

<b>HUMAN GENOME SCIENCES, INC.,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil Action No. 10-0575 (ESH)</b>
	)	
<b>HON. DAVID J. KAPPOS,</b>	)	
<b>Under Secretary of Commerce for</b>	)	
<b>Intellectual Property &amp; Director of the</b>	)	
<b>United States Patent &amp; Trademark</b>	)	
<b>Office,</b>	)	
	)	
<b>Defendant.</b>	)	
	)	

Plaintiff Human Genome Sciences seeks to have the patent term adjustments (PTAs) for four of its patents recalculated due to alleged miscalculations by the United States Patent and Trademark Office (“USPTO”). Plaintiff’s original complaint sought recalculation for two of its patents, and its Amended Complaint added similar claims for two other patents. Defendant moved to strike the Amended Complaint on grounds that it was in fact a supplemental pleading that could not, under Fed. R. Civ. P. 15(d), be filed without the Court’s permission, which plaintiff had not obtained. Defendant also moved to remand the PTA claims in the original complaint to the USPTO for partial recalculation.

As explained herein, the Court finds that plaintiff's Amended Complaint is indeed an amendment and not a supplemental pleading and therefore denies defendant's motion to strike. The Court grants defendant's motion to remand with the understanding that the Court will retain jurisdiction over the matter.

## BACKGROUND

Under 35 U.S.C. § 154(b)(1), a patent's term may be extended if the USPTO causes certain delays in the prosecution process ("USPTO delay") or if the patent takes longer than three years to issue ("3-year maximum pendency delay"). A patent's term is reduced for prosecution delays caused by the applicant ("applicant delay"). *Id.* § 154(b)(2). The USPTO's longstanding method of calculating PTA was rejected by the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), in favor of a method more generous to patent holders.<sup>1</sup>

Plaintiff is the assignee of United States Patent Nos. 7,601,351 ("the '351 patent"), 7,605,236 ("the '236 patent"), 7,064,189 ("the '189 patent"), and 7,138,501 ("the '501 patent"). (First Am. Compl. ¶ 1.) Patents '351 and '236 were issued in October 2009. (Compl. ¶¶ 36, 41). On April 9, 2010, plaintiff sued to have their PTAs recalculated to comply with *Wyeth* and also to correct the USPTO's allegedly erroneous measurement of prosecution delays. (*See* Compl. ¶¶ 61-76.) Plaintiff's suit was timely under § 154(b)(4)(A), which provides that civil actions challenging PTA determinations must be brought "within 180 days after the grant of the patent."

On July 20, 2010, plaintiff amended its complaint to seek similar recalculations for patents '189 and '501. (First. Am. Compl. ¶¶ 100-131.) These patents were issued and their PTAs determined in 2006.<sup>2</sup> (First Am. Compl. ¶¶ 76, 79, 91-92.) Plaintiff alleges that these PTA claims are timely because the 180-day limitations period is either inapplicable or should be tolled under the doctrine of equitable tolling or under the discovery rule. (*Id.* ¶¶ 137, 144-

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<sup>1</sup> The USPTO had interpreted § 154(b) such that whenever a patent application was subject to both USPTO delay and 3-year maximum pendency delay, the delays overlapped and the applicant could only be awarded PTA for one of the two delays, whichever was longer. The Federal Circuit rejected this reading, holding instead that the two types of delays could only overlap if they occurred on the same calendar dates. *Wyeth*, 591 F.3d at 1369-70.

<sup>2</sup> Patent '189 was issued and its PTA determined in June 2006; patent '501 was issued and its PTA determined in November 2006. (First Am. Compl. ¶¶ 76, 79, 91-92.)

45,151-52.) On March 5, 2010, prior to filing its original complaint, plaintiff had petitioned defendant to reconsider these patents' PTAs in light of *Wyeth*. (*Id.* ¶¶ 77, 97.) However, defendant dismissed plaintiff's '189 petition on April 21, 2010 and to date has made no decision regarding the '501 petition. (*Id.*)

Defendant moves to strike the Amended Complaint on grounds that it is not an amendment under Fed. R. Civ. P. 15(a), but rather a supplemental pleading under Rule 15(d), for which plaintiff was required to obtain leave of court. (Def.'s Mot. to Strike Am. Compl. at 1.) Plaintiff opposes defendant's motion or, in the alternative, seeks leave to file the pleading *nunc pro tunc*. (*Id.* at 5.)

Defendant also moves to remand plaintiff's '351 and '236 claims to the USPTO for recalculation of the patents' PTAs in light of *Wyeth* and for reconsideration of plaintiff's applicant delay claims. (Def.'s Mot. to Remand at 1.) Plaintiff consents to a remand only if all of its claims relating to all four patents are remanded and the Court retains jurisdiction over the action. (Pl.'s Conditional Opp'n. to Def.'s Mot. to Remand at 2.)

## ANALYSIS

### I. AMENDED COMPLAINT

The parties disagree as to whether plaintiff's Amended Complaint is in fact an amendment under Fed. R. Civ. P. 15(a) or a supplemental pleading under Fed. R. Civ. P. 15(d). The significance of this distinction lies in the fact that while the rules permit amendments without leave of court under certain circumstances, supplements always require leave of court. Fed. R. Civ. P. 15(a)(1), (d).

Unlike amendments, which "typically rest on matters in place *prior to* the filing of the original pleading," *U.S. v. Hicks*, 283 F.3d 380, 385 (D.C. Cir. 2002), supplements set out "transaction[s], occurrence[s], or event[s] that happened after the date of the pleading to be

supplemented.” Fed. R. Civ. P. 15(d). However, a pleading generally does not become a supplement merely because it references facts that occurred subsequent to the original complaint. Rather, “the appropriate bases for supplemental pleadings are new facts *bearing on the relationship* between the parties.” *Hicks*, 283 F.3d at 386 (emphasis added). Thus, supplemental pleadings are used, e.g., “to set forth new facts that update the original pleading or provide the basis for additional relief; to put forward new claims or defenses based on events that took place after the original complaint or answer was filed; [and] to include new parties where subsequent events have made it necessary to do so.” *Id.* (citing 6A Charles Alan Wright et al., *Federal Practice and Procedure* § 1504 (3d ed. 2010)).

Here, plaintiff’s new claims are based on events that occurred before the original complaint was filed. The Amended Complaint seeks PTA recalculations for patents ’189 and ’501 in light of *Wyeth*. Prior to the filing of the original complaint, both patents were issued and their PTAs calculated, *Wyeth* was decided, and plaintiff sought relief directly from the USPTO. (Pl.’s Opp’n. to Def.’s Mot. to Strike Am. Compl. at 2-3.)

The only events that have allegedly occurred since the original complaint was filed are that the USPTO dismissed plaintiff’s ’189 petition and the ’501 petition remains pending. (Def.’s Mot. to Strike Am. Compl. at 3.) But, defendant fails to explain how these facts are material to plaintiff’s claims. Contrary to defendant’s assertion, the Amended Complaint does not challenge the USPTO’s disposition of plaintiff’s petitions; rather it challenges the USPTO’s original determination of those patents’ PTAs.<sup>3</sup> (Pl.’s Opp’n. to Def.’s Mot. to Strike Am.

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<sup>3</sup> Defendant tries to attach legal significance to plaintiff’s failure to add patents ’189 and ’501 to the original complaint, suggesting that plaintiff was waiting for the USPTO to respond to one of its petitions before amending the complaint. (Def.’s Reply to Pl.’s Opp. to Def.’s Mot. to Strike Am. Compl. at 2.) However, this merely describes plaintiff’s litigation strategy. The USPTO’s dismissal may have prompted plaintiff’s amendment, but it did not contribute to the factual basis

Compl. at 3-4.)

This case is therefore easily distinguished from *Hall v. C.I.A.*, 437 F.3d 94 (D.C. Cir. 2006). The plaintiff in *Hall* requested information from the CIA under the Freedom of Information Act (FOIA), and filed suit when the CIA failed to adequately respond. *Id.* at 97. Thereafter, the plaintiff made an *additional* FOIA request to the CIA and attempted to incorporate claims based on this request into his original complaint. *Id.* The Court found that plaintiff's pleading was a supplement rather than an amendment because his new claims were based on the FOIA request that occurred after the original complaint was filed. *Id.* at 100. Here, by contrast, plaintiff's claims are based on the USPTO's original PTA determinations, which were made well before plaintiff's original complaint was filed.

Finally, defendant does not suggest that the USPTO's dismissal of plaintiff's petition was a prerequisite to plaintiff's cause of action. Indeed, 35 U.S.C. § 154(b)(4) clearly provides for direct appeal of PTA determinations to the United States District Court for the District of Columbia. Therefore, this is not like *Montgomery Env. Coal. v. Fri*, 366 F. Supp. 261 (D.D.C. 1973), where the plaintiff sued under a statute which provided that no action could be commenced until sixty days after the plaintiff gave notice to certain parties. *Id.* at 266. The court found that because the "amended complaint" added the allegation that the sixty days had passed, the amended complaint was in fact a supplemental pleading. *Id.* at 265. There, unlike here, the additional allegations had legal significance because they created a cause of action where none had previously existed.

In sum, the Court finds that the material facts underlying the claims in plaintiff's Amended Complaint all occurred before the original complaint was filed. The USPTO's

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for plaintiff's additional claims.

dismissal of one petition and continued consideration of the other do not bear on plaintiff's PTA claims, and therefore, they do not render the Amended Complaint a supplemental pleading. Therefore, defendant's motion to strike the Amended Complaint is denied.

## **II. MOTION TO REMAND**

Defendant has moved to remand the '351 and '236 patent claims to the USPTO for recalculation of their PTAs in light of *Wyeth* and for reconsideration of plaintiff's applicant delay claims under 35 U.S.C. § 154(b)(2)(C) . (Def.'s Mot. to Remand at 1.) Plaintiff requests that the Court retain jurisdiction over these two patent claims. (Pl.'s Conditional Opp'n. to Def.'s Mot. to Remand at 3.)<sup>4</sup> Accordingly, defendant's motion to remand is granted with the understanding that the Court will retain jurisdiction over the matter.

## **CONCLUSION**

For the foregoing reasons, defendant's motion to strike the Amended Complaint is denied, and its motion to remand is granted with the understanding that the Court will retain jurisdiction over the matter. This Memorandum Opinion is accompanied by a separate Order.

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/s/  
ELLEN SEGAL HUVELLE  
United States District Judge

DATE: September 23, 2010

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<sup>4</sup> Plaintiff also requests that remand only be granted if all of plaintiff's claims relating to all four patents are remanded. (Pl.'s Conditional Opp'n. to Def.'s Mot. to Remand at 2.) However, plaintiff offers no argument in support of this position.