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

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC.	)	
Plaintiffs,	)	
v.	)	Civil Action No. 2:23-cv-836
SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS PUERTO RICO INC.	)	JURY TRIAL DEMANDED
Defendants.	)	*DOCUMENT FILED ELECTRONICALLY*

COMPLAINT

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Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. (collectively "Mylan") bring this Complaint against Sanofi S.A., Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi-Aventis Puerto Rico Inc. (collectively "Sanofi"), by and through their counsel, and allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief:

I. Nature of the Case

1. This is an antitrust action under the Sherman Act and state law claims arising out of Sanofi's illegal anticompetitive conduct to insulate, extend, and protect its monopoly over the injectable form of diabetes drug insulin glargine, commercially marketed in the United States by Sanofi as Lantus SoloSTAR and Toujeo.

2. Sanofi was always callously aware of the effects of its conduct. Materials made public by Congressional investigations are rife with admissions and acknowledgements. Indeed, the footer appearing on *every page* of at least one internal document discussing price increases warned "All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding."[1] However, Sanofi was armed with a plan to protect its monopoly power, ensuring Sanofi had the ability to confidently state:

- "Last year's sales goal was hit primarily because of two price increase [*sic*] totaling almost 18% growth in total revenue for Lantus."

[1] U.S. Committee on Oversight and Reform, Majority Staff Report, Drug Pricing Investigation: Selected Investigation Documents (Dec. 2021) at 217, https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/final-copy-packet-release.pdf (hereinafter "Drug Pricing Documents").

- "Sales of Lantus are critical to hitting the quarterly earnings expectations that keeps our stock price growing."
- "[insulin products] ranked #1 in cumulative YTD price increases (26.8%) out of the Top 25 most commonly dispensed drugs"[2]

Sanofi increased prices to supracompetitive levels as quickly as possible, and then ensured competition would not emerge that could either introduce downward pressure on prices or increase available output until Sanofi was able to move the market away from Lantus and to its Toujeo product.

3. Sanofi's multifaceted monopolization scheme includes three distinct parts, each of which is comprised of multiple types of separately illegal practices. First, Sanofi delayed regulatory approval of "generic" or biosimilar competition from Mylan through a pattern of regulatory abuse that combined improperly listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") a thicket of invalid and/or uninfringed patents with endless sham litigation to exploit the automatic stay derived from the improper Orange Book listings. Second, Sanofi wielded its Lantus market power to coerce payors to shift demand from Lantus to Toujeo, a therapeutically indistinguishable higher-dose version of Lantus. Sanofi accomplished this product shift by tying Lantus rebates to inclusion of Toujeo on commercial formularies and steering diabetes patients – new and existing alike – to forego the safety and stability of the imminently "genericized" Lantus product. Third, once Sanofi coerced enough of the market to adopt Toujeo (roughly 20% of Sanofi sales), the tying of rebates began to work in reverse, with Toujeo protecting Lantus, as payers could not accept a less expensive biosimilar Semglee™ at the expense of losing Toujeo rebates.

[2] Drug Pricing Documents at 221, 219.

4. Pattern of Regulatory Abuses. Beginning shortly before Lantus's legitimate loss of exclusivity, Sanofi embarked on a strategy to amass a thicket, or a collection of patents designed to deter competition by force of sheer size regardless of validity or strength, of invalid patents and to improperly list them in the Orange Book, which allowed Sanofi to trigger a statutory automatic stay of litigation that Sanofi could never have obtained without cheating the system. Sanofi's patents were all either invalid and/or uninfringed by Mylan, and none of these patents would have been enough to thwart competition by themselves. However, by combining a collection of these invalid patents into a patent thicket and then leveraging the Orange Book to ensure none could be challenged by an at-risk launch for at least 30 months, Sanofi created the perfect weapon to illegally maintain its monopoly: the otherwise inconsequential patents became unassailable, with competitors such as Mylan having no opportunity to prove their invalidity and/or non-infringement until Sanofi already achieved its objective to delay the regulatory approval process.

5. It is no exaggeration to say that Sanofi's post-2015 expiry patents could not have forestalled competition absent the Orange Book abuse. Mylan submitted notice letters to Sanofi regarding twenty-one Orange Book-listed patents purporting to cover Lantus, and Sanofi failed to prevail on a single claim of any of them. The demise of Sanofi's Orange Book patents took several routes – some Sanofi chose not to litigate or dropped shortly after filing a perfunctory Hatch-Waxman complaint; others Sanofi litigated through the *inter partes* review ("IPR") process before having each and every one of those patents invalidated; and still others Sanofi litigated and lost in federal court – but any loss by Sanofi paled in comparison to the benefit of forcing Mylan (and other would-be competitors) to languish in the judicial and regulatory systems, allowing Sanofi to continue raising prices and bilking customers.

6. The below table collects a list of the patents in Sanofi's insulin patent thicket listed in the Orange Book, along with a summary of which claims have been invalidated:

Patent No.	Patent Name	Final Outcome Vis-à-vis Mylan	Properly Listed in Orange Book?
First Notice Letter Patents			
7,476,652	Acidic Insulin Preparations Having Improved Stability	Determined invalid by the Patent Trial and Appeal Board ("PTAB") and affirmed by the Federal Circuit **Patent has since been cancelled**	Yes, but only for vials.
7,713,930	Acidic Insulin Preparations Having Improved Stability	Determined invalid by the PTAB and affirmed by the Federal Circuit **Patent has since been cancelled**	Yes, but only for vials.
7,918,833	Pen-Type Injector	Determined invalid by the Federal Circuit	No
8,512,297	Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
8,556,864	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay First Circuit determined Sanofi improperly listed the '864 patent in Orange Book	No
8,603,044	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings	No
8,992,486	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings PTAB findings affirmed by the Federal Circuit	No
9,011,391	Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
9,233,211	Relating to a Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
9,408,979	Pen-Type Injector	Covenant not to sue granted to Mylan after automatic stay	No
9,526,844	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings DNJ found Mylan did not infringe	No

		PTAB findings affirmed by the Federal Circuit	
9,533,105	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,561,331	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,604,008	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Most claims determined unpatentable by PTAB IPR proceedings and affirmed by the Federal Circuit	No
9,604,009	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,610,409	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,623,189	Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
8,679,069	Pen-Type Injector	Determined invalid by the PTAB and affirmed by the Federal Circuit	No
Second Notice Letter Patent			
9,775,954	Pen-Type Injector	Covenant not to sue granted to Mylan	No
Third Notice Letter Patent			
9,827,379	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan	No
Fourth Notice Letter Patent			
9,717,852	Cartridge Holder and Pen-Type Injector	Covenant not to sue granted to Mylan	No

7. Sanofi listed each and every patent in the above table in the FDA Orange Book, triggering the protections afforded by the Hatch Waxman Act. In reality, the only patents plausibly listed properly in the Orange Book were the 7,476,652 and 7,713,930 patents – the polysorbate patents – and only with respect to insulin vials (not injector pens, which do not contain polysorbate). Any other Orange Book listing was improper and done with the specific intent to monopolize the

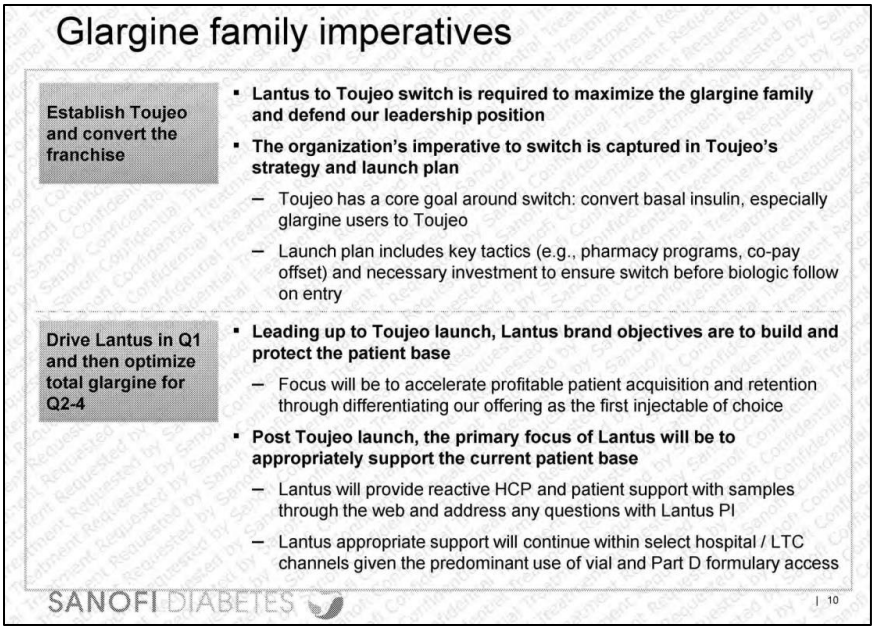
market for injectable insulin glargine and prevent competition in violation of the Sherman Act and state laws. The polysorbate patents were improperly listed in the Orange Book to the extent that listing included insulin injector pens because those patents did not cover injector pens.

8. Coercive Market Switch. Sanofi engaged in coercive tactics to switch the market from Lantus (for which Sanofi expected it would lose exclusivity by 2017) to the therapeutically indistinguishable Toujeo. As the United States House of Representatives Committee on Oversight and Reform unearthed in its landmark 2021 report entitled *Drug Pricing Investigation: Majority Staff Report* (December 2021) (hereinafter "Drug Pricing Report"),[3] "[d]ocuments obtained by the Committee reveal[ed] new evidence of Sanofi's product-hopping strategy to switch patients from its long-acting insulin Lantus, as it neared the end of its patent exclusivity period, to Toujeo, a more recently patented formulation of the drug . . . . Sanofi hoped to extend the company's market share of its basal insulin franchise and get patients committed to their new branded product before biosimilar Lantus competitors entered the market." Drug Pricing Report at 114.

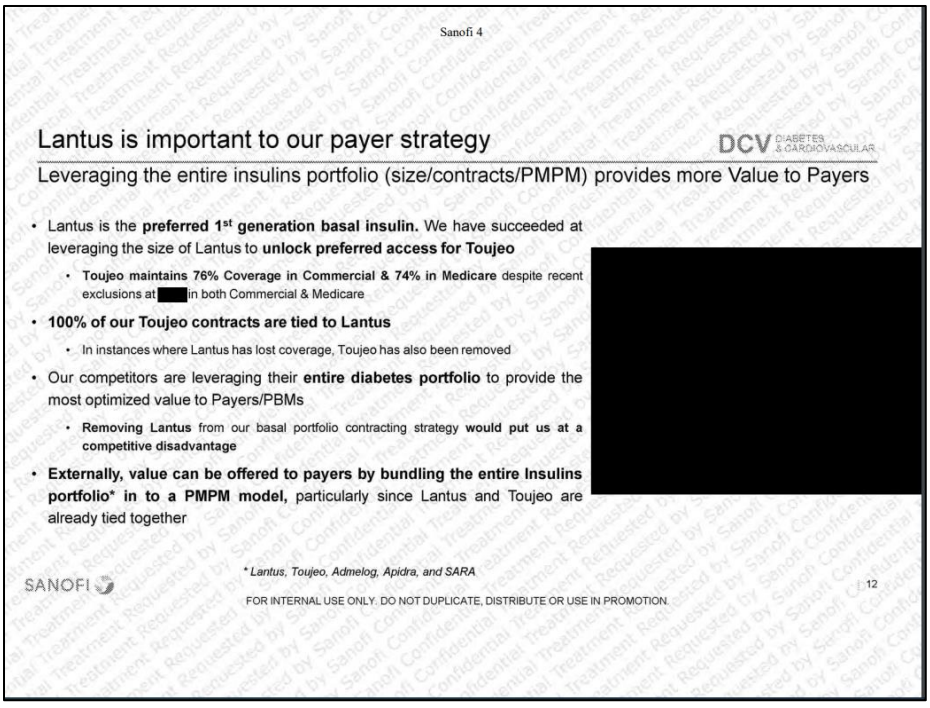
9. Sanofi's desire to switch to Toujeo was urgent by the time it received FDA approval. In a 2015 Operational Plan and Budget, Sanofi acknowledged the need to "defend our leadership position" by switching patients to Toujeo "before biologic follow on entry.":[4]

[3] U.S. Committee on Oversight and Reform, Majority Staff Report, Drug Pricing Investigation (Dec. 2021) https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (hereinafter "Drug Pricing Report").

[4] Drug Pricing Documents at 230.



10. Sanofi's stated goal was achieved, namely "leveraging the size of Lantus to unlock preferred access for Toujeo" because "100% of our Toujeo contracts are tied to Lantus.":[5]



[5] Drug Pricing Documents at 225.

11. Sanofi accomplished this coercive switch by weaponizing pharmaceutical supply chain intermediaries called Pharmacy Benefit Managers, or PBMs, to steer prescribers and patients away from Lantus and to Toujeo. Sanofi priced Toujeo "at parity" with Lantus and then conditioned rebates for Toujeo on PBMs' agreement to exclude biosimilar insulin glargine products from formularies. Sanofi explained both its motivation and execution:

> Glargine Brand Objective: Protect glargine family access from increasing payer control and disrupt competitive access to maintain the broadest Tier 2 coverage . . . . Commercial Channel Strategy: Leverage market leader position of the glargine franchise to maintain current preferred access and manage profitability . . . all offers contingent upon all forms of Lantus, Lantus SoloStar and Toujeo being on preferred brand formulary tier.[6]

12. Sanofi knew that that "premium pricing [for Toujeo] [would] impede access" to formularies because "there [were] few unmet needs with [Sanofi's] current basal therapy" and "Toujeo is seen as a parity product to Lantus" because "payers believe there are few unmet needs with the current basal therapy [i.e., Lantus]" and the "differentiation may not be meaningful enough to warrant preferred access" [i.e., payers are not willing to pay for Toujeo]:[7]

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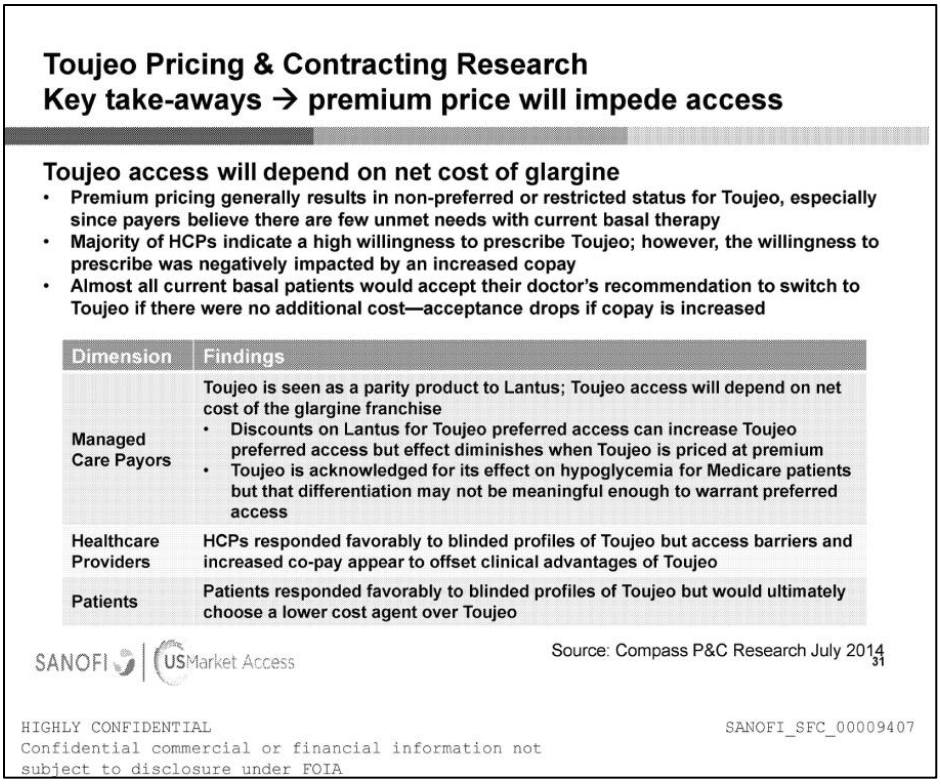
[6] U.S. Senate Finance Committee, Documents Produced by Sanofi in Insulin Investigation at 316 (2021), https://www.finance.senate.gov/imo/media/doc/Sanofi_Redacted.pdf (hereinafter "Insulin Report Documents").

[7] Insulin Report Documents at 174.



Toujeo Pricing & Contracting Research
Key take-aways → premium price will impede access

Toujeo access will depend on net cost of glargine

- Premium pricing generally results in non-preferred or restricted status for Toujeo, especially since payers believe there are few unmet needs with current basal therapy
- Majority of HCPs indicate a high willingness to prescribe Toujeo; however, the willingness to prescribe was negatively impacted by an increased copay
- Almost all current basal patients would accept their doctor's recommendation to switch to Toujeo if there were no additional cost—acceptance drops if copay is increased

Dimension	Findings
Managed Care Payors	Toujeo is seen as a parity product to Lantus; Toujeo access will depend on net cost of the glargine franchise • Discounts on Lantus for Toujeo preferred access can increase Toujeo preferred access but effect diminishes when Toujeo is priced at premium • Toujeo is acknowledged for its effect on hypoglycemia for Medicare patients but that differentiation may not be meaningful enough to warrant preferred access
Healthcare Providers	HCPs responded favorably to blinded profiles of Toujeo but access barriers and increased co-pay appear to offset clinical advantages of Toujeo
Patients	Patients responded favorably to blinded profiles of Toujeo but would ultimately choose a lower cost agent over Toujeo

SANOFI | US Market Access

Source: Compass P&C Research July 2014

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13. Pairing Lantus and Toujeo distinguishes Sanofi's conduct from single-product rebating practices and was critical for Sanofi for two reasons: first, it effectuated a product shift to Toujeo that would not have been possible had a less expensive version of Lantus been available by itself given what Sanofi considered minor differences between the two products; and second, it permitted Sanofi to bundle Toujeo with Lantus and thereby made it impossible for any equally efficient single-product competitor like Mylan to compete. In other words, Sanofi illegally extended its market power from Lantus to Toujeo, and now continues to maintain its market power over insulin glargine by tying the two together through rebates. Sanofi engineered the shift from Lantus to Toujeo solely to evade "generic" competition and further prolong higher prices for payers, federal and state governments, and ultimately consumers.

14. Leveraging the Tie to Protect Lantus. Initially Sanofi used conditional rebates to leverage the market power of Lantus to drive adoption of Toujeo. 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. Indeed, this was always the plan, as evidenced by Sanofi's own materials published as part of the Insulin Report Documents[8]:

- "Reassert Lantus' leadership position to secure and accelerate volume growth in light of the aggressive market challenges, Toujeo launch and biosimilar defense"
- "Lantus to Toujeo switch is required to maximize the glargine family and defend our leadership position"
- "Toujeo has a core goal around switch: convert basal insulin, especially glargine users to Toujeo."
- "[T]he primary focus of Lantus will be to appropriately support the current patient base."
- "Launch plan includes key tactics (e.g., pharmacy programs, co-pay offset) and necessary investment to ensure switch before biologic follow on entry"
- "Establish Toujeo and convert the franchise"
- "Externally, value can be offered to payers by bundling the entire Insulins portfolio* in to a PMPM model, particularly since Lantus and Toujeo **are already tied together**" (emphasis added)

In other words, Sanofi was aware that Lantus would lose its importance strategically for the overall franchise and become the protected product rather than the protecting product.

15. Having Lantus and Toujeo "tied together" proved an insurmountable barrier to competition when Mylan launched its biosimilar Semglee product in 2020. For over a year Mylan's less expensive biosimilar remained effectively excluded from commercial and noncommercial formularies and out of the reach of patients.

16. In the fall of 2021, more than nine years after Mylan embarked on its journey to bring price relief to diabetes patients, and only after achieving interchangeability for its injectable

[8] For the Report *see* U.S. Senate Finance Committee, Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug (2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf (hereinafter "Insulin Report").

insulin glargine product, Mylan was finally able to reach competitively meaningful agreements with some payers.

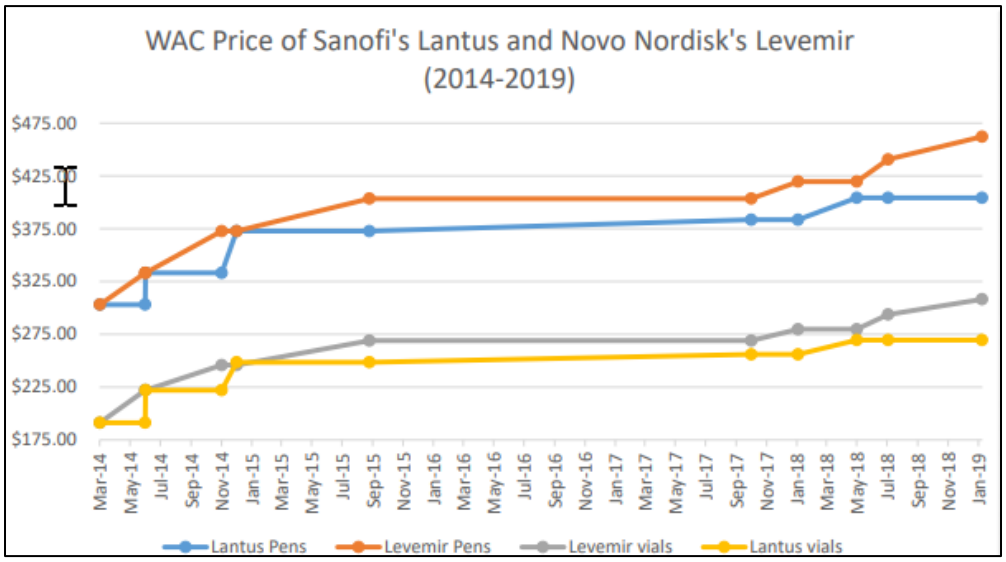
17. Sanofi continues to offer steep rebates to payers only if they include all Sanofi injectable insulin glargine products on preferred tiers. While Sanofi's current rebating values are not public, public sources reveal that Sanofi offered rebates of 60%-70% for Toujeo for large PBMs in 2018; at that time, Toujeo had a list of over $300 per box. It was economically impossible for a single product manufacturer to cover this difference in a vacuum.

18. Sanofi's unscrupulous conduct to protect and prolong its monopoly power has been lucrative. In 2014, the year before Toujeo received FDA approval and the last full year of Sanofi's lawful patent exclusivity, Lantus generated revenues in the United States of approximately €4.225 billion.[9] In 2015, Sanofi should have faced "generic" competition and seen its revenues drop precipitously. Instead, Sanofi's revenues remained artificially high as the company moved the focus of its business to Toujeo, which ended 2020 as more than 20% of Sanofi's insulin glargine sales.

[9] Sanofi-Aventis N/A, Form 20-F (2015), https://www.sanofi.com/dam/jcr:1e369ccf-81c3-4b14-9341-5678af63aa4c/Sanofi_20-F_2015_V2.pdf. Note that because Sanofi Aventis is based in France, it reports financial results in Euros. Though the exchange rate for Dollars and Euros varies every year and in fact every day, the average closing price always remained between 0.97-1.33 Dollars/Euros.

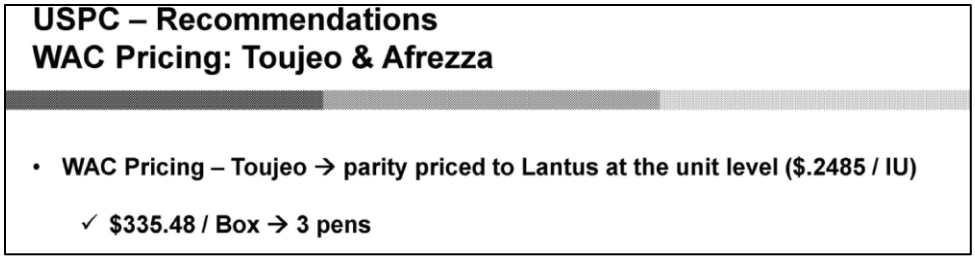
Sanofi Lantus/Toujeo Percentage of Insulin Glargine Sales in the United States		
	Lantus % of Sales	**Toujeo % of Sales**
2014	100 %	N/A
2015	96.7 %	3.29 %
2016	88.13 %	11.87 %
2017	84.82 %	15.18 %
2018	82.43 %	17.57 %
2019	79.90 %	20.10 %
2020	77.68 %	22.32 %

19. Despite the staggering numbers, Sanofi's financials understate the company's dominance. Even as Sanofi transitioned patients to Toujeo, it continued increasing the wholesale acquisition cost, or WAC, for Lantus, as reported by the Insulin Report:[10]



20. Of course, because Sanofi committed to a strategy of "parity pricing" for Lantus and Toujeo, this strategy ensured the continued increase in WAC for Toujeo as well.[11]

[10] Insulin Report at 43.
[11] Insulin Report Documents at 145.



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. As one example, Mississippi alleged that Sanofi participated in a scheme whereby it "reported exaggerated prices, knowing that other entities, including the State, relied on these prices" and that these "prices have become so untethered from the actual prices [] that they constitute a false price." *Mississippi, ex rel. Fitch v. Eli Lilly et al.*, 2022 U.S. Dist. LEXIS 141284 (S.D. Miss. Aug. 22, 2022). As of the filing of this complaint, Sanofi faces the following insulin-related litigations:[12]

[12] *Mississippi, ex rel. Fitch v. Eli Lilly et al.*, No. 3:21-cv-00674 (S.D. Miss.); *Arkansas, ex rel. Rutledge v. Eli Lilly et al.*, No. 4:22-cv-00549 (E.D. Ark.); *County of Albany, New York v. Eli Lilly et al.*, No. 1:22-cv-00981 (N.D.N.Y.); *Montana, ex rel. Knudsen v. Eli Lilly et al.*, No. 6:22-cv-00087 (D. Mont.); *Kansas, ex rel. Schmidt v. Eli Lilly et al.*, No. 5:23-cv-04002) (D. Kan.); *Illinois, ex rel. Raoul v. Eli Lilly et al.*, No. 1:23-cv-00170 (N.D. Ill.); *California v. Eli Lilly et al.*, No. 2:23-cv-01929 (C.D. Cal.); ; *Jackson County, Missouri v. Eli Lilly and Co. et al.*, No. 4-23-cv-00206 (W.D. Mo.); *Government of Puerto Rico et al. v. Eli Lilly and Co. et al.*, No. 3:23-cv-01127 (D.P.R.); *Louisiana ex rel. Landry v. Sanofi-Aventis U.S. LLC et al.*, No. 3:23-cv-00302 (M.D. La.); *Lake County, Illinois v. Eli Lilly and Co. et al.*, No. 1:23-cv-024-2 (N.D. Ill.).

Competition Cases Against Sanofi regarding Insulin Glargine	
In re Lantus Direct Purchaser Litigation (filed 12/30/2016)	In discovery; dismissal reversed and remanded in 2/13/2020
In re Indirect Purchaser Insulin Pricing Litigation (filed 2/2/2017)	In discovery
In re Direct Purchaser Insulin Pricing Litigation (filed 3/30/2020)	In discovery
Mississippi (filed 6/7/2021)	Motion to dismiss denied; in discovery
Arkansas (filed 5/11/2022)	Motion to dismiss pending
Albany County (NY) (filed 9/16/2022)	Motion to dismiss pending
Montana (filed 9/29/2022)	Motion to dismiss pending
Kansas (filed 12/2/2022)	Motion to dismiss pending
Illinois (filed 12/2/2022)	Motion to dismiss pending
Jackson County (MO) (filed 1/11/2023)	Motion to dismiss not yet briefed
California (filed 1/12/2023)	Motion to dismiss not yet briefed
Government of Puerto Rico (filed 1/24/2023)	Motion to dismiss not yet briefed
Louisiana (filed 3/14/2023)	Motion to dismiss not yet briefed
Lake County (IL) (filed 4/18/2023)	Motion to dismiss not yet briefed

22. Regardless of the eventual legality of these practices, Sanofi would not have been able to pursue this strategy in a world where it faced timely "generic" competition, as it would have faced absent the illegal conduct alleged herein. And without this strategy, Sanofi would not have been able to shift the market to its Toujeo product or condition lucrative rebates on this therapeutically indistinguishable product.

23. This suit, brought under federal antitrust laws and state laws, seeks to recover damages for lost sales of Mylan's "generic" or biosimilar insulin glargine product that would have occurred but for Sanofi's illegal exclusionary conduct.

II. Parties

24. Plaintiff Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

25. Plaintiff Mylan Specialty L.P. is a limited partnership registered in Delaware. Mylan Specialty L.P. has its business address at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

26. Plaintiff Mylan Inc. is a corporation incorporated in Pennsylvania with its principal place of business located at 1000 Mylan Boulevard in Canonsburg, PA 15317. Mylan Inc. is the parent company of Mylan Pharmaceuticals Inc. and Mylan Specialty L.P. The complaint refers to Mylan Pharmaceuticals, Inc., Mylan Specialty L.P., and Mylan Inc. as "Mylan."

27. On information and belief, Defendant Sanofi S.A. is a corporation, organized and existing under the laws of France, with its principal place of business at 54 Rue La Boetie, 75008, Paris, France.

28. On information and belief, Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

29. On information and belief, Aventis Pharma S.A. is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

30. On information and belief, Defendant Sanofi-Aventis Puerto Rico Inc. ("Sanofi PR") is a corporation organized under the laws of Puerto Rico and is a wholly owned, indirect subsidiary of Sanofi, a société anonyme organized under the laws of, and doing business in, France.

Its principal place of business is Metro Office Park, Edificio De la Cruz #9, Suite 100, Guaynabo, Puerto Rico 00968.[13]

31. This complaint refers to each Defendant and all Defendants collectively as "Sanofi."

III. Jurisdiction and Venue

32. This action arises under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a). The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. §§ 4 and 15.

33. This Court has personal jurisdiction over Sanofi.

34. During the course of Sanofi's anticompetitive scheme, Sanofi manufactured, sold, and shipped insulin glargine, including its flagship products Lantus SoloSTAR and Toujeo in an uninterrupted flow of interstate commerce.

35. Sanofi has transacted business, maintained systemic and continuous business contacts, and/or committed overt acts in furtherance of its illegal scheme in this district and throughout the United States generally.

36. Sanofi's scheme was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business in this district and throughout the United States generally.

37. Venue is proper in this district under 28 U.S.C. § 1391 (general venue provisions) and 15 U.S.C. §§ 15(a), 22 (nationwide venue for antitrust matters).

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[13] Sanofi lists hundreds of subsidiaries and affiliates on its websites. *See* List of Sanofi affiliates, https://www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy/list-of-sanofi-affiliates.

38. A substantial part of the events giving rise to this claim occurred in this district.

39. Sanofi's conduct was within the flow of, was intended to, and did have a substantial effect on, interstate commerce in the United States, including in this district.

40. During the alleged time period, Sanofi manufactured, sold, and shipped insulin glargine, including Lantus SoloSTAR and Toujeo, in an uninterrupted flow of interstate commerce.

41. Sanofi transacts business within this district, carries out interstate trade and commerce in this district, and/or its agents may be found in this district. The scheme in which Sanofi participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

42. Sanofi caused harm or injury to Mylan by acts or omissions in Pennsylvania and this district through overt acts in furtherance of the illegal scheme.

IV. Statement of Facts

A. Statutory and Regulatory Background

43. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

44. During the periods relevant here, section 505 of the Act described three pathways for approval of drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form,

strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)).

45. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must contain scientific data demonstrating that a drug is safe and effective.

46. A company must identify and ask the FDA to list certain types of patents – patents covering the drug product and methods of use – in a volume known as the Orange Book. The FDA is required by law to list any patents that are identified by the NDA applicant. The FDA does not (and, indeed cannot) evaluate for itself whether those patents can be listed at all or are properly listed for the NDA to which they are associated.

47. The NDA holder may list in the Orange Book any patents that (i) claim the drug or a method of using the drug, and (ii) reasonably could be asserted against a would-be competitor seeking to make, use, or sell a competing version of the brand drug.

48. Once any patent is listed, a would-be competitor must notify the brand company if the competitor intends to sell the product. That gives the brand company the opportunity to sue and potentially delay FDA approval of the competing product for thirty months.

49. The FDA relies completely on the brand manufacturer's truthfulness about whether a patent claims the drug product or a method of using the drug product and about whether an infringement claim could reasonably be asserted against a competitor – i.e., whether the patent is valid, enforceable, and actually claims the NDA product or a method of using it. The FDA does not have the resources, specialization, or legal authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA performs merely a ministerial act.

50. The Supreme Court has confirmed the FDA's ministerial role with respect to the Orange Book. In *Caraco Pharm. Labs v. Novo Nordisk*, the Court explained "[t]he FDA takes [the use description provided by a brand when listing a patent in the Orange Book] as a given: It does not independently assess the patent's scope or otherwise look behind the description authored by the brand. According to the agency, it lacks 'both [the] expertise and [the] authority' to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own 'role with respect to patent listing is ministerial.'" 566 U.S. 399, 406-07 (2012).

51. The Hatch-Waxman Act also permits drug manufacturers to streamline the NDA process by relying on already-conducted scientific studies, rather than incurring the expense and burden of redoing the studies from scratch. This is codified in § 505(b)(2).

52. A 505(b)(2) application is an NDA. But, unlike other NDAs, applications submitted under this pathway need not contain voluminous, expensive studies and data developed by the drug sponsor, and instead may rely on studies and data provided by an original sponsor under § 505(b)(1). A § 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." 21 U.S.C. 355(b)(2).

53. An applicant needs to provide a scientific "bridge" to demonstrate the relationship of the referenced and proposed products. For example, the applicant may conduct bioavailability or bioequivalence studies to establish a bridge and establish that the proposed product is a pharmaceutical alternative.

54. Pharmaceutical alternatives are drug products that contain the identical therapeutic ingredient, but not necessarily in the same amount, dose, or form. A pharmaceutical alternative is

held to the same standards of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. 21 C.F.R. § 320.1(d).

55. Generally, any differences in rate and extent of absorption should be reflected in the labeling of the 505(b)(2) product. The proposed product does not need to be shown to be clinically better than the previously-approved product. Nor does it need to be bioequivalent.

56. In 2010, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA") to establish a fourth pathway for FDA drug approval for "biosimilar" drugs. But this pathway is available only if the brand biologic product is approved, or "licensed," under the Public Health Service ("PHS") Act. Biologics approved under the FDCA, like insulin glargine, enjoy the same efficiencies of approval as biosimilars under the 505(b)(2) pathway. *See* § 7002(e) of the Affordable Care Act ("ACA").

57. Section 505(b)(1) of the FDCA and FDA regulations require that a sponsor of an NDA submit to the FDA a list of patents claiming either the approved drug substance or drug product, or an approved method of using the drug product described in the NDA.

58. Specifically, section 505(b)(l) of the Act requires NDA applicants to file as part of the NDA,

> the patent number and the expiration date of any patent <u>which claims the drug</u> for which the applicant submitted the application <u>or which claims a method of using such drug</u> and with respect to <u>which a claim of patent infringement could reasonably be asserted</u> if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[14]

[14] 21 U.S.C. § 355(b)(l) (emphasis added).

59. If an NDA applicant obtains additional patents that claim the drug or a method of using the drug after its NDA obtains approval, section 505(c)(2) requires the prompt submission of that patent information.[15]

B. The Orange Book

60. In October 1994, the FDA issued final rules addressing the submission of patent information. The rule clarified that statutory language referring to patents "which claim the drug" or "a method of using such drug" consist only of "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,344 (Oct. 3, 1994) (new and final rule publishing text of newly created § 314.53, "Submission of patent information," and responding to comments regarding that section). The FDA admonished that "[f]or patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product." And it admonished that, for method-of-use patents, "the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." *Id.*

[15] 21 U.S.C. § 355(c)(2) (emphasis added) ("If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent *which claims the drug for which the application was submitted or which claims a method of using such drug* and with respect to which a claim of *patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").

61. The rule set forth the patent information a drug sponsor must provide, including "the type of patent, i.e., drug, drug product, or method of use" and the patent's expiration. 21 C.F.R. § 314.53(c)(1).

62. The rule also required a specific declaration for formulation, composition, and/or method-of-use patents stating: "The undersigned declares that Patent No. _____ covers the formulation, composition, and/or method of use of (name of drug product). This product is (currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act) [or] (the subject of this application for which approval is being sought): _____." *Id*. at § 314.53(c)(2)(i). The declaration had to be signed by "the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative) or other authorized official." *Id*. at § 314.53(c)(4).

63. During its rulemaking, the FDA considered and rejected the argument that the FDCA required NDA applicants to provide only patent numbers and patent expiration dates. The FDA explained that requiring additional patent information was consistent with the purposes of the Act, particularly in light of the FDA's lack of patent expertise:

> FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements under § 314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.[16]

[16] Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,345 (Oct. 3, 1994) (new and final rule).

64. The FDA likewise considered and rejected a comment suggesting that there was no need to identify a patent according to whether it claimed a formulation, composition, or method-of-use – that comment "suggested deleting the proposed rule's classification of patents and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement . . . ." The FDA concluded that NDA applicants should identify which claims cover the drug or drug product and which claims cover a method of use:

> *FDA acknowledges that a patent may contain a variety of claims*, and has revised proposed § 314.53(c)(2) by creating a single certification statement . . . . However, because section 505(b)(1) of the act specifically requires applicants to 'file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug,' and because FDA lacks patent law expertise, the agency strongly encourages applicants to identify, to the best of their ability, the type of patent covering the drug or drug product. This information will help FDA determine *which claims cover the drug or drug product and which claims cover a method of use*.[17]

65. Elsewhere in the commentary accompanying the amendment, the FDA stated:

> FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims.[18]
>
> The requirement in § 314.53(b) and (c) that applicants provide information on the type of patent … is consistent with the purpose of section 505(b)(1) of the act.[19]
>
> The statute expressly requires applicants to file 'the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application . . . (section 505(b)(1) of the act). Thus, if the

[17] *Id.* at 50, 343-44 (emphasis added).
[18] *Id.* at 50, 343.
[19] *Id.*

> formulation patent claimed the drug product in the application, the applicant must file information on that patent. [20]

66. On June 18, 2003, the FDA amended § 314.53 "to help ensure that NDA applicants submit only appropriate patents."

67. A drug product with an effective approval under section 505(c) of the Act is known as a *listed drug*.

68. As described above, the Act permits submission of 505(b)(2) or 505(j) applications for generic versions of listed drugs. Both processes shorten the time and effort needed for approval by, among other things, allowing applicants to rely on the FDA's previous finding of safety and effectiveness for a listed drug. Each applicant must identify the listed drug on which it seeks to rely for approval.

69. The timing of 505(b)(2) and Abbreviated New Drug Applications ("ANDA") approvals depends on, among other things, the intellectual property protections for the listed drug that the 505(b)(2) or ANDA application references and whether the applicant challenges those protections (*see* sections 505(b)(2), (c), (j)(2)(A)(vii), and (j)(5)(B) of the Act). In general, a would-be competitor who has submitted a 505(b) application or ANDA may not obtain final approval until listed patents and any marketing exclusivity have expired or until NDA holders and patent owners have had the opportunity to assert and defend relevant patent rights in court.

70. With respect to each patent submitted by the sponsor and listed in the Orange Book for the listed drug, a 505(b)(2) applicant generally must submit to FDA one of four specified

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[20] *Id.* at 50, 344

certifications under section 505(b)(2)(A) of the Act. The certification must state one of the following.

> (I) That the required patent information relating to such patent has not been filed ("paragraph I certification").
>
> (II) That such patent has expired ("paragraph II certification").
>
> (III) That the patent will expire on a particular date ("paragraph III certification").
>
> (IV) That such patent is invalid or will not be infringed by the drug for which approval is being sought ("paragraph IV certification").

71. The purpose of these certifications is "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of infringement can be resolved as quickly as possible." *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003).

72. If an applicant files a paragraph I or II certification, the patent in question will not delay application approval. If an applicant files a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking full effective approval of its application.

73. If the patent has not expired, but the applicant believes its product does not infringe any valid listed patent, a paragraph IV certification may be filed as to substance or formulation patents. (Product method-of-use claims have special procedures not relevant here).

74. As described, a 505(b)(2) applicant may seek FDA approval before expiry of all Orange Book listed patents by filing a paragraph IV certification stating that a listed patent "is invalid or will not be infringed by the manufacturer, use, or sale of the [applicant's] drug." 21 U.S.C. 355(b)(2).

75. The applicant filing a paragraph IV certification must also provide notice to the NDA holder and the patent owner stating that it has submitted an ANDA with a paragraph IV

certification and explaining the factual and legal bases for the applicant's opinion that the patent is invalid or not infringed (*see* section 505(b)(2)(B) and (j)(2)(B) of the Act).

76. Filing a paragraph IV certification can provoke litigation. The patent statute treats such filing as an act of technical infringement and provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the patent owner or NDA holder brings a patent infringement suit against the 505(b)(2) applicant within 45 days of the date it received notice of the paragraph IV certification, the approval of the 505(b)(2) application will automatically be stayed for 30 months or less if the patent litigation is resolved sooner. *See* FDCA §§ 505(c)(3)(C) & (j)(5)(B)(iii). When the 30 months have expired, the patent ceases to be a barrier to final FDA approval, even if the patent litigation is ongoing. Similarly, if the patent owner or NDA holder receives notice of a paragraph IV certification and does not sue within 45 days of receipt of notice, the patent will not be a barrier to FDA final approval.

77. If the branded drug manufacturer initiates a patent infringement action against its would-be competitor within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the 505(b)(2) applicant's product.

78. Until one of those conditions occurs, the FDA may grant "tentative approval" but cannot grant "final approval," which would authorize the 505(b)(2) applicant to market its product. The FDA may grant a 505(b)(2) application tentative approval when it determines that the application would otherwise be ready for final approval were it not for the regulatory 30-month stay. Tentative approval is granted only when the applicant satisfies all scientific and procedural preconditions to final approval.

79. At bottom: under the procedures established in the Hatch-Waxman Amendments, a 505(b)(2) application will not be approved until all listed patents: (l) have expired; (2) have been subject to a paragraph IV certification pursuant to which the patent owner or NDA holder has declined to sue within 45 days; or (3) have been subject to a paragraph IV certification that led to a lawsuit and either (i) a decision favorable to the applicant was reached, or (ii) the automatic 30-month stay that issued upon the filing of suit has expired.

C. The Effect of Follow-on Generic Drugs or Biosimilars on Competition

80. Generic and biosimilar drugs typically are sold at substantial discounts from the price of the brand drug. As additional companies enter the market, these later entrants drive down prices further, hoping to take market share from earlier generic entrants by competing on price. A 2017 study commissioned by the Association for Accessible Medicines ("AAM") found that while brand drug prices generally increased by over 200% between 2008 and 2016, generic drug prices generally decreased by approximately 75% during this period.[21]

81. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry, the launch of a generic product can result in the rapid shift of purchasers from brand to generic. Pharmacists often substitute the generic drug when presented with a prescription for the brand drug. Since passage of the Hatch-Waxman Act, states have adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for brand drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

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[21] Association for Accessible Medicines, *Generic Drug Access & Savings in the U.S.* (2017), http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

D. Sanofi's Development and Launch of Lantus

82. In August of 1997, the Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,656,722 ("the '722 patent") for insulin glargine to a German inventor. The patent was assigned to Hoechst AG, a German chemicals life-sciences company that became Aventis Deutschland after a merger with France's Rhône-Poulenc S.A. in 1999. With the new company's 2004 merger with Sanofi-Synthélabo, it became a subsidiary of the resulting Sanofi-Aventis pharmaceuticals group.

83. The '722 patent claimed insulin glargine and also disclosed the addition of zinc, m-cresol, glycerol, water, and pH adjusted by solutions of hydrochloric acid (HCl) and sodium hydroxide (NaOH), as used in the Lantus formulations approved by the FDA in April 2000.

84. The '722 patent expired on August 12, 2014.

85. Pursuant to FDA regulation, Sanofi earned an additional period of pediatric exclusivity extending to February 12, 2015.

86. On or about April 20, 2000, the FDA approved NDA No. 21-081 for Lantus (insulin glargine [rDNA origin] injection).

87. Sanofi listed the '722 patent in the Orange Book.

88. Lantus is a sterile solution of insulin glargine for use as an injection.

89. As first approved, Lantus was indicated for once-daily subcutaneous administration at bedtime in the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. Its potency is approximately the same as human insulin, and it exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing.

90. When Lantus was approved by the FDA in April 2000, it had two package forms: (1) vials (5 and 10 mL) for use with single-dose syringes, and (2) cartridges (3 mL) for use in an

injector pen Sanofi called "OptiPen™ One." Different pens are marketed for use by diabetic patients to inject their insulins.

91. At some point on or about the time of approval of Lantus, Sanofi caused the '722 patent to be listed in the Orange Book. 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 in 5 mL and 10 mL amounts), and "injection" with an OptiClick injector pen (i.e., the "cartridge formulation"). The '722 patent claimed the drug substance and drug product contained in both the injectable and injection formulations.

92. After approval by the FDA of NDA No. 21-081, in May 2001, Sanofi launched Lantus for sale in the United States. Lantus was prescribed and sold in the United States from May 2001 through the present.

93. From the launch of Lantus in May 2001 through February 2015, sales of the product were protected by the '722 patent and its listing in the Orange Book. As a result, the sales of Lantus were protected for almost 15 years – from launch until February 2015 – from competition from "generic" or biosimilar glargine products.

94. During Sanofi's period of lawful exclusivity, it realized staggering profits. In 2014 alone, U.S. gross sales for Lantus products were $7.87 billion, and Sanofi reported internally that the "Diabetes Division remains a bright spot for the company and represents about 50% of global profit." Drug Pricing Report at 32.

E. Sanofi's First Ploy to Extend Lantus Exclusivity Illegally by Conflating its Vial and Injector Pen Products for Purposes of Orange Book Abuse

95. In 2005, five years after Lantus was approved, Sanofi received FDA approval to add an ingredient, polysorbate 20, to the 10 mL Lantus **vial** formulation. The supplemental new drug application did not provide for the addition of polysorbate 20 to the 3 mL cartridge

formulation of Lantus; the Lantus cartridge formulation for use in the OptiPen One injector pen remained unchanged. *See* Supplemental NDA No. 21-081/S-017:[22]

> Dear Dr. Sekar
>
> Please refer to your supplemental new drug application dated November 15, 2004, received November 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lantus (insulin glargine [rDNA origin] injection), 10 mL vials and 3 mL cartridges.
>
> This supplemental new drug application provides for an additional stabilizing agent, 20 ppm of polysorbate 20, added to the drug product formulation for the 10 mL vial presentation.

96. In 2007, Sanofi received an approval from the FDA for a "package change" – allowing Sanofi to sell Lantus in another, disposable injector pen called SoloSTAR. Each milliliter of Lantus SoloSTAR contains 100 Units (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and the pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide. It does **not** contain polysorbate 20.

97. With Lantus SoloSTAR, Lantus products were approved in three product formulations; only the vial formulation provided for the addition of 20 ppm of polysorbate 20:

- the original 10 mL vials (NDC 0088-2220-33)
- the original 3 mL cartridge system using the OptiClik injector pen, package of 5 (NDC 0088-2220-52)
- the new 3 mL SoloSTAR disposable insulin device, package of 5 (NDC 0088-2220-60)

98. On January 13, 2009, the PTO issued U.S. Patent No. 7,476,652 ("the '652 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '652 patent expires July 23, 2023, with a six-month period of pediatric exclusivity extending until January 23, 2024.

[22]Food and Drug Administration, Letter Approval of NDA 21-081/S-017 (2004), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/21081s017ltr.pdf.

99. On May 11, 2010, the PTO issued U.S. Patent No. 7,713,930 ("the '930 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '930 patent expires June 13, 2023, with a six-month period of pediatric exclusivity extending to December 13, 2023.

100. By assignment, Sanofi GmbH owns all right, title, and interest in and to the '652 and '930 patents. It licenses exclusively to Sanofi U.S. all rights under the '652 and '930 patents, including the rights to sell and offer to sell in the United States the technologies, products, or services claimed by them. But neither Sanofi GmbH nor Sanofi U.S. has the right to assert rights in those patents beyond the scope of the claims contained in them.

101. The '652 and '930 patents set forth examples of an insulin glargine formulation in which polysorbate 20 or 80 was added. The patents claim a formulation requiring use of "polysorbate 20," "polysorbate 80," "polysorbate[s]" or "poloxamers."

102. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not polysorbate.

103. Lantus SoloSTAR does not contain a polysorbate.

104. Lantus SoloSTAR does not contain a poloxamer.

105. Lantus SoloSTAR does not contain an ester of a polyhydric alcohol.

106. Lantus SoloSTAR does not contain an ether of a polyhydric alcohol.

107. Lantus SoloSTAR is not within the scope of any independent claim of the '652 patent.

108. Lantus SoloSTAR is not within the scope of any independent claim of the '930 patent.

109. Following the issuance of each of the polysorbate vial formulation patents, Sanofi listed the '652 patent and the '930 patent to be identified in the Orange Book as indiscriminately

claiming "LANTUS" in all of its product formulations – both vial and cartridge – despite the fact that the cartridge product does not embody either patent.

110. Under the Hatch-Waxman Act and applicable regulations, the FDA requires that an NDA holder submit information identifying only a "patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

111. The '652 patent and the '930 patent only claim the vial formulation of Lantus (as now modified to add the polysorbate). They do not claim Lantus in its cartridge formulations, i.e., the original Lantus OptiClik injector pen and the Lantus SoloSTAR disposable insulin device. Accordingly, these patents should *not* have been identified in the Orange Book as applicable to the two cartridge formulations of Lantus.

112. However, when providing information to the FDA, Sanofi did not delineate the scope of the '652 and '930 patents. It falsely and misleadingly indicated to the FDA that both patents covered the two injector formulations.

113. Sanofi had no reasonable basis for listing the '652 and '930 patents in the Orange Book.

F. Sanofi's Second Ploy to Extend Lantus Exclusivity by Constructing a Thicket of Invalid Injector Pen Patents and Improperly Listing them in The Orange Book

114. In or around 2011, Sanofi – in an effort to build a patent thicket to pair with the Orange Book to illegally block competition to its Lantus franchise – began to collect a series of injector pen patents ("Pen Patents"):

- On April 5, 2011, United States Patent No. 7,918,833 ("the '833 patent"), entitled "Pen-Type Injector" was issued by the PTO. The '833 patent expires September 23, 2027, with a period of pediatric exclusivity extending to March 23, 2028. On information and belief, this was listed in the Orange Book in March 2015.

- On August 20, 2013, United States Patent No. 8,512,297 ("the '297 patent"), entitled "Pen-Type Injector" was issued by the PTO. The '297 patent expires September 15, 2024. On information and belief, this was listed in the Orange Book in March 2015.
- On October 15, 2013, United States Patent No. 8,556,864 ("the '864 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices," was issued by the PTO. The '864 patent expires December 29, 2024. On information and belief, this was listed in the Orange Book in March 2015.
- On December 10, 2013, United States Patent No. 8,603,044 ("the '044 patent"), entitled "Pen-Type Injector," was issued by the PTO. The '044 patent expires March 2, 2024. On information and belief, this was listed in the Orange Book in March 2015.
- On March 31, 2015, the PTO issued United States Patent No. 8,992,486, entitled "Pen-Type Injector." The '486 patent expires June 5, 2024. Sanofi listed the '486 patent in the Orange Book on March 9, 2015, contending the patent claimed the Lantus drug product.
- On April 21, 2015, the PTO issued United States Patent No. 9,011,391, entitled "Pen-Type Injector." The '391 patent expires March 26, 2024. Sanofi listed the '391 patent in the Orange Book on May 1, 2015, claiming the patent covered the Lantus drug product and a method of using the drug product.
- On January 12, 2016, the PTO issued United States Patent No. 9,233,211, entitled "Relating to a Pen-Type Injector." The '211 patent expires March 2, 2024. Sanofi listed the '211 patent in the Orange Book on January 13, 2016, claiming the patent covered the Lantus drug product.
- On August 9, 2016, the PTO issued United States Patent No. 9,408,979, entitled "Pen-Type Injector." The '979 patent expires March 2, 2024. Sanofi listed the '979 patent in the Orange Book on September 15, 2016, claiming the patent covered the Lantus drug product.
- On December 27, 2016, the PTO issued United States Patent No. 9,526,844, entitled "Pen-Type Injector." The '844 patent expires on March 2, 2024. Sanofi listed the '844 patent in the Orange Book on December 27, 2016, claiming the patent covered the Lantus drug product.
- On January 3, 2017, the PTO issued United States Patent No. 9,533,105, entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '105 patent expires August 17, 2024. Sanofi listed the '105 patent in the Orange Book on January 3, 2017, claiming the patent covered the Lantus drug product.
- On February 7, 2017, the PTO issued United States Patent No. 9,561,331, entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '331 patent expires August 28, 2024. Sanofi listed it in the Orange Book on February 7, 2017, claiming the patent covered the Lantus drug product.
- On March 28, 2017, the PTO issued United States Patent No. 9,604,008, entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '008 patent expires August 14, 2024. Sanofi listed the '008 patent in the Orange Book on March 28, 2017, claiming the patent covered the Lantus drug product.
- On March 28, 2017, the PTO also issued United States Patent No. 9,604,009, entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices."

The ’009 patent expires August 18, 2024. Sanofi listed the ’009 patent in the Orange Book on March 28, 2017, claiming the patent covered the Lantus drug product.

- On April 4, 2017, the PTO issued United States Patent No. 9,610,409, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices.” The ’409 patent expires August 27, 2024. Sanofi listed the ’409 patent in the Orange Book on April 4, 2017, claiming the patent covered the Lantus drug product.
- On April 18, 2017, the PTO issued United States Patent No. 9,623,189, entitled “Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices.” The ’189 patent expires August 19, 2024. Sanofi listed the patent in the Orange Book on April 18, 2017, claiming the patent covered the Lantus drug product.
- On October 3, 2017, the PTO issued United States Patent No. 9,775,954, entitled “Pen-Type Injector.” The ’954 patent expires March 2, 2024. Sanofi listed the ’954 patent in the Orange Book on October 3, 2017, claiming the patent covered the Lantus drug product.
- On November 28, 2017, the PTO issued United States Patent No. 9,827,379, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices.” The ’379 patent expires June 9, 2024. Sanofi listed the ’379 patent in the Orange Book on November 28, 2017, claiming the patent covered the Lantus drug product and a method of using that drug product.

115. None of the new patents claim insulin or insulin glargine.

116. All of the new patents were invalid.

117. All of the new patents were improperly listed in the Orange Book for the sole purpose of delaying competition.

118. Until the summer of 2013, Sanofi had identified a single product, Lantus, available in two formulations (vial and cartridge), in the FDA’s Orange Book.

119. In or about August 2013, Sanofi for the first time split the listing in the Orange Book to reference two products under a single NDA: product 001 identifying “Lantus,” and product 002 for “Lantus SoloSTAR.” The Orange Book also continued to include Lantus (now product 001) in two general formulations: “INJECTABLE” (i.e., the vial formulation), and “INJECTION” (i.e., the cartridge formulation).

120. By wrongfully listing the other patents, by the end of 2013, Sanofi had created an unlawful Orange Book roadblock for would-be follow-on biologic competitors for the insulin

glargine market. It had falsely and misleadingly listed the '652 and '930 vial formulation patents as ostensibly claiming the cartridge formulation of Lantus (even though Sanofi's FDA approvals did not provide for the addition of 20 ppm of polysorbate 20 to the 3 mL cartridge presentation of Lantus insulin glargine [rDNA origin] injection).

121. As a result, a competitor seeking FDA approval to market a follow-on, injector pen formulation of insulin glargine after expiration of exclusivities associated with the '722 patent in mid-February, 2015 would be, and in fact was, forced to file unnecessary paragraph IV certifications as to the vial formulation patents and the DCA injector pen patents. And Sanofi could then sue, triggering the 30-month statutory bar on final FDA approval to the competitor's application.

122. Sanofi was not re-investing its windfall Lantus profits into research and development to produce new and life-saving medications as intended by the Hatch-Waxman Act. Instead, it was developing new devices that offered little benefit to patients and that did nothing to substantively advance the science of diabetes medicine. Sanofi's strategy is laid bare by a simple review of the record: it filed the vast majority of its patent applications *after Lantus was already on the market*. According to one study, 95% of Sanofi's patent applications for Lantus (69 out of 74) were filed after the drug was approved in 2000.[23]

G. Mylan Partners with Biocon to Introduce an Insulin Glargine Biosimilar, and Pivots as Sanofi Spams the Orange Book

123. Just as Sanofi was embarking on its aggregation and Orange Book listing of Insulin Pen Patents, Mylan began positioning itself to compete with Sanofi on or near expiry of Sanofi's

[23] IMAK, *Overpatented, Overpriced Special Edition – Lantus* (2018), http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf.

sole legitimate insulin glargine patent, the '722 patent, in February 2015 (accounting for Sanofi's additional six months of pediatric exclusivity). In certifying to noninfringement of Sanofi's polysorbate vial formulation patents ('652 and '930), Mylan explained "The formulation of Mylan's product in both configurations is identical to the Lantus formulation in prefilled disposable pens. The Lantus vial product contains one additional ingredient that is not included in the Mylan product."

124. Mylan announced a partnership with Indian biopharmaceutical research company Biocon Limited ("Biocon") in February 2013 for a strategic collaboration for insulin products.[24] Headquartered in Bengaluru, India, Biocon offered unparalleled experience in developing insulin products. Biocon first introduced Insugen in India in 2004 and launched a biosimilar version of insulin glargine named Basalog in India in 2009.[25] Biocon introduced a reusable injector pen in 2011, marking the company's foray into medical devices, before partnering with Mylan in 2013. Under the terms of the agreement, Mylan and Biocon shared development costs and profits and Mylan held exclusive commercialization rights in the United States.

125. Biocon was the original sponsor for Investigational New Drug ("IND") 105279, submitted in December 2011, and had already started the process of obtaining regulatory approval for an insulin glargine product from the FDA when the companies formed their joint venture. In August 2013, Biocon transferred the sponsorship of IND 105279 to Mylan. In this same month

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[24] *Mylan Enhances Partnership with Biocon through Strategic Collaboration of Insulin Products*, (Feb. 13, 2013), https://investor.mylan.com/news-releases/news-release-details/mylan-enhances-partnership-biocon-through-strategic.

[25] *A Century of Insulins and Biocon Biologics*, https://www.biocon.com/a-century-of-insulins/.

Sanofi's strategy of assembling insulin pen patents began in earnest, with Sanofi amassing and listing in the Orange Book an additional 16 patents within four years.

126. Sanofi's slew of new patents in the Orange Book short-circuited Mylan's original aspirations for timing to the market. Before this list of injector pen patents appeared in the Orange Book, Sanofi's only patents in the Orange Book post-expiry of the '722 patent were the polysorbate vial formulation patents, both of which literally and facially were not infringed by Mylan's product (which contained no polysorbate), and a single pen-type injector patent that did not claim insulin (and that Sanofi in fact never asserted against Mylan).

127. However, in 2013 Sanofi began deploying its injector pen patents to delay Mylan's ability to enter the market, and by November 2013 both 8,512,297 and 8,556,864 were in the Orange Book, meaning that Mylan had no path to market that did not require enduring a 30-month stay, regardless of the invalidity and noninfringement of these patents.

H. Mylan Confronts the Regulatory Dead Zone

128. Upon accepting the transfer of Biocon's IND application in 2013 Mylan proceeded with seeking regulatory guidance under the IND framework. However, in a March 2014 meeting during which Mylan discussed its intention to seek marketing approval under 505(b)(2), the FDA indicated that the passage of the BPCIA may complicate Mylan's path, as its insulin glargine product would be a biosimilar and therefore governed by a different statute. As late as June 2016, Mylan was still inquiring of the FDA whether a traditional ANDA approach, 505(b)(2), or different pathway would be appropriate for Mylan's application. All of this would have been avoided had it not been for Sanofi's improperly listed patents because Mylan would have obtained FDA approval of its insulin glargine product earlier.

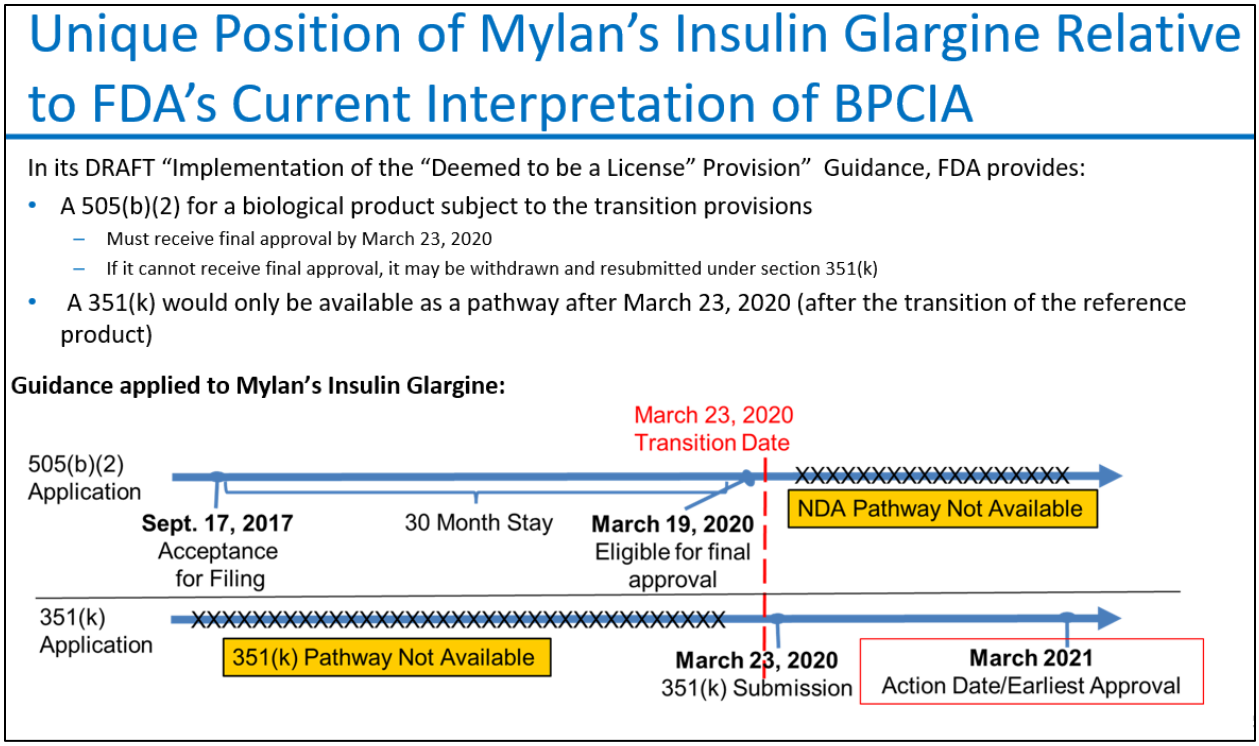
129. On April 27, 2017, Mylan submitted a 505(b)(2) NDA for Semglee, after finally receiving guidance from the FDA on the best regulatory path forward. Mylan's NDA application

included a paragraph IV certification consistent with 505(b)(2). As discussed above, this triggered the 30-month stay for Sanofi's many improperly listed, largely invalid, and uninfringed patents in the Orange Book.

130. On August 15, 2017, the FDA held a "Refuse-to-File" meeting with Mylan. During this meeting, the agency informed Mylan that if the FDA did not approve Mylan's NDA by March 23, 2020, Mylan's Semglee would be regulated as a biologic rather than an NDA.

131. In this August 15, 2017 meeting Mylan explained to the FDA that the current interpretation of the transition provisions under the BPCIA creates a "dead zone" in which Mylan feared the FDA would be unable to complete review and approval in time. In that scenario, a company that spent millions of dollars developing a therapeutically equivalent product under the 505(b)(2) regime could risk losing all of its progress if it did not secure regulatory approval by March 23, 2020, at which point the BPCIA would govern.

132. During that same meeting, Mylan confirmed that the 30-month stay created by Sanofi's illegal conduct was the foundation of the timing decisions affecting Mylan's application:



133. The existence of the 30-month stay, in conjunction with the March 23, 2020 transition date created by the BPCIA, complicated the FDA's review and approval of Mylan's application in a way that would not have occurred had there been no 30-month stay preventing Mylan's final approval until just four days before the transition date.

134. On August 31, 2017, Mylan requested that its NDA be "Filed over Protest" seeking to push forward on the review of its NDA. On September 25, 2017, the FDA filed the NDA over protest. Mylan continued to progress on the prosecution of its NDA, submitted additional clinical data, and continued to fervently pursue regulatory approval.

135. Mylan requested that the FDA agree to deem Mylan's 505(b)(2) application as a 351(a) BLA application and then allow for the 351(a) BLA for Semglee to be administratively converted to a 351(k) application demonstrating interchangeability.

136. The FDA approved Mylan's application on June 11, 2020. In its approval letter, the FDA notified Mylan that, upon approval, its NDA 210605 would "be deemed to be an approved

biologics license application ("BLA") under section 351(a) of the Public Health Service Act (*see* section 7002(e)(4)(B)(iii) of the Biologics Price Competition and Innovation Act of 2009."

137. Although Mylan filed its application as an NDA, this transition to a biologic resulted from the FDA's interpretation of a provision in the BPCIA that went into effect during the course of the FDA' review. As a result, Mylan filed its application for Semglee on July 29, 2020, as BLA 761201. The purpose of this submission was to request licensure of Semglee as interchangeable with Lantus.

138. Just under a year later, on July 28, 2021, the FDA approved Mylan's BLA 761201. The FDA issued a press release on the same day, noting that Semglee "is the first interchangeable biosimilar product approved in the U.S. for the treatment of diabetes."[26]

139. In that press release, then-Acting FDA Commissioner Janet Woodcock stated that the development was "momentous" for diabetes patients, "as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs." Commissioner Woodcock stated that the approval "furthers FDA's longstanding commitment to support a competitive marketplace for biological products and ultimately empowers patients by helping to increase access to safe, effective and high-quality medications at potentially lower cost."

I. Sanofi Further Exploits the Orange Book and Regulatory Framework by Pursuing Serial Baseless Patent Litigation Against Mylan

140. As Mylan navigated the regulatory complications that arose from Sanofi's conduct, it also began a protracted legal battle with Sanofi in federal courts and at the Patent Trial and

[26] FDA News Release, FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes.

Appeal Board. As the meandering road of litigation would confirm, all of the patents listed in the Orange Book after the '722 patent (which expired in 2015) were invalid and improperly listed. In other words, at no time did Sanofi have a reasonable expectation of winning litigation pertaining to any patent in the chart below:

Patent No.	Patent Name	Final Outcome Vis-à-vis Mylan	Properly Listed in Orange Book?
First Notice Letter Patents			
7,476,652	Acidic Insulin Preparations Having Improved Stability	Determined invalid by the PTAB and affirmed by the Federal Circuit **Patent has since been cancelled**	Yes, but only for vials.
7,713,930	Acidic Insulin Preparations Having Improved Stability	Determined invalid by the PTAB and affirmed by the Federal Circuit **Patent has since been cancelled**	Yes, but only for vials.
7,918,833	Pen-Type Injector	Determined invalid by the Federal Circuit	No
8,512,297	Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
8,556,864	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay First Circuit determined Sanofi improperly listed the '864 patent in Orange Book	No
8,603,044	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings	No
8,992,486	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings PTAB findings affirmed by the Federal Circuit	No
9,011,391	Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
9,233,211	Relating to a Pen-Type Injector	Covenant not to sue granted to Mylan after the automatic stay	No
9,408,979	Pen-Type Injector	Covenant not to sue granted to Mylan after automatic stay	No

9,526,844	Pen-Type Injector	Determined unpatentable by the PTAB IPR proceedings DNJ found Mylan did not infringe PTAB findings affirmed by the Federal Circuit	No
9,533,105	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,561,331	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,604,008	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Most claims determined unpatentable by PTAB IPR proceedings and affirmed by the Federal Circuit	No
9,604,009	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,610,409	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
9,623,189	Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan after the automatic stay	No
8,679,069	Pen-Type Injector	Determined invalid by the PTAB and affirmed by the Federal Circuit	No
Second Notice Letter Patent			
9,775,954	Pen-Type Injector	Covenant not to sue granted to Mylan	No
Third Notice Letter Patent			
9,827,379	Drive Mechanisms Suitable for Use in Drug Delivery Devices	Covenant not to sue granted to Mylan	No
Fourth Notice Letter Patent			
9,717,852	Cartridge Holder and Pen-Type Injector	Covenant not to sue granted to Mylan	No

141. But Sanofi was indifferent to the ultimate viability of any of its individual patents. The true rationale for its serial petitioning activity was to obtain an extensive patent estate to wield as an anticompetitive weapon, blocking any competitors from accessing the market.

142. Patent litigation brought by Sanofi against Mylan as to any of the patents in the above chart constitutes sham litigation because it was brought without any reasonable chance at prevailing and with the specific purpose of inhibiting competition. Moreover, Sanofi's broader pattern of conduct evinces a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival as proscribed in *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015).

143. Of the challenges to over 50 claims in Sanofi's patents brought through *inter partes* reviews, *only two* claims have survived (neither of which could have excluded Mylan), leaving Sanofi with an abysmal success rate of 4%.

144. On September 15, 2017, Mylan sent a letter notifying Sanofi it had filed an NDA containing paragraph IV certifications and explaining its positions. Mylan's letter was accompanied by an offer of confidential access to portions of Mylan's application.

145. Sanofi sued Mylan in the District of New Jersey on October 24, 2017, alleging that Mylan infringed every one of Sanofi's eighteen injector pen patents and vial formulation patents.[27] *Sanofi-Aventis US LLC v. Mylan NV*, 2-17-cv-09105 (D.N.J. Oct. 24, 2017):

[27] Sanofi also filed a complaint against Mylan in the Northern District of West Virginia on October 26, 2017. The court later dismissed this action without prejudice on February 21, 2018 pursuant to a stipulation between the parties. *Sanofi-Aventis US LLC v. Mylan NV*, 1-17-cv-181 (N.D.W.V. Oct. 26, 2017).

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. arising from Mylan's filing of New Drug Application ("NDA") No. 210605 with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market Mylan's proposed copies of Sanofi's Lantus® and Lantus® SoloSTAR® drug products ("Proposed Products") prior to the expiration of United States Patent Nos. 7,476,652 ("the '652 patent"), 7,713,930 ("the '930 patent"), 7,918,833 ("the '833 patent"), 8,512,297 ("the '297 patent"), 8,556,864 ("the '864 patent"), 8,603,044 ("the '044 patent"), 8,679,069 ("the '069 patent"), 8,992,486 ("the '486 patent"), 9,011,391 ("the '391 patent"), 9,233,211 ("the '211 patent"), 9,408,979 ("the '979 patent"), 9,526,844 ("the '844 patent"), 9,533,105 ("the '105 patent"), 9,561,331 ("the '331 patent"), 9,604,008 ("the '008 patent"), 9,604,009 ("the '009 patent"), 9,610,409 ("the '409 patent"), and 9,623,189 ("the '189 patent"), (collectively, "the patents-in-suit"), which cover Lantus® and/or Lantus® SoloSTAR®.

146. Sanofi's suit was objectively baseless. At each step of this protracted litigation, Mylan demonstrated the invalidity of Sanofi's patents, the noninfringement as to Mylan's products, the sham nature of Sanofi litigation strategy, and the monopolistic scheme driving Sanofi's conduct.

147. In order to protect from the invalidation of some of its patents, Sanofi granted Mylan a covenant not to sue for the following patents, removing them from the litigation: 7,918,833, 8,512,297, 8,556,864, 9,011,391, 9,223,211, 9,408,979, 9,533,105, 9,561,331, 9,604,009, 9,610,409, 9,623,189, 9,775,954, and 9,827,379.

a. *The '652 Patent*

148. The '652 was invalid for obviousness.

149. Sanofi improperly listed the ’652 patent on the Orange Book as claiming the Lantus Cartridge.

150. Sanofi’s ’652 patent – one of its two polysorbate vial formulation patents – did not cover the formulation for the Lantus cartridge or Lantus SoloSTAR. Nevertheless, following the issuance of this patent, Sanofi listed the ’652 patent in the Orange Book for those products.

151. On June 5, 2017, Mylan filed a Petition to request an *inter partes* review under 35 U.S.C. § 311 to determine whether claims 1-25 of the ’652 were invalid.

152. Sanofi sued Mylan on this patent on October 24, 2017. In so doing, Sanofi triggered the 30-month automatic stay.

153. On December 17, 2017, the PTAB held a trial to assess Mylan’s claims. On December 12, 2018, the PTAB found that all 25 claims of the ’652 patent were invalid. The Federal Circuit affirmed, and the mandate issued February 18, 2020. Sanofi petitioned the Supreme Court for review of the decision, which the Supreme Court denied on October 5, 2020.

b. *The ’930 Patent*

154. The ’930 was invalid for obviousness.

155. Sanofi’s ’930 patent – the second of the polysorbate vial patents – did not cover the formulations for the Lantus cartridge or Lantus SoloSTAR. Nevertheless, Sanofi listed this in the Orange Book for those products.

156. On June 5, 2017, Mylan filed a petition seeking an *inter partes* review of the ’930 patent.

157. Sanofi sued Mylan on this patent on October 24, 2017. In so doing, Sanofi triggered the 30-month automatic stay.

158. On December 12, 2018, the PTAB found the ’930 patent invalid. The Federal Circuit affirmed, and the mandate issued February 18, 2020. Sanofi petitioned the Supreme Court for review of the decision, which the Supreme Court denied on October 5, 2020.

c. *The ’069 Patent*

159. The ’069 patent was invalid for obviousness.

160. By June 2017, Sanofi added its initial injector patents to the Orange Book, including the ’069 patent. The patent did not claim Lantus or a method of using the drug, and therefore was improperly listed in the Orange Book.

161. Sanofi sued Mylan on this Orange Book patent on October 24, 2017. In so doing, Sanofi triggered the 30-month automatic stay.

162. On September 10, 2018, Mylan filed a petition seeking an *inter partes* review of the ’069 patent.

163. On April 2, 2020, the PTAB found the ’069 patent invalid for obviousness.

164. On December 29, 2021, more than four years after Mylan sought *inter partes* review, the Federal Circuit upheld the PTAB’s decision invalidating the ’069 patent.

d. *The ’486 Patent*

165. The ’486 was invalid for obviousness.

166. By June 2017, Sanofi added its initial injector patents to the Orange Book, including the ’486 patent. The patent did not claim Lantus or a method of using the drug, and therefore was improperly listed in the Orange Book.

167. Sanofi sued Mylan on this Orange Book patent on October 24, 2017. In so doing, Sanofi triggered the 30-month automatic stay.

168. On September 10, 2018, Mylan filed a petition seeking an *inter partes* review of the ’486 patent.

169. On April 2, 2020, the PTAB found the ’486 patent invalid for obviousness.

170. On December 29, 2021, more than four years after Mylan sought *inter partes* review, the Federal Circuit upheld the PTAB’s decision invalidating the ’486 patent.

e. *The ’044 Patent*

171. The ’044 was invalid for obviousness.

172. By June 2017, Sanofi added its initial injector patents to the Orange Book, including the ’044 patent. The patent did not claim Lantus or a method of using the drug, and therefore was improperly listed in the Orange Book.

173. Sanofi sued Mylan on this Orange Book patent on October 24, 2017. In so doing, Sanofi triggered the 30-month automatic stay.

174. On September 10, 2018, Mylan filed a petition seeking an *inter partes* review of the ’044 patent.

175. On April 2, 2020, the PTAB found the ’044 patent invalid for obviousness.

176. On December 29, 2021, more than four years after Mylan sought *inter partes* review, the Federal Circuit upheld the PTAB’s decision invalidating the ’044 patent.

f. *The ’844 Patent*

177. The ’844 patent was invalid as unpatentable.

178. Sanofi’s ’844 patent is one of several of the new injector patents that were listed in the Orange Book by June 2017.

179. On October 24, 2017, Sanofi sued Mylan on Sanofi’s ’844 patent, thus initiating the 30-month stay.

180. On September 10, 2018, Mylan filed a petition seeking an *inter partes* review of the ’844 patent.

181. On March 9, 2020, Judge Chesler issued an opinion finding all asserted claims of the ’844 patent not infringed by Mylan’s insulin glargine product, and further finding all asserted claims of the ’844 patent invalid for failure to meet the written description requirement of § 112.[28]

182. On May 29, 2020, the PTAB found all challenged claims invalid.

183. On December 29, 2021, the Federal Circuit affirmed the invalidity of the ’844 patent.

g. *The ’008 Patent*

184. All but two challenged claims of the ’008 were invalid for obviousness. Even if any claims were not invalid, they were not infringed by Mylan as evidenced by Sanofi’s decision to dismiss claims regarding patent ’008 from its lawsuit with Mylan.[29]

185. Sanofi’s ’008 patent is one of several of the new injector patents that were listed in the Orange Book by June 2017.

186. On October 24, 2017, Sanofi sued Mylan on Sanofi’s ’008 patent, thus initiating the 30-month stay.

187. On September 10, 2018, Mylan filed a petition seeking an *inter partes* review of the ’008 patent.

188. On February 4, 2019 Sanofi voluntarily dismissed all claims pertaining to the ’008 from its litigation with Mylan.

189. On May 29, 2020, the PTAB found that four of the six challenged claims were invalid.

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[28] *Sanofi-Aventis U.S. LLC v. Mylan GMBH*, No. 17-cv-09105-RC-CLW, ECF No. 582 (D.N.J.).

[29] *Id*. at ECF No. 272 (D.N.J.).

190. On December 29, 2021 the Federal Circuit affirmed the invalidity of the '008 patent claims.

J. Sanofi's Ploy Successfully and Illegally Delayed Mylan's Market Entry

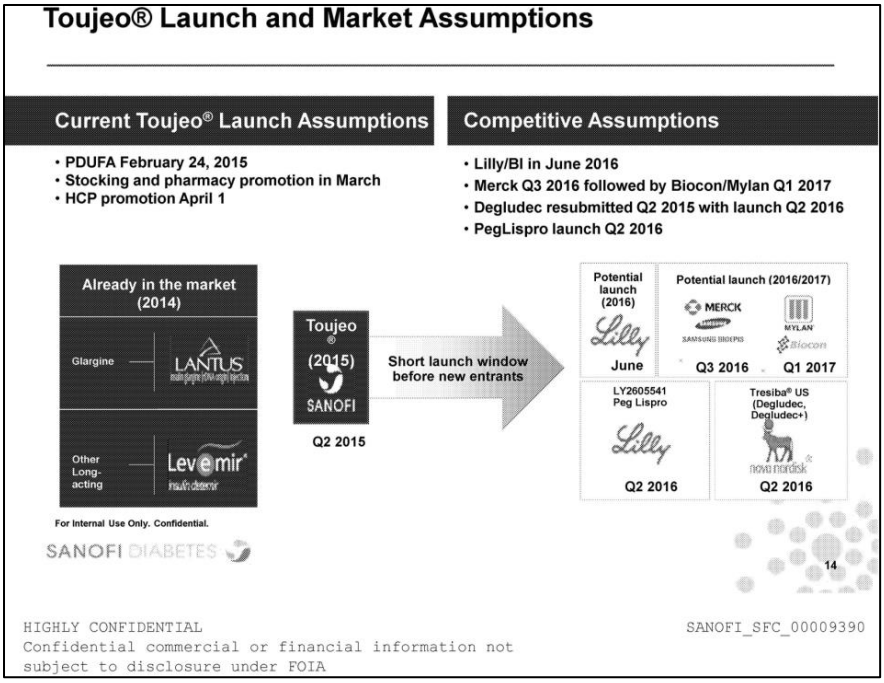
191. Despite all efforts to overcome Sanofi's tactics, Mylan did not launch an insulin glargine product until late 2020, many years after it should have. Sanofi is the culprit for this delay.

192. Sanofi's Orange Book abuse and serial sham litigation proved to be a barrier. Combined, these two tactics allowed Sanofi to exploit statutory and regulatory procedures that are supposed to accelerate and facilitate competition in pharmaceutical markets.

193. The FDA too would have approved Mylan's product more quickly in the absence of the 30-month stay.

194. Sanofi itself anticipated Mylan would be competing with Lantus by "Q1 2017" in a 2013-2014 internal report:[30]

[30] Insulin Report Documents at 157.



K. Sanofi Launches Toujeo to Extend and Protect its Monopoly by Coercing a Market Shift

195. Sanofi submitted its NDA 21081 for Toujeo on April 25, 2014. Toujeo is a basal insulin drug with the same active ingredient, insulin glargine, as Lantus, but it is three times more concentrated and releases the insulin more slowly. Despite containing three times the dosage of Lantus, Toujeo lasts only four hours longer (30 hours compared to Lantus's 26 hours). Sanofi initially intended to demonstrate bioequivalence between Toujeo and Lantus.[31]

196. The FDA concluded the following regarding Toujeo:[32]

- "[L]ess glargine insulin is systemically absorbed when it is administered as Toujeo compared to Lantus and that Toujeo has less glucose lowering effect on a unit-to-unit basis compared to Lantus."

[31] Center for Drug Evaluation and Research, Application Number: 20658Oig1s000 (Feb. 25, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206538Orig1s000SumR.pdf.
[32] *Id.*

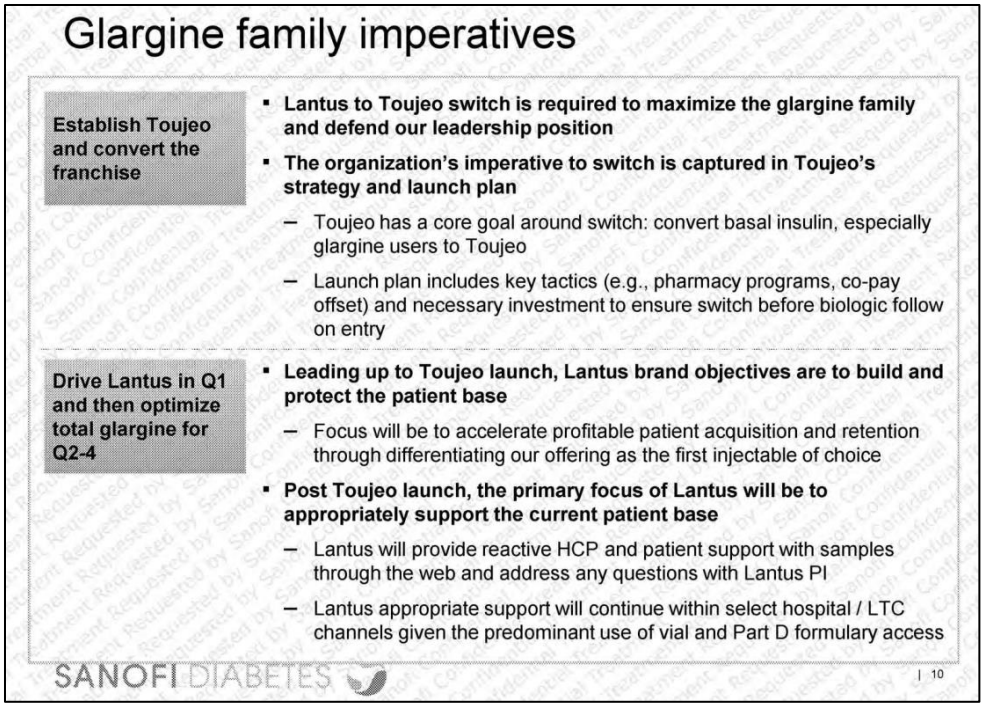
- "The safety of Toujeo was not clinically meaningfully different than the safety of the approved product Lantus."
- "We did not agree with [Sanofi's] conclusion that the data in the application provide conclusive evidence that Toujeo is comparatively safer than Lantus from a hypoglycemia risk perspective"
- "The glucose lowering effect of Toujeo begins to wane approximately 30 hours after injection compared to 26 hours for Lantus (refer to Figure 5 in Dr. Yanoff's review), suggesting Toujeo is **slightly** longer lasting than Lantus." (emphasis added)
- "The higher glargine protein concentration in Toujeo is expected to increase the tendency for subcutaneous precipitation and to limit the amount of glargine available for systemic absorption."

197. Toujeo offered no unique therapeutic value or advantage over Lantus. In fact, there have been reports that, for some people, "[t]he maximum glucose lowering effect achieved with Toujeo was ~ 19% lower than that of Lantus and the overall glucose lowering in the 24 and 36 hours that followed the injection was also lower relative to Lantus by 27% and 15% respectively."[33]

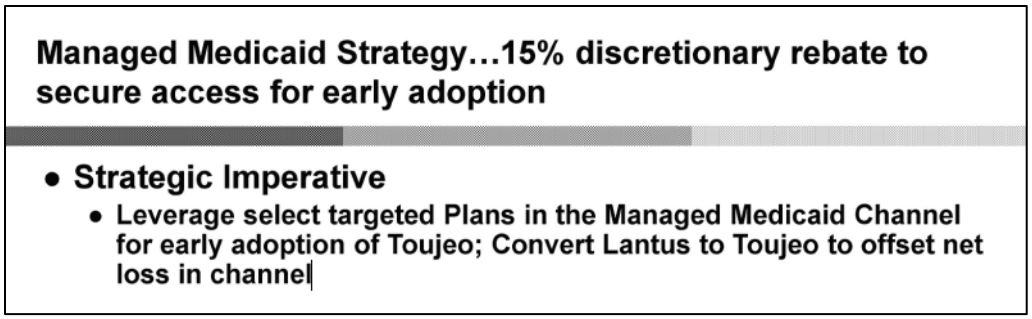
198. Sanofi received approval for Toujeo in February 2015 and launched Toujeo in March 2015, shortly after the only validly listed Orange Book patents for insulin glargine expired.

199. Sanofi recognized pushing the market to Toujeo as the only viable way to maintain its market power over injectable insulin glargine:[34]

[33] *Id*. at 5.
[34] Drug Pricing Documents at 230.



200. Sanofi understood that the same logic applied to protect Medicaid sales, as Sanofi needed to "Convert Lantus to Toujeo to offset net loss in channel.":[35]



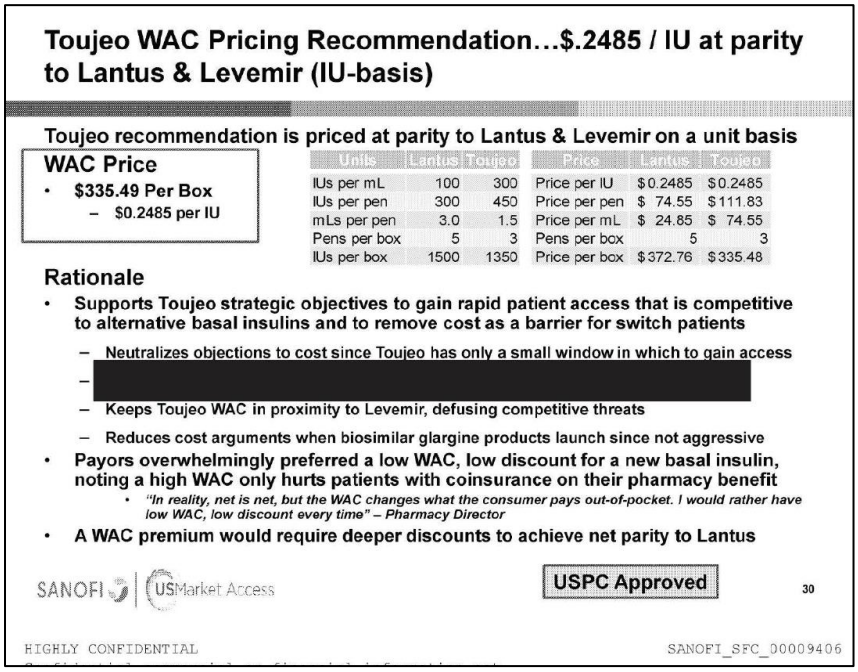
L. Sanofi Conditioned Rebates for Lantus on the Inclusion of Toujeo on Formularies in Order to Coerce a Market Switch to Toujeo, Eliminating Consumer Choice

201. At the time of Toujeo's introduction "there are few unmet needs with current basal therapy" and patients and doctors alike would only consider switching to Toujeo "if there were no

[35] Insulin Report Documents at 209.

additional cost." That meant that Toujeo could only succeed if it were not any more expensive than the product it was purporting to improve, or as Sanofi posited internally, "Toujeo access will depend on the net cost of the glargine franchise."

202. Sanofi understood that there was nothing innately appealing about Toujeo as a product, and that its commercial viability relied entirely on Sanofi's ability to impose it on the market, opining that "Toujeo has only a small window in which to gain access" before it is not able to rely on the market power of Lantus to drive adoption.



[36]

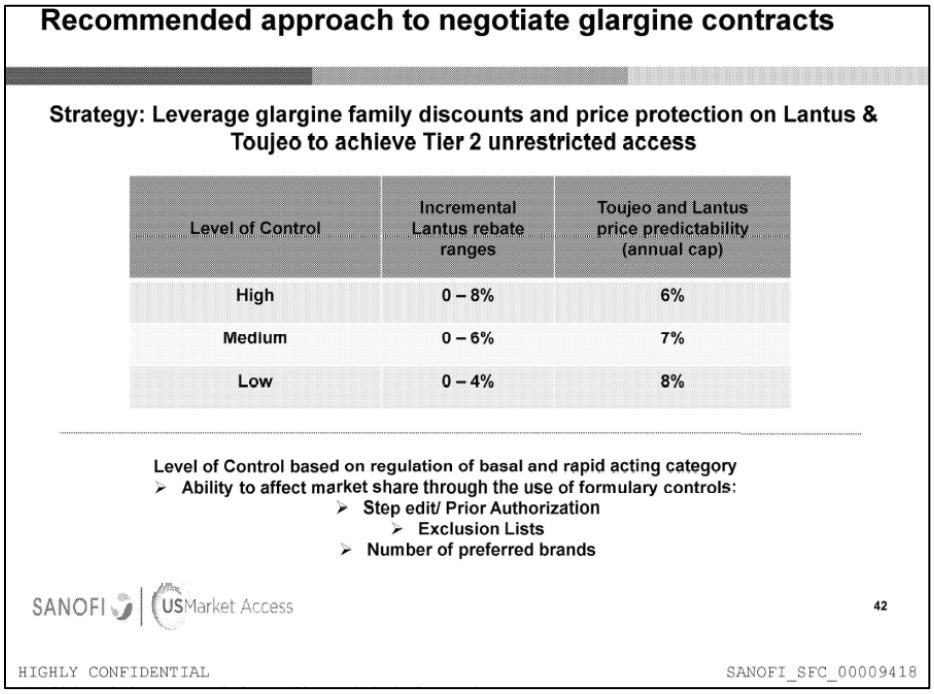
203. As detailed in the Drug Pricing Report, Sanofi succeeded in increasing Toujeo sales by over 25% within the first year. Sanofi accomplished this by leveraging Lantus in its contracts

[36] Insulin Report at 173.

with customers to "unlock preferred access for Toujeo" on covered drug formularies, with "100% of our Toujeo contracts…tied to Lantus."[37]

204. Sanofi introduced a scheme to "secure 2017 access for Lantus & Toujeo" with a "Portfolio Option (LAN & TJO Bundle):"[38] Thus, when Mylan finally entered the market years later, the scheme ensured Mylan was unable to secure a position on most commercial formularies.[39]

205. Sanofi recognized that paying marginally more in rebates would improve Sanofi's "Level of Control" and bestow the "Ability to affect market share through the use of formulary controls" Step edit/ Prior Authorization, Exclusion Lists, Number of preferred brands":[40]



Recommended approach to negotiate glargine contracts

Strategy: Leverage glargine family discounts and price protection on Lantus & Toujeo to achieve Tier 2 unrestricted access

Level of Control	Incremental Lantus rebate ranges	Toujeo and Lantus price predictability (annual cap)
High	0 – 8%	6%
Medium	0 – 6%	7%
Low	0 – 4%	8%

Level of Control based on regulation of basal and rapid acting category
- Ability to affect market share through the use of formulary controls:
  - Step edit/ Prior Authorization
  - Exclusion Lists
  - Number of preferred brands

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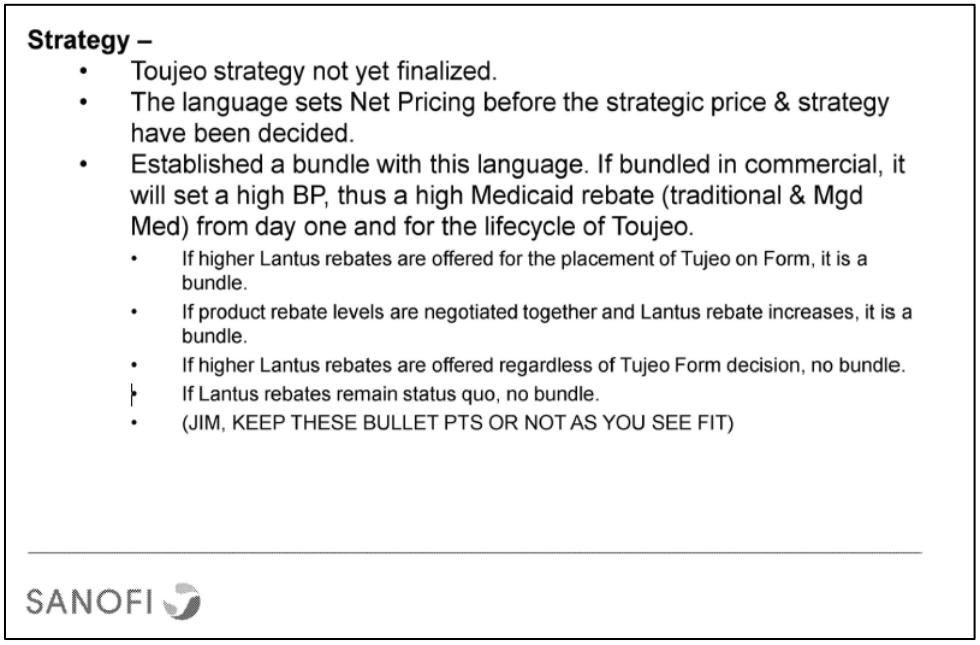
[37] Drug Pricing Report at 115.
[38] Insulin Report at 68.
[39] Insulin Report Documents at 313.
[40] Insulin Report Documents at 185.

206. Internal Sanofi documents explain well the commercial benefit of combining "Lantus rebates" with "placement of Tujeo [sic] on Form[ulary]" and confirms that the company understood the ramifications of its bundling:[41]


Strategy –

- Toujeo strategy not yet finalized.
- The language sets Net Pricing before the strategic price & strategy have been decided.
- Established a bundle with this language. If bundled in commercial, it will set a high BP, thus a high Medicaid rebate (traditional & Mgd Med) from day one and for the lifecycle of Toujeo.
  - If higher Lantus rebates are offered for the placement of Tujeo on Form, it is a bundle.
  - If product rebate levels are negotiated together and Lantus rebate increases, it is a bundle.
  - If higher Lantus rebates are offered regardless of Tujeo Form decision, no bundle.
  - If Lantus rebates remain status quo, no bundle.
  - (JIM, KEEP THESE BULLET PTS OR NOT AS YOU SEE FIT)

SANOFI

207. Sanofi coupled its contracting conduct with a marketing blitz. In documents reviewed in connection with the Drug Pricing Report, Sanofi "spent millions to market Toujeo to patients and doctors and mostly stopped promoting Lantus, except in market segments where Toujeo was not available." Per the Drug Pricing Report, Sanofi spent "more than double Toujeo's manufacturing costs on marketing, sales force, and promotion" and this expenditure "was paying off: 'Toujeo market share (volume) correlates to Sales Force spending in US and EU.'"[42]

[41] Insulin Report Documents at 380.
[42] Drug Pricing Report at 114 (quoting SANOFI_COR_00105420, at Slide 10).

M. Once Toujeo Attained Market Share, it Became Sanofi's Protection Against Biosimilar Competition for Lantus

208. Initially Sanofi used bundling and conditional rebates to leverage the market power of Lantus to drive adoption of Toujeo. 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. Indeed, this was always the plan: "Lantus to Toujeo switch is required to maximize the glargine family and defend our leadership position" and "Toujeo has a core goal around switch: convert basal insulin, especially glargine users to Toujeo." Once accomplished, "the primary focus of Lantus will be to appropriately support the current patient base," i.e., Lantus will lose its importance strategically for the overall franchise and become the protected product rather than the protecting product.

209. And protect Lantus with Toujeo Sanofi did. By the time Mylan finally got through Sanofi's endless labyrinth of litigation and regulatory delays, Toujeo was established enough that payers and customers could not afford to risk losing the rebates associated with Toujeo to switch away from Lantus. 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.

210. 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. As Mylan did not, and does not, offer a competing product to Toujeo, Mylan would have to cover the value of the rebate of both products through Semglee.

211. It was not until late 2021, after Mylan secured interchangeability for Lantus, that Mylan was able to secure any measurable sales at all.

V. Market Power and Market Definition

212. At all relevant times, Sanofi had monopoly power in the market for injectable insulin glargine because it had the power to raise or maintain the price of injectable insulin glargine at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable and the power to exclude competitors.

213. At all times during its monopoly, a small but significant, non-transitory increase to the price of the injectable insulin glargine would not have caused a significant loss of sales; and in fact large, durable increases in price did not result in lost sales.

214. Sanofi's injectable insulin glargine products do not exhibit significant, positive cross-elasticity of demand with respect to price with any other insulin product other than other insulin glargine products; notwithstanding the commercialization of a competing insulin glargine product, in 2016 Sanofi continued to charge supracompetitive prices and exclude competitors, confirming its market power.

215. Sanofi needed to control only Lantus and Toujeo and their "generic" or biosimilar equivalents, and no other products, in order to maintain its injectable insulin glargine franchise profitably at supracompetitive prices.

216. On information and belief, Sanofi sold Lantus and Toujeo at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

217. Sanofi had, and exercised, the power to exclude competition to injectable insulin glargine.

218. Sanofi, at all relevant times, enjoyed high barriers to entry with respect to the brand and "generic" or biosimilar versions of injectable insulin glargine.

219. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Sanofi's ability to control the prices of its injectable insulin glargine products, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, (a) the fact that competing insulin glargine products would have entered the market at substantial discounts to the brand versions but for Sanofi's anticompetitive conduct; (b) Sanofi's success in coercing the market to adopt its Toujeo product by forcing it on to formularies and conditioning rebates for either product on the inclusion of both on formularies; and (c) Sanofi's continued supracompetitive pricing for its injectable insulin glargine products notwithstanding the purported availability of other diabetes treatments.

220. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiffs allege that the relevant antitrust market is the injectable insulin glargine market.

221. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

222. Sanofi was able to set the prices of Lantus Solostar and Toujeo above that which would be charged in a competitive market.

VI. Antitrust Impact and Impact on Interstate Commerce

223. Sanofi's anticompetitive scheme to maintain its monopoly in the injectable insulin glargine market included delaying Mylan's entry through Orange Book abuse and serial sham litigation, executing a coercive product hop, and tying Lantus and Toujeo for the purposes of rebates has denied consumers the benefits of generic or biosimilar competition for its insulin glargine products contemplated by the Hatch-Waxman Amendments. Sanofi's scheme to protect and extend its monopoly power in the injectable insulin glargine market has been multifaceted and

diverse, but the cumulative effect has been consistent: Sanofi has successfully and illegally insulated itself from competition.

224. Sanofi's anticompetitive scheme has had a direct, substantial, and adverse effect on Mylan and competition by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the injectable insulin glargine market. But for Sanofi's conduct, Mylan would have been able to enter the injectable insulin glargine market and compete for sales within the injectable insulin glargine market substantially earlier than it did. Had Mylan entered when it should have, Sanofi efforts to coerce the market to adopt Toujeo would have been unsuccessful, as Sanofi would have been unable to leverage Lantus's market power at the time to induce the shift.

225. By impeding competition from "generic" injectable insulin glargine products, including Mylan's, Sanofi's anticompetitive scheme has allowed (and unless restrained by this Court, will continue to allow) Sanofi to maintain and extend its monopoly power in the relevant market and to sell injectable insulin glargine products at artificially inflated monopoly prices.

226. Sanofi's anticompetitive scheme has harmed the competitive process and allowed Sanofi to perpetuate supracompetitive prices against wholesalers, retailers, payers, and consumers. But for Sanofi's anticompetitive conduct, consumers and federal, state, and private payers would have enjoyed the benefits of lower-priced "generic" or biosimilar competition years earlier. Instead, as a result of Sanofi's strategies to thwart "generic" entry, consumers and federal, state, and private payers have been, and unless Sanofi is restrained by this Court, will continue to be, forced to pay monopoly rents for Sanofi's injectable insulin glargine products in the magnitude of hundreds of millions of dollars in overcharge. The impact of Sanofi's conduct is felt throughout the health care

industry, impacting pharmaceutical competitors, health care providers, insurers and other direct purchasers, intermediaries, and consumers.

227. Sanofi's efforts to protect its insulin franchise is the subject of numerous lawsuits brought by state attorneys general, including (at least) Arkansas, California, Illinois, Kansas, Minnesota, and Mississippi. The ability of Sanofi to orchestrate and execute the strategies at issue was entirely dependent upon preventing additional insulin competition from disrupting the scheme.

228. The harm to Mylan from Sanofi's conduct is manifold:

- Sanofi's conduct deprived Mylan of the sales and profits it would have realized had Mylan not been delayed by Sanofi's baseless patent assertions and the attendant automatic stay.
- Sanofi's conduct forced Mylan to expend years and millions of dollars fighting baseless patent litigation.
- Sanofi's conduct deprived Mylan of the sales and profits it would have realized had Sanofi not illegally tied rebates between its two insulin glargine products.
- Sanofi's conduct deprived Mylan of the additional sales and profits it would have made had Sanofi not shifted the market to the Toujeo product for the sole purpose of further extending its monopoly power.
- Sanofi's conduct enabled Sanofi to set and stabilize the broader insulin market, and further monopolize the injectable insulin glargine market, by locking in market shares and preventing putative entrants such as Mylan from gaining market share.

229. Sanofi's anticompetitive conduct as alleged herein is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine, or any statute of limitations. Sanofi's illegal conduct has been continuing in nature and has been fraudulently concealed from Mylan.

230. There is and was no legitimate, procompetitive justification for Sanofi's anticompetitive conduct. Even if there were some conceivable and cognizable justification, Sanofi's conduct was not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the scheme's anticompetitive effects on Mylan, competition, and consumers.

231. Mylan seeks damages through November 29, 2022.

FIRST COUNT
Sherman Act Section 2
Monopolization

232. Mylan repeats and re-alleges the allegations of paragraphs 1-231 as if set forth fully herein.

233. Sanofi possesses monopoly power in the injectable insulin glargine market. This market is characterized by significant barriers to entry.

234. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Sanofi has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by maintaining its monopoly of the injectable insulin glargine market.

235. Through the foregoing acts, Sanofi, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used its power in the injectable insulin glargine market to maintain its monopoly of the injectable insulin glargine market.

236. Sanofi knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully delay market entry of Mylan's biosimilar insulin glargine and to unlawfully hinder adoption of Mylan's biosimilar insulin glargine, and thus to willfully maintain its monopoly power. First, Sanofi amassed a thicket of invalid patents and listed those invalid patents in the Orange Book to provide a platform for baseless litigation against would-be competitors. Second, Sanofi engaged in a pattern of sham filings that abused the governmental processes through a years-long scheme of obtaining and asserting patents against would-be competitor Mylan without regard to the merits of its filings and for the purpose of harassment of would-be competitors. Third, Sanofi used coercive tactics to executive a product hop to an injectable insulin glargine product for the

sole purpose of protecting its monopoly power. Fourth, Sanofi wielded bundles and conditioned rebates for its injectable insulin glargine products to prevent biosimilar competition from any company lacking a deep portfolio of comparable products.

237. Sanofi engaged in this anticompetitive scheme and each of the component conduct with the specific intent to unlawfully delay market entry of a "generic" (and later interchangeable) version of injectable insulin glargine.

238. Sanofi's scheme and component conduct have no procompetitive, legitimate business justification. Sanofi's scheme and conduct can only be explained by anticompetitive motives and a desire to foreclose competition in the injectable insulin glargine market. For example, there is no legitimate business rationale for conducting baseless litigation against would-be "generic" (and later interchangeable) entrants. The only justification for these practices is Sanofi's desire to block "generic" competition and harm "generic" competitors.

239. By this scheme, Sanofi intentionally and wrongfully maintained and attempted to maintain monopoly power with respect to the injectable insulin glargine market in violation of Section 2 of the Sherman Act. As a result of Sanofi's unlawful actual and attempted maintenance of monopoly power, Mylan has suffered injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

240. Sanofi's conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of injectable insulin glargine was delayed;
- Purchasers of injectable insulin glargine were deprived of the benefits of free and open competition;
- Payers and consumers paid supracompetitive prices for injectable insulin glargine products;
- Mylan was deprived of revenues and profits it otherwise would have achieved but-for Sanofi's illegal conduct.

241. Sanofi's conduct occurred in, and has had a substantial effect on, interstate commerce.

242. Mylan is entitled to a judgment that Sanofi has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

SECOND COUNT
Sherman Act Section 2
Attempted Monopolization

243. Mylan repeats and re-alleges the allegations of paragraphs 1-231 as if fully set forth herein.

244. Sanofi's scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the injectable insulin glargine market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Sanofi amassed a thicket of invalid patents, purposefully and knowingly listed invalid patents in the Orange Book, and abused the statutory automatic stay conferred by having these patents improperly listed in the Orange Book. Sanofi then commenced patent litigation against Mylan fully knowing that the patents were invalid and uninfringed by Mylan. During the time that Sanofi embroiled Mylan in baseless litigation Sanofi used coercive tactics to shift the market from Lantus to Toujeo, a product without any meaningful therapeutic differences to Lantus, for the sole and specific purpose of prolonging its monopoly and hampering "generic" competition. Sanofi then conditioned, and on information and belief continues to condition, rebates for both Lantus and Toujeo on having both on formularies, effectively blocking biosimilar competition.

THIRD COUNT
Clayton Act Section 3
Conditional Sales Resulting in Substantial Lessening of Competition and Tending to Create a Monopoly

245. Mylan repeats and re-alleges the allegations of paragraphs 1-231 as if fully set forth herein.

246. Section 3 of the Clayton Act prohibits the sale or contract for sale of goods on the condition, agreement, or understanding that the purchaser shall not use or deal in the goods of a competitor of the seller "where the effect of such lease, sale, or contract for sale or such condition, agreement, or understanding may be to substantially lessen competition or tend to create a monopoly in any line of commerce." 15 U.S.C. § 14.

247. Sanofi entered into conditional rebates with payers that required both Lantus and Toujeo appear on formulary in order to qualify for Sanofi's full rebate offer. The effect of these contracts was intended by Sanofi, and in fact was, to create and protect Sanofi's marker power in the market for injectable insulin glargine.

248. Mylan's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Sanofi's anticompetitive conduct in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14. Mylan seeks actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

FOURTH COUNT
The New Jersey Antitrust Act, N.J.S.A. 56:9-4

249. Mylan repeats and re-alleges the allegations of paragraphs 1-231 as if fully set forth herein.

250. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. 56:9 et seq., and seeks a judgment that Sanofi's conduct as alleged herein has violated New Jersey Antitrust Act, N.J. Stat. Ann. 56:9-4 – Monopolization.

251. Sanofi's conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. 56:9-4.

252. Specifically, Sanofi's anticompetitive scheme, including abuse of the regulatory processes and court filings, coercive product hop, and bundling to exclude rivals were calculated to maintain monopoly power in the relevant market, in violation of N.J. Stat. Ann. 56:9-4.

253. Sanofi's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

254. Mylan is entitled to a judgment that Sanofi has violated Section 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. 56:9-12, plus interest; and to its costs and attorneys' fees.

FIFTH COUNT
Tortious Inducement of Refusal to Deal

255. Mylan repeats and re-alleges the allegations of paragraphs 1-231 as if fully set forth herein.

256. Mylan develops and sells pharmaceutical products in the commerce of the State of Pennsylvania.

257. Sanofi's conduct gives rise to common law liability for tortious inducement of refusal to deal.

258. Mylan had a reasonable expectation of economic benefit from prospective contractual and economic relationships with thousands of purchasers, pharmacies, and diabetic patients across the country, all of whom would purchase Mylan's Semglee.

259. Defendants had knowledge of Mylan's prospective business relationships with its various prospective customers of Semglee.

260. In connection with its anticompetitive scheme, including its component conduct alleged above, Sanofi had the purpose or intent to harm Mylan by preventing relationships from

occurring with prospective contractual and economic relationships with thousands of purchasers, pharmacies, and diabetic patients across the country, all of whom would purchase Mylan's Semglee. Because of Sanofi's conduct, payers were induced into not dealing with Mylan and instead remaining beholden to Sanofi's larger insulin franchise.

261. Defendants' conduct was wrongful, improper, and without privilege or justification.

262. Defendants' motives were to gain an unfair marketplace advantage over Mylan in connection with the relevant markets.

263. If Sanofi had not interfered, Mylan would not be deprived of its benefit from the prospective contractual and economic relationships with purchasers, pharmacies, and consumers, or delayed in entering the relevant market, and would receive the anticipated benefit of sales and profits from "generic" entry.

264. As a direct and proximate cause of Defendants' conduct, Mylan has been injured and has sustained damages. Sanofi's tortious inducement of refusal to deal has directly and proximately caused injury to Mylan's business and property, including but not limited to lost profits and lost business opportunities. As a result of Sanofi's improper conduct, Mylan suffered actual damages in an amount to be determined at trial.

265. Sanofi's conduct as complained herein was malicious, wanton, oppressive, reckless, and in willful disregard of Mylan's rights (as well as those of pharmacies and patients), thereby warranting the imposition of punitive damages in order to deter similar unlawful conduct by Sanofi in the future.

VII. Prayer for Relief

WHEREFORE, Mylan respectfully requests judgment in its favor and against Sanofi as follows:

a. Compensatory damages for Mylan's lost sales and profits of injectable insulin glargine products, and profits on those sales, that are caused by the delay in approval of Mylan's biosimilar insulin glargine and interference with Mylan's ability to make sales;

b. Treble damages pursuant to 15 U.S.C. § 15;

c. Exemplary and punitive damages as appropriate to deter any future willful misconduct by Sanofi in reckless disregard of Mylan's rights;

d. Ordering Sanofi to pay Mylan's reasonable attorneys' fees, costs, and disbursements of this action; and

e. Such other and further relief as the Court deems just and proper.

VIII. Jury Trial Demanded

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. demand a trial by jury as to all issues of right to a jury.

Dated: May 17, 2023

Respectfully submitted,

/s/ John Schwab

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