

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division



GILEAD SCIENCES, INC.,

Plaintiff,

-v-

TERESA STANEK REA,
Acting Undersecretary of Commerce for
Intellectual Property and Acting Director of
United States Patent and Trademark Office,

Defendant.

Civil Action No. 1:12-cv-1090

MEMORANDUM OPINION

This matter comes before the Court on the parties' cross-motions for summary judgment (Dkt. Nos. 11 and 15). Plaintiff Gilead Sciences, Inc. ("Gilead") asks the Court to find that the Defendant United States Patent and Trademark Office ("USPTO") improperly calculated the patent term adjustment for the U.S. Patent No. 8,148,374 ("the '374 patent"). The cross-motions for summary judgment were opposed and argument on the matter was held on July 19, 2013. The facts in this case are undisputed and the legal disagreement between the parties is narrow, namely whether the USPTO's construction of 35 U.S.C. § 154(b)(2)(C) is permissible. For the reasons that follow, the Court finds that the Defendant is entitled to judgment as a matter of law.

I. BACKGROUND

a. Statutory Framework

To acquire a patent, an applicant must submit an application with the USPTO. 35 U.S.C. § 111. The USPTO then examines the application to determine whether the applicant is entitled to a patent. *Id.* at § 131. If the USPTO determines that the application claims "two or more

independent and distinct inventions,” the office may mandate that the application be restricted to one of the inventions. *Id.* at § 121. This is commonly referred to as a restriction requirement. Upon examination, notification of a restriction requirement must be sent to the applicant in the same manner as notification of a rejection or other objection to the application. *Id.* at § 132. If the USPTO determines at any time during the examination that an application is patentable it will likewise notify the applicant of the allowance. 37 C.F.R. § 1.311(a). Throughout the application process, an applicant has a duty to disclose “all information known to that individual to be material to patentability.” *Id.* at § 1.56(a). One way in which an applicant meets this duty to disclose is through the filing of an information disclosure statement (“IDS”).

The law governing the content and term of a patent is outlined in 35 U.S.C. § 154. Under §154 a patent grant is issued for twenty years measured from the earliest filing date of the application. *Id.* Understanding that delays in the examination process might decrease the length of a patent term, Congress created provisions under which a patent owner can seek a patent term adjustment (“PTA”) for certain delays caused by the USPTO between the filing and issuance of a patent. Section 154(b)(1) outlines the general sources of delay for which a PTA can be sought. The first, commonly referred to as “A Delay,” allows for a patent term extension if the USPTO fails to provide a notification under §132 or a notice of allowance within fourteen months of an application filing. 35 U.S.C. § 154(b)(1)(A)(i). The second, commonly referred to as “B Delay,” allows for a one day extension for every day that the USPTO fails to issue a patent after three years have passed between the application and allowance dates. *Id.* at § 154(b)(1)(B). Finally, a “C Delay” allows a PTA for some types of delays excluded from the computation of a “B Delay.” *Id.* at § 154(b)(1)(C).

An applicant's conduct also impacts the calculation of a PTA. In particular, a PTA is reduced by a period of time equal to the number of days which an applicant "failed to engage in reasonable efforts to conclude prosecution of the application." *Id.* at § 154(b)(2)(C)(i). Congress has explicitly directed the USPTO to issue regulations establishing what constitutes an applicant's failure to engage in such reasonable efforts. *Id.* at § 154(b)(2)(C)(iii). The application of regulations promulgated by the USPTO pursuant to this mandate is the focus of the controversy before the Court.

b. Material Facts

The facts in this case are not in dispute. On February 22, 2008, Gilead filed application number 12/036,124 with the USPTO. On November 18, 2009, the USPTO mailed a restriction requirement to Gilead, dividing the claims within the application into four groups of inventions and directing Gilead to select one for examination. On February 18, 2010, Gilead filed a response to the restriction requirement selecting one of the four groups for examination on the merits. On April 16, 2010, approximately two months after the USPTO received a response to the restriction requirement, Gilead filed a supplemental IDS. The IDS requested that the USPTO consider two additional co-pending patent applications owned by Gilead as part of the agency's next office action. After further prosecution of the application, the USPTO issued a notice of allowance on July 29, 2011 and the '374 patent issued on April 3, 2012.

The parties agree that Gilead is entitled to a PTA as a result of USPTO's failure to meet the timeliness requirements of §154 in issuing the '374 patent. In calculating the appropriate PTA, the USPTO included 245 days of "A Delay" for the Office's failure to meet the specific statutory response deadlines and 406 days of "B delay" for the Office's failure to issue the patent within three years of the application's filing date. Those 651 combined days were reduced by 35

days of overlapping delay, for a cumulative USPTO delay of 616 days. The USPTO further reduced the PTA by subtracting an additional 57 days for Gilead's delay. This 57-day penalty was based on the period between Gilead's initial reply to the restriction requirement and its filing of the additional IDS on April 16, 2010. With all of the delays accounted for, the USPTO calculated a total PTA of 559 days.¹

On October 27, 2011, Gilead contested the 57-day assessment for applicant delay, arguing that its delay in filing the supplemental IDS should not be subtracted from the PTA. The USPTO rejected this argument on March 1, 2012, reasoning that "under 35 U.S.C. § 132, the first action mailed by the USPTO was the restriction requirement mailed November 18, 2009." *See* Dkt. No. 16 at 12-13. Under this interpretation Gilead's filing of a supplemental IDS after it had filed a response to the restriction requirement constituted a failure to engage in a reasonable effort to conclude prosecution as dictated by 37 C.F.R. § 1.704(c)(8).

Gilead filed the current action before the Court after the USPTO refused to reverse its PTA calculation for the '374 patent. In particular, Gilead complains that the USPTO's interpretation and application of §154(b), which resulted in the 57-day assessment for applicant delay, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation." *See* Dkt. No. 1 at ¶ 28. *See also* 5 U.S.C. §§ 701-706.

The parties filed cross-motions for summary judgment, agreeing that only questions of law were in dispute. The Court heard argument from the parties in open court on July 19, 2013 and took the matter under advisement.

¹ The full calculation for the PTA in this case was: 245 days of A Delay + 406 days of B Delay – 35 days of overlapping USPTO delay – 57 days of applicant delay = 559 days.

II. ANALYSIS

a. Standard of Review

Summary judgment is appropriate where there are no genuine issues of material fact and the reviewing court finds that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The USPTO's patent term adjustment decisions are reviewed under the Administrative Procedure Act ("APA"). See 35 U.S.C. § 154(b)(4)(A). Under the APA, this Court can only set aside the USPTO's action if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). The Court's review is therefore limited to the task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment. *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006).

b. *Chevron*

The parties agree that the *Chevron* two-step analysis applies to this case. The first step requires the Court to determine if Congress has spoken to the precise question at issue. *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984). Here the precise issue is whether filing a supplemental IDS after submitting a reply to a restriction requirement constitutes a failure "to engage in reasonable efforts to conclude prosecution of the application." Contrary to Gilead's far-reaching argument, Congress has not addressed this question. In fact Congress explicitly directed the USPTO to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). The Court must therefore turn to the second step of the *Chevron* framework. This leaves one narrow question for the Court to decide: is the

USPTO's construction and application of the statute permissible? *See Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 843 (1984) ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.").

c. USPTO's Construction is Permissible

As dictated by Congress, the USPTO promulgated regulations identifying what circumstances "constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application." 37 C.F.R. 1.704. In its letter to Gilead denying reconsideration of its PTA decision, the USPTO stated that the submission of Gilead's supplemental IDS constituted applicant delay pursuant to 37 C.F.R. § 1.704(c)(8). That regulation lays out a particular circumstance amounting to an unreasonable effort by an applicant under § 154(b)(2)(C):

Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the day after the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

37 C.F.R. § 1.704(c)(8). Gilead's filing of a supplemental IDS after it sent its reply to the restriction requirement fits squarely within the circumstance outlined in §1.704(c)(8). Gilead's contention, therefore, is that §1.704(c)(8) itself constitutes an impermissible construction of the statute.

Gilead primarily argues that the USPTO's interpretation under §1.704(c)(8) is unreasonable because it penalizes a group of applicants who have not caused an actual delay in the examination process. Gilead contends that allowing the USPTO to interpret the statute such

that the agency penalizes applicants who have not caused an actual delay leaves the USPTO without any boundaries in issuing regulations under §154(b)(2)(C). This line of argument is unavailing. Congress clearly intended for the USPTO to use its expertise and experience in dictating what circumstances demonstrate a lack of reasonable effort on the part of an applicant. The explicit focus of the statute therefore is on whether the applicant's efforts were reasonable, not whether the outcome of those efforts caused actual delay.²

Moreover, the USPTO has demonstrated that the conduct penalized under 37 C.F.R. § 1.704(c)(8) amounts to behavior that interferes with the Office's ability to process an application. As the USPTO explains, an examiner must review an application before issuing a restriction requirement. After receiving a reply to the restriction requirement the examiner will continue his or her review of the application. Receiving relevant information after a reply to a restriction requirement clearly interferes with an examiner's ability to conclude the prosecution of the application, particularly when §154 penalizes the USPTO if the examiner fails to do so within four months of the applicant's reply. 35 U.S.C. § 154(b)(1)(A)(ii). It is reasonable to conclude that an examiner reviewing Gilead's application would be delayed by learning of the existence of material information fifty-seven days after receiving the company's response to his or her restriction requirement. This argument, of course, is limited to viewing Gilead's application in total isolation. As the USPTO also shows, "a supplemental reply or paper often causes delay not only in processing an examination of the particular applicant's application, but also with the processing and examination of other applications before the examiner." *See* Dkt.

² Tellingly, at no point does Gilead attempt to explain why it did not include the information relating to *its own co-pending applications* when it replied to the restriction requirement, opting instead to wait fifty-seven days before notifying the USPTO of information it had been in possession of for approximately a year prior. Notwithstanding its theoretical argument about hypothetical non-delays, Gilead fails to show how its failure to disclose this information when it initially responded to the restriction requirement was reasonable.

No. 19 at 6. The USPTO's concerns are reasonable and do not show an arbitrary and capricious application of the statute.

Gilead also argues that the USPTO's interpretation is impermissible because a restriction requirement is not a final action on the merits. Because of this, Gilead contends, it makes no sense to penalize an applicant for submitting a supplemental IDS before the USPTO mails its first office action on the merits. *See* Dkt. No. 13 at 8. Gilead concedes, however, that a restriction requirement is clearly an office action. *See* 35 U.S.C. § 132. *See also Univ. of Massachusetts v. Kappos*, 903 F. Supp. 2d 77, 87 (D.D.C. 2012) ("Plaintiffs do not dispute, nor can they, that 'an action' is clearly defined under 35 U.S.C. § 132 as a rejection, an objection, or a requirement."). There is also no debate that an applicant's reply to a restriction requirement triggers the four-month clock for measuring the "A Delay." *See* 35 U.S.C. § 154(b)(1)(A)(ii). A supplemental IDS, such as the one that Gilead submitted, forces an examiner to *go back* and review the application again, while still trying to meet his or her timeliness obligations under §154. It is reasonable to penalize an applicant for actions that could lead to this result.

None of this is to say that an applicant who submits a supplemental IDS after replying to a restriction requirement will always be penalized. Under 37 C.F.R. § 1.704(d) there is no PTA reduction when an applicant promptly provides an IDS containing information recently acquired through communication from the USPTO or a foreign patent office. The USPTO has determined, however, that when an applicant sits on material information in its possession, after replying to a restriction requirement, with no good excuse for having done so, it has failed to engage in "reasonable efforts to conclude processing or examination of an application." This interpretation of the statute is both reasonable and permissible.

