UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 11-542 (ESH)**
	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION

Plaintiff Cephalon, Inc., a Delaware corporation with its principal place of business in Pennsylvania, has sued Kathleen Sebelius, the Secretary of Health and Human Services, and Margaret Hamburg, the Commissioner of the Food and Drug Administration, in their official capacities. Plaintiff, the manufacturer of Fentora, a name brand or "pioneer" drug, brings this suit under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*, claiming that the Food and Drug Administration ("FDA") erroneously approved a generic version of Fentora. Before the Court is defendants' motion to dismiss for lack of subject matter jurisdiction on the grounds that plaintiff lacks standing and its claims are not ripe. For the reasons set forth below, the Court will dismiss this case because it is not ripe.

BACKGROUND

I. REGULATORY FRAMEWORK

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, a pioneer drug may not be marketed until the FDA has approved a new drug application ("NDA") that includes "full reports of investigations which have been made to show whether or not such drug is safe for

use and whether such drug is effective in use" and "a full statement of the composition of such drug." 21 U.S.C. § 355(b)(1). In addition, the pioneer manufacturer must provide the patent number and expiration date of any patent related to the drug. *Id.* If the FDA approves the pioneer drug, it is published in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). *See id.* The pioneer's listing in the Orange Book includes patents claiming the drug or its method of use. *Id.*

After a pioneer drug is approved, a generic manufacturer may obtain FDA approval to market a generic version by submitting an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). Instead of relying on its own clinical studies to prove that the generic is effective, the generic manufacturer can show, among other things, that its drug is the same as the pioneer drug in terms of active ingredient(s), route of administration, dosage form, and strength, and that the generic is bioequivalent to the pioneer drug. 21 U.S.C. § 355(j)(2)(A). If the pioneer contains a single active ingredient, the ANDA must include "information to show that the active ingredient of the new drug is the same as that of the listed drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I).

Submission of an ANDA constitutes a patent infringement of patents claiming the pioneer drug. 35 U.S.C. § 271(e)(2). Thus, if the generic manufacturer wants to market its drug before the requisite patent(s) in the Orange Book expires, the generic manufacturer must show "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

II. FACTUAL HISTORY

Plaintiff manufactures the pioneer drug Fentora, which is a "potent opioid analgesic" that is used to treat breakthrough pain in cancer patients who have become tolerant to other opioids. (Complaint ["Compl."] at ¶ 16.) Fentora contains a single active ingredient, fentanyl citrate,

which is a Schedule II narcotic. (*Id.* at ¶ 17.) Fentora comes in a tablet, which is placed inside the patient's mouth to allow the tablet to disintegrate and deliver the fentanyl citrate to the patient's body. (*Id.*) Clinical studies have shown that pain relief occurs in patients from fifteen to thirty minutes after placing the tablet in the mouth. (*Id.*) Cephalon listed at least two patents for Fentora in the Orange Book. A third patent, U.S. Patent No. 6,264,981 ("the '981 patent"), was ineligible for listing in the Orange Book[1] but was filed with the United States Patent and Trade Office on October 27, 1999, and the patent will expire in 2019. (Defendant's Motion to Dismiss ["Def.'s Mot."] at 3-4 & nn.4-5.) The FDA approved Fentora on September 25, 2006. (Compl. at ¶ 16.)

Watson Laboratories, Inc. ("Watson") filed an ANDA for a generic version of Fentora ("the Watson generic") on July 10, 2007, which was ultimately approved by the FDA on January 7, 2011. (*Id.* at ¶¶ 18, 25; Def.'s Mot. at 3.) Between the filing of the ANDA and its approval three and a half years later, plaintiff took a number of steps to delay or prevent approval. Plaintiff first attempted to block Watson's ANDA by filing a patent infringement claim based on the two Orange Book patents on June 2, 2008, in federal court in Delaware. (Compl. at ¶ 18.) Plaintiff filed a second patent infringement claim based on the '981 patent in the same court on September 25, 2009. (*Id.*) The court consolidated both claims and held a bench trial. *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 08-330, 2011 WL 845376, at *1 (D. Del. Mar. 11, 2011) [hereinafter *Cephalon I*].

During the trial, plaintiff learned that the manufacturing process for the Watson generic could potentially create a second active ingredient (in addition to fentanyl citrate) and that the FDA had knowledge of that possibility. (Compl. at ¶¶ 18, 19.) Based on that information,

[1] Because the '981 patent describes manufacturing methods, and the Orange Book lists approved drug products, it cannot be listed in the Orange Book. (*See* Def.'s Mot. at 3 n.4.)

plaintiff filed a citizen petition with the FDA on July 13, 2010, arguing that the second active ingredient should have prevented the FDA from approving the Watson generic because the FDA's regulations require that the pioneer and the generic have the same active ingredient. (*Id.* at ¶ 23.) Plaintiff filed a second citizen petition on July 23, 2010. (*Id.* at ¶ 24.) In that petition, plaintiff asked the FDA "to revise its bioequivalence guidelines" to accommodate Fentora's rapid release of fentanyl citrate by requiring generic manufacturers to prove that the generic could be absorbed into the body as quickly as Fentora. (*Id.*) On January 7, 2011 (the same day that the FDA approved the Watson generic), the FDA denied both petitions. (*Id.* at ¶ 25.)

On March 11, 2011, the Delaware court ruled against plaintiff in the first patent suit. *Cephalon I*, 2011 WL 845376, at *27. However, on March 25, 2011, the court ruled for plaintiff on the second patent claim, finding that the Watson generic violated the '981 patent. *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 09-724, 2011 WL 1088008, at *23 (D. Del. Mar. 24, 2011) [hereinafter *Cephalon II*]. Following that decision, Cephalon and Watson entered a stipulated agreement and the district court issued a permanent injunction barring Watson from infringing the '981 patent for the life of the patent, which expires in 2019. *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 09-724 (D. Del. Apr. 25, 2011), ECF No. 204 (order granting permanent injunction) (included in Def.'s Mot. as Attach. A); *id.*, (D. Del. Apr. 20, 2011), ECF No. 202 (stipulated agreement for separate judgments and permanent injunction) (included in Plaintiff's Memorandum in Opposition to the Federal Defendants' Motion to Dismiss ["Pl.'s Opp."] at Ex. 1). The agreement reserves the right for Watson to move "to vacate and dissolve the permanent injunction in the event of changed circumstances that Defendants reasonably believe shift the balance of factors relevant to entry of a permanent injunction," including the entry of an additional generic version of Fentora into the market. (Pl.'s Opp. at Ex. 1 at 2.) Watson filed a

notice of appeal with the Federal Circuit on April 25, 2011, but the case has not been set for argument.

Plaintiff filed this suit on March 15, 2011. (Compl. at 1.) The Court granted an unopposed motion for Watson to intervene as a defendant on March 22, 2011. Now before the Court is defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(1).

ANALYSIS

I. LEGAL STANDARDS

A. Motion to Dismiss

On a motion to dismiss pursuant to Rule 12(b)(1), plaintiff bears the burden of establishing by a preponderance of the evidence that the court has subject matter jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). The Court must accept all factual allegations in the complaint as true and give plaintiff the benefit of all reasonable inferences from the facts alleged. *See Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253-54 (D.C. Cir. 2005). A court may dismiss for lack of subject matter jurisdiction only if "'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Richardson v. United States*, 193 F.3d 545, 549 (D.C. Cir. 1999) (quoting *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1086 (D.C. Cir. 1998)). Moreover, where a court's subject matter jurisdiction is called into question, the court may consider matters outside the pleadings to ensure it has power over the case. *See Teva Pharms., USA, Inc. v. U.S. Food & Drug Admin.*, 182 F.3d 1003, 1006 (D.C. Cir. 1999).

Further, a court "'need not identify every ground for holding that a claim is not justiciable.'" *Fourth Branch Assocs. (Mechanicville) v. FERC*, 253 F.3d 741, 745 (D.C. Cir. 2001) (quoting *Indep. Petroleum Ass'n of Am. v. Babbitt*, 235 F.3d 588, 594 (D.C. Cir. 2001)). "Indeed, [a court has] no trouble dismissing a claim 'based on one jurisdictional bar rather than

another.'" *Id.* (quoting *La. Envtl. Action Network v. Browner*, 87 F.3d 1379, 1384 (D.C. Cir. 1996)).[2]

II. RIPENESS

"'Ripeness is a justiciability doctrine' that is 'drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.'" *Devia v. Nuclear Regulatory Comm'n*, 492 F.3d 421, 424 (D.C. Cir. 2007) (quoting *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 807-08 (2003)) (internal quotation marks omitted) (brackets and decapitalization omitted). A ripeness determination requires the Court to apply a two-part analysis: (1) "'the fitness of the issues for judicial decision'" and (2) "'the hardship to the parties of withholding court consideration.'" *Id.* (quoting *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996)) (internal quotation marks omitted). The underlying purpose of ripeness in the administrative context "is 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." *Id.* (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). Ripeness also prevents a court from making a decision unless it absolutely has to, underpinned by the idea that if the court does not decide the claim now, it may never have to. *Id.*

A. The Fitness Analysis

"[T]he fitness analysis requires the court to consider both whether the context in which the issue is presented is sufficiently concrete and conducive to judicial determination, and whether deciding the issue now would violate principles of judicial restraint and efficiency."

[2] Therefore, since the Court is resting its decision on ripeness grounds, it need not address the alternative jurisdictional argument of lack of standing.

Alcoa Power Generating Inc. v. FERC, No. 10-1066, 2011 WL 1642442, at *3 (D.C. Cir. May 3, 2011). "'Among other things, the fitness of an issue for judicial decision depends on whether it is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.'" *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378, 397 (D.C. Cir. 2008) (quoting *Atl. States Legal Found., Inc. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003)) (internal quotation marks omitted). "[W]hen an agency decision may never have 'its effects felt in a concrete way by the challenging parties,' the prospect of entangling [the court] in a challenge to such a decision is an element of the fitness determination as well." *Devia*, 492 F.3d at 424 (quoting *Abbott Labs.*, 387 U.S. at 148-49) (internal quotation marks omitted) (citation omitted).

Contrary to plaintiff's argument (*see* Pl.'s Opp. at 10), the fact that the agency has issued final approval of the ANDA submitted by a generic applicant does not establish ripeness.[3] Although the fitness prong of the ripeness test favors a plaintiff if the agency action is final, that determination is not dispositive either for the fitness prong, which entails other factors as well, or overall ripeness, as the second prong can predominate. *See Friends of Keeseville, Inc. v. FERC*, 859 F.2d 230, 235-36 (D.C. Cir. 1988) (holding a claim unripe when the plaintiff challenged a final agency decision but failed to show how postponing review would create a direct and immediate hardship for the plaintiff).

Here, the fitness factors arguably favor plaintiff. Because plaintiff challenges the FDA's approval of the Watson generic's ANDA, including the issue of whether a generic may contain

[3] Moreover, the Circuit's decision in *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999), does not undercut this conclusion. Although the Court reasoned that an eventual FDA approval of a generic ANDA could make the case ripe, it did not establish a *per se* rule that automatically makes ripe a case involving final agency action. On the contrary, the Court acknowledged that "a final agency action nonetheless can be unripe for judicial review." *Id.* at 980.

multiple active ingredients when the pioneer contains only one, this is first, a purely legal dispute, and second, a dispute over a final agency action. However, "[e]ven though the legal issues may be clear, a case may not be ripe for review [under the second prong] when it would be inappropriate for a court to spend scarce resources on claims that, 'though predominantly legal in character, depend[ ] on future events that may never come to pass, or that may not occur in the form forecasted.'" *Flint Hills Res. Alaska, LLC v. FERC*, 627 F.3d 881, 889 (D.C. Cir. 2010) (quoting *Devia*, 492 F.3d at 425) (third brackets in original). With this in mind, the Court now turns to the second prong.

B. Hardship to the Parties and Benefit to the Court

The second prong of the ripeness tests requires the Court to consider "'not whether the parties have suffered any "direct hardship," but rather whether *postponing* judicial review would impose an undue burden on them or would benefit the court.'" *Village of Bensenville v. FAA*, 376 F.3d 1114, 1120 (D.C. Cir. 2004) (quoting *Harris v. FAA*, 353 F.3d 1006, 1012 (D.C. Cir. 2004)) (brackets omitted).[4] "'The second prong . . . requires that the contested action impose an impact on the parties sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage.'" *Friends of Keeseville*, 859 F.2d at 236 (quoting *Alascom, Inc. v. FCC*, 727 F.2d 1212, 1217 (D.C. Cir. 1984)) (internal quotation marks omitted). Thus, "[e]ven

[4] The D.C. Circuit's decision in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010), has not changed this test. In *Teva*, the Court reasoned that "where there are no institutional interests favoring postponement of review, a petitioner need not satisfy the hardship prong." *Id.* at 1310 (quoting *AT&T Corp. v. FCC*, 349 F.3d 692, 700 (D.C. Cir. 2003)). The Court found that the plaintiff would likely suffer a substantial hardship if it failed to act and that there was no significant interest in the Court postponing review. *Id.* at 1310-11. Although the *Teva* Court determined that the hardship prong favored a finding of ripeness, *Teva* did not alter the two-prong ripeness test. Further, *Teva* would not apply here because there are significant institutional interests which favor the postponement of review.

when . . . the governmental interest in withholding adjudication is relatively slight, an issue may nevertheless be unripe if the petitioner's interest in immediate resolution is insignificant." *Id.*

Plaintiff asserts that the case is ripe because postponing review will cause immediate, direct, and significant harm for several reasons. First, plaintiff contends that it will be forced to "alter its long-range financial planning . . . and to divert resources to preparing customer-education strategies" for patients who might equate the Watson generic with Fentora. (Pl.'s Opp. at 11-12.) Second, plaintiff argues that it will suffer direct hardship, including the loss of sales and reputational damage, should the present circumstances change in a way that causes the Delaware court to lift the injunction. (*Id.*) Third, plaintiff points to the hardship that will occur if another Fentora generic is approved under the FDA's alleged erroneous interpretation of the law. (*Id.*) Each of these reasons is too speculative to establish an undue burden on plaintiff. Further, the Court would benefit from postponement of the case.

1. Financial Planning

Plaintiff contends that it will suffer an immediate and direct burden because it must spend financial resources now to plan for the entry of the Watson generic into the market. (Pl.'s Opp. at 11-12.) This hardship, however, is not "sufficiently direct and immediate," because it either relies on a future judicial proceeding or is too remote and speculative.

First, any financial planning undertaken in the short term would be based on the outcome of future speculative events that are neither direct nor immediate. In order for the Watson generic to enter the market before 2019 and financially damage plaintiff (either by competing directly with Fentora or damaging Fentora's reputation as an effective drug), the injunction currently barring the Watson generic from entering the market would have to be rescinded. A plaintiff's claim of undue burden, however, cannot rely on the outcome of a future judicial proceeding to prove that it will suffer immediate harm should the Court fail to act. "'It is not this

court's job to ferret out or even to speculate as to possible impacts of possible outcomes of existing lawsuits upon future litigation; it is the petitioner's responsibility to show the specifics of the aggrievement alleged.'" *Friends of Keeseville*, 859 F.2d at 235 (quoting *N.C. Utils. Comm'n v. FERC*, 653 F.2d 655, 663 (D.C. Cir. 1981)); *see also Devia*, 492 F.3d at 425; *see also, e.g.*, *Platte River Whooping Crane Critical Habitat Maint. Trust v. FERC*, 962 F.2d 27, 35 (D.C. Cir.), *reh'g denied*, 972 F.2d 1362 (D.C. Cir. 1992) (holding that the reliance on a future court proceeding is too speculative for the injury-in-fact prong of standing).[5]

Plaintiff cannot base an argument of undue burden from postponement of a judicial decision on its having to plan for a future event, as opposed to the actual event, if that event is too speculative in the first instance. If the Court were to adopt that reasoning, it would effectively create a rule where any future event, however remote or speculative, could constitute a burden when a plaintiff claims that it must prepare now for this future contingency. For example, plaintiff argues that it will have to undertake a consumer education campaign should the injunction be lifted. (*See* Pl.'s Opp. at 11-12.) But since the hardship prong cannot be based on a future court decision, *see Friends of Keeseville*, 859 F.2d at 235, it necessarily follows that planning for that future court decision is also too speculative.

In this regard, the Court finds the D.C. Circuit's decision in *Pfizer Inc. v. Shalala* to be particularly persuasive. In *Pfizer*, the plaintiff pioneer drug manufacturer challenged the FDA's acceptance of an ANDA for processing. 182 F.3d at 976. As the case developed, the FDA took a further step and tentatively approved the generic, conditioned on the expiration of a thirty-month waiting period. *Id.* at 980. The Court held that the case was unripe not because the

[5] Standing and ripeness are closely related and "indeed not always clearly separable" from one another. *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 48 (D.C. Cir. 1999). In fact, both doctrines recognize that future outcomes of judicial proceedings are too speculative to provide standing or ripeness.

agency's decision was not final, but because the plaintiff could not suffer hardship during the thirty-month waiting period. *Id.* The Court also reasoned that the plaintiff could renew the challenge once the FDA finally approved the generic, as it would then have a more concrete and immediate hardship. *Id.*

Although the case before this Court also presents a final agency action, the situation as it currently exists will present no hardship to plaintiff until 2019, because the injunction bars the Watson generic from entering the market until then. Just as the thirty-month waiting period postponed the potential hardship to the plaintiff in *Pfizer*, so too does the injunction here. In fact, the present facts go further than *Pfizer*—if a thirty-month waiting period could allow for a number of events that could materially alter the case, then the ninety-six-month window offers even more possibilities.[6] In addition, just as the plaintiff in *Pfizer* could renew its challenge if the FDA eventually approved the ANDA, plaintiff can rebring this suit if the injunction is lifted.

In the alternative, plaintiff claims two types of financial damages in the long term: preparing for a substantial loss of earnings and preparing an education strategy to prevent reputational damage. (Pl.'s Opp. at 12.) Assuming that both of plaintiff's claims regarding damages are true, both are still too remote and speculative. Plaintiff's first argument, that it will lose earnings, is based on the claim that a number of private and state insurance programs mandate the use of a generic if one is available. (*Id.* at 11-12; *see* Compl. at ¶ 17.) In 2019, however, when the '981 patent expires, if other Fentora generics exist, they too will enter the market and, regardless of whether the Watson generic is also being marketed, will affect plaintiff's financial well-being. Therefore, plaintiff's first claim that it must plan for entry of

[6] Similarly in the standing context, the D.C. Circuit, in *LaRoque v. Holder*, No. 10-5433, 2011 WL 2652441 (D.C. Cir. July 8, 2011), differentiated an injury that was only nineteen months away from an injury in a separate case that was more than four years away, reasoning that the former time period, *inter alia*, created an imminent injury whereas the latter did not. *Id.* at *8.

only the Watson generic may well never come to pass, for even plaintiff predicts that other generic versions of Fentora might be "eligible for approval as early as July 2012." (Pl.'s Opp. at 6.)

Plaintiff's second long-term financial planning argument, that it will have to undertake an education campaign, suffers the same fate. An education campaign whose goal is to educate consumers now for the possible entry of a competitor generic at some future time is not the type of direct and immediate burden that makes a case ripe.

Finally, financial planning for speculative future events is not an activity that the FDA's decision requires the plaintiff to engage in. For example, in *CTIA-The Wireless Ass'n v. FCC*, 530 F.3d 984 (D.C. Cir. 2008), the Court held that a case was unripe when a pending rule did not require the petitioner to actually engage in or refrain from activity even though the pending rule might have required the petitioner to financially prepare for compliance. *Id.* at 988-89. The Court reasoned that "until the rule does take effect, petitioners 'are not required to engage in, or to refrain from, any conduct during the time the case is held in abeyance.'" *Id.* at 989 (quoting *Devia*, 492 F.3d at 427) (internal quotation marks omitted); *see also Atl. States Legal Found. v. EPA*, 325 F.3d 281, 285 (D.C. Cir. 2003).

Although the approval of an ANDA is not a direct regulation of a pioneer manufacturer, the reasoning in *CTIA* is persuasive because, similar to the abeyance in that case, the injunction prevents the FDA's approval of the Watson ANDA from taking effect until 2019. During that eight-year window, plaintiff would enjoy exclusivity and the burdens of planning for the future could be minimal or unquantifiable.

2. Changed Circumstances

Plaintiff contends that the circumstances underlying the stipulation that led to the injunction could change,[7] causing Watson to seek a rescission of the injunction. (Pl.'s Opp. at 11-12.) Plaintiff further argues that the rescission of the injunction could create a hardship because it would allow the Watson generic to enter the market, thus decreasing sales of Fentora and potentially damaging Fentora's reputation. (*Id.*) This argument, however, relies on the outcome of a future judicial proceeding, and, as discussed above, the hardship prong of ripeness cannot rest on the outcome of a future judicial proceeding. *Friends of Keeseville*, 859 F.2d at 235 (quoting *N.C. Utils. Comm'n*, 653 F.2d at 663).

3. FDA Approval of Another Fentora Generic

Plaintiff further contends that it could suffer hardship if the FDA approves another Fentora generic based on the FDA's allegedly erroneous interpretation of the law (*i.e.*, approving a generic that has two active ingredients to the pioneer's one active ingredient). (Pl.'s Opp. at 11-12.) Just as reliance on a future judicial proceeding cannot create a direct and immediate burden, reliance on a future agency action does not satisfy the hardship prong of ripeness. *Atl. States Legal Found.*, 325 F.3d at 284; *see also Devia*, 492 F.3d at 426-27.

For instance, in *Atlantic States Legal Foundation*, the plaintiffs challenged an EPA regulation that would have potentially allowed utility companies to accumulate hazardous waste at collection facilities without a permit. 325 F.3d at 282. Several steps stood between the regulation and the actual collection of hazardous waste, including several steps by the utility companies themselves and approval by the state agency, both of which could have required more

[7] For instance, another Fentora generic could be approved, Watson could prevail on its appeal in the Federal Circuit, or there could be changes in the marketability of Fentora. (Pl.'s Opp. at 11-12.)

action on the EPA's part. *Id.* at 283. The Court held that the case was unripe for adjudication because, in part, plaintiff's hardship claim was based on a future agency action (albeit a New York state agency) that could trigger further action by the EPA. *Id.* at 284. Here, for plaintiff to suffer a harm based on the FDA's interpretation of the single-active-ingredient rule, the FDA *would have to act* by approving another ANDA for a Fentora generic. Like the plaintiff's reliance on future speculative agency actions in *Atlantic States Legal Foundation*, reliance on the possible approval of an additional Fentora generic is too speculative to create a direct and immediate hardship.

4. Benefit to the Court

Balanced against this rather tenuous showing of hardship to the plaintiff, the Court would benefit from postponement of this case because a number of events could occur that could either make adjudication unnecessary or materially alter the complexion of the case. For example, if *Cephalon II* is affirmed, then plaintiff's short-term injury claims become even more speculative. If the FDA approves another generic version of Fentora that enters the market in July 2012, as plaintiff predicts (Pl.'s Opp. at 6), then plaintiff's current arguments could change since it cannot be known if the Watson generic would even be a competitor at that time.

Although the Court appreciates plaintiff's concern that postponing adjudication could result in a compressed TRO or PI proceeding (*see* Pl.'s Opp. at 2, 6-7), the argument has little legal merit in the ripeness context. The second prong of ripeness looks at the burden on the *parties* of postponing adjudication and the *benefit to the Court* of postponing adjudication. *Village of Bensenville*, 376 F.3d at 1120. While a TRO or PI proceeding may impose an administrative burden, benefits from the postponement of adjudication far outweigh whatever burden could arise from having to confront an expedited proceeding, since there is a very real possibility that the case will not become ripe, if at all, until 2019.

Because "[t]he central judicial interest in deferring resolution . . . lies in the possibility that if the issue is not adjudicated at this time, it may not require adjudication at all," *Friends of Keeseville*, 859 F.2d at 236, the eight-year window between now and the expiration of the '981 patent in 2019 offers far too many contingencies that could substantially change the tenor of this case or make its resolution unnecessary.[8] The Court will not entangle itself in a dispute with an agency when the law instructs the Court not to, *see Devia*, 492 F.3d at 424, for "[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. Products Co.*, 473 U.S. 568, 580-81 (1985)) (internal quotation marks omitted).

CONCLUSION

The Court grants defendants' motion to dismiss, finding that the case lacks ripeness because postponing adjudication would cause plaintiff no undue burden and would benefit the Court. The case is dismissed without prejudice for lack of subject matter jurisdiction. A separate order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: July 14, 2011

[8] For instance, the drug could be removed from the market, the manufacturer could go bankrupt, or some other competitive product could undercut the commercial value of Fentora.