PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 24-2510

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NOVO NORDISK INC.; NOVO NORDISK PHARMA, INC.,
Appellants

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES

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On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3:23-cv-20814)
District Judge: Honorable Zahid N. Quraishi

_____

Argued on April 8, 2025

Before: HARDIMAN, PHIPPS, and FREEMAN, *Circuit Judges*.

(Filed: October 6, 2025)

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OPINION OF THE COURT

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HARDIMAN, *Circuit Judge*.

The Inflation Reduction Act of 2022 (the Act) established the "Drug Price Negotiation Program" (the Program) to reduce prescription drug expenditures. The

Program directs the Department of Health and Human Services (HHS)—through the Centers for Medicare and Medicaid Services (CMS)—to negotiate prices with drug manufacturers. *See* 42 U.S.C. § 1320f(a)(3).

Novo Nordisk appeals a summary judgment rejecting its statutory and constitutional challenges to the Program. It contends that CMS violated the Act by deeming six of its products to be one "negotiation-eligible drug" and by imposing binding regulations on manufacturers without following notice and comment procedures. It also argues that the Program violates the nondelegation doctrine, the Fifth Amendment's Due Process Clause, and the First Amendment. We will affirm.

I

"Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of HHS*, 137 F.4th 116, 119 (3d Cir. 2025). "Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes." *Id.*

The Program at issue in this appeal targets Medicare Parts B and D. *See id.* at 120. Part B is a "supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician." *Id.* Part D is a "prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *Id.* (citation omitted).

Part D is administered through prescription drug plans operated by private insurers called "sponsors." *Id.* Sponsors

bid to be accepted into Medicare Part D and contract with CMS for reimbursement. *See* 42 U.S.C. §§ 1395w-111–1395w-112; *see also* 42 C.F.R. § 423.301 *et seq.* (setting forth rules for reimbursing sponsors). Sponsors, in turn, work with subcontractors, such as pharmacy benefit managers, who process claims and perform other administrative tasks. *See AstraZeneca*, 137 F.4th at 120. Those subcontractors then work with the pharmacies that dispense prescription drugs to Medicare Part D beneficiaries. *See id*.

When Congress enacted Part D in 2003, it prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and from "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Almost twenty years later, however, the Act created an exception, directing CMS to "negotiate . . . maximum fair prices" for certain drugs, *id.* § 1320f(a)(3), subject to price ceilings derived from a benchmark market-based price, *id.* § 1320f-3(c). "[A] selected drug's 'maximum fair price' applies beginning in a given drug-pricing period (a period of one calendar year), the first of which is 2026, until the drug is no longer eligible for negotiation or the price is renegotiated." *AstraZeneca*, 137 F.4th at 120 (citing 42 U.S.C. §§ 1320f(b)(1)–(2), 1320f–1(c), 1320f–3(f)).

The Act required CMS to select ten drugs for the first drug-pricing period. *See* 42 U.S.C. §§ 1320f(d), 1320f–1(a). As the Program ramps up, CMS must select 15 more drugs per year for the 2027 and 2028 drug-pricing periods and up to 20 more drugs per year for 2029 and subsequent drug-pricing periods. *See id.* § 1320f–1(a). The selected drugs must have accounted for the largest costs for Medicare that prior year. *See id.* § 1320f–1(b)(1)(A). And once selected, a drug remains in

the Program until CMS determines that a generic or biosimilar version of the drug has been approved and is being marketed. *See id.* §§ 1320f–1(c)(1), 1320f–2(b).

After selecting a drug for the Program, CMS must "enter into [an] agreement[]" with the drug's manufacturer to "negotiate . . . a maximum fair price for such selected drug." *Id.* § 1320f–2(a)(1). For the first round of selections, the manufacturer of a selected drug had until October 1, 2023, to enter an agreement to "negotiate" a "maximum fair price" for the drug. *See id.* § 1320f(b)(4), (d)(2)(A).

CMS drafted a template agreement that manufacturers must sign to comply with this negotiation obligation. *See* CMS, *Medicare Drug Price Negotiation Program Agreement*, https://perma.cc/ZC3E-XCQ5 (last visited June 20, 2025), at 1–6 (hereinafter Agreement). The Agreement states that "CMS and the Manufacturer agree" that they "shall negotiate to determine (and, by not later than the last date of [the negotiation] period, agree to) a maximum fair price for the Selected Drug." *Id.* at 2; *see also* 42 U.S.C. § 1320f–2(a)(1).

Once a manufacturer signs the Agreement, the agency makes a "written initial offer." 42 U.S.C. § 1320f–3(b)(2)(B). The agency must issue the offer by a statutory deadline, propose a "maximum fair price," and include a concise justification for the offer based on statutory criteria. *Id.* The manufacturer then has 30 days to accept the offer or make a counteroffer. *See id.* § 1320f–3(b)(2)(C). CMS must respond in writing to any counteroffer. *See id.* § 1320f–3(b)(2)(D).

Negotiations for the first round of selections were to end by August 1, 2024. *See* 42 U.S.C. §§ 1320f(b)(4), (d)(2)(B), (d)(5)(C), 1320f–3(b)(2)(E). Before that deadline, the

manufacturer had to "respond in writing" to the agency "by either accepting or rejecting the final offer." CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 158 (June 30, 2023) (2023 Revised Guidance), https://perma.cc/AV2Z-4F9U. The agency and manufacturers must follow a similar process for future drug-pricing periods, except the deadlines will be set for different times of the calendar year. *See* 42 U.S.C. § 1320f–3(b)(2).

The Act sets a price ceiling for selected drugs that CMS cannot exceed when it makes a manufacturer an offer. *Id.* § 1320f–3(c)(1)(A). And it requires CMS to "aim[] to achieve the lowest maximum fair price for each selected drug," *id.* § 1320f–3(b)(1), not to exceed 75 percent of a benchmark based on private market prices for the drug, *id.* § 1320f–3(b)(2)(F), (c)(1)(C), (c)(3). Lower price ceilings (65 or 40 percent) apply to drugs that have been approved for a longer time (at least 12 or 16 years, respectively). *Id.* There is no price floor, but the offer must be "justified" based on certain factors identified in the statute. *Id.* § 1320f–3(b)(2)(B), (b)(2)(C)(ii), (e). The Act forecloses judicial review of, among other things, CMS's pricing decisions, selection of drugs, and determinations about which drugs are eligible for selection. *See id.* § 1320f–7(2).

Together with the Agreement, CMS created a template addendum a manufacturer must sign to formalize a price for its selected drug. *See* Agreement at 7–9. The addendum states that "[t]he parties agree to a price of [$]," which the addendum's recitals note is called a "maximum fair price" in the statute. *Id.* at 7. Once the process is completed, the Act directs CMS to publish the "maximum fair price" that it "negotiated with the

manufacturer" and its "explanation" for the price. 42 U.S.C. § 1320f–4(a).

Once signed, the Agreement obliges the manufacturer to "provide access to such price" for its selected drug to Medicare beneficiaries beginning in 2026. Agreement at 2; 42 U.S.C. § 1320f–2(a)(1). Failure to do so triggers a civil monetary penalty of ten times the difference between the price charged and the maximum fair price for every unit sold. 42 U.S.C. § 1320f–6(a). An offending manufacturer also will be subject to a civil monetary penalty of $1,000,000 for each day the Agreement was violated. *Id.* § 1320f–6(c).

After CMS includes a drug in the Program, the manufacturer can walk away and choose not to do business with the government. But if a manufacturer continues to participate in certain Medicare and Medicaid programs without signing an agreement under the Program, it must pay a daily excise tax that begins at 185.71 percent and rises to 1,900 percent of the selected drug's total daily revenues from all domestic sales. *See* 26 U.S.C. § 5000D.

We have held that the Act provides an escape hatch for a company that declines to participate in the Program. A manufacturer can cause the excise tax to be "[s]uspen[ded]" by terminating its extant Medicare and Medicaid agreements under the Medicare Coverage Gap Discount Program, the Manufacturer Discount Program, and the Medicaid Drug Rebate Program. *Id*. § 5000D(c); *Bristol Myers Squibb v. Sec'y U.S. Dep't of HHS*, ___ F.4th ____, ____, 2025 WL 2537005, at *3 (3d Cir. Sept. 4, 2025).

CMS may terminate a manufacturer's extant Medicare agreements under the Coverage Gap Discount and

Manufacturer Discount Programs for "good cause" effective upon 30 days' notice. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on that authority, CMS promised to offer manufacturers a 30-day exit from the Coverage Gap Discount and Manufacturer Discount Programs upon request, which it said would enable a manufacturer to avoid excise tax liability. 2023 Revised Guidance at 33–34, 120–21. We have held that CMS has statutory authority to do so and that participation in the Program is therefore voluntary. *See Bristol Myers Squibb*, ___ F.4th at ____, 2025 WL 2537005, at *7-8.

II

In the first round of selections, CMS selected six of Novo Nordisk's biological products for inclusion in the Program: Fiasp, Fiasp FlexTouch, Fiasp PenFill, NovoLog, NovoLog FlexPen, and NovoLog PenFill. Novo Nordisk signed an Agreement to participate in the Program by the October 1, 2023, deadline and an addendum setting a "maximum fair price" by the August 1, 2024, deadline.

In September 2023, Novo Nordisk sued HHS and its Secretary along with CMS and its Administrator. As relevant here, it argued that CMS violated the Act by treating its six products as one "negotiation-eligible drug" and by imposing legislative rules without following notice and comment procedures. It also argued that the Program violated the nondelegation doctrine, the Fifth Amendment's Due Process Clause, the First Amendment, and the unconstitutional conditions doctrine.

The parties cross-moved for summary judgment. The District Court denied Novo Nordisk's motion, granted the

Government's motion, and entered judgment. *See Novo Nordisk Inc. v. Becerra*, 2024 WL 3594413, at *1 (D.N.J. July 31, 2024). It concluded that it lacked subject matter jurisdiction to review CMS's decision to treat six of Novo Nordisk's products as one negotiation-eligible drug. It also held that Novo Nordisk lacked standing to argue that CMS violated the Act by identifying more than ten drugs for the 2026 drug-pricing period. The District Court rejected Novo Nordisk's unconstitutional conditions and due process claims, reasoning that the Program does not deprive the company of a protected property interest. Similarly, it rejected the nondelegation claim, concluding that the Act provides CMS with an intelligible principle and deeming the Act's judicial review bar irrelevant. Finally, it rejected the First Amendment claim by reasoning that the Program primarily regulates conduct rather than speech. Novo Nordisk appealed.[1]

III

Novo Nordisk argues that CMS violated the Act when it treated six of Novo Nordisk's products as one negotiation-eligible single-source drug. Because of the Act's judicial review bar, we lack jurisdiction to reach the merits of that

[1] The District Court had jurisdiction under 28 U.S.C. § 1331, and we have jurisdiction under 28 U.S.C. § 1291. Our review of the District Court's summary judgment is de novo. *See Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

statutory claim. *See Wheaton Indus. v. EPA*, 781 F.2d 354, 356–57 (3d Cir. 1986) (treating a statute precluding judicial review of agency action as jurisdictional); *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204–05 (D.C. Cir. 2019) (treating statutory language that "[t]here shall be no administrative or judicial review" as jurisdictional).

Agency action is presumptively subject to judicial review. *See Bouarfa v. Mayorkas*, 604 U.S. 6, 19 (2024). However, this presumption may be overcome by a clear statement of congressional intent to preclude judicial review. *Id.* Although we construe jurisdiction-stripping provisions narrowly, *United States v. Dohou*, 948 F.3d 621, 625 (3d Cir. 2020), we must give effect to Congress's will to set the limits of federal jurisdiction, *see Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008).

The Act includes the requisite clear statement. It provides that "[t]here shall be no . . . judicial review of," among other things, "the determination of negotiation-eligible drugs" or "the determination of qualifying single source drugs." 42 U.S.C. § 1320f–7(2). This provision shields from review CMS's treatment of Novo Nordisk's six insulin aspart products as one drug.

CMS announced in the Guidance that, when identifying qualifying single-source drugs, it would group together "all dosage forms and strengths of [a] biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs." 2023 Revised Guidance at 99. The six NovoLog and Fiasp products have the same active ingredient and the same holder of a BLA. CMS grouped

those six products together and treated them as one biological product during the Program's drug-identification process.

CMS determined that this biological product was a qualifying single-source drug under 42 U.S.C. § 1320f-1(e)(1)(B), and that this single-source drug's associated expenditures through Medicare made it a negotiation-eligible drug under § 1320f-1(d)(1) and (2). We are barred from reviewing that "determination of qualifying single source drugs" and that "determination of negotiation-eligible drugs." *Id.* § 1320f–7(2). Next, based on a ranking of all negotiation-eligible drugs' Medicare expenditures, CMS selected Novo Nordisk's insulin aspart products for negotiation under § 1320f-1(b)(1). (We are also barred from reviewing that selection, *id.* § 1320f–7(2), and Novo Nordisk does not argue otherwise.)

Novo Nordisk asserts that it is not challenging CMS's "determination of qualifying single source drugs" or its "determination of negotiation-eligible drugs." Instead, it says it challenges an earlier step in the process: CMS's decision to group products into a single potentially qualifying drug. But we have held that when a statute prohibits review of a particular "determination," the bar extends to the ultimate decision *and* "the process by which [the agency] reaches this decision." *Bakran v. Sec'y, DHS*, 894 F.3d 557, 563 (3d Cir. 2018). In *Bakran*, we considered a judicial review bar that covered the Department of Homeland Security's "determin[ation]" about a citizen's risk to a beneficiary relative. *Id.* at 560, 563 (citing 8 U.S.C. § 1252(a)(2)(B)(ii)). We held that the bar applied to a challenge to two DHS memoranda: one that instructed field officers to "rare[ly]" make a no-risk determination, and another that required citizens to prove beyond any reasonable doubt that they posed

no risk. *Id.* We explained that the statutory term "determine" means "to fix conclusively or authoritatively" *and* "to come to a decision concerning as the result of investigation or reasoning." *Id.* at 563 (quoting *Determine*, *Webster's Third New International Dictionary* (1993)); *accord Determination*, *The Merriam-Webster Dictionary* (2022) ("the act of coming to a decision; *also*: the decision or conclusion reached"). Thus, Congress's choice to make DHS's determinations unreviewable meant that the internal processes DHS used to reach its decisions were also unreviewable. *Bakran*, 894 F.3d at 563–64.

Here, CMS adopted a definition of qualifying single-source drug that led the agency to group Novo Nordisk's products together and ultimately select them for negotiation as one drug. We cannot review CMS's determinations or the internal processes CMS used to make them.

Novo Nordisk resists this conclusion in various ways. Primarily, it attempts to frame the issue as whether CMS complied with the ten-drug limit the Act set for the first program year. But CMS treated Novo Nordisk's related insulin aspart products, collectively, as one qualifying single-source drug—not six. Treating those products as one drug, CMS selected only ten drugs for negotiation. This treatment was part of CMS's "determination of qualifying single source drugs" that is barred from our review. 42 U.S.C. § 1320f–7(2).

Next, Novo Nordisk argues that the judicial review bars only apply to two specific determinations in the Act: determinations to exclude certain low-spend Medicare products from the universe of qualifying single-source drugs and to exclude small biotech products from the universe of negotiation-eligible drugs. *See* 42 U.S.C. § 1320f-1(d)(2),

(e)(3)(B); But the text of the judicial review bar plainly applies to a broader set of agency decisions than these exclusions.

Finally, Novo Nordisk argues that CMS's decisions are reviewable as ultra vires agency action. *See Leedom v. Kyne*, 358 U.S. 184 (1958). In its view, the judicial review bar only applies to determinations CMS makes within the bounds of its statutory authority, permitting us to review claims that CMS's determinations exceeded its authority. However, an argument that CMS did not comply with a statutory mandate in making a particular determination is still a challenge to that determination. More to the point, ultra vires review is available "only when an agency has taken action entirely in excess of its delegated powers and contrary to a *specific prohibition* in a statute." *Nuclear Regul. Comm. v. Texas*, 605 U.S. 665, 681 (2025) (internal quotation marks omitted). The Supreme Court has clarified that it is not available when a statute explicitly bars judicial review. *See Bd. of Governors of the Fed. Reserve Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 44 (1991); *see also DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019) ("Following *MCorp*, there is not much room to contend that courts may disregard statutory bars on judicial review just because the underlying merits seem obvious."). Here, an explicit judicial review bar encompasses Novo Nordisk's claim, so ultra vires review is not available.

IV

Novo Nordisk next contends that CMS violated the Administrative Procedure Act, the Medicare Act, and the Inflation Reduction Act by promulgating legislative rules

without following notice and comment procedures.[2] A statutory note to the Act provides that HHS "shall implement [the Program] . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f (note); *see also* Inflation Reduction Act of 2022, Pub. L. No. 117–169, § 11001(c), 136 Stat. 1818, 1854 (2022); 42 U.S.C. § 1320f–1 (note); Inflation Reduction Act of 2022, Pub. L. No. 117–169, § 11002(c), 136 Stat. 1818, 1862 (2022). Novo Nordisk argues that this note prohibits CMS from promulgating legislative rules that implement the Program and take effect before 2029.

Ordinarily, CMS must comply with the rulemaking procedures set forth in the APA and Medicare Act when it promulgates legislative rules. *See* 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2). But the APA and Medicare Act recognize that Congress may "expressly" authorize an agency to conduct rulemaking without following those procedures. 5 U.S.C. § 559; 42 U.S.C. § 1395hh(b)(2)(A). In *Bristol Myers Squibb*, this Court concluded that this statutory note expressly permits CMS to promulgate legislative rules by issuing guidance for the first three drug-pricing periods. ___ F.4th at ____ & n. 18,

[2] The Government argues that Novo Nordisk's challenge to CMS's rulemaking is covered by the Act's judicial review bar. Not so. As discussed above, the review bar applies to CMS's determination of qualifying single source drugs and its determination of negotiation-eligible drugs. *See supra* Section III. Neither of those determinations encompasses CMS's promulgation of legislative guidance implementing the Program as a whole without notice and comment rulemaking.

2025 WL 2537005, at *7-8 & n.18. So we will affirm the District Court's summary judgment on this claim.

V

A

We now turn to Novo Nordisk's constitutional arguments, beginning with its claim that the Act violates the nondelegation doctrine. "The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government." *Gundy v. United States*, 588 U.S. 128, 132 (2019) (plurality opinion). "If Congress could pass off its legislative power to the executive branch, the vesting clauses, and indeed the entire structure of the Constitution, would make no sense." *Id.* at 155 (Gorsuch, J., dissenting) (citation modified). In considering Novo Nordisk's claim, we ask whether "Congress has supplied an intelligible principle to guide the delegee's use of discretion." *Id.* at 135 (plurality opinion). We conclude that it has.

The Act contains detailed rules governing which products may be subject to price controls. *See* 42 U.S.C. § 1320f–1. It also limits the number of products that may be selected and grants CMS only narrow discretion to determine whether certain products should be excepted. *See id.* § 1320f–1(a), (d)–(f). Under a complex set of criteria, a drug is typically eligible for selection if, among other things, it is a "qualifying single source drug" (1) that has been approved for at least 7 years (or 11 years for biological products) and (2) for which there is no generic or biosimilar product that has been approved and marketed. *Id.* § 1320f–1(d)–(e). Selected medicines must remain in the Program until CMS determines that a generic or

biosimilar version of the drug has been approved and is being marketed. *Id*. § 1320f–1(c)(1).

Along with limiting product selection, the Act constrains CMS's pricing determinations. It sets a price ceiling that the agency cannot exceed, ranging from 75 to 40 percent of a benchmark based on private market prices for the drug, depending on how recently the drug was approved. *Id.* § 1320f–3(b)(2)(F), (c)(1)(C), (c)(3). And although there is no price floor, CMS's offer must be "justified," 42 U.S.C. § 1320f–3(b)(2)(B), (b)(2)(C)(ii), (e), based on certain factors identified in the statute, including "the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities, FDA product approvals, sales data, and alternative treatments." *AstraZeneca*, 137 F.4th at 121 (citation omitted).

In sum, the Act provides CMS with detailed guidance and restrains its discretion at many turns. Because that guidance clears the "intelligible principle" hurdle, the Program does not violate the nondelegation doctrine.

B

Novo Nordisk also contends that the Act violates the Fifth Amendment's Due Process Clause. We recently rejected this argument when it was advanced by a different manufacturer, *AstraZeneca*, 137 F.4th at 125–26, and our

answer remains the same today: the Act does not violate the Due Process Clause.[3]

C

Finally, we address Novo Nordisk's claim that the Act violates the First Amendment. We decided this issue in *Bristol Myers Squibb*. *See* ___ F.4th at ____, 2025 WL 2537005, at *10-15. For the reasons we explained there, we will affirm the District Court's summary judgment on Novo Nordisk's compelled speech claim.

* * *

The Act's judicial review bar precludes our review of Novo Nordisk's claim about the grouping of its products, the Act provides CMS with an intelligible principle, and Novo Nordisk's remaining statutory and constitutional claims are

[3] Novo Nordisk urges us to take a "holistic[]" view of its due process and nondelegation arguments. Novo Nordisk Br. 54 (quoting *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc), *rev'd*, 145 S. Ct. 2482 (2025)). In its view, a confluence of issues with the Act work together to violate the separation of powers: the Act delegates a major question to CMS; allows CMS to act without guaranteeing regulated parties significant procedural rights; and forecloses judicial review of CMS's pricing decisions, selection of drugs for negotiation, and determinations about what drugs are eligible for selection. But "[t]wo wrong claims do not make one that is right," so our conclusion about each individual argument resolves Novo Nordisk's "combination claim" as well. *Consumers' Rsch.*, 145 S. Ct. at 2511 (citation modified).

foreclosed by our precedent. So we will affirm the District Court's judgment.