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

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC., *Plaintiffs*, v. SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS PUERTO RICO INC. *Defendants*.	No. 2:23-cv-00836-MRH

DEFENDANTS SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS PUERTO RICO INC., AND AVENTIS PHARMA S.A.'S ANSWER TO PLAINTIFFS' COMPLAINT

COME NOW Defendants Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Sanofi-Aventis Puerto Rico Inc. ("Sanofi P.R."), and Aventis Pharma S.A. ("Aventis") (collectively, "Defendants"), by and through their undersigned counsel, and hereby answer the Complaint filed by Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. (collectively, "Plaintiffs") on May 17, 2023 (ECF No. 1).

PRELIMINARY STATEMENT

This case is directed exclusively to competition in the U.S. "market for injectable insulin glargine," involving allegations related to U.S. patents, U.S. patent litigation, and contracts with U.S. purchasers. Notwithstanding the U.S.-focused nature of the alleged conduct, the Complaint contains an unabashed mashup of claims against not just the two U.S. Defendants, Sanofi U.S. and Sanofi P.R., but also two French Defendants, Aventis and Sanofi S.A. The Complaint provides *no* indication whether or how each individual Defendant participated in the alleged unlawful conduct—instead collectively referring to "Sanofi" across 265 paragraphs and 5 counts. Each

Defendant has endeavored to answer the allegations in the Complaint based upon a reasonable investigation, including insofar as the allegations reflect publicly available information. (Sanofi S.A.'s motion to dismiss the Complaint for lack of personal jurisdiction is currently held in abeyance, *see* ECF No. 85, and as such this Answer is not filed on behalf of Sanofi S.A.)

To be clear, each Defendant specifically denies any and all liability to Plaintiffs. Unless expressly stated otherwise, Defendants deny each and every allegation in the Complaint, including any allegations in the unnumbered and numbered paragraphs, titles, headings, subheadings, and footnotes. To the extent not expressly denied, all allegations for which Defendants deny possessing knowledge or information sufficient to form a belief are denied. An admission or denial by one Defendant does not constitute an admission or denial by all Defendants, unless expressly stated otherwise. In addition, an admission or denial by one or more Defendants does not constitute an admission that they participated in the alleged conduct, have non-public knowledge of the alleged facts, or possess responsive documents or information.

Defendants reserve the right to seek to amend and supplement this Answer as may be appropriate or necessary. Section headings from the Complaint are repeated below solely for ease of reference; by copying section headings, Defendants do not admit or attest to their accuracy. In addition, the sources that Plaintiffs cite speak for themselves. Defendants do not vouch for the accuracy of any source or citation and deny any characterizations or conclusions drawn therefrom in the Complaint.

I. Response to "Nature of the Case"

Complaint ¶ 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.

Answer to Complaint ¶ 1

Defendants deny the allegations in Paragraph 1, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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."
- "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.

Answer to Complaint ¶ 2

Defendants deny the allegations in Paragraph 2, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 2.

[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").

[2] Drug Pricing Documents at 221, 219.

Complaint ¶ 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.

Answer to Complaint ¶ 3

Defendants deny the allegations in Paragraph 3, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 4

Defendants deny the allegations in Paragraph 4, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 5

Defendants deny the allegations in Paragraph 5, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that Mylan submitted notice letters to Sanofi U.S. regarding twenty-one patents listed in the Orange Book for NDA 21-081.

Complaint ¶ 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 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

Answer to Complaint ¶ 6

Defendants admit, insofar as it is publicly available information, the patent numbers and patent names in the table in Paragraph 6. Defendants deny the remaining allegations in Paragraph 6, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited sources speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 6.

Complaint ¶ 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.

Answer to Complaint ¶ 7

Defendants admit, insofar as it is publicly available information, that the patents identified in the table in Paragraph 6 were listed in the Orange Book for NDA 21-081. Defendants deny the remaining allegations in Paragraph 7, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 8

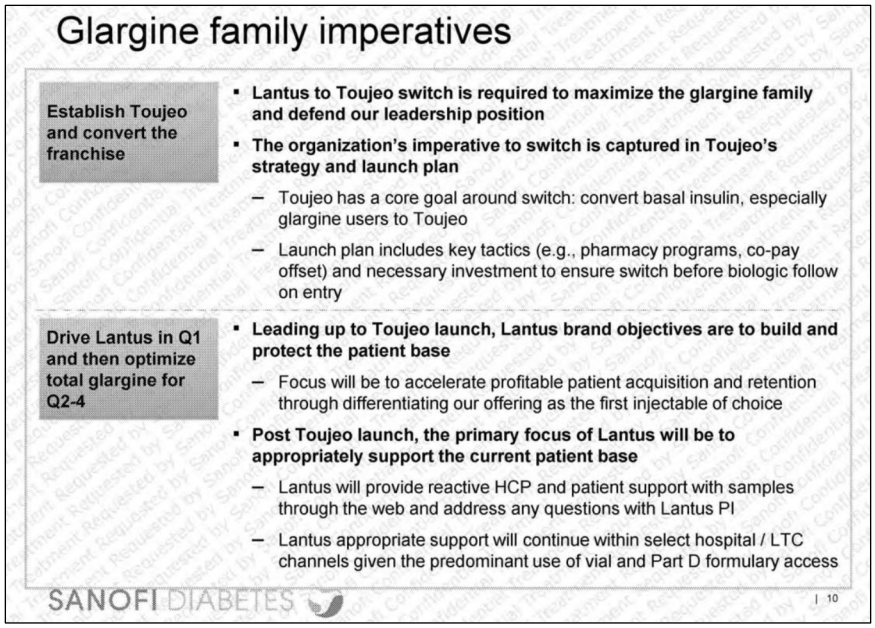
Defendants deny the allegations in Paragraph 8, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 8. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.



Answer to Complaint ¶ 9

Defendants deny the allegations in Paragraph 9, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 9. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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]

Answer to Complaint ¶ 10

Defendants deny the allegations in Paragraph 10, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any

[5] Drug Pricing Documents at 225.

characterizations or conclusions drawn therefrom in Paragraph 10. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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]

Answer to Complaint ¶ 11

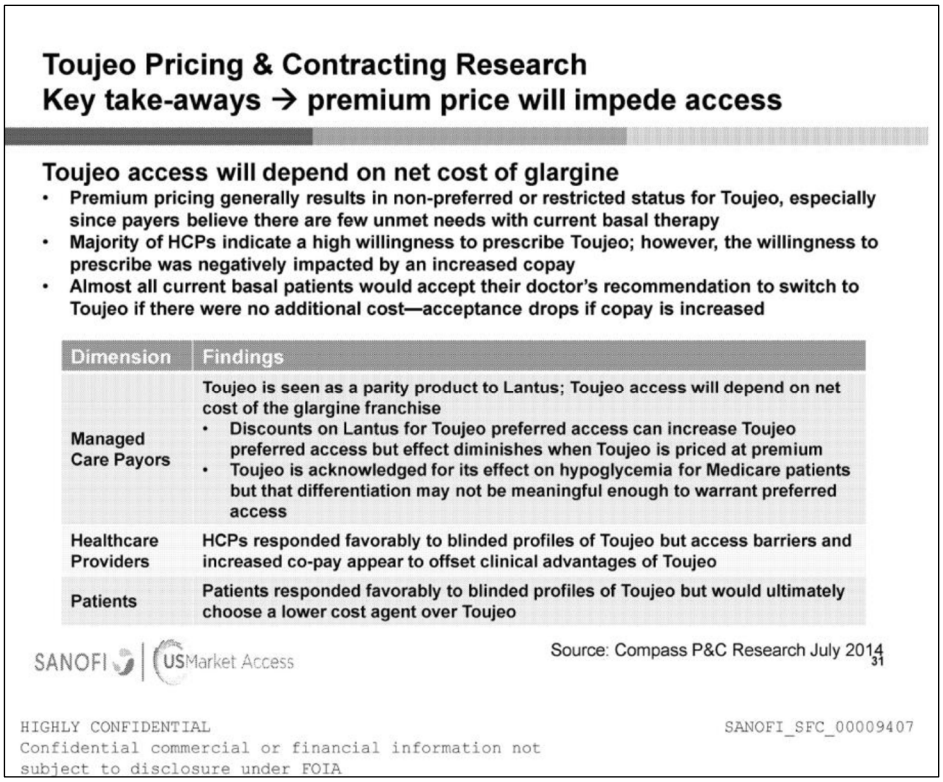
Defendants deny the allegations in Paragraph 11, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 11. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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]

[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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HIGHLY CONFIDENTIAL
Confidential commercial or financial information not subject to disclosure under FOIA

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Answer to Complaint ¶ 12

Defendants deny the allegations in Paragraph 12, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 12. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 13

Defendants deny the allegations in Paragraph 13, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

[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").

Answer to Complaint ¶ 14

Defendants deny the allegations in Paragraph 14, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 14.

Complaint ¶ 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.

Answer to Complaint ¶ 15

Defendants admit, insofar as it is publicly available information, that the FDA approved Mylan's 505(b)(2) New Drug Application for its follow-on biologic product Semglee in June 2020, and that Mylan launched the product in August 2020. Defendants deny the remaining allegations in Paragraph 15, including allegations containing characterizations and legal or other conclusions to which no response is required.

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

Answer to Complaint ¶ 16

The allegations in Paragraph 16 contain characterizations and legal or other conclusions to which no response is required, and are otherwise denied. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 and therefore deny them.

Complaint ¶ 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.

Answer to Complaint ¶ 17

Defendants deny the allegations in Paragraph 17, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

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 %

Answer to Complaint ¶ 18

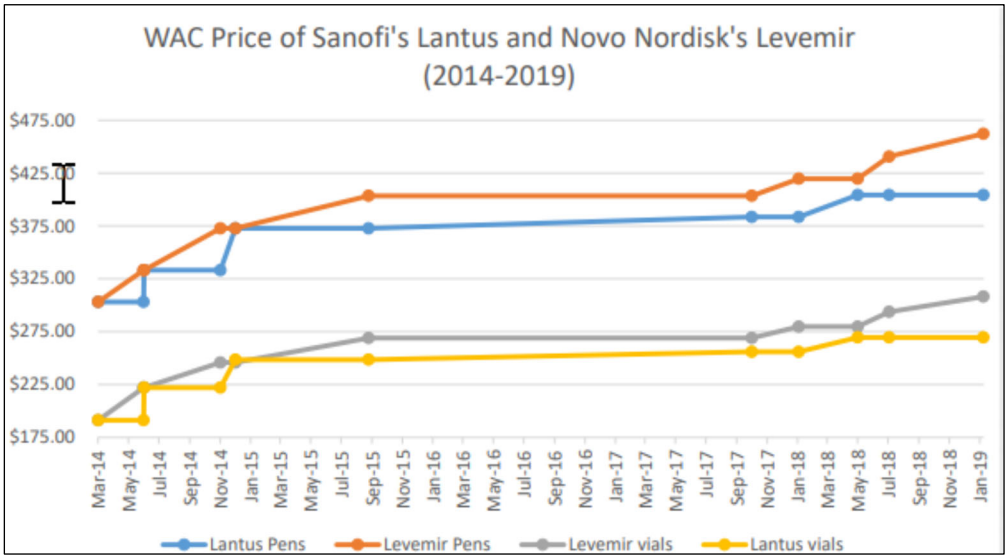
Defendants deny the allegations in Paragraph 18, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

[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.

document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 18.

Complaint ¶ 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]



Answer to Complaint ¶ 19

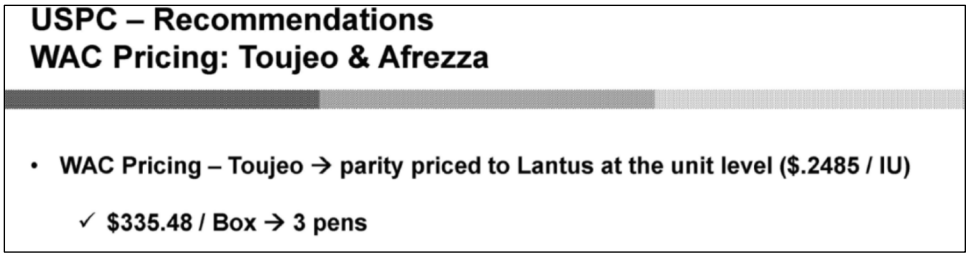
Defendants deny the allegations in Paragraph 19, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 19.

Complaint ¶ 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.



Answer to Complaint ¶ 20

Defendants deny the allegations in Paragraph 20, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 20.

Complaint ¶ 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]

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

[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.).

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

Answer to Complaint ¶ 21

Defendants deny the allegations in Paragraph 21, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the dockets that Plaintiffs cite out of context speak for themselves, including with respect to any status changes occurring since the Complaint was filed on May 17, 2023, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 21.

Complaint ¶ 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.

Answer to Complaint ¶ 22

Defendants deny the allegations in Paragraph 22, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 23

Defendants deny the allegations in Paragraph 23, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

II. Response to "Parties"

Complaint ¶ 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.

Answer to Complaint ¶ 24

Defendants admit that Mylan Pharmaceuticals Inc. is a corporation existing under the laws of West Virginia, with their principal place of business located at 3711 Collins Ferry Road, Morgantown, West Virginia.

Complaint ¶ 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.

Answer to Complaint ¶ 25

Defendants admit that Mylan Specialty L.P. is a limited partnership registered in Delaware. Defendants otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 and therefore deny them.

Complaint ¶ 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."

Answer to Complaint ¶ 26

Defendants admit that Mylan Inc. is a corporation incorporated in Pennsylvania with its principal place of business located at 1000 Mylan Boulevard in Canonsburg, PA 15317. Defendants also admit that Mylan Inc. is the parent company of Mylan Pharmaceuticals Inc. and Mylan Specialty L.P. Defendants deny the remaining allegations in Paragraph 26, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 27

Defendants admit that Sanofi S.A. is a société anonyme organized and existing under the laws of France. Defendants deny that the corporate designation "S.A." is part of the entity's name but nonetheless refer to the entity as "Sanofi S.A." to avoid confusion. Defendants deny that Sanofi S.A.'s principal place of business is located at 54 Rue La Boetie, 75008, Paris, France. Sanofi S.A.'s principal place of business is located at 46 Avenue De La Grande Armée, 75017, Paris, France.

Complaint ¶ 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.

Answer to Complaint ¶ 28

Defendants admit that Sanofi U.S. is a Delaware limited liability corporation and that its principal place of business was located at 55 Corporate Drive, Bridgewater, New Jersey 08807

until June 2025. As of June 2025, Sanofi U.S.'s principal place of business is located at 100 Morris Street, Morristown, New Jersey 07690.

Complaint ¶ 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.

Answer to Complaint ¶ 29

Defendants admit that Aventis Pharma S.A. is a société à responsabilité limitée organized and existing under the laws of France. Defendants deny that the corporate designation "S.A." is part of the entity's name but nonetheless refer to the entity as "Aventis Pharma S.A." to avoid confusion. Defendants deny that Aventis Pharma S.A.'s principal place of business is located at 20 Avenue Raymond Aron, 92160, Antony, France. Aventis Pharma S.A.'s principal place of business is located at 82 Avenue Raspail, 94250, Gentilly, France.

Complaint ¶ 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]

Answer to Complaint ¶ 30

Defendants admit that Sanofi P.R. is a corporation organized under the laws of Puerto Rico. Defendants further admit that Sanofi P.R. is a wholly-owned subsidiary of Sanofi S.A. Defendants deny that Sanofi P.R.'s principal place of business is located at Metro Office Park, Edificio De la Cruz #9, Suite 100, Guaynabo, Puerto Rico 00968. Sanofi P.R.'s principal place of business is located at City View Plaza 2/4, Suite 24, Guaynabo, 00968, Puerto Rico.

[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.

Complaint ¶ 31

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

Answer to Complaint ¶ 31

The allegations in Paragraph 31 contain characterizations and legal or other conclusions to which no response is required, and are otherwise denied.

III. Response to "Jurisdiction and Venue"

Complaint ¶ 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.

Answer to Complaint ¶ 32

Defendants deny the allegations in Paragraph 32, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 33

This Court has personal jurisdiction over Sanofi.

Answer to Complaint ¶ 33

Defendants deny the allegations in Paragraph 33, including allegations containing characterizations and legal or other conclusions to which no response is required, except to state that Sanofi U.S., Sanofi P.R., and Aventis do not intend to challenge that this Court has personal jurisdiction over them.

Complaint ¶ 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.

Answer to Complaint ¶ 34

Defendants deny the allegations in Paragraph 34, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that it sold Lantus SoloSTAR and Toujeo in interstate commerce during the alleged time period.

Complaint ¶ 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.

Answer to Complaint ¶ 35

Defendants deny the allegations in Paragraph 35, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. and Sanofi P.R. admit that they have transacted business within the United States.

Complaint ¶ 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.

Answer to Complaint ¶ 36

Defendants deny the allegations in Paragraph 36, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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).

Answer to Complaint ¶ 37

Defendants deny the allegations in Paragraph 37, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 38

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

Answer to Complaint ¶ 38

Defendants deny the allegations in Paragraph 38, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 39

Defendants deny the allegations in Paragraph 39, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 40

Defendants deny the allegations in Paragraph 40, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that it sold Lantus SoloSTAR and Toujeo in interstate commerce during the alleged time period.

Complaint ¶ 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.

Answer to Complaint ¶ 41

Defendants deny the allegations in Paragraph 41, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 42

Defendants deny the allegations in Paragraph 42, including allegations containing characterizations and legal or other conclusions to which no response is required.

IV. Response to "Statement of Facts"

A. Statutory and Regulatory Background

Complaint ¶ 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.

Answer to Complaint ¶ 43

Defendants deny the allegations in Paragraph 43, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 43.

Complaint ¶ 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)).

Answer to Complaint ¶ 44

Defendants deny the allegations in Paragraph 44, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 44.

Complaint ¶ 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.

Answer to Complaint ¶ 45

Defendants deny the allegations in Paragraph 45, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 45.

Complaint ¶ 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.

Answer to Complaint ¶ 46

Defendants deny the allegations in Paragraph 46, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 46.

Complaint ¶ 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.

Answer to Complaint ¶ 47

Defendants deny the allegations in Paragraph 47, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 47.

Complaint ¶ 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.

Answer to Complaint ¶ 48

Defendants deny the allegations in Paragraph 48, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 48.

Complaint ¶ 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.

Answer to Complaint ¶ 49

Defendants deny the allegations in Paragraph 49, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 regarding the FDA's resources and specialization and therefore deny them.

Complaint ¶ 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).

Answer to Complaint ¶ 50

Defendants deny the allegations in Paragraph 50, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the decision that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 50.

Complaint ¶ 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).

Answer to Complaint ¶ 51

Defendants deny the allegations in Paragraph 51, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 51.

Complaint ¶ 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).

Answer to Complaint ¶ 52

Defendants deny the allegations in Paragraph 52, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 52.

Complaint ¶ 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.

Answer to Complaint ¶ 53

Defendants deny the allegations in Paragraph 53, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 53.

Complaint ¶ 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).

Answer to Complaint ¶ 54

Defendants deny the allegations in Paragraph 54, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited regulation speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 54.

Complaint ¶ 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.

Answer to Complaint ¶ 55

Defendants deny the allegations in Paragraph 55, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 55.

Complaint ¶ 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").

Answer to Complaint ¶ 56

Defendants deny the allegations in Paragraph 56, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited statutes speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 56.

Complaint ¶ 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.

Answer to Complaint ¶ 57

Defendants deny the allegations in Paragraph 57, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

FDCA and regulations speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 57.

Complaint ¶ 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 which claims the drug for which the applicant submitted the application 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.[14]

Answer to Complaint ¶ 58

Defendants deny the allegations in Paragraph 58, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 58.

Complaint ¶ 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]

Answer to Complaint ¶ 59

Defendants deny the allegations in Paragraph 59, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

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

[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.").

FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 59.

B. The Orange Book

Complaint ¶ 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*.

Answer to Complaint ¶ 60

Defendants deny the allegations in Paragraph 60, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited regulation and Federal Register publication speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 60.

Complaint ¶ 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).

Answer to Complaint ¶ 61

Defendants deny the allegations in Paragraph 61, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited regulation speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 61.

Complaint ¶ 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).

Answer to Complaint ¶ 62

Defendants deny the allegations in Paragraph 62, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited regulation speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 62.

Complaint ¶ 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]

Answer to Complaint ¶ 63

Defendants deny the allegations in Paragraph 63, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

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

cited Federal Register publication speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 63.

Complaint ¶ 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]

Answer to Complaint ¶ 64

Defendants deny the allegations in Paragraph 64, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited Federal Register publication speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 64.

Complaint ¶ 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]

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

[18] *Id.* at 50, 343.

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

Answer to Complaint ¶ 65

Defendants deny the allegations in Paragraph 65, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited Federal Register publication speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 65.

Complaint ¶ 66

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

Answer to Complaint ¶ 66

Defendants deny the allegations in Paragraph 66, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited Federal Register publication speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 66.

Complaint ¶ 67

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

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[19] *Id.*

[20] *Id.* at 50, 344

Answer to Complaint ¶ 67

Defendants deny the allegations in Paragraph 67, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 67.

Complaint ¶ 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.

Answer to Complaint ¶ 68

Defendants deny the allegations in Paragraph 68, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 68.

Complaint ¶ 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.

Answer to Complaint ¶ 69

Defendants deny the allegations in Paragraph 69, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 69.

Complaint ¶ 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 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").

Answer to Complaint ¶ 70

Defendants deny the allegations in Paragraph 70, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 70.

Complaint ¶ 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).

Answer to Complaint ¶ 71

Defendants deny the allegations in Paragraph 71, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the decision that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 71.

Complaint ¶ 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.

Answer to Complaint ¶ 72

Defendants deny the allegations in Paragraph 72, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 72.

Complaint ¶ 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).

Answer to Complaint ¶ 73

Defendants deny the allegations in Paragraph 73, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 73.

Complaint ¶ 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).

Answer to Complaint ¶ 74

Defendants deny the allegations in Paragraph 74, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 74.

Complaint ¶ 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).

Answer to Complaint ¶ 75

Defendants deny the allegations in Paragraph 75, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 75.

Complaint ¶ 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.

Answer to Complaint ¶ 76

Defendants deny the allegations in Paragraph 76, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited statutes speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 76.

Complaint ¶ 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.

Answer to Complaint ¶ 77

Defendants deny the allegations in Paragraph 77, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 77.

Complaint ¶ 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.

Answer to Complaint ¶ 78

Defendants deny the allegations in Paragraph 78, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 78.

Complaint ¶ 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.

Answer to Complaint ¶ 79

Defendants deny the allegations in Paragraph 79, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the FDCA speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 79.

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

Complaint ¶ 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]

Answer to Complaint ¶ 80

Defendants deny the allegations in Paragraph 80, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the source that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 80.

Complaint ¶ 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).

Answer to Complaint ¶ 81

Defendants deny the allegations in Paragraph 81, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited laws speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 81.

[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

Complaint ¶ 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.

Answer to Complaint ¶ 82

Defendants deny the allegations in Paragraph 82, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the PTO issued U.S. Patent No. 5,656,722 for insulin glargine in August 1997.

Complaint ¶ 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.

Answer to Complaint ¶ 83

Defendants deny the allegations in Paragraph 83, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited patent speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 83.

Complaint ¶ 84

The '722 patent expired on August 12, 2014.

Answer to Complaint ¶ 84

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 84.

Complaint ¶ 85

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

Answer to Complaint ¶ 85

Defendants deny the allegations in Paragraph 85, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the period of pediatric exclusivity for the '722 patent expired on February 12, 2015.

Complaint ¶ 86

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

Answer to Complaint ¶ 86

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 86.

Complaint ¶ 87

Sanofi listed the '722 patent in the Orange Book.

Answer to Complaint ¶ 87

Sanofi U.S. denies the allegations in Paragraph 87, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that it submitted information regarding the '722 patent to the FDA for NDA 21-081. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 87 and therefore deny them.

Complaint ¶ 88

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

Answer to Complaint ¶ 88

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 88.

Complaint ¶ 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.

Answer to Complaint ¶ 89

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 89.

Complaint ¶ 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.

Answer to Complaint ¶ 90

Defendants deny the allegations in Paragraph 90, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that in April 2000, the FDA approved NDA 21-081 in 5 mL vials, 10 mL vials, and 3 mL cartridges for use in the OptiPen One Insulin Delivery Device.

Complaint ¶ 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.

Answer to Complaint ¶ 91

Sanofi U.S. denies the allegations in Paragraph 91, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that it submitted information regarding the '722 patent to the FDA for NDA 21-081. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 91 and therefore deny them. In addition, the Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 91.

Complaint ¶ 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.

Answer to Complaint ¶ 92

Defendants deny the allegations in Paragraph 92, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Lantus has been sold and prescribed in the United States and its territories since May 2001 through the date of this Answer.

Complaint ¶ 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.

Answer to Complaint ¶ 93

Defendants deny the allegations in Paragraph 93, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 94

Defendants deny the allegations in Paragraph 94, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 94.

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

Complaint ¶ 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.

Answer to Complaint ¶ 95

Defendants deny the allegations in Paragraph 95, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the FDA approved NDA 21-

[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.

081/S-017 in 2005. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 95.

Complaint ¶ 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.

Answer to Complaint ¶ 96

Defendants deny the allegations in Paragraph 96, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the FDA approved NDA 21-081/S-024 in 2007. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 96.

Complaint ¶ 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)

Answer to Complaint ¶ 97

The allegations in Paragraph 97 are unintelligible and are denied on that basis.

Complaint ¶ 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.

Answer to Complaint ¶ 98

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 98.

Complaint ¶ 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.

Answer to Complaint ¶ 99

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 99.

Complaint ¶ 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.

Answer to Complaint ¶ 100

Sanofi U.S. denies the allegations in Paragraph 100, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that Sanofi U.S. and Sanofi Winthrop Industrie were licensees of certain rights in or to the '652 and '930 patents and that they had the right to sue and recover damages for infringement of the '652 and '930 patents. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100 and therefore deny them.

Complaint ¶ 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."

Answer to Complaint ¶ 101

Defendants deny the allegations in Paragraph 101, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited patents speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 101.

Complaint ¶ 102

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

Answer to Complaint ¶ 102

The allegations in Paragraph 102 are unintelligible and are denied on that basis.

Complaint ¶ 103

Lantus SoloSTAR does not contain a polysorbate.

Answer to Complaint ¶ 103

Defendants deny the allegations in Paragraph 103, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that a polysorbate is not an ingredient of the Lantus SoloSTAR formulation.

Complaint ¶ 104

Lantus SoloSTAR does not contain a poloxamer.

Answer to Complaint ¶ 104

Defendants deny the allegations in Paragraph 104, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that a poloxamer is not an ingredient of the Lantus SoloSTAR formulation.

Complaint ¶ 105

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

Answer to Complaint ¶ 105

Defendants deny the allegations in Paragraph 105, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that an ester of a polyhydric alcohol is not an ingredient of the Lantus SoloSTAR formulation.

Complaint ¶ 106

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

Answer to Complaint ¶ 106

Defendants deny the allegations in Paragraph 106, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that an ether of a polyhydric alcohol is not an ingredient of the Lantus SoloSTAR formulation.

Complaint ¶ 107

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

Answer to Complaint ¶ 107

Defendants deny the allegations in Paragraph 107, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 108

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

Answer to Complaint ¶ 108

Defendants deny the allegations in Paragraph 108, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 109

Sanofi U.S. denies the allegations in Paragraph 109, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that it submitted information regarding the '652 and '930 patents to the FDA for NDA 21-081. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109 and therefore deny them.

Complaint ¶ 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).

Answer to Complaint ¶ 110

Defendants deny the allegations in Paragraph 110, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited statute speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 110.

Complaint ¶ 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.

Answer to Complaint ¶ 111

Defendants deny the allegations in Paragraph 111, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 112

Defendants deny the allegations in Paragraph 112, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 113

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

Answer to Complaint ¶ 113

Defendants deny the allegations in Paragraph 113, including allegations containing characterizations and legal or other conclusions to which no response is required.

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

Complaint ¶ 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.

Answer to Complaint ¶ 114

Defendants deny the allegations in Paragraph 114, including allegations containing characterizations and legal or other conclusions to which no response is required, with the below exceptions. Insofar as it is publicly available information, Defendants admit that the patents identified in Paragraph 114 issued on the specified dates with the specified titles and expired on the specified dates, except Defendants deny that the '009 patent expired on August 18, 2024. The '009 patent expired on August 16, 2024. Sanofi U.S. admits that it submitted information regarding the patents identified in Paragraph 114 to the FDA for NDA 21-081.

Complaint ¶ 115

None of the new patents claim insulin or insulin glargine.

Answer to Complaint ¶ 115

Defendants deny the allegations in Paragraph 115, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the patents cited in Paragraphs 114 and 115 speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 115.

Complaint ¶ 116

All of the new patents were invalid.

Answer to Complaint ¶ 116

Defendants deny the allegations in Paragraph 116, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the patents cited in Paragraphs 114, 115, and 116 speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 116.

Complaint ¶ 117

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

Answer to Complaint ¶ 117

Defendants deny the allegations in Paragraph 117, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 118

Defendants deny the allegations in Paragraph 118, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 118.

Complaint ¶ 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).

Answer to Complaint ¶ 119

Defendants deny the allegations in Paragraph 119, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 119.

Complaint ¶ 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).

Answer to Complaint ¶ 120

Defendants deny the allegations in Paragraph 120, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 121

Defendants deny the allegations in Paragraph 121, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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]

Answer to Complaint ¶ 122

Defendants deny the allegations in Paragraph 122, including allegations containing characterizations and legal or other conclusions to which no response is required.

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

Complaint ¶ 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 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."

Answer to Complaint ¶ 123

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 123 regarding Mylan's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 123, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the source that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 123.

Complaint ¶ 124

Mylan announced a partnership with Indian biopharmaceutical research company Biocon Limited ("Biocon") in February 2013 for a strategic collaboration for insulin products.[24]

[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.

[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.

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.

Answer to Complaint ¶ 124

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 124 regarding Mylan's and Biocon's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 124, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited sources speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 124.

Complaint ¶ 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 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.

Answer to Complaint ¶ 125

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 125 regarding Mylan's and Biocon's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 125, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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

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

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).

Answer to Complaint ¶ 126

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 126 regarding Mylan's intentions and therefore deny them. Defendants deny the remaining allegations in Paragraph 126, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 127

Defendants deny the allegations in Paragraph 127, including allegations containing characterizations and legal or other conclusions to which no response is required.

H. Mylan Confronts the Regulatory Dead Zone

Complaint ¶ 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.

Answer to Complaint ¶ 128

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 128 regarding the FDA's and Mylan's conduct and therefore deny them.

Defendants deny the remaining allegations in Paragraph 128, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 129

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 129 regarding the FDA's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 129, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Mylan submitted NDA 210605 on April 27, 2017.

Complaint ¶ 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.

Answer to Complaint ¶ 130

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 130 regarding the FDA's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 130, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that there was an August 15, 2017, meeting between Mylan and the FDA.

Complaint ¶ 131

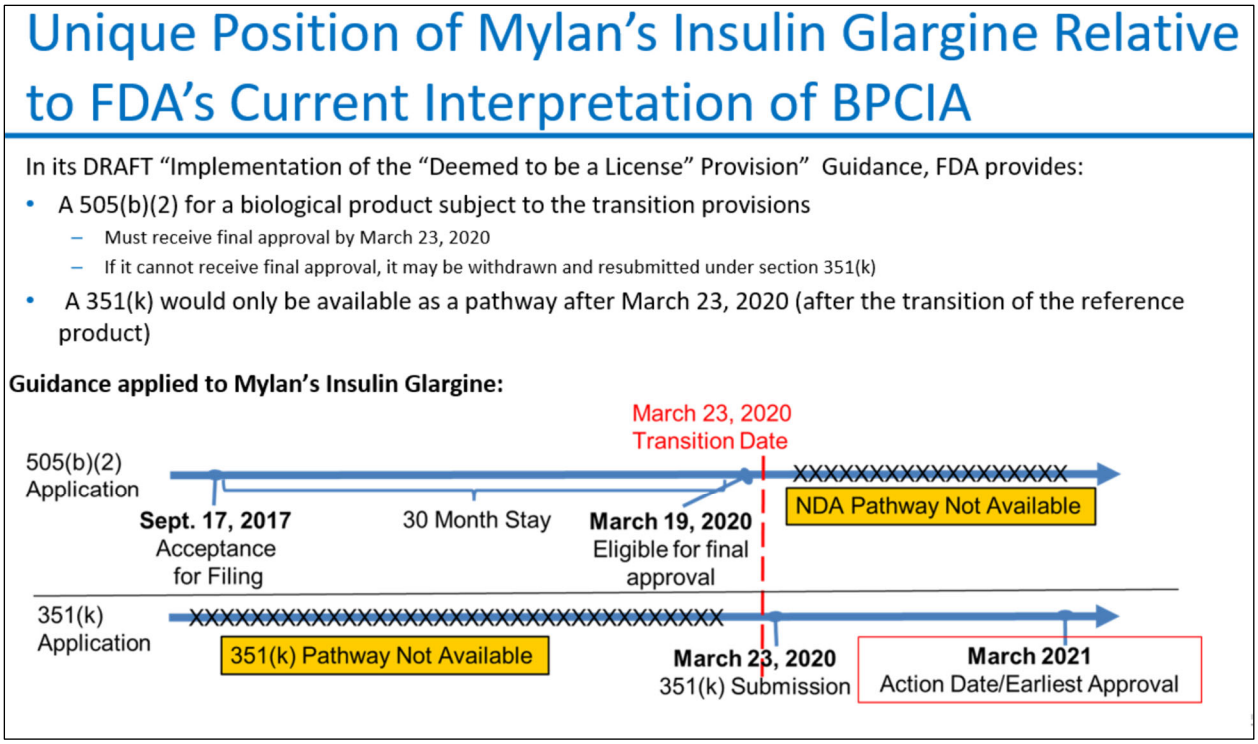
In this August 15, 2017 meeting Mylan explained to the FDA that the current interpretation of the transition provisions under the BPCIA creates a "dead zone" in which Mylan feared the FDA would be unable to complete review and approval in time. In that scenario, a company that spent millions of dollars 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.

Answer to Complaint ¶ 131

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 131 regarding Mylan's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 131, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information that there was an August 15, 2017, meeting between Mylan and the FDA.

Complaint ¶ 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:



Answer to Complaint ¶ 132

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 132 regarding Mylan's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 132, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited source speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 132.

Complaint ¶ 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.

Answer to Complaint ¶ 133

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 133 regarding the FDA's review and therefore deny them. Defendants

deny the remaining allegations in Paragraph 133, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 134

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 134 regarding Mylan's intentions and therefore deny them. Defendants deny the remaining allegations in Paragraph 134, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on August 31, 2017, Mylan requested that NDA 210605 be filed over protest, and that on September 15, 2017, the FDA filed NDA 210605 over protest.

Complaint ¶ 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.

Answer to Complaint ¶ 135

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 135 regarding Mylan's conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 135, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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."

Answer to Complaint ¶ 136

Defendants deny the allegations in Paragraph 136, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the FDA approved NDA 210605 on June 11, 2020. In addition, the cited source speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 136.

Complaint ¶ 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.

Answer to Complaint ¶ 137

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 137 regarding Mylan's intentions and therefore deny them. Defendants deny the remaining allegations in Paragraph 137, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Mylan filed BLA 761201 on July 29, 2020.

Complaint ¶ 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]

[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.

Answer to Complaint ¶ 138

Defendants deny the allegations in Paragraph 138, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on July 28, 2021, the FDA approved BLA 761201. In addition, the cited source speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 138.

Complaint ¶ 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."

Answer to Complaint ¶ 139

Defendants deny the allegations in Paragraph 139, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the source that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 139.

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

Complaint ¶ 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 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 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 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

Answer to Complaint ¶ 140

Defendants admit, insofar as it is publicly available information, the patent numbers and patent names in the table in Paragraph 140. Defendants deny the remaining allegations in Paragraph 140, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 141

Defendants deny the allegations in Paragraph 141, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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).

Answer to Complaint ¶ 142

Defendants deny the allegations in Paragraph 142, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 142.

Complaint ¶ 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%.

Answer to Complaint ¶ 143

Defendants deny the allegations in Paragraph 143, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 144

Sanofi U.S. denies the allegations in Paragraph 144, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi

U.S. admits that it received a Paragraph IV notice from Mylan on or about September 18, 2017. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 144 and therefore deny them.

Complaint ¶ 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):

> **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®.

Answer to Complaint ¶ 145

Defendants deny the allegations in Paragraph 145, including allegations containing characterizations and legal or other conclusions to which no response is required, except

[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).

Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan in the District of New Jersey on October 24, 2017, and in the Northern District of West Virginia on October 26, 2017. In addition, the cited sources speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 145.

Complaint ¶ 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.

Answer to Complaint ¶ 146

Defendants deny the allegations in Paragraph 146, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 147

Sanofi U.S. denies the allegations in Paragraph 147, including allegations containing characterizations and legal or other conclusions to which no response is required, except Sanofi U.S. admits that Sanofi U.S. granted Mylan a covenant not to sue for the following patents: 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. Sanofi P.R. and Aventis lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 147 and therefore deny them.

a. *The '652 Patent*

Complaint ¶ 148

The '652 was invalid for obviousness.

Answer to Complaint ¶ 148

Defendants deny the allegations in Paragraph 148, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 149

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

Answer to Complaint ¶ 149

Defendants deny the allegations in Paragraph 149, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 150

Defendants deny the allegations in Paragraph 150, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 151

Defendants admit, insofar as it is publicly available information, that on June 5, 2017, Mylan filed a Petition to request an *inter partes* review of claims 1-25 of the ’652 patent under 35 U.S.C. § 311. That Petition speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 151.

Complaint ¶ 152

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

Answer to Complaint ¶ 152

Defendants deny the allegations in Paragraph 152, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan on October 24, 2017.

Complaint ¶ 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.

Answer to Complaint ¶ 153

Defendants deny the allegations in Paragraph 153, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the PTAB instituted a trial on December 13, 2017, and issued a decision regarding the '652 patent on December 12, 2018; on November 19, 2019, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '652 patent, for which the mandate issued on February 18, 2020; and on October 5, 2020, the Supreme Court denied review of the Federal Circuit's decision regarding the '652 patent. The records of those proceedings and the decisions rendered therein speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 153.

b. *The '930 Patent*

Complaint ¶ 154

The '930 was invalid for obviousness.

Answer to Complaint ¶ 154

Defendants deny the allegations in Paragraph 154, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 155

Defendants deny the allegations in Paragraph 155, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 156

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

Answer to Complaint ¶ 156

Defendants admit, insofar as it is publicly available information, that on June 5, 2017, Mylan filed a Petition to request an *inter partes* review of claims 1-20 of the '930 patent. That Petition speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 156.

Complaint ¶ 157

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

Answer to Complaint ¶ 157

Defendants deny the allegations in Paragraph 157, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan on October 24, 2017.

Complaint ¶ 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.

Answer to Complaint ¶ 158

Defendants deny the allegations in Paragraph 158, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 12, 2018, the PTAB issued a decision regarding the '930 patent; on November 19, 2019, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '930 patent, for which the mandate issued on February 18, 2020; and on October 5, 2020, the Supreme Court denied review of the Federal Circuit's decision regarding the '930 patent. The records of those proceedings and the decisions rendered therein speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 158.

c. *The '069 Patent*

Complaint ¶ 159

The '069 patent was invalid for obviousness.

Answer to Complaint ¶ 159

Defendants deny the allegations in Paragraph 159, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 160

Defendants deny the allegations in Paragraph 160, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the '069 patent appeared in

the Orange Book for NDA 21-081 by June 2017. The Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 160.

Complaint ¶ 161

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

Answer to Complaint ¶ 161

Defendants deny the allegations in Paragraph 161, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan for infringement of the '069 patent on October 24, 2017.

Complaint ¶ 162

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

Answer to Complaint ¶ 162

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 162.

Complaint ¶ 163

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

Answer to Complaint ¶ 163

Defendants deny the allegations in Paragraph 163, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on April 2, 2020, the PTAB issued a decision regarding the '069 patent. The PTAB's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 163.

Complaint ¶ 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.

Answer to Complaint ¶ 164

Defendants deny the allegations in Paragraph 164, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 29, 2021, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '069 patent. The Federal Circuit's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 164.

d. *The '486 Patent*

Complaint ¶ 165

The '486 was invalid for obviousness.

Answer to Complaint ¶ 165

Defendants deny the allegations in Paragraph 165, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 166

Defendants deny the allegations in Paragraph 166, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the '486 patent appeared in the Orange Book for NDA 21-081 by June 2017. The Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 166.

Complaint ¶ 167

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

Answer to Complaint ¶ 167

Defendants deny the allegations in Paragraph 167, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan for infringement of the '486 patent on October 24, 2017.

Complaint ¶ 168

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

Answer to Complaint ¶ 168

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 168.

Complaint ¶ 169

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

Answer to Complaint ¶ 169

Defendants deny the allegations in Paragraph 169, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on May 29, 2020, the PTAB issued a decision regarding the '486 Patent. The PTAB decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 169.

Complaint ¶ 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.

Answer to Complaint ¶ 170

Defendants deny the allegations in Paragraph 170, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 29, 2021, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '486 patent. The Federal Circuit's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 170.

e. *The '044 Patent*

Complaint ¶ 171

The '044 was invalid for obviousness.

Answer to Complaint ¶ 171

Defendants deny the allegations in Paragraph 171, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 172

Defendants deny the allegations in Paragraph 172, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the '044 patent appeared in the Orange Book for NDA 21-081 by June 2017. The Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 172.

Complaint ¶ 173

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

Answer to Complaint ¶ 173

Defendants deny the allegations in Paragraph 173, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi sued Mylan for infringement of the ’044 patent on October 24, 2017.

Complaint ¶ 174

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

Answer to Complaint ¶ 174

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 174.

Complaint ¶ 175

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

Answer to Complaint ¶ 175

Defendants deny the allegations in Paragraph 175, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 176

Defendants deny the allegations in Paragraph 176, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 29, 2021, the Federal Circuit issued a decision regarding the PTAB’s decision regarding the ’044 patent. The

Federal Circuit's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 176.

f. *The '844 Patent*

Complaint ¶ 177

The '844 patent was invalid as unpatentable.

Answer to Complaint ¶ 177

Defendants deny the allegations in Paragraph 177, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 178

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

Answer to Complaint ¶ 178

Defendants deny the allegations in Paragraph 178, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the '844 patent appeared in the Orange Book for NDA 21-081 by June 2017. The Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 178.

Complaint ¶ 179

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

Answer to Complaint ¶ 179

Defendants deny the allegations in Paragraph 179, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan for infringement of the '844 patent on October 24, 2017.

Complaint ¶ 180

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

Answer to Complaint ¶ 180

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 180.

Complaint ¶ 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]

Answer to Complaint ¶ 181

Defendants deny the allegations in Paragraph 181, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Judge Chesler issued an opinion regarding the '844 patent on March 9, 2020. Judge Chesler's opinion speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 181.

Complaint ¶ 182

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

Answer to Complaint ¶ 182

Defendants deny the allegations in Paragraph 182, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 183

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

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

Answer to Complaint ¶ 183

Defendants deny the allegations in Paragraph 183, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 29, 2021, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '844 patent. The Federal Circuit's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 183.

g. *The '008 Patent*

Complaint ¶ 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]

Answer to Complaint ¶ 184

Defendants deny the allegations in Paragraph 184, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited source speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 184.

Complaint ¶ 185

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

Answer to Complaint ¶ 185

Defendants deny the allegations in Paragraph 185, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the '008 patent appeared in

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

the Orange Book for NDA 21-081 by June 2017. The Orange Book speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 185.

Complaint ¶ 186

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

Answer to Complaint ¶ 186

Defendants deny the allegations in Paragraph 186, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. sued Mylan for infringement of the '008 patent on October 24, 2017.

Complaint ¶ 187

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

Answer to Complaint ¶ 187

Insofar as it is publicly available information, Defendants admit the allegations in Paragraph 187.

Complaint ¶ 188

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

Answer to Complaint ¶ 188

Defendants deny the allegations in Paragraph 186, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. voluntarily dismissed its claims pertaining to the '008 patent on February 4, 2019.

Complaint ¶ 189

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

Answer to Complaint ¶ 189

Defendants deny the allegations in Paragraph 189, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the PTAB issued a decision regarding the '008 patent on May 29, 2020. The PTAB's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 189.

Complaint ¶ 190

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

Answer to Complaint ¶ 190

Defendants deny the allegations in Paragraph 190, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that on December 29, 2021, the Federal Circuit issued a decision regarding the PTAB's decision regarding the '008 patent. The Federal Circuit's decision speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 190.

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

Complaint ¶ 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.

Answer to Complaint ¶ 191

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 191 regarding Mylan's efforts and therefore deny them. Defendants deny the remaining allegations in Paragraph 191, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Mylan launched its insulin glargine product in 2020.

Complaint ¶ 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.

Answer to Complaint ¶ 192

Defendants deny the allegations in Paragraph 192, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 193

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

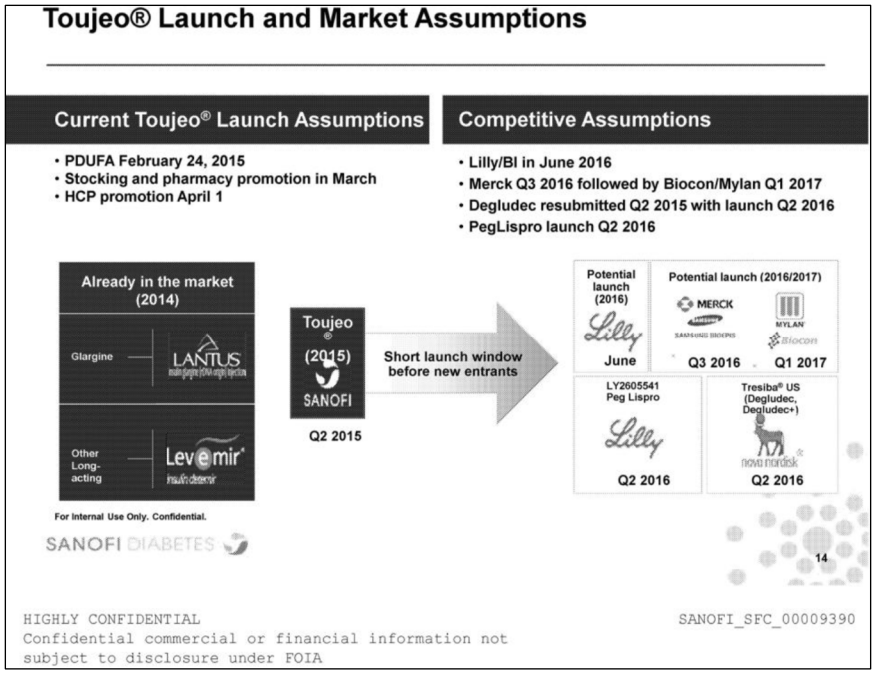
Answer to Complaint ¶ 193

Defendants deny the allegations in Paragraph 193, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.



Answer to Complaint ¶ 194

Defendants deny the allegations in Paragraph 194, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 194.

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

Complaint ¶ 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]

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

Answer to Complaint ¶ 195

Defendants deny the allegations in Paragraph 195, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that Sanofi U.S. submitted NDA 206538 on April 25, 2014. In addition, the cited source speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 195.

Complaint ¶ 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."
- "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."

Answer to Complaint ¶ 196

Defendants deny the allegations in Paragraph 196, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 196.

[32] *Id.*

Complaint ¶ 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]

Answer to Complaint ¶ 197

Defendants deny the allegations in Paragraph 197, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the document that Plaintiffs cite out of context speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 197.

Complaint ¶ 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.

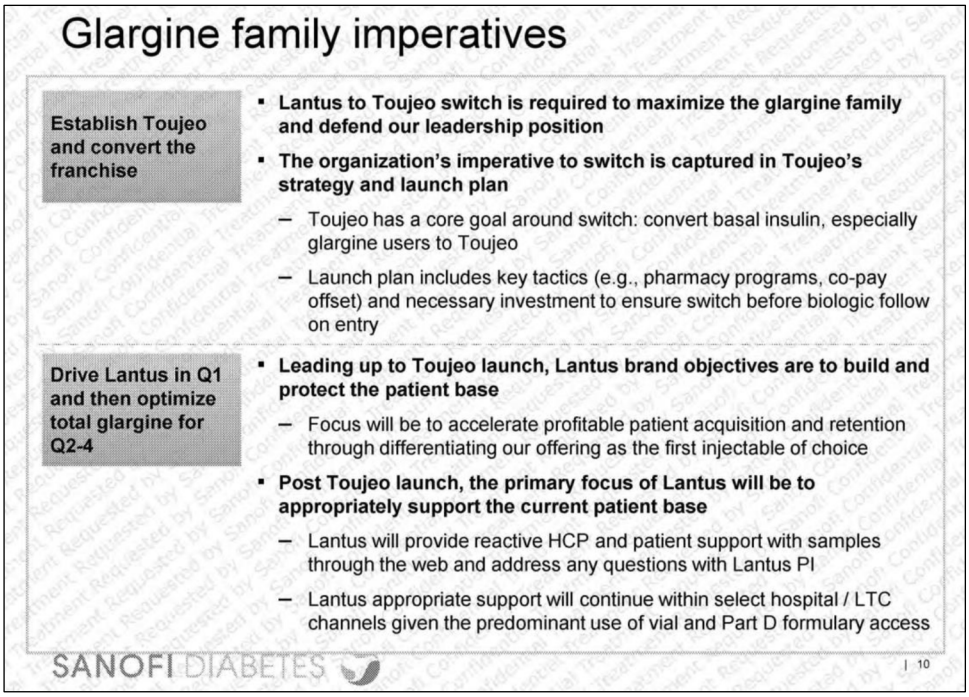
Answer to Complaint ¶ 198

Defendants deny the allegations in Paragraph 198, including allegations containing characterizations and legal or other conclusions to which no response is required, except Defendants admit, insofar as it is publicly available information, that the FDA approved NDA 206538 on February 25, 2015, and Sanofi U.S. launched Toujeo in March 2015.

Complaint ¶ 199

Sanofi recognized pushing the market to Toujeo as the only viable way to maintain its market power over injectable insulin glargine:

[33] *Id*. at 5.



[34]

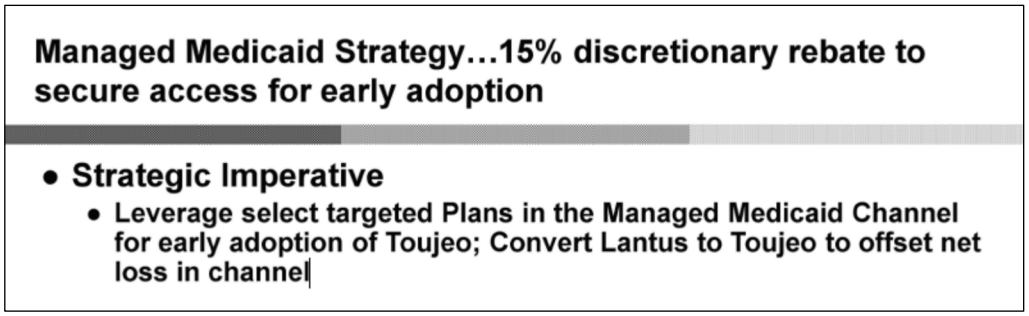
Answer to Complaint ¶ 199

Defendants deny the allegations in Paragraph 199, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 199. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.":

[34] Drug Pricing Documents at 230.



[35]

Answer to Complaint ¶ 200

Defendants deny the allegations in Paragraph 200, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 200. Further, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

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

Complaint ¶ 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 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."

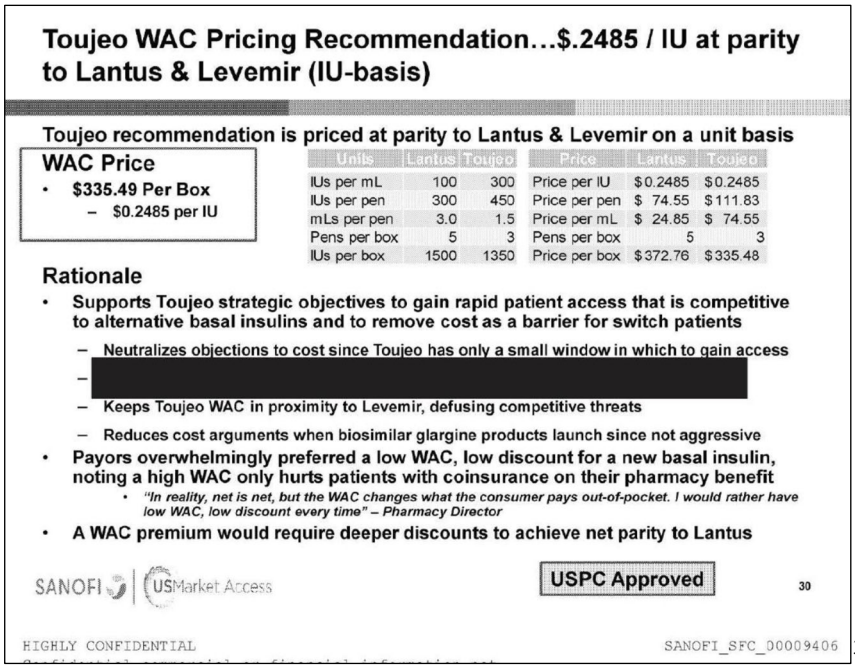
Answer to Complaint ¶ 201

Defendants deny the allegations in Paragraph 201, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 201.

[35] Insulin Report Documents at 209.

Complaint ¶ 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.



Toujeo WAC Pricing Recommendation…$.2485 / IU at parity to Lantus & Levemir (IU-basis)

Toujeo recommendation is priced at parity to Lantus & Levemir on a unit basis

WAC Price
- $335.49 Per Box
  - $0.2485 per IU

Units	Lantus	Toujeo	Price	Lantus	Toujeo
IUs per mL	100	300	Price per IU	$0.2485	$0.2485
IUs per pen	300	450	Price per pen	$ 74.55	$111.83
mLs per pen	3.0	1.5	Price per mL	$ 24.85	$ 74.55
Pens per box	5	3	Pens per box	5	3
IUs per box	1500	1350	Price per box	$372.76	$335.48

Rationale
- Supports Toujeo strategic objectives to gain rapid patient access that is competitive to alternative basal insulins and to remove cost as a barrier for switch patients
  - Neutralizes objections to cost since Toujeo has only a small window in which to gain access
  - [redacted]
  - Keeps Toujeo WAC in proximity to Levemir, defusing competitive threats
  - Reduces cost arguments when biosimilar glargine products launch since not aggressive
- Payors overwhelmingly preferred a low WAC, low discount for a new basal insulin, noting a high WAC only hurts patients with coinsurance on their pharmacy benefit
  - *"In reality, net is net, but the WAC changes what the consumer pays out-of-pocket. I would rather have low WAC, low discount every time" – Pharmacy Director*
- A WAC premium would require deeper discounts to achieve net parity to Lantus

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USPC Approved

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[36]

Answer to Complaint ¶ 202

Defendants deny the allegations in Paragraph 202, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 202.

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

[36] Insulin Report at 173.

[37] Drug Pricing Report at 115.

Answer to Complaint ¶ 203

Defendants deny the allegations in Paragraph 203, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 203.

Complaint ¶ 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]

Answer to Complaint ¶ 204

Defendants deny the allegations in Paragraph 204, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 204.

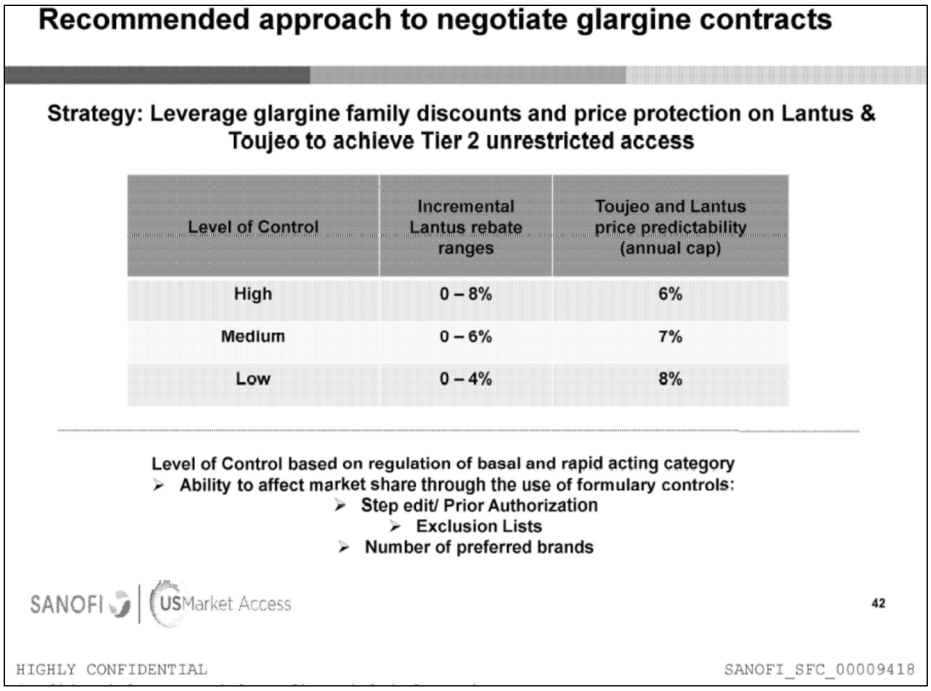
Complaint ¶ 205

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]

[38] Insulin Report at 68.

[39] Insulin Report Documents at 313.

[40] Insulin Report Documents at 185.



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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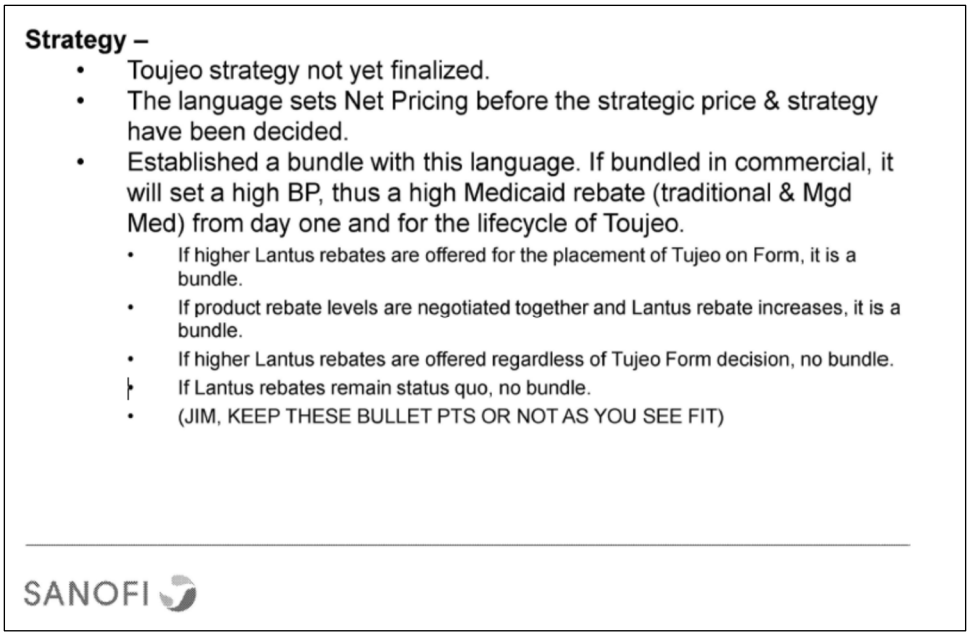
Answer to Complaint ¶ 205

Defendants deny the allegations in Paragraph 205, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 205.

Complaint ¶ 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]

[41] Insulin Report Documents at 380.



Answer to Complaint ¶ 206

Defendants deny the allegations in Paragraph 206, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 206.

Complaint ¶ 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]

Answer to Complaint ¶ 207

Defendants deny the allegations in Paragraph 207, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the

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

cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 207.

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

Complaint ¶ 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.

Answer to Complaint ¶ 208

Defendants deny the allegations in Paragraph 208, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited document speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 208.

Complaint ¶ 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.

Answer to Complaint ¶ 209

Defendants deny the allegations in Paragraph 209, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 210

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 210 regarding payers or Mylan and therefore deny them. Defendants deny the remaining allegations in Paragraph 210, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 211

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

Answer to Complaint ¶ 211

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 211 regarding Mylan and therefore deny them. Defendants deny the remaining allegations in Paragraph 211, including allegations containing characterizations and legal or other conclusions to which no response is required.

V. Response to "Market Power and Market Definition"

Complaint ¶ 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.

Answer to Complaint ¶ 212

Defendants deny the allegations in Paragraph 212, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 213

Defendants deny the allegations in Paragraph 213, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 214

Defendants deny the allegations in Paragraph 214, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 215

Defendants deny the allegations in Paragraph 215, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 216

Defendants deny the allegations in Paragraph 216, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 217

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

Answer to Complaint ¶ 217

Defendants deny the allegations in Paragraph 217, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 218

Defendants deny the allegations in Paragraph 218, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 219

Defendants deny the allegations in Paragraph 219, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 220

Defendants deny the allegations in Paragraph 220, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 221

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

Answer to Complaint ¶ 221

Defendants admit the allegations in Paragraph 221.

Complaint ¶ 222

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

Answer to Complaint ¶ 222

Defendants deny the allegations in Paragraph 222, including allegations containing characterizations and legal or other conclusions to which no response is required.

VI. Response to "Antitrust Impact and Impact on Interstate Commerce"

Complaint ¶ 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.

Answer to Complaint ¶ 223

Defendants deny the allegations in Paragraph 223, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 224

Defendants deny the allegations in Paragraph 224, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 225

Defendants deny the allegations in Paragraph 225, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 226

Defendants deny the allegations in Paragraph 226, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 227

Defendants deny the allegations in Paragraph 225, including allegations containing characterizations and legal or other conclusions to which no response is required. The cited lawsuits speak for themselves, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 227.

Complaint ¶ 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.

Answer to Complaint ¶ 228

Defendants deny the allegations in Paragraph 228, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 229

Defendants deny the allegations in Paragraph 229, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 230

Defendants deny the allegations in Paragraph 230, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 231

Mylan seeks damages through November 29, 2022.

Answer to Complaint ¶ 231

Defendants deny the allegations in Paragraph 231, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

FIRST COUNT
Sherman Act Section 2
Monopolization

Complaint ¶ 232

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

Answer to Complaint ¶ 232

Paragraph 232 is a paragraph of incorporation to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 232.

Complaint ¶ 233

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

Answer to Complaint ¶ 233

Defendants deny the allegations in Paragraph 233, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 234

Defendants deny the allegations in Paragraph 234, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 235

Defendants deny the allegations in Paragraph 235, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 236

Defendants deny the allegations in Paragraph 236, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 237

Defendants deny the allegations in Paragraph 237, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 238

Defendants deny the allegations in Paragraph 238, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 239

Defendants deny the allegations in Paragraph 239, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 240

Defendants deny the allegations in Paragraph 240, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 241

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

Answer to Complaint ¶ 241

Defendants deny the allegations in Paragraph 241, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 242

Defendants deny the allegations in Paragraph 242, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that Plaintiffs are entitled to judgment in this action, or that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

SECOND COUNT
Sherman Act Section 2
Attempted Monopolization

Complaint ¶ 243

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

Answer to Complaint ¶ 243

Paragraph 243 is a paragraph of incorporation to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 243.

Complaint ¶ 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.

Answer to Complaint ¶ 244

Defendants deny the allegations in Paragraph 244, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

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

Complaint ¶ 245

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

Answer to Complaint ¶ 245

Paragraph 245 is a paragraph of incorporation to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 245.

Complaint ¶ 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.

Answer to Complaint ¶ 246

Defendants deny the allegations in Paragraph 246, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the cited statute speaks for itself, and Defendants deny any characterizations or conclusions drawn therefrom in Paragraph 246.

Complaint ¶ 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.

Answer to Complaint ¶ 247

Defendants deny the allegations in Paragraph 247, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 248

Defendants deny the allegations in Paragraph 248, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

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

Complaint ¶ 249

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

Answer to Complaint ¶ 249

Paragraph 249 is a paragraph of incorporation to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 249.

Complaint ¶ 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.

Answer to Complaint ¶ 250

Defendants deny the allegations in Paragraph 250, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 251

Defendants deny the allegations in Paragraph 251, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 252

Defendants deny the allegations in Paragraph 252, including allegations containing characterizations and legal or other conclusions to which no response is required. In addition, the Court has dismissed Plaintiffs' "allegation of a Sherman Section 2 violation based solely on a 'product hop' theory." ECF No. 85.

Complaint ¶ 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.

Answer to Complaint ¶ 253

Defendants deny the allegations in Paragraph 253, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 254

Defendants deny the allegations in Paragraph 254, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants

specifically deny that Plaintiffs are entitled to judgment in this action, or that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

FIFTH COUNT
Tortious Inducement of Refusal to Deal

Complaint ¶ 255

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

Answer to Complaint ¶ 255

Paragraph 255 is a paragraph of incorporation to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 255.

Complaint ¶ 256

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

Answer to Complaint ¶ 256

Defendants deny the allegations in Paragraph 256, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 257

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

Answer to Complaint ¶ 257

Defendants deny the allegations in Paragraph 257, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 258

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 258 regarding Mylan's or purchasers' conduct and therefore deny them. Defendants deny the remaining allegations in Paragraph 258, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 259

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

Answer to Complaint ¶ 259

Defendants deny the allegations in Paragraph 259, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 260

Defendants deny the allegations in Paragraph 260, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 261

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

Answer to Complaint ¶ 261

Defendants deny the allegations in Paragraph 261, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 262

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

Answer to Complaint ¶ 262

Defendants deny the allegations in Paragraph 262, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 263

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 263 regarding Mylan's or purchasers' conduct and therefore deny them. Defendants deny the allegations in Paragraph 263, including allegations containing characterizations and legal or other conclusions to which no response is required.

Complaint ¶ 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.

Answer to Complaint ¶ 264

Defendants deny the allegations in Paragraph 264, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

Complaint ¶ 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.

Answer to Complaint ¶ 265

Defendants deny the allegations in Paragraph 265, including allegations containing characterizations and legal or other conclusions to which no response is required. Defendants specifically deny that any of the Defendants, individually or collectively, are liable to Plaintiffs for damages.

VII. Response to "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.

Answer to Demand for Judgment

Defendants deny that Plaintiffs are entitled to judgment or any relief in this action.

VIII. Response to "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.

Answer to Jury Demand

Defendants acknowledge Plaintiffs' request for a trial by jury in this matter. Defendants also demand a jury trial on all issues so triable in this action.

AFFIRMATIVE AND OTHER DEFENSES

Having answered the allegations in Plaintiffs' Complaint, and having denied any liability whatsoever, Defendants further deny any allegations that have not been expressly admitted and set forth below their affirmative and other defenses. By setting forth these defenses, Defendants do not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiffs. Moreover, Defendants do not intend these defenses to be, nor shall they be construed as, an acknowledgement that any particular issue or subject matter is relevant to Plaintiffs' allegations. Defendants do not admit or acknowledge that they bear the burden of proof or burden of persuasion with respect to any such defense. Upon completion of discovery, if the facts warrant, Defendants may withdraw any of these defenses as may be appropriate. Defendants reserve the right to (1) rely on any other applicable defenses set forth in any Answer or listing of affirmative defenses of any other party in this action, (2) rely on any other defenses that may become apparent during fact or expert discovery in this matter, and (3) amend this Answer to assert any such defenses.

FIRST DEFENSE

The Complaint fails to state facts sufficient to support a claim upon which relief may be granted against Defendants.

SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations, and the doctrines of laches, waiver, and estoppel. Defendants have not committed any act, such as fraudulent concealment, that could render these defenses inapplicable.

THIRD DEFENSE

Any and all of Defendants' actions alleged by Plaintiffs were lawful, justified, procompetitive, and carried out in furtherance of Defendants' legitimate business interests.

FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, and/or Plaintiffs lack standing because Plaintiffs have not suffered injury proximately caused by any conduct of Defendants and/or have not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990).

SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged damages, if any, are too speculative and uncertain.

SEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the alleged injuries and damages, if any, resulted from an intervening or superseding cause.

EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the acts or omissions alleged did not substantially lessen competition through the exercise of market power in any properly defined market.

NINTH DEFENSE

Plaintiffs are not entitled to any form of preliminary or permanent injunctive relief.

TENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of collateral estoppel and/or res judicata.

ELEVENTH DEFENSE

Plaintiffs' claims fail to the extent they rest on an argument that Defendants lacked a basis for enforcing their patents against competitors, including Mylan, as such conduct would be protected by the *Noerr-Pennington* doctrine of immunity and the First Amendment to the United States Constitution.

TWELFTH DEFENSE

Plaintiffs' claims are preempted or otherwise barred by the Federal Food, Drug, and Cosmetic Act; the Hatch-Waxman Act; and/or the Patent Act.

THIRTEENTH DEFENSE

An award of punitive damages would violate Defendants' rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution, insofar as such damages are awarded by a jury or other fact-finder that: (a) is not provided with a standard of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (b) is not adequately and clearly instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of Defendants; (d) is permitted to award punitive damages under a standard for

determining liability for such damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and/or (e) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards.

FOURTEENTH DEFENSE

Any award of punitive damages would violate Defendants' rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution, insofar as such damages are (a) imposed and determined without bifurcating the trial and trying all punitive damages issues only if and after the liability of Defendants has been found on the merits, and/or (b) imposed and determined based on anything other than Defendants' conduct in connection with the sale of the product alleged in this litigation, or in any other way subjecting Defendants to impermissible multiple punishments for the same alleged wrong.

FIFTEENTH DEFENSE

Plaintiffs are not entitled to an award of costs, penalties, or attorneys' fees under any theory alleged in the Complaint.

SIXTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent they involve contracts with State entities such as Medicaid programs.

SEVENTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Sanofi U.S. submitted patent information to the Food and Drug Administration for NDA 21-081 based on its "reasonable, good-

faith attempt to comply with the Hatch-Waxman scheme." *See In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 14 (1st Cir. 2020).

EIGHTEENTH DEFENSE

The procompetitive benefits of Defendants' alleged conduct substantially outweigh its purportedly anticompetitive effects.

NINETEENTH DEFENSE

To the extent Plaintiffs' Sherman Act claims are based on Defendants' rebates, these claims fail because Plaintiffs cannot show that Defendants priced their rebates below their costs. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 408 (3d Cir. 2016).

TWENTIETH DEFENSE

To the extent any of Plaintiffs' claims are based on conduct that was taken pursuant to a "clearly articulated and affirmatively expressed . . . state policy" that is "'actively supervised' by the State itself," Defendants are immune from antitrust liability under the state action doctrine. *Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980) (citation omitted).

TWENTY-FIRST DEFENSE

To the extent any of Plaintiffs' Sherman Act allegations exceed four years from the date of the filing of the Complaint, such claims or allegations are barred by the four-year statute of limitations under the Clayton Act, 15 U.S.C. § 15b.

TWENTY-SECOND DEFENSE

If Plaintiffs recover any damages, such award must be reduced by all damages attributable to Plaintiffs' failure to take appropriate action and mitigate damages prior to and subsequent to the institution of this action.

TWENTY-THIRD DEFENSE

Defendants reserve the right to supplement this Answer with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend this Answer accordingly.

JURY DEMAND AND PRAYER FOR RELIEF

WHEREFORE, Defendants pray for relief and judgment as follows:

A. That Plaintiffs take nothing by reason of the Complaint;

B. That this action be dismissed with prejudice;

C. That Defendants recover their costs and attorneys' fees incurred herein; and

D. Such further and other relief as the Court deems proper.

Dated: March 13, 2026

Respectfully submitted,

/s/ *Katherine E. Eayre*

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CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served on all counsel of record via ECF filing on March 13, 2026.

/s/ *Katherine E. Eayre*
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