UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc., 1090 Horsham Road North Wales, PA 19454, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, 200 Independence Ave. S.W. Washington, DC 20201; SCOTT GOTTLIEB, M.D., in his official capacity as Commissioner of Food and Drugs, 10903 New Hampshire Ave. Silver Spring, MD 20903; UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Ave. Silver Spring, MD 20903, Defendants.	Case No. ____________

TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

This lawsuit seeks immediate injunctive and declaratory relief that will bar FDA from depriving plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") of its statutory right to 180 days of marketing exclusivity for its generic version of the brand-name drug Restasis®. Teva earned that reward because it was the first generic applicant that complied with the Hatch-Waxman Act's requirements for challenging at least one of the patents covering Restasis®. Yet FDA now has ruled that an applicant which concededly ***did not*** comply with those requirements (and so assumed ***no risk*** of patent infringement litigation) nonetheless qualified for 180-day exclusivity—and thereby blocks every company which ***did*** comply with the statute (and ***realized the risk*** of infringement litigation) from qualifying for the exclusivity period Congress intended as a "reward for generics that stick out their necks (at the potential cost of a patent infringement suit)." *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

That perverse result is remarkable in its own right. But it is particularly startling because FDA took precisely the opposite position for nearly two decades. Until now, FDA consistently maintained that eligibility for 180-day exclusivity hinges on a generic applicant submitting a legally valid challenge to the innovator's patents that complies with all statutory requirements for such challenges—including the requirement to notify the brand manufacturer of any such challenge so that it can evaluate whether to sue the generic applicant for patent infringement. Not surprisingly, both this Court and the D.C. Circuit agreed with that commonsense position. *See, e.g.*, *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 80 (D.D.C. 2003), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 888-89 (D.C. Cir. 2004). And while this case arises under a more recent version of the statute, FDA recently promulgated binding regulations—after formal notice-and-comment rulemaking—that not only affirmed its longstanding position, but expressly relied on the court cases upholding that well-settled rule. *Abbreviated New Drug Applications and 505(b)(2) Applications—Final Rule* (the "MMA Final Rule"), 81 Fed Reg. 69580, 69609 (Oct. 6, 2016) (adopting proposed rule that applicants must "satisfy the notice requirement of the [Hatch-Waxman] Act … to qualify for 180-day exclusivity"); *see also Abbreviated New Drug Applications and 505(b)(2) Applications—Proposed Rule* (the "MMA Proposed Rule"), 80 Fed. Reg. 6802, 6835 (Feb. 6, 2015) (citing *Purepac* to support proposal that a patent challenge is "effective only as of the date that the applicant has both submitted … the paragraph IV certification and sent the notice"). FDA's attempt to jettison that rule in the context of a quasi-adjudicatory proceeding is thus as procedurally defective as it is substantively baffling.

Without injunctive relief, Teva faces a significant, imminent, and well-recognized irreparable harm from FDA's decision—the loss of its statutory right to 180-day exclusivity and ***tens of millions of dollars*** that Teva can never recover from either FDA or its competitors. That is so, as both this Court and the D.C. Circuit again have recognized, because it is impossible to remediate the loss of 180-day exclusivity once competing products enter the market: "[A] first applicant's loss of its statutory entitlement to the 180-day exclusivity period is irreparable because once lost 'it cannot be recaptured.'" *Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 313 (D.D.C. 2012) (quoting *Apotex, Inc. v. FDA*, No. Civ. A. 06-627, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006), *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006)); *Teva v. Sebelius*, 595 F.3d at 1311 ("If we refrained from adjudicating this dispute now, Teva [faces] an injury that would not be remedied by Teva's securing 180 days of exclusivity later on."). And as those courts likewise have recognized, the balance of harms and public interest likewise favor the entry of injunctive relief to protect 180-day exclusivity, which "is a pro-consumer device [that] Congress has chosen to induce challenges to patents." *Teva v. Sebelius*, 595 F.3d at 1318. Consistent with well-settled precedent, this Court immediately should enjoin FDA from stripping Teva's statutory entitlement to the exclusivity reward it earned by opening the market to competition years before the brand manufacturer's patents otherwise would have allowed.

BACKGROUND

A. The Hatch-Waxman Framework

1. Overview

As modified by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066, the Food, Drug, and Cosmetic Act establishes the procedure for obtaining FDA approval to sell pharmaceutical products. 21 U.S.C. § 355 *et seq*. To obtain approval for brand-name drugs like

Restasis®, manufacturers must file a New Drug Application ("NDA") that contains clinical-trial data establishing the proposed drug's safety and efficacy. *Id.* § 355(b)(1).[1] Before Hatch-Waxman, generic applicants likewise had to conduct new clinical trials and file full NDAs—even though generic drugs contain the same active pharmaceutical ingredients ("APIs") as their brand-name equivalents and have the same safety and efficacy profile. That made generic market entry cost-prohibitive, and patients therefore lacked access to affordable generic medicines.

Hatch-Waxman sought to remove those barriers, increase the availability of generic drugs, and reduce prescription drug costs. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998). To do so, it authorizes FDA to approve a generic version of a previously-approved drug so long as the proposed generic drug is "the same as" a previously-approved drug in certain key respects—the chemical composition of its API; the rate at which its API is released into the body (called "bioequivalence" or "BE"); the drug's strength (*e.g.*, 50mg or 100mg of API); its route of administration (*e.g.*, oral or injected); its form (*e.g.*, tablet or capsule); and its labeling. 21 U.S.C. § 355(j)(2)(A). Generic applicants seek approval for their products by submitting Abbreviated New Drug Applications ("ANDAs") with data establishing those characteristics. If a proposed generic product meets these "sameness" criteria, the applicant need not conduct new clinical trials; instead, FDA can approve the product based on its prior finding that the generic drug's brand-

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[1] Unless otherwise noted, all citations are to the current version of the statute.

name equivalent is safe and effective. *Id.* § 355(j)(2)(A); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

2. The "Paragraph IV" Patent-Challenge Process

At the same time Hatch-Waxman sought to speed generic approvals, it recognized that brand manufacturers often hold valuable patents on their products. Hatch-Waxman thus struck a balance between expediting generic entry and respecting innovators' patent rights. Whenever a brand manufacturer believes it holds valid patent rights on an approved drug, Hatch-Waxman requires that company to file with FDA "the patent number and the expiration date of any patent which claims the drug … and with respect to which a claim of patent infringement could reasonably be asserted [against a generic competitor]." 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.50(h). The statute then obligates FDA to "publish" and regularly "revise" a list of all such patent data. *Id.* § 355(j)(7)(A)(i)-(iii); *see also id.* § 355(c)(2). FDA does so in a resource known as "the Orange Book." *Purepac*, 354 F.3d at 880; *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001). These intertwined patent-submission and patent-listing requirements thus allow prospective ANDA applicants to identify patent barriers that might bar them from entering the market even after FDA approves their products.

Congress also recognized that the U.S. Patent and Trademark Office ("PTO") sometimes issues patents that are not valid or cannot be enforced, and that generic applicants often seek approval for products that will not infringe the listed patents—in which case those patents should not delay generic entry. To speed the resolution of patent disputes between brands and generics so that competition can start as soon as the law permits, Congress required each ANDA to include "a certification … with respect to each [Orange Book-listed] patent which claims the listed drug … or … a use for such listed drug." *Id.* § 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.53(f). Four such certifications are available:

> (I) that no patent information was filed for the referenced NDA [a "Paragraph I certification"],
>
> (II) that a listed patent has expired [a "Paragraph II certification"],
>
> (III) that the generic drug will not be marketed until a listed patent is set to expire [a "Paragraph III certification"], or
>
> (IV) that a listed patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug [a "Paragraph IV certification"].

21 U.S.C. § 355(j)(2)(A)(vii).

Paragraph IV certifications play a vital role in the statutory scheme. These certifications signal that a generic applicant disputes the innovator's patent rights and therefore intends to enter the market before a listed patent is set to expire. *Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (*Teva v. Leavitt*) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier."). But in crafting the Paragraph IV challenge process, Congress recognized that merely telling FDA that a listed patent is invalid, unenforceable, or would not be infringed accomplishes nothing on its own. FDA, after all, does not resolve patent disputes; the federal courts do. And before Hatch-Waxman, the federal courts lacked jurisdiction to adjudicate patent disputes before a generic applicant risked potentially ruinous liability (including potential treble damages) by committing acts of actual infringement. 35 U.S.C. § 271(a) (cause of action for infringement); *id.* § 284 (treble damages). That made it impossible for generic applicants to obtain certainty about their rights without risking damages—and the shadows cast by dubious patents in turn threatened to delay the launch of approved generics that otherwise could have been on the market.

So Hatch-Waxman engineered a fix. To help generics obtain certainty about a listed patent's coverage without subjecting them to the *in terrorem* threat of massive damages, the statute deemed an ANDA applicant's submission of a Paragraph IV certification to FDA to be a "highly artificial" act of patent infringement that immediately can be litigated without subjecting the generic applicant to damages. 35 U.S.C. § 271(e); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("Quite obviously, the purpose of [35 U.S.C. § 271](e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend."). And because that fix would enable the resolution of pre-launch patent disputes only if the brand manufacturer learns that an applicant has submitted a Paragraph IV certification (and so can be sued), Hatch-Waxman naturally required generic applicants to notify the brand manufacturer and any registered patentee(s) when they submit Paragraph IV certifications to FDA. 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Where an ANDA applicant submits a Paragraph IV certification in its original ANDA, such notice must be provided "not later than 20 days after the date … [on] which [FDA] informs the applicant that the application has been filed." *Id.* § 355(j)(2)(B)(ii)(I). And where an applicant submits a Paragraph IV certification by amending a previously-filed ANDA, it must notify the innovator "at the time at which the applicant submits the amendment or supplement" to FDA. *Id.* § 355(j)(2)(B)(ii)(II).

Because the whole point of Hatch-Waxman's patent-submission, patent-listing, Paragraph IV certification, and Paragraph IV notice provisions is to resolve patent disputes before FDA approval, the statute incentivizes brand manufacturers to sue as soon as they receive the legally-required notice. Indeed, the entire Paragraph IV scheme is keyed to the innovator's receipt of the legally-required notice. Where the brand manufacturer sues within 45 days of receiving the legally-required notice, FDA may not approve the ANDA until 30 months after the brand manufacturer receives the legally-required notice. 21 U.S.C. § 355(j)(5)(B)(iii). This incentive is known as a "30-month stay." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348-49 (Fed. Cir. 2009). Where, by contrast, the brand manufacturer declines to file suit, the generic applicant can itself initiate a declaratory-judgment action to obtain certainty about its rights—but only after 45 days have elapsed from the brand manufacturer's receipt of the legally-required notice. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa). Whether such litigation is initiated by the brand manufacturer or generic applicant, however, an applicant that prevails in the district court (like Teva did here) can obtain FDA approval immediately—even if a 30-month stay otherwise would bar approval; even if the challenged patent won't expire for several years; and even if an appeal is pending. *Id.* at § 355(j)(5)(B)(iii).

3. The 180-Day Exclusivity Reward

Because Paragraph IV certifications are all about producing potential litigation over a challenged patent, *bona fide* Paragraph IV applicants necessarily assume significant risks. Beyond making the initial investments needed to develop either a non-infringing formulation that meets the statute's "sameness" requirements or a viable legal challenge to a listed patent, valid Paragraph IV applicants must be prepared to defend their proposed product in years of costly patent litigation. But because successful patent challenges can open the market to early generic competition, Congress encouraged generic applicants to take on those risks. To that end, Hatch-Waxman rewards the first generic applicant that submits a valid Paragraph IV challenge and thereby subjects itself to the risk of infringement litigation with a 180-day period of marketing exclusivity during which FDA may not approve any subsequently-filed ANDA referencing the same brand-name drug. As the D.C. Circuit has explained, this exclusivity period

> is a pro-consumer device [that] Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted.

Sebelius, 595 F.3d at 1318.

Needless to say, such "[m]arketing exclusivity is valuable." *Teva v. Leavitt*, 548 F.3d at 104. By allowing the first generic patent challenger to enter the market without competition for six months, this exclusivity can be worth tens (or even hundreds) of millions of dollars when it comes to top-selling drugs like Restasis®—for which brand manufacturer Allergan, Inc.'s net revenues exceeded $1.4 billion in 2017. *Allergan Reports Solid Finish to 2017 with 12% Increase in Fourth Quarter GAAP Net Revenues to $4.3 Billion*, Feb. 6, 2018, *available at* https://tinyurl.com/AllerganEarningsRelease (last visited Oct. 16, 2018) (reporting $1,412,300,000 in 2017 net revenues from U.S. sales of Restasis®).

a. The Pre-MMA 180-Day Exclusivity Provisions

Before Congress enacted the MMA in 2003, Hatch-Waxman established this 180-day exclusivity reward by delaying FDA approval of any ANDA that "contains a [Paragraph IV] certification … and is for a drug for which a previous [ANDA] has been submitted under this subsection cont[ain]ing such a certification" until 180 days after the first Paragraph IV challenger either prevailed in its patent case or began selling its drug. 21 U.S.C. § 355(j)(5)(B)(iv) (pre-2003). Given the central role that notice of a Paragraph IV certification plays in making Hatch-Waxman's litigation engine work, FDA consistently held that Paragraph IV certifications are legally invalid—and so cannot qualify an applicant for 180-day exclusivity—unless the applicant timely notifies the brand manufacturer of its Paragraph IV certification in accordance with the statute's mandatory notice requirements:

> [T]he statute makes the first applicant to submit a paragraph IV certification to a patent eligible for exclusivity, and it also requires that the ANDA applicant give notice. [In determining] the relevant date for exclusivity purposes…, the agency will look to the date that [the first applicant] actually sent the required notice, since this is the date upon which [the first applicant] effectively met the statutory requirements by having both submitted a paragraph IV certification and sent notice of the submission.

Letter from G. Buehler to ANDA Applicants for Gabapentin (the "Gabapentin Letter Decision") at 7-8 (Jan. 28, 2003).

This structural interpretation of the law was challenged, but both this Court and the D.C. Circuit affirmed FDA's position as appropriately recognizing that Hatch-Waxman's patent-listing, patent-certification, Paragraph IV notice, and 180-day exclusivity provisions are inextricably intertwined. *TorPharm*, 260 F. Supp. 2d at 80 (affirming FDA's decision as recognizing "that notice and certification must occur together, and therefore refus[ing] to give legal recognition to one act until the other has been effectuated as well"), *aff'd Purepac*, 354 F.3d at 888-89. Since that time, FDA repeatedly has affirmed this interpretation. *See, e.g.*, Letter from K. Uhl to Celecoxib ANDA Applicants (the "Celecoxib Letter Decision") at 2 n.6 (Apr. 24, 2014) ("[F]or exclusivity purposes ... the agency will look to the date the applicant actually sent the required notice, since that is the date the applicant effectively met the statutory requirements by having both submitted a paragraph IV certification and sent notice of the submission.").

b. The Post-MMA 180-Day Exclusivity Provisions

Congress updated the original Hatch-Waxman Act in 2003. Like the original statute, the MMA grants the first Paragraph IV applicant a 180-day exclusivity period by barring FDA from approving a subsequently-filed Paragraph IV ANDA until "180 days after the date of the first commercial marketing of the drug … ***by any first applicant***." 21 U.S.C. § 355(j)(5)(B)(iv)(I) (emphasis added). That term had not appeared in the original statute (which as set forth earlier awarded exclusivity to the first generic applicant by reference to the submission of "a previous application cont[ain]ing a Paragraph IV certification"), so the amended statute defined "first applicant" as "an applicant that, on the first day on which a substantially complete application containing a [Paragraph IV] certification … is submitted for approval of a drug, [1] submits a substantially complete application that [2] contains and [3] lawfully maintains a [Paragraph IV] certification … for the drug." *Id.* § 355(j)(5)(B)(iv)(II)(bb).

For more than a decade after the MMA's enactment, FDA declined to implement the MMA's amendments through notice-and-comment rulemaking. Instead, it opted to resolve legal questions that arose under the MMA on a case-by-case basis, through informal letter rulings—occasionally after seeking comment from interested parties, but often not. On February 6, 2015, however, FDA proposed new regulations that expressly sought to maintain FDA's pre-MMA rule that proper notice of a Paragraph IV certification is necessary to qualify for 180-day exclusivity—even invoking the D.C. Circuit's *Purepac* decision for support:

> [T]he controlling date for purposes of first applicant eligibility is the date on which the amendment or supplement to the ANDA containing a paragraph IV certification is submitted (*i.e.*, officially received (date-stamped) by the OGD Document Room) ***as long as notice is timely provided in accordance with the statute***…. If an ANDA applicant does not provide notice of a paragraph IV certification [in accordance with the applicable statutory deadline for doing so], ***FDA will consider the paragraph IV certification to be effective only as of the date that the applicant has both submitted … the paragraph IV certification and sent the notice (see Purepac Pharmaceutical Co. v. Thompson,* 354 F.3d 877 (D.C. Cir. 2004)*)**.

80 Fed Reg. at 6835 (emphasis added).

FDA didn't merely announce this rule in the MMA Proposed Rule's preamble; it incorporated that rule directly into its proposed regulations: "***If an ANDA***

applicant's notice of its paragraph IV certification is timely provided in accordance with paragraph (b) of this section, FDA will base its determination ***of whether the applicant is a first applicant*** on the date of submission of the amendment containing the paragraph IV certification." *Id.* at 6890 (emphasis added) (proposed 21 C.F.R. § 314.95(d)(2)). Other proposed rules likewise reflected FDA's adherence to its pre-MMA position that qualifying for 180-day exclusivity hinges on timely notice of a Paragraph IV certification. *See id.* at 6835-36 (proposing rule that ANDA applicants cannot dispatch notice of a Paragraph IV certification until "the first working day after the day the patent is listed in the Orange Book" because "the opportunity ***to be a first applicant*** with respect to a patent that is newly listed in the Orange Book ***(i.e., to submit an amendment to the ANDA containing a paragraph IV certification*** <u>and</u> ***send notice of the paragraph IV certification on that same day)*** could be affected by, among other things, the time zone in which the ANDA applicant resides") (citing proposed 21 C.F.R. §§ 314.95(b)(2) and 314.94(a)(12)(viii)(C)(1)(ii); emphases added).

After receiving comments, FDA finalized its proposed regulations without relevant alteration on October 6, 2016. *See* 81 Fed. Reg. 69580. Indeed, FDA's Final Rule expressly reiterated that applicants must dispatch "notice within the required timeframe … to satisfy the notice requirement of the FD&C Act ***and, in the case of a first applicant, to qualify for 180-day exclusivity***," and altered the text of the relevant regulations only to underscore that first-applicant status requires "***an ANDA applicant's notice of paragraph IV certification [to be]***

timely provided." *Id.* at 69609-10 (emphasis added); *see also* 21 C.F.R. § 314.95(d)(2) ("***If an ANDA applicant's notice of its paragraph IV certification is timely provided***..., FDA will base its determination of whether the applicant is a first applicant on the date of submission of the amendment containing the paragraph IV certification.") (emphasis added).

By October 2016, then, FDA had adopted formal regulations—through APA notice-and-comment rulemaking—making clear (A) that, as under the original statute, post-MMA eligibility for 180-day exclusivity hinges on timely providing the legally-required notice of a Paragraph IV certification, and (B) that, in determining whether a Paragraph IV challenger qualifies as an exclusivity-eligible "first applicant," an applicant would be credited only, and so long as, it timely provides notice in accordance with both the MMA and FDA's regulations.

B. Facts Related to Restasis® and Generic Cyclosporine Products

1. Restasis®

Restasis® (cyclosporine ophthalmic emulsion) is "indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca." Restasis® Full Prescribing Information, at l (July 2017 ed.), *available at* https://www.allergan.com/assets/pdf/restasis_pi.pdf (last visited Oct. 16, 2018). FDA first approved Restasis® on December 23, 2002 under NDA No. 050790, and Allergan initially listed two patents in the Orange Book: U.S. Patent Nos. 4,839,342 ("the '342 patent"), which expired August 2, 2009, and 5,474,979 ("the '979 patent"), which expired May 17, 2014. Compl. ¶ 29.

2. Initial Developments Regarding Teva's ANDA

On January 23, 2012, Teva submitted its cyclosporine ANDA to FDA. At that time, FDA had not yet released any guidance recommending the tests ANDA applicants should perform or the standards they should satisfy in attempting to demonstrate BE to Restasis®. Consistent with FDA's longstanding position that such guidance is non-binding even when finalized and that applicants always remain free to use alternative approaches, *see* 21 C.F.R. § 10.115(d), Teva's ANDA thus included substantial data and provided a detailed justification explaining why its data and analytical methods were sufficient to demonstrate its product's chemical equivalence and BE to Restasis®. Finally, Teva's ANDA included a Paragraph III certification to the '979 patent, which by then was the only unexpired patent listed in the Orange Book. Compl. ¶ 30.

Once Teva submitted its ANDA, FDA began its customary pre-filing review of Teva's ANDA for "substantial completeness," which entails a threshold assessment of whether the as-submitted ANDA is "on its face is sufficiently complete to permit a substantive review and contains all the information required by [21 U.S.C. § 355(j)](2)(A)." 21 U.S.C. §355(j)(5)(B)(iv)(II)(cc); *see also* 21 C.F.R. § 314.101(b)(1). That process, however, was plagued by irregularities. On April 19, 2013 (more than a year after Teva submitted its ANDA), FDA requested additional information from Teva—nearly all of which had been provided in Teva's original ANDA. Compl. ¶ 31 (citing Letter from M. Shimer to Teva (the "IR"), at 1 (Apr. 19, 2013)). Teva contacted FDA on May 1, 2013 to discuss the IR, and on May 9, 2013 submitted a formal response (A) identifying where the original ANDA included the requested information and (B) either re-providing or summarizing the information already contained in Teva's ANDA. *Id*. (citing Letter from P. Jaworski to K. Uhl (the "IR Resp."), at 1-6 (May 9, 2013)).

While FDA was considering Teva's IR Response, the Agency published its first draft BE guidance document for Restasis®-referencing ANDAs in June 2013. *See* FDA, Draft Guidance on Cyclosporine (the "June 2013 Draft Guidance") (June 2013 ed.). FDA then notified Teva that it was refusing to file (or "receive") the company's ANDA because Teva's ***January 2012*** ANDA "ha[d] not demonstrated bioequivalence [to] the RLD" in accordance with the methods FDA recommended in its ***June 2013*** Draft Guidance. Compl. ¶ 32 (quoting Letter from W. Rickman & M. Shimer to Teva (the "RTR Letter") at 1 (Sept. 5, 2013)). The RTR Letter directed Teva to "follow the draft guidance" and resubmit its ANDA. *Id*. (same).

That development was doubly problematic. ***First***, and as noted above, such guidance documents aren't binding even when finalized, and FDA's review for substantial completeness is not in any event supposed to evaluate whether a submitted ANDA actually "demonstrated bioequivalence [to] the RLD." *Id*. Instead, the relevant question is whether the submitted ANDA is facially sufficient—meaning that it makes a plausible effort to show BE:

> This assessment [for substantial completeness] does ***not*** involve evaluating whether the data and information in the ANDA are in fact sufficient to demonstrate that the [ANDA] meets a requirement for approval, such as bioequivalence. Rather, the assessment involves

> evaluating whether the data and information in the ANDA are the types of data and information that could plausibly support an approval action and hence merit further review by the Agency.

FDA Docket No. 2015-P-0065-0027, at 39 (Feb. 10, 2016) (emphasis added); *see also* 21 C.F.R. § 314.101(d)(3) (allowing FDA to refuse to receive an ANDA only if "it does not ***on its face*** contain information required") (emphasis added). FDA's refusal even to receive Teva's ANDA for review because it "has not demonstrated bioequivalence" violated that rule.

Second, FDA's RTR decision jeopardized Teva's ability to qualify for 180-day exclusivity. Though Teva's original ANDA had contained only a non-exclusivity-qualifying Paragraph III certification to the '979 patent, Allergan had filed a new Restasis®-related patent application with the PTO shortly after FDA issued its RTR Letter and—while Teva was considering its response to the RTR Letter—PTO announced that it would issue U.S. Patent No. 8,629,111 ("the '111 patent") on January 14, 2014. Official Gazette of the PTO (Dec. 12, 2013). Because Teva believed Allergan's forthcoming patent was vulnerable to challenge, Teva naturally wanted to submit a Paragraph IV certification that could qualify it for exclusivity and enable the company to bring a lower-cost generic version of Restasis® to market before the '111 patent's scheduled expiry. But if Teva were forced to submit a new ANDA based on the June 2013 Draft Guidance and another applicant challenged the '111 patent in the interim, Teva would not be eligible for exclusivity—and indeed could be delayed in launching its generic version of Restasis® at the conclusion of FDA's review process. Compl. ¶ 34.

On January 13, 2014, Teva therefore asked FDA to vacate its RTR decision and receive Teva's previously-submitted ANDA so that the company could challenge the '111 patent as soon as Allergan listed it. Compl. ¶ 35 (citing Letter from S. Tomsky to K. Uhl (the "Rescission Request") at 1-2 (Jan. 13, 2014)). Beyond providing a legal rationale for vacating the RTR decision, Teva informed FDA that it would "begin submitting Paragraph IV certifications to the '111 patent upon issuance, in order to fully preserve its rights if and when FDA grants the relief requested." *Id.* (quoting Rescission Request at 2). On January 14, 2014—the same day that PTO issued the '111 patent and Allergan listed it in the Orange Book—Teva therefore amended its ANDA to include a Paragraph IV certification to the newly-issued and newly-listed '111 patent. *Id.* (citing Letter from S. Tomsky to K. Uhl (the "P-IV Amendment"), at 1-2 (Jan. 14, 2014)). Accordingly, Teva challenged the '111 patent on the first possible day—*i.e.*, the first day the '111 patent was submitted for listing in the Orange Book. *Id.*

Because Teva's Paragraph IV certification was contained in an amendment to its previously-submitted-but-not-yet-received ANDA, the statute ordinarily would have required Teva to notify Allergan of its certification at the same time it submitted its amendment to FDA. *Supra* at 7-8 (discussing 21 C.F.R. § 314.95(d)). But FDA consistently has held that applicants may not dispatch such notice until FDA receives first an ANDA for review; instead, FDA's judicially-affirmed rule is and has been that the legally-required notice will be considered timely-provided only (and so long as) it is dispatched within 20 days after FDA's acknowledgement letter receiving a previously-submitted ANDA for review. *See, e.g.*, *Allergan, Inc. v. Actavis, Inc.*, Nos. 2:14-cv-638 & 2:14-cv-188, 2014 WL 7336692, *11-12 (E.D. Tex. Dec. 23, 2014) (affirming FDA's position). Teva's P-IV amendment therefore informed FDA that the company would send the legally-required notice to Allergan and the '111 patentees once FDA reversed its RTR decision and received Teva's ANDA for review. Compl. ¶ 36 (citing P-IV Amendment at 2).

On June 25, 2015 (some 29 months after Teva submitted its original ANDA to FDA), the Agency rescinded its RTR Letter—declaring that Teva's ANDA in fact had been substantially complete from the outset and concluding "that ANDA 203880 may be received for review as of January 23, 2012 (*i.e.*, the original submission date)." Compl. ¶ 37 (quoting Letter from J. Young to Teva (the "Rescission Letter") at 1 (June 25, 2015)). As FDA explained: "FDA has determined that the RTR decision erroneously was made [based upon a] product-specific bioequivalence (BE) guidance Draft guidance on Cyclosporine, which was not publicly available at the time of ANDA submission." *Id.* (same). FDA subsequently issued a formal letter acknowledging the receipt of Teva's ANDA, *id.* (citing Letter from V. Phung to Teva (the "Acknowledgement Letter") (July 9, 2015)), and Teva timely notified Allergan and the '111 patentees of its Paragraph IV certification. *Id.* (citing Letter from C. Wohlbach to FDA (the "Patent Amendment"), at 1 (Sept. 8, 2015) (confirming that Teva dispatched its notices on July 22, 2015 and that Allergan received Teva's notice on July 23, 2015)). Allergan then sued Teva for infringing the '111 patent—meaning that Teva not only assumed the risks associated with the submission and notice of its Paragraph IV certification, but in fact realized the very risks that 180-day exclusivity is intended to reward. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-01455 (E.D. Tex. filed Aug. 24, 2015).[2]

3. FDA Proceedings Concerning 180-Day Exclusivity For Cyclosporine ANDAs

On July 28, 2015, FDA opened a docket regarding 180-day exclusivity for ANDAs referencing Restasis®. Compl. ¶ 38 (citing Letter from T. Jetton to ANDA Applicants for Cyclosporine Ophthalmic Emulsion (the "Cyclosporine Comment Request"), FDA Docket No. 2015-N-2713 (July 28, 2015)). In particular, the Agency for the first time disclosed that at least one ANDA applicant had attempted to submit a Paragraph IV certification to the '979 patent before January 14, 2014 (*i.e.*, the date Allergan listed the '111 patent in the Orange Book and Teva submitted its Paragraph IV certification), "[b]ut the '979 patent expired before FDA issued an Acknowledgement Letter to any applicant with a pending ANDA." *Id.* (quoting Cyclosporine Comment Request at 3-4). Because this so-called "'979 Applicant" never notified Allergan of its certification before that patent expired, FDA asked cyclosporine ANDA applicants whether the '979 Applicant may have qualified for 180-day exclusivity despite failing to provide the legally-required notice. *Id.* (citing Cyclosporine Comment Request at 4).

[2] Allergan subsequently obtained several additional patents on Restasis®, which Teva likewise challenged by Paragraph IV certification. Those patents ultimately were added to Allergan's lawsuit, but are not relevant here.

The fact that FDA asked that question in July 2015 was puzzling. As set forth above, FDA proposed its MMA regulations in February 2015, and those proposed rules expressly and unambiguously provided that "first applicant" status hinges on providing the legally-required notice. *Supra* at 12-13. But FDA had not yet finalized its proposed regulations at the time it opened this docket, and its request for comments thus ensured that any potentially-affected ANDA applicants would focus on that aspect of the Proposed Rule. So along with its other comments on the Proposed Rules, Teva timely submitted comments to the cyclosporine docket that embraced FDA's proposal that "'[n]otice of paragraph IV certification in accordance with applicable regulations also is necessary for an ANDA applicant to be eligible for 180-day exclusivity.'" Compl. ¶ 39 (quoting Letter from M. Shumsky to M. Toufanian (the "Teva Cyclosporine Comments") at 8 (Sept. 28, 2015) (itself quoting 80 Fed. Reg. at 6862)). As Teva explained: "Because the '979 Applicant(s) failed to provide a valid notice prior to the '979 patent's expiration, any putative paragraph IV certification that the '979 Applicant(s) sent to FDA was incapable of grounding eligibility for exclusivity; it was a legal nullity given the absence of a valid notice." *Id.* (quoting Teva Cyclosporine Comments at 10 (itself citing 80 Fed. Reg. at 6862)).

4. FDA Promulgates Its MMA Regulations—And Then Reneges On Them

On October 6, 2016, FDA finalized its MMA-implementing regulations—expressly maintaining its proposed rule that eligibility for 180-day exclusivity hinges on the provision of a valid Paragraph IV notice to the brand manufacturer.

Supra at 13-14. With FDA having made clear that the '979 Applicant could not have qualified for 180-day exclusivity, and thus that Teva had qualified for 180-day exclusivity by virtue of its Paragraph IV certification to the '111 patent, Teva prioritized its cyclosporine ANDA with the aim of launching the product, with exclusivity, at the earliest opportunity. Compl. ¶ 40. On October 16, 2017, Teva won its patent litigation with Allergan—securing a district court decision declaring Allergan's asserted patents to be invalid and thereby opening the market to competition years before those patents were set to expire. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, Case No. 2:15-cv-1455-WCB, 2017 WL 4803941 (E.D. Tex. Oct. 16, 2017) (Bryson, Cir. J., sitting by designation).[3] While Teva continued to work on perfecting its pending ANDA in proceedings before the Agency, Health Canada—FDA's Canadian counterpart—approved Teva's Canadian application in May 2018 for the same formulation Teva is seeking to market here and Teva successfully launched its product as the first-approved generic version of Restasis® in Canada. Compl. ¶ 40. Given the success of that launch, Teva ramped up its production in anticipation of an imminent U.S. approval with 180-day marketing exclusivity, in full accordance with FDA's now-effective MMA regulations. Compl. ¶ 40 (citing Decl. of C. Groff ¶ 12, attached as Compl. Exh. A).

[3] Allergan timely noticed an appeal to the U.S. Court of Appeals for the Federal Circuit, and that appeal remains pending. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, Case No. 18-1130 (Fed. Cir. docketed Nov. 1, 2017).

On July 13, 2018, however, FDA blindsided Teva by issuing a letter decision in another matter holding that ANDA applicants can qualify for 180-day exclusivity even if they never provide the brand manufacturer with the legally-required notice of a putative Paragraph IV certification. Letter from C. Pruitt to ANDA Applicants for Buprenorphine and Naloxone Sublingual Film (the "Letter Decision") at 12 (July 13, 2018) (attached as Compl. Exh. B). There, as here, a generic applicant submitted a Paragraph IV certification to a listed patent before any other applicant had done so, but never provided the brand manufacturer with notice of its putative Paragraph IV certification. *Id.* at 6. In addressing whether that applicant nonetheless qualified for 180-day exclusivity, FDA initially conceded that its MMA regulations expressly maintained the Agency's longstanding position that eligibility for 180-day exclusivity requires timely notice of the exclusivity-qualifying Paragraph IV certification. *Id.* at 8 & n.35 (quoting MMA Final Rule, 81 Fed. Reg. at 69608-10, 69617). But FDA quickly dismissed that fact on the ground that the MMA regulations principally addressed cases in which a Paragraph IV certification was submitted *via* amendment to an ANDA rather than in an original ANDA, *id.*—even though exclusivity can be awarded only to a "first applicant," even though the MMA defines "first applicant" without regard to whether the potentially-exclusivity-qualifying certification is contained in an original ANDA or submitted *via* amendment, *see* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb), and even though the Agency's decision went on to adopt the same rule for both amended ANDAs and original ANDAs. *See* Letter Decision at 9-10.

On the merits, FDA asserted that its new rule was more consistent with the statute's language than its duly-promulgated MMA regulations because the MMA's definition of "first applicant" allegedly provides that

> there can only ever be one "first day on which a substantially complete application containing a paragraph IV certification … is submitted," ***regardless of whether the applicant that submits its application (or an amendment or supplement to its application) on that "first day" gives or fails to give timely notice of and/or otherwise lawfully maintains its paragraph IV certification***.

Id. at 9 (emphasis added). FDA further asserted that its new rule was more "consistent with the structure of the MMA" because the statute elsewhere provides that 180-day exclusivity does not "roll" to a subsequent applicant after the "first applicant" loses its eligibility for 180-day exclusivity. *Id*. at 10-11. Given the unavoidable implication of that decision for Teva's cyclosporine exclusivity in light of the '979 Applicant's failure to notify Allergan of its Paragraph IV certification, this lawsuit follows. *See Teva v. Sebelius*, 595 F.3d at 1308-15 (holding that an alleged first applicant can obtain pre-enforcement judicial review of a precedential letter decision regarding FDA's 180-day exclusivity rules).

LEGAL STANDARD

To secure temporary injunctive relief, a plaintiff must establish "[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014) (citing *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011)). Teva readily meets all four prongs of this standard.

ARGUMENT

I. TEVA IS LIKELY TO SUCCEED ON THE MERITS.

A. FDA Violated The APA's Procedural Requirements.

FDA's Letter Decision violated the APA's procedural requirements in two ways. ***First***, it violated the APA by undoing legislative rules promulgated through the notice-and-comment process without undertaking a new round of notice-and-comment rulemaking. ***Second***, it violated the APA by failing to account for the reliance interests it upended by effectively vitiating FDA's longstanding rule.

1. FDA Violated The APA By Overturning Its MMA Regulations Without Notice-and-Comment Rulemaking.

FDA's letter decision upends a legislative rule that duly was promulgated through notice-and-comment rulemaking. That violates the APA, which bars agencies from reversing rules issued through notice-and-comment rulemaking outside the notice-and-comment rulemaking process. FDA may no longer like its MMA implementing rules, but that is not a lawful basis for overturning them outside the notice-and-comment rulemaking process.

We of course acknowledge that agencies generally have leeway to choose between notice-and-comment rulemaking and adjudication in the first instance. *See, e.g.*, *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). And as set forth above, FDA for many years opted to implement the MMA through quasi-adjudicative letter decisions like the one at issue here. But the Agency's decision to undertake formal notice-and-comment rulemaking in 2013 here put FDA on a different path—subjecting it to the well-settled rule that an agency cannot repeal or modify a rule promulgated through the notice-and-comment process in a subsequent adjudicatory proceeding. *See, e.g.*, *Am. Fed'n of Gov't Emps., AFL-CIO v. Fed. Labor Relations Auth.*, 777 F.2d 751, 759 (D.C. Cir. 1985) ("[A]n agency seeking to repeal or modify a legislative rule promulgated by means of notice and comment rulemaking is obligated to undertake similar procedures to accomplish such modification or repeal...."). In short, once an agency promulgates a rule through notice-and-comment rulemaking, it can undo the rule only through notice-and-comment rulemaking. *Cent. Texas Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 211 (D.C. Cir. 2005) ("If a 'second rule repudiates or is irreconcilable with [a prior legislative rule], the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative.'") (quoting *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993), with alterations in original); *cf. Tunik v. Merit Sys. Prot. Bd.*, 407 F.3d 1326, 1341–42, 1345–46 (Fed. Cir. 2005) (overturning agency's abrogation of a prior adjudicatory decision during a new adjudication because it had codified the earlier decision through notice-and-comment rulemaking).

That rule controls here. After a multiyear notice-and-comment-rulemaking process, FDA formally promulgated legislative rules implementing the MMA's 180-day exclusivity, first-applicant, and Paragraph IV notice provisions through notice-and-comment rulemaking. FDA detailed its considered views in its February 2015 Proposed Rule, where it addressed qualification for 180-day exclusivity under the MMA and expressly confirmed its longstanding rule that "[n]otice of paragraph IV certification in accordance with applicable regulations also is necessary for an ANDA applicant to be eligible for 180-day exclusivity based upon a paragraph IV certification." 80 Fed. Reg. at 6862. The Agency then received scores of comments on the proposed rules, including comments relating to the definition of "first applicant." *See* MMA Final Rule, 81 Fed. Reg. at 69580, 69591, 69594–95 (summarizing comments). And while its proposed rules were pending, FDA solicited and received additional comments about this issue, from the applicants it knew would be affected by its final rule in this particular matter. *See* Cyclosporine Comment Request and Docket No. FDA-2015-N-2713.

After considering the entirety of the record it assembled, FDA promulgated a final rule that explicitly and unambiguously maintained the Agency's longstanding rule that applicants are "required to []send notice within the required timeframe after the … ANDA has been … received" in order "to qualify for 180-day exclusivity." *Id.* at 69609. Having thus promulgated final rules through notice-and-comment rulemaking, in which it unambiguously declared that an ANDA applicant cannot qualify for 180-day exclusivity unless it sends the legally-required notice of its Paragraph IV certification, FDA could not lawfully retreat from that position without conducting a new round of notice-and-comment rulemaking. *See, e.g., Cent. Texas Tel. Co-op.*, 402 F.3d at 211. It did so anyway, and FDA should be enjoined from applying its unlawful Letter Decision here.

2. FDA Violated The APA By Overturning Its MMA Rules Without Considering Teva's Reliance Interests.

FDA's abrogation of its MMA regulations violates the APA in a second way: Its decision failed even to mention—much less consider—the affected parties' reliance interests. Separate and apart from the fact that FDA acted outside the legally-required process, its failure to account for those reliance interests is fatal. While "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change" and "'show that there are good reasons for the new policy,'" they must also "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). "[A]n '[u]nexplained inconsistency' in agency policy" is "arbitrary and capricious" by definition. *Id.* at 2126 (quoting *Nat'l Cable & Telecomm. Assn. v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)); *see also Fox Television*, 556 U.S. at 515 ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.") (citing *United States v. Nixon*, 418 U.S. 683, 696 (1974)).

FDA failed to account for those interests here. For nearly two decades, the Agency consistently has conditioned eligibility for 180-day exclusivity on the first applicant's delivery of a valid Paragraph IV notice to the brand manufacturer and patentees. *See supra* at 10-11. And for more than a decade, the courts have embraced that rule. *See, e.g.*, *Purepac*, 354 F.3d 877. This rule's longstanding pedigree in turn has engendered weighty reliance interests. As set forth above, 180-

day exclusivity plays a crucial role in the Hatch-Waxman scheme by incentivizing generic applicants to assume risks they otherwise might forego—namely, to subject themselves to years of costly patent litigation based on the prospect of an exclusive launch. *Teva v. Sebelius*, 595 F.3d at 1318 (explaining that 180-day exclusivity is designed "to induce challenges to patents … by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit)."). This longstanding and repeatedly-reaffirmed rule in turn has assured applicants like Teva that the exclusivity reward they earned by "sticking out their necks … at the potential cost of a patent infringement suit," *id.*, cannot be undone by a stealth applicant who never notifies the brand manufacturer of its patent challenge and so assumes none of the risks Congress sought to reward (and Teva actually realized).

FDA cast no doubt on the vitality of its longstanding approach in the 10-plus years between the MMA's enactment in 2003 and Teva's submission of a Paragraph IV certification to the '111 patent in January 2014. And any abstract questions that could have been raised were settled during FDA's MMA notice-and-comment rulemaking—when its Proposed Rule expressly re-affirmed FDA's longstanding position (even citing *Purepac* for support, 80 Fed. Reg. at 6835), and its Final Rule formally maintained that position after receiving comments both in the cyclosporine docket and in response to the Proposed Rule. 81 Fed. Reg. at 69610.

Interested parties thus had every reason to think this issue was settled and proceed accordingly. For Teva, that meant prioritizing its cyclosporine ANDA at all costs. As set forth in Groff Declaration, Teva not only placed significant "orders for supplies and components necessary to support the launch of its generic Restasis® product with 180-day exclusivity," but made "significant investments to expand its production capacity at the planned manufacturing site for this product—including the design, build, installation, qualification, and validation of an additional production line that was required to support an exclusive launch for generic Restasis® and which Teva purchased in reliance on FDA's longstanding position and recently promulgated regulations regarding 180-day exclusivity." Groff Decl. ¶ 11. Moreover, Teva diverted legal, regulatory, planning, and management resources from other matters to focus on launching its generic Restasis® product with exclusivity, even "alter[ing] its plans for at least one other product in order to focus its limited resources and plant capacity on producing sufficient quantities of generic Restasis® to support a launch of this product with 180-day exclusivity." *Id.* at ¶ 12.

Yet FDA's sudden decision to jettison decades of recently-reaffirmed precedent yanked the rug out from under Teva without even mentioning the significant reliance interests its longstanding policy had engendered, much less "tak[ing] into account" those interests and "show[ing] that there are good reasons for" retroactively applying its new rule to events that were set in motion years earlier. That failure likewise weighs in favor of injunctive relief. *Encino Motorcars*, 136 S. Ct. at 2125-26 (internal quotations omitted).

B. FDA's Decision Conflicts With The MMA's Text And Structure.

FDA's decision fares no better on substance than it does on procedure. By its plain terms, the MMA requires a generic applicant to do three things in order to become a "first applicant" that is eligible for 180-day exclusivity: It must "[1] submit[] a substantially complete application that [2] contains and [3] lawfully maintains a [Paragraph IV] certification." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (defining "first applicant"); *see also id.* § 355(j)(5)(B)(iv)(I) (awarding exclusivity only to a "first applicant"). By linking these requirements with the conjunctive word "and," the MMA's plain language makes clear that an applicant can qualify for 180-day exclusivity only if it satisfies ***each*** of these conditions—and, thus, that an ANDA applicant who fails to complete ***any*** one of those three steps cannot be a "first applicant" that qualifies for exclusivity. *See, e.g.*, *Winkelman ex rel. Winkelman v. Parma City Sch. Dist.*, 550 U.S. 516, 527-28 (2007) (reading the word "and" conjunctively and explaining that any alternative reading "would make no sense"); *Crooks v. Harrelson*, 282 U.S. 55, 58 (1930) (explaining that Congress's use of the word "and" is conjunctive "in its ordinary sense").

That means an ANDA applicant seeking to qualify for 180-day exclusivity as a "first applicant" must do more than merely (1) submit a substantially complete ANDA that (2) contains a Paragraph IV certification. It must also (3) "lawfully maintain" that Paragraph IV certification. Any other approach writes the "lawful maintenance" requirement out of the statute and thereby violates the cardinal rule of statutory interpretation: that "a statute should be construed so that effect is given to all of its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (internal quotation and alteration omitted); *see also N.L.R.B. v. SW General, Inc.*, 137 S. Ct.

929, 941 (2017) (rejecting agency's interpretation of a three-part statutory standard because it "makes the first requirement superfluous, a result we typically try to avoid") (citing *Williams v. Taylor*, 529 U.S. 362, 404 (2000) ("It is ... a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute.") (internal quotation marks omitted)).

There is no dispute over what it takes to "lawfully maintain" a Paragraph IV certification: The applicant must comply with all requirements for Paragraph IV certifications, including the legal requirement to notify the brand manufacturer and patentees of its certification. Again, the Agency has made that clear for more than a decade. *See, e.g.*, Gabapentin Letter Decision at 7 ("[T]he statute makes the first applicant to submit a paragraph IV certification to a patent eligible for exclusivity, ***and it also requires that the ANDA applicant give notice [of its certification]***.") (emphasis added). And nothing in the MMA alters or undermines those legal requirements. Just as the original statute required applicants to notify the brand manufacturer and patentee(s) of their Paragraph IV certifications, the MMA requires applicants to do so. 21 U.S.C. § 355(j)(2)(B). And just as the rest of the original statute turned on the applicant's notice, so too does the MMA. *See, e.g.*, *id.* § 355(j)(5)(B)(iii) (30-month stay in brand-initiated patent infringement litigation pegged to receipt of notice); *id.* § 355(j)(5)(C)(i)(I)(aa) (ANDA applicant cannot file declaratory judgment action until notice has been provided and the 45-day automatic stay clock expires); 35 U.S.C. § 271(e)(5) (same). Even so, FDA's Letter Decision held that the first applicant who submits a Paragraph IV certification to the Agency qualifies for 180-day exclusivity "regardless of whether the applicant … gives or fails to give timely notice of and/or otherwise lawfully maintains its paragraph IV certification." Letter Decision at 9; *see also id.* at 6 (holding that applicant "qualified as a 'First Applicant'" even though "it had not given notice to the NDA holder or patent owner").

To its credit, FDA at least recognized that its interpretation does violence to the statute's text by gutting the lawful-maintenance requirement. That is why the Agency took pains to assert that, despite its interpretation of the "first applicant" definition, "an applicant must [still] meet all three prongs ***to obtain*** 180-day exclusivity," *id.* at 9 (emphasis added)—that is, ***to have*** 180-day exclusivity once its ANDA is approved, and not merely ***to qualify*** for that reward in the first instance. But that attempt to breathe life back into the lawful-maintenance requirement misses the point. The relevant question here is what it takes for an ANDA applicant to become eligible for exclusivity in the first instance—that is, to be a "first applicant"—and the statute makes clear (and always has made clear) that lawful notice of the applicant's Paragraph IV certification is a precondition to so qualifying. Whether a "first applicant" that met all the exclusivity-qualifying statutory criteria actually will enjoy that exclusivity down the road is a separate question that, as FDA's decision elsewhere noted, is addressed by separate statutory "provisions addressing the forfeiture of eligibility for exclusivity by a 'First Applicant.'" *Id.* at 10-11; *see also* 21 U.S.C. § 355(j)(5)(D)(i)(I)-(VI) (providing for the "forfeiture of 180-day exclusivity" where a "first applicant" that initially qualified for such exclusivity does or does not do certain things).

Indeed, FDA long ago recognized the distinction between ***qualifying*** for 180-day exclusivity in the first place and actually ***having*** such exclusivity after approval. As the Agency previously explained to the D.C. Circuit:

> [E]xclusivity does not vest with the first filing of an ANDA with a paragraph IV certification, and the most that can be said for a first-filer is that it is ***eligible*** at the time of filing for a period of generic exclusivity but that factors arising ***after*** its filing … might mean that it will not actually obtain a period of such exclusivity.

Br. for the Appellants, *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), 2006 WL 1757180, *26-27 (filed June 21, 2006) (emphases in original). The fact that FDA now finds itself forced to conflate qualifying for exclusivity at the outset and enjoying exclusivity post-approval does not solve the conflict between its position and the statute's plain language; it highlights it.

As for FDA's apparent belief that the MMA's forfeiture provisions somehow help its argument on this point, *see* Letter Decision at 10-11, they in fact undermine it. Though the MMA enumerates several "forfeiture events" that might cause an exclusivity-qualifying "first applicant" to lose its eligibility for 180-day exclusivity (for instance, by failing to market its product within certain timeframes, 21 U.S.C. § 355(j)(5)(D)(i)(I), withdrawing its ANDA, *id.* § 355(j)(5)(D)(i)(II), or amending its Paragraph IV certification, *id.* § 355(j)(5)(D)(i)(III)), failing to provide the legally-required notice of a Paragraph IV certification assuredly is not one of the MMA's enumerated forfeiture events. Just as FDA cannot write criteria ***out of*** the statute's exclusivity provisions, however, the D.C. Circuit repeatedly has warned

FDA that it cannot write new exceptions ***into*** the law's exclusivity provisions. *See, e.g.*, *Ranbaxy*, 469 F.3d at 125 ("We have previously rejected at *Chevron* step one the FDA's attempt to add to the statutory requirements for exclusivity.") (discussing *Mova*, 140 F.3d at 1069-70). As a result, FDA's decision not only writes the lawful-maintenance requirement out of the MMA's "first applicant" definition; it conflicts with the MMA's forfeiture provisions by writing a new forfeiture event into them.

Rather than engage the statute's express requirement that an applicant can qualify for exclusivity only if it timely notifies the brand manufacturer of its Paragraph IV certification, FDA's letter decision focused exclusively on the "first applicant" definition's timing subclause—which references "the first day on which a substantially complete application containing a [Paragraph IV] certification … is submitted for approval of a drug," but does not itself require that notice be provided on that first day to qualify for exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). According to FDA:

> The requirement that an applicant "lawfully maintain" its paragraph IV certification only appears in the second half of the "First Applicant" definition. Congress did not include the requirement that a paragraph IV certification be "lawfully maintained" in the "when" prong itself, so FDA interprets the requirement to "lawfully maintain" a paragraph IV certification to apply only to "First Applicants" who qualified for "First Applicant" status by submitting their paragraph IV certifications on the first day that a paragraph IV certification was submitted for that drug.

Letter Decision at 10.

But FDA could have made exactly the same argument about the pre-MMA statute. As we noted earlier, the original statute awarded exclusivity to the first Paragraph IV filer by blocking the approval of any subsequently-filed ANDA for which "a previous [ANDA] has been submitted under this subsection cont[ain]ing such a [Paragraph IV] certification." 21 U.S.C. § 355(j)(5)(B)(iv) (pre-2003). Because only one Paragraph IV-containing ANDA can be "previous" to all others, the original statute likewise keyed qualification for exclusivity to submission of a Paragraph IV certification on the "first day" that any such certification was submitted—and, just as the MMA's timing subclause does not embed a notice requirement, the pre-MMA statute's exclusivity provision did not embed a notice requirement. Yet FDA previously had no trouble recognizing that it would make no sense to award exclusivity to an applicant that never provides the legally-required notice and thereafter bar the first applicant who does comply with the statute's notice requirements from qualifying for its statutory reward:

> [T]he statute makes the first applicant to submit a paragraph IV certification to a patent eligible for exclusivity, and it also requires that the ANDA applicant give notice. [In determining] the relevant date for exclusivity purposes…, the agency will look to the date that [the first applicant] actually sent the required notice, since this is the date upon which [the first applicant] effectively met the statutory requirements by having both submitted a paragraph IV certification and sent notice of the submission.

Gabapentin Letter Decision at 7-8. Again, nothing in the MMA changes the structural features of the statute that led FDA to adopt to its longstanding, judicially-affirmed approach. And to reiterate, nothing in the amended statute otherwise distinguishes this aspect of the MMA from the original statute—except that the MMA's "first applicant" definition now expressly requires that notice timely be provided, whereas FDA and the courts previously based that requirement exclusively on the statute's broader text and structure. If anything, then, the

MMA's amended text only strengthens the basis for FDA's longstanding approach, which of course explains why the Agency's MMA rulemaking expressly applied FDA's longstanding approach to post-MMA cases like this one. *See, e.g.*, MMA Proposed Rule, 80 Fed. Reg. at 6835-36 (citing *Purepac*); *id.* at 6890 (requiring that "notice of its paragraph IV certification [be] timely provided" to be "a first applicant"); MMA Final Rule, 81 Fed. Reg. at 69610 (adopting this rule).

Nor does FDA's isolated focus on the timing subclause's reference to the "first day" make sense on its own terms. As we previously explained, both the pre-MMA statute and the MMA make clear that ANDA applicants generally ***cannot*** provide notice of a Paragraph IV certification on the same day they submit that certification to FDA. Instead, where a potential exclusivity-qualifying Paragraph IV certification is contained in an original ANDA (as most such certifications are), the applicant cannot send notice until FDA first receives the applicant's ANDA for review—a process that often takes months and, as Teva's cyclosporine ANDA shows, sometimes takes years. *See* 21 U.S.C. § 355(j)(2)(B)(ii)(I) (requiring that "if the [Paragraph IV] certification is in the [original] application," notice must be given within "20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the [ANDA] has been filed"); *see also Allergan*, 2014 WL 7336692, at *11-12 (affirming that notice may not be sent until FDA first receives an ANDA for review).

It therefore would not have made any sense for Congress to embed the notice requirement within the "first applicant" definition's timing subclause, since submission of a Paragraph IV certification and notice of that certification generally cannot happen on the same "first day." *Id*. Put differently, the MMA's lack of a reference to the "lawful maintenance" requirement within the "first applicant" definition's timing subclause hardly signals Congress's intent to abrogate FDA's longstanding interpretation, absolve Paragraph IV filers of their obligation to provide such notice in order to qualify for exclusivity, and block the first applicant who actually complies with the statute from obtaining its reward; it simply reflects that, in the mine run of cases, there cannot be one "first day" on which an exclusivity-qualifying certification can be submitted ***and*** notice provided.

Rather than rendering the statute's "first day" reference irrelevant (which, to reiterate, is what FDA's approach otherwise does to the lawful maintenance requirement), requiring lawful notice of a Paragraph IV certification to qualify for exclusivity simply ensures that the relevant "first day" is one on which there actually is an exclusivity-qualifying first applicant. Thus, where an applicant lawfully provides notice of its previously-submitted Paragraph IV certification, the statute grants that applicant the full benefit of its original submission date because the applicant's Paragraph IV certification (1) was submitted on that date (2) in a substantially complete ANDA and (3) lawfully maintained. Where, by contrast, an applicant never provides the notice on which the entire Paragraph IV scheme depends, the date of its Paragraph IV certification is irrelevant: That applicant never perfected its Paragraph IV certification and so did not satisfy the statutory criteria that an exclusivity-qualifying "first applicant" must meet. In either case, the date the Paragraph IV certification was submitted to FDA is the relevant "first day" in determining the applicant's place in line for 180-day exclusivity. If notice timely is provided, the applicant is a "first applicant" entitled to 180-day exclusivity by virtue of its first-day submission. And if not, then that applicant isn't eligible for exclusivity, so the day it submitted its putative-but-legally-ineffective Paragraph IV certification is irrelevant; the first applicant who actually meets all three statutory requirements for 180-day exclusivity is the "first applicant" as of the date it submitted its properly-noticed and thus legally-valid Paragraph IV certification.

FDA's only response is that construing the relevant "first day" as one on which there is an applicant which actually met all the statutory criteria for being a "first applicant" somehow conflicts with the statutory rule that "if all first applicants forfeit exclusivity, no applicant is eligible for exclusivity." Letter Decision at 11 (discussing 21 U.S.C. § 355(j)(5)(D)(iii)); *see also id.* ("This outcome that exclusivity rolls to another applicant … thus seems to conflict with Congress's intent and the statutory provision that states that no applicant shall be eligible for a 180-day exclusivity period if all first applicants forfeit the 180-day exclusivity period.") (same). This claim is mystifying. The statute's "anti-rolling" provision applies only where "all ***first applicants*** forfeit the 180-day exclusivity period." 21 U.S.C. § 355(j)(5)(D)(iii) (emphasis added). But an applicant that never provides the legally-required notice of its certification never qualified as a "first applicant" that was eligible for exclusivity in the first place, so it had no exclusivity to "forfeit." *See, e.g.*, *Webster's Third New Int'l Dictionary—Unabridged* 891 (1976) (defining "forfeiture" as the "loss of some right [or] privilege"); *id*. at 1338 (defining "loss" as "failure to keep possession"). In short, one cannot forfeit something it never had—and because an applicant that fails to provide the legally-required notice is not a "first applicant," the statute's anti-rolling provision never comes into play.

FDA's zealously anti-exclusivity but rigorously atextual reading of the statute's anti-rolling provision thus does nothing to reconcile its position with the statute's text, structure, and legislative intent. Instead, it only highlights FDA's departure from Congress's design. As our brief has taken pains to explain, the whole point of the statute's intertwined patent-submission, patent-listing, Paragraph IV certification, Paragraph IV notice, patent-litigation, and 180-day exclusivity provisions is to incentivize generic applicants to take the risks necessary to lift the shadow of uncertainty cast by an innovator's patents and, where an applicant's challenge succeeds, break the patent logjam so that generic competition can begin before the innovator's patents otherwise would allow. *Teva v. Sebelius*, 595 F.3d at 1318 (explaining that 180-day exclusivity "is a pro-consumer device [that] Congress has chosen to induce challenges to patents claimed to support brand drugs [by] reward[ing] generics that stick out their necks (at the potential cost of a patent infringement suit)"); *Teva v. Leavitt*, 548 F.3d at 106 ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

Coupled with its parsimonious reading of the statute's "first applicant" definition, however, FDA's counter-textual invocation of the MMA's anti-rolling provision not only undermines Hatch-Waxman's structure, but effectively stalls its engine. Again, the Agency's decision (A) rewards applicants who do not comply with the statute's requirements, assume no risk from their actions, and thus cannot do what the statute is designed to do, with eligibility for 180-day exclusivity, while (B) denying that reward to an applicant which, like Teva here, does precisely what the statute requires before anyone else, successfully breaks the patent logjam, and opens the market to early generic competition. That is why, until now, FDA consistently maintained that 180-day exclusivity hinges on the submission of a valid Paragraph IV certification and corresponding notice to the innovator (including in its MMA rulemaking). And it is why, to this day, FDA has not articulated any explanation for why abandoning its longstanding position comports with the statute's whole text, its incentive structure, and unmistakable legislative intent. As both this Court and the D.C. Circuit repeatedly have done in similar cases, FDA's ongoing assault on 180-day exclusivity should be enjoined.

II. TEVA WILL SUFFER IRREPARABLE HARM WITHOUT IMMEDIATE INJUNCTIVE RELIEF.

Unless FDA is enjoined, its application of the Letter Decision to Teva's cyclosporine ANDA will harm Teva irreparably by divesting the company of its statutory right to 180-day exclusivity and imposing ***at least $50 million dollars*** in losses that Teva can never recover. *See* Groff Decl. ¶ 14. After all, recalling the competing products that FDA unlawfully approves in the interim is no help: Once a consumer's prescription has been filled by a competitor's product, Teva cannot "make up" for that lost sale by filling the patient's ***next*** prescription; the chance to make ***the first sale*** is gone forever. Nor are monetary damages available to compensate the company for its losses: Teva can't sue competitors who lawfully market their competing ANDA products pursuant to an improper FDA approval, because those companies won't have done anything wrong. Instead, the only entity whose conduct is unlawful—FDA—has sovereign immunity that would preclude Teva from recovering damages. *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) ("Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by [the] plaintiff is irreparable *per se*.'") (quoting *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (alteration in original)), *aff'd sub nom. Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010) ("The district court's finding that this loss would be irreparable absent an injunction appears entirely reasonable.").

As both this Court and the D.C. Circuit thus have explained repeatedly, the loss of 180-day exclusivity therefore is a classic irreparable injury that warrants immediate injunctive relief. *Teva v. Sebelius*, 595 F.3d at 1311 (explaining that "the exclusivity reward … is time-sensitive" and that "'loss of [the] officially sanctioned head start [is] an injury that would not be remediated by [its] securing 180 days of exclusivity later on") (internal quotation omitted); *Mylan*, 910 F. Supp. 2d at 313 ("[A] first applicant's loss of its statutory entitlement to the 180–day exclusivity period is irreparable because once lost 'it cannot be recaptured.'") (quoting *Apotex*, 2006 WL 1030151, at *17, *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006)); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) ("Once the statutory entitlement has been lost, it cannot be recaptured.") (quotation omitted).

III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST FAVOR IMMEDIATE INJUNCTIVE RELIEF.

The final equitable factors—the balance of hardships and public interest—likewise favor granting immediate injunctive relief. With respect to the former, FDA is a federal agency and cannot seriously claim that it would be "harmed" by an injunction requiring it to act in a manner that is consistent with the statutory text, structure, and nearly two decades of precedent. And while competing ANDA applicants who seek to market their versions of generic Restasis® might for now be blocked by Teva's statutory right to exclusivity, "rewarding runners-up was not Congress's object." *Mylan*, 910 F. Supp. 2d at 313; *see also Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 217 (D.D.C. 2012); *Apotex*, 2006 WL 1030151, at *17 (citing *Mova*, 140 F.3d at 1067 n.6).

Finally, the public interest decisively favors granting injunctive relief. Again, Congress decided that the public interest is best served by providing 180 days of exclusivity as a "reward for generics that stick out their necks (at the potential cost of a patent infringement suit)," *Teva v. Sebelius*, 595 F.3d at 1318, in order to "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. BioVail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). This case crystallizes that point: Teva filed a legally-valid challenge to Allergan's patent monopoly on the first day that any applicant could have done so, and after subjecting itself to the risk of litigation, its efforts are responsible for opening the market to competition years before Allergan's monopoly otherwise was scheduled to come to an end. Teva thus realized the very risks and accomplished the very result that 180-day exclusivity is designed to reward.

Suffice to say, it would fundamentally undermine Congress's conception of the public interest to deny Teva its hard-earned exclusivity in these circumstances. Indeed, FDA's interpretation not only undercuts the statutory scheme here. It undermines the legislative incentive for ANDA applicants to mount future challenges, by enabling unscrupulous applicants to eviscerate the 180-day exclusivity incentive by filing sham Paragraph IV certifications without risking litigation—and thereby preventing legitimate patent challengers from securing their statutory prize. Once again, the courts repeatedly have recognized that the long-term costs of such an approach warrant prompt remedial action. *See, e.g.*, *Ranbaxy*, 469 F.3d at 126 ("By thus reducing the certainty of receiving a period of marketing exclusivity, the FDA's [ruling] diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. The FDA may not, however, change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'") (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)).

CONCLUSION

For the foregoing reasons, Teva respectfully requests that this Court grant its motion for a preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 17th day of October, 2018, he caused a copy of **TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION** to be served upon the following attorneys by electronic mail:

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