UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 09-1111 (RMC)
	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services, *et al*.,	)	
	)	
Defendants.	)	

DEFENDANTS' MOTION TO DISMISS

Defendants, Kathleen Sebelius, Secretary of Health and Human Services; Margaret Hamburg, M.D., Commissioner of Food and Drugs; and the Food and Drug Administration hereby move to dismiss plaintiff's complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) on the grounds that plaintiff does not challenge final agency action, plaintiff's claims are not ripe, plaintiff has suffered insufficient injury for Article III standing, and plaintiff has failed to exhaust administrative remedies. The grounds for this motion are explained further in the memorandum of points and authorities attached to this motion.

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CONSOLIDATED MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

Plaintiff, Teva Pharmaceuticals USA, Inc. ("Teva"), a generic drug manufacturer, filed suit against the Food and Drug Administration ("FDA")[1] with respect to two of Teva's pending generic drug applications, despite the fact the earliest those applications will be eligible for approval is April 6, 2010 – a fact that Teva concedes. FDA has not made a final decision regarding the approval of those two abbreviated new drug applications (ANDAs), nor whether Teva is entitled to 180-day marketing exclusivity for these products. Hence, the complaint should be dismissed because it is a challenge to non-final agency action, it is not ripe, and Teva has no present injury. In addition, the complaint can be dismissed for failure to exhaust administrative remedies. Teva has known since at least April 2008 of the possibility that 180-day exclusivity may be an issue for these products, yet it has not tried to resolve the matter with FDA, and now seeks to have this Court make a decision on a matter entrusted to FDA in the first

[1] Kathleen Sebelius, Secretary of Health and Human Services ("HHS"), and Margaret Hamburg, M.D., Commissioner of Food and Drugs, are also named defendants.

instance.

In an attempt to avoid these major flaws in its case, Teva argues that an FDA decision regarding another generic drug that was approved by FDA in May 2008 – which is not manufactured by Teva – constitutes a "rule" that Teva is entitled to challenge in this Court. Teva is thus asking this Court to declare that this decision – made in an informal adjudication, not a rulemaking – constitutes a "rule" subject to judicial review, and then to declare that this "rule" will be used by FDA to improperly deny Teva 180 days of marketing exclusivity when Teva's generic products are eligible for approval next year. The decision FDA made in the context of another generic drug application, however, is not "rule." Teva has failed to demonstrate the basic prerequisites necessary to bring a case in this Court: final agency action and a ripe, actual injury. Significantly, this Court recently faced essentially the same issue in the same context; i.e., a generic drug manufacturer sued FDA before FDA had taken final action on its application because it wanted to know ahead of time whether it would receive 180 days of marketing exclusivity. Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp.2d 1 (D.D.C. 2008). (Teva participated as amicus in Hi-Tech). There, Judge Bates had no trouble recognizing that the case presented no final agency action: "Hi-Tech is not entitled to judicial review of the interpretation and application of the exclusivity forfeiture provisions of the Medicare Modernization Act until the FDA itself first interprets and applies those provisions with respect to Hi-Tech's ANDA – i.e., until there is final agency action." Id. at 8.

So too here. Teva has failed to challenge a final agency action under the Administrative Procedure Act ("APA"), and presents no ripe injury to this Court. There is therefore no final, ripe action for Teva to challenge under the APA, much less any justification to grant its request

for emergency relief, and Teva's complaint should be dismissed and its motion for preliminary injunction denied.

STATUTORY AND REGULATORY BACKGROUND

I. New Drug Applications (NDAs)

Under the FDCA, pharmaceutical companies seeking to market "pioneer" or "innovator" drugs must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. §§ 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug, or a method of using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA must publish the patent information it receives, and does so in "Approved Drug Products with Therapeutic Evaluations" (the "Orange Book"). Id.; see also 21 C.F.R. § 314.53(e).

II. Abbreviated New Drug Applications (ANDAs)

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282, permits manufacturers to submit abbreviated new drug applications requesting approval of generic versions of approved drug products. 21 U.S.C. § 355(j). The Hatch-Waxman Amendments were intended to balance encouraging innovation in the development of new drugs with accelerating the availability to consumers of lower cost alternatives to innovator drugs. See H.R. Rep. No. 98-857 (Part I), 98th Cong., 2d Sess. at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48; see also, e.g., Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 139 (3d Cir. 1987).

ANDA applicants need not submit clinical data to demonstrate the safety and efficacy of the generic product, as with an NDA. See 21 U.S.C. § 355(j). Rather, an ANDA relies on FDA's previous findings that the product approved under the NDA is safe and effective, and the FDCA sets forth in detail the information an ANDA must contain. See 21 U.S.C. § 355(j)(2)(A). Among other information, an ANDA must include data showing that the generic drug product is bioequivalent to the pioneer drug product. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. §§ 314.127(a)(6)(i), 314.94(a)(7). A drug is considered to be bioequivalent if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug . . . ." 21 U.S.C. § 355(j)(8)(B)(i).

A. Patent Protections and 180-Day Exclusivity

The timing for approval of ANDAs depends, in part, on statutory patent protections afforded to the innovator drug. Among other things, an ANDA must contain one of four specified certifications for each patent that "claims the listed drug" or claims "a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii).

This certification must state one of the following:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) . . . the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). If a certification is made under paragraph I or II indicating, respectively, that patent information pertaining to the drug or its use has not been filed with FDA or that the patent has expired, the ANDA may be approved immediately. 21 U.S.C. § 355(j)(5)(B)(i). A paragraph III certification indicates that the ANDA applicant does not intend

to market the drug until after the applicable patent has expired, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

If an applicant wishes to challenge the validity of a patent, or to claim that the patent would not be infringed by the product covered by the ANDA, the applicant must submit a certification pursuant to paragraph IV of this provision. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The applicant must also provide notice of its paragraph IV certification to the NDA holder and the patent owner explaining the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B).

The filing of a paragraph IV certification "for a drug claimed in a patent or the use of which is claimed in a patent" is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This enables the NDA holder and patent owner to sue the ANDA applicant. If such a suit is brought within 45 days of the date notice of the certification was received by the patent owner or NDA holder, FDA must stay approval of the ANDA for 30 months from that date (commonly referred to as the "30-month stay"), unless a final court decision is reached earlier in the patent case or the court orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is brought within the requisite 45-day period, FDA may approve an ANDA with a paragraph IV certification effective immediately, provided that other conditions for approval have been met. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

The statute may provide an incentive and reward to generic drug manufacturers that expose themselves to the risk of patent litigation. It does so by granting, in certain circumstances, a 180-day period of marketing exclusivity vis-a-vis other ANDA applicants to the manufacturer who is first to file an ANDA containing a paragraph IV certification to each listed

patent. 21 U.S.C. § 355(j)(5)(B)(iv); see Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 52-53 (D.C. Cir. 2005); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

Congress amended 21 U.S.C. § 355(j) in 2003 to add the exclusivity forfeiture provisions addressed by Teva in this case, 21 U.S.C. § 355(j)(5)(D). See The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the "MMA"). The MMA is the governing statute for the merits issues raised by Teva because Teva's ANDA was submitted after the effective date of the MMA. See Teva's Memorandum in Support of its Motion for a Preliminary Injunction ("Pl. Mem.") at 21. The Ranbaxy case relied on extensively by Teva was interpreting the statute as it existed prior to the MMA. Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 122 n.* (D.C. Cir. 2006) ("The decisions of the FDA and of the district court were made pursuant to the Act as it stood before the MMA and, because the MMA was not made retroactive . . . , this decision is also geared to the Act pre-MMA."); see also Pl. Ex. 5 at 8; Pl. Ex. 9 at 14.

The MMA forfeiture provisions describe sets of conditions under which an ANDA applicant who was eligible for 180-day exclusivity could lose that eligibility. See 21 U.S.C. § 355(j)(5)(D). The Act provides that a 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv) "shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." 21 U.S.C. § 355(j)(5)(D)(ii). The various types of forfeiture events are described in 21 U.S.C. § 355(j)(5)(D)(i). The forfeiture event that is addressed in Teva's filings pertains to the failure to market, and the statute provides that a first ANDA applicant will forfeit exclusivity if it does not market its drug by a certain date:

> (I) FAILURE TO MARKET. – The first applicant fails to market the drug by the later of –
>
> (aa) the earlier of the date that is –
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; or
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:
>
> (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
>
> (CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

21 U.S.C. § 355(j)(5)(D)(i)(I).

Application of these forfeiture provisions requires a series of analyses based on when specific events occur in relation to each other. The statute directs that a forfeiture event occurs when the first ANDA applicant fails to market the drug by the later of two dates. One of these dates is calculated under section (aa) by determining the earlier of a date that is either 75 days

after the first applicant's ANDA is approved (subsection (AA)) or 30 months after the date of submission of the first applicant's ANDA (subsection (BB)). The second date is calculated under section (bb) by determining the date that is 75 days after the occurrence of at least one of three enumerated events. These events include, very generally, when a court enters a final decision that the patent is invalid or not infringed (subsection (AA)), a court signs a settlement order or consent decree entering final judgment that includes a finding that the patent is invalid or not infringed (subsection (BB)), or the patent information for the listed drug is withdrawn by the NDA holder (subsection (CC)). Until one of these events occurs, there is no forfeiture because forfeiture occurs when the "later" of the events specified in (aa) or (bb) occurs. See Pl. Ex. 1 at 5.

B. Citizen Petitions

FDA regulations permit any "interested person" to "petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a); see 21 C.F.R. § 10.30. "In fact, the FDA's regulations under the FDCA require that a request that the 'Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act.'" Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, 539 F. Supp.2d 4, 21 (D.D.C. 2008). The Court in Ass'n of Am. Physicians & Surgeons dismissed plaintiffs' claims for failure to exhaust their administrative remedies, among other things, and held that "the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed." Id. at 24.

By regulation, FDA must make at least a tentative response to a citizen petition within 180 days. 21 C.F.R. § 10.30(e)(2). In 2007, Congress enacted 21 U.S.C. § 355(q) to direct FDA to make final decisions on citizen petitions relating to drug approvals within 180 days after the petition is submitted. 21 U.S.C. § 355(q)(1)(F). For most such citizen petitions, after 180 days have passed, the statute considers that FDA has taken final agency action for purposes of judicial review, even if FDA has not issued a substantive response by that time. 21 U.S.C. § 355(q)(2)(A). Congress, however, expressly exempted from the scope of the provision "a petition that relates solely to the timing of the approval of an application pursuant to [21 U.S.C. § 355](j)(5)(B)(iv)." 21 U.S.C. § 355(q)(4)(A). The statute thus provides that FDA, not applicants, exercises control over the timing of exclusivity and generic drug approval decisions, and that citizen petitions may not force FDA to act prematurely on these issues.

FACTUAL BACKGROUND

Merck Research Laboratories ("Merck") holds the NDAs for losartan potassium tablets (Cozaar) and losartan potassium-hydrochlorothiazide tablets (Hyzaar), which are both approved to treat hypertension. Teva submitted an ANDA for the generic version of Cozaar on December 18, 2003, and an ANDA for generic Hyzaar on May 24, 2004. Both of Teva's ANDAs contained paragraph III certifications to two patents listed in the Orange Book – U.S. Patent No. 5,138,069 ("the '069 patent") and U.S. Patent No. 5,153, 197 ("the '197 patent") – and a paragraph IV certification to U.S. Patent No. 5,608, 075 ("the '075 patent"). The '069 patent expires on August 11, 2009, and the '197 patent expires on October 6, 2009. The earliest effective date of Teva's ANDAs would be April 6, 2010, the date on which Merck's pediatric exclusivity attached

to the '197 patent expires.[2]

Merck did not sue Teva for infringement of the '075 patent upon receiving Teva's notices that it had filed paragraph IV certifications. Nearly one year later, by letter dated March 18, 2005, Merck requested that the '075 patent be removed from the Orange Book. Merck's delisting request appeared in the Orange Book on April 18, 2008.

ARGUMENT

I. Standards of Review

A. Motion to Dismiss

Plaintiffs bear the burden of establishing that the Court has jurisdiction. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992); McNutt v. Gen. Motors Acceptance Corp. of Indiana, 298 U.S. 178, 182 (1936); Int'l Bhd. of Teamsters v. Transp. Sec. Admin., 429 F.3d 1130, 1134 (D.C. Cir. 2005); Sierra Club v. EPA, 292 F.3d 895, 899-900 (D.C. Cir. 2002); U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000); Hilska v. Jones, 297 F. Supp. 2d 82, 86 (D.D.C. 2003). Moreover, under Article III of the Constitution, a plaintiff also must establish that its claim is ripe. "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas v. United States, 523 U.S. 296, 300 (1998) (citations omitted).

Although Teva seeks declaratory relief, such relief is only permitted if jurisdiction

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[2] Innovators can earn an additional six months of exclusivity beyond the expiration of each listed patent pursuant to 21 U.S.C. § 355a, by conducting studies of their products' safety and effectiveness for children. Merck did so here, and FDA cannot therefore approve any losartan ANDA before six months after the expiration of each of Merck's listed patents. See http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020387&Product_No=002&table1=OB_Rx (electronic Orange Book entry showing Merck's pediatric exclusivity).

otherwise exists. 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction . . . any court . . . may declare the rights. . . ."); Public Service Comm'n of Utah v. Wycoff Co., 344 U.S. 237, 242 (1952) (Declaratory Judgment Act "applies . . . only to 'cases and controversies in the constitutional sense.'") (quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)); Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671-72 (1950) (the Declaratory Judgment Act provides a discretionary, procedural remedy that courts may award, but it does not confer or expand a court's jurisdiction).

In addressing a motion to dismiss brought pursuant to Rule 12(b)(6), the Court generally must accept as true all factual allegations in the complaint. Courts, however, "accept neither 'inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint,' nor 'legal conclusions cast in the form of factual allegations.'" Browning v. Clinton, 292 F.3d 235, 242 (D.C. Cir. 2002) (quoting in part Kowal v. MCI Communications Corp., 16 F.3d 1271, 1275 (D.C. Cir. 1994)); see also Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949-50 (2009); Papasan v. Allain, 478 U.S. 265, 286 (1986); Trudeau v. FTC, 456 F.3d 178, 193 (D.C. Cir. 2006); Luck's Music Library, Inc. v. Ashcroft, 321 F. Supp.2d 107, 112 (D.D.C. 2004).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S.Ct. at 1949 (quoting in part Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that

requires the reviewing court to draw on its judicial experience and common sense." Id. at 1950.

B. Motion for Preliminary Injunction

In order to obtain a preliminary injunction, a party must demonstrate that: (1) it has a substantial likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. See Katz v. Georgetown Univ., 246 F.3d 685, 687-88 (D.C. Cir. 2001); Biovail Corp. v. FDA, 448 F. Supp.2d 154, 158 (D.D.C. 2006). The likelihood of success requirement is the most important of these factors. Id. "Without any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how compelling, do not justify preliminary injunctive relief." Am. Bankers Ass'n v. Nat'l Credit Union Admin., 38 F. Supp.2d 114, 140 (D.D.C. 1999). As the Supreme Court recently made clear, "a party seeking a preliminary injunction must demonstrate . . . 'a likelihood of success on the merits,'" not merely the existence of "questions 'so serious, substantial, difficult and doubtful, as to make them fair ground for litigation.'" Munaf v. Geren, 128 S.Ct. 2207, 2219 (2008) (citations omitted).

Preliminary injunctive relief is an "extraordinary and drastic remedy" that should be sparingly exercised. Mazurek v. Armstrong, 520 U.S. 968, 972 (1997); Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 215 (D.D.C. 1996). Teva's extraordinary request for relief presents an additional and very high hurdle: when a movant seeks mandatory injunctive relief, i.e., an injunction that "would alter, rather than preserve, the status quo . . . the moving party must meet a higher standard than in the ordinary case by showing 'clearly' that he or she is entitled to relief or that 'extreme or very serious damage' will result from the denial of the

injunction." Columbia Hosp. for Women Found., Inc. v. Bank of Tokyo-Mitsubishi, Ltd., 15 F. Supp.2d 1, 4 (D.D.C. 1997) (quoting Phillip v. Fairfield Univ., 118 F.3d 131, 133 (2d Cir. 1997)), aff'd, 159 F.3d 636 (D.C. Cir. 1998); see also Dorfmann v. Boozer, 414 F.2d 1168, 1173 (D.C. Cir. 1969); Nat'l Conference on Ministry to Armed Forces v. James, 278 F. Supp. 2d 37, 43 (D.D.C. 2003) ("A district court should not issue a mandatory preliminary injunction unless the facts and the law clearly favor the moving party.") (internal quotations omitted); Mylan Pharms., Inc. v. Shalala, 81 F. Supp.2d 30, 36 (D.D.C. 2000). The extraordinary relief Teva seeks is demonstrably not to preserve the status quo, but to obtain far-reaching mandatory relief by getting this Court to make a decision on exclusivity regarding ANDAs that are not yet ready for final approval, and will not be for nearly a year, and which decision should be entrusted to FDA in the first place.

II. Teva's Complaint Should Be Dismissed

A. FDA Has Not Taken Final Agency Action with Respect to Teva's ANDA

The APA permits judicial review of: "Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court. . . ." 5 U.S.C. § 704. Teva does not claim it is seeking judicial review of an FDA action "made reviewable by statute." Thus, the issue is whether FDA's prospective future decision regarding Teva's eligibility for 180 days of marketing eligibility is "final agency action." In order to constitute final agency action, the conduct at issue must "mark the 'consummation' of the agency's decisionmaking process" and must also "be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 13 (D.C. Cir. 2005) (quoting in part Bennett v. Spear, 520 U.S. 154, 178 (1997)); cf. FTC v. Standard Oil

Co., 449 U.S. 232, 241, 244 (1980) (FTC issuance of an administrative complaint was not final agency action, even though the complaint was "definitive" on the question regarding whether the Commission had "reason to believe" that Standard Oil was violating the Federal Trade Commission Act, and the burden of responding to this complaint would be "substantial"); Single Stick, Inc. v. Johanns, 601 F. Supp. 2d 307, 316-17 (D.D.C. 2009).

Inasmuch as FDA has not yet made a decision on Teva's eligibility for 180 days of exclusivity, there has been no "final agency action" for this Court to review. In fact, that was the holding recently made by Judge Bates in the HiTech case. There, as here, an ANDA applicant sought 180 days of marketing exclusivity for its generic drug. The earliest its product could be approved was October 28, 2008, and it filed its motion for a preliminary injunction in September 2008. 587 F. Supp.2d at 5-6. Because FDA had not made a decision on the final approval of Hi-Tech's product or its eligibility for 180 days of exclusivity, the Court held that there was no final agency action:

> Hi-Tech is not entitled to judicial review of the interpretation and application of the exclusivity forfeiture provisions of the Medicare Modernization Act until the FDA itself first interprets and applies those provisions with respect to Hi-Tech's ANDA – i.e., until there is final agency action. . . . The Court concludes that because the FDA has not yet construed or applied the forfeiture provisions in this case, Hi-Tech cannot at this time demonstrate a likelihood of success on the merits since its claim is not yet susceptible to judicial review.

587 F. Supp.2d at 8. The Court noted that although Hi-Tech had spent a considerable amount of time addressing the merits of the exclusivity provisions of the MMA, the Court would decline to address those arguments "[b]ecause the FDA has yet to take action with regard to the exclusivity

issue." Id. at 8 n.5.[3]

Teva claims that FDA has created a "delisting rule" that is subject to judicial review now. See Pl. Mem. at 15-18. To the contrary, the alleged "rule" on which Teva so heavily relies is nothing more than FDA's decision regarding whether a different ANDA (for acarbose) was eligible for 180-day exclusivity. See Compl. Ex 5 (letter to Cobalt – a manufacturer of generic acarbose). This letter decision is not a final agency action applicable to Teva or its losartan ANDAs, and FDA has not yet made a decision on exclusivity for losartan.[4]

Nor is the acarbose decision made by FDA a "rule" subject to challenge. The decision was made in the context of fact-specific decisions regarding FDA approval of another ANDA of another manufacturer, and does not constitute a "rule" applicable to Teva's product – which is not eligible for approval until 2010. Under the APA:

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[3] The Court denied the motion for preliminary injunction; however, it did not rule on the government's motion to dismiss. 587 F. Supp.2d at 3 n.1. It should be noted that the Court's decision was rendered less than three weeks before Hi-Tech's product was eligible for approval on October 28, and the Court retained the case and requested that the parties appear before it on October 28 before FDA issued its decision on H-Tech's ANDA. Id. at 13. After FDA decided that Hi-Tech had forfeited exclusivity, it approved the ANDAs of Hi-Tech and Apotex. Hi-Tech then sought permanent injunctive relief on the ground, among others, that Merck's pediatric exclusivity had prevented forfeiture of Hi-Tech's 180-day exclusivity period. The Court denied this motion, and held, among other things, that FDA was entitled to Chevron deference in its interpretation of the statute. Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp.2d 13, 22 (D.D.C. 2008) ("Hi-Tech II").

[4] The litigation cited by Teva that arose out of the acarbose decision, Cobalt Labs., Inc. v. FDA, et al., Civ. No. 08-798 (RBW) (D.D.C.), was filed after FDA had taken final agency action; i.e., after FDA had found that Cobalt's 180-day exclusivity had been forfeited and FDA had approved Cobalt's ANDA and the ANDA of a competitor, Roxane Laboratories. Pl. Ex. 5 at 1 n.1. On May 9, 2008, Judge Walton denied Cobalt's motion for a temporary restraining order from the bench on the grounds, among other things, that Cobalt had shown no substantial likelihood of success on the merits of the forfeiture issue. See Attachment A. Cobalt dismissed its complaint on May 16. See Attachment B.

> "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing.

5 U.S.C. § 551(4). "Rule making" "means agency process for formulating, amending, or repealing a rule." Id. § 551(5). On the other hand, "adjudication" "means agency process for the formulation of an order." Id. § 551(7). An "order" "means the whole or part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rulemaking. . . ." Id. § 551(6). FDA's decision with respect to acarbose is an informal adjudication, not a rulemaking. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 218-21 (1988) (Scalia, J., concurring) (discussing difference between rulemaking and adjudication); cf. Goodman v. FCC, 182 F.3d 987, 993-94 (D.C. Cir. 1999) (agency decision was adjudication, not rulemaking, despite public comment period, potential affect on a broad class, and publication in Federal Register under heading "Final Rules" because decision addressed only a proposal made by certain licensees for a temporary waiver of rules).

Rules are legislative in nature, i.e., agency statements with future effect. See Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993). Agency decisions made in the context of approvals of a specific drug for a specific manufacturer do not come close to meeting this definition. In Am. Mining Cong., the D.C. Circuit identified four criteria that indicate a rule is legislative (none of which is present in this case): (1) in the absence of the rule, no legislative basis would exist for an enforcement action; (2) the agency has published the rule in the Code of Federal Regulations ("CFR"); (3) the agency explicitly invoked

its general legislative authority to pass the rule; (4) the rule effectively amends a prior legislative rule. 995 F.2d at 1112; see also In re Long-Dist. Tel. Service, 539 F. Supp.2d 281, 307-11 (D.D.C. 2008) (discussing the requirements of a substantive rule). Teva has not demonstrated that the so-called "Delisting Rule" meets any of these four criteria. In addition, a decision made by FDA in approving one manufacturer's product does not have a "binding effect" on other manufacturers (or on Teva). See Cement Kiln Recycling Coalition v. EPA, 493 F.3d 207, 226-27 (D.C. Cir. 2007).

As Teva is well aware, it is FDA's practice to make exclusivity decisions at the time that an ANDA is ready for final approval.[5] This practice ensures that FDA's decision takes all appropriate facts into account, ensures that any intervening changes in policy may be applied, and avoids premature adjudication of issues that are not yet ripe. Although losartan ANDAs may be eligible for approval on April 6, 2010 (but no sooner), there remains the potential for an intervening event, e.g., the NDA holder could list an additional patent, sue for infringement, and obtain a preliminary injunction, there could be a court decision or settlement regarding the '075 patent, or Teva could be unable to obtain final approval for reasons unrelated to the issues in this case that could delay final approval of any losartan ANDAs or alter eligibility for exclusivity. In addition, multiple ANDAs are often submitted for blockbuster drugs,[6] which further complicates FDA's analysis of exclusivity under the complex provisions of the MMA, and the strain that

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[5] See, e.g., Pl. Ex. 1 at 1 n.1; Pl. Ex. 5 at 1 n.1; Pl. Ex. 9 at 1 n.1.

[6] See, e.g., approved ANDAs for simvastatin (available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=SIMVASTATIN .); approved ANDAs for fluoxetine hydrochloride (available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=FLUOXETINE%20HYDROCHLORIDE).

premature exclusivity decisions – particularly multiple such decisions – would place on the agency's resources would be enormous. FDA fully intends to make a decision regarding 180-day exclusivity when an ANDA for losartan becomes ready for final approval, but until that time, there is no final agency action for this Court to review.[7]

B. Teva's Claims are not Ripe and Present No Current Injury

For essentially these same reasons, Teva's request for a judicial declaration on the exclusivity issue before Teva's ANDAs are ready for approval is not ripe. Abbott Labs. v. Gardner, 387 U.S. 136, 148 (1967); Reno v. Catholic Soc. Servs., Inc., 509 U.S. 43, 57-58 (1993). As the D.C. Circuit has explained: "Ripeness entails a functional, not a formal, inquiry." Pfizer Inc. v. Shalala, 182 F.3d 975, 980 (D.C. Cir. 1999). Here the Court "would benefit from further factual development of the issues presented," Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998), because FDA has not applied the statute to the facts of Teva's application. See Florida Power & Light Co. v. EPA, 145 F.3d 1414, 1421 (D.C. Cir. 1998).

The Pfizer case is particularly instructive. There, Pfizer, like Teva, wanted to prevent FDA from approving the ANDA of a competitor. Pfizer claimed that its product had a unique release mechanism, and no ANDA could be approved without an identical mechanism because ANDAs are required to have the same "dosage form" as the listed drug. Pfizer had filed a citizen petition with FDA making this argument, and FDA had issued a decision denying the citizen petition, finding that other release mechanisms could be the same dosage form. Moreover, FDA

[7] Another reason that the acarbose decision is not a "rule" is that there FDA was applying the terms of the statute (MMA) to the facts of the acarbose ANDA. See Pl. Ex. 5 at 1; Pl. Ex. 9 at 1. Ranbaxy invalidated an FDA regulation and FDA is now applying the statute directly to each case; thus, it is really the statute with which Teva has its dispute on the merits regarding forfeiture of exclusivity. See also Hi-Tech II, 587 F. Supp.2d at 16-17.

had accepted for processing the ANDA of a competitor, Mylan, that did not have Pfizer's unique dosage form. Pfizer brought suit against FDA, but the D.C. Circuit held that it did not present a ripe case because FDA had not approved Mylan's ANDA. 182 F.3d at 978-79. The Court held that Pfizer's challenge to FDA's denial of its citizen petition was not ripe, even though the denial was "final agency action." Id. at 979-80. In its citizen petition response, FDA had definitively answered Pfizer's argument that no other release mechanism could be the same dosage form; however, "FDA did not apply that interpretation to a particular set of facts." Id. at 979. Perhaps most significantly, the Court held that, in the event Mylan's ANDA were approved, "Pfizer may then challenge the reasons underlying [FDA's] final decision." Id. at 979.

Teva has similarly failed to demonstrate that withholding judicial review now will cause it hardship in the form of a direct and immediate impact on its day-to-day operations. By filing paragraph III certifications to two Merck patents, Teva has precluded itself from obtaining approval and marketing its drug products until April 6, 2010, at the earliest. Nevertheless, Teva complains: "Vindication of Teva's rights at some later date would be Pyrrhic, since the market for losartan potassium is so vast that Teva could not, at that point, possibly produce enough product to fully supply the market during its exclusivity." Pl. Mem. at 6. Thus, Teva argues that FDA's practice of making exclusivity decisions at the same time it makes approval decisions renders it impossible to seek judicial review, citing the Cobalt and HiTech cases in support of this argument. Pl. Mem. at 5-6, 18-21, 35-36.

This type of hardship was rejected by the D.C. Circuit in Pfizer, which recognized that Pfizer could obtain judicial review if its competitor's product were approved. 182 F.3d at 979. Similarly, in Biovail Corp. v. FDA, plaintiff argued that it was entitled to a response to its citizen

petition before approval of a competing ANDA. Plaintiff sought a court order directing FDA to rule on its citizen petition one week before approving any competing drug product, claiming that it would be harmed if a competitor were approved and then it had to seek judicial review. 448 F. Supp.2d at 157, 165. This Court rejected this argument, noting that there was no basis for ordering FDA to respond to the citizen petition prior to approval of ANDAs, and that plaintiff could "appeal any denial of its citizen petition, albeit after the ANDA is approved." Id. at 162, 165.

Additionally, although Teva argues that once it loses its exclusivity, it can never be regained, that is not correct. In Hi-Tech II, plaintiff asked the Court to enjoin FDA approval of other generics while it enjoyed 180 days of exclusivity. 587 F. Supp.2d at 14, 17. The Court denied Hi-Tech any relief, not because such relief was impossible, but because the FDA's application of the statute was correct. Id. at 19-22. Also, in Mova, the Court held that FDA had improperly denied Mova the 180-day exclusivity period, even though FDA had already approved Mylan's ANDA. The district court ordered FDA to delay approval of Mylan's ANDA for 180 days, and was affirmed by the Court of Appeals. 140 F.3d at 1063, 1074. See also American Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1078 (D.C. Cir. 2001) (court vacated approval of ANDA); Glaxo Group Ltd. v. Leavitt, 481 F. Supp.2d 434, 435 (D. Md. 2007) (court granted plaintiff's motion for a TRO that enjoined the effectiveness of an ANDA for 10 days).

Moreover, Teva faces no looming enforcement action, as in Abbott Labs. Nor has Teva offered any other argument why FDA must alter its priorities and delay other decisions to relieve the company's anxiety. See In re Barr Labs., 930 F.2d 72, 76 (D.C. Cir. 1991) ("In short, we have no basis for reordering agency priorities. The agency is in a unique – and authoritative –

position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way. Such budget flexibility as Congress has allowed the agency is not for us to hijack.").

Finally, even if it were "likely" that FDA will determine that Teva has forfeited its exclusivity, that is only a "future contingent event" that does not present a ripe case or controversy. Even after Mylan's product was tentatively approved by FDA, the D.C. Circuit in Pfizer held that there was no ripe case before the Court: "Although it is now more likely that the FDA will eventually approve Mylan's drug, the agency's tentative approval causes Pfizer no hardship at present or in the near future, nor does it render Pfizer's challenge fit for review." 182 F.3d at 980.

Additionally, for these same reasons, Teva does not have standing. As summarized by the Supreme Court:

> Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. . . . To invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision.

Lewis v. Cont'l Bank Corp., 494 U.S. 472, 477 (1990) (citations omitted); see also Lujan, 504 U.S. at 560; Int'l Bhd. of Teamsters v. Transp. Sec. Admin., 429 F.3d at 1134; Sierra Club v. EPA, 292 F.3d at 899. Inasmuch as FDA has made no decision with respect to Teva's ANDA, it has suffered no injury. An FDA decision made in the adjudication of the application of another manufacturer has caused no injury to Teva. See Shipbuilders Council of America v. United States, 868 F.2d 452, 456-57 (D.C. Cir. 1989) (trade association did not have standing to bring complaint requesting court to direct agency not to issue decisions similar to those issued in

a prior adjudication because there was no justiciable case and no direct injury); Radiofone, Inc. v. FCC, 759 F.2d 936, 938-39 (D.C. Cir. 1985) (Scalia, J.) (no standing to challenge adjudication if challenge is not to "the particular activity which the agency adjudication approved," but allegation of injury is "from the mere precedential effect of the agency's rationale in later adjudications.").[8]

C. Teva Has Failed to Exhaust Administrative Remedies

Teva's complaint is also subject to dismissal for failure to exhaust administrative remedies. Indeed, Teva has made no attempt to avail itself of, much less exhaust, the administrative remedy available to it under FDA regulations – a citizen petition pursuant to 21 C.F.R. § 10.25. Under FDA regulations, a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action," and that request must "be the subject of a final administrative decision based on [the citizen petition] . . . before any legal action is filed in a court." 21 C.F.R. § 10.45(b).

The exhaustion of administrative remedies doctrine "provides 'that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" McKart v. United States, 395 U.S. 185, 193 (1969) (quoting Myers v.

[8] 5 U.S.C. § 706(1) provides for judicial relief due to agency delay, but Teva has not raised such a claim. Moreover, any attempt by Teva to amend its complaint to add an unreasonable delay claim would be futile because "[a] claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 63 (2004) (emphasis in original). Here, where there is no requirement that FDA make its exclusivity decision before approval, and Teva cannot point to any action that FDA is legally required to take before April 6, 2010, FDA has not unreasonably delayed any discrete action it is legally required to take. In Hi-Tech, Judge Bates held that "resolving HiTech's entitlement to exclusivity is not a discrete action that the FDA is required to take, pursuant to statute or regulation, by a time certain." 587 F. Supp.2d at 9.

Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51 (1938)). The purpose of the exhaustion requirement is "avoidance of premature interruption of the administrative process . . . to let the agency develop the necessary factual background upon which decisions should be based. And since agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise." McKart, 395 U.S. at 193-94; Burt Lake Band of Ottawa & Chippewa Indians v. Norton, 217 F. Supp. 2d 76, 78 (D.D.C. 2002) ("In cases where Congress has allocated decision-making responsibility to the Executive branch, petitioning parties are required to exhaust all available administrative remedies before seeking judicial relief.") (citation omitted), appeal dismissed, No. 02-5341, 2002 WL 31778064 (D.C. Cir. Dec. 4, 2002). The exhaustion requirement also promotes judicial efficiency because the agency may decide the matter in a manner that obviates the need for judicial review. McKart, 395 U.S. at 195.[9]

Teva has known since at least April of 2008 that Merck requested that the '075 patent be delisted from the Orange Book. In October 2007, Teva submitted comments into the docket of the acarbose decision – in which the forfeiture issue it now seeks to litigate was raised with regard to acarbose. Pl. Mem. at 15; Pl. Exs. 2, 3, 4. Yet Teva has not even attempted to comply with the agency's citizen petition requirement here. For this reason, the exhaustion doctrine applies with particular force. As the D.C. Circuit recently explained:

> Typically, exhaustion ensures that imminent or ongoing administrative proceedings are seen through to completion. But the exhaustion rule does not contain an escape hatch for litigants who steer clear of established agency

[9] Courts decline to apply the exhaustion requirement in certain circumstances. See McCarthy v. Madigan, 503 U.S. 140, 144-49 (1992); Ass'n of Flight Attendants v. Chao, 493 F.3d 155, 159 (D.C. Cir. 2007). None of those circumstances, however, is present here.

> procedures altogether. To the contrary, exhaustion is especially important where allowing the litigants to proceed in federal court would deprive the agency of any opportunity to exercise its discretion or apply its expertise. See McCarthy, 503 U.S. at 145 ("exhaustion principles apply with special force when 'frequent and deliberate flouting of administrative processes' could weaken an agency's effectiveness by encouraging disregard of its procedures" (quoting McKart, 395 U.S. at 195)).

Ass'n of Flight Attendants, 493 F.3d at 158-59.

This Court has applied the FDA exhaustion requirement. For example, in Ass'n of Am Physicians & Surgeons, Inc. v. FDA, the Court held that, when the plaintiffs had failed to establish circumstances that might excuse filing a citizen petition, "the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed." 539 F. Supp.2d at 24; see also Garlic v. FDA, 783 F. Supp. 4 (D.D.C. 1992), appeal dismissed, 986 F.2d 546 (D.C. Cir. 1993); Estee Lauder, Inc. v. FDA, 727 F. Supp. 1, 6-7 (D.D.C. 1989); Nat'l Gay Rights Advocates v. HHS, No. 87-1735, 1988 WL 43833 at *2 (D.D.C. Apr. 26, 1988) (dismissing complaint as premature for failure to file a citizen petition when plaintiffs have "chosen to ignore the administrative processes available to them by making no attempt to seek relief in this manner.").

In the Ranbaxy case relied upon so heavily by Teva, Ranbaxy and Ivax (later bought by Teva) filed citizen petitions that challenged Merck's delisting of patents, as well as FDA's subsequent requirement that Ranbaxy and Ivax amend their ANDAs to remove the paragraph IV certifications, and then challenged FDA's denial of those petitions. 469 F.3d at 123. Because exhaustion of administrative remedies would thus promote judicial economy and aid judicial review (if any) in this case, Teva should be precluded from seeking judicial review until after it presents its claims and contentions to the agency. Even though, as in Pfizer, a final decision on a

citizen petition does not guarantee that a plaintiff can present a ripe case or controversy in federal court, Teva should not be excused from attempting to resolve the matter administratively. It is possible that an FDA decision in such a context will provide guidance to Teva in a manner that it will decide not to seek judicial review.

III. Teva Is Not Entitled To A Preliminary Injunction

Even if this case is not dismissed, Teva has failed to satisfy any of the four elements needed to obtain a preliminary injunction: a substantial likelihood of success on the merits; irreparable injury; a showing that other interested parties will not be substantially injured by the requested relief; and a showing that granting relief would serve the public interest. Teva has wholly failed to demonstrate the existence of a live controversy, and thus has no likelihood of succeeding on the merits. All of Teva's purported injuries are conjectural, "merely economic," and not irreparable. Moreover, the public does not benefit from a court stepping in to decide a question that Congress entrusted to an administrative agency to decide in the first instance.

A. Teva is Not Likely to Succeed on the Merits

Teva seeks an advance, advisory ruling from this Court on the exclusivity forfeiture question, and has devoted most of its brief to the merits of that question. See Pl. Mem. at 1-6, 15-20, 23-35. FDA has not made that decision, however, and is not required to do so before an ANDA is ready for final approval. In Hi-Tech, Judge Bates held that "resolving HiTech's entitlement to exclusivity is not a discrete action that the FDA is required to take, pursuant to statute or regulation, by a time certain." 587 F. Supp.2d at 9. Both parties here agree that the earliest an approval decision on Teva's ANDAs could occur is April 2010. Because FDA has not yet made a decision on the merits of the exclusivity forfeiture issue, FDA will not address those

arguments in this opposition. In Hi-Tech, Judge Bates declined to address the exclusivity issue that FDA had not yet addressed: "Because the FDA has yet to take action with regard to the exclusivity issue, the Court declines to address those arguments at this time." Id. at 8 n.5. Moreover, the possibility that FDA may decide that Teva has forfeited 180-day exclusivity is a "future contingent event" that presents no hardship to Teva now, and Teva's challenge to the merits of FDA's eventual decision is not fit for review at this time. See Pfizer, 182 F.3d at 980 (citing Texas, 523 U.S. at 300). There is thus no live case or controversy over that matter. See Abbott Labs., 387 U.S. at 148-49.

Rather, the "merits" questions for purposes of Teva's pending motion are threshold issues: whether there is final agency action, whether Teva has failed to exhaust, whether Teva's claims are ripe for adjudication, and whether Teva has a sufficient injury to demonstrate standing under Article III of the Constitution. For the reasons explained above, this Court should dismiss all of Teva's claims. Teva cannot at this time establish any likelihood of success, and for this reason alone the Court should deny Teva's request for mandatory emergency relief.

B. Teva Will Not Suffer Irreparable Harm Without Injunctive Relief

Courts insist that only irreparable harm justifies the issuance of a preliminary injunction. "The *sine qua non* of granting any preliminary injunctive relief is a clear and convincing showing of irreparable injury to the plaintiff." Experience Works, Inc. v. Chao, 267 F. Supp.2d 93, 96 (D.D.C. 2003). Because Teva is not likely to succeed on the merits, Teva "would have to make a very substantial showing of severe irreparable injury" to prevail on its motion. Nat'l Pharm. Alliance v. Henney, 47 F. Supp.2d 37, 41 (D.D.C. 1999). "Irreparabilty of injury is a very high standard." Bristol-Myers, 923 F. Supp at 220. The injury alleged must be certain, great, actual,

and imminent, Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985), and it must be "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." Mylan, 81 F. Supp. 2d at 42 (quoting Gulf Oil Corp. v. Dep't. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981)).

Teva has not, and cannot, establish that its alleged injury is anything more than anxiety over a possible adverse decision ten months down the road. It cannot be irreparable injury simply because a party does not know something that it would like to know because it would make its life easier – which is the gist of Teva's complaint. If that were so, then all applicants for any type of federal benefit, license, or permit could claim "injury" if they are not told of the government decision before the government is required to make the decision. While such foreknowledge would be nice, it is not required, and Teva has cited no case in which the failure of the government to tell an applicant the results of a decision before the government is required to make the decision constitutes "injury" – irreparable or otherwise.

Moreover, Teva's arguments about the various harms that it will suffer are speculative. Teva speculates that if FDA were to determine that Teva is not entitled to exclusivity and if FDA were to approve multiple ANDAs for losartan in April 2010, then Teva "will sell approximately 50-60 percent fewer losartan potassium tablets and will lose hundreds of millions of dollars in net revenues." Pl. Mem. at 37. That scenario, however, depends on various contingent events that have not taken place: that FDA will decide the forfeiture question unfavorably to Teva, that other ANDAs will be approved on the same date, that multiple losartan manufacturers will immediately begin marketing their products in competition with Teva, and that Teva will lose the market share that it anticipates capturing during an exclusivity period. As explained by the Court

in Hi-Tech: "The injury remains speculative today, since the FDA has not yet acted, and what the FDA does may affect the market loss Hi-Tech faces (i.e., the number of ANDA approvals will determine the market shares)." Hi-Tech, 587 F. Supp.2d at 12. Teva's concerns are simply too speculative to justify preliminary injunctive relief, particularly mandatory relief. If and when the events that Teva is predicting take place, Teva may challenge FDA's approval decision in this Court.

In addition, it is well settled that mere economic loss in and of itself does not constitute irreparable harm. "Mere injuries, however substantial, in terms of money, time and energy necessarily expended" are inadequate. Wisconsin Gas, 758 F.2d at 674 (quoting Virginia Petroleum Jobbers Ass'n v. FPC, 259 F.2d 921, 925 (D.C. Cir. 1958)). Allegations of lost sales must be "sufficiently large in proportion to the plaintiff's operations that the loss of the amount of money involved would also cause extreme hardship to the business, or even threaten destruction of the business." Gulf Oil, 514 F. Supp. at 1025; see also Sociedad Anonima Viña Santa Rita v. Dep't of Treasury, 193 F. Supp.2d 6, 14 (D.D.C. 2001) ("financial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business"); Mylan, 81 F. Supp.2d at 42 ("Because Mylan is alleging a non-recoverable monetary loss, it must demonstrate 'that the injury [is] more than simply irretrievable, it must also be serious in terms of its effect on the plaintiff.'") (quoting in part Gulf Oil Corp., 514 F. Supp. at 1026).

Notwithstanding this well-established doctrine, mere economic loss is precisely the type of harm that Teva alleges it will suffer in the absence of preliminary injunctive relief. See Pl. Mem. at 36-39 (claiming "hundreds of millions of dollars in lost revenues" due to lost sales

absent a preliminary injunction). Teva does not quantify its alleged loss relative to the overall sales of all of its products. Nor does it explain how it arrived at its figure of "hundreds of millions of dollars." See Marshall Decl. ¶ 16. Teva would be hard-pressed to claim its alleged injury would "threaten destruction" of its business, given that Teva is one of the world's largest generic drug manufacturers.[10] For the first quarter of 2009, Teva posted record net sales of $3.15 billion, up 22 percent from the first quarter of 2008, without the sale of a generic version of losartan.[11] Thus, the alleged loss of potential sales that may result from competition with other generic versions of losartan does not threaten Teva's business and does not constitute irreparable harm. See Varicon Int'l v. Office of Personnel Mgmt., 934 F. Supp. 440, 447-48 (D.D.C. 1996) (finding no irreparable harm due to lost contract when movant's revenue would decline by 10%); TGS Tech., Inc. v. United States, Civ. No. 92-0062, 1992 WL 19058, at *4 (D.D.C. Jan. 14, 1992) (finding no irreparable harm where lost contract constituted 20% of movant's business); Experience Works, Inc., 267 F. Supp.2d at 96 ($21.1 million reduction in funding is a serious financial blow, but one frequently faced by other similar entities, and not an economic loss that threatens survival of the business); Bristol-Myers Squibb, 923 F. Supp. at 221 & n.12 (alleged loss of 50-70 percent of $97 million in product sales not irreparable harm because it would be only a small percentage of plaintiff's total sales).

The cases that Teva claims support its contention that the loss of exclusivity alone

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[10] See The History of Teva, available at http://www.tevapharm.com/about/history.asp ("Today, Teva is among the top 20 pharmaceutical companies in the world and one of the largest generic pharmaceutical companies in the world.").

[11] See Teva Reports First Quarter 2009 Results, available at http://www.tevapharm.com/pr/2009/pr_845.asp ("Net sales of $3.15 billion, up 22% compared to the first quarter of 2008").

suffices to show irreparable harm do not support this argument. Pl. Mem. at 36. In Mova, for example, the district court granted a preliminary injunction both because Mova would be harmed by the loss of its exclusivity and because "Mova's small size put it at a particular disadvantage." Mova, 140 F.3d at 1066 n.6. The D.C. Circuit affirmed, noting that both of those factors sufficed to show a "severe economic impact to Mova." Id. In Hi-Tech, the Court stated: "This exposure to competition from much larger companies has been cited in finding that a loss of statutory entitlement may amount to irreparable injury." 587 F. Supp.2d at 11. In Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26 (D.D.C. 2006), plaintiff's claimed loss of 80-90 percent of $31million represented less than one percent of Sandoz' sales, and would not "threaten the company's very existence." Id. at 32. In Apotex v. FDA, Civ. No. 06-0627 2006 WL 1030151, *17 (D.D.C. Apr. 19, 2006), FDA had already determined that the intervenor-defendants were entitled to exclusivity, whereby the court concluded that the loss of that "statutory entitlement" was "sufficiently irreparable." Here, however, Teva has not demonstrated any "statutory entitlement," cannot demonstrate that it is a small company, and has not identified any other factor that would permit its claimed harm to be anything other than merely economic.

Because Teva has not shown that it will suffer an irretrievable loss that would significantly damage its business, its allegations fall well short of the showing necessary to support a finding of irreparable injury.

C. The Requested Relief Will Not Serve The Public

Finally, Teva has also failed to show that any potential harm to its interests in the absence of injunctive relief outweighs the potential harm to other parties, or that the entry of the relief it seeks would further the public interest – the third and fourth requirements for preliminary

injunctive relief. Although FDA has no commercial stake in the outcome of this litigation, FDA is the government agency charged with implementing the statutory scheme governing exclusivity and the approval of generic drugs. As such, FDA's interest coincides with the public interest. See Virginian Ry. Co. v. System Federation No. 40, 300 U.S. 515, 552 (1937) (Congressional purpose "is in itself a declaration of public interest and policy which should be persuasive" to courts).

Teva contends that the public interest is furthered by interpreting the Hatch-Waxman Amendments to safeguard 180-day exclusivity. Pl. Mem. at 40. Teva asserts that it has taken actions to demonstrate the weaknesses in Merck's patent, causing Merck to delist its patent and clearing the way for faster approval of generic losartan, in accordance with the statutory purpose of the Hatch-Waxman Amendments and the MMA. Thus, Teva reasons, a decision that Teva has forfeited its exclusivity would be contrary to the purpose of the Hatch-Waxman Amendments. The public interest, however, ultimately depends on the faithful application of the statute, not a particular result to a particular company, i.e., maintaining exclusivity for Teva if the statute does not support that result. In this case, FDA is charged with administering the statute and does so responsibly and in accordance with its mission. Cf. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971) (courts afford administrative agencies a "presumption of regularity").

Moreover, Teva cannot show that the public interest would be served by delaying approval for other ANDAs for losartan. Such an injunction would result in higher prices for consumers until other ANDAs could be approved and introduce full competition into the market. See Hi-Tech, 587 F. Supp.2d at 12-13; Biovail, 448 F. Supp.2d at 166 (discussing the public

interest in "'receiving generic competition to brand-name drugs as soon as is possible'" (quoting Boehringer Ingelheim Corp. v. Shalala, 993 F. Supp. 1, 3 (D.D.C. 1997), and "'in reduced prices'" (quoting Schering Corp. v. Sullivan, 782 F. Supp. 645, 652 (D.D.C. 1992)). Similarly, granting Teva the drastic remedy it seeks would encourage other applicants to request advance FDA decisions so that they, too, could make more informed marketing decisions, forcing the agency to shift its resources from activities that it deems most pressing for the public health. See, e.g., In re Barr Labs., 930 F.2d at 76. That result would also be contrary to the greater public interest. Thus, Teva's requested relief would, if accepted, have far-reaching, negative consequences. Because Teva has failed to establish that it has any rights at issue that are being threatened, public interest "would be better served by denying plaintiff's motion." Boehringer Ingelheim, 993 F. Supp. at 3.

CONCLUSION

For the foregoing reasons, Teva's complaint should be dismissed and its motion for a preliminary injunction should be denied.

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