23-410(L)

23-418(CON), 23-420(CON), 23-423(CON)

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IN RE BYSTOLIC ANTITRUST LITIGATION

(*caption continued on inside cover*)

On Appeal from the United States District
Court for the Southern District of New York
(Case No. 20-cv-5735) (Judge Lewis J. Liman)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING DEFENDANTS-APPELLEES AND AFFIRMANCE

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July 21, 2023

CVS PHARMACY, INC., RITE AID CORPORATION, RITE AID HDQTRS. CORP., J M SMITH CORPORATION, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED, D/B/A SMITH DRUG COMPANY, KPH HEALTHCARE SERVICES, INC., INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, A/K/A KINNEY DRUGS, INC., MAYOR AND CITY COUNCIL OF BALTIMORE, UFCW LOCAL 1500 WELFARE FUND, TEAMSTERS WESTERN REGION & LOCAL 177 HEALTH CARE PLAN, FRATERNAL ORDER OF POLICE MIAMI LODGE 20, INSURANCE TRUST FUND, LAW ENFORCEMENT HEALTH BENEFITS, INC., TEAMSTERS LOCAL NO. 1150 PRESCRIPTION DRUG BENEFIT PLAN, TEAMSTERS LOCAL 237 WELFARE FUND AND TEAMSTERS LOCAL 237 RETIREES BENEFIT FUND, ALBERTSONS COMPANIES, INC., H-E-B L.P., THE KROGER CO., AND WALGREEN CO.,

Plaintiffs-Appellants,

v.

FOREST LABORATORIES, INC., FOREST LABORATORIES IRELAND, LTD, FOREST LABORATORIES HOLDINGS LTD., FOREST LABORATORIES, LLC, ALLERGAN SALES LLC, ALLERGAN, INC., ALLERGAN USA, INC., ABBVIE, INC., WATSON PHARMA, INC., WATSON LABORATORIES, INC. (NY), WATSON LABORATORIES, INC. (CT), WATSON PHARMACEUTICALS INC., ACTAVIS, INC., TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMACEUTICALS LTD., TORRENT PHARMA INC., AMERIGEN PHARMACEUTICALS LTD., AMERIGEN PHARMACEUTICALS INC., GLENMARK GENERICS, INC., USA, GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS S.A., HETERO LABS LTD., HETERO DRUGS LTD, HETERO USA INC., INDCHEMIE HEALTH SPECIALTIES PRIVATE LTD., ALKEM LABORATORIES LTD., ASCEND LABORATORIES, LLC, ANI PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (DE), TEVA PHARMACEUTICAL INDUSTRIES LTD., AND GLENMARK PHARMACEUTICALS LTD.,

Defendants-Appellees.

DISCLOSURE STATEMENT

Washington Legal Foundation has no parent company, issues no stock, and no publicly held company owns a ten percent or greater interest in it.

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus in this Court promoting the proper scope of federal antitrust laws. *See, e.g.*, *1-800 Contacts, Inc. v. FTC*, 1 F.4th 102 (2d Cir. 2021). WLF has also filed amicus briefs in cases challenging the Federal Trade Commission's unlawful practices. *See, e.g.*, *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341 (2021).

In *1-800 Contacts*, the FTC urged this Court to disregard well-settled law and apply a presumption of illegality to find unlawful settlements between a trademark holder and companies it had sued for trademark infringement. The settlements barred defendants from buying ads keyed to a competitor's trademarks. This Court rejected the FTC's arguments on two fronts. First, it held that courts must engage in full rule of reason analysis. 1 F.4th at 114-17. Second, because under the

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* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to WLF's filing this brief.

rule of reason the settlements did not facially violate the antitrust laws, it ordered dismissal of FTC's administrative complaint. *Id.* at 117-22.

This Court's decision in *1-800 Contacts* is still good law. The FTC's top-side amicus brief here, though, shows that it does not believe that *1-800 Contacts* is binding precedent. WLF believes that this Court should once again reject the FTC's attempts at discouraging intellectual property settlements that avoid dead-weight loss.

INTRODUCTION

The FTC is a lawless agency. It lacked the lawful authority to file its amicus brief here. Congress may restrict the President's ability to remove principal officers in limited cases. *Humphrey's Ex'r v. United States*, 295 U.S. 602, 621-32 (1935). For principal officers—like FTC commissioners—Congress may "give for-cause removal protections to a multimember body of experts, balanced along partisan lines, that perform[s] legislative and judicial functions and [does] not [] exercise any executive power." *Seila Law LLC v. Consumer Fin. Prot. Bureau,* 140 S. Ct. 2183, 2187 (2020). As the FTC fails all three prongs of this test, its structure is unconstitutional and it lacked authority even to file its amicus brief.

Today's FTC looks nothing like the nonpartisan body Congress thought it was creating and which the Supreme Court approved in *Humphrey's Executor*. Now the FTC has three commissioners, all of whom are members of the same party. No other party has a commissioner. This means that the FTC no longer resembles the agency that existed either at the time of its creation or twenty years later when the Supreme Court blessed its structure.

Another key aspect of *Humphrey's Executor*'s analysis was that the FTC was "a body of experts." 295 U.S. at 624 (quotation omitted); *id.* at 625. But the FTC is not comprised of experts today. All three commissioners held partisan positions in Congress before their appointments; one had so little experience practicing law that she would have been ineligible for bar admission on motion in some jurisdictions when she was appointed. *See, e.g.*, Conn. Bar Examining Comm. R. 2-13(a)(2). Rather than a body of experts, the current FTC operates as a body of partisan politicians bent on implementing radical policies through the FTC. This is the opposite of what Congress thought it was doing in creating the FTC and what the Supreme Court thought it was blessing in *Humphrey's Executor*.

The FTC also exercises executive power. It routinely "seek[s] daunting monetary penalties against private parties on behalf of the United States in federal court." *Seila Law*, 140 S. Ct. at 2200; *see generally AMG Cap. Mgmt., LLC*, 141 S. Ct. 1341. And it "issue[s] final decisions awarding legal and equitable relief in administrative adjudications." *Seila Law*, 140 S. Ct. at 2200. As the Supreme Court recently explained, both functions are exercises of "quintessentially executive power not considered in *Humphrey's Executor*." *Id.* (footnote omitted). The only reasonable interpretation of *Seila Law* is that the FTC exercises executive power today, even if it did not do so 88 years ago. An agency that lacks the authority to file an amicus brief in this case is certainly an agency whose views should not be respected.

ARGUMENT

Even if this Court assumes that the FTC had authority to file its amicus brief, that brief is entitled to no weight.

I. THE FTC HAS NO CREDIBILITY.

A. The FTC Continues To Advance Its Pre-*Actavis* Position That The Supreme Court Rejected.

The FTC argues that this Court should apply a quick look test because all side deals are "highly unusual" and "very uncommon." FTC

Br. 7 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 666 (2009)). In 2009, Professor Hemphill was arguing that "it is appropriate to impose a presumption that [] side deal[s] provide[] disguised payment[s] to the generic firm[s]." Hemphill, 109 Colum. L. Rev. at 669.

The FTC has been parroting this law review article for over a decade. Before the Supreme Court's decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), it advanced the same position before the Third Circuit. *See* Br. of FTC as Amicus Curiae at 24 n.26, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077) ("As Professor Hemphill notes . . . a presumption that the side deal provides disguised payment to the generic firm for delayed entry is appropriate." (cleaned up)).

When the Supreme Court agreed to hear *Actavis*, the FTC argued that "[r]everse-payment agreements should accordingly be treated as presumptively anticompetitive under a 'quick look' rule of reason analysis." Br. for the Petitioner at 17, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (No. 12-416). Professor Hemphill's 2009 article played such a

prominent role in the FTC's *Actavis* brief that the table of authorities used passim for its entry. *See id.* at XI.

Actavis roundly rejected the FTC's quick look argument. The Supreme Court "decline[d]" to adopt the FTC's position "that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach." *Actavis*, 570 U.S. at 158-59. As the Court explained, "an observer with even a rudimentary understanding of economics" would not automatically conclude that "reverse payment settlements" "have an anticompetitive effect on customers and markets." *Id.* at 159. Thus, the quick look test was inappropriate. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999).

As the Court explained in *Actavis*, whether a reverse payment causes "anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." 570 U.S. at 159. And "any anticompetitive consequence may also vary as among industries." *Id.* Then, as now, FTC's quick look test cannot consider all these factors in the analysis. That is

why courts must apply the full rule of reason analysis. Only under that framework can courts weigh all the factors, determine the magnitude of any anticompetitive effects, and then weigh those against the procompetitive benefits of the reverse payment.

That should have been the end of the FTC's attempts at having reverse payments scrutinized under the quick look test. Any agency that respected the rule of law would have abandoned its argument in the courts and instead pursued its goals in Congress. But Congress had its own ideas. *See Antitrust Concerns and the FDA Approval Process, Hearing before the Subcomm. on Regul. Reform, Com. and Antitrust L. of the H. Comm. On the Judiciary*, 115th Cong., 10-11 (2017) (statement of Markus H. Meier, Acting Director, Bureau of Competition, FTC) (asking Congress to change the law to make it easier for the FTC to prevail in these cases). Unhappy about how Congress rejected its arguments, the lawless FTC has turned to the courts to achieve its policy goals.

The FTC continues to contend that almost all reverse payments violate the antitrust laws. In its view, "side deals and no-AG commitments are not necessary to settle pharmaceutical patent litigation." Jamie Towey & Brad Albert, *Then, now, and down the road:*

Trends in pharmaceutical patent settlements after FTC v. Actavis, FTC (May 28, 2019), https://tinyurl.com/ycyzn4y9. Indeed, one of the agency's "top priorities" is "to oppose a costly legal tactic that more and more branded drug manufacturers have been using to stifle competition from lower-cost generic medicines." FTC, *Pay for Delay*, https://tinyurl.com/ymbdu6kx (last visited July 20, 2023).

Of course, the FTC has pressed these arguments in the courts. *See* Br. of FTC as Amicus Curiae at 13, *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022) (No. 20-2402); *see generally* Br. of FTC as Amicus Curiae, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017) (No. 15-3559). Both the Seventh and Third Circuits rejected the FTC's arguments because they conflict with the Supreme Court's *Actavis* decision. *See AbbVie*, 42 F.4th at 714; *Wellbutrin XL*, 868 F.3d at 164-65.

In short, the FTC has pressed the same specious arguments for the past fourteen years. The Supreme Court rejected those arguments a decade ago in *Actavis*. Every court to consider the issue during that ten-year period has told the FTC to go to Congress if it wants the law to change. Yet because its lobbying attempts on Capitol Hill have failed, the

FTC returns to this Court with pleas to ignore the Supreme Court's binding precedent. Such tactics show why the FTC lacks any credibility.

B. The FTC Ignores Its $7 Million Safe Harbor For Litigation Costs.

"[W]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Actavis*, 570 U.S. at 156. Shortly after *Actavis*, the FTC decided that reverse payments of $7 million or less are tolerable. *See* FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2015*, 1 (Nov. 2017), https://tinyurl.com/yhtsjfb3.

The FTC believes that payments up to $7 million are "explained" under *Actavis* and thus legal. It has continually recognized this safe harbor in its public statements and reports. *See* FTC, *Overview of Agreements Filed in FY 2017, A Report by the Bureau of Competition*, 1 (2020), https://tinyurl.com/4xjas3z7; FTC, FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic

Competitors (Dec. 3, 2020), https://tinyurl.com/3b52rf9k; *see also* Brad Albert et al., *MMA Reports: No Tricks or Treats—Just Facts*, FTC (Oct. 27, 2020), https://tinyurl.com/mrfnnmw2 ("[A]n increasing number of agreements categorized as containing explicit compensation involve only minimal payments to the generic company for saved litigation expenses. Under *Actavis*, these agreements are unlikely to raise antitrust concerns.").

The FTC has also applied this safe harbor in the cases it litigates. For example, after the Supreme Court's *Actavis* decision, the case was remanded for further proceedings. After a decade of litigation, the parties eventually agreed to a stipulated order that allowed for a payment up to $7 million for saved litigation costs. *See FTC v. Actavis, Inc.*, No. 1:09-cv-955 (N.D. Ga. Feb. 28, 2019), ECF 868 at 6. This order implies that the FTC may have a higher safe harbor today than it did in 2019. Each year, the amount that can be paid to avoid future litigation costs increases or decreases according to changes in the "Producer Price Index for Legal Services." *Id.* As anyone who has received a bill from a lawyer knows, the cost of legal services continues to skyrocket.

The FTC also agreed to a stipulated order after it sued Cephalon and Teva. That stipulated order allowed "compensation for saved future litigation expenses not to exceed a maximum limit, which [wa]s initially set at seven million dollars." *FTC v. Cephalon, Inc.*, 2015 WL 4931442, *2 (E.D. Pa. June 17, 2015).

Besides the FTC, States have also adopted the FTC's $7 million safe harbor for saved litigation costs. After 18 States sued, they agreed to a consent decree which allowed a payment up to the safe harbor amount. *Alabama v. Endo Int'l PLC*, No. 3:19-cv-04157 (Aug. 6, 2019), ECF 10 at 5-6. In short, the FTC has led the way on allowing up to $7 million for saved litigation costs.

Judging from its amicus brief, the FTC has changed its tune. All the payments here are below the safe harbor amount. *See* S.A. 12 (citation omitted). Yet the FTC does not even mention the safe harbor in its brief. The FTC's ignoring that safe harbor here is just more evidence of why it lacks any credibility.

C. The FTC Did Not Challenge The Agreements Despite Investigating The Deals.

In its brief, the FTC says it "has primary responsibility for federal antitrust enforcement in the pharmaceutical industry" and "has a strong

interest in ensuring the proper application of the antitrust laws." FTC Br. 2, 4. Again, that is why "one of the FTC's top priorities in recent years has been to oppose" pharmaceutical patent-infringement settlements. *Pay for Delay*, *supra*. The FTC "has long recognized that stopping pay-for-delay deals [i]s a matter of pressing national concern." *Antitrust Concerns and the FDA Approval Process*, *supra* at 14.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355 note, "brand-name drug manufacturers and generic drug applicants file certain agreements with the FTC and the Department of Justice." FTC, *Pharmaceutical Agreement Filings*, https://tinyurl.com/5n8zm2fe (last visited July 20, 2023).

Here, Defendants filed the challenged agreements with the FTC and DOJ. *See* J.A. 1482 (citation omitted). Because of those filings, the FTC issued a civil investigative demand and began investigating the agreements. *See* J.A. 1542. Yet the FTC never challenged the agreements. Rather, after investigating the agreements, the FTC was content with allowing them to proceed without challenge. The FTC got involved as an amicus only after the case came before this Court.

The FTC does not want *any* precedent that rejects a challenge to a reverse payment. It therefore sues only when it thinks that it has a better than average chance of extorting a settlement from the defendant. But sometimes private parties sue after the FTC deems a case so weak as to not warrant suit. When this happens, and the possibility of adverse precedent arises, the FTC gets involved as amicus to support challengers—no matter how weak the case is. That is what happened here. After the FTC passed on the chance to challenge the agreements, private parties sued. Afraid that this Court would join its sister circuits in correctly applying *Actavis*, the FTC filed an amicus brief asking this Court to ignore Supreme Court precedent and legislate from the bench. This is yet another reason why the FTC lacks any credibility.

D. The FTC Refuses To Follow Its Own In-House Ethics Advice.

Finally, the FTC lacks any credibility because it refuses to follow its own in-house ethics advice. According to the FTC's top ethics official, "there is a reasonable appearance concern with" Chairman Khan's participating in a case against Meta. Lorielle L. Pankey, Federal Ethics Response To Meta Petition For Chair Khan's Recusal, 14, FTC (Aug. 31, 2022), https://tinyurl.com/2hter39d. So she "recommend[ed] Chair Khan

elect to recuse from participating as an adjudicator in" the case against Meta. *Id.*

After receiving this advice from the in-house ethics official, Chairman Khan has refused to recuse. Leah Nylen, *FTC Rejected Ethics Advice for Khan Recusal on Meta Case (1)*, Bloomberg Law (June 16, 2023), https://tinyurl.com/yw3df636. She did so despite assuring Senators during her confirmation hearing that whenever ethics issues arose, she "would seek the guidance of the relevant ethics officials at the agency and proceed accordingly." Tom Herbert, *Congress should probe Lina Khan's ethics issues*, Wash. Examiner (June 28, 2023), https://tinyurl.com/2a5atb7b. Not only did Chairman Khan refuse to recuse, the two remaining FTC commissioners blessed this ethical lapse. *See* Nylen, *supra*.

It is hard to imagine how a federal agency could have less credibility than one comprised of three individuals who think it is acceptable to mislead Congress and ignore in-house ethics advice. In short, the FTC has about as much credibility as Richard Nixon or John Dean had in August 1973. This Court should treat the FTC's brief here like it would have treated one filed by those men, by throwing it in the recycling bin.

II. THE FTC LACKS ANY EXPERTISE CONSTRUING RULE 12.

The FTC implies (at 2) that it has expertise in general pleading standards. It is making this argument nationwide. *See* Br. of FTC as Amicus Curiae, *Applied Med. Res. Corp. v. Medtronic, Inc.*, No. 23-cv-268 (C.D. Cal. July 3, 2023). This so-called expertise must be newfound. For years, the FTC professed that it was not a Rule 12 expert. *See* Br. of FTC as Amicus Curiae at 14 n.8, *AbbVie*, 42 F.4th 709 ("The FTC takes no position on whether plaintiffs sufficiently pleaded the existence of a reverse payment." (cleaned up)); Br. of FTC as Amicus Curiae at 1, *Staley v. Gilead Scis., Inc.*, No. 19-cv-2573 (N.D. Cal. Oct. 25, 2019) ("The FTC takes no position on . . . the sufficiency of the plaintiffs' factual allegations under" Rule 12.).

The change in stance is unsurprising. The FTC's argument here lacks any merit and ignores the Supreme Court's recent decision rejecting its position. The politically motivated FTC, however, is willing to argue anything if it means the chance of grabbing more power. Unfortunately for the FTC, "the consistency of an agency's position is a factor in assessing the weight that position is due." *Good Samaritan*

Hosp. v. Shalala, 508 U.S. 402, 417 (1993). Here the FTC's newfound litigating position on Rule 12 deserves to be ignored.

The correct interpretation of the Federal Rules of Civil Procedure is a pure question of law. *L-3 Commc'ns Corp. v. OSI Sys., Inc.*, 607 F.3d 24, 27 (2d Cir. 2010) (citing *Williams v. Beemiller, Inc.*, 527 F.3d 259, 264 (2d Cir. 2008); *Reiter v. MTA N.Y.C. Transit Auth.*, 457 F.3d 224, 229 (2d Cir. 2006)). The interpretation of the Constitution is also a question of law. *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1036 (2d Cir. 2014) (citing *Gunn v. Minton*, 568 U.S. 251, 256-57 (2013)).

Earlier this term, the FTC argued that it has expertise in pure questions of law. *See* Br. for the Federal Parties at 54, *Axon Enter., Inc. v. FTC*, 598 U.S. 175 (2023) (No. 21-86). The Supreme Court rejected this argument, explaining that *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477 (2010) "could hardly be clearer." *Axon*, 598 U.S. at 194. The FTC "knows a good deal about competition policy, but nothing special about" constitutional law. *Id.* Rather than being a factual question on which the FTC has expertise, agencies are ill-suited to consider such constitutional issues. *See id.*

The same is true for interpretating the Federal Rules of Civil Procedure. The rules are uniform no matter a case's subject. There is no separate Rule 12 for antitrust cases or securities cases. Rather, the same Rule 12 applies to both. And federal courts are the experts in interpreting those rules.

The FTC has no more expertise interpreting Rule 12 than do the Defendants' lawyers or the Fish and Wildlife Service. This Court would find it odd if the Fish and Wildlife Service appeared here urging the Court to follow its views on general pleading standards because of some alleged expertise on the issue. But that is essentially what the FTC has done. Despite lacking any expertise on the Federal Rules of Civil Procedure, it now claims such expertise just to get the political result it desires. Because its lobbying efforts continue to fail in the halls of Congress, the FTC has turned to this Court to lobby for its preferred policy outcomes. It does so, however, through the guise of its supposed expertise on Rule 12. This Court should reject this heavy-handed attempt and put the FTC's brief where it belongs—in the recycling bin.

CONCLUSION

This Court should affirm.

Respectfully submitted,

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July 21, 2023

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,395 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

/s/ John M. Masslon II
JOHN M. MASSLON II

July 21, 2023