UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., Plaintiff-Appellant, v. KATHLEEN SEBELIUS, *et al.*, as Secretary of Health and Human Services, Defendants-Appellees, and TEVA PHARMACEUTICALS USA, INC. Intervenor-Defendant/Appellee.	Case No. 10-5094

INTERVENOR-DEFENDANT/APPELLEE TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM IN OPPOSITION TO PLAINTIFF'S EMERGENCY MOTION FOR STAY PENDING DISPOSITION OF APPELLANT'S MOTION FOR SUMMARY REVERSAL

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000
(202) 879-5200 fax
Counsel for Teva Pharmaceuticals USA, Inc.

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INTRODUCTION

There is no basis for entering a stay pending the resolution of Apotex's desperate motion for summary reversal. Wholly apart from the merits—on which Apotex has *no* likelihood of success—the requested stay would provide an undeserved windfall to brand manufacturer Merck at the expense of the American public. At midnight tonight, Merck's last remaining barrier to generic competition will fall, and Americans will be entitled to begin purchasing generic losartan potassium products for the first time. The entry of a stay at this point will prevent consumers from obtaining access to generic medicines as early as tomorrow morning, effectively requiring them indefinitely to continue paying Merck's monopoly prices for these widely-prescribed drugs.

Given that Merck's annual sales for these products exceed $1.5 billion, *every day* that this Court enjoins FDA from approving a generic application for losartan potassium products would cost American consumers nearly *$4 million*. That harm stands in marked contrast to the $20.6 million Apotex says it stands to lose *over the course of the next 12 months* if Teva and FDA ultimately prevail *and* Apotex's entry into the market is delayed *by a full six months*—or just *$114,000 per day* over the full six-month period on which the company's calculations of harm are based. *See* Gettenberg Decl. ¶ 16 (attached as Exhibit C to Apotex's Emer. Stay Mot.) (estimating a loss of $20.6 million over 12 months if Apotex is kept off the

market for the full 6-month period of Teva's exclusivity). And, of course, Apotex would be able to enter the market long before the end the six-month period of delay if it prevails in this *expedited* appeal—meaning that a five-day delay that requires the public to pay Merck more than $20 million would save Apotex just $570,000. There is no basis for indulging Apotex's remarkable request to impose that burden on the public, and Apotex's stay request should be summarily denied.

In addition to its impact on the public, entry of an interim stay irreparably would harm Teva. There is no question that Teva has a statutory right to FDA approval of its generic losartan potassium applications after 12:01AM tonight. As the first patent-challenging generic applicant for these products, Teva is not blocked by any other generic applicant's exclusivity, and there are no other patent or regulatory barriers to FDA approval of Teva's losartan potassium ANDAs. Numerous courts have recognized that the loss of a statutory right constitutes irreparable harm, and for good reason: The clock turns in only one direction, so there would be no way for Teva to make up its lost sales once the stay is lifted.

These harms would be particularly pronounced in this case, where Teva not only is entitled to launch its products tomorrow, but is entitled to launch its products *with exclusivity*. As this Court well knows, that right to exclusivity is worth "hundreds of millions of dollars" to Teva over the course of the next six months, *Teva v. Sebelius*, 595 F.3d 1303, 1314 (D.C. Cir. 2010), which is orders of

magnitude greater than the harms Apotex asserts its stands to lose over the same period. The stay requested by Apotex, however, threatens to significantly undercut Teva's long-term realization from that right to exclusivity, since brand manufacturers like Merck frequently allow a so-called "authorized generic" to enter the market at the same time the first true generic applicant would be eligible for approval. If, as appears likely, Merck allows its "authorized generic" to start selling product tomorrow—and before Teva is able to enter the market by virtue of the stay Apotex has requested—the authorized generic would capture a significant portion of the market that Teva would have been able to capture in the absence of the stay sought by Apotex. That would thoroughly undercut the first-mover advantage 180-day exclusivity is designed to confer on the first true generic entrant. *See, e.g.*, *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005) (recognizing the impact of authorized generics on true generic entrants); *see also Teva v. Sebelius*, 595 F.3d at 1318 ("The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs.").

Finally, Apotex has *no* likelihood of success on the merits. "Summary reversal is rarely granted and is appropriate only where the merits are 'so clear, plenary briefing, oral argument, and the traditional collegiality of the decisional

process would not affect [the Court's] decision.'" D.C. CIR. HANDBOOK OF PRAC. & INTERNAL PROCS. § VIII.G, at 35-36 (Dec. 1, 2009) (quoting *Sills v. Federal Bureau of Prisons*, 761 F.2d 792, 793-94 (D.C. Cir. 1985)); *see also Cascade Broadcasting Group, Ltd. v. FCC*, 822 F.2d 1172, 1174 (D.C. Cir. 1987) (*per curiam*). Moreover, because Apotex's emergency appeal and motion for summary reversal arises from the denial of its motion for preliminary injunctive relief, Apotex would have to show that the district court *abused its discretion* by denying relief. Given the high standard that applies to appeals from the denial of injunctive relief, Apotex cannot possibly prevail in the face of these cascading layers of deference—which would, in essence, require Apotex to demonstrate that the district court so clearly abused its discretion that plenary consideration would have no conceivable impact on the outcome of this appeal.

As the foregoing discussion of the equities makes clear, there is no chance that this Court would upend the district court's weighing of those factors. And the merits of Apotex's claims are even clearer. FDA—albeit reluctantly—has finally learned the lesson that this Court now has taught it twice: There is "*not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity," *Teva Pharms. USA, Inc. v. Sebelius* ("*Teva v. Sebelius*"), 595 F.3d 1303, 1317 (D.C. Cir. 2010) (emphasis in original), nor any plausible "reason to conclude that the 2003 addition

of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity." *Id*. at 1318; *see also Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). As FDA thus properly recognized in its letter decision, Apotex's arguments are squarely foreclosed by *Teva*'s *Chevron* step one analysis of the statute's incentive structure. *See* Letter Decision at 7, FDA Docket No. 2010-N-0134 (Mar. 26, 2010) ("[The D.C. Circuit's decision] appears to preclude a forfeiture of exclusivity on the basis of patent expiration where the expiration is in the control of the NDA holder.").

Apotex struggles mightily to distinguish that precedent from this case, but its efforts come up well short. As a threshold matter, this Court already considered and rejected the assertion that Merck's unilateral failure to pay maintenance fees on the '075 patent provides a basis for stripping Teva of its exclusivity, when FDA raised the same claims Apotex now asserts in post-judgment proceedings concerning issuance of the panel's mandate. Under the mandate rule, Apotex's effort to revisit the *Teva* panel's resolution of this issue is squarely foreclosed. Perhaps more important, Apotex's arguments would fail even if this Court were writing on a clean slate. As FDA's letter decision frankly concedes, interpreting the law to let brand manufacturers do through the backdoor (by unilaterally failing to pay maintenance fees on a challenged patent) what the statute categorically forbids them from doing through the front door (by unilaterally delisting a

challenged patent from FDA's Orange Book) plainly would not be "consistent with the Court of Appeals' reasoning in *Teva*." Losartan Letter Decision at 8. The district court thus did not remotely err (much less clearly abuse its discretion) in concluding that "FDA properly followed the logic of the D.C. Circuit's decision in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303." Dist. Ct. Op. at 7.

LEGAL STANDARD

"Summary reversal is rarely granted and is appropriate only where the merits are 'so clear [that] plenary briefing, oral argument, and the traditional collegiality of the decisional process would not affect [the Court's] decision.'" D.C. CIR. HANDBOOK OF PRAC. & INTERNAL PROCS. § VIII.G, at 35-36 (Dec. 1, 2009) (quoting *Sills*, 761 F.2d at 793-94); *see also Cascade Broad. Group*, 822 F.2d at 1174. Moreover, "[i]t is well settled that whether a preliminary injunction should be awarded rests in the sound discretion of the trial court." *Ambach v. Bell*, 686 F.2d 974, 979 (D.C. Cir. 1982). Because preliminary injunctive relief is "an extraordinary remedy and must be sparingly granted," *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996) (citing *Dorfmann v. Boozer*, 414 F.2d 1168 (D.C. Cir. 1969)), it "should not be issued … unless an overwhelming case in the plaintiff's favor is present on the merits and equities of the controversy." *Dorfmann*, 414 F.2d at 1173; *see also Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1292, 1296 (D.C. Cir. 2009) (Kavanaugh and Henderson,

JJ., concurring) (explaining that "a movant cannot obtain a preliminary injunction without showing *both* a likelihood of success *and* a likelihood of irreparable harm, among other things," and that where "substantial harm to the nonmovant is very high and the showing of irreparable harm to the movant very low, the movant must demonstrate a much greater likelihood of success"). Preliminary injunctive relief thus is appropriate only when the party seeking the relief carries its burden of persuasion by a clear showing. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997).

This Court ordinarily will not reverse a district court's order denying interim relief except in cases of abuse of discretion or clear error. *See id*. That deference is warranted because a decision to deny a preliminary injunction typically is based on equitable considerations that are properly weighed by the lower court. *See, e.g.*, *Friends For All Children, Inc. v. Lockheed*, 746 F.2d 816, 834-35 & n.32 (D.C. Cir. 1984); *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 842 (D.C. Cir. 1977). Moreover, the Court "owes special deference to the district court's factfinding, which is always reviewed under a clearly erroneous standard, whether on appeal of a preliminary injunction motion or a final order." *City of Las Vegas v. Lujan*, 891 F.2d 927, 931 (D.C. Cir. 1989) (citing *Friends*, 746 F.2d at 835 n.32)).

ARGUMENT

I. THE EQUITIES DECISIVELY WEIGH AGAINST ENTRY OF A STAY.

A. THE PUBLIC INTEREST WEIGHS AGAINST A STAY.

As the district court properly recognized, the public interest weighs decisively against the entry of a stay pending resolution of Apotex's motion for summary reversal. Dist. Ct. Op. at 6-7. This Court already has explained that "[t]he statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device [that] Congress has chosen to induce challenges to patents claimed to support brand drugs." *Teva v. Sebelius*, 595 F.3d at 1318. Yet Apotex's request for a stay takes direct aim at that legislative choice—not only seeking to undermine that incentive by requesting relief that ultimately would strip Teva of its hard-earned exclusivity reward, but that would effectively keep other generics off the market while Apotex pursues this frivolous appeal in the interim. It would be hard to imagine a result more at odds with the public interest—or with the basic purpose of the statutory scheme—than maintaining the brand manufacturer's monopoly while Apotex seeks to overturn both an FDA decision and district court holding that Teva is entitled to begin delivering price relief to consumers with exclusivity *as early as tomorrow morning*. *See, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("'Congress sought to get generic drugs into the hands of patients

at reasonable prices—fast.'") (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) ("The purpose of the Hatch-Waxman Amendments was, after all, to increase competition [and] make available more low cost generic drugs.").

Indeed, as set forth above, Apotex's stay request seeks to impose *millions of dollars* of unwarranted costs on the hundreds of thousands of Americans who take losartan potassium products in order to save—at most—*a few hundred thousand dollars* while this appeal unfolds. *Supra* at 1-2. Apotex cites no precedent for such an extraordinary stay—and there is none that could justify depriving the public of the first opportunity to access generic alternatives to a drug with over $1.5 billion in annual sales, so that a commercial actor might preserve its interest in a mere $500,000 in lost revenues while these expedited proceedings unfold.

B. APOTEX WILL NOT SUFFER IRREPARABLE HARM ON A SCALE SUFFICIENT TO WARRANT INJUNCTIVE RELIEF.

The fact that Apotex stands to lose so little from the entry of injunctive relief in turn bolsters the district court's conclusion that Apotex will not be sufficiently harmed by FDA's approval of Teva's generic losartan potassium ANDAs in order to warrant injunctive relief. As the district court recognized, "'[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended' do not constitute irreparable harm," Dist. Ct. Op. at 6 (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)) (alteration in original), and "'financial harm

alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business." *Id*. (quoting *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001)) (alteration omitted). Given the paltry harms Apotex asserts it would suffer if the requested relief is denied, it is impossible to conclude that the district court clearly erred in finding that Apotex failed to demonstrate irreparable injury.

C. THE BALANCE OF HARDSHIPS WEIGHS SHARPLY AGAINST A STAY.

Finally, the balance of hardships weighs heavily against injunctive relief. As this Court already recognized, Teva is eligible to enter the market with exclusivity—and to begin providing consumers with price relief from Merck's monopoly for these products—on April 6. *Teva v. Sebelius*, 595 F.3d at 1311. Moreover, this Court has recognized that Teva's exclusivity reward is worth "hundreds of millions of dollars" to the company. *Id*. at 1314. Two consequences flow from those facts. First, the requested stay irreparably would deprive Teva of its *statutory right* to begin marketing its products tomorrow—an injury that itself constitutes irreparable harm wholly apart from the economic losses that flow from that right. Thus, "unlike the harm that Apotex allegedly faces, the potential injury that [Teva faces] is not 'merely economic.' Rather, [Teva] stand[s] to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable. Once the statutory entitlement has been lost, it cannot be recaptured."

Apotex v. FDA, No. Civ. A. 06-0627, 2006 WL 1030151, *17 (D.D.C. April 19, 2006).

Moreover, entry of even a brief stay is likely to jeopardize Teva's long-term ability to take advantage of its exclusivity right. As this Court well knows, brand manufacturers like Merck typically allow a so-called "authorized generic" to enter the market at the same time as the first true generic applicant, allowing the brand company to effectively capture a portion of the generic market and make up for lost revenues through licensing fees on the authorized generic's sales. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005). If, as current market intelligence indicates, Merck allows an authorized generic to enter the market tomorrow morning—while Teva's approval is held up by an interim stay—Teva will suffer an array of hardships while the authorized generic captures a significant portion of the market. *See, e.g.*, *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 33 (D.D.C. 2006) ("An injunction effectively removing [Teva's]'s generic simvastatin product from the market would thus give [the authorized generic supplier] a pronounced advantage in negotiating long-term customer contracts for the supply of generic simvastatin, and would permit [the authorized generic company] to step in to fulfill the contracts Teva … could no longer lawfully fulfill."). These harms to the first true generic applicant's exclusivity period likewise have been recognized as irreparable, and they sharply tilt the balance of

hardships in favor of allowing Teva to launch its products with exclusivity tomorrow—as the district court here recognized. *Id.*; *see also Teva v. Sebelius*, 595 F.3d at 1310, 1311 (noting that "Teva faces … a near-certain loss of the first-mover advantage," and that that "first-mover advantage" cannot be recovered once other generics launch); *Mova*, 140 F.3d at 1066-67 n.6 (holding that loss of the Hatch-Waxman Act's "officially sanctioned head start" is irreparable injury and rejecting FDA's argument that "the public's interest in the rapid movement of generic drugs into the marketplace" outweighs the first applicant's right to exclusivity).

II. APOTEX HAS NO LIKELIHOOD OF SUCCESS ON THE MERITS.

Because the prospect of "substantial harm to [Teva] is very high and the showing of irreparable harm to [Apotex] very low, [Apotex] must demonstrate a much greater likelihood of success." *Davis*, 571 F.3d at 1292 (Kavanaugh and Henderson, JJ., concurring). And here, as set forth above, that burden is higher still, since Apotex's motion seeks *summary reversal* of the district court's balancing of the preliminary injunction factors in the course of denying Apotex's request for injunctive relief, which even in the ordinary course is reviewed for abuse of discretion. *Supra* at 6-7 (collecting cases). Apotex cannot possibly overcome the cascading layers of deference that apply under these circumstances.

In short, FDA finally has gotten it right: This Court's "'*Chevron* step one'" interpretation of "the structure of the MMA exclusivity provisions … does not permit an NDA holder to 'unilaterally' deprive the generic applicant of its exclusivity," and that reasoning applies no less to Merck's unilateral attempt to deprive Teva of its exclusivity reward by abandoning the '075 patent through non-payment of maintenance fees than it does to Merck's unlawful attempt to delist that patent in the first instance. FDA Letter Decision at 7-8 (quoting *Teva v. Sebelius*, 595 F.3d at 1305, 1317); *see also Teva v. Sebelius*, 595 F.3d at 1317 ("The Agency, however, offers *not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity.") (emphasis in original); *id.* (holding that the statute "does *not* permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter") (emphasis added); *id.* at 1318 (holding that there is "*no reason* to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity") (emphasis added); *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) ("FDA may not, however, change the incentive structure adopted by the Congress [by] allow[ing] an NDA holder … to deprive the generic applicant of a period of marketing exclusivity.").

Consistent with these clear instructions, FDA thus reached the only conclusion that the law allows: If Merck cannot unilaterally divest Teva of its exclusivity reward by delisting the '075 patent in response to Teva's Paragraph IV certification, then Merck cannot unilaterally divest Teva of its exclusivity reward by artificially pretermitting that patent's natural term after Teva's Paragraph IV certification *caused* Merck to effectively abandon its patent. Contrary to Apotex's remarkable assertions, there is nothing arbitrary or capricious about FDA's decision to apply *Teva*'s reasoning under these circumstances—and not least of all because this Court already considered FDA's assertion that Merck's decision to unilaterally cease paying certain maintenance fees on the '075 patent might work a forfeiture of Teva's exclusivity period (thereby allegedly divesting the Court of jurisdiction to issue the *Teva* decision), but issued its mandate anyway. *See Teva v. Sebelius*, No. 09-5281 (Mar. 12 Order Compelling Issuance of the Mandate at 1).

Accordingly, Apotex's attempt to relitigate this issue is squarely barred by the mandate rule, which "'forecloses relitigation of issues expressly or *impliedly* decided by the appellate court.'" *United States v. Ben Zvi*, 242 F.3d 89, 95 (2d Cir. 2001) (quoting *United States v. Bell*, 5 F.3d 64, 66 (4th Cir. 1993), with its own added emphasis); *see also United States v. Dionisio*, No. 04-CR-1068 (DLI), 2010 WL 117862, at *2 (E.D.N.Y. Jan. 8, 2010) ("[I]n his petition to the Second Circuit for a rehearing, defendant made the same arguments that he makes now…. The

Second Circuit summarily dismissed defendant's petition. Accordingly, the mandate rule bars this court's consideration of defendant's renewed … argument.").

Even if Apotex's collateral attack on that decision were not squarely foreclosed, however, there still would be no basis for thinking that Apotex is likely to prevail on the merits. In essence, Apotex is taking the position that FDA not only is free to ignore this Court's teaching in *Teva*, but is compelled to do so. As Apotex thus argues, FDA acted "arbitrarily and capriciously" in this case by "substituting the conclusion of the Court of Appeals for its own conclusion." Apotex Stay Mot. at 11. That argument makes a mockery of judicial review and cannot be squared with the most fundamental tenet of our legal system: that it "is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Whether Apotex likes it or not, FDA is bound by the law of this Circuit, and while Apotex is of course free to echo FDA's disdain for the D.C. Circuit's *Chevron* step one analysis of the statute's incentive structure, it cannot sensibly fault FDA for following the law—or reasonably demand that FDA defy it. *See Cooper v. Aaron*, 358 U.S. 1, 18-20 (1958).

Apotex next tries to distinguish *Teva* on the ground that it merely addressed the delisting forfeiture trigger, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), whereas this

case involves the patent expiry forfeiture trigger, 21 U.S.C. § 355(j)(5)(D)(i)(VI). *See* Apotex Stay Mot. 14-17. But its arguments provide no basis for ignoring *Teva*'s sharply-worded instructions about the statute's incentive structure. Apotex first argues that there is precedent for the proposition that "patent expiration extinguishes exclusivity." *Id*. at 14. But none of the precedents Apotex cites address the kind of patent expiration at issue here—a technical patent expiration brought about by the brand manufacturer's unilateral decision to cease paying maintenance fees on a delisted patent, as opposed to natural patent expiration brought about the simple passage of time.

Apotex next argues that "the potential for strategic interference is less real in the patent expiration context" than in the delisting context. *Id*. at 14. But as Teva explained to this Court when FDA raised this issue in post-judgment appellate proceedings, brand manufacturers *routinely* cease paying maintenance fees on challenged patents—and quite often do so at the same time they (impermissibly) seek to delist those patents from the Orange Book. Indeed, since FDA first raised this issue in post-judgment proceedings, Teva has identified no fewer than nine prior cases in which a brand manufacturer sought to delist a patent from the Orange Book and then ceased paying maintenance fees at the PTO, including U.S. Patent Nos. 6,248,741; 5,736,165; 5,667,794; 6,114,144; 6,113,920; 6,020,001; 6,368,627; 5,863,559; and 6,248,735—all of which were at one time listed in the

Orange Book, but then allowed to lapse for non-payment of fees following the brand manufacturer's request that FDA delist the patent. Allowing brand manufacturers to divest the first generic patent challenger of its exclusivity reward through the simple artifice of ceasing to pay maintenance fees on a challenged patent thus would allow brand manufacturers to make an end-run around the statute's clear bar on exclusivity-divesting patent delistings. But there is no conceivable reason why Congress would have intended to take from generics with one hand what it gave them with the other, and Apotex offers none.

Apotex next argues that the concept of patent expiration has patent-law roots, and that FDA should have interpreted the Hatch-Waxman Act to provide for forfeiture whenever a patent expires for purposes of the patent laws without regard to the context of Hatch-Waxman's incentive structure. *Id*. at 15. But that is no way to read a statute. As the Supreme Court long has explained, statutes must be interpreted by reference to "the specific context in which [legislative] language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997) (citing *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 477 (1992); *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991)). Indeed, the Court repeatedly has emphasized a single word can—and, depending on its context, often must—have two different meanings even when it is used within a *single* statute. *See, e.g.*, *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 595

& n.8 (2004) (quoting *Atl. Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932) ("Most words have different shades of meaning, and consequently may be variously construed, not only when they occur in different statutes, but when used more than once in the same statute or even in the same section. Undoubtedly, there is a natural presumption that identical words used in different parts of the same act are intended to have the same meaning. But the presumption is not rigid and readily yields whenever there is such variation in the connection in which the words are used as reasonably to warrant the conclusion that they were employed in different parts of the act with different intent.")).

Here, the context is dispositive. As this Court explained in the *Teva* decision, there is "*not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity," 595 F.3d at 1316, and "*no reason* to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity," *id*. at 1318. As FDA thus recognized, there is no basis for ignoring *Teva*'s lessons here.

Finally, Apotex cannot reasonably argue that FDA's "ministerial role" provides an excuse to let brand companies to manipulate the incentives for generic market entry in this fashion. After all, FDA tried to defend its (now unlawful) delisting policy in *Ranbaxy* on the basis of its supposedly "ministerial" role in the

patent-listing process, and this Court nonetheless rejected FDA's enablement of the same kind of manipulation at issue here. *See* 469 F.3d at 125 (rejecting FDA's delisting policy despite claims that it "preserves the ministerial nature of the FDA's role in maintaining the patent listings in the Orange Book because, when an NDA holder asks it to delist a patent, the agency need not determine whether the NDA holder is acting strategically to deny the generic applicant a period of marketing exclusivity or the patent actually does not cover the drug for which it was submitted—the interpretation of patent listings being outside the agency's expertise").

The "ministerial role" defense is no more availing here than it was in *Ranbaxy*. In fact, it is less so. The whole basis for FDA's "ministerial" role is the Agency's belief that it lacks the ability to carry out *a substantive review of patent claims* in order to ensure that only properly submitted patents are listed in the Orange Book. *See* Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003). That concern has no force here. Ensuring that an Orange Book patent listing reflects the listed patent's natural expiration date—as opposed to the date on which the brand manufacturer unilaterally sought to divest the first applicant of its exclusivity by ceasing to pay maintenance fees to the PTO—does not require FDA to engage in a "substantive agency review of patents," "assess[] patent challenges," "review patents to determine if they meet

the requirements for listing," "hir[e] patent lawyers to review submitted patents," or delve into "complex and important issues of patent law" in the context of "a full administrative hearing process." *Id.* It requires only that FDA ask brand manufacturers to supply the right information in the first instance, and where a given submission subsequently is challenged, that it ask the right follow-up question. FDA's "ministerial" role in policing the Orange Book thus provides no license for allowing Merck to unilaterally vitiate Teva's exclusivity in direct contravention of this Court's repeated instructions about the statute's incentive structure.

Given its exceptionally low likelihood of prevailing on the ultimate merits of its claim that FDA somehow erred in applying *Teva*'s reasoning in this case, Apotex has no likelihood of success in overcoming the cascading layers of deference to which the district court's denial of its motion for preliminary injunctive relief is entitled.

CONCLUSION

For the foregoing reasons, Teva respectfully requests that this Court deny Apotex's motion for a stay pending the resolution of its motion for summary reversal.

Dated: April 5, 2010

Respectfully submitted,

By: Michael D. Shumsky

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000
(202) 879-5200 fax

Counsel for Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that on this 5th day of April, 2010, he caused a copy of the foregoing **OPPOSITION** to be served upon the following attorneys by electronic mail and through this Court's ECF filing system:

Carmen M. Shepard
Kate C. Beardsley
BUC & BEARDSLEY
9191 18th Street, NW. Suite 600
Washington, DC 20006
Email: cshepard@bucbeardsley.com
Counsel for Plaintiff Apotex, Inc.

Drake Cutini
Office of Consumer Litigation
Liberty Square Building
450 5th St. NW, Room 4600 S
Washington, DC 20001
Email: Drake.Cutini@usdoj.gov
Counsel for the Federal Defendants

Dated: April 5, 2010

/s Michael D. Shumsky
Michael D. Shumsky
Counsel for Teva Pharmaceuticals USA, Inc.