UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC., *et al.*, Plaintiffs/Cross-Defendants, and MUTUAL PHARMACEUTICAL CO., INC., Intervenor-Plaintiff/Cross-Defendant, v. MICHAEL LEAVITT, *et al.*, Defendants/Cross-Defendants, TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant/Cross-Claimant, and APOTEX INC., Intervenor-Defendant/Cross-Defendant.	Case No. 07-579 (RMU)

REPLY BRIEF OF TEVA PHARMACEUTICALS USA, INC. IN SUPPORT OF ITS CROSS-CLAIM FOR DECLARATORY AND INJUNCTIVE RELIEF

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INTRODUCTION

The issues in this case are now fully joined. The parties do not dispute any of the underlying facts, and despite the rapidity with which this litigation has unfolded, the parties thus far have filed no fewer than eight briefs (not including this reply or those of Teva's counterparties) that thoroughly canvass the issues raised in FDA's April 18, 2007 Letter Decision. As Teva noted in its opening Brief, the need for an expeditious resolution of these issues justifies consolidating Teva's application for preliminary injunctive relief with a trial on the merits pursuant to Fed. R. Civ. P. 65(a)(2). Teva Brief at 15 n.2. No party has objected to that suggestion, and given the thoroughness with which each party now has articulated its position in this matter, there is no need for further briefing before this Court issues its opinion—and thereby "determines" the merits of this case.

On the merits, no party offers a sound basis for doubting that Congress meant what it said when it required the brand manufacturer to secure a "court ***determin[ation] that the patent is valid and would be infringed***" in order to earn pediatric exclusivity against paragraph IV applicants. 21 U.S.C. § 355a(c)(2)(B). Nonetheless, each of the other parties to this case continues to insist that ***each generic applicant*** must secure its own court determination that the patent is ***in***valid or would ***not*** be infringed in order to ***defeat*** the brand manufacturer's pediatric exclusivity. *See, e.g.*, FDA Opp. at 33 ("[P]ediatric exclusivity [does] not block the approval of an ANDA where the ANDA applicant has prevailed.") (quotation omitted); Mylan Opp. to Teva at 5 ("[T]he [statute] requires a generic applicant to challenge all claims that might cover the listed drug."); Apotex Opp. to Teva at 5 ("[Teva] should have gone to the district court and sued Pfizer in the first instance."). Those assertions turn the plain text of the statute upside down, and no amount of deference to the agency can sustain such inversions of the unambiguous statutory text.

Nor has any party cast reasonable doubt on the fact that the pediatric exclusivity statute focuses on the ***substance*** of the court's determination of patent (in)validity and (non)infringement, and not (in contrast to many other statutes) on the ***timing*** or ***effectiveness*** of such a decision on the parties' rights. Instead, the various parties concede that the term "determines" ordinarily "refer[s] to the substance of a court decision," *e.g.*, FDA Opp. at 25, but nonetheless insist that the term is ambiguous simply because "several interpretations [were] advanced by the interested parties." Mutual Opp. at 6; FDA Opp. at 17 (relying on "the wide divergence in the legal theories and arguments presented to FDA in the comments"). As the legion of 5-4 Supreme Court decisions rejecting agency interpretations under *Chevron* step one makes clear, *see, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); *National Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479 (1998), the ordinary meaning of ordinary terms is not ambiguous simply because high-priced lawyers, agency officials, or dissenting Supreme Court Justices are able to construct "counter-arguments," Mylan Opp. to Apotex at 9—and that is especially so when Congress has expressly adopted the advocated interpretation in other statutes, including other provisions of this statute, but declined to do so here. No party responds to that straightforward point, and it is dispositive.

This Court thus should set aside FDA's April 18 Letter Decision and enter an injunction requiring FDA to grant Teva immediate final approval for its ANDA No. 76-846.

ARGUMENT

I. FDA ERRED BY CONSTRUING THE STATUTE TO REQUIRE EACH GENERIC APPLICANT TO SECURE ITS OWN DETERMINATION THAT A CHALLENGED PATENT IS *IN*VALID OR *NOT* INFRINGED IN ORDER TO DEFEAT PEDIATRIC EXCLUSIVITY.

The key provision of the statute at issue in this case is subclause (c)(2)(B), and that provision is unambiguous: Where an applicant submits a paragraph IV certification to a patent

claimed by the brand manufacturer of the previously approved drug product, that provision awards the brand manufacturer six months of pediatric exclusivity ***only*** if "in the patent infringement litigation resulting from the certification the court ***determines that the patent is valid and would be infringed***." 21 U.S.C. § 355a(c)(2)(B) (emphasis added).

That should be the beginning and end of this matter. The statute unambiguously requires a brand manufacturer to secure a court determination that its patent is "***valid and infringed***" in "***litigation resulting from the certification***" in order to qualify for pediatric exclusivity against any applicant that submitted a paragraph IV certification before the patent expired. Teva submitted a paragraph IV certification to the '303 patent before it expired. It provided notice to Pfizer, but no litigation resulted from the certification. And where there was litigation involving the '303 patent, the Federal Circuit held that every claim of the '303 patent that Pfizer ever has asserted against ***any*** applicant for generic amlodipine drug products is ***invalid***, and thus cannot successfully be asserted against any other paragraph IV applicant for generic amlodipine drug products—including Teva. *See Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 350 (1971); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) ("[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel."). The plain meaning of the statute thus forecloses FDA's determination that Pfizer is entitled to pediatric exclusivity against Teva.

FDA and Mutual initially respond by arguing that because the '303 patent expired before FDA granted Teva's ANDA final approval, Teva's paragraph IV certification was converted to a paragraph II certification and § 355a(c)(2)(B) no longer applies to Teva's ANDA. FDA Opp. at 30; Mutual Opp. at 10-11. Both then assert that Judge Friedman upheld a similar determination

in the *Fluconazole* case and (according to FDA) "flatly rejected" the assertion that a brand manufacturer must prevail in the underlying paragraph IV litigation in order to obtain pediatric exclusivity. FDA Opp. at 30 (citing *Ranbaxy Labs. Ltd. v. FDA* [*Fluconazole*], 307 F. Supp. 2d 15, 18 (D.D.C. 2004)); *see also* Mutual Opp. at 10 (citing *Fluconazole*, 307 F. Supp. 2d at 20).

They are incorrect. As Teva explained in its opening brief, the *Fluconazole* case is readily distinguishable, because—unlike Teva—the generic applicant in that case was sued, and—again unlike this case—then stipulated to the dismissal of its pending patent litigation with the brand manufacturer before any court ever entered judgment. *Fluconazole*, 307 F. Supp. 2d at 17. As a result, the Federal Circuit never reached the merits of the underlying patent case—and certainly did not hold that every claim of the challenged patent that ever had been asserted was invalid. Judge Friedman's decision thus does not address the factual scenario presented here, and even FDA acknowledges this point by conceding (just two pages after first invoking the *Fluconazole* case) that *Fluconazole* actually "did ***not*** … resolve the question presented here." FDA Opp. at 32 (emphasis added).[1]

In any event, this Court is not bound by *Fluconazole*. That decision was appealed to the D.C. Circuit, reviewed *de novo*, and then affirmed by an unpublished, single-page memorandum disposition. *See Ranbaxy Labs. Ltd. v. FDA*, 96 F. App'x 1, 1 (D.C. Cir. 2004) . As this Court is well aware, "unpublished opinions have no binding precedential value in this Circuit," and while

[1] Mutual also relies on *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004). *See* Mutual Opp. at 10. But that case likewise is distinguishable. There, the generic applicant was sued—unlike Teva—and while the district court in the underlying patent litigation determined that the patent was valid and infringed, the Federal Circuit had not resolved the generic applicant's appeal by the time the pediatric exclusivity period began—again, unlike this case. *Id*. at 1277; *see also Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 114 (D.D.C. 2004). Notably, the Federal Circuit affirmed the district court's determination of patent validity and infringement in that case—which likewise distinguishes it from this case. *See Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1367 (Fed. Cir. 2004).

courts may "refer for guidance to an unpublished opinion ***which involves similar facts***," they also are free to "independently examine[] both the facts and the law." *Alexis v. District of Columbia*, No. 98-0151, 1999 WL 680384, at *5 n.5 (D.D.C. June 15, 1999) (Urbina, J.) (emphasis added); *see also* D.C. Cir. R. 36(c)(2). Teva thus respectfully submits that this Court should apply the plain text of the pediatric exclusivity statute, which—to reiterate—unambiguously requires the brand manufacturer to obtain a court determination that the challenged "patent is ***valid and infringed***" in order to secure pediatric exclusivity against applicants that submitted a paragraph IV certification prior to the patent's expiration. 21 U.S.C. § 355a(c)(2)(B) (emphasis added). No party to this case has identified any ambiguity in the operative statutory language, and there is thus no basis for deferring to the agency's interpretation. *See Chevron USA, Inc. v. NRDC*, 467 U.S. 837, 842 (1984).

Even if the statute were not clear on this point, the fact remains that FDA's disparate treatment of the paragraph IV ANDAs submitted by Apotex and Teva is unjustified. According to FDA, that disparate treatment is warranted because "the language of the subsection 355a(c)(2)(B) 'manifests a clear Congressional intent that pediatric exclusivity not block the approval of an ANDA where the ANDA applicant has prevailed in the paragraph IV litigation." *Id*. at 32 (citing FDA Letter Decision at 9). But as Teva explained in its opening brief, that simply is not so. Congress did ***not*** manifest its intent to "not block the approval of an ANDA ***where the ANDA applicant has prevailed in the paragraph IV litigation***," but rather manifested its intent that pediatric exclusivity not block the approval of an ANDA unless ***the brand manufacturer*** secures a "court determin[ation] that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(2)(B).

No party to this case responds to that straightforward point—though Mutual and Mylan at least recognize that FDA is obligated to treat both Teva and Apotex the same way: Either both are entitled to final approval, or neither is. Mylan Opp. to Apotex at 6 n.8; Mutual Opp. to Teva at 10. But the approach advocated by Mutual and Mylan is unsustainable, because it essentially would read § 355a(c)(2)(B) out of the statute. After all, pediatric exclusivity commences only upon the expiration of a patent, so an interpretation that would throw all unapproved applicants into § 355a(c)(2)(A) on patent expiration would essentially render subsection (c)(2)(B) a nullity—as Judge Walton observed in his *Fentanyl Patch* opinion, ***in response to Mylan raising this very point***. 332 F. Supp. 2d at 124 (rejecting Mylan's assertion that FDA had "improperly read out of existence § 355a(c)(2)(B)" ***based on FDA's concession*** that § 355a(c)(2)(B) would apply where the brand manufacturer loses post-paragraph IV patent litigation). The bottom line here is that if FDA is ever going to apply subsection (c)(2)(B) following the expiration of a patent—and it has to, as Judge Walton readily understood—its approach must faithfully reflect Congress's actual intent, which unambiguously requires the brand manufacturer to secure a determination of patent validity (and not that each paragraph IV applicant secure its own determination of patent invalidity or non-infringement).

Indeed, as Teva explained in its opening brief, that straightforward reading of the statute has always been clear to the Agency—which routinely approves paragraph IV ANDAs where the brand manufacturer fails to initiate litigation against a paragraph IV applicant. *See* Teva Br. at 21-22. For their part, neither Apotex, Mylan, nor Mutual contests the existence or validity of that settled agency practice. Nonetheless, Apotex and Mylan make the stunning assertion that in order to defeat pediatric exclusivity, every paragraph IV applicant must not only initiate its own litigation against the brand manufacturer if the brand manufacturer does not sue, but must file a

counterclaim challenging every claim of any patent claimed by the brand manufacturer if the brand manufacturer does sue. *See* Apotex Opp. to Teva at 5 ("[Teva] should have gone to the district court and sued Pfizer in the first instance."); Mylan Opp. to Teva at 5 ("[T]he [statute] requires a generic applicant to challenge all claims that might cover the listed drug. To the extent all of those claims are not asserted by the patent holder, it is an easy matter for the generic applicant to bring a declaratory judgment counterclaim to ensure that all claims are covered.").

Separate and apart from the fact that those arguments are flatly inconsistent with FDA's longstanding practice of approving paragraph IV ANDAs that do not result in patent litigation—which itself is sufficient to dispose of these arguments—these claims border on the frivolous. As a threshold matter, a generic applicant cannot initiate a declaratory judgment action "in the first instance." Apotex Opp. at 5. Instead, the applicant must wait 45 days after the brand manufacturer receives its paragraph IV notice, and then may file suit only if it has not been sued by the brand manufacturer. 21 U.S.C. § 355(j)(5)(c)(i)(I). Even then, the brand manufacturer might challenge the court's jurisdiction to entertain the generic applicant's action. *See, e.g.*, *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, No. 06-1181, ___ F.3d ___, 2007 WL 942201 (Fed. Cir. Mar. 30, 2007). And where the applicant already has been sued but the brand manufacturer has declined to assert all potentially relevant patent claims, it is—with all due respect to Mylan—simply bizarre to require the applicant to file exhaustive declaratory counterclaims, since ordinary principles of *res judicata* would prevent the brand manufacturer from asserting further claims in successive litigation—***as Apotex well knows***. *See, e.g.*, *Apotex, Inc. v. FDA*, 393 F.3d 210, 218 (D.C. Cir. 2004) ("Under *res judicata*, a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action.") (alteration and quotations omitted).

Far more important, the approach advocated by Apotex and Mylan in this case is completely at odds with the purpose of the statute's declaratory judgment provisions. Those provisions were never intended to establish litigation as a prerequisite to generic approval; that much is clear from the D.C. Circuit's rejection of FDA's prior successful defense requirements. *See Mova Pharm. Corp. v. Shalala*,140 F.3d 1060, 1073 (D.C. Cir. 1998) (expressly rejecting claims that the declaratory judgment mechanism sufficed to render FDA's successful defense requirement permissible); *see also Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006).

Instead, the declaratory judgment mechanism is designed to give generic applicants that are not timely sued by a brand manufacturer—but which may not wish to launch their products "at risk" of an adverse patent decision (and potentially ruinous post-launch patent damages)—a means to obtain patent certainty. As the Federal Circuit recently explained:

> [T]here are tactical reasons why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days. For example, the brand drug company might have several patents listed in [FDA's] Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. [That] would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market. In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period.

Teva, 2007 WL 942201 at *9 (internal quotations omitted). The irony here, of course, is that (as Teva explained in its opening brief), FDA's determination in this matter—and the approach now advocated by generic manufacturers Apotex and Mylan—would encourage precisely such gamesmanship by brand manufacturers, and ***require*** generic applicants to use the declaratory judgment mechanism to secure marketing ***approval***, rather than simply ***permit*** them to use that mechanism to secure patent ***certainty*** before launching an approved product.

For its part, FDA attempts to reconcile its routine approval of paragraph IV ANDAs that do not result in brand-initiated litigation with its new successful defense requirement by asserting that those cases "involved approval of an ANDA before the last patent expired." FDA Opp. at 31. But that is no answer. Given that FDA has determined that Apotex's unapproved paragraph IV ANDA is governed by subsection (c)(2)(B) despite the '303 patent's expiration, the key question in this case is whether, on one hand, the text of that provision requires the generic applicant to secure a court determination that the patent is ***invalid or not infringed*** in order to ***defeat*** pediatric exclusivity, or, on the other (and as the statute unambiguously provides), whether it requires the brand manufacturer to secure a court determination that the patent is ***valid and infringed*** in order to ***earn*** pediatric exclusivity. Having long established that subsection (c)(2)(B) requires the latter—as manifested in the agency's routine approval of paragraph IV ANDAs that do not result in patent litigation at all—FDA's departure from that settled approach is arbitrary and capricious, and cannot be sustained under *Chevron*. *See King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988).

As a result, FDA ultimately falls back on the argument that so long as a single unasserted patent claim remains eligible for listing in the Orange Book, all unapproved ANDAs (except, inexplicably, Apotex's ANDA) are barred by Pfizer's pediatric exclusivity. FDA Opp. at 33-37. The basic problem with that argument is that it once again inverts the plain text of the statute, which (at the risk of beating a dead horse) simply does not put the burden on ***every single generic applicant*** to knock out every single asserted claim of a listed patent in order to ***defeat*** the brand manufacturer's pediatric exclusivity. Instead, it puts the burden squarely on ***the brand manufacturer*** to secure a determination that the patent is valid and infringed in order to ***earn*** pediatric exclusivity. Whether or not the brand manufacturer holds certain claims "in reserve,"

as Congress long has warned against, *see, e.g.*, 149 Cong. Rec. S15882-85 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (quoted in *Teva*, 2007 WL 942201 at *9), the fact of the matter is that the brand manufacturer's refusal to assert those claims in paragraph IV litigation is not a court "determin[ation] that the [unasserted] patent [claims are] valid and infringed." 21 U.S.C. § 355a(c)(2)(B). If it is anything other than pure gamesmanship by the brand manufacturer, it is tantamount to a concession that the reserved patent claims are invalid or not infringed, as would be the case where different patent claims cover different drug products (*e.g.*, where one claim covers tablets and another covers capsules), different molecules (*e.g.*, where one claim covers a methyl and another covers an ethyl, or one covers a besylate and another covers a maleate), or different treatments (*e.g.*, where one claim covers a treatment for headaches and another covers a treatment for nausea, but the proposed generic product is intended only for treating headaches).

No party—including FDA—responds to Teva's argument that the agency's approach thus would open the entire process to manipulation by the brand manufacturer, in direct contravention of repeated judicial warnings against adopting such interpretations. *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997). Instead, Mylan and FDA argue—for the first time—that Teva's plain-text interpretation of the statute "would permit gamesmanship on the part of ANDA applicants" by allowing them to change their certifications shortly before patent expiration. FDA Opp. at 36; Mylan Opp. to Teva at 1. There are at least three responses to that argument.

First, while Teva submitted its paragraph IV certification only a few days before the patent expired, the insinuation that Teva's conduct was improper is baseless. As Teva has observed from the outset of this case, FDA has long required applicants to "amend a submitted

certification if, ***at any time*** before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate." 21 C.F.R. § 314.94(a)(12)(viii)(c) (emphasis added). Of course, once the Federal Circuit issued a unanimous, published opinion invalidating every asserted claim of the '303 patent, Teva's conversion to a paragraph IV stating that the patent was invalid, unenforceable, or otherwise not infringed was entirely appropriate: It not only reflected Teva's wholly accurate belief that the '303 patent was invalid—as the Federal Circuit squarely held less than 24 hours before Teva submitted its paragraph IV certification to FDA and dispatched its paragraph IV notice to Pfizer—but was consistent with other aspects of FDA's regulation, which expressly permit applicants to amend "[a] certification … ***at any time*** before the effective date of the approval of the application." *Id*. § 314.94(a)(12)(viii) (emphasis added).

Teva can hardly be faulted for following FDA's own duly promulgated regulations on amending patent certifications. Indeed, given that FDA's regulations expressly preclude applicants from amending their certifications under certain circumstances—but not this one—there is no basis for concluding that Teva's conduct in this case was at all improper; *inclusio unius est exclusio alterius*. *See, e.g.*, *United States v. Lopez*, 938 F.2d 1293, 1297 (D.C. Cir. 1991).[2] If FDA now wishes to bar applicants from converting to a paragraph IV certification in these circumstances despite the plain text of its longstanding regulations, it is free to amend those regulations (so long as doing so would be consistent with the statute). But FDA cannot revamp

[2] In particular, the regulation provides that "an applicant who has submitted a paragraph IV patent certification may not change it to a paragraph III certification if a patent infringement suit has been filed against another paragraph IV applicant unless the agency has determined that no applicant is entitled to 180-day exclusivity or the patent expires before the lawsuit is resolved or expires after the suit is resolved but before the end of the 180-day exclusivity period." 21 C.F.R. § 314.94(a)(12)(viii).

its regulations without engaging in a new round of formal notice-and-comment rulemaking. *See, e.g., Marseilles Land & Water Co. v. FERC*, 345 F.3d 916, 920 (D.C. Cir. 2003) ("[A]n administrative agency may not slip by the notice and comment rule-making requirements needed to amend a rule by merely adopting a *de facto* amendment to its regulation through adjudication."); *National Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 241 (D.C. Cir. 1992) ("Once a regulation is adopted by notice-and-comment rulemaking its text may be changed only in that fashion.") (alteration and quotation omitted).

Second, even if the concerns over gamesmanship by ANDA applicants were legitimate, FDA did ***not*** decline to approve Teva's ANDA on that basis. FDA's Letter Decision does not mention the point; that, after all, is why FDA's ***litigation brief*** in this case relies on a Letter Decision the agency issued in ***another*** case involving ***another*** manufacturer and ***another*** factual scenario. *See* FDA Opp. at 36. Of course, it is axiomatic that "the courts may not accept appellate counsel's *post hoc* rationalizations for agency action. It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (citation omitted) ("*State Farm*"). That point is dispositive here.

Finally, and at bottom, the concern Mylan and FDA express about potential gamesmanship by ANDA applicants simply reflects their disagreement with the words Congress chose—not with Teva's conduct. Had Congress intended to preclude the application of subsection (c)(2)(B) in these circumstances, it could have required each generic applicant to secure its own determination of patent ***invalidity*** or ***non-infringement***, and thereby required the manufacturer to submit its paragraph IV certification well in advance of the relevant patent's expiration. But Congress did not do so. Instead, it provided that the brand manufacturer must

secure a "court determin[ation] that the patent is ***valid and would be infringed*** … in the patent infringement litigation resulting from the certification." 21 U.S.C. § 355a(c)(2)(B) (emphasis added). Congress thus put the onus to pursue litigation squarely on the brand manufacturer—not the generic applicant. Administrative agencies are of course free to rely on policy rationales when they interpret an ambiguous statute, but where Congress has spoken clearly, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress" regardless of whether it agrees with the choice Congress made. *Chevron*, 467 U.S. at 842-43.

Ultimately, because FDA's interpretation of the statute conflicts with the plain text and policies underlying the statute, prior case law, and settled agency practice, its Letter Decision should be set aside and this Court should require the agency to immediately approve Teva's ANDA for generic amlodipine drug products.

II. FDA ERRED BY CONSTRUING THE STATUTE TO REQUIRE AN APPELLATE MANDATE.

Just as FDA has failed to justify its inversion of plain statutory text, it has failed to demonstrate that its mandate requirement faithfully applies the statutory text. Indeed, the various parties to this case do little to dispute Teva's straightforward argument that the key statutory phrase—"the court determines"—unambiguously refers to the substantive holding of a court, as contained in its opinion and judgment. After all, as Teva noted in its opening brief, jurists, litigants, and laymen routinely describe appellate court opinions as "determin[ing]" the merits of a case. Teva Br. at 23 (collecting cases).

FDA's initial response is actually a concession: "[B]ecause a court's reasoning is contained in its opinion, most ***ordinary references to the substance of a court decision*** will be to that opinion." FDA Opp. at 25 (emphasis added); *id.* at 26 (acknowledging "[t]hese ***routine***

references") (emphasis added). This is precisely the point. "Ordinary" and "routine" usage demonstrate that the "court's reasoning" and the "substance of [its] decision" make up a court's "determination" of the merits—not procedural technicalities like an appellate court's issuance of its formal mandate. And make no mistake: it is ***substance*** that this statute is concerned about, because it conditions a brand manufacturer's eligibility for pediatric exclusivity on the court's substantive determination of patent "validity and infringement," not on the ***timing*** of the technical effectiveness of that judgment.[3]

In an effort to elide this straightforward point, FDA next asserts that the term "determines" must be ambiguous simply because "FDA's decisional letter set forth the first four definitions it found in the Webster's Third New International Dictionary (2002). Of these definitions, one supports Teva's definition and other three [*sic*] support FDA's ultimate conclusion." FDA Opp. at 26. But that argument stumbles over the straight-face test. After all, "[a]mbiguity is a creature not of definitional possibilities, but of statutory context." *Brown v. Gardner*, 513 U.S. 115, 117-118 (1994) (internal citation omitted). In other words, "[t]he issue is not so much whether the [term] is, in some abstract sense, ambiguous, but rather whether, read in context and using the traditional tools of statutory construction [it appears that] Congress has directly spoken to the precise question at issue." *California Ind. Sys. Operator Corp. v. FERC*, 372 F.3d 395, 400, 401 (D.C. Cir. 2004).

Here, both context (as set forth above) and the ordinary tools of statutory construction confirm that an appellate court determines the merits of a case in its opinion and judgment. That

[3] While the point is fairly obvious, it is worth noting that the pediatric exclusivity provision at issue in this case is an ***eligibility*** provision, not a ***timing*** provision. After all, the time pediatric exclusivity commences is already fixed as the date of patent expiration, so what matters is ***how*** the court rules (and not ***when*** it issues a mandate), since that is what determines the manufacturer's eligibility for exclusivity.

is so, as Teva explained in its opening brief, because when Congress wants to do so, it plainly knows how to key events to the date an appellate "mandate" issues, or to the date "a court enters a final decision from which no appeal … can be taken." Teva Br. at 24 (collecting examples; internal quotation omitted). It did not do so here.

Contrary to FDA's argument, then, Congress did not need to be any "more precise" in § 355a(c)(2)(B). FDA Opp. at 24. Instead, when it chose to use to the term "determines" and not (as elsewhere) the term "mandate" or "final decision," it made a deliberate decision to focus on substance—not on timing. Other than FDA's conclusory assertion that "[n]one of those instances … involved either the language ("the court determines") or the context (pediatric exclusivity)," neither the agency nor its defenders offer any basis for undermining the strong presumption that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation and alteration omitted). That well-settled principle is sufficient to dispose of this case at *Chevron* step one.[4]

In the event this Court proceeds to *Chevron* step two, FDA's policy rationales for interpreting the statute to require a mandate fare no better. FDA's principal justification for tying pediatric exclusivity to the issuance of the appellate mandate is that that interpretation advances the goal of achieving "finality." FDA Opp. at 24; Mylan Opp. to Apotex at 8. But FDA does not even attempt to explain how it divined Congress's preference for finality from the

[4] In any event, there is nothing imprecise about the term "determines." By definition, courts do not "determine" anything ***in*** the mandate. Rather, the mandate—which "consists of a certified copy of the judgment, a copy of the court's opinion, if any, and any direction about costs," Fed. R. App. P. 41(a)—is merely a procedural device by which the appellate court informs the district court ***of*** its "determination."

statute at issue in this case (or even from its legislative history). Indeed, no party has put forward any evidence that Congress even considered finality in passing this provision of the statute. In short, absolute finality is FDA's own preference—not Congress's.

Far more important, as Teva explained in its opening brief, *see* Teva Br. at 29, FDA's interpretation of the statute threatens to slow the flow of generic drugs into the market in violation of the recognized ***congressional*** intent underlying the statute, *see, e.g.*, *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998), but does not meaningfully further its ***own*** goal of securing strict decisional finality. The agency does not dispute that only a miniscule fraction of appellate decisions are subject to further review. Rather, it expressly concedes the point, asserting that "the extreme delays posited by Teva and Apotex do not seem realistic" given the "rarity of *en banc* review and certiorari." Opp. at 29.

On this point, FDA appears to misunderstand both Teva's argument and the appellate process in general. The key point here is that brand manufacturers almost certainly will be able to delay issuance of an appellate mandate ***regardless*** of whether its petitions for rehearing *en banc* and writ of *certiorari* are successful. And given FDA's acknowledgment of the "rarity" with which such efforts meet success, it is hard to give much credence to the Agency's desire to promote even "greater finality." FDA Opp. at 29. After all, the fact that it is virtually impossible to obtain further review of a Federal Circuit decision proves that awaiting its mandate does not add any greater finality to the pediatric exclusivity process.

Finally, FDA argues that its interpretation is acceptable because it "reasonably balanced" Congress's desire to speed the approval of generic drugs with "the competing objective of the pediatric exclusivity provision—to reward manufacturers for conducting pediatric studies."

FDA Opp. at 28-29 (capitalization omitted); *see also* Mylan Opp. to Apotex at 6; Mutual Opp. at 12. But there are two problems with that assertion. First, FDA's Letter Decision in this case simply makes no effort to "balance" those considerations; one can read and re-read the Letter Decision, but the section containing FDA's analysis of whether the mandate is necessary does not mention either Congress's desire to speed generic drug approvals or its desire to reward brand manufacturers for conducting pediatric studies. Whether or not FDA's decision would constitute a reasonable balancing of those competing policies if FDA had attempted to balance them (and as set forth in its briefs, Teva does not believe it would), the fact remains that the agency did not even attempt to do so—and this Court "may not accept [agency] counsel's *post hoc* rationalizations for agency action." *State Farm*, 463 U.S. at 50 (internal citations omitted); *see also, e.g.*, *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1243 (D.C. Cir. 2007).

In any event, to the extent the pediatric exclusivity statute evinces a policy to reward brand manufacturers for submitting pediatric studies, it only rewards those brand manufacturers whose patents are ***valid*** and ***enforceable***. After all, under the plain language of the statute, pediatric exclusivity attaches only when a court "determines that the patent ***is valid and would be infringed***." 21 U.S.C. § 355a(c)(2)(B) (emphasis added). Here, the key point is that a "statute … is designed to do what it does in fact [and its] stopping points are as important as the other provisions." Frank H. Easterbrook, *Foreword: The Court and the Economic System*, 98 HARV. L. REV. 4, 46 (1984). FDA offers no basis for thinking that Congress intended to offer six months of post-expiration exclusivity a brand manufacturer for asserting an invalid or unenforceable patent, and FDA cannot reasonably untether such broad congressional objectives from their particulars.

Here, too, because FDA's interpretation conflicts with the plain text of the statute and cannot be justified under either prong of *Chevron*, its Letter Decision should be set aside and this Court should require the agency to grant immediate final approval to Teva's ANDA for generic amlodipine drug products.

CONCLUSION

For the foregoing reasons, this Court should vacate FDA's April 18, 2007 Letter Decision and compel FDA to grant immediate final approval to Teva's ANDA No. 76-846.

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Respectfully submitted,

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