Nos. 14-1522, 14-1529, 14-1593

United States Court of Appeals for the Fourth Circuit

MYLAN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., and LUPIN PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and TEVA PHARMACEUTICALS USA, INC.

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of West Virginia (Keeley, J.)
Case No. 1:14-cv-00075

RESPONSE BRIEF OF DEFENDANT-APPELLEE TEVA PHARMACEUTICALS USA, INC.

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CORPORATE DISCLOSURE STATEMENT

Teva Pharmaceuticals USA, Inc. is directly owned by (i) Orvet UK Unlimited (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Limited; and (ii) Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Limited is the only publicly-traded direct or indirect parent company of Teva Pharmaceuticals USA, Inc., and no other publicly-traded company owns more than 10% of Teva Pharmaceuticals USA, Inc.'s stock.

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INTRODUCTION

Each plaintiff claims that Hatch-Waxman's "plain language" resolves this case, but even they cannot agree about what the statute's "plain language" means in light of the historically unprecedented circumstances giving rise to this case. As a result, the five parties to this appeal now offer three different answers to the single question presented: Who gets 180-day generic marketing exclusivity where the original exclusivity-grounding patent is partially invalidated after the first applicant's Paragraph IV challenge, but that patent is reissued in substantially identical form before any generic application is eligible for approval and the first applicant timely maintains its Paragraph IV challenge?

Plaintiffs Mylan and Watson assert that an original patent and its reissued version are distinct from each other for purposes of FDA's "patent-by-patent" approach to 180-day exclusivity and thus necessarily give rise to distinct exclusivity rights—even though the "patent-by-patent" approach is itself a discretionary response to long-recognized statutory ambiguity. From that faulty premise, Mylan and Watson contend they should "share exclusivity" with Teva for generic celecoxib

products because a court decision allegedly triggered Teva's original exclusivity period by partially invalidating the original patent Teva challenged, and the three companies in turn share first-to-file status regarding the reissued version of the original patent's partially invalidated claims.

Plaintiff Lupin expressly disagrees: It recognizes that the statute is ambiguous and argues that FDA reasonably concluded that original patents and their reissued versions should not give rise to distinct exclusivity rights under the Agency's discretionary "patent-by-patent" approach because such patents are inextricably linked. Despite conceding that the original patent's claims survived the Federal Circuit's decision, however, Lupin simultaneously argues that the appellate court's decision triggered and exhausted Teva's exclusivity. Finally, interpreting the statute's ambiguities and addressing the novel circumstances giving rise to this case, FDA takes a third position: that in these circumstances, the party which first challenged both the original patent and its reissued version deserves 180-day exclusivity—and here, that party was Teva. Teva agrees.

As the plaintiffs' internal disagreement with each other illustrates in spades, the statute does not remotely mandate that only one of these three interpretations is permissible and the other two forbidden. To the contrary, the statute does not mention reissue patents expressly, does not specify their effect on 180-day exclusivity, and does not address what happens to 180-day exclusivity where a partially invalidated patent is reissued by the Patent and Trademark Office ("PTO"). And as the courts long have recognized, the very "patent-by-patent" approach to 180-day exclusivity against which these issues now arise is itself the product of statutory gap-filling by the expert agency charged with administering this remarkably complex statute. This case thus arises in *Chevron*'s heartland, where the courts repeatedly have deferred to FDA's discretionary policy choices.

The district court properly recognized that the result should be no different here. Facing statutory silence and confronted with a factual scenario that is unprecedented in Hatch-Waxman's thirty-year history, FDA resolved the question presented in a manner that is "consistent with both the objectives of the Hatch-Waxman Act and also with relevant principles of patent law," JA335, "comports with its decisions

in three prior situations involving exclusivity and a reissued patent," JA338, and "allows the agency to administer the Hatch-Waxman Act in a predictable manner." JA339. The district court's judgment should be affirmed, and FDA's letter decision upheld.

JURISDICTIONAL STATEMENT

Teva does not contest plaintiffs' jurisdictional statements.

STATEMENT OF THE ISSUE

Whether FDA reasonably concluded that the first applicant to challenge an original patent is alone entitled to 180-day generic marketing exclusivity where the original exclusivity-grounding patent is partially invalidated following the first applicant's Paragraph IV challenge, but that patent is reissued in substantially identical form before any applicant is eligible for approval and the first applicant timely maintains its Paragraph IV challenge?

STATEMENT OF THE CASE AND THE FACTS

A. Relevant Statutory and Regulatory Background

1. An Overview Of the Hatch-Waxman Act

As modified by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"), the Food, Drug and Cosmetic Act ("FDCA") governs the approval of prescription drugs in

the United States. *See* 21 U.S.C. § 355 (2002).[1] To obtain approval for a brand-name drug like Celebrex®, applicants must submit a New Drug Application ("NDA") that contains clinical data demonstrating the proposed drug's safety and efficacy. *See id.* § 355(b)(1). Applicants also must "file with the [NDA] the patent number and the expiration date of any patent which claims the drug … or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if [another person] engaged in the manufacture, use, or sale of the drug." *Id.* Because NDA holders often obtain new patents after FDA first approves a brand-name drug, NDA holders must update the patent information for their approved products. *Id.* § 355(c)(2).

Generic drugs contain the same active ingredients and provide the same therapeutic benefits as their brand-name counterparts. But before Hatch-Waxman, generic applicants generally had to submit a full NDA—including new clinical trial data—to obtain approval. That made

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[1] All parties agree that this case is controlled by the original version of Hatch-Waxman's exclusivity provisions (*i.e.*, those in force prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("MMA")). Unless noted, all citations thus are to the 2002 statute.

generic entry cost-prohibitive, and Congress enacted Hatch-Waxman to remove that barrier, increase the availability of generic drugs, and thereby reduce prescription drug costs. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998). The statute rests on a simple premise: Because two drugs with the same chemical and biological properties will be equally safe and effective, FDA can approve a generic drug without requiring new safety or efficacy trials whenever an Abbreviated New Drug Application ("ANDA") demonstrates that a proposed generic product has the same clinically active ingredient(s) and is bioequivalent to a previously approved drug. 21 U.S.C. § 355(j).

Two statutory requirements help balance the public interest in speedy generic market entry against the intellectual-property rights of NDA holders. First, Hatch-Waxman grants NDA holders an exclusivity period (called "data exclusivity") which generally bars submission of an ANDA for five years after FDA first approves the NDA (unless the applicant challenges one of the NDA holder's patents, in which case its ANDA may be submitted after four years). *Id.* § 355(j)(5)(D)(ii). This exclusivity period ensures that NDA holders can recoup their investments even if their products lack patent protection. Second,

Congress recognized the importance of the NDA holder's patent rights by requiring each ANDA to include "a certification … with respect to each patent which claims the listed drug … or which claims a use for such listed drug." *Id.* § 355(j)(2)(A)(vii). To help applicants identify relevant patents, FDA publishes the patent data NDA holders are required to submit in a resource called "the Orange Book." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

ANDA applicants can make one of four different certifications to the listed patents, but the most important is a so-called "Paragraph IV certification" stating that a "patent identified as claiming the referenced NDA is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug." 21 U.S.C. § 355(j)(2)(A)(vii). Paragraph IV certifications are critical: By challenging the brand manufacturer's patent monopoly, they create a possibility that generic competition might begin before the brand manufacturer's patent protection otherwise would expire. *Teva Pharms. USA, Inc. v. Leavitt* [*Teva v. Leavitt*], 548 F.3d 103, 106 (D.C. Cir. 2008).

But filing such certifications is risky. It is both challenging and expensive to identify weaknesses in a competition-blocking patent and

develop a non-infringing-yet-interchangeable formulation or legal defense to the patent. And where those efforts succeed, the statute virtually insists on litigation: The very submission of a Paragraph IV certification is an "artificial" act of infringement that can generate costly litigation long before the Paragraph IV applicant could begin selling its product. 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). To speed the resolution of such patent disputes, the statute requires Paragraph IV challengers to notify the NDA holder of their challenge. 21 U.S.C. § 355(j)(2)(B)(i)-(ii) (current). Where the NDA holder promptly sues after receiving such notice, FDA generally cannot approve the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). This delay is known as the "30-month stay."

To encourage generic applicants to take those risks, Hatch-Waxman rewards the first Paragraph IV challenger with a 180-day exclusivity period during which no other generic version of the referenced drug may be approved. *Id.* § 355(j)(5)(B)(iv) (barring approval of any ANDA that "contains a [Paragraph IV] certification … and is for a drug for which a previous application has been submitted [with] such a certification"). This exclusivity period is "valuable,

designed to compensate manufacturers for research and development costs as well as the risk of litigation." *Teva v. Leavitt*, 548 F.3d at 104. Indeed, 180-day exclusivity can be worth hundreds of millions of dollars in cases like this one, where Celebrex®'s annual U.S. sales exceed $2.2 billion. And exclusivity is of course "a pro-consumer device" that "Congress has chosen to induce challenges to patents." *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

Under the applicable version of Hatch-Waxman, *supra* n.1, the first applicant's exclusivity period begins to run on (a) the date the first applicant first sells its generic product (the "commercial marketing trigger"), or (b) the date of a final appellate-court decision that conclusively rejects the challenged patents ("the court decision trigger"). *Id.* § 355(j)(5)(B)(iv). The idea behind these triggers is that first applicants should launch their products once the cloud created by a listed patent's claims has been removed; where sale of the product no longer would risk the imposition of damages for infringing the patent's claims, applicants must "use or lose" their exclusivity reward.

2. FDA's "Patent-By-Patent" Approach To 180-Day Exclusivity

Though the *concept* of awarding exclusivity to the first generic patent challenger is relatively straightforward, its *application* is incredibly complex given the array of fact patterns that unfold in real life. As often is the case, Congress did not attempt to specify how exclusivity should be applied to every conceivable circumstance that might arise (nor could it have done so). Instead, Congress delegated that task to FDA as the expert agency charged with administering Hatch-Waxman, and FDA repeatedly has grappled with how to apply the statute to the myriad factual scenarios it has encountered. This case is the latest in a long line of complex exclusivity disputes, and it arises at the very bottom of the rabbit hole—in an area where courts repeatedly have deferred to FDA's expertise, and where the parties' dispute centers on how to apply prior agency decisions which *themselves* were affirmed as permissible exercises of the Agency's discretion.

Like this case, the antecedent precedents address exclusivity where there are multiple generic applicants and/or multiple listed patents. FDA first grappled with these issues in cases where *multiple applicants* submitted ANDAs containing Paragraph IV certifications *to*

the same listed patent on *the same day*. The pre-MMA statute is ambiguous on the question of whether the applicant whose ANDA randomly happens to be opened first in FDA's mailroom is truly a "previous applicant" to a competitor whose ANDA randomly happens to be opened minutes later (the "minute-by-minute" approach), or whether both applicants should be deemed first filers since both companies' ANDAs were filed the same day (the "same day" approach). Indeed, lingering uncertainty about that issue prompted overnight camping—and, reportedly, occasional brawls—in FDA's parking lots, as applicants jockeyed to be first in line on the day the brand manufacturer's data exclusivity expired and ANDAs containing Paragraph IV certifications could be filed. FDA ultimately resolved that ambiguity by adopting the "same day" approach, deeming both companies first applicants entitled to "share" 180-day exclusivity before other ANDAs could be approved. FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day* (July 2003) at 5 (http://tinyurl.com/2003-FDA-Guidance) (last visited August 1, 2014).

At the same time FDA was addressing that issue, disputes began to arise over exclusivity in cases where *different applicants* were first to challenge *different listed patents* for the same drug on *different days*:

	Day 1	**Day 2**	**Day 3**	**Day 4**
A	P4 to Patent 1			P4 to Patent 2
B		P4 to Patent 1	P4 to Patent 2	

In this example, applicant A was first to challenge Patent 1 on Day 1, and applicant B was first to challenge Patent 2 on Day 3—with each applicant thus being *a first filer* on one listed patent but *a later filer* on the other. To reiterate, this can happen because NDA holders must update the Orange Book to disclose newly issued patents, and ANDA applicants then must update their certifications. A *later filer* to the *first listed patent* (here, applicant B) thus can become the *first filer* on a *later-listed patent*, and the *first filer* to the *first listed patent* (here, applicant A) can become a *later filer* to the *later-listed patent*.

Not surprisingly, the applicants in such cases advocated different positions on exclusivity: The original first filer (applicant A) asserted that it *alone* was entitled to 180-day exclusivity because it challenged *one of the listed patents* before another applicant challenged *any* listed patent (the "one first applicant" approach), while the subsequent first

filer (applicant B) *also* claimed exclusivity because it was first to challenge *a particular patent* (the "patent-by-patent" approach). FDA eventually adopted the "patent-by-patent" approach, under which each patent grounds its own exclusivity period and pursuant to which both applicants are deemed "first applicants" with distinct exclusivities.

Advocates of the "one first applicant" approach vigorously challenged FDA's decision, and the first court that faced this issue agreed with them: It invalidated FDA's patent-by-patent approach as "contrary to [Hatch-Waxman's] plain language." *Torpharm, Inc. v. FDA*, No. 03-2401, 2004 WL 64064, at *1 (D.D.C. Jan. 8, 2004). But two other courts quickly disagreed, finding the statute ambiguous and upholding FDA's patent-by-patent approach under *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Ivax Pharms., Inc. v. FDA*, No. 04-1603, 2004 WL 6068164, at *1 (D.D.C. Sept. 17, 2004) ("FDA acted reasonably in adopting a patent-based approach."); *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 74 (D.D.C. 2006) (holding the statute ambiguous and the patent-by-patent approach to be a permissible interpretation). The D.C. Circuit resolved that split by adopting the majority view, holding that FDA's discretionary adoption

of the "patent-by-patent" approach warranted judicial deference. *Apotex, Inc. v. FDA*, 226 Fed. App'x 4, 5 (D.C. Cir. 2007).

In practice, however, the patent-by-patent approach could unleash its own problems: If two applicants have distinct claims to distinct exclusivity periods based on Paragraph IV certifications to different patents, then a literal application of the patent-by-patent approach would result in "mutually blocking exclusivities" that preclude FDA from approving either ANDA. In the example above, applicant A's exclusivity for challenging Patent 1 would bar approval of applicant B's ANDA (which was a later filer on that patent), while applicant B's exclusivity for challenging Patent 2 would bar approval of applicant A's ANDA (which was a later filer on *that* patent). To avoid the potential absurdity of such an "exclusivity standoff," FDA held that the applicants should share exclusivity, just as if both applicants challenged the same patent the same day. *See, e.g.*, Mylan/Watson Br. at 9.

Even then, however, FDA long ago made clear that shared exclusivity under the patent-by-patent approach is not absolute. To the contrary, it is an "exception to the patent-based approach in order to avoid the incongruous result of an exclusivity stand-off" and so does *not*

apply outside the narrow context of mutually-blocking exclusivities. *Apotex*, 414 F. Supp. 2d at 73. FDA thus has refused to extend shared exclusivity to cases where only one applicant first challenges *each* listed patent (even if others share first-to-file status as to *one* of the patents):

	Day 1	**Day 2**	**Day 3**
A	P4 to Patent 1		P4 to Patent 2
B		P4 to Patent 1	P4 to Patent 2

In such cases—where applicant A is first on Patents 1 and 2, and applicant B is second on Patent 1 and shares first position on Patent 2—there is no exclusivity standoff because the first applicant's approval is not blocked by any other applicant. As a result, FDA consistently has *rejected* the shared-exclusivity solution. *See* D. Ct. Dkt. No. 71-5, Ltr. from K. Webber to M. Goshko, ANDA No. 076596 (Apr. 4, 2012), at 6 ("The Agency has not extended shared exclusivity to a situation … where one applicant … was the only applicant to be among the first to file paragraph IV certifications to both listed patents [because t]here are no 'mutually blocking' 180-day exclusivities.").

It is against this background—of cascading statutory ambiguities that prompted the discretionary adoption of a patent-by-patent approach which sometimes yields shared exclusivity and sometimes

does not, based again on discretionary decisionmaking—that plaintiffs now assert that FDA violated the plain language of the statute.

3. Hatch-Waxman Does Not Specifically Address Exclusivity for Reissued Patents

As set forth in greater detail below, this case presents the unique situation in which a subsequently listed patent is merely a reissued version of a previously listed patent that had been partially invalidated, and where only one applicant (Teva) was first to file Paragraph IV certifications on both the original patent and its successor version.

	Day 1	**Day 2**	**Day 3**	**Day 4**
Teva	P4 to Original Patent ("OP")		P4 to Reissued Version of OP ("RP")	
Mylan		P4 to OP	P4 to RP	
Watson		P4 to OP	P4 to RP	
Lupin		P4 to OP		P4 to RP

In these unusual circumstances, the award of 180-day exclusivity under FDA's discretionary patent-by-patent approach necessarily is informed by the relationship between an original patent and its subsequently reissued version.

Governed by 35 U.S.C. §§ 251 and 252, reissue patents are unusual creatures of patent law that allow patentees to resuscitate

their patent protection "[w]henever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." 35 U.S.C. § 251(a). By law, the original patent must be "surrender[ed]" before the Patent and Trademark Office ("PTO") can reissue a new version. *Id.* Even so, reissue patents are closely tethered to their predecessors. The reissued patent's claims must be "for the invention disclosed in the original patent" and "[n]o new matter shall be introduced into the application for reissue." *Id.* As a result, it confers protection only "for the unexpired part of the term of the original patent" and is not awarded a new patent term of its own. *Id.*

The patent laws further link original patents and their reissued versions by providing for so-called "claim continuity" where claims in the original patent and its reissued version are "substantially identical." *Id.* § 252. Under this doctrine, *reissue patentees* may recover damages for any infringement that occurred beginning *the date the original patent issued*—even if the original patent was invalidated in the interim—whenever claims in the reissued version mirror those in the

original. *Id.* (authorizing recovery for pre-reissuance infringement "in so far as the claims of the original and reissued patents are substantially identical" and directing that "the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent").

While the patent laws thus specifically address "original patents" and "reissued patents," the Hatch-Waxman Act does not expressly address reissue patents or specify the consequences the patent reissuance has on the approvability of pending ANDAs or the exclusivity available to ANDA applicants in cases involving reissuance of a previously challenged patent. Instead, just as Congress left it to FDA to decide whether to adopt a "one first applicant" or "patent-by-patent" approach to generic exclusivity in the first instance, Congress did not resolve the question of whether an original patent and its subsequently reissued version should support separate, independent periods of exclusivity under FDA's discretionary patent-by-patent approach, much less how to administer the statute's exclusivity

provisions where only one applicant was first to challenge both the original patent and its relisted version.

B. Celebrex® and Generic Celecoxib ANDAs

Celebrex® (celecoxib capsules) is a nonsteroidal anti-inflammatory drug marketed by Pfizer Inc. ("Pfizer") under NDA No. 020998 in 50mg, 100mg, 200mg, and 400mg strengths, the latter three of which are at issue here. JA26-27 (Mylan Compl. ¶¶ 29-30). As relevant here, Pfizer originally listed three Celebrex®-related patents in the Orange Book: U.S. Patent No. 5,466,823 ("the '823 patent"), which expired on Nov. 30, 2013; U.S. Patent No. 5,563,165 ("the '165 patent"), which expired on Nov. 30, 2013; and U.S. Patent No. 5,760,068 ("the '068 patent"), which was set to expire on June 2, 2015. JA27 (Mylan Compl. ¶ 31). Pfizer later studied Celebrex®'s safety and efficacy in younger patients, and so earned a six-month period of "pediatric exclusivit[y]" that bars ANDA approvals for six months after each listed patent's expiration. *Id*.

On November 13, 2003, Teva submitted ANDA No. 76-898 referencing Celebrex®. That ANDA not only was the first one filed for generic celecoxib; it also contained the first-filed Paragraph IV certifications to the '823 and '165 patents and claims 1-17 of the '068

patent. JA27 (Mylan Compl. ¶ 32).[2] It is undisputed that Teva therefore became eligible for 180-day exclusivity. Pfizer sued Teva for infringement, and the district court eventually held that all three patents were valid and would be infringed by Teva's product. JA27-28 (Mylan Compl. ¶ 33). Teva appealed, and the Federal Circuit partially affirmed and partially reversed—agreeing with the district court that the '823 and '165 patents were valid and would be infringed, but also holding that "claims 1-4 and 11-17" (but not claims 5-10) of the '068 patent were invalid as originally written. *Id.*

That decision of course left claims 5-10 of the '068 patent intact. And it did not spell the end of the patent's other claims in any event: After the Federal Circuit decision, Pfizer promptly initiated the PTO's reissue process and sought to correct the deficiencies that led to the '068 patent's partial invalidation. On March 5, 2013, PTO decided those claims should be reissued: It granted Pfizer's application, and assigned the '068 patent a reissue number signaling the reissued status of its claims: RE44048 ("the '048 patent"). JA29 (Mylan Compl. ¶ 39).

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[2] Teva's ANDA also included a so-called "section viii statement" to claim 18 of the '068 patent, indicating that Teva was not seeking approval for the method of use covered by that claim and thus that it did not bar approval of Teva's product. *See* 21 U.S.C. § 355(j)(2)(A)(viii).

As a reissued version of the '068 patent, the '048 patent necessarily is tethered to its predecessor for the reasons set forth earlier. *See supra* at 16-18. And that's precisely what Pfizer told FDA: On the day PTO reissued the patent, Pfizer not only asked FDA to list the reissue number in the Orange Book but specifically informed FDA that the reissued version was a continuation of the '068 patent:

> Enclosed is an original and one copy of patent information for CELEBREX. The enclosed Form 3542 is for the reissue of Pat. No. 5,760,068 that is currently listed in the Orange Book for CELEBREX. ***The reissue patent, RE44048, represents the continued existence of the '068 patent.***

D. Ct. Dkt. No. 71-1, at 1 ("Pfizer Listing Letter") (emphasis added).

FDA apparently processed Pfizer's listing request on March 7, 2013, JA41 n.1 (FDA letter decision), and Teva (allegedly along with Mylan and Watson) both updated its Paragraph IV certification to cover the '068 patent's new number and notified Pfizer of its certification that day. *Id.*; *see also* JA30 (Mylan Compl. ¶ 44); JA129 (Watson Compl. ¶ 45). Lupin, however, failed to update its certification until March 28, 2013. JA107 (Lupin Compl. ¶42).

After reviving the '068 patent, Pfizer sued Teva, Mylan, Watson, and several other ANDA applicants. JA29-30 (Mylan Compl. ¶ 42).

The district court eventually held that the '048 patent was invalid. JA29-30 (Mylan Compl. ¶ 42). Pfizer and Teva then settled their litigation, allowing Teva to enter the market in December 2014—one year before the pediatric exclusivity period attached to the reissued version of the '068 patent would expire if Pfizer prevails in its appeal of the district court's ruling. JA28 (Mylan Compl. ¶ 37). Watson and Mylan likewise settled with Pfizer, JA300, while Lupin continues to battle Pfizer at the Federal Circuit.

C. FDA's Letter Decision

On April 24, 2014, FDA issued a letter decision announcing how it intended to apply its discretionary patent-by-patent approach to 180-day exclusivity where only one applicant is first to challenge both an original patent and its reissued version. JA41-51. After summarizing Hatch-Waxman's 180-day exclusivity provisions and discussing the nature of reissue patents, JA43-44, FDA observed that "[n]either the FD&C Act nor FDA's regulations directly address the effect of patent reissuance on the approval of a pending ANDA," much less how to apply the statute in the unique circumstances giving rise to this case. JA45.

In filling the resulting gap, FDA explained that it typically "does not consider a reissued patent to be a new and distinct patent for purposes of 180-day exclusivity," but instead "has generally treated the original and reissued patent as a single 'bundle' of patent rights." *Id.*; *id.* at 46-48 (discussing agency precedents). That is so, FDA explained, because reissue patents are both substantively and procedurally tied to their predecessors. Among other things:

- "A reissued patent references the original patent on its face and has the same expiration date as the original patent because the patent is reissued for the unexpired part of the term of the original patent." JA44 (citing 35 U.S.C. § 251(a)).
- The patent laws include a "requirement that 'no new matter shall be introduced into the application for reissue.'" JA46 (quoting 35 U.S.C. § 251(a)).
- The patent laws also provide that "'the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent,'" JA44 (quoting 35 U.S.C. § 252), which means *both* that a party can be held liable for infringing a reissued patent's claims even if they acted before the reissuance, *id.*, *and* that "a pending cause of action based on the original patent [can] continue after reissuance to the extent that claims of the original and reissued patent are substantially identical." JA46 (citing 35 U.S.C. § 252).

Given those principles, FDA noted that it long ago had held that "any applicant eligible for 180-day exclusivity based on a paragraph IV certification to the original patent remains eligible for that exclusivity

after patent reissuance." JA45. This approach "consistently and predictably implement[s] the [FDCA] and reflect[s] the nature of reissued patents while preserving FDA's ministerial role in patent listings." JA45-46. And given the procedural and substantive linkages between original patents and their reissued versions, FDA likewise concluded that "when a paragraph IV certification has been made to an original patent, subsequent paragraph IV certifications to a reissued patent that references the original patent should not be the basis for separate periods of 180-day exclusivity" under its discretionary patent-by-patent approach. JA49 (citing 35 U.S.C. §§ 251(a), 252).

That left a final wrinkle: Because reissuance almost always takes place *after* a court partially or completely invalidates the original patent, how should the foregoing principles be applied following such a decision? As FDA observed, a judicial decision that decisively invalidates a previously challenged patent typically triggers the first applicant's exclusivity for having challenged that patent. *Id.* But as FDA then noted, the nature of reissue patents raises questions about whether "the patent which is the subject of the certification [was in fact] invalid or not infringed." JA50. That is so because reissue patents

often reflect *the continued existence* of the original patent's claims despite the intervening judicial decision. Again, those claims remain "in effect in its reissued form" (precisely as Pfizer informed FDA here); are "considered presumptively valid" despite the prior court decision; and indeed have retroactive effect dating back to the original patent's issuance despite the intervening judicial decision (as FDA again had explained). JA50 (citing 35 U.S.C. § 252). Given "the relation between the original and reissued patent," FDA thus concluded:

> [U]pon the listing of a reissued patent, a prior court decision on the invalidity or non-infringement of the original patent should not be considered an event triggering exclusivity. *The contrary view would introduce an incongruity into the statutory framework. This view would consider the court decision on the original patent to be sufficient to trigger (and exhaust) 180-day exclusivity, while at the same time considering the patent at issue in that case to be in effect in its reissued form.* Our interpretation of the ambiguous court-decision-trigger provision to find that there has been no triggering event in this situation avoids this conflict …, furthers the objectives of the Hatch-Waxman Amendments, and provides a predictable framework that is consistent with our ministerial role in patent listing.

JA50 (emphasis added).

Finally, FDA noted that it was "*not* making a determination with respect to 180-day exclusivity in a particular case, because we will not make such a determination until such time as an applicant or

subsequent applicant is ready for approval. Rather, this letter clarifies the regulatory framework to be applied to the relevant ANDAs when such exclusivity determination is made." JA46; *see also* JA337 ("The FDA made no decision regarding any particular applicants.").

D. Proceedings Before the District Court

Though FDA's letter decision expressly refrained from formally awarding or denying 180-day exclusivity for ANDAs referencing Celebrex®, its import for this case was clear: Because Teva alone was first to challenge the '068 patent and promptly renewed its Paragraph IV certification when PTO reissued that patent, application of the general principles announced in FDA's letter decision would ensure that only Teva's generic Celebrex® ANDA could enjoy 180-day exclusivity.

On April 25, 2014, Mylan therefore sued FDA under the APA and the FDCA, asserting that the interpretive principles announced in FDA's letter decision violated Hatch-Waxman's plain language. JA320-21. Three days later, Mylan sought entry of a mandatory preliminary injunction that not only would vacate the letter decision, but would compel FDA to approve Mylan's ANDA immediately and grant the company shared exclusivity alongside Teva. JA321.

On May 1, Watson moved to intervene as a plaintiff, D. Ct. Dkt. Nos. 25-26 (motion and brief), asserting (like Mylan) that it too was entitled to share exclusivity with Teva. Lupin moved to intervene the next day, D. Ct. Dkt. Nos. 31-32 (motion and brief), but took a fundamentally different position: Though it agreed with Mylan and Watson that Teva is not entitled to sole marketing exclusivity, it rejected their claim that Teva, Mylan, and Watson should share exclusivity—asserting that FDA reasonably interpreted this statutory ambiguity to provide that a reissue patent should not give rise to an exclusivity period separate from the one based on challenges to its predecessor. D. Ct. Dkt. No. 32, at 7 ("Mylan is advocating for one position, the FDA is advocating for a second position, and Lupin asserts a third and different position."). On May 5, 2014, Teva moved to intervene as a party-defendant, D. Ct. Dkt. Nos. 34-35 (motion and brief), arguing that FDA's Letter Decision represented a permissible resolution of statutory ambiguity.[3]

[3] The district court later granted each party's motion to intervene. *See* D. Ct. Dkt. Nos. 41 (granting Watson's motion); 42 (granting Lupin's motion); 68 (granting Teva's motion).

On May 8, FDA and Teva opposed the motions for preliminary injunctive relief, and the court heard several hours of argument on May 15. JA141-250. On May 29, the district court issued an opinion and order denying the motions. JA251-283. It first recognized that *Chevron* governed its review of FDA's decision and then held that an "ambiguity exists here with respect to [Hatch-Waxman's] treatment of exclusivity periods for reissued patents." JA270. As the court explained, "[r]eissued patents … are unique patent entities in patent law," JA272, which "sometimes … are contiguous [with their predecessors] and sometimes not." JA273. But "the Hatch-Waxman Act is silent [regarding] how reissued patents affect generic exclusivity rights." JA272-73. As such, "Congress left it for the FDA to decide how reissued patents affect generic exclusivity rights." JA273.

Turning to *Chevron* step two, the district court held that "FDA's treatment of reissued patents for exclusivity purposes is consistent with the statutory treatment of reissued patents generally," JA275 (citing 35 U.S.C. § 252), and carefully explained that "FDA provided a well-reasoned explanation for its decision." *Id.* at 276-77 (citing FDA Letter Decision at 5-6, 9-11). The Court accordingly determined that plaintiffs

had no likelihood of success on the merits, and went on to hold that plaintiffs likewise failed to satisfy the remaining preliminary injunction factors—citing their failure to show irreparable harm, that the balance of hardships weighed in their favor, or that the public interest favored injunctive relief. JA278-83. It therefore denied the pending motions.

E. Post-Decision Proceedings

As noted previously, FDA's letter decision did not actually award or deny exclusivity in a particular case; consistent with its longstanding "practice to make decisions on eligibility for 180-day exclusivity in the context of specific ANDAs that are otherwise eligible for approval," the Agency's letter decision instead established a general framework for addressing these issues. JA46. The time for formally assessing 180-day exclusivity for celecoxib ANDAs arrived on May 30—the day after the district court's decision, when the pediatric exclusivity periods attached to the '823 and '165 patents expired—and that day, FDA formally awarded Teva's celecoxib ANDA sole marketing exclusivity.

Even so, neither Mylan, Watson, nor Lupin has ever challenged the FDA's actual award of 180-day exclusivity to Teva: None sought to amend their complaints, nor did any of them move to enjoin FDA's

decision awarding Teva exclusivity. Instead, Mylan noticed its appeal from the denial of its preliminary injunction regarding FDA's letter decision on May 30, JA284, and Lupin followed suit days later. JA287.

While this Court was processing those preliminary-injunction appeals, Mylan took the unusual step of moving the trial court to enter final judgment *against itself and in favor of FDA and Teva*. The district court granted that motion and on June 16, 2014 issued a companion opinion, order, and judgment. JA320-41. Mylan then noticed an appeal challenging the very final judgment it had asked the court to enter, JA347; Watson (which had not previously appealed the district court's preliminary-injunction decision) noticed an appeal citing both the preliminary-injunction decision and the final judgment to which it had consented, JA342-43; and Lupin filed a new notice of appeal citing the district court's final judgment on July 2, D. Ct. Dkt. No. 134. All appeals now have been consolidated.

SUMMARY OF ARGUMENT

This case presents a single question: Who, if anyone, is entitled to 180-day exclusivity where the original exclusivity-grounding patent is partially invalidated after the first applicant's Paragraph IV challenge,

but that patent is reissued in substantially identical form and the first applicant timely renews its Paragraph IV challenge before any ANDA is eligible for approval? As both FDA and the district court correctly held, Hatch-Waxman's plain language does not remotely dictate a single permissible answer to that single question, and plaintiffs' attempt to divide-and-conquer the Agency's letter decision by splitting the relevant inquiry into "separate and distinct questions" is both inconsistent with FDA's longstanding approach to resolving exclusivity matters and flawed even on its own terms—since the very same principles resolve both of the questions plaintiffs say are at issue here. Given the statute's silence on the actual question FDA confronted and the Agency's reasonable resolution of the interpretive issue implicated by these unique facts, the district court properly upheld FDA's letter decision at *Chevron* step two.

The fact that FDA reasonably interpreted the statutory scheme is sharply underscored by the facts of this case. Though FDA's letter decision addressed general principles, its decision—and, of course, its eventual award of exclusivity to Teva's celecoxib ANDA—faithfully reflects Pfizer's express representation that its reissue patent

"represents the continued existence of the [original] patent." Given plaintiffs' repeated assertions that FDA is obligated to follow a "ministerial role" in addressing patent-related issues that arise under Hatch-Waxman, plaintiffs cannot credibly fault FDA for following the innovator's lead in concluding that original patent's claims survived the Federal Circuit's 2008 decision and thus that Teva alone (as the sole first filer to that patent's claims) is entitled to exclusivity.

Finally, plaintiff-intervenor Lupin's arguments only confirm the reasonableness of FDA's decisionmaking. As Lupin properly observes, Hatch-Waxman itself "is silent on the effect of reissued patents on 180-day exclusivity," Lupin Br. at 1, and both FDA and the district court reasonably concluded that the original patent and its subsequently reissued version were co-extensive for purposes of administering the Agency's discretionary patent-by-patent approach to 180-day exclusivity. Given that explicit concession, however, Lupin's assertion that the original patent's claims were decisively invalidated and Teva's 180-day exclusivity period therefore triggered is internally inconsistent: Either the two patents are properly treated as co-extensive, in which case Teva's exclusivity was not triggered, or they are totally distinct, in

which case Teva, Mylan, and Watson should share exclusivity as co-first applicants to the distinct reissue patent. But Lupin's position "would consider the court decision on the original patent to be sufficient to trigger (and exhaust) 180-day exclusivity, while at the same time considering the patent at issue in that case to be in effect." JA50. Needless to say, agencies are supposed to avoid such logical contradictions—and that is precisely what FDA did here. The district court's decision upholding FDA's letter decision should be affirmed.

STANDARD OF REVIEW

This Court reviews a district court's legal rulings *de novo*. *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 167 (4th Cir. 2000) (citation omitted). But its review of an administrative agency's underlying decision is sharply circumscribed by the deferential standard set forth in the APA, which allows courts to invalidate only those agency decisions that are "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* (quoting 5 U.S.C. § 706(2)(A)). "In determining whether agency action violates … the APA, [appellate courts] perform 'only the limited, albeit important, task of reviewing agency action to determine whether the agency has conformed with

controlling statutes,' and whether the agency has committed a 'clear error of judgment.'" *Id.* (quoting *Maryland Dep't of Human Res. v. USDA*, 976 F.2d 1462, 1475 (4th Cir. 1992)). Accordingly, "the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

ARGUMENT

FDA's Letter Decision Reasonably Resolved Hatch-Waxman's Ambiguity Concerning The Effect Of Reissue Patents On 180-Day Exclusivity.

A. *Chevron* Governs This Court's Review Of FDA's Decisionmaking.

All parties agree that *Chevron*'s two-step framework governs the review of FDA's decisionmaking in this case. Under that approach, "courts are instructed to defer to the reasonable interpretations of expert agencies charged by Congress to fill any gap left, implicitly or explicitly, in the statutes they administer." *Nat'l Elec. Mfrs. Ass'n [NEMA] v. U.S. Dep't of Energy*, 654 F.3d 496, 504 (4th Cir. 2011) (quoting *AOL, Inc. v. AT&T Corp.*, 243 F.3d 812, 817 (4th Cir. 2001)). That makes deference virtually the rule, because "[f]ew phrases in a complex scheme of regulations are so clear as to be beyond the need for

interpretation when applied in a real context." *Id.* at 505 (quoting *Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 418 (1992)). Outside the rare cases in which "Congress has directly spoken to the precise question at issue," courts therefore "defer … to the agency's interpretations so long as the construction is a reasonable policy choice." *Id.* at 504-05 (internal quotations omitted); *see also United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 407 n.21 (4th Cir. 2012) (same). "*Chevron* deference of this sort stands at the heart of modern administrative law," because it "ensures that agency officials, who are subject to greater political accountability and possess greater relevant expertise than judges, take the lead in implementing programs delegated to their care." *Schafer v. Astrue*, 641 F.3d 49, 61 (4th Cir. 2011).

Those general principles have special force in cases involving complex statutory regimes like Hatch-Waxman: "In a statutory area as complicated as this one, the administrative authorities are far more able than this Court to determine congressional intent in the light of experience in the field." *Mowbray v. Kozlowski*, 914 F.2d 593, 598-99 (4th Cir. 1990); *see also West Virginia v. Thompson*, 475 F.3d 204, 212

(4th Cir. 2007) ("The Medicaid statute is a prototypical 'complex and highly technical regulatory program' benefitting from expert administration, which makes deference particularly warranted."); *Community Care Found. v. Thompson*, 318 F.3d 219, 225 (D.C. Cir. 2003) ("The Supreme Court has stated that the deference is 'even more warranted' when the Secretary's interpretation concerns such a 'complex and highly technical regulatory program.'") (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)).

B. This Case Presents Only One Issue, Not Two "Separate And Distinct Questions" That Can Be Resolved Independently From Each Other.

Against this backdrop, it is important to clarify the actual question that is subject to *Chevron* review. Each of the plaintiffs attempts to frame this appeal as though it presents two "separate and distinct questions" that require two "separate and distinct" answers under the statute. Mylan/Watson Br. at 16; Lupin Br. at 1 ("This case presents two separate questions."). The first question, they say, is whether a reissued version of a patent can give rise to a distinct period of exclusivity from the one associated with its previously-challenged predecessor. Lupin Br. at 1; Mylan/Watson Br. at 6. And—as if to

underscore the statute's ambiguity concerning the impact of reissue patents on 180-day exclusivity—plaintiffs expressly disagree about the answer: Lupin says "no," Lupin Br. at 3, while Mylan and Watson say "yes." Mylan/Watson Br. at 38.

The second question, plaintiffs say, is whether a court decision invalidating portions of an originally-listed-and-challenged patent triggers the first applicant's right to sole marketing exclusivity despite PTO's subsequent reissuance of that patent's partially invalidated claims. Lupin Br. at 1-2; Mylan/Watson Br. at 6. This time the plaintiffs agree: Each says the answer to that question is "yes." Lupin Br. at 4-5; Mylan/Watson Br. at 22. Indeed, Mylan and Watson claim that "had this Court inquired of FDA (or Teva) on May 14, 2008, as to whether Teva's 180-day exclusivity tied to the '068 patent had been triggered and was then running, the answer would have been an unequivocal 'yes.'" Mylan/Watson Br. at 21 (citation omitted).

Mylan and Watson are wrong about that; as noted earlier and addressed further *infra*, they expressly concede that the Federal Circuit's decision invalidated only certain claims of the '068 patent while leaving others intact. JA27-28 (Mylan Compl. ¶ 33). But the key

point here is that plaintiffs fundamentally misunderstand the inquiry FDA's letter decision addressed. That decision did not address two "separate and distinct" issues, and it is irrelevant how FDA would have assessed the facts or their legal consequences "on May 14, 2008." Instead, the only question FDA ever addresses in this context is whether a given ANDA is entitled to exclusivity on the date it becomes eligible for approval—*in light of all the facts that bear on that inquiry*—because "many factors … may influence eligibility for exclusivity up to the time an application is ready for approval … and could thus render a premature eligibility determination incorrect." JA46. Here, as explained below, the answer to that question hinges on the relationship between an original patent and its reissued version—and it is both artificial and inconsistent with FDA's longstanding practice to separate this case into two questions that self-consciously obfuscate the inherent relationship between the facts giving rise to FDA's decision.

It thus is irrelevant how FDA would have addressed exclusivity in 2008, because FDA does not make piecemeal exclusivity determinations at cherry-picked points in time. Instead, it addresses exclusivity when an ANDA otherwise is eligible for approval and necessarily answers

that question in light of the record as a whole. Plaintiffs of course disagree with FDA (and each other) about the legal significance of the events underlying FDA's decision, but as FDA made clear, those events necessarily are linked together for purposes of resolving exclusivity.

C. Hatch-Waxman Is Silent Regarding The Effect Of Patent Reissuance On 180-Day Exclusivity.

You can search the Hatch-Waxman Act from top to bottom, but it does not mention reissue patents expressly or specify their effect on 180-day exclusivity—as the district court, FDA, Teva, and even plaintiff Lupin agree. *See, e.g.*, JA334 (district court) ("[T]he patent statutes specifically address the distinction between 'original patents' and 'reissued patents' … while the Hatch-Waxman Act is silent on the issue; thus, Congress left it for the FDA to decide how reissued patents affect generic exclusivity rights."); JA45 (FDA decision) ("Neither [Hatch-Waxman] nor FDA's regulations directly address the effect of patent reissuance on the approval of a pending ANDA."); Lupin Br. at 1 ("FDA correctly concluded that the statute is silent on the effect of reissued patents on 180-day exclusivity.").

In a single footnote, however, Mylan and Watson contend that Hatch-Waxman *implicitly* addresses reissue patents and so *plainly*

requires FDA to treat an original patent and its reissued version as entirely separate from each other for purposes of evaluating 180-day exclusivity: "Because [Hatch-Waxman] defines 'patent' as 'a patent issued by the [PTO]'—which would include both original and reissue patents—original and reissue patents are separate patents for the purposes of the [statute]." Mylan/Watson Br. at 23 n.11 (quoting 21 U.S.C. § 355(m)) (second alteration in original); *see also id.* at 31 n.13 ("As noted [in footnote 11], 'patent' is defined by the FDC Act to mean any patent issued by the PTO.").

Nonsense. That provision merely specifies that *American patents alone* count for Hatch-Waxman purposes, not foreign patents issued by the European Patent Office in Munich or the Controller General of Patents Designs and Trade Marks in Mumbai. It sheds no light on the relationship between original patents and their reissued versions, nor does it specify the consequences of that relationship for purposes of administering this complex statute or assessing how the relationship between an original patent and reissued version affects the law's byzantine 180-day exclusivity regime.

As a result, this simply is not a case where the statute is "so clear as to be beyond the need for interpretation when applied in a real context." *NEMA*, 654 F.3d at 505 (internal quotations omitted). And FDA hardly can be faulted for filling the gap created by Hatch-Waxman's silence. That is exactly what Congress expects agencies to do, and as the district court recognized, this necessarily is a *Chevron* step 2 case because "'the text and reasonable inferences from it do not give a clear answer against the FDA.'" JA335 (quoting *Brown v. Gargner*, 513 U.S. 114, 120 (1994) (alterations omitted)); *see also Philip Morris USA, Inc. v. Vilsack*, 736 F.3d 284, 289-90 (4th Cir. 2013) ("To elucidate the gaps and ambiguities in the programs created by Congress is one of the core functions of an administrative agency, a function that we presume Congress intentionally invokes in drafting such a statute. We therefore will not usurp an agency's interpretive authority by supplanting its construction with our own, so long as the interpretation is not arbitrary, capricious, or manifestly contrary to the statute.") (internal quotations and citations omitted).

D. FDA Reasonably Filled The Statutory Gap.

In seeking to fill the resulting statutory gap, FDA's letter decision explained that the Agency typically "does not consider a reissued patent to be a new and distinct patent for purposes of 180-day exclusivity. Instead, FDA has generally treated the original patent and the reissued patent as a single 'bundle' of patent rights … for purposes of administering the [statute]," including both its 30-month stay and 180-day exclusivity provisions. JA45; *see also* JA46-48 (collecting FDA precedents). That general approach allows FDA "to consistently and predictably implement the FD&C Act," JA45, and likewise "reflect[s] the nature of reissued patents." *Id.*

> We note that FDA's treatment of reissued patents for 180-day exclusivity and 30-month stay purposes is consistent with the statutory treatment of reissued patents generally, including the provision that allows a pending cause of action based on the original patent to continue after reissuance to the extent that claims of the original and reissued patent are substantially identical (see 35 U.S.C. § 252). It is also consistent with the limitation on reissuance to the unexpired part of the term of the original patent (see 35 U.S.C. 251(a)). Additionally, it is consistent with the requirement that "no new matter shall be introduced into the application for reissue" (35 U.S.C. 251(a)).

JA46; *see also* JA44 (noting that reissued patents can "'have effect continuously from the date of the original patent'" and generate liability

for pre-reissuance actions that infringe "'a valid claim of the reissued patent which was in the original patent'") (quoting 35 U.S.C. § 252).

Once again, the district court, Teva, and even plaintiff Lupin agree that FDA's decision reasonably addresses the statute's silence concerning the effect of reissued patents and so should be upheld. *See, e.g.*, JA336 ("[T]reating an original and reissued patent as a 'single bundle of patent rights' is consistent with both the objectives of the Hatch-Waxman Act and also with relevant principles of patent law."); Lupin Br. at 4 ("FDA's decision is consistent with the statutory treatment of reissued patents generally[;] comports with [FDA's] prior decisions[; and] is a reasonable interpretation that allows FDA to administer its statute in a predictable manner.").

The scattershot array of arguments lodged by Mylan and Watson does nothing to undermine that conclusion. They initially assert that the statute's court-decision trigger requires the Agency to treat original patents and their reissued versions as wholly distinct because it refers in the singular to "*a* decision of a court on *the* patent which is the subject of the certification." Mylan/Watson Br. at 22 (internal quotation and alterations omitted; emphasis in original); *see also id.* at 23 ("The

meaning FDA seeks to attribute to the court decision trigger can only be achieved by inserting plural elements that are not in the statute…. For [FDA to prevail] the use by Congress of the singular term 'patent' would have to be disregarded.").

That argument merely begs the question of how to define "the patent which is the subject of the certification." On one hand, "the patent which is the subject of the certification" conceivably could be determined solely by reference to its number (*e.g.*, '068 or '048), as Mylan and Watson assume. In that case, an original patent and its reissued version reasonably could be viewed as distinct for Hatch-Waxman purposes. Even then, however, FDA would have to confront a subsidiary question under the court-decision trigger—whether the decision "holding the [original] patent which is the subject of the certification to be invalid or not infringed" must address *all* of the patent's claims or *only some of them* in order to trigger exclusivity.

On that issue, the only sensible view is that *all claims* covered by a given patent number must be invalidated or deemed non-infringed, not just *some of them*. Otherwise, the first applicant's exclusivity would be triggered *even if selling its product would infringe "the patent"*—

meaning that the first applicant could be subjected to potentially ruinous liability if it tried to enjoy the exclusivity reward Congress bestowed on it. Congress could not possibly have intended that result, and given the conceded facts of this case, there was not a court-decision trigger here even if Mylan and Watson are right to assume that "the patent which is the subject of the certification" is defined solely by reference to its number. In short, Teva would be entitled to sole marketing exclusivity even if this Court embraces Mylan and Watson's assumption that only the listed patent's number matters.[4]

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[4] Watson responded below by claiming that the Federal Circuit at least invalidated the claims *Pfizer chose to assert* and arguing that "it is difficult to imagine Teva taking [the claim-by-claim] position with respect to the termination of the 30-month stay," which lifts "when 'the court decides that such patent is invalid or not infringed.'" D. Ct. Dkt. No. 81, at 4 n.2 (quoting 21 U.S.C. § 355(j)(5)(B)(iii)(I)). But this Court and the D.C. Circuit both have held that the first applicant's eligibility for exclusivity does not hinge on whether the NDA holder opts to assert its patent rights; it hinges on the first applicant's challenge alone, regardless of whether the NDA holder asserts its rights. *See Granutec, Inc. v. Shalala*, 139 F.3d 889 (table), 1998 WL 153410, at *7 (4th Cir. 1998); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069-70 (D.C. Cir. 1998). And Teva's positions regarding the court-decision trigger and 30-month stay are fully consistent given the objectives those provisions serve. The former encourages first applicants to use their exclusivity *when all potential patent barriers are eliminated conclusively*, while the thirty-month stay incentivizes NDA holders *to assert all patent claims so that the parties can obtain a conclusive resolution of all potential patent disputes*. It thus makes no sense to maintain a thirty-month

But there is no reason to think that Mylan and Watson are right to assume that "the patent which is the subject of the certification" is defined solely by its number. Instead, "the patent which is the subject of the certification" also could be defined by reference to *its substance*—that is, the particular claims that define its exclusionary scope. After all, patents matter not because of the number PTO assigns them for identification purposes, but because their individual claims grant particular exclusionary rights. And since individual patent claims can (and often do) carry over from an original patent that has been invalidated to its reissued version, it makes little sense to say that two substantially identical patent claims are "separate" or "distinct" simply because they fall under different numbers: Substantively speaking—given their exclusionary effect in the real world—they are the same.

And that is exactly what FDA's decision recognized. It explained that a patent is more than just a number: It "'is … a bundle of rights which may be divided and assigned, or retained in whole or in part.'"

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stay based on potential patent claims the NDA holder declined to assert, just as it makes no sense to strip first filers of their exclusivity for not launching products that could be held to infringe a previously-unasserted patent claim.

JA45 n.13 (quoting *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991)). Each claim (*i.e.*, each "stick" in the "bundle") must therefore be assessed on its own terms—which is why the Federal Circuit decision at issue here could address "claims 1-4 and 11-17" of the '068 patent, JA27 (Mylan Compl. ¶ 33), without affecting claims 5-10 of that patent (which Teva also challenged in its Paragraph IV certification) or claim 18 of that patent (to which Teva had submitted a section viii statement). *See supra* at 19-20 & n.2.

Consistent with those bedrock principles of patent law, FDA always has interpreted Hatch-Waxman as permitting applicants to submit patent certifications on a substantive claim-by-claim basis:

> If … there are listed patents that present both a product and method of use claim, the applicant may file a paragraph IV certification with respect to the product patent *or patent claim* and a statement that the product that is the subject of the application does not involve a patented method of use with respect to the method of use patent *or patent claim*.

FDA, *Final Rule: Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,347 (Oct. 3, 1994) (emphasis added) (citing 21 U.S.C. §§ 355(j)(2)(A)(vii)-(viii); 21 C.F.R. §§ 314.94(a)(12)(i)(A), 314.94(a)(12)(iii)). Again, that is precisely what Teva did here when it filed a so-called "split certification"

comprised of a Paragraph IV certification to claims 1-17 of the '068 patent and a section viii statement with respect to claim 18 of that patent. And again, no court ever addressed Teva's challenge to claims 5-10 of that patent—in Teva's favor or against it—which forecloses any argument that Teva's exclusivity was triggered.

Mylan and Watson never seriously challenge the Agency's longstanding position that Hatch-Waxman focuses on substance over form as gauged on a claim-by-claim basis. And they cannot credibly do so: Both companies routinely file their own split certifications on a claim-by-claim basis. *See, e.g.*, *Watson Labs., Inc. v. Sebelius*, No. 12-1344, 2012 WL 6968224, at *4 n.3 (D.D.C. Oct. 22, 2012) ("In this case, both Watson and Mylan originally filed split certifications as to the drug composition/use patents."). Instead, they now assert that FDA misunderstood the "bundle of rights" concept when it observed that an original patent and its reissued version often claim overlapping rights:

> [R]ather than bundling two patents together to create the 'bundle of rights' invented by FDA, patent cases discussing the 'bundle of rights' recognize that a single patent can bestow this bundle, even if the patent is a reissue patent. By the logic of these 'bundle of rights' patent cases, the '048 reissue patent would be a completely separate 'bundle of rights' disconnected from the 'bundle of rights' that comprised the original '068 patent.

Mylan/Watson Br. at 34-35 (internal citations omitted).

Mylan and Watson misconstrue the Agency's point. Rather than suggesting that an original patent and its reissued version somehow join "together to create" a novel bundle of patent rights, FDA's point is simply that the individual "sticks" comprising the original patent's "bundle" often serve as the very "sticks" comprising that patent's later-reissued bundle, and so are neither "completely separate" nor "disconnected" from the original patent. Instead, the sticks often are the same, which helps explain why reissue patents confer protection only until *the original patent's* previously scheduled expiration, JA46 (citing 35 U.S.C. § 251(a)): In such cases, the reissue patent's "sticks" do not claim anything new, and so do not deserve a new exclusionary term.

That view not only is reasonable; it is unassailable. Though Mylan and Watson assert that "over a hundred and fifty years of patent case law dictate that a reissue patent is separate and distinct from the original patent," Mylan/Watson Br. at 35 & n.14, that assertion ignores the doctrine of claim continuity—as both FDA and the district court explained below and plaintiff Lupin echoes here. JA44 (FDA decision) (discussing 35 U.S.C. § 252); JA45-46 (discussing 35 U.S.C. §§ 251(a),

252); JA49-50 (same); JA333-34, 336 (district court) (same); Lupin Br. at 3-4 (expressly adopting the FDA/district court analysis).

That long-established doctrine "provides for continuity between 'substantially identical' claims of the original and reissued patents. A patentee may recover for all infringement which happens after the date of the original patent if the respective 'claims of the original and reissued patents are substantially identical.'" JA333-34 (district court decision) (quoting 35 U.S.C. § 252); *see also Bloom Eng'g Co., v. N. Am. Mfg. Co.,* 129 F.3d 1247, 1250 (Fed. Cir. 1997) ("[W]hen the reexamined or reissued claims are identical to those of the original patent, they shall 'have effect continuously from the date of the original patent.' [That] does not mean verbatim, but means at most without substantive change.") (quoting 21 U.S.C. § 252); *Artemi Ltd. v. Safe-Strap Co.,* 947 F. Supp. 2d 473, 478 (D.N.J. 2013) ("[A] reissued patent can be enforced against infringing activity that allegedly occurred from the time the original patent was issued if the claims of the original and reissue patents are substantially identical.").

To be sure, "the patentee has no rights except such as grow out of the reissued patent." *Peck v. Collins*, 103 U.S. 660, 664 (1880); *Moffitt*

v. Garr, 66 U.S. 273, 279 (1861) ("The only right saved is under a reissue, and in virtue of the new patent."). But as FDA reasonably concluded, that is irrelevant for Hatch-Waxman purposes. Where a reissued patent's individual claims are substantially identical to ones from the original patent, FDA's central insight is that the "first applicant" to challenge those claims is the one that attacked them in the original patent—not the Johnny-come-latelies who waited until those same claims were reissued years later. And where those claims initially are invalidated *but then are reissued in substantially identical form*, it is illogical to treat them as having been disposed of for all time. Given the potential for claim continuity, the overlapping claims in a reissued patent are "presumptively valid" even if challenged successfully in prior litigation, and they can give rise to liability for conduct dating back to their initial issuance *in the original patent*—which confirms that the intervening court decision did not actually clear the cloud of uncertainty created by those claims or free the first applicant to market its product without risk of liability for infringing those claims. JA50 (citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985); 35 U.S.C. § 252).

Deeming the first applicant's exclusivity to have been triggered by the intervening court decision thus "would introduce an incongruity into the statutory framework. This view would consider the court decision on the original patent to be sufficient to trigger (and exhaust) 180-day exclusivity, while at the same time considering the patent at issue in that case to be in effect in its reissued form." JA50. But agencies are supposed to avoid such contradictions, and FDA deserves credit for resolving this tension—not condemnation. *Scialabba v. Cuellar de Osorio*, 134 S. Ct. 2191, 2207 (2014) ("When an agency thus resolves statutory tension, ordinary principles of administrative deference require us to defer."); *see also* JA331-32 ("FDA's interpretation avoids an incongruity that would arise if a court decision on the original patent were sufficient to [strip the first filer of] 180-day exclusivity, but the patent at issue was still in effect in its reissued form.").

Indeed, FDA's resolution of that tension not only was a permissible approach to this issue; it best serves the statute's objectives. Because claim continuity could make first-filers liable for infringing conduct that occurs between the intervening court decision and PTO's reissuance of previously invalidated claims, plaintiffs'

position would require the first applicant to launch its product at risk of potentially ruinous liability in order to enjoy its exclusivity—a position sharply at odds with the court-decision trigger's textually manifest objective of preventing applicants from having to launch their products *until* the challenged patent's claims are fully cleared. *See* MMA, § 1102(b)(3), 117 Stat. 2066, 2460 (conditioning court-decision trigger on a "final decision of a court from which no appeal … has been or can be taken"). FDA did not abuse its discretion in concluding that Congress did not intend to lure generic companies into the marketplace once an original patent is declared partly invalid, only to whipsaw them with infringement liability—and possible treble damages—where the original patent's claims are reissued in substantially identical form.[5]

Faced with all of that, Mylan and Watson ultimately attack FDA for even asking whether the relationship between original patents and their reissued versions is relevant to Hatch-Waxman—claiming that the Agency somehow abandoned its "ministerial role with respect to

[5] In an effort to blunt the absurd results their position would generate, plaintiffs repeatedly complain that PTO did not reissue the patent at issue in this case for several years. *See, e.g.*, Mylan/Watson Br. at 3, 21, 36. But as they elsewhere concede, "Pfizer submitted the '068 patent to the PTO for reissue proceedings [just] four months after the Federal Circuit's mandate." *Id.* at 13 (citing JA120).

patents" by considering how that relationship might affect its administration of Hatch-Waxman's complex exclusivity provisions. Mylan/Watson Br. at 32. But FDA's ministerial role does not require the Agency to bury its head in the sand when patent issues arise—as they often do in a complex exclusivity regime that revolves around patents. And it certainly did not require FDA to ignore those issues when Mylan itself raised them in "private correspondence to the Agency, followed by meetings … during [which] we specifically asked that the Agency render a decision" on them. JA183 (counsel for Mylan).

Instead, FDA's "ministerial role" means only that it "does not independently assess [a] patent's scope or otherwise look behind the description authored by the brand." *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012); *see also Teva v. Leavitt*, 548 F.3d at 106 ("When it comes to the veracity of the patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information.") (citing, *inter alia*, *aaiPharma v. Thompson*, 296 F.3d 227, 242-43 (4th Cir. 2002)); *Am. Bioscience, Inc. v. Thompson,* 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("FDA has a longstanding policy not to get

involved in patent disputes. It administers [Hatch-Waxman] in a ministerial fashion simply following the intent of the parties that list patents [*i.e.*, NDA holders].").

To the extent any party's position here would deviate from that ministerial role, it thus is the plaintiffs' position. As set forth above, Pfizer specifically informed FDA that "[t]he reissue patent, RE44048, *represents the continued existence of the '068 patent*." Pfizer Listing Letter at 1 (emphasis added). Given Pfizer's explicit invocation of the claim continuity doctrine, FDA had no choice but to consider its implications for exclusivity. And in light of Pfizer's explicit representation about the relationship between the '068 patent and its reissued version, FDA could not lawfully have come to any conclusion but that the '068 patent's claims continued to exist despite the Federal Circuit's decision—as the Agency repeatedly made clear by observing that its decision faithfully reflected the Agency's ministerial role. *See, e.g.*, JA42 ("FDA's role in patent listing is ministerial. FDA has stated that it will not evaluate a patent to assess whether the declaration is accurate.") (internal quotation omitted); JA45-46 (stating that the Agency's decision "preserv[es] FDA's ministerial role in patent

listings"); JA49 (invoking FDA's "ministerial role in patent listing decisions"); JA50 (explaining that the Agency's decision is "consistent with our ministerial role in patent listing").[6]

With both the law and the facts against them, Mylan and Watson ultimately resort to policy arguments. They first assert that FDA's decision is "absurd" because subsequent applicants cannot be "certain that the exclusivity period expires as otherwise expected [after a court decision on the original patent]—nor commence the expensive and time-consuming preparations to market their products once [Hatch-Waxman] permits generic competition—because at some point in the future a reissue patent may be issued that resuscitates the 'zombie' exclusivity period." Mylan/Watson Br. at 27; *see also id.* at 37-38 ("[T]here can be

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[6] To the extent Mylan and Watson dispute the Agency's conception of its ministerial role, they bear an especially heavy burden: An agency's interpretation of its own regulations is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989) (further internal quotation omitted)); *see also Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 146 (4th Cir. 2002) ("[O]ur review in such cases is more deferential than that afforded under *Chevron*.") (citations, internal quotation marks, and alterations omitted).

no predictability ... because a reissue patent could be sought and granted at any time.").

They have a point. Life *is* unpredictable. But filing an ANDA does not entitle applicants to make fail-safe predictions about the future. Instead, exclusivity is inherently uncertain because "many factors … may influence eligibility for exclusivity up to the time an application is ready for approval ... and could thus render a premature eligibility determination incorrect." JA46. To take an obvious example, brand manufacturers can *always* obtain a new patent (even an original one) that threatens a planned launch. And it's precisely that possibility that Mylan and Watson seek to take advantage of in this case: The whole back end of their brief is devoted to claiming they should share exclusivity with Teva—and thereby disrupt *Lupin's* expectations—precisely because Pfizer happened to get its patent reissued. It takes real chutzpah to make both of these arguments in the span of three sentences. *See* Mylan/Watson Br. at 38 (first claiming that FDA's decision is absurd "because a reissue patent could be sought and granted at any time" and then claiming that "Mylan, Watson, and Teva

[should] be granted shared 180-day exclusivity" precisely because Pfizer sought and obtained a reissued version of the '068 patent).

As a last resort, Mylan and Watson assert that FDA's decision "diminishes the statutory incentive structure by depriving [them] of the shared statutory exclusivity period to which they are entitled after having borne the risks and costs associated with [a Paragraph IV certification]." Mylan/Watson Br. at 42. Yet merely filing such a certification is not sufficient to qualify for 180-day exclusivity; you also have to be first, and in this case, FDA rightly recognized that Teva *alone* was first to challenge the patent giving rise to 180-day exclusivity and then maintained that challenge when Pfizer secured reissuance of the few claims that temporarily had been invalidated.

It thus is irrelevant that "the risk and costs of patent litigation borne by ANDA applicants who certify to a reissue patent are equal to those borne by ANDA applicants who certify to an original patent." *Id.* at 43. Were that sufficient to confer exclusivity, then Lupin and Apotex would be eligible to share exclusivity with Mylan, Watson, and Teva because they likewise were sued for filing Paragraph IV certifications to the reissued version of the '068 patent, *id.*—though neither of them has

the temerity to suggest that they are entitled to exclusivity (much less that exclusivity was essential to induce their certifications). Indeed, Apotex has chosen not to challenge the Agency's decision at all.

At bottom, FDA's decision does exactly what it said and should be affirmed for precisely those reasons. In the face of statutory silence, it makes the rules of the road transparent and thereby allows applicants to plan according to how the facts—which of course are beyond FDA's control—unfold. JA45, JA49. Far from diminishing the "statutory incentive" to challenge patents, it helps ensure that applicants both challenge competition-blocking patents early and maintain those challenges if the brand manufacturer restores its patent protection through the reissue process. JA51. Given the doctrine of claim continuity, it avoids the incongruity that would arise if a court decision on the original patent were sufficient to extinguish exclusivity even if the patent's claims survive and can generate liability retroactively. JA50. And it is consistent with—if not compelled by—the Agency's ministerial role of deferring to the NDA holder's representations about the patents it submits to the Orange Book. JA42, 45-46, 49, 50. Given the statute's silence on how patent reissuance affects 180-day

exclusivity, the district court's thoughtful decision upholding the Agency's letter decision should be affirmed.

E. Lupin's Position Is Internally Inconsistent.

Though we obviously disagree with much of what Mylan and Watson say, our positions align in one respect: In the event this Court holds that the statute's plain text forecloses FDA's determination that Teva alone is entitled to exclusivity, the only permissible alternative is that Teva, Mylan, and Watson should share exclusivity. As set forth above, this case hinges on the reasonableness of FDA's conclusion that the relationship between original patents and their reissued versions has consequences for the administration of Hatch-Waxman's exclusivity provisions: Either the original patent's claims and their substantially identical reissued versions are linked for Hatch-Waxman purposes (so Teva alone was first to challenge the claims at issue here) or they are totally distinct (and, leaving aside the fact that the '068 patent was never invalidated in its entirety, Teva, Mylan, and Watson at least share first-applicant status as to the reissue patent).

Lupin of course agrees with FDA, the district court, and Teva that the original patent's partially invalidated claims and their reissued

versions are substantively indistinguishable and thus that "FDA's [single bundle of rights] approach was reasonable, and therefore, lawful, under 'Step 2' of *Chevron*." Lupin Br. at 1. Yet it nonetheless argues that "the district court erred in upholding FDA's decision that the 2008 court decision … did not trigger Teva's 180-day exclusivity." *Id.* at 2.

Those two arguments are irreconcilable, as FDA's decision explained: "This view would consider the court decision on the original patent to be sufficient to trigger (and exhaust) 180-day exclusivity, while at the same time considering the patent at issue in that case to be in effect in its reissued form." JA50. Lupin never responds to the Agency's analysis, and as the district court recognized, FDA's rejection of Lupin's internally inconsistent position warrants deference. JA331-32 ("FDA's interpretation avoids an incongruity that would arise if a court decision on the original patent were sufficient to trigger (and exhaust) 180-day exclusivity, but the patent at issue was still in effect in its reissued form.").

CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 12,302 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 point Century Schoolbook.

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I, Michael D. Shumsky, hereby certify that on August 1, 2014, I caused a virus check to be performed on the electronically filed copy of this brief using Microsoft Forefront Endpoint Protection Client (updated as of August 1, 2014) and, according to the program, no virus was detected.

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Michael D. Shumsky

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I, Michael D. Shumsky, hereby certify that on this 1st day of June 2014, I caused eight (8) copies of the Response Brief of Defendant-Appellee Teva Pharmaceuticals USA, Inc. to be dispatched by Federal Express Overnight delivery to the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit, and filed an electronic copy of the Brief via CM/ECF, the latter of which will served on all counsel of record via this Court's CM/ECF system.

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