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

Alexandria Division

ABBVIE INC, et al.,	)	
	)	
Plaintiffs,	)	
	)	
	)	
v.	)	Civil Action No. 1:24-cv-2344
	)	
	)	
COKE M. STEWART, in her official role as Acting Under Secretary of Commerce For Intellectual Property and Acting Director of the United States Patent and Trademark Office,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Plaintiffs' Motion for Summary Judgment and Defendant's Motion to Dismiss and Motion for Summary Judgment. There is no dispute of material facts, and this case is ripe for summary judgment.

On July 24, 2014, AbbVie filed U.S. Patent Application No. 14/340,435 for an invention entitled "Melt-Extruded Solid Dispersions Containing an Apoptosis-Inducing Agent." The United States Patent and Trademark Office ("USPTO") first rejected AbbVie's claims on June 19, 2015. The Examiner requested that AbbVie make an election to the one of the three patentably distinct inventions claimed in the application. About three months later,

AbbVie responded to the USPTO and made the requested election: electing to proceed on the claims that pertain to compositions. Over the next four years, this back and forth continued, including the mailing of final rejections that applicant addressed by filing Requests for Continued Examination ("RCEs") and continuing its prosecution of the application.

On November 8, 2019, during prosecution of the '435 application, AbbVie filed an amendment and response ("November 2019 Amendment"), responding to an Office Action dated August 9, 2019, and amending the claims to be more particular. That is where this case begins. On February 12, 2020, the PTO issued a Form PTO-90 containing a Notice of Non-Responsive Amendment ("February 2020 Notice"); the examiner stated that AbbVie's November 2019 Amendment "shifted to an independent and distinct invention" that had a "materially different design" from the originally claimed invention. The February 2020 Notice gave AbbVie two months to respond and "supply the omission or correction to avoid abandonment."

On March 9, 2020, AbbVie participated in an interview it requested with the examiner. On March 16, 2020, AbbVie submitted an amendment to its claims and a Petition to Withdraw Notice of Non-Responsive Amendment. That amendment included new claims that were not previously before USPTO: claims 111-140. Three days later, USPTO granted the Petition and vacated the February 2020 Notice.

The Examiner evaluated AbbVie's claims presented in its November 2019 Amendment and the 30 additional claims. After additional examination, on June 8, 2022, the USPTO issued a notice that the allowable claims in Patent Application No. 14/340,435 could issue as a patent. Many of the claims added in AbbVie's March 2020 filing (i.e., 111-120, 122-138) were allowed. The allowable claims in Patent Application No. 14/340,435 issued as U.S. Patent No. 11,369,599.

After the issuance of the Patent, AbbVie applied for a patent term adjustment ("PTA") of 568 days. The USPTO granted an adjustment of 439 days. At dispute in this case is that 129 day difference. USPTO attributed the delay to AbbVie in connection with the amendment because "the amendment filed March 16, 2020 included new claims in addition to what was required by the examiner in order to support the petition to withdraw the Notice mailed February 12, 2020." As such, the USPTO concluded that AbbVie's March 16, 2020, paper was a supplemental reply or other paper under 37 C.F.R. § 1.704(c)(8) and thus "the reduction of 129 days for its submission is warranted." On April 30, 2024, AbbVie sought reconsideration of the USPTO's PTA determination. It was denied. The USPTO reasoned that "[n]othing in the record reflects that the examiner expressly requested that the applicant file the amendment on March 16, 2020, adding all the new claims."

On December 23, 2024, AbbVie filed suit in this Court. Now, both parties have filed Motions for Summary Judgment and Defendants have also filed a partial Motion to Dismiss.

Summary judgment is appropriate where the moving party demonstrates that no genuine issues of material fact exist, thus entitling the moving party to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). PTA decisions are reviewed in accordance with the deferential standards of the Administrative Procedure Act ("APA"). 35 U.S.C. § 154(b)(4)(A). Under the APA, a court may set aside the USPTO's final agency action only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

"[T]he scope of review is narrow and a court may not 'substitute its judgment for that of the agency.'" Burandt v. Dudas, 528 F.3d 1329, 1332 (Fed. Cir. 2008). "A court reviewing the agency decision must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id. "An abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." Id.

AbbVie brings three counts challenging USPTO's ruling. First, USPTO cannot reduce PTA for a period during which AbbVie could take no action to conclude prosecution, nor for a period during which AbbVie took reasonable efforts to conclude prosecution in the face of USPTO error. Second, USPTO's *per se* application of 37 C.F.R. § 1.704(c)(8) to the facts of this case, and the agency's refusal to account for its own error, is unreasonable, arbitrary, capricious, and contrary to the statute. Third, USPTO's promulgation of 37 C.F.R. § 1.704(c)(8) exceeded its statutory authority under 35 U.S.C. § 154(b)(2)(C)(i). Each will be dealt with in turn.

First, AbbVie's as applied challenge. By statute, PTAs "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). Congress directed the USPTO with its "expertise in identifying applicant conduct" 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." Gilead Scis., Inc. v. Lee, 778 F.3d 1341, 1349 (Fed. Cir. 2015); 35 U.S.C. § 154(b)(2)(C)(iii). USPTO's regulation at issue, 37 C.F.R. § 1.704(c)(8), specifies that applicants fail to engage in reasonable efforts to conclude examination when they submit 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."

Here, the USPTO reasonably concluded that AbbVie's submission of new claims on March 16, 2020, constituted a failure to engage in reasonable efforts to conclude prosecution because it is a "supplemental reply or other paper" that was not expressly requested by the Examiner. 37 C.F.R. § 1.704(c)(8), (10). The USPTO's February 2020 Notice only requested AbbVie "to supply the omission or correction to avoid abandonment." The Examiner did not seek new claims for consideration. Indeed, as the USPTO reasoned, "the Notice simply required correction such that the independent claim was not drawn to an independent and distinct invention." In short, the March 2020 Amendment was never expressly requested by the examiner.

Plaintiff also maintains that adding claims 111-140 was necessary following the February 2020 Notice, relying on Supernus Pharmaceuticals, Inc. v. Iancu, 913 F.3d 1351 (Fed. Cir. 2019). There, Supernus had filed a request for continued examination. Prior to any PTO action and 546 days after filing, Supernus received a communication from the European Patent Office ("EPO") regarding a notice of opposition from a third party. Supernus disclosed this to USPTO. Later, USPTO included those 546 days in its reduction. The Federal Circuit disagreed, holding that "there was no action Supernus could have taken to advance prosecution of

the patent during the 546 day period, particularly because the EPO notice of opposition did not yet exist." Id. at 1360. That is not the case here. Plaintiff could have filed claims 111-140 in the November 2019 Amendment. Moreover, Supernus had no control over the notice from the European Patent Office; in fact, it did not even exist at the time of its initial filing. Conversely, AbbVie had control over its own invention and the claims it files.

AbbVie also maintains that claims 111-140 were only supposed to be considered if its petition appealing the February 2020 Notice was denied. But that is not what it said to the USPTO. Nor does AbbVie cite any authority that allows for submitting conditional claims. AbbVie requested:

> any claim presented in the Amendment and Response that is deemed by the Examiner to not otherwise be entitled to examination, will be withdrawn pending the outcome of this Petition. Applicant respectfully submits that the approach being taken here acts to fairly ensure that (a) the present application remains pending, (b) examination of the present application can continue without further delay, and (c) Applicant retains the right to timely seek withdrawal of the Notice so as to prevent any prosecution delay being attributed to Applicant for purposes of Patent Term Adjustment calculations in the future.

Assuming AbbVie was even able to submit conditional claims, stating claims "deemed by the Examiner to not otherwise be entitled to examination" is not the same as "do not consider these claims unless the Petition is denied." AbbVie's request still requires the Examiner to *evaluate* its claims to determine if it is "entitled

to examination," which is exactly the kind of resource drain USPTO seeks to avoid by punishing the filing of supplemental papers. And despite stating in its submission that AbbVie "retains the right to timely seek withdrawal of the Notice"—AbbVie never withdrew its amendment; despite receiving notice three days after filing that its Petition was granted. As a result, the Examiner considered, and even granted, some of AbbVie's new claims. Thus, the USPTO's reduction of 129 days was reasonable.

Second, AbbVie argues the PTO's *per se* application of 37 C.F.R. § 1.704(c)(8) to the facts of this case, and the agency's refusal to incorporate the reversal of the February 2020 Notice, is unreasonable, arbitrary, capricious, and contrary to the statute. This is the same argument as above. The only difference is this AbbVie brings this claim under the American Procedures Act ("APA"). As such, it fails on the merits for the same reasons as above. But it also fails for lack of subject matter jurisdiction.

The APA provides a right of action to set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). However, it crucially provides review of only "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Thus, when a party already has an "available remedy," the party's APA claim cannot proceed. Randall v. United States, 95 F.3d 339, 346 (4th Cir. 1996).

Here, 35 U.S.C. § 154(b)(4) supplies patent owners with a cause of action to challenge the USPTO's PTA determination. In fact, it is the basis of AbbVie's Count I claim. The statute specifies that it is the "exclusive remedy" to challenge such a determination. 35 U.S.C. § 154(b)(4)(a). The remedy AbbVie could obtain from its § 154 claim (Count I) would not be any different from its freestanding APA claims (Counts II and III). Thus, with an adequate remedy under 35 U.S.C. § 154, AbbVie's Count II cannot proceed.

Finally, AbbVie argues that the USPTO exceeded its statutory authority when it promulgated 37 C.F.R. § 1.704(c)(8), the regulation that punishes supplemental papers that are not expressly requested. This count lacks subject matter jurisdiction over this APA challenge for the same reasons discussed immediately above. In addition, this matter has been forfeited. AbbVie failed to present this argument to USPTO; thus, AbbVie cannot bring it now. Even if it did not fail on either of those grounds, it fails on the merits.

Agency action is beyond its mandate if the agency "is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden." Ancient Coin Collectors Guild v. U.S. Customs & Border Prot., 698 F.3d 171, 179 (4th Cir. 2012).

In 1999, Congress 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). Though Congress directed USPTO to establish the circumstances that constitute a failure to engage in reasonable efforts, Congress set the consequence of any act that met that definition: "[t]he period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." Id. § 154(b)(2)(C)(i).

AbbVie argues that Supernus supports its position that the USPTO's promulgation of 37 C.F.R. § 1.704(c)(8) exceeded its statutory authority. 913 F.3d at 1359. That is incorrect. The Federal Circuit did not set aside the USPTO's regulation; it held that the statute precluded reducing the PTA unless it is equal to the period time during which the applicant failed to engage in reasonable efforts. Id. at 1361. Specifically, the Federal Circuit found the *application* of the USPTO's regulations in that case to violate its statutory mandate; it did not find the regulation itself to violate USPTO's statutory mandate. As stated previously, the application of USPTO's regulations here was "equal to" the period AbbVie failed to engage in reasonable efforts. Id. Thus,

Supernus does not support that the promulgation of § 154 is in violation of USPTO's congressional mandate.

§ 154 empowers the USPTO to identify circumstances that qualify as applicant delay irrespective of whether an actual delay accrues. By its plain terms, Congress directed USPTO to ascertain the "circumstances" where an applicant failed to engage in "reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). Drawing on its expertise, USPTO's contemporaneous regulations appreciated that piecemeal replies and papers routinely interfere with USPTO's ability to efficiently respond to and examine applications, especially given the four-month deadline imposed by Congress for USPTO to provide an office action under 35 U.S.C. § 132. That statutory construction is also consistent with the statute's purpose—to facilitate the prompt examination of patent applications and maximize the term of their effect. Thus, § 154 does not violate Congresses mandate.

For the forgoing reasons Defendant's Motion to Dismiss and Motion for Summary Judgment should be granted; AND

Plaintiffs' Motion for Summary Judgment should be denied.

An appropriate Order shall issue.

Alexandria, Virginia
July 29, 2025

/s/
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE