UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

MARGARET A. HAMBURG, M.D., Commissioner of Food and Drugs, and

KATHLEEN SEBELIUS, Secretary of Health and Human Services,

Defendants.

Civil Action No. 12-00388 (CKK)

MEMORANDUM OPINION
(March 23, 2012)

Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") holds new drug applications for SEROQUEL® ("Seroquel") and SEROQUEL XR® ("Seroquel XR"), antipsychotic drugs used to treat serious psychological disorders such as schizophrenia. Since AstraZeneca first obtained approval to market these drugs in the United States from the Food and Drug Administration (the "FDA"), it has been free to market them without "generic" competition. Next week, on Monday, March 26, 2012, one of AstraZeneca's exclusivity rights, a so-called "pediatric exclusivity" period, will expire, leading AstraZeneca to become concerned that the FDA will then give final approval to one or more abbreviated new drug applications that would allow generic competitors to enter the market.

For its part, AstraZeneca maintains that it is entitled to an additional exclusivity right, a so-called "new patient population" exclusivity period, which, in AstraZeneca's view, would

effectively extend its monopoly on the market through December 2, 2012. On this basis, AstraZeneca filed two "citizen petitions" with the FDA in September 2011, essentially asking the agency to represent in advance of the March 26, 2012 expiration of AstraZeneca's pediatric exclusivity period that it does not intend to give final approval to any generic competitors until after December 2, 2012. On March 7, 2012, the FDA denied both of AstraZeneca's citizen petitions, taking the position that it has not yet made a final determination to approve or disapprove any applications by potential generic competitors. On March 12, 2012, AstraZeneca responded by bringing this action against the FDA,[1] claiming that the agency has run afoul of the Administrative Procedure Act by denying AstraZeneca's citizen petitions.

Currently before the Court is AstraZeneca's [3] Application for Preliminary Injunction,[2] through which AstraZeneca seeks an order enjoining the FDA from giving final approval to a generic version of Seroquel or Seroquel XR before this action is resolved on the merits. Because AstraZeneca's pediatric exclusivity period will end on March 26, 2012, AstraZeneca's application has been briefed on an expedited basis. Upon careful consideration of the parties' submissions, the administrative record,[3] the relevant authorities, and the record as a whole, the Court finds that AstraZeneca has failed to make a clear showing that it is entitled to the

---

[1] To be precise, the defendants include, in addition to the FDA, Margaret A. Hamburg, M.D., in her official capacity as the FDA's Commissioner of Food and Drugs, and Kathleen Sebelius, in her official capacity as the Secretary of the Department of Health and Human Services. However, for purposes of convenience, the Court shall simply refer to all the defendants collectively as "the FDA."

[2] Although AstraZeneca's submission is also styled in the alternative as a motion for summary judgment, the matter has been briefed on an expedited basis only as an application for a preliminary injunction. *See* Min. Order (Mar. 14, 2012).

[3] The FDA filed the certified administrative record, as defined by 21 U.S.C. § 355(q)(2)(C), on March 16, 2012. *See* Notice of Filing of Administrative R., ECF No. [10]. Where appropriate, the Court shall cite to the administrative record with the abbreviation "A.R." followed by the relevant page number(s).

extraordinary remedy of a preliminary injunction. Accordingly, AstraZeneca's Application for Preliminary Injunction shall be **DENIED**. Furthermore, because the Court concludes that AstraZeneca's only claim is not yet ripe for judicial review, this action shall be **DISMISSED WITHOUT PREJUDICE**.

I. BACKGROUND

A. Statutory and Regulatory Background

1. New Drug Applications and Abbreviated New Drug Applications

In the United States, new drugs, including "generic" versions of previously approved "pioneer" or "innovator" drugs, may not be marketed without the FDA's prior approval. *See* 21 U.S.C. § 355(a). The approval process is governed by the Federal Food, Drug, and Cosmetic Act, as amended by, among other enactments, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the "Hatch-Waxman Amendments." For pioneer drugs, a company files what is known as a new drug application ("NDA") supported by extensive scientific data showing that the drug is both safe and effective. *See* 21 U.S.C. § 355(b)(1). Often, this process requires pioneer drug applicants to conduct costly and time-consuming clinical studies and to submit full reports to the FDA. *See id.*

Through the Hatch-Waxman Amendments, Congress sought to encourage the development of generic versions of pioneer drugs. Most notably, once the FDA approves a pioneer drug, a competitor seeking to market a generic version may file what is known as an abbreviated new drug application ("ANDA"). *See id.* § 355(j). Unlike a pioneer drug applicant, a generic drug applicant generally need not submit extensive scientific data and clinical studies showing that the drug is safe and effective, but rather may rely on the data and studies that

supported the approval of the pioneer drug. *See id.* In this way, the Hatch-Waxman Amendments reduced the barriers to market entry facing potential generic competitors.

2. The "Sameness" Requirement

Generally speaking, the presumption is that the labeling for any generic drug will mirror the labeling for the pioneer drug. By statute, a generic applicant must submit proposed labeling with its application for approval, which must be "the same as" the labeling approved for the pioneer drug unless changes are required (1) because the generic drug has a different active ingredient or has a different route of administration, dosage form, or strength or (2) because the pioneer drug and the generic drug are produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v). "[S]uch differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity." 21 C.F.R. § 314.94(a)(8)(iv).

3. The Three-Year "New Patient Population" Exclusivity

Through the Hatch-Waxman Amendments, even while creating new incentives for the development of generic drugs, Congress sought to encourage innovation. To this end, pioneer drug companies are entitled to certain periods of marketing exclusivity during which they are protected from generic competition. Broadly speaking, these exclusivity periods work in practice either by placing a moratorium on the submission of ANDAs by potential generic competitors or by delaying the effective date that the FDA can give final approval to an ANDA.

Included among these various exclusivity periods is what is sometimes referred to as a "new patient population" or "new indication" exclusivity because it frequently arises when a

pioneer drug company conducts post-approval clinical studies, submits a supplemental application to the FDA, and secures the FDA's approval to market an approved drug to a new population or for a new indication.[4] A pioneer drug company is entitled to a three-year new patient population exclusivity period under the following circumstances:

> If a supplement to [an NDA] . . . is approved . . . and the supplement contains reports of new clinical investigations[5] (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the [FDA] may not make the approval of an [ANDA] submitted . . . for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement . . . .

21 U.S.C. § 355(j)(5)(F)(iv). "[A]n applicant is not entitled to 3-year exclusivity merely because it supplements an approved application based in part on a clinical investigation." Abbreviated New Drug Application Regulations, 59 FED. REG. 50,338, 50,357 (Oct. 3, 1994). Rather, as the statute makes clear, the clinical investigation must be "essential" to approval. 21 U.S.C. § 355(j)(5)(F)(iv). If a pioneer drug company is entitled to a new patient population exclusivity, then, for a three-year period, the FDA is precluded from giving final approval to an ANDA

---

[4] For simplicity's sake, the Court shall refer to the period as the "new patient population" exclusivity period.

[5] A "new clinical investigation" is defined as follows:

> New clinical investigation means an investigation in humans the results of which have not been relied on by FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population and do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patient population of a previously approved drug product. For purposes of this section, data from a clinical investigation previously submitted for use in the comprehensive evaluation of the safety of a drug product but not to support the effectiveness of the drug product would be considered new.

21 C.F.R. § 314.108(a).

"submitted . . . for a change approved in the supplement." 21 U.S.C. § 355(j)(5)(F)(iv). The FDA has interpreted this language as establishing a relationship between the information obtained from the clinical investigation, the change approved through the pioneer drug company's supplemental application, and the scope of the information relied upon by a generic competitor in a specific ANDA. In short, the FDA will not give final approval to an ANDA that "relies on the information supporting a change approved in the supplemental [NDA]." 21 C.F.R. § 314.108(b)(5)(ii).

4. Tentative and Final Approval of ANDAs

When the FDA first receives an ANDA from a potential generic competitor, it makes the threshold determination of whether the application should even be accepted for processing, which simply requires that the application be "sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(b)(1). Thereafter, if the FDA finds that the generic drug satisfies the requirements for approval at the time of review, but final approval is blocked by a stay, a marketing exclusivity period, or some other barrier, the FDA will give the drug "tentative approval." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). By statute, "[a] drug that is granted tentative approval . . . is not an approved drug and shall not have an effective approval until the [FDA] issues an approval after any necessary additional review of the application." *Id.* § 355(j)(5)(B)(iv)(II)(dd)(BB). "In order for an approval to be made effective . . . the applicant must receive an approval letter from the agency indicating that the application has received final approval." 21 C.F.R. § 314.107(b)(3)(v). Ultimately, if the FDA finds the generic drug satisfies the requirements for approval, it must approve the application. *See* 21 U.S.C. § 355(j)(4).

5. Citizen Petitions

So-called "citizen petitions" allow any interested person to ask the FDA to take, or refrain from taking, any form of administrative action. *See* 21 C.F.R. §§ 10.25(a), 10.30. By statute, when the relief requested in a citizen petition could delay the approval of a pending NDA or ANDA, the FDA must "take final agency action on [the] petition not later than 180 days after the date on which the petition is submitted," a period that cannot be "extend[ed] . . . for any reason." 21 U.S.C. § 355(q)(1)(F). As the statute makes clear, this 180-day deadline applies only to the FDA's decision on the petition itself. Congress did not expect the FDA to rule on the NDA or ANDA that is the subject of the petition at the same time. *See id.* § 355(q)(2)(C)(iii) (providing that the administrative record shall include information related to the FDA's determination "regardless of whether the [FDA] responded to the petition at or *before* the approval of the application at issue in the petition") (emphasis added).

On this subject, the FDA has issued a non-binding guidance document that sets forth the agency's current thinking on the relationship between its review of citizen petitions of this ilk and pending NDAs and ANDAs. *See* Guidance for Industry, Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (June 2011) ("Section 505(q) Guidance"), at A.R. 000276-00292. According to that document, the FDA "will consider the review status of the affected application(s) in determining whether it would be appropriate for the Agency to respond to the request to take the action requested in the petition within the 180-day timeframe." *Id.*, at A.R. 000290. At the heart of the FDA's concern is that the applicable statutory and regulatory framework "establish[es] certain procedures by which the [FDA] reviews an NDA or ANDA," a process that is designed to "ensure that applicants have an adequate opportunity to challenge a finding by the Agency that a product does

not meet the requirements for approval." *Id.*, at A.R. 000290-00291. In contrast, the process for resolving citizen petitions "carr[ies] with [it] none of the procedural rights for the affected applications," meaning that if the FDA "were to respond substantively to a petitioner's request regarding the approvability of a certain aspect of a pending application . . . , such response could interfere with the statutory and regulatory scheme governing the review of applications." *Id.*, at A.R. 000291. As a result, the FDA "do[es] not interpret section 505(q) to require a substantive final Agency decision within 180 days on the approvability of a specific aspect of a pending application when a final decision on the approvability of the application as a whole has not yet been made and when to render such a decision could deprive an applicant of procedural rights established by statute and regulations." *Id.* "In such a situation, [the FDA] would expect to deny a petition without comment on the substantive approval issue." *Id.*

B. Case-Specific Background[6]

1. AstraZeneca's NDAs for Seroquel and Seroquel XR

AstraZeneca discovers, develops, manufactures, and markets prescription medicines. It holds NDAs for Seroquel and Seroquel XR, two antipsychotic drugs that are used to treat serious psychological disorders such as schizophrenia. *See* Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), at A.R. 000066-000067, 000173-000174. AstraZeneca first received the FDA's approval to market Seroquel in September 1997, and it first received approval to market Seroquel XR, an extended-release version, in May 2007. *Id.*, at 000066, 000173. Since then, AstraZeneca has marketed Seroquel and Seroquel XR in the United States without facing generic competition.

---

[6] The Court avoids the phrase "factual background" because, when a party seeks review of agency action under the Administrative Procedure Act, "[t]he entire case is a question of law" and the "complaint, properly read, actually presents no factual allegations, but rather only arguments about the legal conclusion[s] to be drawn about the agency action." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

2. Patents and Exclusivities for Seroquel and Seroquel XR

Everyone agrees that AstraZeneca is entitled to a six-month pediatric exclusivity period for Seroquel that will expire on March 26, 2012.[7] *See* Orange Book, at A.R. 000068. In addition, AstraZeneca is listed in the Orange book, a directory that includes a list of approved drug products, as claiming a series of other overlapping patents and exclusivities for certain patient populations and indications for both Seroquel and Seroquel XR that would expire at various points between April 2012 and November 2017. *Id.*, at A.R. 000068, 000175-000176; *see also* Federal Defs.' Opp'n to Pl.'s Mot. for Prelim. Inj. ("Def.'s Opp'n"), ECF No. [7], at 10-12 (identifying the overlapping patents and exclusivities).

One of these potential exclusivities is particularly important to AstraZeneca and, unsurprisingly, central to this litigation. Specifically, AstraZeneca claims that it is entitled to a new patient population exclusivity period that, in its view, would effectively extend its monopoly on the market through December 2, 2012. The origin for this claim is found in supplemental NDAs that AstraZeneca submitted to the FDA in 2008. In February 2008, AstraZeneca asked the FDA to approve Seroquel XR for a new indication of adjunctive therapy to antidepressants for the treatment of Major Depressive Disorder ("MDD"). And in October 2008, AstraZeneca asked the FDA to approve Seroquel for the treatment of schizophrenia in adolescents thirteen to seventeen years of age and the treatment of bipolar mania in children and adolescents ten to seventeen years of age. On December 2, 2009, the FDA gave approval to AstraZeneca's supplemental NDAs. *See* Supplement Approval for Seroquel, at A.R. 000095-000099; Supplement Approval for Seroquel XR, at A.R. 000194-000198. At the same time, the FDA approved the addition of a table to the labeling for both Seroquel and Seroquel XR, referred to as

---

[7] Although not immediately relevant to this action, pediatric exclusivity arises when a pioneer drug company conducts certain pediatric studies at the FDA's request. *See* 21 U.S.C. § 355a.

"Table 2" in this litigation, which sets forth composite, glucose-related data relevant to patients with hyperglycemia. *See* Labeling, at A.R. 000209-000210.

Although AstraZeneca contends that "[o]ver 50% of the Table 2 data comes from new clinical investigations that were submitted to [the FDA]," Mem. in Supp. of Pl.'s Mot. for Summ. J. or, in the Alt., Appl. for Prelim. Inj. ("Pl.'s Mem."), ECF No. [3-1], at 7, the FDA rejoins, and AstraZeneca does not contest, that the pooled data are not indication-specific and are "derived from 15 clinical trials [for both Seroquel and Seroquel XR] conducted in schizophrenia (two trials), bipolar depression (three trials), bipolar disorder (two trials), MDD (four trials), generalized anxiety disorder (three trials), and healthy volunteers (one trial)," Def.'s Opp'n at 12. Nonetheless, citing correspondence with the agency, AstraZeneca claims that the glucose-related Table 2 data were included in the labeling for Seroquel and Seroquel XR at the FDA's request. *See* Ltr. from T. Laughren, M.D., to G. Limp dated Dec. 22, 2009, at A.R. 000042 ("The following section on Hyperglycemia needs to be enhanced with any information from your clinical trials on hyperglycemia."); Ltr. from T. Laughren, M.D., to K. Bradley dated Dec. 18, 2008, at A.R. 000011 ("[T]he data for weight change, glucose changes, and lipid changes from the clinical trials, both adult and pediatric, need to be elevated to the Warnings/Precautions section of labeling."); E-mail from K. Updegraff to P. Patterson dated Oct. 16, 2009, at A.R. 000018 ("Please include a table summarizing the shift changes from normal to high fasting glucose and from borderline to high fasting glucose for the short-term, placebo-controlled clinical trials in adults."). According to AstraZeneca, this means that the new clinical investigations that underlie part of the data in Table 2 were "essential" to the FDA's approval of the company's supplemental NDAs on December 2, 2009, giving rise to a three-year new patient

population exclusivity period that would end on December 2, 2012. *See* 21 U.S.C. § 355(j)(5)(F)(iv).

3. ANDAs Referencing Seroquel and Seroquel XR

Relying on documents outside the certified administrative record,[8] AstraZeneca claims, and the FDA does not dispute, that the agency has already given tentative approval to a handful of potential generic competitors to Seroquel and Seroquel XR, including Accord Healthcare, Inc. ("Accord Healthcare") and Handa Pharmaceuticals LLC ("Handa Pharmaceuticals").[9] *See* Decl. of John Ramsey ("Ramsey Decl."), ECF No. [3-2], Ex. 6 (Orange Book Excerpts).

Accord Healthcare first submitted its ANDA referencing Seroquel XR in June 2008, and it last updated its application before receiving tentative approval in November 2010. *See* Ramsey Decl. Ex. 7 (Ltr. from K. Webber, Ph.D., to Samir Mehta, Ph.D., dated Dec. 14, 2010) at 1. The FDA granted Accord Healthcare tentative approval in December 2010, concluding that "based upon the information [Accord Healthcare] ha[d] presented to date . . . the drug is safe and effective for use as recommended in the submitted labeling." *Id.* The tentative approval letter includes the caveat that the "determination [was] based upon information available to the agency at [that] time" and "is subject to change on the basis of new information." *Id.* Accord Healthcare was directed to submit a request for final approval approximately ninety days prior to the date Accord Healthcare believes that its application will be eligible for approval. *Id.* at 2.

---

[8] The Court is not convinced that these extra-record materials should even be considered. *See* 21 U.S.C. § 355(q)(2)(C) (defining the scope of the administrative record); *Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 284 (D.C. Cir. 1981) ("[J]udicial review of agency action is normally confined to the full administrative record before the agency at the time the decision was made."). Nonetheless, because the ultimate result is the same regardless of whether or not the materials are considered, the Court has taken them into account out of an abundance of caution.

[9] Although AstraZeneca has introduced documents suggesting that the FDA gave tentative approval to other potential generic competitors between December 2008 and September 2011, it has introduced documentation that provides any meaningful measure of detail only as to Accord Healthcare and Handa Pharmaceuticals.

Meanwhile, Handa Pharmaceuticals first submitted its ANDA referencing Seroquel XR in March 2008, and it last updated its application before receiving tentative approval in November 2010. *See* Ramsey Decl. Ex. 8 (Ltr. from K. Webber, Ph.D., to M. Chang, Ph.D., dated Dec. 9, 2010) at 1. As with Accord Healthcare, the FDA granted Handa Pharmaceuticals tentative approval in December 2010, similarly concluding "based upon the information [Handa Pharmaceuticals] ha[d] presented to date . . . that the drug is safe and effective for use as recommended in the submitted labeling." *Id.* Again, the tentative approval letter includes the caveat that the FDA's "determination [was] based on information available to the agency at [that] time . . . and is therefore subject to change on the basis of new information." *Id.* Like Accord Healthcare, Handa Pharmaceuticals was directed to submit a request for final approval ninety days prior to the date the company believes that its application will be eligible for approval. *Id.* at 2.

4. AstraZeneca's Citizen Petitions

On September 9, 2011, AstraZeneca filed two citizen petitions with the FDA, one relating to Seroquel and the second relating to Seroquel XR, asking the FDA to refrain from granting final approval to any generic drug that would omit the Table 2 data from its labeling. *See* Seroquel Citizen Petition, at A.R. 000001-000021; Seroquel XR Citizen Petition, at A.R. 000028-000059. According to AstraZeneca's citizen petitions, the new clinical investigations that it conducted with Seroquel XR for the treatment of bipolar disorder and MDD were "essential" to the approval of the labeling for both Seroquel and Seroquel XR, giving rise to a three-year new patient population exclusivity period that would end on December 2, 2012. *See* Seroquel Citizen Petition, at A.R. 000006; Seroquel XR Citizen Petition, at A.R. 000032. In

AstraZeneca's view, this means that a generic competitor cannot include any of the data in Table 2 in its own labeling until after December 2, 2012.

Significantly, AstraZeneca's citizen petitions do not stop at suggesting that generic competitors are *precluded* from relying on Table 2 data in their own labeling until December 2, 2012, but rather proceed to make the further claim that generic competitors are simultaneously *required* to include Table 2 data in their own labeling. According to AstraZeneca, "[i]f [the] FDA were to permit a generic to omit such information from its labeling—after requiring its inclusion in the labeling for [Seroquel and Seroquel XR]—the agency would run afoul of the Administrative Procedure Act's prohibition on arbitrary and capricious agency action." Seroquel Citizen Petition, at A.R. 000004; Seroquel XR Citizen Petition, at A.R. 000031. In this regard, AstraZeneca tenders two basic, overlapping arguments in its citizen petitions. First, AstraZeneca argues that if the FDA thought these data "important enough to insist" that they be included in Seroquel and Seroquel XR's labeling, then the agency "cannot now rationally find that this information may be omitted from the labeling of an ANDA drug." Seroquel Citizen Petition, at A.R. 000004; Seroquel XR Citizen Petition, at A.R. 000032. Second, AstraZeneca argues that permitting generic competitors to omit such information would violate the "sameness" requirement for generic labeling and would effectively treat generic products differently than similar antipsychotics, including Seroquel and Seroquel XR. *See* Seroquel Citizen Petition, at A.R. 000004-000005; Seroquel XR Citizen Petition, at A.R. 000033-000034. In short, AstraZeneca's citizen petitions are premised on the twin assertions that generic competitors must include the Table 2 data in their own labeling, but are precluded from doing so until December 2, 2012. In other words, AstraZeneca effectively contends that it is entitled to a monopoly on the market through December 2, 2012.

On March 7, 2012, the final day of the 180-day period for responding, the FDA denied both of AstraZeneca's citizen petitions. *See* Ltr. from J. Woodcock, M.D., to K. McKenna, Ph.D., dated Mar. 7, 2012 ("Denial Ltr."), at A.R. 000023-000027. In both instances, AstraZeneca's petitions were "denied without comment on whether [the FDA] will take the actions that [AstraZeneca] request[ed]." *Id.*, at A.R. 000023. More specifically, the FDA "den[ied] [AstraZeneca's] requests without comment on the specific requirements for approval of any ANDA for [a generic version of Seroquel or Seroquel XR]." *Id.*, at A.R. 000027. The FDA's denial letter explains:

> [The] FDA has not yet made a final determination with respect to whether to approve or not approve any ANDA relying on Seroquel or Seroquel XR as the [reference listed drug]. [The] FDA's decision to approve or not approve a specific application will be based on the particular facts that are applicable to that application at the time of the decision. The periods of exclusivity . . . for Seroquel and Seroquel XR may or may not apply or be relevant to the Agency's final decisions with respect to any individual application and its labeling depending on the particulars of an ANDA and the timing of its approval. Such decisions are made by the Agency on a case-by-case basis and in the normal course of the review process.

Id., at A.R. 00026. Consistent with the guidance document discussed above, *see supra* Part I.A.5, the FDA takes the position in its denial letter that the applicable statutory and regulatory framework "establish[es] procedural protections in the context of application review," and reaffirms that the agency "does not interpret section 505(q) to require that [it] render a final Agency decision within 180 days on the approvability of a specific aspect of any ANDA for [a generic version of Seroquel or Seroquel XR] when a final decision on the approvability of any such application has not been made." *Id.*, at A.R. 000027.

C. Procedural Background

On March 12, 2012, following the denial of its citizen petitions, AstraZeneca commenced this action against the FDA. AstraZeneca asserts a single claim for relief—specifically, it claims that the FDA violated the Administrative Procedure Act by acting arbitrarily, capriciously, and not in accordance with law, and abusing its discretion, in denying AstraZeneca's citizen petitions. *See* Compl. for Declaratory & Injunctive Relief, ECF No. [1], ¶ 98.

On the same day that it commenced this action, AstraZeneca filed the pending Application for Preliminary Injunction, asking the Court to enjoin the FDA from giving final approval to a generic version of Seroquel or Seroquel XR. *See* Pl.'s Mem. Upon receipt of the application, the Court held an on-the-record conference call with the parties and set an expedited schedule for the resolution of AstraZeneca's application in advance of March 27, 2012, the day following the expiration of AstraZeneca's pediatric exclusivity period. *See* Min. Order (Mar. 14, 2012). In accordance with that expedited schedule, the FDA filed its Opposition on March 15, 2012. *See* Def.'s Opp'n. Later that day, the Court issued an Order observing that the FDA's Opposition raises an argument that AstraZeneca is not entitled to a preliminary injunction because its claim is not yet ripe for judicial review. *See* Order (Mar. 15, 2012), ECF No. [8], at 1. Emphasizing that it had not yet reached a conclusion, one way or another, as to the merits of the argument, the Court ordered AstraZeneca, in responding to the FDA's argument in its Reply, to also "show cause" why this action should not be dismissed without prejudice in the event the Court finds that AstraZeneca's claim is not yet ripe. *See id.* at 1-2. On March 16, 2012, AstraZeneca filed its Reply. *See* Reply Mem. in Supp. of Pl.'s Appl. for Prelim. Inj. ("Pl.'s Reply"), ECF No. [9]. On March 19, 2012, with the Court's leave, the FDA filed a Surreply confined to the discrete issue of whether or not this action should be dismissed without prejudice

for lack of ripeness. *See* Defs.' Surreply ("Def.'s Surreply"), ECF No. [13]. As a result, AstraZeneca's Application for Preliminary Injunction is now fully briefed. In an exercise of its discretion, the Court finds that the application can and should be decided on the papers and that hearing live testimony and oral argument is not appropriate. *See* LCvR 7(f); LCvR 65.1(d).

II. LEGAL STANDARD

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 21 (2008). A plaintiff seeking a preliminary injunction must establish that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of the equities tips in its favor, and (4) an injunction would be in the public interest. *Id.* at 20. Historically, these four factors have been evaluated on a "sliding scale" in this Circuit, such that a stronger showing on one factor could make up for a weaker showing on another. *See Davenport v. Int'l Bhd. of Teamsters*, 166 F.3d 356, 360-61 (D.C. Cir. 1991). Recently, the continued viability of that approach has been called into some doubt, as the United States Court of Appeals for the District of Columbia Circuit has suggested, without holding, that a likelihood of success on the merits is an independent, free-standing requirement for a preliminary injunction. *See Sherley v. Sebelius*, 644 F.3d 388, 392-93 (D.C. Cir. 2011); *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009). However, absent binding authority or clear guidance from the Court of Appeals, the Court considers the most prudent course to bypass this unresolved issue and proceed to explain why a preliminary injunction is not appropriate under the "sliding scale" framework. If a plaintiff cannot meet the less demanding "sliding scale" standard, then it cannot satisfy the more stringent standard alluded to by the Court of Appeals.

III. DISCUSSION

Through its [3] Application for Preliminary Injunction, AstraZeneca asks the Court to enjoin the FDA from giving final approval to a generic version of Seroquel or Seroquel XR during the pendency of this action. Because the Court finds that AstraZeneca has failed to make a clear showing that it is entitled to the extraordinary remedy of a preliminary injunction, its application shall be **DENIED**. Furthermore, because the Court concludes that AstraZeneca's only claim is not yet ripe for judicial review, this action shall be **DISMISSED WITHOUT PREJUDICE**.

A. AstraZeneca's Application for Preliminary Injunction Shall Be Denied

AstraZeneca, as the party seeking preliminary relief, must make a "clear showing" that it is entitled to the "extraordinary remedy" of a preliminary injunction. *Winter*, 555 U.S. at 21. For the reasons set forth below, considering the record as a whole, the Court concludes that AstraZeneca has failed to make this clear showing. Accordingly, AstraZeneca's [3] Application for Preliminary Injunction shall be **DENIED**.

1. Likelihood of Success on the Merits

AstraZeneca bears the burden of establishing that it is likely to succeed on the merits, *Winter*, 555 U.S. at 20, but it is unable to discharge that burden here because its only claim in this action is not even ripe for judicial review. The ripeness doctrine is designed to "prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). In determining whether

administrative action is ripe for review, the district court must begin with a presumption of reviewability and then evaluate "the fitness of the issues for judicial decision and the hardship to the parties of withholding the court consideration." *Id.* at 149. However, before applying this inquiry, the Court begins by disposing of a couple red herrings.

First, under the Administrative Procedure Act, this Court's review must be confined to "final agency action." 5 U.S.C. § 704. On this note, AstraZeneca argues, and the Court agrees, that the FDA's denial of its citizen petitions constitutes final agency action. *See* Pl.'s Mem. at 15 (citing 21 U.S.C. § 355(q)). But that fact does not, as AstraZeneca suggests, render its claim ripe. Long has it been established that even a "purely legal challenge" to "final agency action" may not be fit for judicial review. *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 162-63 (1967). Indeed, the Court of Appeals has found that a challenge to the FDA's denial of a citizen petition raising an abstract question that could affect the approvability of related ANDAs submitted by generic competitors, although constituting final agency action, may not be ripe until the agency makes a concrete determination on the related applications. *See Pfizer Inc. v. Shalala*, 182 F.3d 975, 979-80 (D.C. Cir. 1999); *cf. Cephalon, Inc. v. Sebelius*, 796 F. Supp. 2d 212, 216 (D.D.C. 2011) (holding that even final approval of an application submitted by a generic competitor does not establish ripeness). In the end, "[r]ipeness entails a functional, not a formal inquiry." *Pfizer*, 182 F.3d at 980.

Second, AstraZeneca argues that the FDA's decision to deny its citizen petitions without resolving them on the merits is "contrary to consistent FDA practice." Pl.'s Mem. at 30. The argument is wholly unpersuasive, and need not detain this Court long. The FDA provided a sound and reasonable rationale for refusing to resolve the abstract question raised in the company's twin citizen petitions outside of the "procedural protections . . . of application

review," Denial Ltr., at A.R. 000027, and that rationale is completely consistent with the agency's stated policy, which was announced long before it ruled on AstraZeneca's citizen petitions, *see* Section 505(q) Guidance, at A.R. 000290-00291; *see also Biovail Corp. v. U.S. Food & Drug Admin.*, 448 F. Supp. 2d 154, 160-62 (D.D.C. 2006) (suggesting that the FDA may refuse to rule on a citizen petition before ruling on a related ANDA). Although AstraZeneca reels off a litany of decisions by the FDA that it contends evidence a different practice, *see* Pl.'s Mem. at 31 n.9, many of those decisions predate the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, in which Congress first required the FDA to consider the effect of citizen petitions on pending new drug applications. Of the remainder, the varied outcomes, if anything, evidence only that the FDA has adopted the case-by-case approach it has articulated.

With those preliminary matters aside, the Court now turns to evaluating "the fitness of the issues for judicial decision and the hardship to the parties of withholding the court consideration." *Abbott*, 387 U.S. at 149. In this regard, the Court has no doubt that the substantive issues raised by AstraZeneca in this action are not presently fit for judicial review. AstraZeneca may have its own views as to the scope of its new patient population exclusivity and the relationship between that exclusivity and ANDAs submitted by potential generic competitors, but the FDA may or may not decide to give final approval to competing generics and it may or may not decide to give final approval in a manner that would interfere with AstraZeneca's interpretation of its new patient population exclusivity. At this juncture, the Court simply is not in a position to project whether the FDA will ultimately decide to give final approval to a competing generic, when that hypothetical decision might happen, or what relationship the agency's proffered rationale for that hypothetical decision would have to the

specific claim raised by AstraZeneca in this action. Absent further administrative action, the Court cannot say how the legal arguments tendered by AstraZeneca in this case will matter or even whether they will matter at all. As this Court has observed in the past, such a "state of uncertainty . . . translates into a lack of ripeness." *Mylan Pharm. v. U.S. Food & Drug. Admin.*, 789 F. Supp. 2d 1, 13 (D.D.C. 2011). A few examples will suffice.

First, despite AstraZeneca's fervent belief to the contrary, there is no reason to presume that the FDA will necessarily grant final approval to one or all of the potential generic competitors seeking to market a generic version of Seroquel or Seroquel XR or that it will do so between March 26, 2012 and December 2, 2012, the period between the expiration of AstraZeneca's pediatric exclusivity period and new patient population exclusivity period. Against the FDA's representation that it has not yet determined whether it will give final approval to a generic competitor, AstraZeneca offers only its conclusory assertion that "it is not credible that [the] FDA does not know whether it will grant final approval." Pl.'s Reply at 4. This speculative assertion, unsupported by any competent evidence, is insufficient to overcome the presumption of administrative regularity. *See United States v. Chem. Found.*, 272 U.S. 1, 14-15 (1926) ("The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."). Ultimately, the FDA may or may not decide to give final approval to a competing generic and it may or may not decide to give final approval in a manner that would interfere with AstraZeneca's interpretation of its new patient population exclusivity. Because AstraZeneca's claim "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all," it is not presently fit for judicial review. *Texas v. United States*, 523 U.S. 296, 300 (1998) (quotation marks omitted).

Second, relying on documents outside the certified administrative record,[10] AstraZeneca claims, and the FDA does not dispute, that the agency has already given tentative approval to a handful of potential generic competitors to Seroquel and Seroquel XR. However, as AstraZeneca's own extra-record materials reveal, a potential generic competitor may secure tentative approval from the FDA *years* before it is eligible for final approval, but the FDA makes it clear that its tentative determination is based on the information available at the time and remains subject to change. *See* Ramsey Decl. Ex. 6 (Orange Book Excerpts) at 1, Ex. 7 (Ltr. from K. Webber, Ph.D., to Samir Mehta, Ph.D., dated Dec. 14, 2010) at 1, and Ex. 8 (Ltr. from K. Webber, Ph.D., to M. Chang, Ph.D., dated Dec. 9, 2010) at 1. As the FDA observes, "[a]ny number of events occurring after [the] FDA gives its tentative approval to an ANDA may prevent or delay final approval." Def.'s Opp'n at 7. For instance, with the passage of time, the FDA might conclude upon final review that "[t]he methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to ensure and preserve its identity, strength, quality, and purity." 21 C.F.R. § 314.127(a)(1). In other words, the FDA may deny final approval to one or all of the potential generic competitors seeking to market a generic version of Seroquel or Seroquel XR "for some entirely different reason" than the one pressed by AstraZeneca in this case. *Pfizer*, 182 F.3d at 978; *cf. ViroPharma, Inc. v. Hamburg*, 777 F. Supp. 2d 140, 146 (D.D.C. 2011) (noting in the context of evaluating the plaintiff's standing that "it cannot be assumed" that "if and when the FDA ultimately approves an ANDA," the agency would rely on the reasoning challenged by the plaintiff). Accordingly, there may never be a need for a court to opine on the merits of AstraZeneca's interpretation of its new patient population exclusivity. In other words, it is not

[10] Again, the Court is not convinced that these extra-record materials should even be considered, but it has taken them into account in an abundance of caution.

clear how the arguments raised by AstraZeneca in this case will matter or whether they "will matter at all." *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1309 (D.C. Cir. 2010). The ripeness doctrine is designed to avoid precisely this sort of entanglement in "abstract disagreements over administrative policies." *Abbott*, 387 U.S. at 148.

Third, AstraZeneca further argues, and this Court accepts, that in granting tentative approval to potential generic competitors, the FDA must have reviewed and approved draft labeling submitted by the applicants. But that does not necessarily mean, as AstraZeneca suggests, that the FDA brought its expertise to bear on AstraZeneca's current argument that generic competitors are simultaneously required to and precluded from relying on the Table 2 data in their own labeling. As the FDA persuasively rejoins, "[t]entative approvals are based only on draft labeling," and "[i]t may be months or even years between a tentative and final approval, and the labeling may be required to change in the interim, particularly if the innovator makes changes and the agency must evaluate how those may impact the draft ANDA labeling." Def.'s Opp'n at 8. In fact, AstraZeneca's own extra-record materials suggest that this is true with at least some of the applications pending before the FDA. According to those materials, the FDA gave tentative approval to two competing generics in December 2008 and June 2009, *before* the FDA approved the supplemental NDAs that undergird AstraZeneca's interpretation of its new patient population exclusivity period and *before* the FDA approved AstraZeneca's labeling that sets forth the Table 2 data. *See* Supplement Approval for Seroquel, at A.R. 000095-000099; Supplement Approval for Seroquel XR, at A.R. 000194-000198; Ramsey Decl. Ex. 6 (Orange Book Excerpts). In granting tentative approval, the FDA could not possibly have determined whether approval would interfere with a new patient population exclusivity that did not then exist. Nor is there any credible indication that when the FDA considered the draft

labeling submitted in connection with the remaining generic applications postdating these events, the agency presumed that final approval would be sought between March 26, 2012 and December 2, 2012, the period between the expiration of AstraZeneca's pediatric exclusivity period and new patient population exclusivity period.[11]

Fourth, AstraZeneca concedes that the "FDA's regulations permit limited 'carve outs' from [generic drug] labels," but argues that the "FDA is not permitted to remove information from labeling that is relevant to the indication for which the drug is approved, and especially not when the information . . . is information that [the] FDA has deemed to be 'important.'" Pl.'s Mem. at 24. The FDA asserts, and AstraZeneca does not dispute, that "each prospective labeling carve-out involves line-by-line review of the labeling" and the outcome of the FDA's review "could change over time as different exclusivities expire." Def.'s Opp'n at 18. In this case, AstraZeneca claims a series of overlapping patents and exclusivities for certain patient populations and indications that would expire at various points between March 26, 2012 and November 2017. *See* Orange Book, at A.R. 000068, 000175-000176. Because the propriety of any labeling "carve-outs" necessarily depends on what exclusivities are in play at the time of final approval and the specific indications for which approval is sought, the "carve-out inquiry is fact-specific and could change over time as different exclusivities expire." Def.'s Opp'n at 18; *see Mylan*, 789 F. Supp. 2d at 11-13 (concluding that factual questions regarding a pioneer drug

[11] AstraZeneca speculates that potential generic competitors may have already submitted final proposed labeling to the FDA. *See* Pl.'s Reply at 4. Even crediting that speculation, there is no indication that the FDA has actually reviewed that proposed labeling and determined, one way or another, whether it would interfere with an exclusivity held by AstraZeneca if and when final approval is given.

company's eligibility for certain exclusivities and the status of pending ANDAs rendered the action unfit for judicial review).[12]

Regardless of what AstraZeneca may believe, it is beyond cavil that this litigation does not involve the sort of "questions of law and undisputed facts" that might justify immediate judicial intervention. Pl.'s Mem. at 20. Nor is the Court willing to assume, as AstraZeneca apparently is, that the outcome of, and basis for, the FDA's decisions on pending generic applications is preordained. Considering the record as a whole, the Court concludes that the issues raised in this case are not "sufficiently concrete and conducive to judicial determination," and deciding those issues "now would violate principles of judicial restraint and efficiency." *Alcoa Power Generating Inc. v. Fed. Energy Regulatory Comm'n*, 643 F.3d 963, 967 (D.C. Cir. 2011). This action is not, in short, presently fit for judicial review. If judicial intervention ever proves to be necessary, it should wait until the FDA's "decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott*, 387 U.S. at 148-49.

Turning to "the hardship to the parties of withholding the court consideration," *Abbott*, 387 U.S. at 149, it only becomes more clear that this action is not ripe. The Court fully understands AstraZeneca's concern that, absent immediate review, it might be required to seek judicial intervention in an expedited proceeding if and when the FDA grants final approval to a

---

[12] In this action, AstraZeneca argues that "once [the] FDA has determined . . . that AstraZeneca has submitted 'new clinical investigations' that entitles it to a three-year exclusivity . . . the scope of that exclusivity extends to *any changes* approved in [the supplemental NDA]." Pl.'s Mem. at 28 (emphasis in original). However, there is no indication that the FDA has determined that a specific pending application needs to and in fact does rely "on the information supporting a change approved in [AstraZeneca's] supplemental [NDAs]." 21 C.F.R. § 314.108(b)(5)(ii). It makes perfect sense for the FDA, and if necessary a future reviewing court, to address that question in the concrete setting of the approvability of specific ANDAs and not in the abstract. *See Sprint Corp. v. Fed. Commc'ns Comm'n*, 331 F.3d 952, 955 (D.C. Cir. 2003) ("[I]ssues still may not be fit for review where the agency retains considerable discretion to apply the new rule on a case-by-case basis, particularly where there is a complex statutory scheme or there are other difficult legal issues that are implicated by the agency action.").

competing generic after March 26, 2012, but before December 2, 2012. Generally speaking, the "burden of participating in further administrative and judicial proceedings" does "not constitute sufficient hardship for purposes of ripeness." *Fla. Power & Light Co. v. Envtl. Prot. Agency*, 145 F.3d 1414, 1421 (D.C. Cir. 1998). Nonetheless, the Court understands that the market exclusivity claimed by AstraZeneca is time-sensitive, and that permitting generic competitors to enter the market even for a short time could have significant implications for AstraZeneca's market share, but any concern in this regard is ameliorated somewhat by the fact that the FDA has already voluntarily bound itself to provide AstraZeneca with advance notice of its intention to issue a final decision adverse to AstraZeneca and represents that it will consent to expedited briefing in the event preliminary relief is sought in the future. *See* Def.'s Opp'n at 29-30; Def.'s Surreply at 2 n.1. AstraZeneca has shown itself more than capable of availing itself of the procedures for securing preliminary relief, and although the Court has no illusion that the merits issues are likely to be "miraculously resolve[d] . . . instantaneously," *Teva*, 595 F.3d at 1311, courts are more than capable of acting with sufficient promptness to preserve the *status quo* if appropriate.

More importantly, against AstraZeneca's interest in securing immediate judicial review, the Court considers it prudent to "balance . . . the agency's interest in crystallizing its policy before that policy is subjected to judicial review." *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 49 (D.C. Cir. 1999) (quotation marks omitted). In this regard, the FDA's interest is compelling. Significantly, "the possibility that further consideration will actually occur . . . is not theoretical, but real," *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 735 (1998), because, sooner or later, the FDA will decide whether or not to grant final approval to one or more generic competitors. For all of the reasons enumerated above, the resolution of pending

generic applications implicates the complex application of legal principles to specific factual circumstances, and the Court declines to deprive the FDA of the opportunity to engage in this exercise in a concrete and formal setting. The Court finds that the FDA's interest in crystallizing its policies before they are subjected to a court's scrutiny is compelling, and outweighs whatever interest AstraZeneca has in securing immediate judicial review.

In a similar vein, the Court is convinced that "further factual development would 'significantly advance [a reviewing court's] ability to deal with the legal issues presented.'" *Ohio Forestry*, 523 U.S. at 737 (quoting *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 89 (1978)). Contrary to what AstraZeneca may believe, permitting the FDA to reach a final, reasoned decision on the approvability of pending ANDAs will afford a reviewing court the benefit of the agency's informed and documented consideration of the scope of, and relationship between, the various exclusivities claimed by AstraZeneca and their relationship to specific applications at the time of final approval. The Court is disinclined to resolve the abstract and complex issues raised by AstraZeneca in this action without the benefit of the FDA's superior expertise or the administrative record that would support the agency's substantive decision. *Cf. Cephalon*, 796 F. Supp. 2d at 220-21 (concluding that "the Court would benefit from postponement . . . because a number of events could occur that would either make adjudication unnecessary or materially alter the complexion of the case").

No doubt seeing the writing on the wall, AstraZeneca relies heavily on *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010), in which the United States Court of Appeals for the District of Columbia Circuit found that the plaintiff, a generic drug company laying claim to a future marketing exclusivity period, could obtain judicial review even though the FDA was yet to issue a final determination resolving the plaintiff's application

one way or another. For at least two reasons, AstraZeneca's reliance on *Teva* is misplaced. First, by the time the plaintiff brought suit in *Teva*, the FDA had already made its position abundantly clear. The case hinged on a question of statutory interpretation, the FDA had twice found that its interpretation was compelled by the statutory language, and, in so finding, the FDA had unambiguously rejected the identical competing interpretation pressed by the plaintiff. *Id.* at 1308. In short, there was no question either as to "what approach the agency [would] apply" to resolve the plaintiff's application or "precisely" what the FDA thought the end result should be. *Id.* at 1309-10. The same cannot be said here, where the FDA may or may not decide to give final approval to one or more competing generics and it may do so for any number of reasons. At this time, this Court simply cannot predict what approach the FDA will apply or what the end result will be. Second, the single dispositive issue in *Teva* was a pure question of statutory interpretation and the parties' competing interpretations were categorical and "impervious . . . to factual variation." *Id.* at 1308-09. By contrast, in this case, there are open questions about the status of pending applications for competing generics and their relationship to AstraZeneca's interpretation of its new patient population exclusivity. Although AstraZeneca tenders a number of legal arguments in support of its interpretation, the FDA could decide to approve or not approve pending applications for any number of reasons independent of AstraZeneca's interpretation of its new patient population exclusivity. At this juncture, it is not clear precisely how the arguments relied upon by AstraZeneca will matter or even if they "will matter at all." *Id.* at 1309. In other words, there is a "material ambiguity about essential facts" that was altogether absent from *Teva*, compelling a different outcome in this case. *Id.* at 1311.

In truth, this action has much more in common with the Court of Appeals' decision in *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999). In that case, the plaintiff, a pioneer drug

company like AstraZeneca, submitted a citizen petition to the FDA essentially asking the agency to rule on an abstract question that could affect the approvability of ANDAs submitted by generic competitors. When the FDA denied the petition, refusing to reach the merits, the plaintiff sought judicial intervention. Notably, as is the case here, by the time the Court of Appeals rendered its decision, the FDA had already given tentative approval to a generic competitor. Even while acknowledging that this development made final approval "more likely," the Court of Appeals nonetheless found the case unripe for judicial review. *Id.* at 980. Seizing on open questions that apply equally to this case, the Court of Appeals underscored that it was not clear whether the FDA would ever give final approval to the generic competitor's application and, if it denied final approval, whether it would do so "for some entirely different reason" than the one pressed by the plaintiff. *Id.* at 978. As a result, permitting premature judicial intervention could "lead to piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary." *Id.* at 980 (quotation marks omitted). In the end, the Court of Appeals found the most prudent course was to await a final decision from the FDA, when the plaintiff would be in a position to address any other arguments "aris[ing] from the agency's final approval—if and when it is given." *Id.* The Court sees no good reason to depart from *Pfizer*'s reasoning here, when there is no meaningful measure of clarity as to what approach the FDA will apply when resolving pending ANDAs referencing Seroquel or Seroquel XR or what the FDA believes the end result should be.

The Court understands that AstraZeneca, like many other pioneer drug companies, would like advance knowledge as to whether and when a generic competitor will enter the market. However, the simple fact is that the substantive issues raised by AstraZeneca in this action are not fit for judicial review at this time. AstraZeneca clearly has its own views as to the scope of

its new patient population exclusivity and the relationship between that exclusivity and applications submitted by potential generic competitors, but the FDA may or may not decide to give final approval to competing generics and it may or may not decide to give final approval in a manner that would interfere with AstraZeneca's interpretation of its new patient population exclusivity. At this posture, the Court can only speculate whether the FDA will decide to give final approval to a competing generic, when that hypothetical decision might happen, and what relationship the agency's proffered rationale for that hypothetical decision would have to the specific claim raised by AstraZeneca in this action. Indeed, the precise "controversy" envisioned by AstraZeneca in this action may *never* ripen into a dispute amenable to judicial review. As a result, the Court finds that AstraZeneca has failed to establish a likelihood of success on the merits, and this factor does not weigh in favor of granting the preliminary injunction sought.

2. Irreparable Harm

AstraZeneca bears the burden of "demonstrat[ing] that irreparable injury is *likely* in the absence of an injunction," and not a mere possibility. *Winter*, 552 U.S. at 22 (emphasis in original). The injury identified must "be both certain and great; it must be actual and not theoretical." *Wisconsin Gas Co. v. Fed. Energy Regulatory Comm'n*, 758 F.2d 669, 674 (D.C. Cir. 1985). Here, claiming that potential generic competitors are already preparing to enter the market, AstraZeneca contends that it will suffer significant economic injury in the event the FDA ultimately decides to grant final approval to a competing generic. *See* Pl.'s Mem. at 39; Ramsey Decl. ¶¶ 23-28. However, even assuming that economic injury of this kind may constitute a cognizable harm, AstraZeneca has fallen woefully short of showing that such harm is "certain," and "not theoretical." *Wisconsin Gas*, 758 F.2d at 674. For reasons already discussed, the Court is not in a position to project whether the FDA will ultimately decide to give final approval to a competing generic, when that hypothetical decision might happen, or whether that hypothetical

decision would actually interfere with AstraZeneca's interpretation of its new patient population exclusivity. *Cf. Hi-Tech Pharmacal Co., Inc. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 12 (D.D.C. 2008) (concluding that the plaintiff's claimed injury remained "speculative" absent formal administrative action). On this record, the Court concludes that AstraZeneca has failed to establish that the injury it has identified is likely, and not a mere possibility. Accordingly, this factor does not weigh in favor of granting AstraZeneca's requested injunction.

3. The Balance of the Equities and the Public Interest

Finally, AstraZeneca bears the burden of establishing that the balance of the equities tips in its favor and that an injunction would be in the public interest. *See Winter*, 555 U.S. at 20. AstraZeneca has failed to meet this burden because, at best, the public and private interests are in equipoise. The public has an interest in promoting drug innovation by protecting the patent and exclusivity rights allocated to pioneer drug companies like AstraZeneca, but it also has an interest in seeing that generic competitors are able to enter the market as soon as possible and in the manner envisioned by Congress. Furthermore, the Court understands AstraZeneca's desire to have advance knowledge as to whether and when it might face generic competition, but the Court cannot disregard the interest of generic competitors to have their applications resolved on the merits of the specific circumstances presented and in the context of the procedural safeguards created by Congress and the FDA. Meanwhile, the FDA has an interest in being able to discharge the duties entrusted to it by Congress free from judicial interference until it has been afforded an opportunity to bring its superior expertise to bear on the complex factual and legal issues raised by AstraZeneca in this case and to make a formal decision in a more concrete setting. Likewise, as reflected in the ripeness doctrine itself, the Judiciary has an interest in waiting until an administrative decision has been formalized and its effects felt in a concrete way

before conducting judicial review. On this record, the Court cannot conclude that AstraZeneca has met its burden of establishing that the balance of the equities tips in its favor and that an injunction would be in the public interest. Accordingly, this factor does not weigh in favor of granting AstraZeneca's requested injunction.

* * *

For the reasons set forth above, considering the record as a whole, the Court concludes that AstraZeneca has failed to make a "clear showing" that it is entitled to the "extraordinary remedy" of a preliminary injunction. *Winter*, 555 U.S. at 21. Accordingly, AstraZeneca's [3] Application for Preliminary Injunction shall be **DENIED**.

B. The Court Shall Dismiss this Action Without Prejudice

On March 15, 2012, after having the opportunity to review the FDA's Opposition, the Court directed AstraZeneca to "show cause" why this action should not be dismissed without prejudice in the event the Court found that AstraZeneca's claim is not yet ripe. *See* Order (Mar. 15, 2012) at 1-2. AstraZeneca responded on March 16, 2012 and, with the Court's leave, the FDA filed a Surreply confined to this issue on March 19, 2012. Upon consideration of the parties' submissions, and having now found that AstraZeneca's claim is not yet ripe, the Court declines AstraZeneca's invitation to hold this action in abeyance for an indefinite period to wait and see whether this premature action ever ripens into a justiciable case or controversy. *See* Pl.'s Reply at 22-25. This Court simply is not in a position to prophesy whether the FDA will ultimately decide to give final approval to a competing generic, when that hypothetical decision might happen, or what relationship the agency's proffered rationale for that hypothetical decision would have to the specific claim raised by AstraZeneca in this action. Indeed, the Court is mindful that the precise "controversy" envisioned by AstraZeneca in this action may *never* ripen into a dispute amenable to judicial review. The FDA may or may not decide to give final

approval to a competing generic and it may or may not decide to give final approval in a manner that would interfere with AstraZeneca's interpretation of its new patient population exclusivity. If and when the FDA makes a final decision adverse to AstraZeneca, it would present "a different case based on a different set of facts." Def.'s Surreply at 2. Should AstraZeneca seek judicial intervention in that instance, the case would necessarily turn on intervening agency action and the subject matter, posture, and administrative record would be different.

Nor is the Court persuaded by AstraZeneca's argument that requiring it to bring a new action if and when its claim ripens would present an undue hardship or prejudice its ability to secure meaningful relief. *See* Pl.'s Reply at 23-24. Should the FDA ever give final approval to a competing generic in a manner that is not to AstraZeneca's liking, AstraZeneca will have a full and fair opportunity to seek judicial intervention in a new action. AstraZeneca has shown itself more than capable of availing itself (albeit prematurely) of the procedures for securing preliminary relief that are contemplated by the Federal Rules of Civil Procedure and the Local Rules of this Court, and the Court sees no good reason why AstraZeneca could not do so again in a new action, should that ever prove to be necessary. The FDA has already represented that it will consent to expedited briefing in such a situation. *See* Def.'s Opp'n at 29-30. It matters little whether preliminary relief is litigated on an expedited basis in this action or in a new action. Meanwhile, although AstraZeneca suggests that permitting this case to remain open indefinitely would allow the Court to require the FDA to provide advance notice of its intention to issue a final decision adverse to AstraZeneca, the FDA has already voluntarily bound itself to provide AstraZeneca with advance notice regardless of whether or not this case is dismissed. *See* Def.'s Surreply at 2 n.1.

Under these circumstances, the Court declines to exercise its discretion to hold this action in abeyance indefinitely despite the absence of a ripe case or controversy. Instead, the action shall be **DISMISSED WITHOUT PREJUDICE** to AstraZeneca's right to commence a new and different action if and when its claim ever ripens into a justiciable case or controversy. *See Cephalon*, 796 F. Supp. 2d at 221 (dismissing action without prejudice when claims were not ripe for judicial review); *Arizona Pub. Serv. Co. v. Envtl. Prot. Agency*, 2000 WL 1582754, at *1 (D.C. Cir. Sept. 14, 2000) (dismissing petition without prejudice in lieu of holding case in abeyance pending final agency action).

IV. CONCLUSION

The Court has considered the remaining arguments tendered by the parties and has concluded that they are either without merit or need not be reached in light of the reasons for the Court's decision. Therefore, and for the reasons set forth above, AstraZeneca's [3] Application for Preliminary Injunction shall be **DENIED** and this action shall be **DISMISSED WITHOUT PREJUDICE**. An appropriate Order accompanies this Memorandum Opinion.

Date: March 23, 2012.

_____/s/_____
COLLEEN KOLLAR-KOTELLY
United States District Judge