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.	)	

MEMORANDUM OPINION

Teva Pharmaceuticals USA, Inc. ("Teva"), a manufacturer of generic drugs, seeks a preliminary injunction to invalidate a "Delisting Rule" instituted by the Food and Drug Administration ("FDA"). The FDA contends that there is no such "Delisting Rule." Instead, in informal adjudications regarding other drugs, the FDA has held that a name brand manufacturer's withdrawal of a patent as a basis for its drug(s) (*i.e.*, a request that the patent be "delisted") triggers a forfeiture provision excising the generic company's eligibility for a 180-day exclusive marketing period. Teva contends that by way of these decisions the FDA has created a "rule" that is subject to challenge. The FDA moves to dismiss, arguing that its decisions do not constitute a final rule subject to challenge and that, because there has been no final agency action on Teva's own request for generic drug approval, the matter is not ripe and Teva lacks standing. The Court held oral argument on July 13, 2009, and now decides that the FDA's motion to dismiss will be denied. Further, the preliminary injunction proceedings are combined with trial on the merits and judgment

will be granted in favor of the FDA. The FDA's statutory interpretation is not arbitrary or capricious.

I. BACKGROUND FACTS

A. Statutory Scheme

The Drug and Price Competition and Patent Term Restoration Act of 1983 (the "Hatch-Waxman Amendments"),[1] 21 U.S.C. § 355 & 35 U.S.C. §§ 156, 271, & 282, established a streamlined procedure for FDA approval of generic drugs. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). The original applicant for approval of a drug (the "Innovator") must file a New Drug Application ("NDA"), including data from studies showing the drug's safety and effectiveness. *Id.*; *see also* 21 U.S.C. § 355(a) & (b). The Innovator also is required to submit information on any patent that claims the drug or a method of using the drug for which patent infringement could be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1) & (c)(2). The FDA lists such patent information in a publication called the "Approved Drug Products with Therapeutic Evaluations," commonly known as the "Orange Book." *Id.*; 21 C.F.R. § 314.53(e).

Subsequent applicants who want to manufacture generic versions of the Innovator's drug may file an Abbreviated New Drug Application ("ANDA"). *Mova*, 140 F.3d at 1063; 21 U.S.C. § 355(j). The ANDA is not required to include new safety and effectiveness data, but instead may rely on the safety and effectiveness data in the original filing. 21 U.S.C. § 355(j). In this way, the Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs., Inc. v. United States*, 836

[1] The Hatch-Waxman Amendments amended the Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 *et seq*.

F.2d 135, 139 (3d Cir. 1987).

An ANDA applicant must certify whether the generic drug would infringe any existing patents relied on and listed by the Innovator. The applicant may certify:

> (I) that the required patent has not been filed;
>
> (II) that the patent has expired;
>
> (III) that the patent has not expired, but will expire on a particular date; or
>
> (IV) that the 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).[2] A paragraph III certification means that the ANDA applicant does not intend to market the drug until after the patent expires; approval of the ANDA may be made effective on the expiration date. *Id*. § 355(j)(5)(B)(ii). A paragraph IV certification contemplates that the ANDA applicant challenges the validity of the patent or claims that the patent would not be infringed by the generic product proposed in the ANDA. An applicant must provide notice of a paragraph IV certification to the Innovator. *Id*. § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of infringement under patent law, 35 U.S.C. § 271(e)(2)(A), and the Innovator, as patent holder, has 45 days to bring suit against the ANDA applicant. *Id*. § 355(j)(5)(B)(iii). If the Innovator brings such a suit, the FDA must delay approving the ANDA for 30 months. *Id*. This provision, known as the 30-month stay, gives the Innovator time to assert its patent rights before the generic competitor is permitted to enter the market. *Mova*, 140 F.3d at 1064. If the Innovator does not bring suit within 45 days, the FDA may approve a paragraph IV ANDA, and the approval may be effective immediately despite the unexpired patent, provided that

[2] Paragraph I and II certifications are not relevant to this case.

other conditions have been met. *Id.*; 21 C.F.R. § 314.107(f)(2).

Under certain circumstances, the statute provides a 180-day exclusive marketing period vis-a-vis other ANDA applicants to the first applicant who files an ANDA with a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv). That is, the first patent-challenging generic applicant may be awarded a six-month period during which that applicant is the only company allowed to sell a generic version of the name brand drug. Thus, the statute may reward the first generic manufacturer that exposes itself to the risk of patent litigation. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); *Mova*, 140 F.3d at 1064.

Congress amended 21 U.S.C. § 355(j) in 2003 to add the exclusivity provisions raised by Teva in this case. *See* 21 U.S.C. § 355(j)(5)(D) (part of the Medicare Modernization Act of 2003 (the "MMA"); *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).[3] The MMA contains certain "forfeiture provisions" setting forth the conditions under which an ANDA applicant may lose eligibility for the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i) & (ii). The forfeiture provision at issue in this case is the one that provides that a first ANDA filer will forfeit exclusivity if it fails to market the drug by a certain date:

> (I) Failure to Market. The first [ANDA] 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

[3] The parties agree that the MMA applies to the ANDAs filed by Teva, as they were filed after the MMA was enacted.

> (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 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) of this section* [i.e., the Innovator].

Id. § 355(j)(5)(D)(i)(I) (emphasis added to highlight provision at issue here). Forfeiture occurs only when the "later" of the events in (aa) or (bb) occurs.

The FDA has twice applied the subsection (bb)(CC) forfeiture provision in public letter decisions, after providing notice and comment. For example, with regard to an ANDA for the drug acrabose, the FDA applied the failure to market forfeiture provision under (bb)(CC), finding that this subsection requires marketing within 75 days from when the patent information is withdrawn by the Innovator. Compl. Ex. 5, Letter from Gary Buehler, Director, Office of Generic

Drugs, at 7-9 (May 7, 2008), FDA Dkt. No. 2007-N-0445 ("Acrabose Decision"). The FDA announced its interpretation of subsection (bb)(CC) in broadly applicable terms — "Therefore, FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply *whenever* a patent is withdrawn (or requested to be 'delisted') by the NDA holder." *Id*. at 8 (emphasis added). Likewise, with regard to an ANDA for generic Cosopt, the FDA again explained its interpretation of subsection (bb)(CC) of the MMA — that this subsection applies "whenever" a patent is withdrawn by the Innovator. Compl. Ex. 9, Letter from Gary Buehler, Director, Office of Generic Drugs, at 14 n.15 (Oct. 28, 2008), FDA Dkt. No. 2008-N-0483 ("Cosopt Decision").[4]

B. Facts of This Case

The facts of this case are not in dispute. Merck & Co., Inc. ("Merck") is the name brand manufacturer that holds approved NDA No. 20-386 for losartan potassium ("losartan") tablets (sold under the name "Cozaar") and NDA No. 20-0387 for losartan potassium hydrochlorothiazide ("losartan HCTZ") tablets (sold under the name "Hyzaar"). Cozaar and Hyzaar are primarily used to treat hypertension. During the twelve month period that ended March 31, 2009, pharmacists in the United States filled over fifteen million prescriptions for Cozaar and Hyzaar, dispensing 848 million tablets, which amounts to nearly $1.5 billion in sales. Pl.'s Mot. for Prelim. Inj. [Dkt. # 5], Ex. A, Decl. of David Marshall ("Marshall Decl.") ¶ 4.

Merck provided patent information to the FDA for listing in the Orange Book: (1) U.S. Patent No. 5,138,069 ("the '069 patent"); (2) U.S. Patent No. 5,153,197 ("the '197 patent");

[4] The FDA has determined that the 75 day period runs from the date that the FDA receives the patent holder's request to remove the patent from the Orange Book, even though this date generally does not become public until the FDA publishes the request to delist in the Orange Book. Acrabose Decision at 7 n.13; Cosopt Decision at 7.

and (3) U.S. Patent No. 5,608,075 ("the '075 patent").[5]

Teva filed an ANDA to market generic losartan on December 18, 2003, and an ANDA for generic losartan HCTZ on May 24, 2004. The ANDAs contained paragraph III certifications to the '069 patent and the '197 patent and a paragraph IV certification to the '075 patent. Teva sent a notice of its paragraph IV certification to Merck, but Merck did not sue Teva for infringement within 45 days. Instead, on March 18, 2005, Merck withdrew its reliance on the '075 patent by requesting that the FDA remove it from the Orange Book. Merck holds an additional six-month pediatric exclusivity on the'069 and '197 patents. *See* 21 U.S.C. § 355a(b) (pediatric exclusivity prevents the FDA from approving generic applications for six months after the patent expires). Thus, the '069 patent expires on August 11, 2009, and Merck's pediatric exclusivity with regard to this patent expires February 11, 2010; the '197 patent expires on October 6, 2009, and Merck's pediatric exclusivity expires April 6, 2010. Accordingly, the FDA is barred from approving any ANDAs until April 6, 2010, the date that Merck's pediatric exclusivity on the '197 patent expires.

Under the FDA's interpretation of the law, the time calculations under the failure-to-market forfeiture provision quoted above are not in dispute. Under that provision, an ANDA first-filer loses its eligibility by failing to market its generic drug by the later of two dates. One of the dates is calculated under subsection (aa) — the earlier of the date that is 75 days after the ANDA approval (there is no such date here, as Teva's ANDA has not been approved) or 30 months after the ANDA was submitted (June 19, 2006 for Teva's generic version of Cozaar and November 25, 2006

[5] Merck also provided information regarding another patent regarding the method of use of Cozaar. This patent is not relevant here because Teva does not seek approval for this method of use.

for Teva's generic version of Hyzaar). In other words, the "earlier" date under subsection (aa) is June 19, 2006 for Teva's Cozaar ANDA and November 25, 2006 for Teva's Hyzaar ANDA.

The second date is calculated under subsection (bb). Because Merck did not file suit against Teva, the first two events under subsections (bb)(AA) and (BB) which relate to litigation do not apply. Under subsection (bb)(CC), Merck withdrew the patent information on the '075 patent on January 1, 2009. According to the FDA, because Teva did not market its generic drugs within 75 days after January 1, 2009, Teva forfeited exclusivity.[6] The FDA's Acrabose Decision and Cosopt Decision make it clear that the FDA applies the forfeiture provision set forth in (bb)(CC) this way.

Teva brought this suit asking the Court to set aside the FDA's new "Delisting Rule," as reflected in the FDA's Acrabose and Cosopt Decisions. The FDA moves to dismiss for lack of jurisdiction and failure to state a claim. Teva seeks a preliminary injunction and requests that the Court combine the hearing on the preliminary injunction with trial on the merits. *See* Fed. R. Civ. P. 65(a)(2) (a court may advance the trial on the merits and consolidate it with the hearing on preliminary injunction). The FDA did not object to a combined proceeding. Because the issue presented here is purely a matter of law, the preliminary injunction motion and trial on the merits are consolidated.

II. LEGAL STANDARDS

The FDA moves to dismiss for failure to state a claim pursuant to Federal Rule of

[6] This is so even though Teva was barred from bringing its drugs to market because Merck's pediatric exclusivity with regard to the'069 and '197 patents has not expired. Teva's right to exclusivity was based only on the '075 patent; if Teva had challenged the'069 and '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

Civil Procedure 12(b)(6), arguing that Teva does not challenge a final agency action and that Teva did not exhaust its administrative remedies. A Rule 12(b)(6) motion challenges the adequacy of a complaint on its face, testing whether a plaintiff has properly stated a claim. A complaint must be sufficient "to give a defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). Although a complaint does not need detailed factual allegations, a plaintiff's obligation to provide the grounds for his entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* Federal Rule of Civil Procedure 8(a), which requires that a complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief, requires a "showing" and not just a blanket assertion of a right to relief. *Id.* at n.3. A court must treat the complaint's factual allegations as true, "even if doubtful in fact," *id*. at 1965, and must draw all reasonable inferences in the plaintiff's favor. *Macharia v. United States*, 334 F.3d 61, 64, 67 (D.C. Cir. 2003).

While the FDA does not explicitly move to dismiss for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1), it impliedly seeks a Rule 12(b)(1) dismissal as well by arguing that Teva's claim is not ripe and that Teva lacks standing. On a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction. *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936); *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999). To determine whether it has jurisdiction, a court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. ANALYSIS

A. Final Agency Action

The FDA contends that Teva has not stated a claim because Teva does not complain of any final agency action. The FDA will not render any decision regarding Teva's ANDAs until April 2010, and the FDA "intends to make a decision regarding 180-day exclusivity when an ANDA for losartan becomes ready for final approval." Def.'s Mot. to Dismiss [Dkt. # 9] at 18. The FDA reasons that the Acrabose and Cosopt Decisions are FDA decisions regarding whether other ANDAs were eligible for the 180-day exclusivity and do not constitute any decision regarding whether Teva's ANDAs for losartan and losartan HCTZ are eligible for the 180-day marketing exclusivity period. The FDA asserts that what Teva really wants is a determination now regarding whether it will be entitled to exclusivity if and when the FDA approves its ANDAs in the future. The FDA points out that when another generic manufacturer sought advance approval in *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008), the court held that the manufacturer was not entitled to advance approval of marketing exclusivity. In that case, a generic manufacturer (Hi-Tech) brought suit against the FDA, seeking a finding by the FDA that Hi-Tech was entitled to the 180-day marketing exclusivity period and seeking an injunction to prevent the FDA from granting final approval to any other generic drug producer while Hi-Tech enjoyed its marketing exclusivity. The court held that the manufacturer was not entitled to review until there was final agency action. 587 F. Supp. 2d at 8. In addition, the court in *Hi-Tech* determined that the FDA was not required to approve Hi-Tech's request for exclusivity by a time certain, and the FDA's failure to act with respect to the issue of exclusivity did not constitute final agency action. *Id*. at 9-10.

Because the FDA misconstrues Teva's claim, this case is not analogous to *Hi-Tech*.

Teva does not seek an advance determination on its request for exclusivity as Hi-Tech did. Teva challenges the FDA's interpretation of the MMA as arbitrary, capricious, and an abuse of discretion in violation of section 706 of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. *See* Compl. ¶ 68. The FDA has interpreted the MMA forfeiture provision (bb)(CC) as applying "*whenever*" an Innovator withdraws a patent. *See* Acrabose Decision at 8. In the Cosopt Decision, the FDA felt bound by its Acrabose Decision and applied the same statutory construction. Cosopt Decision at 14 n.15. The statutory interpretation was not reliant on any particular factual circumstance presented by those cases; it was entirely based on the language of the statute. The FDA interpreted the MMA to authorize exclusivity-divesting patent delistings effectuated by a name brand manufacturer's voluntary request.

The APA provides a cause of action to a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." 5 U.S.C. § 702. Review under the APA is limited to "final agency action"[7] for which there is no other adequate remedy in a court. *Id*. § 704; *Heckler v. Chaney*, 470 U.S. 821, 828 (1985) (a person adversely affected by final agency action is entitled to judicial review so long as no statute precludes review and the action is not committed to agency discretion by law). "Whether there has been 'agency action' or 'final agency action' within the meaning of the APA are threshold questions; if these requirements are not met, the action is not reviewable." *Fund for Animals, Inc. v. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006).

[7] A final agency action "(1) marks the consummation of the agency's decision making process — it must not be of a merely tentative or interlocutory nature; and (2) the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Domestic Secs., Inc. v. SEC*, 333 F.3d. 239, 246 (D.C. Cir. 2003) (internal quotation marks omitted).

An "agency action" is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof." 5 U.S.C. § 551(13). A "rule" is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id*. § 551(4). Thus, the term "final agency action" includes an agency's interpretation of a statute. *UAW v. Brock*, 783 F.2d 237, 248 (D.C. Cir. 1986). "[W]hen a legal challenge focuses on an announcement of a substantive statutory interpretation, courts are emphatically qualified to decide whether an agency has acted outside the bounds of reason." *Id.* at 245. Further, an agency's statement of policy is reviewable whether it is set forth in a formal regulation or is articulated in another context, such as a letter ruling. *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676-77 (D.C. Cir. 1994). An agency may establish binding policy through rulemaking procedures or through adjudications which constitute binding precedent. *Brock*, 783 F.2d at 248.[8] An agency's interpretation of its own governing statute is final agency action fit for judicial review. *Id*. Accordingly, the FDA's interpretation of the MMA in the context of the Acrabose and Cosopt Decisions constitutes a rule of decision made through adjudication, and the FDA's interpretation of the MMA constitutes "final agency action" that is subject to review under APA §§ 702 and 704. Thus, Teva has stated a claim under the APA seeking to set aside the FDA's statutory interpretation as arbitrary and capricious under § 706(2).

[8] The FDA argues that the Acrabose and Cosopt Decisions constituted informal adjudication, not rulemaking. For the purpose of this decision, the distinction makes no difference. Both final rules and final orders are reviewable. 5 U.S.C. § 706. Further, binding policy, whether created by rulemaking or adjudication, is reviewable. *Brock*, 783 F.2d at 248.

B. Exhaustion

The FDA also contends that this case should be dismissed for failure to state a claim due to failure to exhaust administrative remedies. FDA regulations require that, before filing suit in court, a party requesting that the FDA take or refrain from taking an action must first use the citizen petition process set forth in 21 C.F.R. § 10.25. 21 C.F.R. § 10.45(b). Exhaustion required by agency regulation, however, is not jurisdictional. *Ass'n of Flight Attendants v. Chao*, 493 F.3d 155, 158-59 (D.C. Cir. 2007). Courts have the discretion to decline to require exhaustion where a plaintiff would be irreparably harmed by delay, where the agency lacks the power to grant effective relief, or where exhaustion would be futile. *McCarthy v. Madigan*, 503 U.S. 140, 146-49 (1992). Exhaustion is futile when there is a certainty of an adverse decision, *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986), or when the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *James v. HHS*, 824 F.2d 1132, 1137 (D.C. Cir. 1987).

Teva submitted comments in the docket of the Acrabose Decision in which the precise forfeiture issue it now seeks to litigate was raised. The FDA considered and rejected Teva's argument:

> We have considered and rejected the argument made in [Teva's] comments to FDA's docket that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). . . . These comments argue that the forfeiture event described in section 505(j)(5)(D)(i)(I)(bb)(CC) of the Act applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act. Section 505(j)(5)(C)(ii) contemplates that, as a result of a counterclaim by the ANDA applicant in patent infringement litigation, a court may issue an order requiring that

> patent information be corrected or deleted. Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. We do not find this argument persuasive [and] FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Acrabose Decision at 8. The FDA evidenced its strong position and its unwillingness to reconsider in the Cosopt Decision by stating, "[w]e also have considered and rejected in both this case and in the . . . Acrabose Decision, the argument that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy*." Cosopt Decision at 14. The FDA went on to explain, just as it had in the Acrabose Decision, that it reads subsection (bb)(CC) of the MMA to broadly apply whenever an Innovator withdraws a patent and not only when a patent is withdrawn as a result of counterclaim litigation:

> [A]s noted in the Acrabose Decision at pp. 8-9, we also have considered the argument that the forfeiture event described [in subsection (bb)(CC)] applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act . . . . Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. . . . [T]he scope of the patent delisting forfeiture provision is much broader. . . . FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Id. at 14 n.15. Teva has exhausted its remedies by participating unsuccessfully in the Acrabose litigation and pursuit of administrative remedies would be futile. In these circumstances, the law does not require further administrative exhaustion.

C. Ripeness

Jurisdiction requires that a claim be ripe for decision. Under the Constitution, federal courts are limited to deciding "actual, ongoing controversies." *Honig v. Doe*, 484 U.S. 305, 317

(1988). 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) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81 (1985)). By requiring that claims be ripe before adjudicating them, courts promote judicial economy, avoid becoming entangled in abstract disputes, and ensure a record adequate to support an informed decision when a case is heard. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

To show that a claim is ripe, a plaintiff must demonstrate (1) the fitness of the issues for judicial decision, and (2) the hardship to the parties caused by withholding court consideration. *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 854 (D.C. Cir. 2006) (citing *Abbott Labs.*, 387 U.S. at 149). To determine the fitness of an issue for judicial review, a court must look to see "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002) (quoting *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998)). A petition for review that presents a "purely legal question" satisfies the "fitness" prong of the test for ripeness. *Edison Elec. Institute v. EPA*, 996 F.2d 326, 333-34 (D.C. Cir. 1993); *see also CropLife Am. v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003) (press release announcing that EPA would not consider third party human studies in regulatory decision-making was a statement of a blanket agency policy that presented a purely legal question, ripe for review); *IBEW v. ICC*, 862 F.2d 330, 335 (D.C. Cir. 1988) (a matter is fit for review when agency's decision is "crystallized"); *Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 695 (D.C. Cir. 1971) (an issue is fit for judicial resolution where there is no need to identify or refine the facts). The "hardship" prong of the ripeness test requires a court to avoid interfering with an agency's

decision unless and until the decision involves "effects felt in a concrete way by the challenging party." *Nat'l Automatic Laundry*, 443 F.2d at 696.

The issue raised by Teva — whether the FDA's interpretation of subsection (bb)(CC) of the MMA is arbitrary and capricious under the APA — is purely a legal question fit for judicial review. It is a challenge to the FDA's interpretation of the statute on its face and not as applied to a particular set of facts. There is no need for further factual development as there is no material fact missing from the record that could alter the FDA's interpretation of the MMA.

Further, the decision affects Teva in a concrete way. To explain how it is affected by the right to exclusive marketing and the loss of that right, Teva submitted the declaration of David Marshall, Teva's Vice President of New Products Portfolio Strategy. Mr. Marshall explains that when a generic manufacturer such as Teva files a paragraph IV certification, it takes on the risk of costly and protracted patent litigation. Marshall Decl. ¶ 10. However, by being the first to take on such risk, Teva became eligible for the 180-day exclusive marketing period. *Id*. ¶ 11. The exclusivity period provides a strong incentive because it provides a permanent advantage — "that officially sanctioned 'head start' permits first entrants to secure distribution channels and access to customers; enter into long-term sales agreements; increase sales across all of its product lines; and retain greater market share in the long-run." *Id*. Under the FDA's interpretation of the MMA as set forth in the Acrabose and Cosopt Decisions, Teva already has lost its right to the 180-day exclusive marketing period; Teva will sell 50- 60% fewer losartan tablets during its first year in the market and will experience a loss of hundreds of millions of dollars in net revenue. *Id*. ¶ 16.

Teva's current day-to-day operations are concretely affected by the FDA's interpretation of forfeiture under the MMA. Teva must obtain materials to begin manufacturing

generic losartan products in the immediate future, and it must obtain more materials if it is preparing for exclusive marketing than if it is preparing for non-exclusive marketing. *Id*. ¶ 22. If it enjoyed an exclusive product launch, Teva would need to place an order immediately — for delivery no later than August 2009 — for the manufacture of the active pharmaceutical ingredient used to make losartan products as well as non-active ingredients and packaging materials. *Id*. ¶ 22-23. Also, Teva would need to dedicate plant capacity and human resources earlier for an exclusive product launch as opposed to a non-exclusive launch. *Id*. ¶ 24.[9]

The FDA argues that this case is not ripe for review, relying on *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999). In that case, Pfizer sought to prevent the FDA from approving the ANDA of a competitor, Mylan. Pfizer claimed that its drug product had a unique release mechanism and that the FDA could not approve an ANDA without the same release mechanism because ANDAs are required by statute to have the same "dosage form" as the name brand drug. *See* 21 U.S.C. § 355(j)(2)(A)(i)-(iii). Prior to filing suit, Pfizer had filed a citizen petition. The FDA had denied the petition, finding that another release mechanism could provide the same dosage form. 182 F.3d at 978. Pfizer filed suit in district court, and the court granted summary judgment to the FDA. *Id*. Pfizer then appealed, and the D.C. Circuit held that Pfizer did not present a ripe claim. While the FDA had "refused to affirm the negative proposition that no other extended release

[9] Mr. Marshall further explains, "Commercial uncertainty will impose an array of irreparable harms on Teva." Marshall Decl. ¶ 25. If Teva manufactures losartan products assuming that it does not have exclusivity and later it is awarded exclusivity, it will not have manufactured sufficient quantity of products to meet the market demand, resulting in reduced sales and loss of customer good will. *Id*. ¶ 26. If Teva manufactures generic losartan products assuming that it has exclusivity and then in April 2010 the FDA decides that it is not entitled to such exclusivity, Teva will have wasted resources manufacturing tons of tablets it cannot and may never sell, forcing Teva to dispose of excess product or liquidate it at a loss. *Id*. ¶ 27.

mechanism could ever be deemed under the statute to constitute the same dosage form as Pfizer's," the FDA had not yet applied this finding to any particular set of facts. *Id*. at 979. The court held that Pfizer's challenge raised an abstract disagreement over agency policy and was not sufficiently crystallized to constitute an actual case or controversy. *Id*. at 979-80. The FDA's reliance on *Pfizer* stems from its mischaracterization of Teva's claim. Unlike Pfizer, Teva does not ask the Court to preclude the FDA from approving a competitor's ANDA. Moreover, *Pfizer* is distinguishable because there the FDA had not yet applied its policy to a particular set of facts. Here, Teva challenges the FDA's interpretation of the MMA on purely legal grounds.

The FDA also relies on *Biovail Corp. v. FDA*, 448 F. Supp. 2d 157 (D.D.C. 2006). There, Biovail sought to require the FDA to rule on its citizen petition before approving any competing ANDA. Biovail alleged in its citizen petition that a competitor's proposed generic drug posed an unreasonable risk of seizures because it was not bioequivalent to the name brand drug. 448 F. Supp. 2d at 161. The court found that the FDA was not required to rule on the citizen petition by any particular date and that the court would not assume that the FDA would approve an unsafe drug if it did not immediately rule on the citizen petition. *Id*. at 162. In contrast, Teva is not asking the FDA to rule on the issue presented by a particular date; the FDA *already* has interpreted subsection (bb)(CC) of the MMA. To resolve this issue, the Court is not required to presume that the FDA will take any particular action in the future. Teva's challenge to the FDA's statutory interpretation is ripe for review.

D. Standing

The FDA further suggests that Teva's suit should be dismissed for lack of standing. Lack of standing is a defect in subject matter jurisdiction. *See Haase v. Sessions*, 835 F.2d 902, 906

(D.C. Cir. 1987). To have Article III standing, a plaintiff must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). "This triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998). A court may "intervene in the administration of the laws only when, and to the extent that, a specific 'final agency action' has an actual or immediately threatened effect." *Lujan*, 504 U.S. at 894.

The FDA contends that Teva lacks standing, in that it can show no injury because the FDA has not made a decision regarding Teva's ANDAs. Yet as described above, Teva has been injured by the FDA's statutory interpretation. The FDA's interpretation imminently will cause Teva to lose its right to exclusive marketing, and Teva already has altered its operations due to this imminent loss. Teva's current operations are affected because it has not ordered the additional materials and dedicated the plant capacity and human resources it would need if it were planning to market its generic losartan products in an exclusive market. Marshall Decl. ¶¶ 22-24. The loss of the 180-day exclusive marketing period imminently will cause Teva to lose the ability to: secure distribution channels and access customers, enter into long-term sales agreements, increase sales across all of its product lines, and retain greater market share in the long-run. *Id.* ¶ 11. Also, the loss of exclusivity imminently will cause Teva to sell fewer losartan tablets during its first year in the

market, resulting in a loss of hundreds of millions of dollars in net revenue. *Id*. ¶ 16. Teva has demonstrated standing.

E. APA Challenge to the FDA's Interpretation of the MMA

Teva challenges the FDA's interpretation of the MMA forfeiture provision set forth at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). The APA requires a reviewing court to set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986). An agency action may be arbitrary or capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). "[T]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id*. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

When reviewing an agency's interpretation of a statute, a court must undertake a two-step analysis as set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984). First, a court must determine whether "Congress has directly spoken to the precise question at issue" and if so the court must "give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. To decide whether Congress has addressed the precise question at issue, a court must analyze the text, purpose, and structure of the statute. *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 124 (D.C. Cir. 2006).

If the statute is silent or ambiguous on the question, the court must proceed to the second step of the *Chevron* analysis and determine whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. When an agency's interpretation of a statute is challenged at step two, its "interpretation need not be the best or most natural one by grammatical or other standards . . . . Rather [it] need be only reasonable to warrant deference." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). "The court need not conclude that the agency's construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron*, 467 U.S. at 844 n.11. If the agency's statutory construction is permissible, then the court must defer to the agency's interpretation. *Id.*

At *Chevron* step one, this Court must give effect to the clear intent of Congress as reflected in the statute because subsection (bb)(CC) is not ambiguous on its face. Section 355(j)(5)(D)(i)(I) provides that an ANDA filer will forfeit exclusivity if it fails to market the drug by the later of two dates, and under subsection (bb)(CC), one of those dates is 75 days after "[t]he patent information submitted under subsection (b) or (c) is withdrawn by the holder of the

application approved under subsection (b) [the Innovator]." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

Teva asserts that the statute is ambiguous if read as a whole. First, Teva argues that the MMA governs only the effect of the withdrawal of a patent by an Innovator, but that it does not address the circumstances in which a patent may be delisted. Teva is correct that the statute does not address when an Innovator may withdraw a patent, but what is important is that the statute does not limit the Innovator's right to withdraw patent information. The Court cannot take on the role of the legislature by creating such limitations when they were omitted by Congress.[10]

Second, Teva argues that subsection (bb)(CC) should only apply when a court has ordered the Innovator to withdraw the patent pursuant to a counterclaim suit filed by an ANDA applicant. The MMA includes a "counterclaim provision" that permits an ANDA applicant sued for infringement to file a counterclaim to force an Innovator to withdraw patent information. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). Teva claims that subsection (bb)(CC) is linked to the counterclaim provision and that (bb)(CC) only applies when a court has ordered an Innovator to withdraw patent information pursuant to a counterclaim. The problem with this interpretation is that the MMA contains no language linking the forfeiture provision and the counterclaim provision as Teva would prefer. The provisions simply do not refer to one another.

Moreover, even if subsection (bb)(CC) were construed in the context of the whole statute to be ambiguous, the Court would be required to defer to the FDA's interpretation under

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[10] Further, it is not that the FDA made an incorrect judgment about whether the '075 patent should be listed or delisted. The FDA does not adjudge the propriety of patent listings. It is not required to determine the correctness of listings in the Orange Book because it lacks expertise in patent law. *Apotex v. Thompson*, 347 F.3d 1335, 1349-50 (Fed. Cir. 2003). "When it comes to the veracity of patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information." *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008).

Chevron step two. It is not arbitrary or capricious for the FDA to interpret (bb)(CC) as broadly applying *whenever* an Innovator withdraws patent information because the statute provides no limitations on withdrawal of patent information and subsection (bb)(CC) makes no reference to the counterclaim provision.[11] The FDA's interpretation of the statute is reasonable.

Teva further argues that *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), applies. In *Ranbaxy*, the FDA had determined that an ANDA applicant's eligibility for the 180-day exclusive marketing period would be lost if the Innovator withdrew its patent on which the exclusivity was based and did not sue the ANDA applicant for infringement. The FDA also found that the ANDA applicant would not lose the right to exclusivity if the Innovator had sued the ANDA applicant. Ranbaxy and Teva brought suit against the FDA, arguing that the FDA could not condition eligibility for the exclusive marketing period on whether or not the Innovator had filed suit. The Circuit agreed: "[T]he FDA's requirement that a generic manufacturer's patent challenge give rise to litigation as a condition of retaining exclusivity when a patent is delisted is inconsistent with

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[11] Teva also argues that the FDA's interpretation of the MMA forfeiture provision permits a name brand manufacturer to manipulate the market by causing a first filing ANDA applicant to forfeit its right to exclusivity. This presumes that Merck was motivated to withdraw the '075 patent based solely on market concerns, when there is no evidence in the record regarding why Merck withdrew the patent. It could be that the patent was erroneously listed, Merck's interest in it lapsed, or Merck was required to withdraw the patent based on new FDA regulations. *See* Opp'n to Mot. for Prelim. Inj. filed by proposed intervenor Apotex, Inc. ("Apotex's Opp'n") [Dkt. # 11-6] at 19. The Court permits the filing of this brief on an amicus basis. *See infra*, section III.F. of this Opinion. In 2003, the FDA promulgated 21 C.F.R. § 314.53(b) which established new requirements regarding polymorph patents and the circumstances under which such patents can be said to claim a drug. The '075 patent is a polymorph patent. Teva's Mot. for Prelim. Inj. [Dkt. # 5] at 27 (the '075 patent is titled "Polymorphs of losartan and the process for the preparation of form II of losartan"). Also, Teva itself is partly responsible for the forfeiture. Teva's right to exclusivity was based only on the '075 patent because Teva filed a paragraph IV certification as to only that patent. If Teva had challenged the'069 or '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

the Act, which provides that the first generic manufacturer to file an approved application is entitled to exclusivity when it either begins commercially to market its generic drug or is successful in patent litigation." *Id*. at 121.

Teva reads *Ranbaxy* broadly, construing the case as overturning the FDA's interpretation of the statute because it undermined the Hatch-Waxman incentive structure. Teva reasons that this Court similarly should overturn the FDA's rule of decision set forth in the Acrabose and Cosopt Decisions for the same reason — because the FDA's interpretation of MMA subsection (bb)(CC) as applying "whenever" an NDA holder withdraws its patent also undermines the Hatch-Waxman incentive structure.

Ranbaxy was decided under the Hatch-Waxman Amendments as they existed prior to the enactment of the MMA. The Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs.*, 836 F.2d at 139. However, prior to the MMA, there was no provision for forfeiture of the 180-day exclusivity period. The MMA now provides that the first generic manufacturer is entitled to exclusivity *if* it has not forfeited that exclusivity. *See* 21 U.S.C.§ 355(j)(5)(D). Thus, Congress modified the incentive structure. When enacting the MMA, Congress sought to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Hi-Tech*, 587 F. Supp. at 4 (quoting 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (Statement of Sen. Schumer)). "Because the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which Congress expressed that judgment." *Teva Pharm. Indus., Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). The FDA's interpretation of the MMA is a

reasonable interpretation of the balance Congress struck between these competing goals.

F. Motion to Intervene As a Defendant

Apotex, Inc. ("Apotex") filed a motion to intervene as a defendant. *See* Dkt. # 11. Apotex filed ANDAs seeking FDA approval to market its own generic versions of losartan and losartan HCTZ products. Apotex hopes and expects that it will receive approval in time to begin marketing its products in April 2010. If Teva obtains the 180-day exclusive marketing right that it seeks in this suit, Apotex will have to sit on the sidelines for six months while Teva enjoys exclusive marketing.

An applicant may intervene as of right when the applicant (1) makes a timely motion; (2) has an interest relating to the property or transaction which is the subject of the action; (3) is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) where the applicant's interests are not adequately represented by the existing parties. Fed. R. Civ. P. 24(a)(2); *see also Sierra Club v. Van Antwerp*, 523 F. Supp. 2d 5, 6 (D.D.C. 2007). Article III standing is required for intervention under Rule 24(a)(2). *S. Christian Leadership Conference v. Kelley*, 747 F.2d 777, 779 (D.C. Cir. 1984). To demonstrate standing, a party must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth*, 528 U.S. at 180-81 (citing *Lujan*, 504 U.S. at 560-61).

Apotex asserts that its ANDAs are under review by the FDA and it expects to receive final approval to begin marketing on April 6, 2010. Apotex's expectation of final approval depends

on the FDA's completion of scientific review of Apotex's ANDAs and finding no deficiencies in the ANDAs. The interest that Apotex alleges in this suit — its desire to market generic losartan in the future — presumes final approval of its ANDAs and is speculative.[12] Thus, Apotex's motion to intervene as of right will be denied.

A court may grant permissive intervention where the applicant: (1) makes a timely motion; (2) has a claim or defense; and (3) that claim or defense shares with the main action a common question of law or fact. Fed. R. Civ. P. 24(b). The requirements for permissive intervention are construed liberally in favor of intervention in special cases. *Equal Employment Opportunity Comm'n v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998). The decision whether to grant permissive intervention is discretionary. *In re Vitamins Antitrust Class Actions*, 215 F.3d 26, 32 (D.C. Cir. 2000).[13] Apotex's interest in this suit is a speculative business interest, *i.e.*, a desire to enter the generic losartan market earlier rather than later. Apotex presumes that the FDA will approve its ANDAs at some point. Under these circumstances, Apotex's interest does not warrant intervention, and the Court will deny Apotex's request to intervene. However, the Court will permit Apotex to file, as amicus curiae, its opposition to preliminary injunction, which the Court has considered. *See Firestone Tire & Rubber Co. v. PBGC*, 695 F. Supp. 43, 44 (D.D.C.

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[12] The Hatch-Waxman Amendments provide that the FDA may grant a tentative approval notifying an applicant that the ANDA meets scientific standards but cannot receive final approval until some patent barrier or other regulatory barrier (such as the exclusivity period) is overcome. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id*. § 355(j)(2)(a); 21 C.F.R. § 314.105(d). Final approval may be granted when an applicant has met the scientific standards for approval and the patent and regulatory barriers no longer apply. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id*. § 355(j)(2)(a); 21 C.F.R. § 314.105(d). The FDA has granted tentative approval to Teva's ANDAs but not to those submitted by Apotex.

[13] There is uncertainty under D.C. Circuit law whether standing is required for permissive intervention. *In re Vitamins Antitrust Class Actions*, 215 F.3d at 31-32.

1988) (the decision to appoint an amicus rests within the broad discretion of the district court).

IV. CONCLUSION

For the reasons stated above, the FDA's motion to dismiss [Dkt. # 9] will be denied. Teva's motion for preliminary injunction [Dkt. # 5] is consolidated with trial on the merits pursuant to Federal Rule of Civil Procedure 65(a)(2), and judgment will be entered in favor of the FDA. Further, the motion to intervene as a defendant filed by Apotex [Dkt. # 11] will be denied, but the Court will permit Apotex to file, as amicus curiae, the opposition to preliminary injunction set forth as Exhibit 5 to Apotex's motion to intervene [Dkt. # 11-6]. A memorializing order accompanies this Memorandum Opinion.

Date: July 31, 2009

/s/
ROSEMARY M. COLLYER
United States District Judge