David P. Langlois (DL 2319)
SUTHERLAND ASBILL & BRENNAN LLP
Grace Building
1114 Avenue of the Americas, 40th Floor
New York, New York 10036-7703
Phone: 212-389-5000
Fax: 212-389-5099

Of Counsel:
John L. North
Jeffrey J. Toney
Laura Fahey Fritts
Kristin E. Goran
SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street NE
Atlanta, Georgia 30309-3996
Phone: 404-853-8000
Fax: 404-853-8806

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc., Plaintiffs, v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., Defendants.	Civil Action No.: 09-cv-4665

MEMORANDUM IN SUPPORT OF TEVA'S MOTION FOR LEAVE TO SUPPLEMENT ITS PLEADINGS TO ADD A NEWLY MATURE COUNTERCLAIM

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

Defendant Teva Pharmaceuticals USA, Inc. ("Teva") seeks leave to supplement its existing Answer and Affirmative Defenses to add a newly mature counterclaim against plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc. (collectively, "Takeda"), pursuant to Rules 13(e), 15(d), and 16(b)(4) of the Federal Rules of Civil Procedure. A copy of Teva's proposed First Supplemental Answer, Affirmative Defenses and Counterclaim is attached hereto as Exhibit A.

Teva's proposed counterclaim arises from certain actions taken by the U.S. Food and Drug Administration ("FDA") just two weeks ago at Takeda's prompting. As described more fully below, on March 15, 2010, the FDA changed the Orange Book status of two of the patents at issue in this case, U.S. Patent Nos. 5,965,584 ("the '584 patent") and 6,329,404 ("the '404 patent"). The FDA took that action in sole and explicit reliance on recent submissions by Takeda regarding the scope and coverage of those patents in relation to the NDA for Actos® tablets. The information submitted by Takeda was false, misleading, and/or incorrect in that it stated or strongly implied that the drug product claims in those two patents cover the Actos® drug product, when in fact they unequivocally do not. Due to its reliance on Takeda's submissions, the FDA now lists the drug product claims of those patents in the Orange Book as covering Actos®, even though those claims cannot legally be listed to the Actos® NDA.[1] Further, and also as a direct result of Takeda's submissions, the FDA now states that Teva must submit paragraph IV certifications to those claims as part of its ANDA for a generic version of

[1] The Orange Book had already shown the listing of the method-of-use claims of the '584 and '404 patents as covering certain (though not all) approved uses for Actos®. Teva does not challenge Takeda's listing of the method-of-use claims (as opposed to the drug product composition claims) of those patents in relation to Actos®. Teva filed a "section viii statement" with regard to the method-of-use claims, indicating that the label for Teva's generic will not include the uses covered by those claims.

Actos®. The inevitable effect of this change will be to substantially and impermissibly delay FDA approval for Teva's ANDA.

Neither the Hatch-Waxman statute itself nor FDA regulations properly provide a basis for requiring Teva to file paragraph IV certifications to those patents. Simply put, the drug product claims in those patents do not cover the Actos® drug product, and therefore those claims cannot properly be listed for the Actos® NDA. Nonetheless, the FDA's policy and practice is to defer to an NDA holder's representations about the nature and scope of its patents for purposes of Orange Book listing. As a result the FDA has implemented these otherwise impermissible changes because Takeda told the FDA that the patents contain drug product claims, without explaining that those claims do not cover the Actos® product.

In response to these new developments, Teva seeks leave to file its proposed supplemental counterclaim. Teva's counterclaim arises under 21 U.S.C. § 355(j)(5)(C)(ii), a provision that was added to Hatch-Waxman in 2003 to provide a remedy for the exact type of situation in which Teva now finds itself. That provision permits a defendant in a patent infringement action to bring a counterclaim against the NDA holder for a mandatory order requiring the NDA holder "to correct or delete" patent information the NDA holder had submitted to the FDA improperly. Pursuant to that provision, Teva seeks an order requiring Takeda to correct or delete the misleading and/or incorrect information it submitted to the FDA concerning the scope of the drug product claims in the '584 and '404 patents in relation to the Actos® NDA. If Takeda is ordered to make such a correcting submission to the FDA, that information would show that the drug product claims in the '584 and '404 patents do *not* cover Actos®, which in turn means as a matter of law that those claims cannot be listed in the Orange Book in relation to the Actos® NDA and that there is no basis for requiring Teva to submit a

paragraph IV certification to those claims in connection with Teva's Actos® ANDA. As a result, the FDA would be free to approve Teva's Actos® ANDA after U.S. Patent No. 4,687,777 ("the '777 patent") covering the compound pioglitazone expires in January 2011 on the basis of Teva's section viii statements to the method-of-use claims in those patents (the only claims that can properly be listed as to the Actos® NDA).

Teva's motion should be granted. The circumstances here easily satisfy the requirements for permitting a supplemental pleading that adds a newly matured counterclaim:

1. Teva's proposal to file a supplemental pleading is authorized by Rules 13(e) and 15(d). Rule 13(e) provides that a court "may permit a party to file a supplemental pleading asserting a counterclaim that matured or was acquired by the party after serving an earlier pleading." That is what happened here: Teva filed its responsive pleading on July 10, 2009, and this counterclaim did not mature until March 15, 2010, some eight months later. Rule 15(d) likewise authorizes supplemental pleadings, and the liberal standards for permitting amendments to pleading apply in these circumstances. For the same reasons, Teva has "good cause" under Rule 16(b)(4) for any necessary modification to the scheduling order.

2. Teva has acted with diligence in seeking leave to supplement its pleading. This claim became mature only two weeks ago, when the FDA changed its treatment of the '584 and '404 patents in the Orange Book and changed its stated requirements for approval of an ANDA to sell a generic version of Actos®.

3. Teva's proposed counterclaim states a viable cause of action under the relevant provisions of Hatch-Waxman, so permitting supplementation would not be futile.

4. Takeda would suffer no undue prejudice from allowance of Teva's motion, while Teva would sustain substantial and undue prejudice if the motion were denied.

5. Permitting Teva's amendment should have no effect on the upcoming June date for trial of the patent infringement claims in this matter. The issues that arise under the counterclaim are distinct from the issues related to the patent infringement claims, and the Court can address them separately. The counterclaim addresses the listing of certain drug product claims in the '584 and '404 patents in the Orange Book in relation to Actos®, and the fact that those claims do not cover the Actos® product, making the listing of them impermissible. But Takeda has not sued Teva on the ground that its Actos® ANDA would

infringe those claims, so the patent infringement trial need not and will not address the same issues as the counterclaims.[2]

For all of these reasons, as discussed more fully below, Teva's motion should be granted.

FACTUAL BACKGROUND

This is a patent infringement action by Takeda against Teva. As relevant to this motion, Takeda alleges patent infringement claims against Teva under certain claims of the '584 and '404 patents in relation to Teva's ANDA for a generic version of pioglitazone hydrochloride tablets, which Takeda sells under the brand name Actos®.[3] Teva submitted its Actos® ANDA on or about July 14, 2004. With respect to the '777 patent, which covers the pioglitazone compound, Teva's Actos® ANDA contains a paragraph III certification, indicating that Teva did not challenge that its product would infringe valid and enforceable claims of the patent, and that the FDA should not approve Teva's ANDA until the patent expires. All the remaining patents listed in the Orange Book for NDA 21-073 at the time Teva filed its Actos® ANDA—including the '584 and the '404 patents—were listed with method-of-use codes, and the only claims in those patents that might arguably apply to a generic product that uses the Actos® NDA as the reference listed drug are method-of-use claims. Teva filed section viii statements to all those patents indicating that Teva will not include language in the label for its proposed generic version of Actos® that refers to combination use, and thereby that Teva's product will not practice the method-of-use claims of the '584 and the '404 patents.[4]

---

[2] Even though Takeda has not sued Teva under those claims for Teva's Actos® ANDA, the new Orange Book status of those claims for Actos® will substantially delay FDA approval of Teva's Actos® ANDA, as discussed below.

[3] This motion, and Teva's proposed counterclaim, do not bear on Teva's ANDA to sell the combination product pioglitazone plus metformin, which Takeda sells under the brand name Actoplus Met®.

[4] The question of whether Teva's generic version of Actos® infringes the method-of-use claims of the '584 and '404 patents despite the carveout in Teva's label per section viii is one of the issues that will be addressed in the patent infringement trial.

On February 7, 2006, the FDA granted tentative approval to Teva's ANDA. The FDA noted in the tentative approval letter that Teva had filed a paragraph III certification to the '777 patent and section viii statements as to all the other patents, including the '584 patent and the '404 patent. The FDA made no statement or suggestion to Teva in the tentative approval letter that Teva's filings as to the '584 patent and the '404 patent were legally insufficient, or that Takeda had submitted information to the FDA as of that time indicating that the '584 patent or the '404 patent contained drug product claims to which a section viii statement would be insufficient.

On March 15, 2010, the FDA changed the Orange Book status of the '584 and the '404 patents in relation to the Actos® NDA. Before March 15, 2010, the listing for Actos® in the Orange Book had contained only method-of-use codes for those patents, and the FDA had not treated those patents as having drug product claims that claim Actos®. The FDA now treats those patents as containing both (a) method-of-use claims that claim one of the approved uses of Actos®, and (b) drug product (composition) claims that cover the Actos® drug product.

The FDA made this change entirely on the basis of information that Takeda submitted to the FDA in November 2009 and January 2010. At those times, Takeda submitted information to the FDA stating that the patents, which were already listed in the Orange Book for Actos® as containing method-of-use claims, also contain drug product claims. Takeda pointedly failed to tell the FDA, however, that the drug product claims in those two patents do *not* cover the Actos® drug product. As a result, Takeda's submissions gave the strong—but false—impression that the drug product claims in those patents do cover Actos®. The FDA did not separately analyze whether the patents properly claim the Actos® drug product. Instead, acting in a purely

ministerial capacity consistent with its policy and practice, the FDA deferred entirely to Takeda's submission in that regard.

Because the FDA (in reliance on Takeda's submissions) now treats the '584 and '404 patents as containing both drug product claims and method-of-use claims that claim Actos®, the FDA has stated that an ANDA applicant for a generic version of Actos® must submit a paragraph IV certification to the drug product claims if—as Teva has—it has submitted a section viii statement to the method-of-use claims. Without a paragraph IV certification, the FDA now states, an ANDA for a generic version of Actos® cannot be approved.

Under both the Hatch-Waxman statute itself and the FDA's implementing regulations, the drug product claims for the '584 patent and the '404 patent do not form a permissible basis for listing those patents in the Orange Book in relation to the Actos® NDA. The drug product claims in those patents could properly be listed in the Orange Book for the Actos® NDA only if those patent claims in fact claimed the Actos® drug product. The patents unequivocally do not do so. The active ingredient in Actos® tablets is pioglitazone hydrochloride. By contrast, the drug product claims in the patents claim only drug products that contain *both* pioglitazone *and* certain additional active ingredients, *not* a drug product that contains pioglitazone as its sole active ingredient. Therefore, those patents do not claim the Actos® drug product as a matter of law and cannot permissibly be listed for Actos®. Furthermore, because the drug product claims cannot be properly listed in relation to the Actos® NDA, there is no basis for requiring ANDA applicants for a generic version of Actos® to file a paragraph IV certification to those claims.

Teva will be substantially harmed unless Takeda is required to correct or delete the patent information concerning the drug product claims of the '584 patent and the '404 patent in the Orange Book in relation to the Actos® NDA. The consequence of those incorrect listings—and

the resulting directive by the FDA that ANDA applicants must file paragraph IV certifications—will likely cause a substantial delay of approximately *two years* in FDA approval of Teva's ANDA, from January 2011 to February 2013.[5] In addition, Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available. By contrast, if Takeda were required to correct or delete the information it previously submitted to the FDA, none of these improper delays would occur, and ANDAs for generic versions of Actos® could be approved in the manner and within the time-frames that Hatch-Waxman actually contemplates.

In response to these recent events, Teva seeks leave to supplement its pleadings to add a counterclaim as authorized by 21 U.S.C. § 355(j)(5)(C)(ii). Teva seeks to have the Court enter a mandatory order requiring Takeda to correct or delete the information submitted to the FDA for the Actos® NDA concerning the drug product claims of the '584 and '404 patents. Takeda should be required to submit information to the FDA clarifying that the '584 and '404 patents do *not* contain any drug product claims that claim the drug product approved by the Actos® NDA, and that the *only* claims in the patents that pertain in any way to the Actos® NDA are method-of-use claims. Given the FDA's policy and practice, such clarifications by Takeda should lead the FDA to correct the Orange Book listings and rescind its requirement that Teva submit paragraph IV certifications, which in turn would allow Teva's ANDA for a generic version of Actos® to be

[5] January 2011 is the month that the '777 patent expires and when the FDA would be free to approve Teva's Actos® ANDA (which already has tentative approval) but for the issue raised by this counterclaim. If, however, Teva is required to file paragraph IV certifications to drug product claims in the '584 and '404 patents, then Teva will be blocked from launching until 181 days after the first-filers trigger their exclusivity. Certain first-filers have announced settlements with Takeda in which they likely will not launch their generic versions of Actos® until August 2012. If Teva is required to wait 181 days after those launch dates to obtain FDA approval, that would delay Teva's approval until February 2013.

approved in January 2011 (assuming, as Teva believes, that Teva will defeat Takeda's claim that Teva's generic would induce infringement of the '584 and '404 method-of-use claims).

PROCEDURAL HISTORY

Takeda filed the Complaint in this matter on or about May 18, 2009. (D.I. 1.) Teva filed its responsive pleading, containing Teva's Answer and Affirmative Defenses, on our about July 10, 2009. (D.I. 11.) In that pleading, Teva did not assert any counterclaims. The July 24, 2009 Scheduling Order, and subsequent amendments to that Order, do not provide a deadline for the amendment of pleadings. (D.I. 30.) Trial on Takeda's patent infringement claims currently is scheduled for June 7, 2010. (D.I. 40.)

Teva's proposed new counterclaim matured on March 15, 2010, approximately two weeks ago, when the FDA changed the Orange Book status of the '584 and '404 patents in relation to the Actos® NDA due to Takeda's recent submissions to the FDA. Teva promptly filed this motion for leave to supplement its pleadings on March 30, 2010.

LEGAL STANDARD

Rules 13(e) and 15(d)[6] permit the supplemental pleading of a counterclaim that matured after the serving of an earlier pleading.[7] The liberal standard of Rule 15(a) that leave to amend

---

[6] Rule 13(e) states that a court "may permit a party to file a supplemental pleading asserting a counterclaim that matured or was acquired by the party after serving an earlier pleading." Fed. R. Civ. P. 13(e). Rule 15(d) states: "On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d).

[7] Here, the Scheduling Order does not have a deadline to amend pleadings and, therefore, the schedule need not be modified to grant Teva's motion. Nonetheless, in an abundance of caution and because Teva meets the "good cause" requirement of Rule 16, Teva addresses the potential requirements of Rule 16 in its motion. If a party seeks leave to amend or supplement after the deadline in the scheduling order has passed, then Rule 16's "good cause" standard first must be satisfied. While the "good cause" standard of Rule 16 must be balanced against the liberal amendment standard of Rule 15, Rule 16(b) "provides the district courts with discretion to ensure that limits on time to amend pleadings does not result in prejudice or hardship to either side." *See Kassner v. 2nd Ave. Delicatessen, Inc.*, 496 F.3d 229, 243-44 (2d Cir. 2007); *Schiller v. City of New York*, Civ. A. No. 04-7922, 2009 WL 497580, at *3 (S.D.N.Y. Feb. 27, 2009). A party seeking leave to amend or supplement satisfies the "good cause" requirement of Rule 16 by, among other things, acting with reasonable diligence. *See, e.g., Bridgeport Music, Inc. v. Universal Music Group, Inc.*, 248 F.R.D. 408, 413-14 (S.D.N.Y. 2008).

should be freely granted in the absence of undue delay, bad faith, or undue prejudice, is equally applicable to motions to supplement under Rules 13(e) and 15(d). *Aktiebolag v. Andrx Pharms., Inc.*, Civ. A. Nos. 99-8926, 99-9887, 2010 WL 572109, at *2 (S.D.N.Y. Feb. 2, 2010); *Nordco, A.S. v. Ledes*, Civ. A. No. 95-7753, 1999 WL 1243883, at *9 (S.D.N.Y. Dec. 21, 1999) ("Read together, [Rules 13(e) and 15(d)] provide a liberal standard for granting leave to amend under Rule 13(e)."); *Four Seasons Solar Prods. Corp. v. Sun Sys. Prefabricated Solar Greenhouses, Inc.*, 101 F.R.D. 292, 294 (E.D.N.Y. 1983) ("The liberal amendment policy of Rule 15(a) applies to supplemental pleadings."); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) ("In the absence of any apparent or declared reason—such as undue delay, bad faith . . ., undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be 'freely given.'").

The Second Circuit and district courts within the Circuit have been liberal in permitting leave to amend. *See, e.g.*, *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993) ("The rule in this Circuit has been to allow a party to amend its pleadings in the absence of a showing by the nonmovant of prejudice or bad faith."); *Spiegler v. City of New York*, No. 04-cv 1066, 2006 U.S. Dist. LEXIS 64377, at *9 (S.D.N.Y. Sept. 8, 2006). Indeed, leave to amend is appropriate even when the request is made well after discovery, up to the eve of trial. *See, e.g., Guzman v. Bevona*, 90 F.3d 641, 649 (2d Cir. 1996).

ARGUMENT

Teva should be granted leave to supplement its Answer and Counterclaims pursuant to Rules 13, 15, and 16. Teva acted diligently in moving to supplement its counterclaims, Teva's motion is not futile, permitting Teva to file its supplemental counterclaims will not unduly prejudice Takeda, and Teva acted in good faith. In contrast, if the Court does not grant Teva leave to add what is effectively a compulsory counterclaim, then Teva likely will be precluded

from raising this claim altogether and Takeda will get away with the precise kind of abuse that 21 U.S.C. § 355(j)(5)(C)(ii) is intended to curb.

I. Teva Should be Permitted to Supplement its Counterclaims Because it Acted Diligently and Without Delay.

Teva's diligence in bringing this motion easily satisfies the "good cause" standard of Rule 16, as well as Rule 15's standard that leave to amend should be freely granted absent undue delay. As noted above, the FDA changed the Orange Book status of the '584 and '404 patents with regard to Takeda's Actos® NDA on March 15, 2010. Teva's counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) arises directly from those March 15 actions.[8]

Further, Teva filed this motion approximately two weeks after this counterclaim became mature on March 15, 2010. There can be no question that moving to amend or supplement in that rapid time frame does not amount to undue delay. *See, e.g.*, *Lawrence v. Starbucks Corp.*, Civ. A. No. 08-3734, 2009 WL 4794247, at *3 (S.D.N.Y. Dec. 10, 2009) (moving to amend to add new plaintiffs 36 days after the first request of a potential plaintiff to join as a party and 15 days after the final request did not constitute undue delay and satisfied Rule 16's "good cause" standard); *Eng-Hatcher v. Sprint Nextel Corp.*, Civ. A. No. 07-7350, 2008 WL 4865194, at *2 (S.D.N.Y. Oct. 31, 2008) (finding no delay and granting motion to amend answer approximately eight months after the case was initiated and four weeks after the expiration of a suspension of the case); *Bridgeport*, 248 F.R.D. at 413-14 (finding moving party met the "good cause" requirement by moving to amend pleadings three weeks after it confirmed information it originally learned three years earlier); *Sec. & Exch. Comm'n v. DCI Telecomms., Inc.*, 207 F.R.D. 32, 34-35 (S.D.N.Y. 2002) (permitting amendment based on facts learned four months

[8] Therefore, even if the scheduling order in this case set a deadline for amending or supplementing pleadings (which it does not), Teva could not have met any deadline for amending pleadings prior to March 15, 2010 in any event.

prior to motion and one year and nine months after the action was initiated, noting that parties are often permitted to amend pleadings long after they acquired the facts necessary to support the claims). Even if the 15-day period between when the relevant facts arose and when Teva filed this motion did constitute delay (and it does not), it still would not be a basis for denying Teva leave to supplement absent bad faith or prejudice. *Lawrence*, 2009 WL 4794247, at *3.

Finally, that this case is not at its early stages is not a legitimate basis for denying Teva's motion on the ground of delay. This inquiry does not center on the stage of the litigation, but rather on the moving party's diligence in seeking to amend or supplement. *Id.* Indeed, in this Circuit, amendment of pleadings on the eve of trial is permissible. *Guzman*, 90 F.3d at 649.

II. Teva Should Be Permitted to Supplement its Pleadings Because Teva's Proposed Counterclaim is Not Futile.

Teva's motion to supplement cannot be denied on the basis of futility. Courts in this Circuit determine whether an application to amend or supplement a pleading would be futile by determining whether the proposed claim would survive a Rule 12(b)(6) motion to dismiss. *Eng-Hatcher*, 2008 WL 4865194, at *3. "Where a litigant sets forth a claim that is plausible, the claim will withstand a motion to dismiss made pursuant to Fed. R. Civ. P. 12(b)(6)." *Id.* Teva's proposed counterclaim meets that standard because it comports with the requirements of and policy underlying 21 U.S.C. § 355(j)(5)(C)(ii). Indeed, in a case almost identical to this one, the court denied a motion to dismiss a counterclaim based on 21 U.S.C. § 355(j)(5)(C)(ii) and ultimately granted the ANDA-holder's motion for summary judgment on that counterclaim. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 649 F. Supp. 2d 661 (E.D. Mich. 2009) ("*Novo Nordisk I*") (denying motion to dismiss); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F.

Supp. 2d 729 (E.D. Mich. 2009) ("*Novo Nordisk II*") (ordering NDA holder to correct information in Orange Book).[9]

The provision authorizing Teva's counterclaim is 21 U.S.C. § 355(j)(5)(C)(ii). That provision states, in relevant part:

> (ii) Counterclaim to infringement action
>
> (I) In general
>
> If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim ***seeking an order requiring the holder to correct or delete the patent information submitted by the holder*** under subsection (b) or (c) of this section on the ground that the patent does not claim either--
>
> **(aa)** the drug for which the application was approved; or
>
> **(bb)** an approved method of using the drug.
>
> (II) No independent cause of action
>
> Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

21 U.S.C. § 355(j)(5)(C)(ii) (emphasis added). The *Novo Nordisk* cases reviewed the legislative history of this amendment and concluded that its "counterclaim provision" has "broad scope" that was intended to permit ANDA filers who were sued to require the patent holder to make changes in the Orange Book as necessary to "correct or delete" prior submissions. *See, e.g.*, *Novo Nordisk I*, 649 F. Supp. 2d at 669-70.

Teva's proposed counterclaim fits squarely within both the intent and the language of this provision. Teva brings this counterclaim to obtain precisely the type of remedy for which the

[9] The *Novo Nordisk* matter is currently on appeal in the Federal Circuit. On October 27, 2009, the Federal Circuit entered a non-precedential order, without opinion and prior to oral argument, staying the District Court's injunction pending appeal.

provision was created: to "correct" Orange Book listings so that patent claims that cannot properly be listed in the Orange Book for the particular NDA as a matter of law do not delay FDA approval of an ANDA for that product. The specific terms of the statute also are met. Takeda brought a patent infringement action against Teva. That action alleges, among other things, infringement of claims in the '584 and '404 patents in relation to Teva's Actos® ANDA. Teva is the ANDA applicant and brings this action as a counterclaim in a patent infringement action. In relation to the NDA for Actos®, the drug product claims of the '584 and '404 patents do not claim either "(aa) the drug for which the application was approved" (*i.e.*, pioglitazone hydrochloride tablets in which that is the sole active ingredient) or "(bb) an approved method of using the drug" (because they are drug product claims, not method-of-use claims). By the statute's plain terms, therefore, Teva's proposed counterclaim states a valid cause of action under Section 355(j)(5)(C)(ii).

While Teva seeks an order requiring correction with regard to one category of the claims in the '584 and '404 patents (the drug product claims), not delisting of the patents entirely, that should make no difference. First, the statutory language permits an order to "correct ***or*** delete" the Orange Book information. 21 U.S.C. § 355(j)(5)(C)(ii) (emphasis added). The term "correct" must be given meaning in that phrase, and it would be rendered superfluous if the statute were read narrowly to permit only an action to delete the patent entirely from the Orange Book. The Court should not credit such an interpretation. *See, e.g.*, *United States v. Shim*, 584 F.3d 394, 396 (2d Cir. 2009) ("We are not inclined to accept an interpretation of the statute that would nullify one of its key terms."); *Connecticut v. U.S. Dept. of Interior*, 228 F.3d 82, 88 (2d Cir. 2000) ("[W]e are required to disfavor interpretations of statutes that render language superfluous." (internal quotations and citation omitted)).

Second, there is no policy reason to read the statute narrowly to prevent Teva's claim. If the '584 and '404 patents contained only their drug product claims, without the separate method-of-use claims, there is no doubt that they could not legally be listed for Actos®, *see* 21 C.F.R. § 314.53, and Teva would have an action to delist them under this provision. The improper effect of delaying generic entry by the inclusion in the Orange Book of patent claims that should not legally be there is identical in both circumstances. There is no logical reason for a different result here, or to suppose that Congress would intend to create an action to correct the Orange Book listing in one circumstance and not the other. *See, e.g.*, *Johnson v. United States*, 123 F.3d 700, 703 (2d Cir. 1997) ("[T]he appropriate methodology to employ in interpreting a statute is to look to the common sense of the statute, to its purpose, to the practical consequences of the suggested interpretations, and to the agency's own interpretation for what light each might shed." (internal citations and quotations omitted)).

The Court must be guided by the structure of Hatch-Waxman in interpreting the act's provisions, including those provisions that address Orange Book listing issues. *See, e.g.*, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1315-18 (D.C. Cir. 2010). It would be completely contrary to the statute's structure to permit an NDA holder to (a) list patent claims in the Orange Book that may not permissibly be listed, (b) rely on those mislisted claims to require an ANDA applicant to submit paragraph IV certifications it should not have to file, and then (c) rely on the regulatory provisions that delay ANDA approval solely in the paragraph IV context, all in order to push back the generic approval and entry dates later than they otherwise would occur. Yet that will be exactly the result of Takeda's conduct, unless it is remedied. The counterclaim provision of Section 355(j)(5)(C)(ii) was intended to provide a remedy for exactly this problem.

That provision plainly creates a cause of action in the circumstances presented here, consistent with the purpose of the counterclaim provision to prevent incorrect Orange Book listings.

Therefore, there is no basis to deny Teva's motion on the basis of futility.

III. Teva Should be Permitted to Supplement its Counterclaims Because Teva's Actions Will Not Prejudice Takeda, Whereas a Denial of Teva's Motion Would Prejudice Teva.

Granting Teva's motion to supplement its pleading to add the proposed counterclaim will not cause any prejudice to Takeda, whereas Teva will be highly prejudiced if its motion is not granted. In deciding whether the non-moving party will be prejudiced by an amendment or supplementation, courts consider whether the amendment or supplementation would (1) require the opponent to expend significant resources to conduct discovery and prepare for trial or (2) cause significant delay in the resolution of the dispute. *Bridgeport*, 248 F.R.D. at 414. Neither of those factors applies here. Further, "[a]llegations that an amendment will require the expenditure of some additional time, effort, or money do not constitute undue prejudice." *Id.* (internal citation and quotations omitted).

Takeda will not have to expend significant resources to defend against Teva's proposed counterclaim. Teva's proposed counterclaim is mostly legal in nature and, therefore, will require little, if any, fact discovery and should not require expert testimony. Moreover, the facts underlying Teva's proposed counterclaim arise from a Citizen's Petition before the FDA concerning Takeda's NDA, in which Takeda participated. Takeda already is in possession of the facts and information necessary to defend against Teva's proposed counterclaim.

By contrast, if Teva's motion is not allowed, Teva will be highly prejudiced because Teva cannot bring its claim under Section 355(j)(5)(C)(ii) in a separate action. The language of 21 U.S.C. § 355(j)(5)(C)(ii) is clear that a claim arising under this amendment must be brought as a counterclaim and may not be asserted in any other manner. The statute states that if the

patent-holder or NDA-holder "brings a patent infringement action against the [ANDA] applicant," then the ANDA applicant "may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information." 21 U.S.C. § 355(j)(5)(C)(ii). As if that were not clear enough, the next full paragraph of that amendment states that it "does not authorize the assertion of a claim [under this amendment] in any civil action or proceeding other than a counterclaim described" in the previous paragraph. *Id.* Thus, Teva may only invoke 21 U.S.C. § 355(j)(5)(C)(ii) in a pending patent infringement action, like this one, and by filing a counterclaim. If Teva is not permitted to raise this counterclaim here, it likely will be precluded from raising it in the future. Given that Congress chose to limit the forum in which such a claim could be brought in this way, this Court should not deny Teva the ability to file its counterclaim in the one forum Congress permitted.[10]

IV. Teva Should Be Permitted to Supplement its Counterclaims Because Teva is Not Acting in Bad Faith.

Teva has not acted in bad faith in moving to supplement its counterclaims. Teva seeks to add its counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) for the exact reasons that the amendment to the Hatch-Waxman Act was enacted: to prevent patent-holders, like Takeda, from gaining improper advantages based on misinformation the patent-holder provided to the FDA concerning Orange Book patents. *See Novo Nordisk II*, 656 F. Supp. 2d at 731. Teva does not seek to supplement its counterclaims for any dilatory or other improper purpose, and Teva has not delayed in filing this motion. There is simply no evidence (nor can there be even a suggestion) that Teva has acted in bad faith.

---

[10] In this respect, Teva's counterclaim is analogous to a compulsory counterclaim. Cases recognize that courts "should be particularly liberal" in granting leave to amend to add such claims, precisely because denying leave to amend could foreclose the counterclaimant's ability to bring its claim altogether. *See, e.g., Feitshans v. Kahn*, Civ. A. No. 06-2125, 2007 WL 998400, at *2 (S.D.N.Y. April 2, 2007). The same line of reasoning applies equally here.

V. Teva's Counterclaim Can and Should be Bifurcated for Separate Trial; Therefore, Permitting Teva's Motion Should Not Delay the Patent Trial Scheduled for June.

Teva's proposed counterclaim should have no effect on the timing or content of the upcoming patent infringement trial. The issues raised in the counterclaim are distinct from the issues raised in the patent infringement trial. Moreover, the Court has the right to order a separate trial of the counterclaim pursuant to Rule 42(b).[11] Teva submits that maintaining the current date for the patent infringement trial, and having the Court set a separate trial for Teva's counterclaim, would maximize convenience and efficiency for the Court and the parties.

While the patent infringement claims and the counterclaim involve the same parties, the same patents, and the same ANDAs, the issues presented by the two sets of claims are entirely distinct. Most importantly, trial of the patent infringement claims will *not* address the precise issue raised by the counterclaim. The substantive issue at the heart of the counterclaim is whether the drug product claims in the '584 and '404 patents can properly be listed for the Actos® NDA. To determine whether those claims could properly be listed, two related questions apply. In one phrasing (from the language of Hatch-Waxman), the question is whether Takeda could reasonably assert a patent infringement claim against the filer of an ANDA for a generic version of Actos® under the drug product claims if such an ANDA applicant were to sell its generic version of Actos® without a license to those claims. 21 U.S.C. § 355(b)(1)(G); *see also* 21 C.F.R. § 314.53(b) (2008). In an alternate phrasing (from FDA regulations), the question is whether the drug product claims of those patents claim the drug product (*i.e.*, the finished dosage form) that is approved by the NDA for Actos®. *See* 21 C.F.R. §§ 314.53(b), 314.3(b), 314.53(c)(2)(ii)(O)(1). These questions are determinative of the counterclaim because, as the

[11] Rule 42(b) provides in relevant part: "For convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims." Fed. R. Civ. P. 42(b).

FDA has stated, "[t]he drug product (formulation and composition) patents submitted [for the Orange Book] must claim the specific drug product described in the pending or approved NDA." Patent Submission and Listing Requirements and Application of 30-Month Stay on Approval of ANDAs, 68 Fed. Reg. 36675, 366697 (June 18, 2003).[12]

While Teva submits that the answer to this inquiry is clear beyond dispute, for these purposes the point is that this same inquiry will play *no role* in the upcoming patent infringement trial. The reason for this is simple: Takeda does not allege that Teva, through its ANDA for a generic version of Actos®, infringes the drug product claims of the '584 and '404 patents. Takeda's allegations against Teva under the '584 and '404 patents with respect to Teva's Actos® ANDA are limited to alleging infringement of the method-of-use claims of those patents. Therefore, in the patent trial, the Court will *not* have to determine whether Teva's Actos® ANDA infringes the drug product claims of the '584 and '404 patents, whereas that is the *only* inquiry the Court will have to determine on the merits of the counterclaim.

This lack of overlap between the two sets of claims provides more than ample basis for bifurcating Teva's counterclaim. *See, e.g.*, *In re Innotron Diagnostics*, 800 F.2d 1077, 1084-86 (Fed. Cir. 1986) (affirming bifurcation of patent and antitrust claims in large part because the issues to be tried regarding each claim is "distinct and separable"). As a result, the Court can—and Teva respectfully submits that the Court should—permit Teva leave to supplement its pleading without making any change to the date for the upcoming patent infringement trial.

---

[12] The questions are different in language, but not in substance. If the drug product claims do not claim the drug product approved by the Actos® NDA—*i.e.*, a finished dose form tablet that has pioglitazone hydrochloride as its sole active ingredient—then Takeda could not reasonably assert a claim of patent infringement under those claims against an ANDA applicant seeking to sell a generic version of Actos®, even if the ANDA applicant does not have a license to those patent claims.

CONCLUSION

For the foregoing reasons, Teva respectfully requests leave to supplement its pleading by filing its proposed First Supplemental Answer, Affirmative Defenses, and Counterclaim.

Dated: March 30, 2010

/s/ David P. Langlois
David P. Langlois (DL 2319)
SUTHERLAND ASBILL & BRENNAN LLP
Grace Building
1114 Avenue of the Americas, 40th Floor
New York, New York 10036-7703
Phone: 212-389-5000

Of counsel:
John L. North (admitted *pro hac vice*)
Jeffrey J. Toney (admitted *pro hac vice*)
Laura Fahey Fritts (admitted *pro hac vice*)
Kristin E. Goran (admitted *pro hac vice*)
SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street NE
Atlanta, Georgia 30309-3996
Phone: 404-853-8000

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.