14-4624

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York

Plaintiff-Appellee,

V.

ACTAVIS PLC, FOREST LABORATORIES, LLC,

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK CASE NO. 14-CV-7473 (RWS)

BRIEF AMICUS CURIAE OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLANTS

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Dated: January 15, 2015

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rules 26.1 and 29(c) of the Federal Rules of Appellate Procedure, *amicus* states as follows:

The Chamber of Commerce of the United States of America has no parent company. No publicly held company owns 10% or more of its stock.

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INTEREST OF AMICUS CURIAE¹

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber thus regularly files *amicus curiae* briefs in cases raising issues of concern to the Nation's business community, including in antitrust cases.

The Chamber has a strong interest in this important case. The court below issued an unprecedented preliminary injunction that effectively commandeered a drug manufacturer's factory, seizing control and supervision of its day-to-day business operations and requiring it to make and distribute a product for which it had planned to curtail production. And the court justified this drastic remedy as vindicating the "spirit of the Hatch-

Pursuant to Fed. R. App. P. 29(c), *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this brief.

Waxman Act and the public policy underlying it." Special Appendix of Defendants-Appellants ("SA") 135.

If left uncorrected, the decision below would set a dangerous precedent that could allow any court to conscript a private business into federal control based on nothing more than a cursory review of the merits and the "spirit" of whatever federal or state statute might be implicated by an antitrust plaintiff. Because this would threaten serious harm to the Chamber's members, the Chamber has a strong interest in participating in this case.

The Chamber agrees with Defendants-Appellants that the decision below must be reversed and the injunction vacated. The Chamber writes separately to underscore that this preliminary injunction is extraordinary.

SUMMARY OF ARGUMENT

The preliminary injunction entered below is tantamount to a federal court commandeering a private business and its factories. The court below ordered Defendants Forest Laboratories, LLC and its parent company Actavis plc (collectively, "Forest") to make and distribute a pharmaceutical drug for which it had planned to curtail production. Specifically, the court ordered that Forest must "continue to make" its patented Alzheimer's drug, twice-daily Namenda Instant-Release ("IR") tablets, "available on the same terms and conditions applicable since July 21, 2013," SA-137, and must keep that product on the market for at least thirty days past the market entry of competing generic drugs. In other words, the court seized control of Forest's day-to-day operations and ordered the production and distribution of a product for the benefit of Forest's competitors.

Such a seizure of an American factory and takeover of its day-to-day operations by a federal court is, in a word, unprecedented. Our Constitution created a federal government of enumerated, and thus limited, powers. *See Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1, 33 (1824). Absent careful compliance with important safeguards, the commandeering of a private business by the federal government runs counter both to our system of

ordered liberty enshrined in the Constitution and to our free-market economy.

Over 150 years of history teaches that the federal seizure of a private company and takeover of its operations in this manner is a drastic measure that has been employed only by the political branches within circumscribed limits—never by the courts. This kind of consistent historical precedent is highly relevant in determining the scope and nature of federal powers, *see*, *e.g.*, *Mistretta v. United States*, 488 U.S. 361, 401 (1989); *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988), and it demonstrates that such a seizure of private business can properly be undertaken only by the political branches.

That only the political branches have employed such measures is no historical accident. Only the political branches—not the unelected judicial branch—are directly responsive and accountable to the people for the proper discharge of this power.

The injunction here flouts that precedent. This Court should vacate it.

ARGUMENT

I. The Federal Seizure of a Private Company's Operations Is a Drastic Measure Appropriate Only in Rare Circumstances that Do Not Exist Here.

Given the prominent role of private property in our nation's founding,² it is no surprise that the federal government historically has exercised the authority to seize private facilities cautiously. In fact, insofar as *amicus* can tell, since Reconstruction the federal government has taken over a private company's business operations only in extraordinary circumstances and only through action by the political branches. This case satisfies neither predicate: *judicial* action effected this takeover of Forest's operations in the decidedly ordinary circumstances of a patent holder exercising its patent rights while running its business. This injunction is thus unique and uniquely erroneous in American history. This Court should vacate it.

See, e.g., GeorgiaCarry.Org, Inc. v. Georgia, 687 F.3d 1244, 1265 (11th Cir. 2012) ("It is simply beyond rational dispute that the Founding Fathers, through the Constitution and the Bill of Rights, sought to *protect* the fundamental right of private property, not to *eviscerate* it.") (citing John Adams, James Madison, and Thomas Paine).

A. Allowing Only the Elected Branches to Exercise the Power to Seize a Private Company's Operations Ensures Direct Political Accountability for Such Actions.

When the federal government has unleashed the power to seize a private company's operations as the court below did here, it has done so only through Congress and the Executive—the two branches directly politically accountable to the people—and within circumscribed limits. Such historical precedent provides strong evidence of the proper scope and nature of this intrusive federal power. *See, e.g., Mistretta*, 488 U.S. at 401; *Gulfstream Aerospace Corp.*, 485 U.S. at 289.

In particular, over the past 150 years, Congress has on several occasions authorized the President to commandeer private industry, restricting the exercise of this power "to particular circumstances such as 'time of war or when war is imminent,' the needs of 'public safety' or of 'national security or defense,' or 'urgent and impending need." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 600 (1952) (Frankfurter, J.). This ensures that both elected branches agree on the need for—and the need to bear political responsibility for—such extreme governmental intrusions into private affairs. For example, during the Civil War, Congress authorized the President to seize the "telegraph lines" and "railroad lines" and to place them "under military control." Railroad and

Telegraph Act of 1862, 12 Stat. 334. Half a century later, during World War I, Congress similarly authorized the President to "take possession ... of [and operate] any telegraph, telephone, marine cable or radio system," Joint Resolution of 1918, 40 Stat. 904; to take possession of plants "equipped for the building or production of ships or material," Emergency Shipping Fund Act of 1917, 40 Stat. 182; to "take immediate possession of any factory" producing ships or war material for the Navy, Naval Emergency Fund Act of 1917, 39 Stat. 1168, 1192-1195; and to "take over and operate" any "plant or facility" necessary for the national defense, National Defense Act of 1940, 54 Stat. 676, 680. A few decades later, Congress authorized the President to seize private business as a means of resolving labor disputes in times of war, see, e.g., War Labor Disputes Act of 1943, 57 Stat. 163, 164, and to seize communications stations and equipment in cases of national emergency, see, e.g., Communications Act of 1934, 48 Stat. 1064, 1104.

In this same period, the Executive likewise effected seizures of private industrial plants and facilities during times of war or in response to labor disputes implicating national interests. Such actions were typically undertaken by way of order or proclamation, often with citation to extant statutory authority. For example, during World War I, President Wilson assumed federal control of the railroads and telephone and telegraph lines.

1419—Government Assumption of Control See Proclamation Transportation Systems (Dec. 26, 1917) (relying on "section 1 of the Act 29, August 1916"), available approved at http://www.presidency.ucsb.edu/ws/?pid=24412. And during World War II, President Franklin Delano Roosevelt issued executive orders seizing private businesses in response to work stoppages or planned strikes that threatened to halt the supply of materials to the military during World War II. For example, in June 1941, President Roosevelt seized the Los Angeles plant of the North American Aviation Company in order to remedy a work stoppage that halted the production of military airplanes. See Executive Order 8773 on the Seizure of the North American Aviation Company Plant at Inglewood, California (June 9, 1941). available at http://www.presidency.ucsb.edu/ws/?pid=16126. Α few years President Roosevelt assumed federal control of the railroads to prevent the "interruption of vital transportation facilities." Executive Order 9412— Seizure and Operation of the Railroads (Dec. 27, 1943), available at http://www.presidency.ucsb.edu/ws/?pid=16357. And President Harry S. Truman issued an executive order seizing most of the nation's steel mills in order to ensure the continued availability of steel for weapons and war materials. Executive Order 10340—Directing the Secretary of Commerce to

Take Possession of and Operate the Plants and Facilities of Certain Steel Companies (Apr. 8, 1952), available at http://www.presidency.ucsb.edu/ws/index.php?pid=78454.³

Importantly, when such seizures were authorized, both Congress and the Executive almost uniformly cabined the authorizations to a limited period of time or for a defined emergency. *See Youngstown*, 343 U.S. at 600 (Frankfurter, J.) ("The power to seize has uniformly been given only for a limited period or for a defined emergency, or has been repealed after a short period."); *see, e.g.*, Railroad and Telegraph Act of 1862, 12 Stat. 334 (authorizing seizures for not "longer than is necessary for the suppression of this rebellion"); Joint Resolution of 1918, 40 Stat. 904 (authorizing seizures "during the continuance of the present war"); Communications Act of 1934, 48 Stat. 1064, 1104 (authorizing seizures during "war or threat of war" or a "state of public peril or disaster or other national emergency"); *Executive*

The power to seize and take over a company is so extraordinary and its effect on liberty and property so drastic that it is understood to be at the outer edge of executive power, and thus most appropriately exercised under our Constitution when occurring with the express consent of Congress. *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952). Accordingly, instances where the Executive effected seizures without specific congressional authorization that were later invalidated or otherwise called into question serve only to underscore the extraordinary nature of this awesome power. *See id.* at 589 (invalidating President's Truman's executive order seizing the steel mills).

Order 9412—Seizure and Operation of the Railroads, (Dec. 27, 1943) (assuming federal control of the railroads to prevent the "interruption of vital transportation facilities"), available at http://www.presidency.ucsb.edu/ws/?pid=16357. That these authorizations were circumscribed this way reflects Congress's and the President's recognition that the power of seizing and operating a private company is a drastic measure that should be used only rarely—and typically when both elected branches act in concert.

B. The Decision Below Is the First Time in American History that a Federal Court Has Commandeered a Private Company and Enjoined It to Make a Product.

In sharp contrast to the political branches, the courts have *never* themselves (*i.e.*, absent congressional or Presidential authorization) effectively seized a private company's facility and required it to make and distribute a product for which it had planned to curtail production. And for good reason. Such a preliminary injunction is tantamount to confiscating the operations of a facility. That is anathema to American tradition and contrary to the precedent described above, making it constitutionally suspect (if not altogether illegitimate). And by effectively substituting the judgment of an Article III judge for that of the business's board of directors or management, such an injunction reverses a host of business-related decisions—on such

issues as procurement, supply-chain, management, processing, distribution, employee-resource allocation, and compensation—made by persons who previously considered those issues and decided that acting on them as the court now requires is not in the business's best interest. Article III judges are not institutionally competent to override those judgments; and unlike the managers who must implement the judge's order, they bear no career or other responsibility should the injunction's requirements inure to the business's detriment. In short, "[n]o court before has ... commandeered a manufacturer's factory" and "seize[d] control and supervision of day-to-day business operations" in this manner. Brief of Defendants-Appellants ("Forest Br.") 60. This is not the time—and this case provides no warrant—to break this new ground.⁴

New York argues otherwise, but the cases it cites are inapposite; in fact, they undermine its case. *See* Memorandum of Law in Opposition to Motion for a Stay Pending Appeal ("NY Opp.") 19 & n.3. In *none* of these cases had the business planned to cease or limit production of the products at

To be sure, Congress created the Sherman Act cause of action under which this suit was brought, but nothing in the Sherman Act shows that Congress approved remedying an alleged antitrust violation in the way the district court chose—effectively seizing a private company's factory and taking over its day-to-day business operations.

issue. In other words, the Supreme Court has never ordered a business to make and distribute a product the business does not want to make and distribute; it has simply put conditions on a business that already has chosen to make and sell a product. See Lorain Journal Co. v. United States, 342 U.S. 143, 156 (1951) (ordering the defendant to stop selectively refusing advertisements in its paper); United States v. Grinnell Corp., 384 U.S. 563. 579 (1966) (requiring defendants "to sell, on nondiscriminatory terms, any devices manufactured by them for use in furnishing central station service"); Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 598 n.23 (1985) (noting that the district court had entered an injunction "requiring the parties to offer jointly a 4-area, 6-out-of-7-day coupon booklet" to their ski resorts); United States v. Glaxo Group Ltd., 410 U.S. 52, 62 (1973) (recognizing that the defendants could "choose to discontinue bulk-form manufacturing or the sale of' the product and requiring the defendants "to sell to all applicants only so long as they sell to any United States purchasers") (emphasis added).

That New York can find no precedent on point is not surprising. Requiring a company to *sell* a product at a certain price—itself a type of order that is (and should be) extraordinarily rare—is different from ordering a company to *make* a product. In the former situation, a company already

has a finished product and actively participates in a market. But in the latter, the company is at square one, and thus must undertake all of the complex judgments that producing and marketing any product entails.

The manufacturing process for medicine provides a good example. In the court's view, Forest apparently need only flip a switch and its factories will begin churning out mass quantities of Namenda IR tablets. But manufacturing medicine is not a simple, one-step process. Far from it:

[Drug companies] count, and/or test their product at every stage of the manufacturing process. They maintain extensive "batch" records for each step to ensure in-specification production and control over the validated process. An FDA-approved specification, formula, or regulation governs every step of the manufacturing process. This includes (1) the formula (weighing measuring raw materials); (2) blending equipment, quality-control measures and testing of samples to assure blend uniformity); (3) tableting (process, equipment, and quality-control measures for inspection of tablets for thickness, weight, appearance and hardness and weighing and counting of final product to reconcile with amount of raw ingredient used); (4) packaging (equipment and process of packaging operation); and (5) affirmative product testing (chemical testing of finished tablets to ensure specifications on a.p.i. ("assay") and content uniformity or consistency in dose from tablet to tablet).

In re Digitek Products Liab. Litig., 821 F. Supp. 2d 822, 827 (S.D. W.Va. 2011). The district court, in effect, has ordered Forest to take these steps. As Forest correctly points out, this injunction will cause Forest significant harms. Forest Br. 32-33.

* * * * *

As a matter of legal and historical precedent, the government's power

to seize a private company and operate its facilities has always been

understood to be an extraordinary one that properly may be exercised only

by the political branches and only in rare circumstances. The district court

thus broke new ground by ordering Forest to produce and market a product

for which it had planned to curtail production, and to keep doing so for the

next seven months on judicially dictated terms and conditions. Nothing in

this case supports this first-in-American-history injunction. This Court

should vacate it.

CONCLUSION

The injunction below should be vacated.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), undersigned counsel certifies

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of January, 2015, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Second Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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