]owhere . . . allege that [Defendants'] prices are now, or ever were, too low," the "predatory pricing rubric is . . . inappropriate here.").

to sell them under two separate brand names would make no sense, particularly given the expense and effort required for creating and promoting a new brand name. *See* Compl. ¶ 207. The "commercial realities" of the pharmaceutical industry only reinforce that Lantus and Toujeo are different products. *Eastman*, 504 U.S. at 482 (1992); *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 337 (3d Cir. 2018).

Sanofi also argues that its use of bundled rebates to secure exclusive positions on state Medicaid formularies are immune from antitrust scrutiny from *Noerr-Pennington*. *See* D.I. 50 at 7. But *Noerr* deals with petitions to the government to make a choice, not efforts to coerce the government. *See* Areeda & Hovenkamp ¶ 209a; *see also Sacramento Coca-Cola Bottling Co. v. Chauffeurs, Teamsters & Helpers Local No. 150*, 440 F.2d 1096, 1099 (9th Cir. 1971) (*Noerr* immunity does not apply to "coercive measures"). Sanofi's bundled rebates constrained the free exercise of choice by private and government payers alike. And there is no *Noerr* immunity where the government is "forced to purchase the defendant's bundle." Areeda & Hovenkamp ¶ 209b; *see also Suboxone*, 622 F. Supp. 3d at 76–77 (concluding *Noerr* did not apply to anticompetitive scheme involving Medicaid).[14]

Sanofi's argument that Mylan can offer a competing bundle based on its diverse catalogue of drugs is both wrong and perverse from a competitive standpoint. *See* D.I. 50 at 7–8. First, when Mylan launched, it offered a single insulin glargine product: Semglee. *See* Compl. ¶ 139. It is nonsensical to interpret *ZF Meritor*'s statement that "*LePage*'*s* is limited to cases in

[14] *EpiPen* is not to the contrary. There, the court held *Noerr* immunized Mylan's efforts to secure favorable positions on state Medicaid formularies. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 2017 WL 6524839, at *10–11 (D. Kan. Dec. 21, 2017). The difference is *EpiPen* concerned the use of a "single-product loyalty discount or rebate," *In re EpiPen*, 44. F.4th 959, 983 n.7 (10th Cir. 2022), which the Third Circuit considers a pricing practice subject to the price-cost test, *id.* (quoting *Eisai*, 821 F.3d at 409 (3d Cir. 2016)), and not a coercive tying arrangement like *bundled* rebates, *see Eisai*, 821 F.3d at 405. In the absence of coercion, Mylan's offers to state Medicaid agencies in *EpiPen* "amount[ed] to nothing more than lobbying of government officials"—the very conduct *Noerr* shields. *In re EpiPen*, 2017 WL 6524839, at *11 (quotation omitted).

which a single-product producer is excluded through a bundled rebate program" (696 F.3d at 274 n.11) to refer to competitors that *literally* offer only a single product.[15] As *ZF Meritor* explained, the reason LePage's could not compete with 3M was not because it only sold one product, but because "it did not sell *the same* diverse array of products as 3M." *Id.* (emphasis added); *see also Eisai*, 821 F.3d at 404. Second, Sanofi's proposed solution is a race to the bottom that would require Mylan, and others, to also engage in coercive contracting practices. But the solution to anticompetitive behavior is not more anticompetitive behavior. *See United States v. Apple Inc.*, 952 F. Supp. 2d 638, 708 (S.D.N.Y. 2013) ("Another company's alleged violation of antitrust laws is not an excuse for engaging in your own violations of law."), *aff'd*, 791 F.3d 290 (2d Cir. 2015).

At bottom, Mylan alleges that Sanofi created demand for Toujeo, released a therapeutically indistinguishable but nonetheless *different* product not facing generic competition to satisfy that demand, and then tied rebates between both Lantus and Toujeo to preserve its monopoly over the injectable insulin glargine market. *See* Compl. ¶¶ 195–211. Put differently, Sanofi found a way to manufacture a new market for the same drug and compete with Mylan on terms other than the merits, raising prices for patients and harming competition. That this anticompetitive conduct collectively includes components of bundling, tying, and product-hopping is no basis for dismissal. *See Suboxone*, 622 F. Supp. 3d at 59–60.

[15] To begin, *LePage's* itself sold more than one product. *See* Second Am. Compl. ¶ 1, *LePage's Inc. v. 3M*, No. 97-cv-3983 (E.D. Pa. Sept. 2, 1998), D.I. 93, at 2 ("LePage's manufactures home and office products, with its principal product being invisible and transparent home and office tape. In 1995, more than 80% of LePage's total sales consisted of tape sales."). So to interpret *ZF Meritor* to limit *LePage's* to instances where the plaintiff sells only a single product would be to effectively overrule *LePage's*, which the *ZF Meritor* panel could not do. *See In re Aleckna*, 13 F.4th 337, 344 n.38 (3d Cir. 2021) (precedential panel decisions are binding on future panels and can only be overturned by en banc court). For its part, the FTC agrees that the proper analysis compares the defendant's bundle and the plaintiff's competing products, not the plaintiff's entire portfolio. *See* Amicus Br. on Behalf of the FTC at 13, *Applied Med. Resources Corp. v. Medtronic, Inc.*, No. 8:23-cv-268 (C.D. Cal. July 3, 2023), D.I. 27–1 at 19 ("[Bundling] is most concerning when a dominant firm sells a full bundle, while a smaller firm sells only some *products* in that bundle.") (emphasis added).

b. Sanofi's product hop is not dependent on a "hard switch."

Finally, Sanofi argues that Mylan's monopolization claims must fail because it did not allege a "hard switch" from Lantus to Toujeo. D.I. 50 at 9 (citing cases where the alleged monopolist removed the earlier product from the market). But a hard switch is not necessary for a product hop to be anticompetitive. What is required is some form of coercion that constrains the free choice of consumers, and "withdrawal of an old product is not the only means of coercion." *In re HIV Antitrust Litig.*, 2023 WL 3088218, at *8 (N.D. Cal. Feb. 17, 2023); *see also In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 330 (D.R.I. 2019) ("This argument [that no hard switch may occur where the prior product is not withdrawn] is easily snuffed out by the law.").[16] Here, Sanofi coerced purchasers through the bundling of rebates. The cases Sanofi cites are distinguishable because they did not involve similarly coercive practices.

B. Sanofi Has Monopoly Power in The Relevant Market.

Mylan alleges that at all relevant times, Sanofi had monopoly power in the market for injectable insulin glargine. *See* Compl. ¶ 212. Monopoly power is the ability to control prices and exclude competition in a given market. *Broadcom*, 501 F.3d at 307. "If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power." *Id.* Thus, where evidence indicates that a firm has profitably cut back the market's total output and raised price, the existence of monopoly power is clear. *United States v. Microsoft Corp*., 253 F.3d 34, 51 (D.C. Cir. 2001). Courts use two methods to

[16] Even the cases Sanofi cites confirm that coercion is the watchword. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) ("Well-established case law makes clear that product redesign is anticompetitive when it *coerces* consumers and impedes competition.") (emphasis added); *id.* at 652 n.23 (collecting cases); *Mylan Pharms. Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421, 440 (3d Cir. 2016) (concluding that the product-hop claim asserted in that case was not viable but recognizing "the possibility that certain insignificant design or formula changes, *combined with other coercive conduct*, could present a closer call with respect to establishing liability in future cases.") (emphasis added).

assess monopoly power: (1) direct evidence of power to control prices and exclude competition, or (2) indirect evidence such as the defendant's share in the relevant market and the existence of barriers to entry. *Broadcom*, 501 F.3d at 307. Although these are alternative tests, Mylan has sufficiently alleged market power in *both* ways.

1. Mylan sufficiently alleged direct evidence of Sanofi's monopoly power.

To demonstrate direct evidence of Sanofi's monopoly power, Mylan may demonstrate that Sanofi profitably raised prices without causing competing firms to expand output and drive down prices. *See Broadcom*, 501 F.3d at 307. Sanofi's Lantus profits skyrocketed, and Sanofi sold Lantus at prices well in excess of marginal costs. *See* Compl. ¶ 216. From 2004–2019, Lantus generated $43.9 billion in U.S. net revenue. Drug Pricing Report at 28. During this time, Sanofi profitably raised prices (Compl. ¶ 19), and the market did not respond to such supracompetitive prices with increased output. In fact, Sanofi did not face any meaningful pricing constraints on Lantus or Toujeo.

The presence of Eli Lilly's Basaglar does not diminish Sanofi's monopoly power as alleged in Mylan's Complaint. *See* Compl. ¶¶ 212–222. Eli Lilly launched Basaglar in 2016 (D.I. 50 at 10), but Sanofi's insulin glargine prices continued to increase above competitive levels after this launch. *See* Compl. ¶ 19. And, in fact, Eli Lilly agreed to pay Sanofi royalties as part of the patent litigation settlement pertaining to Basaglar—Sanofi granted Eli Lilly a royalty-bearing license to sell Basaglar beginning in December 2016. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 6 (1st Cir. 2020). Basaglar also never obtained a significant market share as compared to Sanofi's insulin glargine products. Insulin Report Documents at 32;[17] Eli Lilly Documents Produced with Insulin Report at 155; *see also Presque Isle Colon & Rectal*

[17] These documents are incorporated by reference in Mylan's Complaint. *See* Compl. ¶ 11, n.6.

Surgery v. Highmark Health, 391 F. Supp. 3d 485, 502 (W.D. Pa. 2019) (explaining that 65% market share was sufficient to plead monopoly power).

Sanofi also restricted market output by delaying FDA approval of Mylan's Semglee and minimizing market uptake once Semglee received FDA approval. *See* Compl. ¶¶ 4–17. Sanofi's ability to restrict the total market output by excluding Mylan's lower cost product is indicative of Sanofi's monopoly power. *Broadcom*, 501 F.3d at 307. Mylan did not secure any measurable sales until more than one year from market entry. *See* Compl ¶ 211. Such a stark deviation from a properly functioning generic market is a clear indication of Sanofi's monopoly power and demonstrates that Sanofi "broke the competitive mechanism." *Indivior Inc. v. Alvogen Pine Brook LLC*, 2023 WL 6936749, at *18 (D.N.J. July 10, 2023). That Sanofi was able to restrict generic market output while raising prices to supracompetitive levels is evidence of a textbook monopoly. *See* Compl. ¶ 19.

2. Mylan also alleged indirect evidence of monopoly power in the relevant market.

Monopoly power "may also be inferred from the structure and composition of the relevant market." *Broadcom*, 501 F.3d at 307. To support an inference of monopoly power, a plaintiff may plead that a firm has a dominant share in a relevant market, and that there were barriers to entry in the market. *FTC v. AbbVie Inc.*, 976 F.3d 327, 371 (3d Cir. 2020). "Barriers to entry are factors, such as regulatory requirements, high capital costs, or technological obstacles, that prevent new competition from entering a market in response to a monopolist's supracompetitive prices." *Broadcom*, 501 F.3d at 307.

Because Mylan alleged direct evidence of market power, it need not identify indirect evidence of monopoly power nor identify a relevant market. *See Broadcom*, 501 F.3d at 307 n.3. But, in any event, Mylan also sufficiently alleged indirect evidence of Sanofi's monopoly power.

a. Mylan identified the relevant market: injectable insulin glargine products.

The determination of a relevant product market is "highly factual" and best left to the trier of fact. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992). Despite this well-settled precedent, Sanofi asks this Court to decide this highly factual issue on a motion to dismiss. Mylan alleges that the relevant market is injectable insulin glargine products, including Lantus, Toujeo, and Semglee. *See* Compl. ¶¶ 212–22.[18] Sanofi incorrectly argues that the relevant market is all basal insulin products. *See* D.I. 50 at 12. This is a factual dispute and, on a motion to dismiss, *Mylan's* allegations prevail. *See Fineman*, 980 F.2d at 199.[19] But even if the Court accepts Sanofi's invitation to weigh the facts—and it should not—Sanofi's arguments still fall short.

Sanofi leveraged its market share in the insulin glargine market from both Lantus and Toujeo to delay Semglee's FDA approval and diminish uptake once approved. *See* Compl. ¶¶ 4–17. Failure to consider these products as one market ignores the "commercial realities" of the market Sanofi created, that Mylan encountered upon entry, and that consumers faced. *Eastman*,

[18] *See also, e.g.*, *id.* ¶ 7 ("Any other Orange Book listing was improper and done with the specific intent to monopolize the market for injectable insulin glargine and prevent competition in violation of the Sherman Act and state laws."); *id.* ¶ 14 ("Sanofi did this not for any patient benefit or medical necessity, but to ensure that it prolonged its market power in the injectable insulin glargine market."); *id.* ¶ 17 ("Sanofi continues to offer steep rebates to payers only if they include all Sanofi injectable insulin glargine products on preferred tiers."); *id.* ¶ 21 ("Sanofi's monopolization of the injectable insulin glargine market and other related conduct has resulted in Sanofi facing lawsuits throughout the country alleging a variety of competition and unfair business practices violations in litigation brought by purchasers, payers, and at least six states and three counties."); *id.* ¶ 91 ("Over the years, the Orange Book identified Lantus as a single product made in two formulations: 'injectable' (i.e., the 'vial formulation,' which was initially sold 5 mL and 10 mL amounts), and 'injection' with an OptiClick injector pen (i.e., the 'cartridge formulation')."); *id.* ¶ 199 ("Sanofi recognized pushing the market to Toujeo as the only viable way to maintain its market power over injectable insulin glargine"); *id.* ¶ 209 ("In fiscal year 2020 Toujeo accounted for approximately 22% of Sanofi's injectable insulin glargine sales in the United States (measured by revenues, Sanofi does not report doses); this was easily enough to create a critical mass to force payers to remain loyal.").

[19] *See also, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 326 (D.R.I. 2017) (relevant market is a "fact-intensive" issue "to be decided on a motion for summary judgment (if no genuine issue of material fact exists) or at trial"); *Indivior*, 2023 WL 6936749, at *15 n.25 ("[T]he determination of a relevant product market or submarket . . . is a highly factual one best allocated to the trier of fact.") (citations omitted).

504 U.S. at 482. In fact, it is common for courts considering the monopolization of pharmaceutical markets, with their unique regulatory attributes, to define the product market in this manner. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 646–47 (2d Cir. 2015) (defining the market as the original brand product facing generic competition, the newly introduced brand product, and the generic foreclosed from the market).

"Competing products are in the same market if they are readily substitutable for one another; a market's outer boundaries are determined by the reasonable interchangeability of use between a product and its substitute, or by their cross-elasticity of demand." *Broadcom*, 501 F.3d at 307. Cross-elasticity measures "the extent to which consumers will change their consumption of one product in response to a price change in another," all else being equal. *Eastman*, 504 U.S. at 469 n.15. Two products that may appear to "compete" with each other to some degree, may not be part of the same antitrust market because they do not provide a price constraint. *See 3Shape Trios*, 2020 WL 2559777, at *10 (D. Del. May 20, 2020) (concluding that the complaint sufficiently alleged that dental aligners and metal braces were not in the same market), *R&R adopted*, 2020 WL 6938054 (D. Del. Nov. 25, 2020).

First, Sanofi argues that Mylan's market definition fails because it does not include additional insulin products, such as Levemir (insulin detemir), Tresiba (insulin degludec), Humalog Mix (insulin lispro), and Novolog Mix (insulin aspart). *See* D.I. 50 at 12–13. But these products have different active ingredients than Lantus, Toujeo, and Semglee (all insulin glargine). Sanofi is purposefully conflating therapeutic classes with relevant markets to hide its monopoly power despite clear market evidence that these products are not in the relevant market. These products did nothing to curb Sanofi's supracompetitive prices and provided no pricing constraint on Sanofi's Lantus or Toujeo. *See* Compl. ¶ 19; *Eastman*, 504 U.S. at 469–71. And

these products did not exhibit significant, positive cross-elasticity of demand with respect to Sanofi's insulin glargine products. *See* Compl. ¶ 219.

In short, not all basal insulin products belong in the relevant market, because not all basal insulin products have the same active ingredients, and PBMs do not include all of them on their formularies. *See* Insulin Rep. at 29. If a PBM chooses insulin glargine, that means it will likely choose to place Lantus on formulary, and accordingly Toujeo, given that the rebates for each product are tied, but *not* other basal insulins offered by ostensible competitors. *See* Compl. ¶ 203. Sanofi might disagree. *See* D.I. 50 at 12–13. But this dispute is not for this Court to decide on a motion to dismiss. *See Fineman*, 980 F.2d at 199.

Second, Sanofi claims that Mylan says nothing about Sanofi's dominance in the injectable insulin glargine market. *See* D.I. 50 at 14–15. But that is not true. Sanofi maintains a huge share of the *entire* basal insulin market and proclaims so in its documents. *See* Compl. ¶¶ 10, 18. In fact, Mylan's Complaint includes excerpts of Sanofi's internal documents produced to Congress that confirm Sanofi has the dominant share of the market for *all basal insulin*. *See id.* ¶ 10 ("Lantus is the **preferred** 1st **generation basal insulin**. We have succeeded at leveraging the size of Lantus to unlock preferred access for Toujeo."); *see also* Insulin Report Documents at 220. Thus, Mylan's indirect monopoly power allegations stand even if Sanofi's market definition were accepted over the one alleged in Mylan's Complaint.

b. Mylan also alleged barriers to entry protecting Sanofi's dominant share in the relevant market.

Sanofi next argues that Mylan's allegations about barriers to entry are conclusory. *See* D.I. 50 at 15 (citing Compl. ¶ 218). Not so. Mylan offered detailed allegations *throughout the Complaint* about the lengthy approval process to bring a pharmaceutical product to market. *See e.g.*, Compl. ¶¶ 43–44, 51–56, 68–79 (detailing regulatory hurdles for generic drug applications);

id. ¶ 76 (explaining that pursuing FDA approval through a paragraph IV certification results in a 30-month stay or less if the related patent litigation is resolved sooner); *see also, e.g.*, *id.* ¶ 128 (Mylan waiting for regulatory guidance from FDA regarding application process); *id.* ¶ 140–190 (Mylan's protracted legal battle with Sanofi regarding its 18 Orange Book listed patents). And FDA approval is not the end of the road for would-be generic competitors. In order to get to market, such competitors would require sufficient manufacturing facilities and ultimately will need to contract with PBMs to ensure formulary placement. *See id.*¶ 11, 15. Moreover, would-be generic competitors may also need to market the product to compete with Sanofi's marketing blitz regarding Toujeo. *See id.* ¶¶ 207. All these barriers to entry, which the Complaint adequately alleges, support Mylan's indirect evidence of monopoly power. *See AbbVie*, 976 F.3d at 372–73 (upholding the district court's finding of barriers to entry because a "generic drug has significant capital, technical, regulatory, and legal barriers to overcome."); *see also Sandoz, Inc. v. United Therapeutics, Corp.*, 2020 WL 697137, at *12 (D.N.J. Jan. 29, 2020) (same).

C. Sanofi's Anticompetitive Conduct Caused Antitrust Injury.

1. Sanofi's unlawful patent listings delayed Mylan's entry into the market.

Sanofi attempts to impose an artificially high causation requirement on Mylan, demanding that Mylan explain how Sanofi's improper Orange Book listings directly delayed Mylan's approval. *See* D.I. 50 at 16–21. But that is not the law. Antitrust causation only requires Mylan to show that Sanofi's antitrust violation was *a* material cause of Mylan's injury. *Suboxone*, 622 F. Supp. 3d at 78; *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 14 (1st Cir. 2020). "[D]ispositive weight should not be given to lists of possible alternative causes, which virtually any defendant can generate." Areeda & Hovenkamp ¶ 338a. "It is . . . enough that the antitrust violation contributes significantly to the plaintiff's injury, even if other factors amounted in the aggregate to a more substantial cause." *In re Lantus*, 950 F.3d at 14 (quoting

Areeda & Hovenkamp ¶ 338a); *Suboxone*, 622 F. Supp. 3d at 79; *Zenith Radio Corp. v. Hazeltine Rsch, Inc.*, 395 U.S. 100, 114 n.9 (1969). Antitrust suits are rarely dismissed on causation grounds.[20]

Despite these legal standards, Sanofi attempts to weave a causation story by inviting the court to take judicial notice of various "facts." *See* D.I. 50 at 16–21. And it relies on *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 151–52 (3d Cir. 2017), an appeal from a *summary judgment* ruling, to support the argument that the Court can credit its version of events. *See* D.I. 50 at 17. This misreads *Wellbutrin*, which concluded that there was no genuine dispute of material fact that the 30-month stay would have continued to apply even if the defendant had not participated in the patent litigation. *See Wellbutrin*, 868 F.3d at 152–53. Here, there is no such agreement between the parties as to the impact of Sanofi's improper Orange Book listings and sham litigation, and there *are* factual disputes as to whether Mylan could have launched in the absence of those roadblocks. *See* Compl. ¶¶ 123–27.

Sanofi argues that, irrespective of its improper Orange Book listings, Mylan would not have applied for Semglee approval before 2017 because: (1) Mylan's desire to pursue a less expensive path for approval placed it in a regulatory dead zone, D.I. 50 at 17–18; and (2) Mylan's Semglee allegedly had issues, including a need for additional data, *id.* at 19–20. Sanofi also argues that the 30-month stay resulting from Sanofi's Orange Book patents did not impede Semglee's approval because FDA never granted tentative approval for Semglee during

[20] Notably, an antitrust plaintiff need not allege material causation separately for each component of the alleged scheme; rather, the injuries inflicted by the defendant's allegedly anticompetitive activities should, instead, be viewed as a whole. *See Suboxone*, 622 F. Supp. 3d at 78. Further, whether conduct constitutes intervening conduct that breaks the chain of causation in an antitrust action and whether intervening conduct is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury. *Id.* So long as "the plaintiff's claim of causation is plausible, it should not be dismissed summarily merely because alternative causation stories are plausible as well." Areeda & Hovenkamp ¶ 338a.

the stay. *Id.* at 18. Sanofi next asserts that these fact-based arguments are supported by judicially noticeable documents, which Sanofi encourages the Court to review and use for drawing inferences in Sanofi's favor. *Id.* at 19. None of these arguments is proper on a motion to dismiss. Although a court may take judicial notice of the "existence" of a document, it may not make a judgment about "the truth of the facts recited therein," let alone draw inferences in the movant's favor on a motion to dismiss. *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quotation omitted); *see also Dunn v. PHH Mortg. Corp.*, 2021 WL 870659, at *3 (D.N.J. Mar. 9, 2021) (judicially noticing documents for their truth would authorize trial by public documents). The Court should reject Sanofi's invitation to draw inferences and make credibility determinations that judicial notice will not permit.

Mylan alleged that it could and would have immediately sought FDA approval for Semglee had Sanofi not improperly listed a thicket of sham patents in the Orange Book. *See* Compl. ¶¶ 126–27. Once Sanofi listed those sham patents, Mylan knew any such application would necessarily be delayed by a 30-month stay (*see id.* ¶ 127), during which time FDA might come to a different conclusion about whether Semglee should be classified as a "generic" or "biologic" due to the passage of a new law—an outcome that would have voided Mylan's application. *See id.* ¶ 128; *see also supra* 2, n.33 above. Given the unavoidable timing roadblocks that Sanofi erected in Mylan's regulatory path, Mylan was forced to wait for FDA to weigh in on whether it should take the generic or biosimilar approval path. *See id.* ¶¶ 128–39. But, and this is critical, Mylan's engagement with FDA for regulatory approval was artificially prolonged *because* Sanofi foreclosed the possibility of expedited final approval by improperly listing numerous invalid patents in the Orange Book. *See id.* Sanofi disputes these allegations, but this factual dispute is not properly resolved on a motion to dismiss. *See Doe*, 30 F.4th at 342.

2. Sanofi's exclusive dealing foreclosed Mylan from the market.

Sanofi argues that Mylan failed to allege market foreclosure. D.I. 50 at 9–10. Not so. Mylan alleged that it did not make *any* measurable sales until 2021. Compl. ¶ 211. And, in any event, even if Mylan did not allege complete market foreclosure, that is not the standard. *See Indivior*, 2023 WL 6936749, at *17.

Mylan's burden is only to show harm to competition, which can be established either through direct evidence or indirect evidence. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Direct evidence can come in the form of "reduced output, increased prices, or decreased quality." *Id.* Indirect evidence can include the extent to which the market is foreclosed as a "proxy for anticompetitive harm." *McWane, Inc. v. FTC*, 783 F.3d 814, 835 (11th Cir. 2015).

While a plaintiff may rely on foreclosure as a proxy for competitive harm, it need not "place an exact number on the percentage foreclosed." *McWane*, 783 F.3d at 838. The plaintiff can always rely on qualitative evidence, *e.g.*, that the exclusive arrangement "tied up the key dealers" in the market. *Id.* Even when a plaintiff eventually relies on a numerical figure, its complaint need not include a specific number. *See FTC v. Qualcomm Inc.*, 2017 WL 2774406, at *24 (N.D. Cal. Jun. 26, 2017). After all, a complaint must offer facts demonstrating a legal wrong, not "mathematical precision." *Landers v. Quality Commc'ns, Inc.*, 771 F.3d 638, 646 (9th Cir. 2015) (as amended). To plead a foreclosure percentage, a plaintiff would need to know the defendant's sales figures and contract terms, which plaintiffs cannot access without discovery. *See E. I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 452 n.12 (4th Cir. 2011). Furthermore, whether an exclusive dealing arrangement forecloses a sufficient share of the market to adversely affect competition "implicate[s] factual disputes that cannot be resolved at [the motion to dismiss] stage." *Regeneron Pharms., Inc. v. Amgen Inc.* 2023 WL 1927544, at

*6 (D. Del. Feb. 10, 2023), *R&R adopted*, 2023 WL 2587809 (D. Del. Mar. 21, 2023).[21]

Sanofi points to Eli Lilly and Novo Nordisk's entry into *a* market as proof there was no foreclosure. *See* D.I. 50 at 10. Whether and how Sanofi's conduct impacted Novo Nordisk is immaterial, because it is not in the relevant market. *See*, *supra* at 23–26. And, in any event, even according to *Sanofi*, Sanofi captured huge swaths of the basal insulin market as a whole. *See* Compl. ¶ 10 (boasting of "76% Coverage in Commercial and 74% in Medicare"); *see also* Insulin Report Documents at 220. Further, Sanofi, Eli Lilly, and Novo Nordisk are alleged co-conspirators in a conspiracy to keep the price of insulin high. *See*, *e.g.*, Second Am. Compl. ¶ 1, *In re: Direct Purchaser Insulin Pricing Litigation*, No. 3:20-cv-3462 (D.N.J. Nov. 8, 2022), D.I. 261. At a minimum, Mylan is entitled to discovery as to how Sanofi targeted Mylan compared to brand manufacturers like Eli Lilly and Novo Nordisk.

Finally, the question is not whether Mylan and other competitors were able to obtain sales but whether Mylan would have obtained more sales but for Sanofi's conduct. "The fact that generics gained market share and competed for some number of payor contracts does not dispel the genuine issues of material fact as to whether the probable effect of [Sanofi]'s conduct would have been to 'substantially lessen competition, rather than merely disadvantage rivals.'" *Indivior*, 2023 WL 6936749, at *18 (quoting *Eisai*, 821 F.3d at 403).

II. Mylan's Additional Claims Succeed for Similar Reasons Already Identified.

A. Mylan's Attempted Monopolization, Exclusive Dealing, and Violation of the New Jersey Antitrust Law Claims Survive.

Mylan has succeeded in establishing a claim for attempted monopolization. To plead attempted monopolization, Mylan must sufficiently allege "(1) that the defendant has engaged in

[21] *See also Regeneron*, 2023 WL 2587809, at *1 ("[F]oreclosure [is an] issue [that] is not all that suitable for a motion to dismiss."); *Indivior*, 2023 WL 6936749, at *17) (foreclosure is a factual issue).

predatory or anticompetitive conduct with (2) specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Presque Isle Colon & Rectal Surgery v. Highmark Health*, 391 F. Supp. 3d 485, 502 (W.D. Pa. 2019) (citation omitted). Sanofi's arguments seeking dismissal of this claim fail for the same reasons previously stated. *See supra* pp. 1–30. Sanofi not only had a "dangerous probability of achieving monopoly power," it, in fact, *did have monopoly power*. *See supra* pp. 20–26. Moreover, determining this question is a "fact-sensitive inquiry" that courts typically should not resolve at the pleading stage. *Broadcom*, 501 F.3d 297, at 319.

Sanofi's arguments that Mylan has not pleaded specific intent (D.I. 50 at 25) ignore the numerous references in Mylan's Complaint to damning statements in *Sanofi's* internal documents declaring anticompetitive intent. *See, e.g.*, Compl. ¶ 14 ("Establish Toujeo and convert the franchise"); *id*. ¶ 199 (Sanofi wanted to "maximize the glargine family and defend our leadership position" before biologic follow on entry); *id.* ¶¶ 9, 14 ("[Toujeo] [l]aunch plan includes key tactics . . . and necessary investment to ensure switch before biologic follow on entry.").

Finally, Mylan's exclusive dealing claims, New Jersey Antitrust Act claims, and Section 3 of the Clayton Act claims survive for the same reasons Mylan's Sherman Act Section 2 claims survive. *Eisai*, 821 F.3d at 402 n.11.

B. Mylan's Claims of Tortious Inducement of Refusal to Deal Survive.

Sanofi argues that Mylan's allegations fail because Mylan does not allege any prospective contractual relationships with any particularity (D.I. 50 at 26), but Mylan need only identify a "prospective contractual relationship," which is "something less than a contractual right, something more than a mere hope." *Thompson Coal Co. v. Pike Coal Co.*, 488 Pa. 198, 209 (1979); *see also Sandoz Inc. v. Lannett Co*., 544 F. Supp. 3d 505, 511–12 (E.D. Pa. 2021)

(quoting *Thompson*, 488 Pa. at 209). The standard is objective, and whether a party's expectation is reasonable "generally involves questions of fact." *Sandoz*, 544 F. Supp. 3d at 512. Thus, whether Mylan's contracting expectations were reasonable is not appropriately decided on a motion to dismiss.

Additionally, the Complaint sufficiently identifies relationships through which contracts would ordinarily arise, identifying the likely contracting parties and how Sanofi excluded Mylan from these contracts. *Sandoz*, 544 F. Supp. 3d at 512. In fact, Mylan explains that "[b]ecause of Sanofi's conduct, payers were induced into not dealing with Mylan and instead remaining beholden to Sanofi's larger insulin franchise." Compl. ¶ 260. Mylan also alleges that, through this switch, Sanofi steered patients away from the imminently genericized Lantus (i.e., Mylan's potential customers) to Toujeo. *Id.* ¶ 3. Mylan specifically alleges that having Lantus and Toujeo tied together resulted in "Mylan's less expensive biosimilar" being "effectively excluded from commercial and noncommercial formularies and out of the reach of patients." *Id.* ¶ 15. Indeed, when Semglee launched in the Fall of 2020, "payers were unwilling to entertain a switch away from Lantus because the prospect of then having to pay more for Toujeo was crippling." *Id.* ¶ 210. These allegations are sufficient.

III. Mylan's Complaint Provides Each Sanofi Entity with Sufficient Notice of the Claims Levied Against It.

Sanofi argues that Mylan has failed to specifically describe how each defendant entity participated in the alleged conduct. *See* D.I. 50 at 27–28. But a complaint need not contain detailed defendant-by-defendant allegations. *In re Processed Egg Prods. Antitrust Litig.*, 821 F. Supp. 2d 709, 719 (E.D. Pa. 2011). Rather, defendants "must have reasonable, not exhaustive, notice of the allegations." *Id.* at 719. So long as the allegations in the complaint are sufficient to put the defendants on notice of the charges against them the complaint passes muster under Rule

8 of the Federal Rules of Civil Procedure ("Rule 8"). *Hotaling & Co., LLC v. Berry Sols. Inc.*, 2021 WL 4860096, at *7 (D.N.J. Oct. 19, 2021).

Nothing in Rule 8 prohibits collectively referring to multiple defendants where the complaint alerts defendants that identical claims are asserted against each. *Hotaling*, 2021 WL 4860096, at *7; *see also Big Dog Energy, LLC v. Primeblock Operations LLC*, 2023 WL 3645960, at *5 (W.D. Pa. May 25, 2023). This is especially true where, as here, the individual Sanofi defendants are related corporate entities and in privity with one another. *See JD Glob. Sales, Inc. v. Jem D Int'l Partners, LP*, 2023 WL 4558885, at *8 (D.N.J. July 17, 2023).

Mylan's allegations are far from the type of group pleadings at issue in the cases Sanofi cites or what Rule 8 intends to prevent.[22] Mylan identifies with specificity the relevant patent litigation and Orange Book listings. Compl. ¶¶ 114–122; 145. And Mylan goes into painstaking detail regarding the demise of Sanofi's Orange Book patents. *Id.* ¶¶ 140–190. Mylan also cites Sanofi's internal documents produced to Congress to show that Sanofi introduced and maneuvered Toujeo to entrench its market dominance. *Id.* ¶ 199. There is nothing unclear or vague as to Mylan's allegations, and Mylan is not privy to the details of Sanofi's internal corporate structure. *See id.* ¶ 33 n.13 (referencing Sanofi's "lists of hundreds of subsidiaries and affiliates"). Discovery will reveal the specific roles of each Sanofi entity. *See Ioengine, LLC v.*

[22] Sanofi relies on inapposite fraud and section 1983 cases involving large groups of unconnected defendants. *See Campbell v. City of New Brunswick*, 2018 WL 2234899, at *2 (D.N.J. May 16, 2018) (false arrest lawsuit); *Grande v. Starbucks Corp.*, 2019 WL 1455445, at *1 (E.D. Pa. Apr. 2, 2019) (customer complaint alleging twelve Starbucks employees "fraudulently promis[ed] stores would be safe and clean when in fact the stores were dirty"); *Hynson ex rel. Hynson v. City of Chester, Legal Dep't*, 864 F.2d 1026, 1026–27 (3d Cir. 1998) (Section 1983 lawsuit); *Caristo v. Blairsville-Saltsburg Sch. Dist.*, 370 F. Supp. 3d 554, 558 (W.D. Pa. 2019) (same); *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 856 (E.D. Pa. 2017) (same). The other cases Sanofi cites are similarly far afield from Mylan's Complaint. *See e.g., Ezekwo v. Jacobs*, 2023 WL 3848332, at *1 (D.N.J. Jun. 6, 2023) (plaintiff was a "frequent filer" who "routinely and frequently submits filings that are unintelligible, duplicative, and aggressive"), *appeal filed* (July 7, 2023); *Mensah v. Manning*, 2020 WL 91089, at *6–7 (D.N.J. Jan. 8, 2020) (plaintiff on notice for previous dismissal under Rule 8 and subsequent complaint bringing claims against seven corporate defendants was only fourteen pages long).

PayPal Holdings, Inc., 2019 WL 330515, at *11 (D. Del. Jan. 25, 2019).

IV. This Court Has Personal Jurisdiction Over Sanofi S.A.

This Court's exercise of specific jurisdiction over Sanofi S.A. is proper. The relevant inquiry is whether a defendant has sufficient contacts with the ***United States***. *See In re Auto. Refinishing Paint Antitrust Litig.*, 2002 WL 31261330, at *6 (E.D. Pa. July 31, 2002) (hereinafter "*Auto Refinishing*"), *aff'd*, 358 F.3d 288 (3d Cir. 2004). As detailed in the appended declaration, Sanofi S.A. has purposefully directed numerous activities towards the United States relating to its monopolistic scheme. *See* Mills Decl. ¶¶ 4–12. Specific jurisdiction exists here. *See In re NBR Antitrust Litig.*, 2005 WL 8179729, at *1 (W.D. Pa. July 5, 2005), *R&R adopted*, 2005 WL 8179728 (W.D. Pa. Aug. 24, 2005).

Perhaps the most striking example of this Court's proper exercise of personal jurisdiction over Sanofi S.A. is the latter's efforts in the U.S. to keep Lantus on preferred formulary placement. *See* Mills Decl. ¶ 9. Sanofi has engaged in significant additional conduct in the United States concerning its scheme. To begin, on February 25, 2015 Sanofi announced that FDA approved Toujeo and expressly stated its intent to direct activities towards the United States, noting that "Toujeo is expected to be available in the U.S. at the beginning of Q2 2015." *See* Mills Decl. ¶ 6. Though Sanofi failed to indicate which entity issued the press release, the announcement was tellingly made from Paris—the principal place of business of Sanofi S.A. *See id.*; Compl. ¶ 27. On June 4, 2015, Sanofi announced—from Paris—clinical trials for Toujeo intended to evaluate Toujeo's effects on people in the United States. *See* Mills Decl. ¶ 7. Likewise, Sanofi issued a September 28, 2015 press release—again from Paris—discussing its settlement with U.S-headquartered Eli Lilly concerning Lantus patents. *See id.* ¶ 8. And on December 4, 2017, Sanofi—from Paris—issued a press release to the "USNewswire" touting Toujeo's clinical success. *See* Mills Decl. ¶ 10.

Moreover, Sanofi S.A. frequently testifies before Congress regarding conduct pertaining to its insulin glargine products in the *United States*. For example, on April 10, 2019, Kathleen W. Tregoning—Executive Vice President of Sanofi and based out of Paris—testified before Congress concerning issues related to pricing and affordability of insulin in the U.S., including Lantus and Toujeo. *See id.* ¶ 11. Further, just recently, Sanofi S.A. CEO, Paul Hudson, testified before the Senate Committee on Health, Education, Labor & Pensions, once again pertaining to affordable insulin access in the United States. *See id*. ¶ 12.

Together, these events demonstrate Sanofi's purposeful activity directed towards the United States as they relate to Sanofi's efforts to monopolize the insulin glargine market and significant financial interest in protecting its profit base. Sanofi S.A. is, thus, subject to the jurisdiction of this Court. *See* 35 U.S.C. § 293; *see also Auto Refinishing*, 2002 WL 31261330, at *9. At a minimum, this Court should permit jurisdictional discovery into Sanofi S.A.'s contacts. *See Auto Refinishing*, 358 F.3d at 291–92; *see also Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003); *In re Diisocyanates Antitrust Litig.*, 2020 WL 1140245, at *7 (W.D. Pa. Mar. 9, 2020). Denying a request for jurisdictional discovery is appropriate only when the claim at issue is "'clearly frivolous.'" *Toys "R" Us, Inc.*, 318 F.3d at 456 (citation omitted)). Here, it is not.

CONCLUSION

For all of these reasons, Sanofi's Motion to Dismiss must be denied.

Dated: November 13, 2023

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC. ET AL., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL., Defendants.	2:23-cv-00836-MRH Chief Judge Mark R. Hornak Oral Argument Requested

DECLARATION OF MELISSA MILLS IN SUPPORT OF PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

I, Melissa Mills, declare as follows:

1. I am a Member of Wilson Sonsini Goodrich & Rosati P.C., and am counsel of record for Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. ("Mylan") in the above-captioned matter. I submit this Declaration in support of Mylan's Response in Opposition to Defendants' Motion to Dismiss. I have personal knowledge of the facts set forth herein and am competent to testify thereto if called as a witness.

2. The action was commenced by Mylan on May 17, 2023. *See* Complaint (Docket No. 1).

3. Attached hereto is a Table of Contents identifying the Exhibits accompanying Mylan's Response in Opposition to Defendants' Motion to Dismiss.

4. Attached hereto as Exhibit 1 is a true and correct list of *inter partes reviews* where Sanofi S.A. was a listed as a real party in interest before the U.S. Patent Trial and Appeal Board.

5. Attached hereto as Exhibit 2 is a true and correct list of federal lawsuits brought by Sanofi S.A.

6. Attached hereto as Exhibit 3 is a true and correct copy of Sanofi announcing FDA approval of Toujeo, https://www.news.sanofi.us/2015-02-25-Sanofi-Receives-FDA-Approval-of-Once-Daily-Basal-Insulin-Toujeo.

7. Attached hereto as Exhibit 4 is a true and correct copy of Sanofi announcing a Study Program Evaluating Toujeo® in a Real-Life Setting, https://www.news.sanofi.us/2015-06-04Sanofi-Announces-Study-Program-Evaluating-Toujeo-in-a-Real-Life-Setting.

8. Attached hereto as Exhibit 5 is a true and correct copy of Sanofi announcing its patent settlement with Eli Lilly regarding Lantus® SoloStar®, https://www.news.sanofi.us/2015-09-28-Sanofi-Reaches-Patent-Settlement-on-Lantus-SoloSTAR.

9. Attached hereto as Exhibit 6 is a true and correct copy of excerpt of Sanofi S.A.'s 20-F for the fiscal year ending on December 31, 2016.

10. Attached hereto as Exhibit 7 is a true and correct copy of Sanofi's press release regarding Toujeo clinical trial results, https://www.news.sanofi.us/2017-12-04-Sanofis-Toujeo-R-met-main-objective-in-head-to-head-study-versus-insulin-degludec.

11. Attached hereto as Exhibit 8 is a true and correct copy of testimony submitted to the House Energy and Commerce Subcommittee on Oversight and Investigations on April

10, 2019, by Kathleen W. Tregoning, former Executive Vice President, External Affairs, Sanofi S.A, https://www.sanofi.us/dam/jcr:e61d57e4-e1f4-49da-a8df-2cc59099a229/Testimony-Tregoning%2004.10.pdf.

12. Attached hereto as Exhibit 9 is a is a true and correct copy of testimony submitted to the Senate Committee on Health, Education, Labor & Pensions on May 10, 2023, by Sanofi S.A. CEO Paul Hudson, https://www.help.senate.gov/imo/media/doc/Sanofi%20-%20HELP%20Hearing%20-%20Hudson%20Testimony%20FINAL.pdf.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury, that the foregoing is true and correct.

Executed on November 13, 2023, in Los Angeles, California.

Melissa Mills

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC. ET AL., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL., Defendants.	2:23-cv-00836-MRH Chief Judge Mark R. Hornak Oral Argument Requested

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EXHIBIT 1

Case List

Trial	Filed On	Institution Decision	Patent	Application	Petitioners	Patent Owners
IPR2015-01624	2015-07-27	2016-02-05	6331415	07205419	Sanofi S.A. Genzyme Corporation Regeneron Pharmaceuticals, Inc. Sanofi-Aventis U.S. LLC	City of Hope Genentech, Inc.
IPR2016-00355	2015-12-16	2016-06-28	8951962	13896937	Sanofi-Aventis U.S. Inc. Sanofi S.A. Sanofi-Aventis Deutschland GmbH	Astrazeneca Pharmaceuticals LP Amylin Pharmaceuticals, LLC
IPR2016-00354	2015-12-16	2016-06-28	8445647	13296120	Sanofi S.A. Sanofi-Aventis Deutschland GmbH Sanofi-Aventis U.S. LLC	Amylin Pharmaceuticals, LLC Astrazeneca Pharmaceuticals LP
IPR2016-00353	2015-12-16	2016-06-28	7691963	12101818	Sanofi S.A. Sanofi-Aventis U.S. LLC Sanofi-Aventis Deutschland GmbH	Amylin Pharmaceuticals, LLC Astrazeneca Pharmaceuticals LP
IPR2016-00348	2015-12-16	None	7297761	10894999	Sanofi S.A. Sanofi-Aventis Deutschland GmbH Sanofi-Aventis U.S. LLC	Astrazeneca Pharmaceuticals LP Amylin Pharmaceuticals, LLC
IPR2016-00383	2015-12-30	2016-06-23	6331415	07205419	Sanofi S.A. Genzyme Corporation	City of Hope Genentech, Inc.
IPR2016-00460	2016-01-15	2016-06-08	6331415	07205419	Genzyme Corporation Sanofi S.A.	Genentech, Inc. City of Hope
IPR2018-00187	2017-11-20	2018-06-05	9492559	14597488	Sanofi Pasteur Inc SK Chemicals Co., Ltd. Sanofi S.A.	Pfizer, Inc.
IPR2018-00188	2017-11-20	None	9492559	14597488	SK Chemicals Co., Ltd. Sanofi S.A. Sanofi Pasteur Inc	Pfizer, Inc.

[redacted]

EXHIBIT 2

Case List

Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
Sanofi et al v. Sandoz, Inc. et al	1:15-cv-00415	Patent	D.Del.	2015-05-21	2017-11-07	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alkem Laboratories Ltd. Glenmark Pharmaceuticals, Inc. (USA) Glenmark Pharmaceuticals, Ltd. Lupin Atlantis Holdings S.A. Lupin Ltd. Lupin Pharmaceuticals, Inc. Sandoz, Inc. Sun Pharma Global FZE Sun Pharmaceutical Industries Ltd. Watson Laboratories, Inc.
sanofi-aventis U.S. LLC et al v. Shilpa Medicare Limited	1:19-cv-01975	Patent	D.Del.	2019-10-17	2020-05-13	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Shilpa Medicare Limited
SANOFI-AVENTIS U.S. LLC et al v. FRESENIUS KABI USA, LLC	3:14-cv-07869	Patent	D.N.J.	2014-12-17	2018-03-05	Aventis Pharma S.A. Sanofi Mature IP Sanofi S.A. Sanofi-Aventis U.S. LLC	Fresenius Kabi USA, LLC
SANOFI-AVENTIS U.S. LLC et al v. SANDOZ INC.	3:16-cv-05678	Patent	D.N.J.	2016-09-16	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Sandoz, Inc.
SANOFI-AVENTIS U.S. LLC et al v. DR. REDDY'S LABORATORIES, INC. et al	3:16-cv-02259	Patent	D.N.J.	2016-04-21	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Dr. Reddy's Laboratories Inc. Dr. Reddy's Laboratories, Ltd.
SANOFI-AVENTIS U.S. LLC et al v. MYLAN LABORATORIES LIMITED	3:15-cv-03392	Patent	D.N.J.	2015-05-15	2017-09-26	Aventis Pharma S.A.	Mylan Laboratories Ltd.

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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi S.A. Sanofi-Aventis U.S. LLC	Onco Therapies Limited
SANOFI-AVENTIS U.S. LLC et al v. ACTAVIS LLC et al	3:15-cv-03107	Patent	D.N.J.	2015-05-01	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Actavis Elizabeth, LLC Actavis LLC
SANOFI-AVENTIS U.S. LLC et al v. FRESENIUS KABI USA, LLC	3:15-cv-02631	Patent	D.N.J.	2015-04-13	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Fresenius Kabi USA, LLC
SANOFI-AVENTIS U.S. LLC et al v. DR. REDDY'S LABORATORIES, INC. et al	3:15-cv-02522	Patent	D.N.J.	2015-04-06	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Dr. Reddy's Laboratories Inc. Dr. Reddy's Laboratories, Ltd.
SANOFI-AVENTIS U.S. LLC et al v. ACCORD HEALTHCARE, INC.	3:15-cv-02520	Patent	D.N.J.	2015-04-06	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Accord Healthcare, Inc.
SANOFI-AVENTIS U.S. LLC et al v. APOTEX CORP. et al	3:15-cv-01835	Patent	D.N.J.	2015-03-11	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Apotex Corp.
SANOFI-AVENTIS U.S. LLC et al v. ACTAVIS LLC et al	3:15-cv-00776	Patent	D.N.J.	2015-02-02	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Actavis Elizabeth, LLC Actavis LLC
SANOFI-AVENTIS U.S. LLC et al v. MYLAN LABORATORIES LIMITED	3:15-cv-00290	Patent	D.N.J.	2015-01-14	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Mylan Laboratories Ltd. Onco Therapies Limited

Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
SANOFI-AVENTIS U.S. LLC et al v. APOTEX CORP. et al	3:15-cv-00287	Patent	D.N.J.	2015-01-14	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Apotex Corp.
SANOFI-AVENTIS U.S. LLC et al v. FRESENIUS KABI USA, LLC	3:14-cv-08082	Patent	D.N.J.	2014-12-29	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Fresenius Kabi USA, LLC
SANOFI-AVENTIS U.S. LLC et al v. ACCORD HEALTHCARE, INC.	3:14-cv-08079	Patent	D.N.J.	2014-12-29	2017-09-26	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Accord Healthcare, Inc.
Sanofi et al v. Watson Laboratories Inc. et al	1:14-cv-00264	Patent	D.Del.	2014-02-26	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alembic Pharmaceuticals Limited Alkem Laboratories Ltd. Amneal Pharmaceuticals LLC Amneal Pharmaceuticals of New York, LLC Amneal Pharmaceuticals, Inc. First Time US Generics LLC Glenmark Generics Inc. (USA) Glenmark Generics Ltd. Glenmark Pharmaceuticals, Inc. (USA) Glenmark Pharmaceuticals, Ltd. Sandoz, Inc. Sun Pharma Global FZE Sun Pharmaceutical Industries Ltd. Watson Laboratories, Inc.
SANOFI-AVENTIS U.S. LLC et al v. BPI LABS, LLC et al	3:15-cv-02521	Patent	D.N.J.	2015-04-06	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	BPI Labs, LLC Belcher Pharmaceuticals, LLC
SANOFI-AVENTIS U.S. LLC et al v. GLENMARK PHARMACEUTICALS INC., USA, et al	3:15-cv-02523	Patent	D.N.J.	2015-04-06	2018-03-05	Aventis Pharma S.A. Sanofi S.A.	Glenmark Generics Inc. (USA) Glenmark Pharmaceuticals, Inc. (USA)

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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi-Aventis U.S. LLC	Glenmark Pharmaceuticals, Ltd.
SANOFI-AVENTIS U.S. LLC et al v. BRECKENRIDGE PHARMACEUTICAL, INC.	3:15-cv-01836	Patent	D.N.J.	2015-03-11	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Breckenridge Pharmaceutical, Inc.
SANOFI-AVENTIS U.S. LLC et al v. BRECKENRIDGE PHARMACEUTICAL, INC.	3:15-cv-00289	Patent	D.N.J.	2015-01-14	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Breckenridge Pharmaceutical, Inc.
SANOFI-AVENTIS U.S. LLC et al v. BPI LABS, LLC et al	3:14-cv-08081	Patent	D.N.J.	2014-12-29	2018-03-05	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	BPI Labs, LLC Belcher Pharmaceuticals, LLC
Sanofi et al v. Aurobindo Pharma USA, Inc.	1:17-cv-01247	Patent	D.Del.	2017-08-31	2018-01-24	Sanofi S.A. Sanofi-Aventis U.S. LLC	Aurobindo Pharma USA, Inc.
Sanofi-Aventis U.S. LLC et al v. Mylan Pharmaceuticals, Inc. et al	1:17-cv-00005	Patent	N.D.W.Va.	2017-01-12	2017-12-28	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Mylan Pharmaceuticals, Inc. Mylan, Inc.
Sanofi-Aventis U.S. LLC et al v. Zydus Pharmaceuticals (USA) Inc. et al	1:17-cv-00034	Patent	D.Del.	2017-01-11	2018-01-02	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Cadila Healthcare Ltd. Zydus Pharmaceuticals (USA) Inc.
Sanofi-Aventis U.S. LLC et al v. Mylan Pharmaceuticals Inc. et al	1:17-cv-00024	Patent	D.Del.	2017-01-10	2018-01-02	Aventisub LLC Genzyme Corporation Sanofi S.A.	Mylan Pharmaceuticals, Inc. Mylan, Inc.

Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi-Aventis U.S. LLC	
Sanofi-Aventis U.S. LLC et al v. Alvogen Pine Brook LLC	1:16-cv-01300	Patent	D.Del.	2016-12-22	2018-01-02	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Alvogen Pine Brook LLC
Sanofi-Aventis U.S. LLC et al v. Cadila Healthcare Limited et al	1:16-cv-01298	Patent	D.Del.	2016-12-22	2018-01-02	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Alvogen Pine Brook LLC Amneal Pharmaceuticals LLC Amneal Pharmaceuticals, Inc. Biocon Ltd. Breckenridge Pharmaceutical, Inc. Cadila Healthcare Ltd. Glenmark Pharmaceuticals, Inc. (USA) Glenmark Pharmaceuticals, Ltd. MSN Laboratories Private Limited MSN Pharmaceuticals Inc. Mylan Pharmaceuticals, Inc. Mylan, Inc. Teva Pharmaceuticals USA, Inc. Watson Laboratories, Inc. Zydus Pharmaceuticals (USA) Inc.
Sanofi-Aventis U.S. LLC et al v. Teva Pharmaceuticals USA, Inc.	1:17-cv-00018	Patent	D.Del.	2017-01-05	2017-11-06	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Teva Pharmaceutical Industries Ltd. Teva Pharmaceuticals USA, Inc.
Sanofi et al v. Alkem Laboratories Ltd	1:15-cv-01200	Patent	D.Del.	2015-12-23	2017-11-07	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alkem Laboratories Ltd.
Sanofi et al v. Sandoz Inc.	1:15-cv-01207	Patent	D.Del.	2015-12-23	2017-11-07	Sanofi S.A.	Sandoz, Inc.

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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi-Aventis U.S. LLC	
Sanofi et al v. Glenmark Pharmaceuticals Inc. USA et al	1:15-cv-01206	Patent	D.Del.	2015-12-23	2017-11-07	Sanofi S.A. Sanofi-Aventis U.S. LLC	Glenmark Pharmaceuticals, Inc. (USA) Glenmark Pharmaceuticals, Ltd.
Sanofi et al v. Watson Laboratories, Inc.	1:15-cv-01209	Patent	D.Del.	2015-12-23	2017-11-07	Sanofi S.A. Sanofi-Aventis U.S. LLC	Watson Laboratories, Inc.
Sanofi et al v. Sun Pharma Global FZE et al	1:15-cv-01208	Patent	D.Del.	2015-12-23	2017-11-07	Sanofi S.A. Sanofi-Aventis U.S. LLC	Sun Pharma Global FZE Sun Pharmaceutical Industries Ltd.
Sanofi-Aventis U.S. LLC et al v. Breckenridge Pharmaceutical, Inc.	1:17-cv-00019	Patent	D.Del.	2017-01-05	2017-10-30	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Breckenridge Pharmaceutical, Inc.
Sanofi-Aventis U.S. LLC et al v. Amneal Pharmaceuticals LLC et al	1:17-cv-00039	Patent	D.Del.	2017-01-12	2017-10-11	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Amneal Pharmaceuticals LLC Amneal Pharmaceuticals, Inc.
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Sanofi-Aventis U.S. LLC et al v. MSN Laboratories Private Limited et al	1:17-cv-00027	Patent	D.Del.	2017-01-10	2017-09-27	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	MSN Laboratories Private Limited MSN Pharmaceuticals Inc.
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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
Sanofi-Aventis U.S. LLC et al v. Glenmark Pharmaceuticals Inc., USA et al	1:16-cv-01326	Patent	D.Del.	2016-12-29	2017-09-22	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Glenmark Pharmaceuticals, Inc. (USA) Glenmark Pharmaceuticals, Ltd.
Sanofi-Aventis U.S. LLC et al v. Biocon Limited	1:17-cv-00003	Patent	D.Del.	2017-01-03	2017-06-23	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Biocon Ltd.
Sanofi-Aventis U.S. LLC et al v. Torrent Pharma Inc. et al	1:16-cv-01333	Patent	D.Del.	2016-12-30	2017-05-09	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Torrent Pharma Inc. Torrent Pharmaceuticals Limited
Sanofi-Aventis U.S. LLC et al v. Alembic Pharmaceuticals Ltd. et al	1:16-cv-01316	Patent	D.Del.	2016-12-28	2017-05-01	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Alembic Global Holding SA Alembic Limited Alembic Pharmaceuticals Limited Alembic Pharmaceuticals, Inc.
Sanofi-Aventis U.S. LLC et al v. Apotex, Inc. et al	1:16-cv-01312	Patent	D.Del.	2016-12-27	2017-05-03	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Apotex Corp.
Sanofi-Aventis U.S. LLC et al v. Emcure Pharmaceuticals Ltd. et al	1:17-cv-00070	Patent	D.Del.	2017-01-25	2017-04-28	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Emcure Pharmaceuticals Ltd. Heritage Pharma Labs Inc. Heritage Pharmaceuticals, Inc.
Sanofi-Aventis U.S. LLC et al v. Emcure Pharmaceuticals Ltd. et al	1:16-cv-01330	Patent	D.Del.	2016-12-30	2017-04-28	Aventisub LLC	Emcure Pharmaceuticals Ltd.

Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Heritage Pharma Labs Inc. Heritage Pharmaceuticals, Inc.
Sanofi-Aventis U.S. LLC et al v. IMPAX Laboratories, Inc.	1:17-cv-00004	Patent	D.Del.	2017-01-03	2017-04-21	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Impax Laboratories, Inc.
Sanofi-Aventis U.S. LLC et al v. Aurobindo Pharma USA, Inc., et al.	1:16-cv-01299	Patent	D.Del.	2016-12-22	2017-04-24	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Aurobindo Pharma Ltd. Aurobindo Pharma USA, Inc.
Sanofi-Aventis U.S. LLC et al v. Par Pharmaceutical, Inc. et al	1:17-cv-00040	Patent	D.Del.	2017-01-12	2017-04-12	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Par Formulations Private Limited Par Pharmaceutical Companies, Inc. Par Pharmaceutical, Inc.
Sanofi-Aventis U.S. LLC et al v. Accord Healthcare, Inc. et al	1:16-cv-01311	Patent	D.Del.	2016-12-27	2017-03-31	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Accord Healthcare Ltd. Accord Healthcare, Inc. Intas Pharmaceuticals Limited
Sanofi-Aventis U.S. LLC et al v. Hetero USA Inc. et al	1:17-cv-00031	Patent	D.Del.	2017-01-11	2017-03-10	Aventisub LLC Genzyme Corporation Sanofi S.A. Sanofi-Aventis U.S. LLC	Hetero Labs Limited Hetero USA Inc.
Sanofi et al v. Sandoz Inc.	1:14-cv-01434	Patent	D.Del.	2014-11-24	2016-09-22	Sanofi S.A.	Sandoz, Inc.

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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi-Aventis U.S. LLC	
Sanofi et al v. Amneal Pharmaceuticals LLC et al	1:14-cv-00875	Patent	D.Del.	2014-07-03	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Amneal Pharmaceuticals LLC Amneal Pharmaceuticals of New York, LLC Amneal Pharmaceuticals, Inc.
Sanofi et al v. Alembic Pharmaceuticals Limited	1:14-cv-00424	Patent	D.Del.	2014-04-04	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alembic Limited Alembic Pharmaceuticals Limited
Sanofi et al v. Sun Pharma Global FZE et al	1:14-cv-00294	Patent	D.Del.	2014-03-06	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Caraco Pharmaceutical Laboratories, Ltd. Sun Pharma Global FZE Sun Pharmaceutical Industries Ltd.
Sanofi et al v. First Time US Generics LLC	1:14-cv-00293	Patent	D.Del.	2014-03-06	2016-04-14	Sanofi S.A. Sanofi-Aventis U.S. LLC	First Time US Generics LLC
Sanofi et al v. Alkem Laboratories Ltd.	1:14-cv-00292	Patent	D.Del.	2014-03-06	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alkem Laboratories Ltd. Ascend Laboratories, LLC
Sanofi et al v. Watson Laboratories Inc.	1:14-cv-00265	Patent	D.Del.	2014-02-26	2016-09-22	Sanofi S.A. Sanofi-Aventis U.S. LLC	Actavis Inc. Watson Laboratories, Inc. Watson Pharmaceuticals, Inc.
Sanofi et al v. First Time US Generics LLC	1:15-cv-01205	Patent	D.Del.	2015-12-23	2016-04-14	Sanofi S.A. Sanofi-Aventis U.S. LLC	First Time US Generics LLC
Sanofi-Aventis U.S. LLC et al v. Apotex Corp. et al	1:15-cv-00044	Patent	D.Del.	2015-01-15	2015-03-24	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Apotex Corp.
Sanofi-Aventis U.S. LLC et al v. Fresenius Kabi USA LLC	1:14-cv-01533	Patent	D.Del.	2014-12-30	2015-03-24	Aventis Pharma S.A. Sanofi S.A.	Fresenius Kabi USA, LLC

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Title	Civil Action #	Case Type	Court	Filed On	Terminated	Plaintiff	Defendant
						Sanofi-Aventis U.S. LLC	
Sanofi-Aventis US LLC et al v. Fresenius Kabi USA LLC	1:14-cv-01496	Patent	D.Del.	2014-12-18	2015-03-24	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Fresenius Kabi USA, LLC
Sanofi-Aventis U.S. LLC et al v. Breckenridge Pharmaceutical, Inc.	9:15-cv-80056	Patent	S.D.Fla.	2015-01-15	2015-03-06	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Breckenridge Pharmaceutical, Inc.
Sanofi-Aventis U.S. LLC et al v. BPI Labs, LLC et al	8:14-cv-03233	Patent	M.D.Fla.	2014-12-30	2015-03-04	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	BPI Labs, LLC Belcher Pharmaceuticals, LLC
SANOFI-AVENTIS U.S. LLC et al v. ACCORD HEALTHCARE, INC.	1:15-cv-00018	Patent	M.D.N.C.	2015-01-07	2015-02-27	Aventis Pharma S.A. Sanofi S.A. Sanofi-Aventis U.S. LLC	Accord Healthcare, Inc.
Sanofi et al v. Unimark Remedies Ltd.	1:14-cv-00876	Patent	D.Del.	2014-07-03	2015-02-20	Sanofi S.A. Sanofi-Aventis U.S. LLC	Unimark Remedies Ltd.
Sanofi et al v. Alkem Laboratories, Ltd. et al	1:14-cv-01957	Patent	N.D.Ill.	2014-03-19	2014-05-15	Sanofi S.A. Sanofi-Aventis U.S. LLC	Alkem Laboratories Ltd. Ascend Laboratories, LLC
Sanofi et al v. Sun Pharma Global FZE et al	1:14-cv-01844	Patent	N.D.Ill.	2014-03-14	2014-05-02	Sanofi S.A. Sanofi-Aventis U.S. LLC	Caraco Pharmaceutical Laboratories, Ltd. Sun Pharma Global FZE Sun Pharmaceutical Industries Ltd.

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EXHIBIT 3

Press Releases

Sanofi Receives FDA Approval of Once-Daily Basal Insulin Toujeo®

PARIS, Feb. 25, 2015 /PRNewswire-USNewswire/ -- Sanofi announced today that the U.S. Food and Drug Administration (FDA) approved Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), a once-daily long-acting basal insulin, to improve glycemic control in adults living with type 1 and type 2 diabetes. Toujeo is expected to be available in the U.S. at the beginning of Q2 2015.

"Sanofi is proud of its long heritage in diabetes and insulin therapies, including Lantus® which has supported patients in the management of their diabetes for more than a decade. With the FDA approval of Toujeo, Sanofi builds on its strong legacy and looks forward to bringing a new treatment option to people living with diabetes," said Pierre Chancel, Senior VP, Global Diabetes, Sanofi.

The approval of Toujeo was based on FDA review of results from the EDITION clinical trial program, which was comprised of a series of international Phase III studies evaluating the efficacy and safety of Toujeo in more than 3,500 adults from broad and diverse diabetes populations (type 1 and type 2). In the clinical trial program leading to approval, once-daily Toujeo was compared to that of once-daily Lantus (insulin glargine [rDNA origin] injection, 100 U/mL) in open-label, randomized, active-control, parallel, treat-to-target studies of up to 26 weeks of duration with 6 months safety extension.

"Nearly 50 percent of people living with diabetes remain uncontrolled," said John Anderson, MD, internal medicine and diabetes specialist, Frist Clinic of Nashville, TN, and Past President of the American Diabetes Association. *"Despite the proven efficacy of insulin, ensuring effective titration and maintenance can be a challenge for both patients and healthcare professionals due to hypoglycemia concerns. Toujeo provides a new option that may help patients manage their diabetes*."

All studies of the EDITION program successfully met the primary study endpoints by demonstrating similar blood sugar control with Toujeo as compared to Lantus.[1,2] The most common adverse events (excluding hypoglycemia) reported for Toujeo included nasopharyngitis (12.8% in type 1 patients and 7.1% in type 2 patients) and upper respiratory tract infection (9.5% in type 1 patients and 5.7% in type 2 patients).

Toujeo's Pharmacokinetic/Pharmacodynamic (PK/PD) information and its rates of severe and documented symptomatic hypoglycemia can be found in the label.

Toujeo will be available in the Toujeo SoloSTAR®, a disposable prefilled pen which contains 450 units of Toujeo and requires one third of the injection volume to deliver the same number of insulin units as compared to the Lantus SoloSTAR®. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the U.S., who require 80 IU or less per day. Toujeo is currently pending marketing authorization with the European Medicines Agency (EMA) and other health authorities around the world.

About Toujeo
Prescription Toujeo is a long-acting insulin used to treat adults with type 2 and type 1 diabetes for the control of high blood sugar. It should be taken once a day at the same time each day to lower blood glucose.

Do not use Toujeo to treat diabetic ketoacidosis.

Important Safety Information for Toujeo (insulin glargine [rDNA origin] injection) 300 Units/mL (U-300)

Do not take Toujeo during episodes of low blood sugar or if you are allergic to insulin or any of the inactive ingredients in Toujeo. Toujeo is not approved for use in people under the age of 18.

Do not share needles, insulin pens or syringes with others. Do NOT reuse needles.
You must test your blood sugar levels daily while using any insulin, including Toujeo. Do not make any changes to your dose or type of insulin without talking to your healthcare provider.

Toujeo contains 300 units per milliliter (300 U/mL). You should always verify that you have the correct insulin before each injection. Your dose for Toujeo may be different from other insulins you have taken. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Toujeo with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Toujeo must only be used if the solution is clear and colorless with no particles visible.

Tell your doctor about other medicines, especially ones commonly called TZDs (thiazolidinediones), and supplements you are taking because they can change the way insulin works. Before starting Toujeo, tell your doctor about all your medical conditions, including if you have liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed. If you have heart failure, it may get worse while taking TZDs with Toujeo.

The most common side effect of any insulin, including Toujeo, is low blood sugar (hypoglycemia), which may be serious and can be life-threatening. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat and blurred vision. Severe hypoglycemia may cause harm to your heart or brain. Other possible side effects may include swelling, weight gain and allergic reactions. In rare cases, some allergic reactions may be life-threatening. Injection site reactions are also possible, and may include changes in fat tissue at the injection site, skin thickening, redness, swelling and itching.

Toujeo SoloSTAR is a disposable prefilled insulin pen. Please talk to your healthcare provider about the proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

Please click here for full Prescribing Information for Toujeo: http://products.sanofi.us/Toujeo/Toujeo.pdf.

About Lantus
Prescription Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and patients (6 years and older) with type 1 diabetes for the control of high blood sugar. It should be taken once a day at the same time each day to lower blood glucose.

Do not use Lantus to treat diabetic ketoacidosis.

Important Safety Information for Lantus
Do not take Lantus if you are allergic to insulin or any of the inactive ingredients in Lantus. You must test your blood sugar levels while using insulin, such as Lantus. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Lantus with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Lantus must only be used if the solution is clear and colorless with no particles visible**. Do not share needles, insulin pens or syringes with others.**

Tell your doctor about other medicines, especially ones called TZDs, and supplements you are taking because they can change the way insulin works. Before starting Lantus, tell your doctor about all your medical conditions including if you have heart failure or other heart problems, liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed. If you have heart failure, it may get worse while you take TZDs with Lantus.

The most common side effect of insulin, including Lantus, is low blood sugar (hypoglycemia), which may be serious. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. Severe hypoglycemia may be serious and life-threatening. It may cause harm to your heart or brain. Other possible side effects may include swelling, weight gain, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life-threatening.

Please click here for the full Prescribing Information: http://products.sanofi.us/lantus/lantus.html.

Lantus SoloSTAR is a disposable prefilled insulin pen. Please talk to your healthcare provider about the proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

About Sanofi Diabetes
Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices including blood glucose monitoring systems. Sanofi markets injectable, inhaled and oral medications for people with type 1 or type 2 diabetes.

About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

- *Ritzel RA, Roussel R, Bolli GB et al. New insulin glargine 300 U/ml: glycaemic control and hypoglycaemia in a meta-analysis of phase 3a EDITION clinical trials in people with type 2 diabetes mellitus. Poster at European Association for the Study of Diabetes congress, 2014, abstract 963.*
- *Home PD, Bergenstal RM, Riddle MC et al. Glycaemic control and hypoglycaemia with new insulin glargine 300 U/mL in people with type 1 diabetes (EDITION 4). Oral presentation at European Association for the Study of Diabetes congress, 2014, abstract 148.*

Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

SOURCE Sanofi

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EXHIBIT 4

 EXHIBIT 4

Press Releases

Sanofi Announces Study Program Evaluating Toujeo® in a Real-Life Setting

PARIS, June 4, 2015 /PRNewswire-USNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) announced today a program of Phase IV clinical trials to study Toujeo® (insulin glargine [rDNA origin] injection, 300 units per mL) in 'real-world' conditions. The Real Life Study program in people with type 2 diabetes comprises the ACHIEVE CONTROL, REACH CONTROL and REGAIN CONTROL studies and will compare the clinical effectiveness of Toujeo® with other basal insulins in a standard care setting, along with additional measures relating to patient experience and health resource utilization.

"There is a need to go beyond drug comparison and move toward investigation of wider diabetes management strategies, where additional factors are considered," commented Riccardo Perfetti, Senior Medical Officer, Vice President Global Medical Affairs, Diabetes Division, Sanofi. *"This study program will evaluate how the safety and efficacy findings for Toujeo® seen in the EDITION studies might now translate into real-life effectiveness in the treatment of adults with type 2 diabetes."*

The research program will involve more than 4,500 adults with type 2 diabetes from the U.S. and Europe. It will investigate control of blood sugar levels, incidence of hypoglycemia, persistence with treatment, patient-reported outcomes and health resource usage, with Toujeo® and other basal insulins as used in the standard care setting.

The ACHIEVE CONTROL study will evaluate the effect of Toujeo® on achieving individualized glycemic targets without hypoglycemia at any time of day in 3,270 uncontrolled insulin-naïve people in the U.S. with type 2 diabetes. REACH CONTROL will follow 800 insulin-naïve people with type 2 diabetes in Europe, comparing HbA_{1c} change with Toujeo® vs. other basal insulins, alongside incidence of hypoglycemia, change in body weight, and measures of persistence with treatment and need for treatment intensification. The REGAIN CONTROL study will compare HbA_{1c} reduction, incidence of hypoglycemia, change in body weight and persistence with treatment on Toujeo® vs. other basal insulins in 600 people with type 2 diabetes in Europe, who are currently uncontrolled on basal insulin. In addition to clinical measures, the studies will also collect patient feedback on treatment satisfaction and their experience of hypoglycemia, along with healthcare resource utilization.

The studies are expected to begin randomizing patients in Q2 2015, with initial results expected in 2017. Results from an extended follow-up period are anticipated in 2018.

"While randomized controlled trials establish the efficacy and safety profile in a defined population and address regulatory needs, healthcare professionals, diabetes educators and payers may find real-world evidence provides important value to the management of diabetes," said Luigi Meneghini, MD, MBA, Professor of Internal Medicine at the University of Texas Southwestern Medical Center, Division of Endocrinology, Dallas, Texas, and Principal Investigator of the ACHIEVE CONTROL study. *"This program of research is a step forward in meeting this need, evaluating the use of Toujeo® and other basal insulins in a real life setting."*

What is Toujeo®?

Prescription Toujeo® is a long-acting insulin used to control blood sugar in adults with diabetes mellitus.

- Toujeo® contains 3 times as much insulin in 1 mL as standard insulin (100 Units/mL)
- Toujeo® is not for use to treat diabetic ketoacidosis
- Toujeo® should not be used in children

Important Safety Information for Toujeo® (insulin glargine injection) 300 Units/mL

Do not take Toujeo® during episodes of low blood sugar or if you are allergic to insulin or any of the inactive ingredients in Toujeo®.

Do not share insulin pens even if the needle has been changed. Do NOT reuse needles.

Before starting Toujeo®, tell your doctor about all your medical conditions, including:

- If you have liver or kidney problems
- If you are pregnant or planning to become pregnant
- If you are breast-feeding or planning to breast-feed

Heart failure can occur if you are taking insulin together with certain medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure, it may get worse while you take TZDs with Toujeo®. Tell your doctor if you have any new or worsening symptoms of heart failure, including:

- Shortness of breath
- Swelling of your ankles or feet
- Sudden weight gain

Your treatment with TZDs and Toujeo® may need to be changed or stopped by your healthcare provider if you have new or worsening heart failure.

Tell your doctor about all the medications you take, including over-the-counter medicines, vitamins, and supplements, including herbal supplements.

Toujeo® should be taken once a day at the same time each day to lower blood glucose. You must test your blood sugar levels daily while using any insulin, including Toujeo®. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. You should always verify that you have the correct insulin before each injection. Your dose for Toujeo® may be different from other insulins you have taken. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Toujeo® with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Toujeo® must only be used if the solution is clear and colorless with no particles visible.

While using Toujeo®, do not drive or operate heavy machinery until you know how Toujeo® affects you. You should not drink alcohol or use other medicines that contain alcohol.

The most common side effects of any insulin, including Toujeo®, is low blood sugar (hypoglycemia), which may be serious and can be life-threatening. Severe hypoglycemia may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision.

Toujeo® may cause serious side effects that can lead to death, such as severe allergic reactions that affect the whole body. Get medical help right away if you have:

- A rash over your whole body
- Trouble breathing
- Shortness of breath
- Fast heartbeat
- Swelling of your face, tongue, or throat
- Sweating
- Extreme drowsiness, dizziness, or confusion

Toujeo® may have additional side effects. Other possible side effects may include swelling, weight gain, and low potassium.

Injection site reactions are also possible and may include change in fat tissue at the injection site, skin thickening, redness, swelling, and itching.

Toujeo® SoloStar® is a disposable prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

Please click here for full Prescribing Information for Toujeo®:
http://products.sanofi.us/Toujeo/Toujeo.pdf.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices including blood glucose monitoring systems. Sanofi markets injectable, inhaled and oral medications for people with type 1 or type 2 diabetes.

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Sanofi Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

EXHIBIT 5

Press Releases

Sanofi Reaches Patent Settlement on Lantus® SoloSTAR®

PARIS, Sept. 28, 2015 /PRNewswire/ -- Sanofi announced today that it has reached a settlement agreement with Eli Lilly and Company ("Lilly"), which addresses patents on Sanofi's Lantus® SoloSTAR® (insulin glargine). The agreement resolves a U.S. patent infringement lawsuit regarding Lilly's pursuit of regulatory approval for a product that would compete with Lantus SoloSTAR. Sanofi and Lilly agreed to end that lawsuit and to discontinue similar disputes worldwide.

Under the agreement, Lilly will pay royalties to Sanofi in exchange for a license to certain Sanofi patents. In the U.S., Lilly will not sell its insulin glargine product before December 15, 2016. The agreement does not include Lantus (vial), Toujeo® or combination products. The remaining settlement terms are confidential.

Sanofi will continue its commitment to develop and deliver innovations for the more than 387 million people globally living with diabetes.

About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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Additional assets available online: Photos (1)

EXHIBIT 6

EXHIBIT 6

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

or

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2016

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Or

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel
54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value €2 per share	New York Stock Exchange
Ordinary shares, par value €2 per share	New York Stock Exchange (for listing purposes only)
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2016 was:

Ordinary shares: 1,292,022,324

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. YES ☐ NO ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies (including exclusive formularies), managing prescribing via various conditions (including prior authorisations and step edits) or otherwise discouraging physicians from prescribing our products (see also "– The concentration of the US payer market exposes us to greater pricing pressure" below).

In the United States, the federal Affordable Care Act has increased the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed rebates and fees on pharmaceutical companies. Some US states are also considering legislation that could affect transparency practices, the marketing and prices of, and access to, drugs. US federal and state officials will continue to focus on healthcare reform in the future, creating multiple risks for the sector.

Government price reporting obligations are complex, and we face risks related to the reporting of pricing data that could affect the reimbursement of and discount provided for our products to US government healthcare programs.

We encounter similar cost containment issues in countries outside the United States. In certain countries, including countries in the European Union, China and Canada, the coverage of prescription drugs, and pricing and levels of reimbursement, are subject to governmental control. For example, in Europe various authorities are developing the use of tenders for expensive products and are considering joint procurement mechanisms to negotiate lower prices. See also below "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business".

We are also unable to predict the availability or level of reimbursement and related restrictions for our product candidates.

Price negotiations in a country may result in a price that is incompatible with the global price positioning of our products, which may lead us not to launch the product in that country, damaging our image and resulting in a decrease in initially anticipated sales.

Finally, our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy products in low cost markets for resale in higher cost markets.

The concentration of the US market exposes us to greater pricing pressure.

In the United States, price is increasingly important to managed care organizations (MCOs) and pharmacy benefit managers (PBMs), and as the MCOs/PBMs grow in size following market consolidation, pharmaceutical companies have faced increased pressure in pricing and usage negotiations, and competition among pharmaceutical companies to have their products included in the care providers' formulary is robust. This can lead to price discounts or rebates in connection with the placement of products. Exclusion of one of our drugs from a formulary can significantly reduce sales in the MCO/PBM patient population. For example, since 2014, we have increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016, CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus®/Toujeo® will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering several million people, thus reducing the potential patient populations to whom Lantus® may be prescribed.

Also, some payers in the United States have put in place significant restrictions on the usage of Praluent®, which has resulted in significant out-of-pocket expenditures for Medicare patients.

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting in consolidation of the distribution channel.

Due to these pressures on our prices, our revenues and margins are, and could continue to be, negatively affected.

We may lose market share to competing therapeutic options, biosimilar or generic products.

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors.

Doctors or patients may choose competitors' products over ours or alternative therapeutic options such as surgery if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and adversely affect our results of operations.

The success of any product also depends on our ability to educate patients when permissible and promote our products to healthcare providers by providing them with innovative data about the product and its uses including through the use of digital tools. If these education efforts are not effective, we may not be able to increase the sales of our products or realize the full value of our investment in their development.

We may not be able to anticipate precisely the date of market entry of generics or biosimilars or the potential impact on our sales, both of which depend on numerous parameters. The introduction of a generic version of a

branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at significantly lower prices, resulting in adverse price and volume effects for our genericized products. Also mandatory price regulations apply in certain countries to off-patent products and classes of products, and generics prices are taken into account for international reference pricing and tenders. Substitution is often permitted for generic products that are considered to be interchangeable or clinically identical. With respect to biosimilars, in the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic and only in circumstances where specific criteria are met. In many European countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless, competition including from non-substitutable biosimilars would likely result in a decrease in prices, additional rebates, increased promotion efforts and lower margins.

Approval of a generic or biosimilar that is substitutable for one of our products would increase the risk of accelerated market penetration by that generic or biosimilar to a greater extent than would be the case for a non-substitutable product.

These trends are exacerbated by applicable legislation which encourages the use of generic products to reduce spending on prescription drugs in many countries such as the United States, France and Germany. Therefore, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as a generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy. We expect this generic competition to continue and to affect more of our products, including those with relatively modest sales.

A substantial share of the revenue and income of Sanofi continues to depend on the performance of certain flagship products.

We generate a substantial share of our revenues from the sale of certain key products (see "Item 5. Operating and Financial Review and Prospects – Results of Operations – Year ended December 31, 2016 compared with year ended December 31, 2015 – Net Sales – Pharmaceuticals segment"). Lantus® is particularly important; it was Sanofi's leading product with revenues of €5,714 million in 2016, representing 16.9% of Sanofi's net sales for the year. Lantus® is a flagship product of the Diabetes franchise. Accounting for market trends, we announced in October 2015 that we project global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at constant exchange rate (CER). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions (for example the outlook for insulin glargine sales, the introduction of one or several biosimilar glargines and their penetration of the market or the market uptake of our new products).

Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the performance of our other businesses may not be sufficient to reduce the relative contribution of Lantus® to our overall performance.

Our flagship products benefit from certain intellectual property protections such as patents and exclusivity periods but patent and proprietary rights, even if they are not challenged, are subject to expiration dates. Expiration of effective intellectual property protections for our products typically results in the entry of one or more lower-priced generic competitors, often leading to a rapid and severe decline in revenues on those products (for information on the expected impact of biosimilar entry on the market see "– We may lose market share to competing therapeutic options, biosimilar or generic products" above).

Furthermore, in general, if one or more of our flagship products were to encounter problems such as material product liability litigation, unexpected side effects, recall, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales of one or more of our flagship products or in their growth, the adverse impact on our business, results of operations and financial condition could be significant.

The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image.

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products to Sanofi quality standards or if they experience financial difficulties. Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. Any of these factors could adversely affect our business, operating results or financial condition. See "Item 4. Information on the Company – B. Business Overview – B.8. Production and Raw Materials" for a description of these outsourcing arrangements.

EXHIBIT 7

Press Releases

Sanofi's Toujeo® met main objective in head-to-head study versus insulin degludec

First head-to-head randomized clinical trial comparing the efficacy and safety of Toujeo (insulin glargine 300 Units/mL) versus insulin degludec

PARIS, Dec. 4, 2017 /PRNewswire-USNewswire/ -- Sanofi's Toujeo® met the primary study objective in the first large head-to-head clinical trial[1], called BRIGHT study, comparing Toujeo with insulin degludec. Sanofi plans to provide full results in 2018.

The primary objective was to determine if the effect of Toujeo on blood sugar levels (HbA1c) was similar to insulin degludec. Secondary objectives included the percentage of patients experiencing adverse events, the total number of participants with low blood sugar events during the study and the rate at which low blood sugar events occurred. The study specifically followed 929 adults whose type 2 diabetes was previously uncontrolled on non-insulin medication.

> *"The most recently introduced long-acting insulins have already demonstrated significant blood glucose lowering benefit to adult patients with diabetes. From the perspective of physicians and patients, hypoglycemia remains a major limiting factor in effective blood sugar management in diabetes. We believe that these first comparative clinical data assessing similarity and difference not only in efficacy, but also in the important safety aspect, such as low blood sugar events, can support physicians in their treatment decisions," said Riccardo Perfetti, Head of Global Diabetes Medical Team, Sanofi. "We look forward to release of the full results of the study."*

About the head-to-head study

The BRIGHT study included adults with type 2 diabetes who had failed to control their HbA1c with oral antihyperglycemic drugs (OADs) with or without a glucagon-like peptide-1 (GLP-1) receptor agonist.

Additional secondary endpoints included the percentage of participants requiring rescue therapy, safety, and patient-reported outcomes measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ, status version and change version) and the Hypoglycemic Attitudes and Behavior Scale.

What is Toujeo® (insulin glargine injection) 300 Units/mL?

Prescription Toujeo® is a long-acting insulin used to control blood sugar in adults with diabetes mellitus.

- Toujeo® contains 3 times as much insulin in 1 mL as standard insulin (100 Units/mL)
- Toujeo® is not for use to treat diabetic ketoacidosis
- Toujeo® should not be used in children

Important Safety Information for Toujeo® (insulin glargine injection) 300 Units/mL

Do not take Toujeo® if you have low blood sugar or if you are allergic to insulin or any of the ingredients in Toujeo®.

Do NOT reuse needles or share insulin pens even if the needle has been changed.

Before starting Toujeo®, tell your doctor about all your medical conditions, including if you have liver or kidney problems, if you are pregnant or planning to become pregnant or if you are breastfeeding or planning to breastfeed.

Heart failure can occur if you are taking insulin together with pills called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with Toujeo®. Your treatment with TZDs and Toujeo® may need to be changed or stopped by your doctor if you have new or worsening heart failure. Tell your doctor if you have any new or worsening symptoms including:

- Shortness of breath
- Sudden weight gain
- Swelling of your ankles or feet

Tell your doctor about all the medications you take, including OTC medicines, vitamins, and supplements, and herbal supplements.

Toujeo should be taken at the same time once a day. Test your blood sugar levels daily while using any insulin, including Toujeo®. Do not change your dose or type of insulin without talking to your doctor. Verify you have the correct insulin before each injection. **Do NOT use a syringe to remove Toujeo® from your SoloStar® pen.** Your dose for Toujeo® may be different from other insulins you have taken. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Toujeo® with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Use Toujeo® only if the solution is clear and colorless with no particles visible.

While using Toujeo®, do not drive or operate heavy machinery until you know how Toujeo® affects you. Don't drink alcohol or use other medicines that contain alcohol.

The most common side effect of any insulin, including Toujeo®, is low blood sugar (hypoglycemia), which may be serious and can be life-threatening. Severe hypoglycemia may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision.

Toujeo® may cause severe allergic reactions that can lead to death. Get medical help right away if you have:

- A rash over your whole body
- Shortness of breath
- Swelling of your face, tongue, or throat
- Extreme drowsiness, dizziness, or confusion
- Trouble breathing
- Fast heartbeat
- Sweating

Toujeo® may have additional side effects including swelling, weight gain, low potassium, and injection site reactions which may include change in fat tissue, skin thickening, redness, swelling, and itching.

Toujeo® SoloStar® is a disposable prefilled insulin pen. Talk to your doctor about proper injection technique and follow instructions in the Instruction Leaflet that comes with the pen.

Please see full Prescribing Information for Toujeo® on Toujeo.com or click here: http://products.sanofi.us/Toujeo/Toujeo.pdf.

References

1. Sanofi, data on file: Insulin glargine 300 U/mL vs insulin degludec in insulin-naïve adults with T2DM: head-to-head trial design and rationale, NCT02738151, November 2017

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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EXHIBIT 8

Testimony of Kathleen W. Tregoning
Executive Vice President, External Affairs
Sanofi

Before the House Energy and Commerce Subcommittee on
Oversight and Investigations
April 10, 2019

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations to discuss issues related to pricing, affordability, and patient access to insulin in the United States.

I am Kathleen Tregoning, Executive Vice President, External Affairs, at Sanofi. I am here today to have an open discussion about the current system for pricing and accessing insulin in the U.S., the actions we have taken to improve patient access and affordability to insulin, and our ideas about what more can be done.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. And we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

Sanofi has a rich history in the United States dating back over 100 years. We currently employ more than 13,000 professionals across the United States in a broad range of critical roles, including business operations, research and development, and manufacturing. Our most significant U.S. presence is in Massachusetts, where we are the largest employer in the life sciences industry, and New Jersey, home to our U.S. headquarters. We also have major business, manufacturing and R&D operations in Pennsylvania and Tennessee.

Last year, Sanofi spent almost $7 billion globally on research and development, an increase of approximately 7 percent from 2017, which reflects our commitment to bringing better therapies to patients. Sanofi plans to maintain this level of R&D investment through 2021, and our R&D pipeline now contains 81 projects, including 33 new molecular entities in clinical development, and 35 projects that are in Phase III or have been submitted to regulatory authorities. This investment means that Sanofi potentially will seek approval for nine new

medications in the next three years, primarily in therapeutic areas where Sanofi sees the greatest nexus between our expertise and patient need: diabetes, vaccines, oncology, immunology, rare diseases, and rare blood disorders.

Our work in R&D includes more than a dozen compounds for the treatment of various kinds of cancers, and we are employing cutting-edge approaches in an effort to make significant advances for patients. Our research includes potential treatments to help the body's own immune system fight cancer, and antibody drug conjugates that we believe can deliver cytotoxic drugs to tumors while sparing normal tissue. Just last month we announced successful results with one such candidate in a mid-stage trial in lung cancer, and we intend to initiate a pivotal study later this year.

I. Evolution of Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy over the last century have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The discovery and development of glargine changed all of that. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The once-daily administration of glargine also provided a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus® in 2000. Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and conducted the first large Cardiovascular Outcome trial (CVOT - (ORIGIN)), to demonstrate the cardiovascular effects of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individual patient needs. While Lantus® provides significant

improvement for long acting (basal) insulin, for some patients, Lantus does not provide sufficient 24-hour basal insulin coverage. For other patients using higher doses, Lantus has a peak of action, which could lead to hypoglycemia. In order to more closely mimic endogenous basal insulin secretion, and to help type 2 diabetes patients meet their glycemic goals, Sanofi developed a next generation basal insulin, Toujeo®. Approved by the FDA in 2015, Toujeo provides an improved therapeutic effect at a higher concentration of glargine and exhibits a different and longer-acting profile than Lantus®.

Recognizing that approximately half of patients treated with basal insulin were still not achieving their blood glucose (HbA1c) targets, Sanofi launched Soliqua 100/33® in 2017. Intended for adults whose Type 2 diabetes is inadequately controlled on basal insulin or an oral antidiabetic medicine, Soliqua is a fixed ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal (GI) side effects. Soliqua has demonstrated reduction in average and overall glucose levels and reduction in GI side effects, with similar rates of hypoglycemia – thus allowing balance of lowered glucose levels without more hypoglycemia. Moreover, Soliqua has been found to have a beneficial effect on body weight, addressing one of the unwanted side effects of insulin.

These three products are among five insulin products currently manufactured by Sanofi.

In 2000, Lantus launched in a vial, so patients needed to inject the product with a syringe. Since that time, we have developed several more convenient injection devices for administering insulin. Our latest pen delivery system, SoloSTAR®, has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration that has improved the lifestyle and medication compliance of millions of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's features include a clutch that couples and decouples complex internal mechanisms from each other to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007, and it very quickly became the gold standard for pre-filled, disposable injection pens. It has won awards for its novel design.

Sanofi developed Toujeo SoloStar with several innovative design features and attributes, ranging from the length of time it can be held without overheating the contents, to other ergonomic features designed to make the pen delivery system easier to use. Additionally, Sanofi developed SoloStar Max®, which holds more units in the reservoir (900 vs 450) and gives

the patient the ability to dose up to 180 units in one injection vs the 80 units in the SoloSTAR pen, allowing for fewer injections and potentially for fewer refills and related copays.

We continue to study the safety and efficacy of our products for higher risk patient populations who would benefit from the more stable pharmacokinetic and pharmacodynamic profile, such as children and geriatric patients with diabetes. Sanofi understands that randomized clinical trials do not always provide a full picture of patient outcomes, so we have launched one of the most comprehensive real world evidence studies for a diabetes medication in the United States. We are studying Toujeo in diverse settings, ranging from a randomized, pragmatic prospective trial to predictive analytics and machine learning applied to large patient datasets. We believe that studying our medications in real world settings will continue to help drive needed innovation in diabetes treatment.

Looking to the future, our scientists are working on ways to potentially transform diabetes care by treating the underlying disease. To this end, Sanofi has a multi-pronged approach, through which we seek to prevent the progression of diabetes to insulin-dependence or restore insulin-producing cells through stem cell technologies. In addition, we recognize that the greatest contributor to the current diabetes epidemic is obesity. Our researchers are exploring the molecular mechanisms by which obesity leads to diabetes, and working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. This type of research, and the development of these new technologies, takes many years, and we continue to invest in these projects with the hope that we can eventually transform the lives of these patients.

II. Rising Costs of Insulin for Patients

While the treatment of diabetes has been transformed by medical innovations, including multiple new discoveries to improve the quality and delivery of insulin, the landscape in which patients access medications has also fundamentally changed, and not for the better. We understand the anger of patients who cannot afford the insulin they need due to rising out-of-pocket drug costs.

In order to develop meaningful solutions for patients, it is critical to take a comprehensive look at what is driving rising costs for patients. Given the number of factors that contribute to determining out-of-pocket costs for patients, every actor of the supply chain, including manufacturers, has a role to play in solving this problem.

We want everyone – including patients, providers, payers, pharmacy benefit managers (PBMs), policy makers, and regulators – to understand why we set prices as we do, and we want to reaffirm our commitment to our core principles of access, affordability and innovation.

While list prices of medicines often receive the most attention, they reflect the initial price we set for our medicines. The list price is not the amount Sanofi receives or the price typically paid by government and commercial insurers, employers, or PBMs. Under the current system,

players within the supply chain – including PBMs, plans, wholesalers, distributors, and group purchasing organizations – receive either rebates and/or fees based on a percentage of the list price. Their economic incentives are therefore directly linked to the list price. As long as the net price grows at a predictable rate or even decreases, the greater the list price, the greater the economic returns for many players in the supply chain.

List price is the starting point for negotiations with payers and sometimes impacts patient out-of-pocket costs. But focusing solely on the list price does not tell the whole story. In the current system, manufacturers pay significant rebates as a percentage of the list price to government and private payers, as well as other intermediaries, in an effort to improve access for patients. As described later in my testimony, due to these rebates, the average aggregate net price of our products, including our insulin products, has declined over the last several years.

In some cases, affordability issues are the result of changes in health plan designs, such as the increase in the number of high deductible health plans (HDHPs). Among those with private health insurance, enrollment in HDHPs has increased since 2010. The design of these plans generally requires patients to pay the full list price of medicines during the deductible phase of the program, rather than the negotiated drug price available in the insurance portion of the plan.

In other cases, affordability issues are caused by changes in insurance design, which increasingly require patients to pay higher cost-sharing amounts for their medicines, even when the prices of those medicines have stayed relatively flat or declined for the health plan. For example, the average net price of Lantus, our most prescribed insulin, has declined by over 30 percent since 2012, while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. In this case, not only are discounts apparently not being passed on to patients, but patients are in fact being asked to pay more when PBMs and health plans are paying less for the medicine.

Increasing out-of-pocket costs also can result from changes to prescription drug formularies, which have a significant impact on the amount of out-of-pocket costs a patient will be asked to pay. A recent opinion piece in the New York Times[1] highlights how changes to prescription drug formularies can not only create confusion and frustration for providers and patients but also ultimately increase costs for patients when the medicines they need are not covered on a formulary's preferred tier.

Sanofi provides rebates to PBMs and health plans to improve patient access to, and affordability for, Sanofi insulins. We want these rebates, which have grown in recent years and have resulted in substantially lower net prices, to benefit patients. Unfortunately, under the current system, savings from insulin rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or coinsurance amounts.

[1] *See* https://www.nytimes.com/2019/01/18/opinion/cost-insurance-diabetes-insulin.html.

Given the complexity in the system and number of factors that impact out-of-pocket costs, every part of the health care system has an obligation to work to solve this problem. I appreciate that this Subcommittee is taking a holistic approach to collecting information on what is causing the problem for patients. As we consider solutions to address patient access and affordability, it is essential that we not undermine the incentives and rewards for scientific risk-taking and discovery that are the hallmark of the United States ecosystem and economy.

III. Sanofi Actions to Improve Patient Access & Affordability

As a global health care leader, Sanofi has a long-standing commitment to promoting health care systems and policies that make our insulins accessible and affordable to patients in need. We believe we can play an important role in the development of constructive solutions that will benefit both patients and the healthcare system as a whole.

Sanofi is – and will continue to be – an industry leader in helping to address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are influenced or controlled by others in the health care system, we recognize that there are actions we can take to help improve access and affordability for patients.

For our part, we recognize that we must price our medicines transparently and according to their value, while at the same time contributing to broader solutions that improve patient outcomes and the financial sustainability of the U.S. health care system. That is why in May 2017 Sanofi announced our progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.[2]

These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a $15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain.

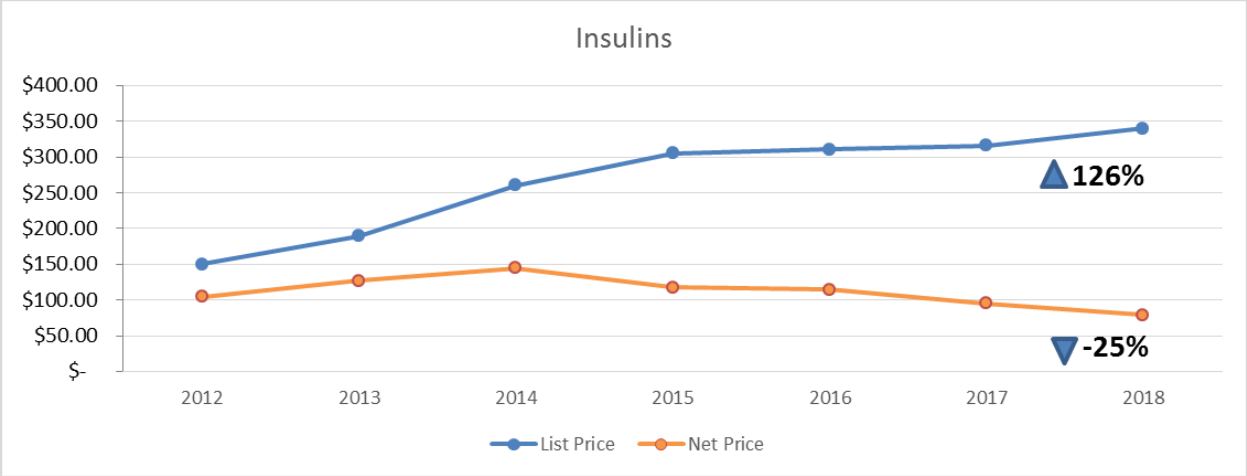
In 2018, all of our price increases were consistent with our principles, as are all pricing actions we have taken in 2019. Across our entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent.

[2] *See* https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf

The declining average aggregate net price in 2018 represents the third consecutive year the amount that health plans and PBMs pay Sanofi for our medicines has declined.

Specific to insulin, the average aggregate net price across all Sanofi insulin products has declined for the past four years, and based on existing contracts, will fall again in 2019. **For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.[3]**

Sanofi Insulins List vs. Net Price Changes[4] Between 2012-2018



When considering the patient access and affordability challenges of insulin, it is important to not only look at list price changes over time, but also net price changes. For example, Lantus, our oldest and most prescribed insulin, is frequently cited in stories about increasing insulin prices. While the list price of Lantus has increased significantly since it was approved, the net price – the amount Sanofi receives after discounts and rebates – has been declining for several years. In fact, the net price of Lantus today is lower than it was in 2006.

Unfortunately, competition among various diabetes treatments, and the resulting insulin net price declines, has not resulted in lower out-of-pocket costs for patients. As noted previously in my testimony, while the net price of Lantus has declined by over 30% since 2012, out-of-pocket costs for patients with commercial insurance and Medicare Part D have increased by approximately 60% over that same period of time.

In addition to our pledge to limit price increases in the U.S., Sanofi's pricing principles include a commitment to transparency in how we price new medicines coming to the market for the first time.

[3] Based on internal review of pricing actions and payer contracting.

[4] List Prices are calculated by dividing Gross Sales (sales at List Prices before discounts and rebates) by total trade units sold. Net prices calculated by dividing Net Sales (sales after discounts and rebates) by total trade units sold.

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers four factors:

1) A holistic assessment of value, including: (a) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; (b) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and (c) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) approaches and other analyses that help define or quantify value and include patient perspectives and priorities.

2) Similar treatment options available or anticipated at the time of launch in order to understand the competitive landscape within the disease areas in which the medicine may be used.

3) Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payers and health care delivery systems.

4) Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials (including longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.

Applying these methodologies, Sanofi has launched a number of innovative products at prices well below the competition. In the insulin space, we launched, and are committed to maintaining, Admelog®, a biosimilar of insulin lispro, at the lowest list price of any mealtime insulin.

With the right incentives in the system, our approach to setting launch prices for these new medicines coupled with our limit on list price increases should have had the effect of ensuring affordable access for patients.

Sanofi Patient Support Programs

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward leaning programs to help patients afford Sanofi's insulin products.

Commercially insured patients qualify for our co-pay assistance program, regardless of income, which reduces the financial burden for insulin products. Through this program, over 90% of participating patients pay either $10 or $0 per month for their Sanofi insulin. While current regulations prohibit us from offering this type of program to patients insured under Medicare

or similar federal or state programs, Sanofi supports efforts that would expand this access program to all those who might benefit.

Additionally, we created the Insulin Val***you*** Savings Program in 2018. The intent of the Insulin Val***you*** Savings Program is to provide relief for those who currently pay high variable retail prices for their insulin and do not qualify for other assistance programs. Through this program, eligible individuals can access all Sanofi insulins for $99 per 10 mL vial or $149 for a pack of SoloStar pens – roughly a one-month supply – at a discount of up to 60 percent below the list price, resulting in savings of up to $3,000 per year. There are no income requirements, and the program is available at U.S. pharmacies. Since it was launched last April, the program has resulted in approximately $10 million in patient savings.

For eligible uninsured and underinsured low-income patients, including Medicare patients, Sanofi offers many of our medicines, including our insulin products, at no charge through its Sanofi Patient Connection patient assistance program. We are proud that, in 2018, more than 93,000 patients participated in the Sanofi Patient Connection program.

Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that today, approximately 75 percent of all patients taking Sanofi insulin pay less than $50 per month. We believe many others may be eligible for one of these programs to reduce their costs, and we continue to promote these programs to raise awareness about the support that is available.

Last week, Sanofi joined other insulin manufacturers to fund a program that limits insulin co-pays to $25 for patients covered under ESI and Cigna plans. While this out-of-pocket maximum is greater than patients may pay if they enroll directly in Sanofi's co-pay assistance program, which may reduce a commercially insured patient's out-of-pocket burden to as low as $0, we believe this new initiative launched by ESI and Cigna will unquestionably lower out-of-pocket costs for some patients.

IV. Solutions

I am proud of Sanofi's leadership to help improve access and affordability to insulin products for patients. However, despite the actions we have taken, on behalf of everyone at Sanofi, I know more needs to be done. My testimony today is intended to provide a more transparent and open picture into the system surrounding access to insulin therapies in order to enable this Subcommittee to consider a common set of facts and design solutions to meet urgent patient needs. I hope we can all agree on market-based policy solutions that will incentivize a high-value, highly competitive, and sustainable health care system that improves the affordability of innovative medicines in the U.S.

It is my belief that targeting list price alone will not be sufficient to address patient access and affordability. Just lowering list prices, without guarantees that those lower-priced medicines would be included on formularies at affordable, low co-pay tiers may not solve the problem for

most patients. Sanofi's Insulin Val***you*** savings program offers significantly less expensive access to all of our insulin products even when compared to recent actions by others to lower list prices. The solution to insulin access and affordability must include protections for patients, tying responsible pricing to both access and affordability.

There are a variety of ways to accomplish this goal, and Sanofi could support any number of options that align to our core principles:

1) The U.S. should continue to maintain a strong ecosystem for innovation. As such, any policy proposals should strictly avoid directly and artificially controlling the price of medicines, either through price controls set by the federal government, or worse, outsourcing that decision to other governments. Policy proposals that we believe would fundamentally undermine the unique innovation ecosystem of the United States include reference pricing, importation, or price controls set by CMS.

   Based on our experience in other countries, these approaches may be effective at controlling budgets for central payers, but come at a steep cost for patients – namely limiting access to innovative treatments. Additionally, given that the U.S. is the world's leader in science and innovation – and the jobs that come with it – these approaches pose additional risks to the U.S. economy and future scientific discovery. Finally, and most importantly, given the differences between systems, these approaches may do little to improve access and affordability for patients.

   As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

2) Changes to the pricing system must be holistic, and the benefits should accrue to patients. As noted previously, simply enacting price controls will not solve the problem of access and affordability for patients. We believe system incentives need to change to encourage smaller list price increases, or list price reductions, by requiring health plans to cover those medicines that meet these standards at affordable co-pay levels and only allow access restrictions consistent with the product label and accepted evidence-based best clinical practice.

If policies solely target the list price of medicines without these common-sense patient protections, our shared goal of lowering insulin costs – for both government and patients – while maintaining the engine of innovation in the United States to bring innovative medicines to patients will not be fully achieved. To appropriately accomplish our shared objective of greater access and affordability for patients, Sanofi is willing to contribute our fair share to offset any financial impact to the health care system as long as patient access and affordability are improved for all patients.

Sanofi supports and recommends several policy solutions to incentivize responsible pricing behavior. To ensure that these changes do not create a windfall for manufacturers or health plans and PBMs, Sanofi recommends applying these policies only to medicines that satisfy certain limits on price increases. This approach will shift the current incentives in the system to reward "good" behavior in a manner that truly helps patients. Several of the solutions outlined below are also priorities for Members of this subcommittee and I look forward to the opportunity to work with you on advancing these and other policy initiatives:

First, reducing out-of-pocket costs for patients is our top priority. Sanofi has identified a number of ways to effectively reduce out-of-pocket costs for consumers and broadly supports tradeoffs between price and access to help patients, including the following:

- Whether through legislation, implementation of the Anti-Kickback Safe Harbor rebate proposed rule, or changes in market dynamics, link lower list prices to improved access and affordability for patients.

- All payments in the supply chain should be de-linked from list price, which would remove the perverse incentive that sometimes feeds the cycle of higher list prices paired with higher rebates.

- Require a substantial portion of the discounts and rebates paid by manufacturers to reduce costs for patients at the pharmacy counter.

- Change government price reporting rules and the Anti-Kickback statute in a manner that would promote value-based contracting.

- Implement an annual out-of-pocket cap for Medicare beneficiaries.

- Allow Medicare beneficiaries to access manufacturer co-pay assistance programs.

- Change or clarify government price reporting rules to make it easier to reduce list prices on medicines that have been on the market for a long time – namely by (1) making clear that the government pricing metrics for the new, lower list price drug do not have to be averaged with the metrics for older, higher list price drug and (2) permitting a company to treat the new lower price drug as a new product for purposes of Medicaid rebate calculations, which will help to link the rebate liability for the new drug to the new drug's lower price as opposed to the higher price for the old drug.

Second, Sanofi supports policies that further cultivate a highly competitive free market system and reward the type of entrepreneurial risk-taking necessary to the discovery and development of life-saving new medicines. A key element of that system is strong and predictable intellectual property protection. However, after a reasonable period of time – which I believe is already reflected in U.S. law – generic and biosimilar medicines should quickly enter the market to offer long-term access at lower costs. To help accomplish these goals, Sanofi supports:

- Increasing competition among medicines. Whether through prohibiting "reverse payment" patent settlements, requiring timely access to samples for generic or biosimilar manufacturers, establishing a clear patent listing of biologics through a "Purple Book", or further encouraging the development of biosimilar insulin products, Sanofi supports robust competition to encourage continued development of life-saving medicines. At Sanofi, we make product supply available to generic and biosimilar manufacturers developing data necessary for FDA applications for their products. We do this in a timely manner and on commercially reasonable terms. We support both the CREATES Act and the Purple Book Continuity Act as passed out of the full Committee last week.

- Increasing system-wide transparency, which would improve competition by making relevant information available to patients and policymakers. Providing more information about what is driving costs in the system and how money is flowing through the system will allow for increased competition and better-informed decision making. Policies that include price reporting requirements to incentivize responsible pricing behavior have the potential to change current practices, but they should be modified to protect confidential information and preempt similar state law policies in order to create a single set of requirements.

- Requiring health plans and PBMs to disclose an annual list of medicines for which the net price has decreased, as well as how the decrease (or value generated by it) was allocated among the health plans, PBMs, government payer, and patients.

Finally, Sanofi supports many of the recommendations made by the Congressional Diabetes Caucus in its whitepaper[5] entitled: "Insulin: A lifesaving drug too often out of reach," including the following:

- Encourage the development and use of value-based contracts between insulin makers and PBMs.

- Promote the use of payment arrangements between insulin makers and wholesalers that involve standardized fees instead of rebates.

- Require insulin makers, PBMs, and health insurers to disclose the value and volume of rebates that they receive and share with other entities in the insulin supply chain.

- Link patient out-of-pocket costs to negotiated prices instead of list prices.

- Allow generic manufacturers to produce older, off-patent insulin formulations.

- Require manufacturers to disclose their insulin's list pricing process.

[5] https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf

- Standardize the process for requesting exemptions or filing appeals from formulary changes.
- Standardize drug formulary disclosure of patient cost-sharing information.
- Limit the number of changes an insurer is permitted to make to a formulary each year.
- Cap out-of-pocket expenses for prescription drugs that are needed for chronic conditions.

V. Conclusion

I look forward to having a productive conversation about the complexities of the current prescription drug pricing system and proposals to improve affordable patient access to high quality, innovative life-saving medications such as insulin to drive optimal health outcomes.

Thank you for the invitation to speak with you today and I look forward to working with you.

EXHIBIT 9

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Testimony of Paul Hudson
Chief Executive Officer
Sanofi

Before the Senate Committee on Health, Education, Labor & Pensions
May 10, 2023

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to appear before the Senate Committee on Health, Education, Labor & Pensions to discuss issues related to pricing, affordability, and patient access to insulin in the United States. I am Paul Hudson, the Chief Executive Officer of Sanofi.

I am here today to have an open discussion about the current system for pricing and accessing insulins in the U.S., the actions we have taken to improve patient access and affordability to our insulins, and, most importantly, what more can be done to make the system work better for patients and ensure every patient has affordable access to insulin.

I. Chasing the Miracles of Science to Improve People's Lives

At Sanofi, we work passionately to prevent, treat, and cure illness and disease, understand and solve health care needs of people across the world, and transform the practice of medicine. Our focus spans therapeutic areas, including immunology, oncology, rare diseases, rare blood disorders, neurology, diabetes, and cardiovascular diseases, as well as vaccines.

We employ approximately 14,000 professionals in the U.S. in a broad range of critical roles, including research and development, manufacturing, and business operations. Our most significant U.S. presence is in Massachusetts, where we are one of the largest employers in the life sciences industry, and in New Jersey. We also have major research and development (R&D), manufacturing, and business operations in Pennsylvania and Tennessee.

Last year, Sanofi spent more than $7 billion globally on R&D, reflecting our commitment to pursuing first-in-class and best-in-class medicines and vaccines that have the greatest potential to transform the practice of medicine, improve peoples' lives, and protect public health. With a strong focus on difficult-to-treat diseases and immunization, our R&D pipeline includes 84 clinical-stage projects, 26 of which are in phase 3 or have been submitted to regulatory authorities for approval.

Today, I am very proud of the progress we've made. Earlier this year, we announced positive results from a Phase 3 study in COPD, the third leading cause of death worldwide. If approved, this medicine will be the first innovation for patients suffering from this disease in over a decade. This fall, we anticipate approval for the first immunization against RSV disease **for all infants**. With this immunization, the burden RSV placed on providers and its toll on families may never happen again. Finally, we also recently launched Tzield, the first medicine proven to **delay** the onset of type 1 diabetes.

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These treatments directed to meet unmet patient needs serve as an important reminder of the importance of fostering a policy environment that makes these breakthroughs possible.

Our responsibility includes demonstrating the value of our medicines through clinical data and real-world evidence, assuming massive risk to discover, develop, and deliver the medicines and vaccines that solve meaningful health problems for patients, and to enable continued investment in the innovation cycle.

II. Evolution in Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant. Much like modern cars bear little resemblance to Ford's Model T, the variety of insulin products available for diabetes patients today reflects years of research that have led to significant improvements over early formulations.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections to control blood glucose levels.

We are proud at Sanofi of our innovation history in insulin and the meaningful ways in which this has transformed the standard of care for patients, from the introduction of Lantus, which provided significant improvements in basal insulin levels, to the introduction of Toujeo®, a next generation basal insulin that more closely mimics the body's endogenous insulin secretions, among others. In addition to delivering meaningful innovation in the types of insulin available to patients, we are proud of the role we have played in transforming the patient experience through the development of devices to ease the daily burden of insulin administration, allowing for fewer injections and, in some cases, fewer refills and related patient copays.

Today, our goal is to transform diabetes care by treating not just symptoms but addressing the underlying disease. We are attempting to understand and disrupt the immunological triggers for the development of diabetes through several partnerships, including the recent launch of a groundbreaking medicine TZIELD, which is approved in the U.S. as the first and only therapy to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 type 1 diabetes.

III. Sanofi's Commitment to Responsible Pricing

Pharmaceutical innovation brings value to patients, our society, and our health care systems. Our responsible approach to pricing reflects our medicines' value, and our commitment to patient access and to minimizing our contribution to health care inflation.

In May 2017, Sanofi announced our commitment to sustainable pricing through our progressive and industry-leading principles. This commitment includes transparency to help stakeholders

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understand our pricing decisions and to advance a more informed discussion regarding our approach to pricing our medicines.[1]

We hold ourselves to a rigorous and structured process, that includes consultation with external stakeholders, when we set the price of a new medicine. Our approach considers the following factors:

- **A holistic assessment of value,** including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to standard of care treatments; 2) economic value, or how the medicine reduces the need—and therefore costs—of other health care interventions; and 3) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessments (HTAs) and other analyses that help define or quantify value and include patient perspectives and priorities.
- **Similar treatment options** available or anticipated at the time of launch, in order to understand the landscape within the disease areas in which the medicine may be used.
- **Affordability**, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.
- **Unique factors** specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to demonstrate the longer-term outcomes of our medicines, implement important regulatory commitments, or explore opportunities to improve care management/patient experience and help decrease the total cost of care.

When evaluating whether to change the list price of any of our medicines, including our insulin products, we consider four factors:

- Our ambition to chase the miracles of science to improve people's lives and ensure patients have access to the medicines they need now and in the future;
- Patient affordability;
- Government policies, including inflation penalties enacted under the Inflation Reduction Act; and
- Evolving trends in the marketplace.

In 2020, 2021, and 2022, Sanofi did not increase the list price of any of its insulin products.[2]

[1] For more information on our Responsible Pricing policies and initiatives, please see our "Sanofi 2023 Pricing Principles Report," at https://www.sanofi.us/dam/jcr:356cc1f5-92dd-47a1-9770-ba60dfdfab1e/Sanofi-2023-Pricing-Principles- Report.pdf.

[2] Price increases on Sanofi's combination product, Soliqua®, have been within the National Health Expenditures (NHE) growth rate, a measure of medical inflation.

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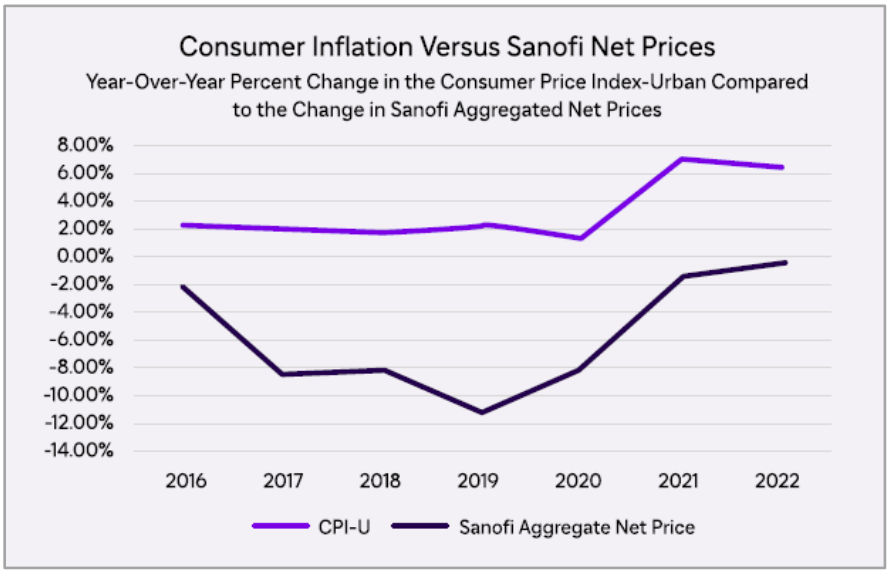
The table and graph below demonstrate how our responsible approach to pricing has been put into action, with limited list price increases resulting in an average aggregate net price decline every year since Sanofi started reporting data in 2017—even as consumer inflation has increased prices on other goods and services:

The net price paid to Sanofi for our products has declined for seven consecutive years:

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% INCREASE	2.1% DECREASE
2017	1.6% INCREASE	8.4% DECREASE
2018	4.6% INCREASE	8.0% DECREASE
2019	2.9% INCREASE	11.1% DECREASE
2020[3]	0.2% INCREASE	7.8% DECREASE
2021	1.5% INCREASE	1.3% DECREASE
2022	2.6% INCREASE	0.4% DECREASE

U.S. Portfolio Annual Aggregate Price Change from Prior Year[4]



A. List Prices versus Net Prices

While list price often receives the most attention, it simply reflects the initial price Sanofi sets for a medicine. It is not the amount Sanofi receives, nor the price typically paid by government and

[3] Price increases or reductions that are taken mid-year may have an impact in two calendar years. In our 2019 pricing report, Sanofi announced that it took a price reduction on Admelog® (insulin lispro injection) 100 Units/mL in July 2019. The 2020 carryover impact of that change is not included in the 2020 Average Aggregate List Price above. If included, the 2020 Average Aggregated List Price change vs. 2019 would have been effectively zero percent, and the Average Aggregate Net Price would decrease by 8.0 percent.

[4] Aggregated across Sanofi's prescription portfolio.

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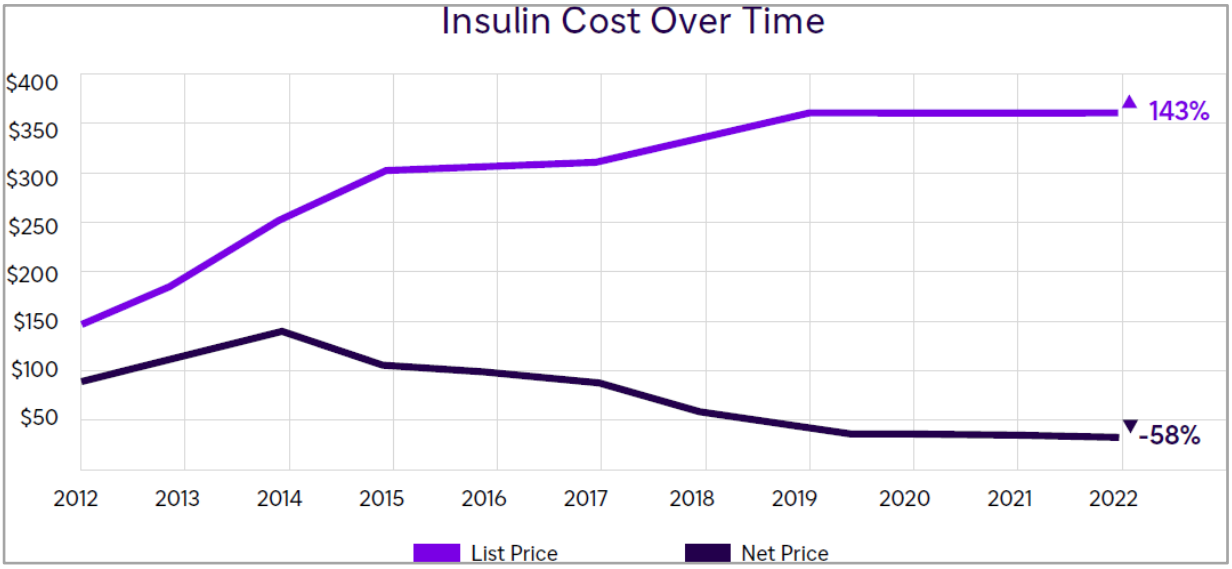
commercial insurers, employers, pharmacy benefit managers (PBMs), or patients. Manufacturers, including Sanofi, pay significant discounts, rebates and fees—often as a percentage of a medicine's list price—to different stakeholders across the health care system with the goal of ensuring our medicines are available to patients at affordable prices. Payors, including their PBMs and government and private insurance plans, ultimately decide which medicines to make available to patients through their plans in part based on the discounts and rebates we give them for each of our medicines. **In 2022 in the U.S., across all insulin medicines, Sanofi returned 84 percent of our gross insulin sales to payors as rebates.**

Due to increased competition, including from biosimilars, the growth of rebates for insulins has been significant. Sanofi is committed to making transparent both the average aggregate list and net price changes across its portfolio to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain, highlighting our discrete role in the broader U.S. health care environment and enabling a better-informed discussion on solutions to improve patient access and affordability. Between 2012–2022, the net price for commercial insurance and Medicare Part D plans for our most prescribed insulin, Lantus®, has fallen by 55 percent. **In fact, the average net price of Lantus® is lower today than it was in 2004.**



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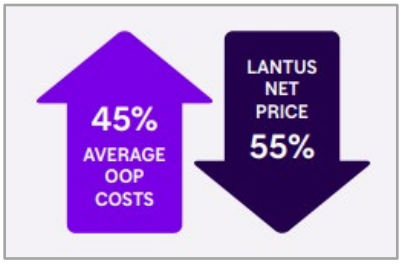
B. The Growing Disconnect Between Net Prices and Patient Out-Of-Pocket Costs

Unfortunately, there is a growing disconnect between net prices and patient out-of-pocket costs.

Indeed, despite the significant decrease in net price, the average out-of-pocket costs for Lantus® for patients with commercial insurance and Medicare have risen approximately 45 percent since 2012. Although PBMs frequently pass rebates on to their plan clients, health plans are placing more of the cost burden on patients through benefit designs that include high deductibles, coinsurance, and multiple cost-sharing tiers—often coupled with narrower drug formularies offering fewer choices in covered medicines.



For individuals on health plans provided by employers, average patient spending on deductibles has increased by 61 percent from 2012 to 2022.[5] Such high cost-sharing, particularly for highly rebated therapies like insulin, creates a financial barrier for patients, making it difficult to obtain essential treatments without the manufacturer's financial assistance programs. Rather than lowering out-of-pocket costs for medicines, plans often use rebates to subsidize premiums or other costs. As a result, the chronically ill in this country subsidize insurance costs for the healthy.

At the same time, there has been significant consolidation across the system. As a result, PBMs, insurers, wholesalers, specialty and retail pharmacies, group purchasing organizations, and, more recently, provider groups, are now increasingly under common corporate ownership, with three consolidated entities now covering 80% of American lives.

In addition to rebates, many of these intermediaries require manufacturers to pay fees, and other payments based on a percentage of a medicine's list price which are increasing in scope and amount. Today, we pay administrative fees, data fees, and GPO fees, among others, to ensure access to our medicines. Over the past 10 years, both the scope and quantity of these fees have grown and are an increasing source of revenue for the various intermediaries in the system[6].

Can the system do more to use the value extracted from manufacturers to lower costs for all patients at the pharmacy counter? We believe the answer is yes. We support policies requiring

[5] Kaiser Family Foundation (KFF), *2022 Employer Health Benefits Survey* (Oct. 27, 2022), https://www.kff.org/report-section/ehbs-2022-summary-of-findings/.
[6] https://wendellpotter.substack.com/p/unitedhealth-cvsaetna-cigna-pulled

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all fees to be calculated based on a flat payment, otherwise the incentive in the system of high list prices will continue.

C. Sanofi's Lower List Price Insulins

Sanofi's recent announcement regarding lowering the list prices of Lantus® and Apidra® is just the latest in a series of actions we have taken to introduce lower list price products. Sanofi has previously launched two insulin products at prices well below other available therapies, but as described below, our experience demonstrates that the current incentives in the system led to limited uptake of our lower list price options.

In 2018, Sanofi launched Admelog®, a follow-on biologic to Eli Lilly's Humalog®, at a list price that was 15 percent lower than the reference product. In July 2019, Sanofi reduced the list price of Admelog® by 44 percent and then again by another 25 percent in January 2022. Despite Admelog® launching at the lowest list price among mealtime insulins and subsequent list price cuts, we continue to see very limited coverage of Admelog® by PBMs and health plans.

Similarly, in June 2022, we launched the unbranded biologic Insulin Glargine Injection 100 Units/mL (U-100)—an insulin identical to Lantus®—at a list price 60 percent less than the 2022 list price of Lantus®. As with Admelog®, commercial and Medicare coverage for our unbranded Insulin Glargine Injection has been limited, with less than 25 percent of commercial and 5 percent of Medicare Part D plans choosing to cover the lower list price version in 2023, even though we offered this version at a similar net price to Lantus.

It appears that the reason these low-priced options have not had broad uptake in the system stems from the precise issues outlined above: because many intermediaries in the pharmaceutical supply chain require manufacturers to make payments based on a percentage of a medicine's list price, rather than as a flat fee, they generate more revenue from high list price medicines. These perverse incentives drive the system's preference for higher cost medications, even if some patients have to pay more out-of-pocket. Until there is a commitment by the full supply chain to make the system work better for patients or policies are enacted to remove these perverse incentives, the reality is that lower list prices will have limited benefit for patients and may lead to reduced coverage and access for lower-priced products.

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IV. Sanofi's US Affordability and Access Programs and Initiatives Related to Diabetes and Insulin

A. Sanofi's Affordability Programs and Initiatives

As stated above, systemic reform is necessary so that patients can access lower costs at the pharmacy counter. But these challenges have not stopped Sanofi from doing our part: within the confines of the system, we have developed and evolved a suite of innovative and patient-informed savings programs to help people reduce their prescription medicine costs, regardless of their insurance status or income level. Each of our programs is tailored to a specific population and designed within the parameters of U.S. legal and regulatory requirements. We broadly inform patients and providers about the availability of these programs through a number of different avenues and continue to look for additional ways to educate the public about their availability so that all eligible patients have access to them.

We are proud that our actions to improve access and affordability have benefited millions of patients, but we are not satisfied stopping here—we are continually listening to patients, patient advocates, caregivers, and others to better understand additional actions we could take to address ongoing and/or emerging access or affordability challenges. As we have done several times in the past, Sanofi will continue to review and evolve these programs to better serve and improve affordability for our diabetes patients.

1. Copayment Assistance Programs

Sanofi offers copayment assistance programs for its insulins and other products covered on commercial formularies. These programs aim to lower out-of-pocket costs for commercially insured patients regardless of income level, and eligible patients can enroll online or over the phone in only a few minutes.[7] Through these programs, in 2022, the majority of participating patients paid $15 or less for their diabetes medicines. Beginning January 1, 2024, all commercially-insured patients who fill their Lantus® prescriptions at participating pharmacies will be auto-enrolled in this program and will not pay more than $35 for a monthly supply.

In 2022, across Sanofi's diabetes medicines, patients used a Sanofi copay assistance card more than 582,000 times at the pharmacy counter, saving more than $70 million.

[7] US Department of Health and Human Services' Office of the Inspector General (HHS-OIG) has issued guidance stating its view that, under the federal Anti-Kickback Statute, manufacturers cannot offer co-pay support through manufacturer-sponsored programs for prescriptions covered by federal healthcare programs, such as Medicare and Medicaid. *See* HHS-OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (May 2014), *available at* https://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf. Consistent with this guidance, Sanofi does not make its co-pay card programs available to patients covered by federal healthcare programs. Sanofi supports policy changes that would expand these financial out-of-pocket support programs to all patients who might benefit from copay assistance.

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2. Insulins Val*you* Savings Program

In 2018, Sanofi launched the Insulins Val*you* Savings Program to lower out-of-pocket costs for uninsured patients who pay cash for their insulin. This program helps patients, regardless of income level, who are exposed to high out-of-pocket prices at the pharmacy counter and who do not qualify for Sanofi's free drug or other patient assistance programs. In June 2019, Sanofi expanded this program to provide eligible patients with a predictable and affordable monthly out-of-pocket cost for any combination of Sanofi insulins, regardless of the quantity they need.

Today, our Insulins Val*you* Savings Program allows uninsured patients with a valid prescription to buy any combination and amount of Sanofi insulins (Lantus®, Insulin Glargine Injection, Toujeo®, Admelog®, and Apidra®) for $35 per 30-day supply.[8] Eligible patients can enroll online or over the phone in only a few minutes.

In 2022, patients used the Insulin Val*you* Savings program more than 98,000 times, resulting in savings of almost $44 million.

3. Sanofi Patient Connection Free Drug Program

Sanofi Patient Connection is a patient assistance program (PAP) that provides free Sanofi medicines, including insulin,[9] to low- and middle-income patients earning ≤400% of the current Federal Poverty Level (in 2023, $120,000 for a family of 4), including Medicare beneficiaries, who meet eligibility criteria.

In 2022, more than 53,000 patients received free diabetes medicines through the PAP, valued at more than $185,000,000.

B. Sanofi's Efforts to Promote Awareness of its Affordability Programs

Sanofi has taken steps to increase awareness of these affordability programs so that as many eligible patients as possible may benefit from them. Sanofi includes descriptions about how to enroll in applicable affordability programs on each medication's website and on the Sanofi Patient Connection website. We also promote these assistance programs directly to patients through social media platforms and syndicated, direct-to-consumer advertisements in local newspapers and radio stations. Sanofi shares program information with patient advocacy groups which then publish that information on their websites and otherwise share program details with their members. Specifically, Sanofi meets with more than a dozen advocacy stakeholders at least quarterly to share information and updates about Sanofi's programs and other information that may benefit patients and to obtain feedback about affordability and access barriers.

[8] Additionally, through the Soliqua® co-pay card, uninsured patients can pay $99 per box of pens for up to two boxes of pens for a 30-day supply.

[9] Sanofi Patient Connection provides eligible patients with access to free supplies of Admelog®, Apidra®, Lantus®, Soliqua® 100/33, and Toujeo® SoloStar®, among other Sanofi medicines and vaccines.

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Sanofi also has partnered with other organizations to disseminate information about its affordability programs. For example, Sanofi's affordability programs are included in the Pharmaceutical Research and Manufacturers of America's (PhRMA) Medication Assistance Tool (MAT), a search engine designed to help patients, caregivers, and healthcare providers locate patient assistance resources offered by biopharmaceutical manufacturers. Information about Sanofi's affordability programs is also available at GetInsulin.org, an online tool created by the patient advocacy organization Beyond Type 1 to connect diabetes patients in the US with insulin access and affordability options, as well as other resources to support diabetes care and management that match a patient's particular circumstances. Lastly, information about Sanofi's affordability programs are accessible through GoodRx's platform and Optum Store's digital pharmacy platform.

C. Participation in the Part D Senior Savings Model

Before the Inflation Reduction Act (IRA) capped insulin out-of-pocket costs in Medicare, Sanofi worked with the Centers for Medicare and Medicaid Services (CMS) Innovation Center to support the creation of the Medicare Part D Senior Savings Model. Launched in January 2021, the Senior Savings program enabled Medicare beneficiaries to access insulins at a maximum $35 copay for a month's supply. Based on CMS's estimates, beneficiaries who used insulin and enrolled in a plan that participated in the Model could see an average out-of-pocket savings of $446 or 66 percent annually, funded in part by an estimated additional $250 million in discounts from manufacturers over the five years of the model.

V. Market-Based Policy Solutions to Address Patient Access and Affordability

Sanofi is committed to working with Congress and other stakeholders to identify market-based policy solutions that will incentivize a high-value and sustainable healthcare system that improves the affordability of innovative medicines in the U.S. and in which the patient truly benefits. By establishing policies that encourage competition and align incentives so the value driven by competition accrues to patients, we can accomplish our shared goal of lowering drug prices and patient costs, while also protecting and cultivating the entrepreneurial risk-taking necessary for pharmaceutical manufacturers to continue to discover, develop, and bring to market life-saving new medicines.

Reducing out-of-pocket costs for patients should remain a top priority, but as we have experienced, limiting launch prices or reducing the list price of medicines alone is not sufficient to solve this problem. We support Congress' recent reforms to the Medicare Part D benefit that cap patient out-of-pocket costs and allow beneficiaries to spread their payments across the benefit year. There are a number of additional policy options that could effectively reduce out-of-pocket costs for patients, including:

- Requiring at least a substantial portion of the discounts and rebates paid by manufacturers to be used to reduce costs for patients at the pharmacy counter (not simply passed through to plans, which is common today), such as requiring any coinsurance amounts be based on the net price and not the list price.

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- De-linking fees (e.g., wholesaler and retailer fees, and PBM and group purchasing organization (GPO) administrative fees) from list price, which would remove the perverse incentives that sometimes feed the cycle of higher list prices paired with higher rebates and fees and create impediments to patient access to lower list price medicines.

- Prohibiting commercial health insurance plans from misappropriating patient-directed savings through accumulator, maximizer, and alternative funding programs, and requiring commercial payers to designate all covered drugs as "essential health benefits" and count manufacturer copay coupons towards any plan deductible and/or out-of-pocket limit.

- Prohibit the use of spread pricing to save money and ensure everyone is getting the best deal possible.

- Let people get the medicines their doctors prescribe at a pharmacy that is most convenient for them, not one that makes the middleman more money.

Our shared goal of lowering drug costs while maintaining the innovation engine of the U.S. to bring novel, beneficial medicines to patients will not be fully realized if policies are enacted that solely target the list price of medicines. Without a holistic approach that addresses current system incentives favoring higher list prices, as well as common-sense patient protections paired with continued incentives for innovation, U.S. health system challenges, including access and affordability of medicines, will not be adequately addressed. For our part, we will continue to listen to patients, patient advocates, caregivers, and others to better understand additional actions we could take to address access and affordability.

* * *

I look forward to having a productive conversation about the complexities of the current system and policy solutions to improve affordable patient access to medicines.

Thank you for the invitation to speak with you today. I welcome the opportunity to work with you on this important issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC. ET AL., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL., Defendants.	2:23-cv-00836-MRH

[PROPOSED] ORDER

AND NOW this _____ day of _____, 202_, IT IS HEREBY ORDERED that Defendants Sanofi-Aventis U.S. LLC, Sanofi-Aventis Puerto Rico Inc., Sanofi S.A., and Aventis Pharma S.A.'s Motion to Dismiss the Plaintiffs' Complaint (ECF No. 49) is DENIED.

BY THE COURT:

Hon. Mark R. Hornak
Chief United States District Judge

Dated: