ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 12, 2008

No. 08-5141

In the United States Court of Appeals for the District of Columbia Circuit

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff/Appellee,

v.

MICHAEL O. LEAVITT, *ET AL.*,

Defendants/Appellants.

On Appeal from the United States District Court for the District of Columbia (No. 08-395, Chief Judge Royce C. Lamberth)

BRIEF OF APPELLEE TEVA PHARMACEUTICALS USA, INC.

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July 21, 2008

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Parties and *Amici*. All parties, intervenors, and *amici* appearing before the district court and this Court are listed in the Brief for the Appellants. In addition, Apotex, Inc. ("Apotex") sought leave from the district court to intervene in this case for purposes of appeal, and later sought to intervene directly in this appeal under Fed. R. App. P. 15. The district court denied Apotex's post-judgment motion for intervention on June 3, and Apotex noticed an appeal from that decision on June 5 (Docket No. 08-5178). On June 11, this Court denied Apotex's Rule 15 motion in this appeal and, *sua sponte*, issued an order to show cause in No. 08-5178 as to why the district court's denial of Apotex's motion for post-judgment intervention should not be summarily affirmed. On June 30, this Court summarily affirmed the district court's decision.

Rulings Under Review. References to the rulings under review appear in the Brief for the Appellants.

Related Cases. Apotex's appeal from the district court's decision on intervention is docketed as No. 08-5178 and bears the same caption as this case.

July 21, 2008

Michael D. Shumsky

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Teva Pharmaceuticals USA, Inc. states as follows:

Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business and corporate headquarters in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly owned, indirect subsidiary of Teva Pharmaceutical Industries Ltd. No other publicly held corporation owns 10% or more of its stock.

July 21, 2008

Michael D. Shumsky

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GLOSSARY

'663 Patent	U.S. Patent No. 4,804,663
'952 Patent	U.S. Patent No. 5,158,952
180-day Exclusivity	A 180-day period of marketing exclusivity awarded to the first generic applicant that submits an Abbreviated New Drug Application containing a Paragraph IV certification to a patent listed in the Orange Book
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984)
Janssen	Janssen Pharmaceutica N.V. and Jannsen Pharmaceutica Products, L.P.
Mylan	Mylan Pharmaceuticals Inc.
NDA	New Drug Application
Orange Book	*Approved Drug Products with Therapeutic Equivalence Evaluations*
Paragraph IV Certification	A certification that a patent listed in the Orange Book is invalid, not infringed by a proposed generic drug, or otherwise unenforceable, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
Teva	Teva Pharmaceuticals USA, Inc.

STATEMENT OF JURISDICTION

FDA's jurisdictional statement is complete and accurate.

STATEMENT OF THE ISSUE

FDA expressly requires generic drug applicants to submit a certification with respect to "each listed patent" for a previously approved drug; defines "the list" of relevant patents as the Orange Book and its monthly Cumulative Supplements; and, at the time of the events giving rise to this case, explicitly directed generic applicants to consult "the most current Cumulative Supplement" to the Orange Book in order to determine whether there had been any "changes, additions, or deletions" from the official patent list before submitting an application for a proposed generic drug. Did FDA lawfully deprive Teva of 180-day marketing exclusivity for generic risperidone tablets when it denied Teva's citizen petition on the ground that U.S. Patent No. 5,158,952 was not a "listed patent," where the Agency concedes (1) that the '952 patent *was* listed in the annual edition of the Orange Book at the time Teva submitted its application, and (2) that "the most current Cumulative Supplement" to the Orange Book at the time Teva submitted its application did *not* reflect that the '952 patent had been delisted?

STATUTES AND REGULATIONS

The applicable statutes and regulations are set forth in the addendum to FDA's brief.

INTRODUCTION

If a federal agency no longer likes its regulations, there are a lot of things it can do. It can amend those regulations; it can repeal them and regulate directly from the statute; or it can seek new legislation from Congress. But a federal agency cannot simply pretend that its regulations don't exist, or assert that its express directives to regulated parties can be ignored because those directives are in fact contrary to law. That, however, is exactly what the government is attempting to do here, and this Court should affirm the district court's rejection of FDA's unprecedented approach.

Indeed, this is one of the simplest Hatch-Waxman cases this Court is ever likely to address. Though you would never know it from reading the government's brief, FDA's own regulations expressly require generic applicants to submit "an appropriate certification for *each listed patent*," even if the applicant disagrees about "the correctness of the patent information ... *published by FDA in the list*." 21 C.F.R. § 314.53(f) (emphasis added). This case thus turns on two uncontested facts. First, the government concedes that the '952 patent was listed in FDA's official patent register—a bound volume formally titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, but commonly called the "Orange Book" because of its bright orange cover—when Teva certified to that patent. FDA Br. at 31 ("[A]t the time Teva submitted its ANDA the '952 patent appeared

in the paper Orange Book."). And second, the government concedes that the Orange Book expressly "direct[ed] applicants to search the paper supplements [to the Orange Book] for updated patent information," FDA Br. at 28, and that "the '952 patent appeared in ... the cumulative supplement" to the Orange Book when Teva certified to that patent. *Id.* at 31.

That should be the beginning and the end of this case. As the district court (Lamberth, C.J.) recognized, "Teva did everything it was required to do by the agency" when it filed its Abbreviated New Drug Application ("ANDA") for generic risperidone tablets. JA25. Teva consulted the then-current edition of the Orange Book to find the "listed patents" for brand-name Risperdal® tablets. Teva searched the most current paper supplement to the Orange Book to make sure that the "listed patents" for Risperdal® had not been updated to reflect additional patent listings or delistings. And once Teva designed a safe, effective, and non-infringing generic risperidone product, Teva submitted "an appropriate certification for each listed patent," 21 C.F.R. § 314.53(f), including the first-ever Paragraph IV certification to the '952 patent. JA23. Teva thus did exactly what the Agency required it to do in order to qualify for 180-day exclusivity, and as the district court held, FDA's refusal to award Teva such exclusivity was unlawful. JA25.

On appeal, the government now does the only thing it can: It employs the ostrich defense. For the first time at any stage of this litigation, the government not

only fails to cite the FDA regulation upon which the district court relied, but pretends that regulation doesn't exist: "In fact, there is no requirement anywhere in the FDCA or FDA's regulations that an ANDA applicant search any version of the Orange Book," FDA Br. at 25. It asserts that the term "*listed patent*"—which it attributes to the district court, rather than FDA's own regulations—does not actually "mean[] a *patent listed* in the Orange Book," FDA Br. at 31 (emphasis added). And it claims that FDA's own express directives that applicants "must" consult the Orange Book and its paper supplements to obtain current patent listings are "not the law," and could not reasonably have been followed by applicants, because they are in fact inconsistent with "the relevant statute." FDA Br. at 29.

With all due respect, these unpreserved arguments are preposterous. Federal agencies may have a lot of leeway when they interpret statutes and regulations, but they cannot blithely deny the existence of those laws or reasonably assert that a regulated party did not do what it was supposed to do when it did precisely what the agency ordered it to do. This is not *1984*, and FDA is not the Ministry of Truth. Instead, FDA is subject to the modest demands of the Administrative Procedure Act, and its failure to follow its own regulations and directives in this case was—as the district court recognized—"arbitrary and capricious, and not in accordance with the law." JA25.

But even if FDA could—at this late date—effectively challenge its own regulations and directives in court, the government's efforts fall well short. Its principal argument here is that FDA's official patent listings are in fact irrelevant, because the statute authorizes applicants to certify only to those patents that "claim" a previously approved drug, and because a brand manufacturer's private request that FDA remove a patent from the Orange Book means that the patent no longer "claims" the brand-name drug—"[r]egardless of whether FDA did or did not properly remove the '952 patent from the ... Orange Book." FDA Br. at 11.

That approach would eviscerate Hatch-Waxman's public-notice provisions. As the Agency well knows, the statute not only requires brand manufacturers to submit information about drug-claiming patents to FDA and generic applicants to certify to those patents, but time and again requires FDA to "publish" all relevant patent information in a regularly updated, publicly available "list." 21 U.S.C. § 355(b)(1); *id.* § 355(c)(2); *id.* § 355(j)(7)(A)(i)-(iii). While the government now asserts that the statute's sequential patent-submission, patent-publication, and patent-certification requirements "are not inexorably linked," FDA Br. at 25, it had no trouble recognizing the obvious link between these provisions of the statute in the district court: "FDA is required to publish this information so that, among other things, generic drug manufacturers can decide whether their products might

infringe such patents." Defs.' Memo. in Opp. to Pls.' Mot. for a Prelim. Inj. ["FDA Dist. Ct. Br."] at 2 (Docket No. 14, Mar. 14, 2008).

In other words (and as FDA once understood), the statute's patent-publication requirements are an integral component of the statutory regime, designed specifically to put potential generic applicants on notice of the patent barriers that might block market entry—and for which patent-challenging Paragraph IV certifications are required if the applicant wishes to launch a generic product before patent expiry and with 180-day exclusivity. That, of course, explains why FDA's own Hatch-Waxman regulations—though FDA never even cites them—expressly require generic applicants to submit "an appropriate certification for *each listed patent*," even if the applicant disagrees about "the correctness of the patent information ... *published by FDA in the list*." 21 C.F.R. § 314.53(f) (emphasis added).

The only question, then, is what "the list" was at the time of Teva's Paragraph IV certification to the '952 patent. On this point, there is no serious dispute that the official patent list was FDA's printed Orange Book, as updated by the Agency's monthly printed Cumulative Supplements. JA24. FDA's own regulations define "the list" as the Orange Book and its supplements, 21 C.F.R. § 314.3(b). The 2001 Orange Book and the Cumulative Supplements themselves expressly stated that they were intended to fulfill the statute's public-notice

requirements. JA34; JA37. And, most important, those publications explicitly directed applicants that "the most current Cumulative Supplement ... *must be used*" to ascertain current patent information, "[b]ecause all parts of the [annual Orange Book] are subject to changes, additions, *or deletions*." JA37 (emphasis added); *see also* JA34.

The government devotes just three pages of its brief to this central issue, and its only credible argument is that nothing in the statute or Agency regulations prevents FDA from using "electronic publication on the Internet to comply with the statute." FDA. Br. at 30. That argument, however, completely misses the point. Teva has always conceded that FDA is not limited to printing patent-listing information in annual Orange Books and monthly Cumulative Supplements, and nothing in the statute or FDA's regulations prevents the Agency from putting those publications on the internet (or even maintaining some entirely different set of patent listings, like the searchable electronic Orange Book Query feature upon which the Agency relies in this case).

Indeed, FDA in 2005 formally notified the public that it would cease printing paper Orange Books and monthly Cumulative Supplements altogether, and instead would make those publications available exclusively on its website in Adobe PDF format. The Agency began updating the searchable electronic Orange Book Query feature on a daily basis. And it made a telling change to the

longstanding directive that applicants "must" consult "the most current Cumulative Supplement" for updated patent information before submitting an ANDA. *See* JA34; JA37. For the first time, the 2005 PDF edition of the Orange Book instructed applicants: "Since all parts of this publication are subject to changes, additions, or deletions, *the Electronic Orange Book, updated daily*, should be consulted for the most recent patent and exclusivity information." JA53 (emphasis added). If, as the government now argues, it was clear that Teva should have known "about, and relied on, the electronic Orange Book for patent information in 2001," FDA Br. at 31, then there would have been no need *in 2005* for FDA to alter the Orange Book to direct applicants—for the very first time—to consult "the Electronic Orange Book, updated daily," rather than "the most current Cumulative Supplement," before submitting an ANDA.

The bottom line here is that when Teva submitted its ANDA in August 2001, the paper Orange Book and monthly Cumulative Supplements comprised FDA's official patent list, and the Agency expressly was directing applicants to use those official patent-listing publications (with their bright orange covers) in order to determine which patents required certifications. And in 2005 (but not earlier), FDA decided that times had changed, and that applicants henceforth would be obligated to "consult ... the Electronic Orange Book, updated daily" when making their certifications. Both approaches are perfectly legitimate under the statute and

relevant FDA's regulations. But as the district court recognized, FDA cannot rewrite history and pretend that Teva was subject to the Agency's 2005 directives at the time Teva submitted its ANDA in 2001. JA25. The district court's decision should be affirmed.

BACKGROUND

A. Statutory And Regulatory Framework

As modified by the Drug Price Competition and Patent Restoration Act of 1984 ("Hatch-Waxman"), the Food, Drug, and Cosmetic Act ("FDCA") sets forth the procedure for obtaining approval to market pharmaceutical products in the United States. 21 U.S.C. § 355 (2001).[1] Pursuant to the statute, applicants for a proposed brand-name drug must file a New Drug Application ("NDA") that, among other things, contains clinical data showing the safety and efficacy of the proposed drug, *id.* § 355(b)(1), and information about any patents that claim that drug. *Id.* Prior to Hatch-Waxman, the statute also required generic drug applicants to complete a full NDA to secure approval for a proposed generic drug—even though generics contain the same active ingredients and provide the same therapeutic value as their brand-name equivalents. Because that requirement often made generic market entry cost-prohibitive, Congress enacted Hatch-Waxman to

[1] As FDA observes, this case is governed by the Hatch-Waxman version of the FDCA, so all references are to the 2001 statute. FDA Br. at 2.

remove that barrier, increase market competition, and thereby reduce the average cost of pharmaceuticals. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984).

To accomplish those goals, Hatch-Waxman authorizes FDA to approve a proposed generic drug if the product's manufacturer can show that its drug is bioequivalent to a drug that FDA already has approved. Generic manufacturers do so by submitting an Abbreviated NDA ("ANDA") to the Agency. *See* 21 U.S.C. § 355(j). If the ANDA successfully demonstrates the proposed generic drug's bioequivalence, the applicant does not need to duplicate prior clinical studies conducted on the previously approved drug. *Id.* § 355(j)(2)(A).

To balance the public interest in generic market entry against the intellectual property rights of brand-name manufacturers, Congress required each ANDA to include a certification regarding every patent that the brand-name manufacturer submitted with its NDA. *See id.* § 355(j)(2)(A)(vii). Four such certifications are available: (I) that no patent information was filed for the brand-name drug [a "Paragraph I certification"]; (II) that such a patent expired [a "Paragraph II certification"]; (III) that the generic drug will not be marketed until such a patent expires [a "Paragraph III certification"]; or (IV) that such a patent is invalid or will not be infringed by the proposed generic product [a "Paragraph IV certification"]. *Id.*

The most important of these is the Paragraph IV certification. Such certifications signal that the applicant intends to begin marketing its product before a competition-blocking patent expires, and thus that the applicant is seeking to provide expedited price relief to consumers. But filing a Paragraph IV certification carries significant risks for generic applicants. Paragraph IV filers must invest significant resources to identify weaknesses in listed patents and develop a non-infringing product or craft a legal defense based on patent invalidity or unenforceability. If those efforts succeed, the very act of submitting a Paragraph IV certification constitutes an "artificial" act of infringement that exposes the applicant to a risk of costly patent litigation. *See* 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

To encourage manufacturers to make those investments and accept those risks, Hatch-Waxman rewards the first Paragraph IV challenger with a 180-day period during which it can market its product without competition from other generics. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998); *see also* 21 U.S.C. § 355(j)(5)(B)(iv). That "180-day exclusivity period" runs from either the date on which a court holds that the challenged patent is invalid, not infringed, or unenforceable, or the date on which the applicant first markets its generic drug product. *Id.* § 355(j)(5)(B)(iv).

To make this patent-challenge system work, Hatch-Waxman requires FDA to "publish and make available to the public" a list containing the patent information brand manufacturers submit to the Agency, *id.* § 355(j)(7)(A)(i); *id.* § 355(b)(1), and to "revise the list ... [e]very thirty days," *id.* § 355(j)(7)(A)(ii)-(iii). At the time of the events giving rise to this case, FDA fulfilled those mandates by (1) publishing an annual patent register (the "Orange Book") that listed every approved drug, every patent identified by the innovator as claiming that drug, and the expiration date of each such patent, and (2) updating the Orange Book with monthly Cumulative Supplements that notified the public of any changes to the official patent-listing information for approved drug products. *See* JA37 ("The [Orange Book] contains appropriate drug patent and exclusivity information required of the Agency by [Hatch-Waxman].... The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised ... patent and exclusivity data.").

Those Supplements were legally required of FDA and legally binding on generic applicants. FDA's own regulations required the Agency to update the annual edition's patent-listing information by publishing the Cumulative Supplements. 21 C.F.R. § 314.53(e) ("Patent information submitted by the last working day of a month *will be published in that month's supplement to the list.*") (emphasis added). And they explicitly required applicants to submit "an

appropriate certification for each *listed patent*," even if the applicants disagreed about "the correctness of the patent information ... *published by FDA in the list*." 21 C.F.R. § 314.53(f) (emphasis added). Finally, and—of special note here—the Orange Book and Cumulative Supplements themselves directed that "the most current Cumulative Supplement ... *must be used*" to ascertain current patent information before submitting an ANDA, "[b]ecause all parts of the [Orange Book] are subject to changes, additions, *or deletions*." JA37 (emphasis added); JA34.

B. Factual Background

Janssen Pharmaceutica ("Janssen") holds the approved NDA for risperidone tablets, which it markets under the brand-name Risperdal®. Janssen originally submitted two patents to FDA as claiming Risperdal® tablets: U.S. Patent No. 4,804,663 ("the '663 patent") and U.S. Patent No. 5,158,952 ("the '952 patent"), and FDA thus listed both of those patents in the Orange Book. The '663 patent expired on December 29, 2007, but Janssen received six further months of exclusivity for conducting studies of Risperdal®'s effectiveness in children. That period of "pediatric exclusivity" expired June 29, 2008. The '952 patent will expire October 27, 2009. JA74.

In August 2001, after developing a non-infringing generic risperidone product and crafting a legal challenge to the '952 patent's validity, Teva submitted

its risperidone ANDA. JA55. FDA expressly concedes that on the date Teva did so, the 2001 Orange Book listed both the '663 and '952 patents for Risperdal® tablets, and that FDA's then-current Cumulative Supplement reflected no change to the official patent information for Risperdal® tablets. FDA Br. at 31; *see also* JA35, JA42. In accordance with Hatch-Waxman, FDA's own regulations, and the Agency's express directives to ANDA filers, Teva thus certified to both patents in its ANDA—a Paragraph III certification to the '663 patent, and a Paragraph IV certification to the '952 patent. JA75. As the first Paragraph IV challenger to the '952 patent, Teva became eligible for 180-day exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *see also Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 125 (D.C. Cir. 2006).

On October 12, 2001, however, FDA asserted that the '952 patent had been "delisted," or removed, from the Orange Book *before* Teva submitted its ANDA, and that the Agency would not even accept Teva's ANDA for filing until Teva withdrew its Paragraph IV certification. JA75. That was a puzzling assertion: After all, the '952 patent continued to appear in the Orange Book, and even the October Cumulative Supplement—issued two months *after* Teva submitted its ANDA—did not reflect the '952 patent's delisting. In fact, neither the Orange Book nor any Cumulative Supplement reflected the delisting until the 2002 annual Orange Book was released the next year. JA48-49. Even so, FDA's refusal to

accept Teva's ANDA or commence its review of that ANDA unless Teva withdrew its Paragraph IV certification left Teva no choice but to comply with the Agency's directive. JA75.

After Teva successfully challenged FDA's approach to patent delistings in the *Ranbaxy* case, 469 F.3d at 125, Teva petitioned FDA to relist the '952 patent in the Orange Book, reinstate Teva's Paragraph IV certification to the '952 patent, and thereby restore Teva's right to exclusivity. JA56. FDA denied Teva's petition on February 26, 2008, asserting that Teva's Paragraph IV certification had been improper (and thus properly was rejected by the Agency) because "the '952 patent was delisted before Teva submitted" its ANDA. JA71. That was so, according to FDA, because the "electronic Orange Book Query" feature on FDA's website was updated "shortly after June 29, 2001, and no later than July 20, 2001" to reflect the '952 patent's delisting. JA76-77. As a result, "the '952 patent was no longer listed for [Risperdal®] when Teva's ANDA 76-228 was submitted [and] a certification to the '952 patent was neither necessary nor permitted." JA77.

Teva sued FDA on March 4, arguing that the Agency's decision violated the APA and seeking expedited injunctive relief. JA7. Mylan Pharmaceuticals Inc. ("Mylan") promptly intervened. JA3. On April 11, after multiple rounds of briefing and argument, the district court (Lamberth, C.J.) consolidated Teva's motion for expedited injunctive relief with a hearing on the merits and entered

judgment for Teva. JA21-27 (oral decision); JA28-29 (order). As the district court's oral decision explained, FDA's putative delisting of the '952 patent through its website was legally ineffective because FDA's own directives "indicated th[at] changes, additions, and deletions to the patent listing information would be in the orange book or the cumulative supplement, and that applicants were required to go to those sources" instead of the electronic Orange Book. JA24-25. Since those official sources plainly reflected "the listing of the '952 patent ... Teva did everything it was required to do by the agency's procedures" when it submitted its ANDA. *Id.*; *see also id.* ("[T]he agency's own procedures require that you go by ... the cumulative supplement, and by the bound orange book, so that the actions of Teva were completely proper, and, in fact, under the agency's procedures, the only procedure that they could have followed.").

The district court also explained that the result in this case would have been different if FDA had directed applicants to consult the electronic Orange Book before submitting their patent certifications. *Id.* ("If [FDA] had changed that [directive] so that the electronic version on the website was required to be consulted, that would make a difference in the outcome."). As the district court observed, however, "there was no such requirement" in 2001, "and the fact that the orange book had been electronically updated is really irrelevant to the procedures that were in place. The procedures in place were you go to the orange book or to

the cumulative supplement." JA25. The court therefore entered judgment for Teva; ordered FDA to relist the '952 patent and reinstate Teva's Paragraph IV certification *nunc pro tunc* to the date of its original submission; and enjoined FDA from approving subsequent risperidone ANDAs until Teva's exclusivity ends. JA28-29.

After judgment was entered, FDA relisted the '952 patent in the Orange Book, but timely noticed an appeal to this Court. JA30. Janssen's pediatric exclusivity for Risperdal® tablets expired on June 29, and the next day, FDA approved Teva's risperidone ANDA with exclusivity. Teva began commercial distribution and marketing of its risperidone tablets shortly after receiving FDA's final approval. Those actions triggered the start of the company's 180-day exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I).

STANDARD OF REVIEW

The district court's grant of summary judgment to Teva is reviewed *de novo*. *See, e.g., National Med. Enters., Inc. v. Shalala*, 43 F.3d 691, 693 (D.C. Cir. 1995).

SUMMARY OF THE ARGUMENT

As the district court recognized, FDA's decision in this case cannot be reconciled with the Agency's own regulations or directives to generic drug manufacturers, and thus epitomizes exactly the sort of arbitrary and capricious agency action that violates the APA. FDA's own regulations—which the

government does not even cite, despite the fact that they were briefed by the parties below and relied upon by the district court—unambiguously require an applicant for a proposed generic drug to submit a certification with respect to each "listed patent" that appears in FDA's official patent register—even if the applicant disagrees about "the correctness of the patent information ... published by FDA in the list." 21 C.F.R. § 314.53(f). FDA's official patent register—which FDA's own regulations define as the Orange Book and its monthly Cumulative Supplements, 21 C.F.R. § 314.3(b)—in turn directs applicants that "the most current Cumulative Supplement" to the Orange Book "must be used" when applicants make the patent certifications required by the Agency's regulations. Because that is exactly what Teva did when it submitted its certification to the Orange Book-listed '952 patent, the Agency cannot seriously maintain that Teva's certification was improper.

In an effort to get around those requirements, FDA now takes the remarkable position that they are irrelevant. According to FDA, Teva's certification was improper "regardless of what appeared in [any version of the] Orange Book." FDA Br. at 10-11. Nonsense. FDA has never even hinted at such an argument during the course of this matter—not in its letter decision, and certainly not in the district court—and the argument cannot in any event be squared with the statute's public-notice provisions. Those provisions—21 U.S.C. § 355(b)(1), *id.*

§ 355(c)(2), *id.* § 355(j)(7)(A)(i), *id.* § 355(j)(7)(A)(ii), and *id.* § 355(j)(7)(A)(iii)—repeatedly require FDA to publish and regularly update the patent information it receives from brand manufacturers. Those requirements are designed precisely to ensure that generic applicants know which patents might block generic market entry and, thus, will require a patent-challenging Paragraph IV certification if a given applicant wishes to enter the market early and with 180-day exclusivity. Accepting FDA's argument that it simply doesn't matter what the Agency puts in its official patent list effectively would write those provisions out of the statute—which, of course, explains why FDA's own regulations require applicants to certify to every patent listed in the Agency's official patent list even if the applicants would rather pick and choose among the listed patents when making their certifications.

As a result, the only issue in this case is which version of FDA's patent list controlled at the time Teva submitted its Paragraph IV certification to the '952 patent. On this point, there can be no serious dispute that the printed Orange Book and its most current Cumulative Supplement controlled. Again, FDA's own regulations define the official patent list as the Orange Book and current Cumulative Supplement, 21 C.F.R. § 314.3(b), and require FDA to include any updated patent information it receives from brand manufacturers in each "month's supplement." *Id.* § 314.53(e). The 2001 Orange Book and the Cumulative

Supplements themselves expressly stated that they fulfilled the Agency's statutory patent-listing obligations. JA34; JA37. And each unambiguously required applicants to "use" the "most current Cumulative Supplement" when making their patent certifications. *Id.* That, at bottom, is exactly what Teva did when it submitted its Paragraph IV certification to the Orange Book-listed '952 patent, and the district court thus properly held that Teva's certification was both proper and exclusivity-qualifying.

ARGUMENT

THE DISTRICT COURT CORRECTLY HELD THAT FDA'S REFUSAL TO AWARD TEVA 180-DAY EXCLUSIVITY WAS UNLAWFUL.

A. FDA's Letter Decision Violated The Agency's Own Regulations And Binding Directives To Applicants.

FDA is trying to make this case about the statute, but it isn't. Instead, as the district court explained in its oral decision, this case is about FDA's failure to follow the plain text of its own rules and implementing regulations. JA25 ("Teva did everything it was required to do by the agency's procedures, and the agency's reactions then are arbitrary and capricious."). Those directives expressly require generic applicants to submit "an appropriate certification for each *listed patent*," even if they disagree about "the correctness of the patent information ... *published by FDA in the list*." 21 C.F.R. § 314.53(f) (emphasis added). And at the time of the events underlying this litigation, those directives expressly required applicants to use the printed Orange Book and its most current Cumulative Supplement to

determine which patents were "listed" for a brand-name drug and thus required an appropriate certification. JA34 ("Since all parts of this publication are subject to changes, additions, or deletions, the Addendum[2] *must be used in conjunction with the most current Cumulative Supplement.*") (emphasis added); JA37 ("Because all parts of the publication are subject to changes, additions, or deletions, the [annual Orange Book] *must be used in conjunction with the most current Cumulative Supplement.*") (emphasis added).

Teva followed each of those directives to the letter when it submitted its Paragraph IV certification to the '952 patent, and FDA's contention that Teva's certification was improper is meritless. After all, FDA concedes that "at the time Teva submitted its ANDA the '952 patent appeared in the paper Orange Book (both the annual edition and the cumulative supplement)." FDA Br. at 31; *see also* JA23 ("The government has conceded that the 952 patent ... appeared in the orange book at the time that Teva submitted its ANDA ... and it has conceded that the cumulative supplement from the orange book did not reflect any delisting."). And, as the district court explained, there is no serious dispute that when Teva submitted its Paragraph IV certification, those sources comprised the Agency's

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[2] Each annual edition of the Orange Book is divided into four sections; the section containing patent and exclusivity information for approved drug products is titled the "Patent and Exclusivity Information Addendum." JA33 (2001 edition); JA46 (2002 edition); JA52 (2005 edition).

official patent "list." JA24 ("[T]he agency's own procedures require that you go by the paper orange book, the cumulative supplement, and by the bound orange book."); JA25 ("The procedures in place were you go to the orange book or to the cumulative supplement.").

Indeed, FDA's own regulations define "the list" as "the current edition of FDA's publication 'Approved Drug Products with Therapeutic Equivalence Evaluations' and any current supplement to the publication," 21 C.F.R. § 314.3(b), and provide that any updated "[p]atent information submitted by the last working day of a month will be published *in that month's supplement to the list.*" *Id.* § 314.53(e) (emphasis added). The 2001 Orange Book and monthly Cumulative Supplements themselves informed applicants that those publications comprised the official patent list that Hatch-Waxman requires FDA to maintain: "The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the [Hatch-Waxman Act]." JA37; *id.* ("The Cumulative Supplement provides ... updated patent and exclusivity data."); *id.* at 34 ("The patent numbers and the expiration dates of appropriate patents claiming drug products that are the subject of approved applications will be published in this *Addendum* or in the monthly Cumulative Supplement to this publication."). And, to reiterate, those publications expressly directed applicants to "use ... the most current Cumulative

Supplement" in order to determine which patents required certifications. JA34; JA37.

It thus should come as no surprise that this Court long has observed that "to determine ... whether any paragraph IV certifications ... are needed, applicants look in the 'Orange Book.'" *Purepac*, 354 F.3d at 880; *see also Allergan, Inc. v. Crawford*, 398 F. Supp. 2d 13, 17 (D.D.C. 2005) ("FDA ... publishes patent information for approved drugs in the 'Approved Drug Products With Therapeutic Equivalence Evaluations' (the 'Orange Book'). Generic drug manufacturers check the Orange Book to determine if a drug product is patent-protected or if it is available for the development of a generic bioequivalent drug.") (citations omitted).

And it likewise explains why this Court repeatedly has held that "[f]or each patent ... listed in the Orange Book, an ANDA applicant must certify whether the proposed generic drug would infringe that patent." *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001); *see also Ranbaxy*, 469 F.3d at 122 ("Each ANDA ... must contain: 'a certification ... with respect to each patent which claims a drug or a method of using a drug listed in the Orange Book.'") (alteration and citation omitted); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003) ("Under FDA policy, an ANDA applicant must make a certification for every patent listed in the Orange Book for the particular approved

drug to which the ANDA relates."); *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 64 (D.D.C. 2006), *aff'd* 226 Fed. Appx. 4 (D.C. Cir. 2007) ("An ANDA-applicant seeking to market its drug before the NDA-drug's patent has expired must make a paragraph IV certification with respect to the 'listed patents' (i.e., the patents that are listed in the Orange Book when the ANDA is filed), as well as those that are placed in the Orange Book subsequently (i.e., 'later-listed patents').").

Given the government's express concessions that the '952 patent appeared in both the Orange Book and the most current Cumulative Supplement at the time Teva submitted its Paragraph IV certification, "the 952 patent was a listed patent," JA23, and "Teva acted properly in submitting their Section four certification, as they were required to do." JA24; *see also id.* ("[T]he actions of Teva were completely proper, and, in fact, under the agency's procedures, the only procedure they could have followed was to submit the Section Four certification with their ANDA because the agency's procedures required that you go by the orange book and the cumulative supplement.").

FDA now offers three responses. It first asserts that "there is no requirement anywhere in the FDCA or FDA's regulations that an ANDA applicant search any version of the Orange Book." FDA Br. at 25. This is the first time that FDA has ever made such an argument, and as this Court repeatedly has held, "[a]rguments not presented to the district court will not be heard on appeal absent exceptional

circumstances." *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 219 (D.C. Cir. 2003) (citation omitted). Far more important, the argument is absurd. Again, FDA's own regulations specifically require applicants to look in the Orange Book in order to determine which patents require certifications. Indeed, 21 C.F.R. § 314.53(f), which FDA now fails even to cite despite discussing that regulation in the district court, *e.g.*, FDA Dist. Ct. Br. at 5, expressly provides that generic applicants must submit "an appropriate certification for each *listed patent*," even if they disagree about "the correctness of the patent information ... *published by FDA in the list*." *Id.* (emphasis added). And, to reiterate, the Orange Book and Cumulative Supplements themselves expressly provided that applicants "must ... use" the latest Cumulative Supplement when making their patent certifications. JA34; JA37. That, of course, is exactly what Teva did when it submitted its Paragraph IV certification to the '952 patent—and that patent, as the district court explained, thus unquestionably "was a listed patent" at the time Teva did so. JA23.

FDA next asserts that "[i]t is unclear exactly what the [district] court meant by 'listed patent,' but to the extent the court meant a patent listed in the Orange Book, the court is mistaken." FDA Br. at 31. That claim—also waived—is even more outlandish. The district court didn't just invent the term "listed patent." It comes from FDA's own patent-listing regulation, which repeatedly was cited in the

parties' briefing and at oral argument. The context in which that term appears in FDA's regulation makes clear that it refers to a patent "published by FDA in the list." 21 C.F.R. § 314.53(f); *see also id.* § 314.53(e) ("FDA will publish in the list the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant."). And that straightforward interpretation of the term comports with its common meaning. *See Webster's Third New Int'l Dictionary (Unabridged)* 1320 (4th ed. 1976) (defining "listed" as "incorporated in a list"); *see also* 6 *The Oxford English Dictionary* 336-37 (4th ed. 1977) (defining the noun "list" as a "catalogue or roll consisting of the a row or series of names, figures, words or the like," and the verb "list" as "to set down or enter in a special, formal, or official list"). While federal agencies generally have broad discretion to interpret regulatory terms, deference is appropriate only where the text of the regulation or directive is ambiguous, *see, e.g.*, *Pfizer, Inc. v. Heckler*, 735 F.2d 1502, 1509 (D.C. Cir. 1984)—and, if nothing else, a federal agency cannot (like Humpty Dumpty) choose to make a term mean "'just what *I* choose it to mean—neither more nor less.'" *TVA v. Hill*, 437 U.S. 153, 173 n.18 (1978) (quoting Lewis Carroll, *Through the Looking Glass*, in *The Complete Works of Lewis Carroll* 196 (1939)) (emphasis in original).

So the government falls back on a third argument: it asserts that Teva's certification nevertheless was improper because FDA "provided notice of the

removal of the '952 patent through its electronic Orange Book," and "nothing prevent[s] FDA's use of electronic publication on the Internet to comply with the statute." FDA Br. at 30. That argument is beside the point. Teva always has conceded that FDA is not limited to printing patent information in the paper Orange Book and Cumulative Supplements, and nothing prevents FDA from maintaining online patent listings—though, to be sure, Congress probably didn't envision online publication when it passed Hatch-Waxman in 1984.

The problem here, however, is that FDA in 2001 was maintaining two *different* versions of the requisite patent list—the printed Orange Book and Cumulative Supplements, on one hand, and the "Electronic Orange Book Query (EOB)" feature on the other, JA76, and those sources were providing the public with conflicting information. The former concededly indicated that the '952 patent was listed for Risperdal® tablets, JA35; JA43, while the latter apparently reflected that patent's delisting. JA74. Needless to say, only one version of the patent-listing information FDA disseminated in 2001 could control, and the district court properly determined that the print listings were dispositive.

Again—and at the risk of redundancy—both the Orange Book and Cumulative Supplement expressly stated that those publications (but not the electronic Orange Book Query feature) were intended to fulfill the Agency's patent-listing obligations under the statute. *See, e.g.*, JA37 ("The Addendum

contains appropriate drug patent and exclusivity information required of the Agency by the [Hatch-Waxman Act].... The Cumulative Supplement provides ... updated patent and exclusivity data."). The government has never argued (much less proven) that the Electronic Orange Book Query feature contained any similar statement about its legal status in 2001. And both the 2001 Orange Book and each of the monthly Cumulative Supplements FDA published that year explicitly directed applicants to "use ... the most current Cumulative Supplement" (but not the Electronic Orange Book Query feature) in order to obtain information about any "changes, additions, *or deletions*" to the official patent-listing information for previously approved drugs:

> "Since all parts of this publication are subject to changes, additions, or deletions, the Addendum *must be used in conjunction with the most current Cumulative Supplement.*" JA34 (emphasis added).
>
> "Because all parts of the publication are subject to changes, additions, or deletions, the [annual Orange Book] *must be used in conjunction with the most current Cumulative Supplement.*" JA37 (emphasis added).

As the district court thus summarized, FDA's own directives expressly provided that "changes, additions, and deletions to the patent listing information would be in the orange book or the cumulative supplement, and that applicants were required to go to those sources." JA24.

FDA nonetheless asserts that the district court erred because "the paper Orange Book itself refers to the electronic version of the patent listing [*sic*]," and

because "[e]ach Cumulative Supplement refers in turn to the availability of the electronic Orange Book." FDA Br. at 27. Those claims are meritless. The Orange Book's statement that it was "Updated on the Internet" appears only in the Library of Congress classification record on the printed publication's inside cover. *Id.* It strains reason to think that such an obscure reference could carry any force, but the key point here is that that opaque allusion is no more probative with respect to which patent-listing source would control in the event of a conflict than the Orange Book's statement that the publication was "updated by monthly cumulative supplements," which also appeared in the Library of Congress record. *Id.*

The Cumulative Supplement's reference to "the electronic version" is no more helpful to the government's position. That reference merely stated that the EOB Query feature was "updated *concurrently* with the publication of the annual edition or monthly cumulative supplements." JA40 (emphasis added). It therefore notified applicants only that it would contain *the same* information as the monthly Cumulative Supplements—not that it would provide more current information (or different information) than the printed Cumulative Supplements.[3]

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[3] The government acknowledges that the Orange Book expressly directed applicants to look for information about patent delistings in the Cumulative Supplements and stated that "the electronic and paper versions of the Orange Book would be updated concurrently," FDA Br. at 26, but now concedes that the Cumulative Supplements apparently did not show delistings at all. *Id.* at 26-27. That, of course, is a serious problem: it is hard to see why an applicant (cont.)

Finally, and as the district court observed, neither of those passing references to FDA's website was hortatory—nothing in them "require[d] that the website be searched" in the same manner as the Orange Book's unambiguous demand that the most current Cumulative Supplement "must be used" by applicants. JA24. At most, those stray references indicated that "there was an additional source that ... [c]ould be queried," not that there was one that *had to* be queried. *Id.*

Most telling of all, however, is the fact FDA in 2005 fundamentally changed its patent-listing practices and Orange Book directives. It began to update the electronic Orange Book daily, rather than concurrently with the monthly Cumulative Supplements. JA53. And instead of directing applicants to consult the "most current Cumulative Supplement" for current patent information, it for the first time instructed applicants that "*the Electronic Orange Book, updated daily*, should be consulted for the most recent patent ... information." *Id.* (emphasis added). As the district court rightly noted, however, "there was no such requirement" in 2001, "and the fact that the orange book had been electronically

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should be penalized when FDA unambiguously instructed applicants to look for certain information in a certain place, and then decided not to put the information there after all. In the district court, the government baldly asserted that "this does not make FDA's [actions] unreasonable." FDA Dist. Ct. Br. at 19. But the government does not even bother to reprise that *ipse dixit* here—and for good reason. FDA's misleading instructions to applicants epitomize the very sort of arbitrary agency action the APA condemns.

updated is really irrelevant to the procedures that were in place. The procedures in place were you go to the orange book or to the cumulative supplement." JA25. In short, FDA is free—as it since has done—to make the Electronic Orange Book its official source for patent listings. But it cannot rewrite history and assert that it already had made that change at the time Teva submitted its Paragraph IV certification in August 2001.

In a last-ditch effort to avoid its own express directives to applicants, the government makes—yet another—new argument. It asserts, for the first time ever, that "the Orange Book statements that form the basis of Teva's case are not the law" and "do not 'control' the outcome of this case." FDA Br. at 27, 28. FDA, however, had every opportunity to make that argument in the district court. It never came close, and it cannot now argue that the district court erred by failing to consider a claim at which the Agency did not even hint below. *See District of Columbia v. Air Fla., Inc.*, 750 F.2d 1077, 1084-85 (D.C. Cir. 1984) ("Decisions in this Circuit have consistently followed a practice of dismissing appeals brought on grounds not asserted in the trial court: 'This is not a mere technicality but is of substance in the administration of the business of the courts. Enormous confusion and interminable delay would result if counsel were permitted to appeal upon points not presented to the court below. Almost every case would in effect be tried twice under any such practice. While the rule may work hardship in individual

cases, it is necessary that its integrity be preserved.") (quoting *Johnston v. Reily*, 160 F.2d 249, 250 (D.C. Cir. 1947)).

In any event, the argument is frivolous. Unlike the "handbook for internal use by ... SSA employees" in *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981); the one-page handout with "no link [to] the Board's regulations" in *Chiron Corp. v. NTSB*, 198 F.3d 935, 943 (D.C. Cir. 1999); the optional guidance specifically disclaiming any intent to bind in *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545-46 (D.C. Cir. 1999); the FDA guide "intended to be used within the agency" in *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 594 (5th Cir. 1995); the guidance document outlining what the Department of Labor "may" do in exercising its enforcement authority in *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538 (D.C. Cir. 1986); and the guide "contain[ing] no mandatory language" in *Farrell v. Dep't of Interior*, 314 F.3d 584, 591-92 (Fed. Cir. 2002), the Orange Book is (1) a legally required publication, 21 U.S.C. § 355(b)(1), that (2) states it is a legally required publication, JA34, JA37; (3) is linked directly to FDA's regulations, 21 C.F.R. § 314.53(f); (4) is disseminated to the public and intended to be relied on by the public, *see* FDA Dist. Ct. Br. at 2; and (5) specifically directs the public as to what they "must" do. JA34; JA37.

The bottom line here is that Teva did precisely what FDA told it do, and the government cannot now maintain that Teva did not do what it was supposed to do when it did exactly what FDA ordered it to do.

B. FDA's Regulatory Directives Are Consistent With The Statute.

Faced with all of this, FDA mounts a back-door challenge to the validity of its longstanding regulations and 2001 Orange Book directives. It now asserts—again for the first time—that those regulations cannot "restrict FDA to considering only patent information appearing in the paper Orange Book when making exclusivity determinations, particularly when the relevant statute and regulations are unequivocal that it is the actual status of the patent that controls, not FDA's paper description." FDA Br. 28-29. Needless to say, however, this is not the forum for FDA to reconsider its regulatory directives. If the Agency does not like those rules, it is free to engage in a new rulemaking proceeding or, as it did in 2005, to exercise its discretion under the existing regulatory framework to change how it lists patents in the Orange Book and directs applicants to use those listings.

Nonetheless, it bears note that FDA's 2001 directives are not only perfectly consistent with Hatch-Waxman's text and structure, but virtually compelled by it. As FDA observes, the statute's patent-submission and patent-certification requirements are contained in parallel subsections of the statute. On one hand, NDA applicants must "file with the [NDA] the patent number and the expiration

date of any patent which claims the [proposed brand-name] drug." 21 U.S.C. § 355(b)(1). And on the other, applicants for a proposed generic drug must submit "a certification ... with respect to each patent which claims the [approved brand-name] drug." 21 U.S.C. § 355(j)(2)(A)(vii). FDA thus asserts that it is irrelevant whether the '952 patent appeared in *any* version of the Orange Book when Teva submitted its ANDA: "Whether a patent 'claims' the drug determines whether FDA publishes the information on a list of patent information—not the other way around.... The continuing inclusion of a patent on FDA's list after the innovator has withdrawn a patent does not mean that the patent still claims the drug and therefore that FDA is compelled to require (or permit) ANDA applicants to certify to the patent." Stay Mot. at 10.

That argument, however, simply ignores—and in the process, fundamentally undermines—the key feature of the statutory scheme's patent-submission and patent-certification provisions. Hatch-Waxman does not merely require NDA holders to submit information about patents that "claim" a drug, and ANDA applicants to certify to patents that "claim" a drug. It expressly requires FDA to "*publish* information submitted under the [patent-submission requirement]." 21 U.S.C. § 355(b)(1) (emphasis added). Indeed, four more statutory sections require FDA to publish the drug and patent information it receives from brand manufacturers and to update that publication every thirty days, as new drugs are

approved and new patent information is submitted with respect to previously approved drugs. *See id.* § 355(c)(2) ("Upon the submission of patent information under this subsection, the Secretary shall publish it."); *id.* § 355(j)(7)(A)(i), (ii), (iii) ("[T]he Secretary shall publish and make available to the public a list ... of each drug which has been approved.... Every thirty days after the publication of the first list ..., the Secretary shall revise the list.... When patent information submitted under [21 U.S.C. § 355(b) or (c)] respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made [every thirty days], include such information for such drug.") (internal enumeration omitted).

As FDA acknowledged below, the whole point of those requirements is to ensure that applicants are clearly informed of the patent barriers they face—and for which certifications will be required—before they invest vast sums to develop a non-infringing generic drug and prepare to defend their efforts in court. *See* FDA Dist. Ct. Br. at 2 ("FDA is required to publish [patent] information so that ... generic drug manufacturers can decide whether their products might infringe [listed] patents."). Indeed, the statutory scheme could not function if FDA did not provide official notice to potential generic applicants of the patents that a brand manufacturer has submitted to FDA in connection with a given drug product. On one hand, were patents not listed at all, generic applicants would have no idea

which patents they need to design around and challenge with Paragraph IV certifications before they can go to market. And on the other, if patents could be delisted without official notice, applicants might spend tens of millions of dollars designing around a listed patent that does not actually block market entry at all. In the worst-case scenario, an applicant might refrain altogether from applying to market a generic drug before patent expiry, based on the erroneous belief that the submission of Paragraph IV certification to an apparently listed patent—whose delisting never has been publicized—would subject them to costly patent litigation.

Read as a whole—with an eye to its structure and context, *see Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997); *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)—the parallelism in the statute's patent-submission, patent-certification, *and patent-publication* requirements thus permits only one interpretation: that generic applicants must submit a certification for each officially listed patent, which (of course) is exactly what FDA's regulations provide. 21 C.F.R. § 314.53(f) (directing that applicants must submit "an appropriate certification for each *listed patent*," even if they disagree about "the correctness of the patent information ... *published by FDA in the list.*") (emphasis added). In short, the statute requires brand manufacturers to submit certain patents to the Agency; the statute requires generic applicants to certify to those same patents; and it requires FDA to publish and maintain a

current, publicly available list of each of those patents precisely so that applicants know which patents require a certification under the statute.

But FDA's counter-interpretation does more than undermine the statute's structure. It would produce demonstrably absurd results. On FDA's view, "it is the actual status of the patent that controls, not FDA's paper description," FDA Br. at 29, so that in the absence of a "patent that claims the [brand-name] drug, or claims a use for the [brand-name] drug, there can be no valid certification," *id.* at 23. By definition, however, every Paragraph IV certification manifests the applicant's belief that the listed patent is "invalid, not infringed, or unenforceable"—that is, that the patent does not actually "claim" the listed drug within the meaning of that patent-law term. And if the brand manufacturer responds to such a certification by seeking to delist its patent, and its request that FDA do so really is enough to demonstrate that "the actual status of the patent" is that it does not "claim the [brand-name] drug," FDA Br. at 23, 29, then no Paragraph IV challenger would ever be entitled to exclusivity because "there can be no valid [Paragraph IV] certification [where] there is no patent that claims the listed drug ... and without a valid paragraph IV certification, [the applicant] cannot claim exclusivity." FDA Br. at 23.

That, in fact, was FDA's position just a few years ago, when it held that Teva was not entitled to 180-day exclusivity for generic simvastatin precisely

because the brand manufacturer had asked FDA to delist several patents from the Orange Book's patent listings for Zocor®. *See Ranbaxy*, 469 F.3d at 120. This Court, however, reversed that decision on the ground that FDA's approach fundamentally would have undermined the statute's structure by removing the incentive to challenge listed patents. *Id.* at 125-26. That is exactly what the Agency's decision in this case will do if this Court reinstates it. As *Ranbaxy* recognized, allowing FDA to divest first-filers of their statutory reward after they invest substantial resources in the development of a generic alternative and subject themselves to potential liability by filing a Paragraph IV certification diminishes the incentive to make such challenges in the future. *See Ranbaxy*, 469 F.3d at 126.

FDA tries to get around *Ranbaxy* in this case by asserting that Teva never really faced litigation risks here, because Janssen sought to delist the '952 patent a few weeks *before* Teva submitted its ANDA and thus could not have sued Teva for infringement. *See* FDA Br. at 9-10; JA78-79. But FDA's perspective is entirely backwards. With the benefit of 20/20 hindsight, it is easy to say that Teva never faced a risk of litigation from its certification in this case. But the key point here is that FDA's official patent-listing publications failed to put Teva on notice of that fact *before* Teva had to choose whether or not it would assume the always-uncertain risk of a suit.

Accepting FDA's argument that generic applicants cannot rely on FDA's official patent-listing publications—and, indeed, cannot even trust FDA's express directives that they consult those publications—thus would undercut the statute by reducing the likelihood that a first-filer eventually will receive exclusivity, *as perceived by the applicant at the time it must decide whether to go through with filing a Paragraph IV certification.* With the prospect of receiving exclusivity less certain, applicants will challenge fewer patents (or delay patent challenges until it becomes clear which patents must be challenged), decreasing the number of generic drugs, slowing the advent of market competition, and ensuring that drug prices remain high—in direct contravention of the statute's core purpose and the principal aim of its exclusivity incentive, which is to "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx*, 256 F.3d at 809 (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

At bottom, then, FDA's position in this case is as fundamentally inconsistent with the statute's structure and incentives as it is with the Agency's own regulations and express directives to applicants.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and D.C. Circuit Rule 32(a), I hereby certify that this brief is proportionately spaced, has a typeface of 14 points, and contains 10,413 words.

Michael D. Shumsky

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2008, I served two true and correct copies of the foregoing Brief of Appellee Teva Pharmaceuticals USA, Inc. by hand delivery and electronic mail on the following counsel:

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