

APPENDIX

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

EULA WINFREY,
Plaintiff-Appellant

v.

**US DEPARTMENT OF COMMERCE, PATENT AND
TRADEMARK OFFICE,**
Defendant-Appellee

2024-1260

Appeal from the United States District Court for the
Middle District of Georgia in No. 3:22-cv-00083-CDL,
Judge Clay D. Land.

Decided: September 25, 2024

EULA WINFREY, Elberton, GA, pro se.

CONRAD JOSEPH DEWITTE, JR., Commercial Litigation
Branch, Civil Division, United States Department of Jus-
tice, Washington, DC, for defendant-appellee. Also repre-
sented by SCOTT DAVID BOLDEN, BRIAN M. BOYNTON.

Before PROST, HUGHES, and CUNNINGHAM, *Circuit Judges*.

PER CURIAM.

Appellant Eula Winfrey appeals a decision from the United States District Court for the Middle District of Georgia granting the Department of Commerce's motion to dismiss for failure to state a claim. We affirm.

I

Ms. Winfrey initiated her suit before the United States District Court for the Middle District of Georgia, seeking "relief for the issue of two pillaged patents." SAppx. 1002.¹ Ms. Winfrey alleged that the United States Patent and Trademark Office (USPTO) "improperly denied her two patent applications^[2] and wrongfully deemed the applications to be abandoned." SAppx. 1001. Additionally, Ms. Winfrey sought damages from the USPTO. SAppx. 1006. The agency, construing Ms. Winfrey's pro se complaint as asserting claims under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701–706, and the Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 2671–2680, moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). According to the agency, Ms. Winfrey failed to file the required administrative claim for her FTCA claim. SAppx.

¹ "SAppx." refers to the supplemental appendix filed by Appellee, United States Department of Commerce. See ECF No. 20.

² The two alleged patent applications are 09/422,542 (the '542 application) for the "step up diaper," SAppx. 1002, and 15/932,395 (the '395 application) for the "stroller buddy," which claimed the benefit of an earlier provisional patent application 62/600,707 (the '707 application), SAppx. 1005. The original complaint raises the abandonment of the provisional '707 application, but due to the twelve-month pendency of the provisional application, the non-provisional '395 application is the subject of Ms. Winfrey's abandonment contentions.

1001. The agency also argued that one of Ms. Winfrey's APA claims was barred by collateral estoppel and the other APA claim failed because Ms. Winfrey did not show that she exhausted administrative remedies. *Id.*

On review, the district court granted the agency's Rule 12(b)(6) motion and dismissed the action. *Winfrey v. Dep't of Com.*, 3:22-cv-83-CDL (M.D. Ga. Jul. 20, 2023) (*Winfrey I*); SAppx. 1001–10. In its decision, the district court separately analyzed Ms. Winfrey's FTCA claim and her two patent-application-related APA claims against the USPTO. As to Ms. Winfrey's claim for money damages, the district court dismissed the tort claim "for failure to exhaust administrative remedies under the FTCA" because Ms. Winfrey had "failed to present an FTCA claim to the USPTO," as required by 28 U.S.C. § 2675(a). SAppx. 1006–07. The district court also dismissed Ms. Winfrey's APA claim related to the '542 patent application "based on the collateral estoppel doctrine," resulting from a prior district court action that dismissed the same APA claim. SAppx. 1007–08 (citing *Winfrey v. Kimberly-Clark Corp.*, 1:08-cv-2817-TWT (N.D. Ga. Dec. 5, 2008) (*Winfrey II*) (granting USPTO's motion to dismiss for failure to exhaust administrative remedies for the abandoned '542 patent application)). In the present case, the district court concluded that the "four conditions [for collateral estoppel we]re met,"³ and noted

³ Applying Eleventh Circuit law, the district court noted that the collateral estoppel doctrine applies when:

(1) [T]he issue at stake is identical to the one involved in the prior litigation; (2) the issue was actually litigated in the prior litigation; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair

that the last time “[Ms.] Winfrey tried to bring another APA action in the Northern District [of Georgia] based on the ’542 patent application,” the trial court similarly found the claims barred by collateral estoppel. SAppx. 1007–08 (citing *Winfrey v. Kimberly-Clark Corp.*, 1:09-cv-02597-TWT (N.D. Ga. Jan. 25, 2010) (*Winfrey III*)). As for the remaining APA claim based on the ’395 patent application, the district court determined that Ms. Winfrey “never filed a petition to revive the ’395 application after the USPTO deemed it abandoned,” and therefore the district court dismissed the claim for failure to exhaust administrative remedies. SAppx. 1009–10, 1010 n.4.

Ms. Winfrey timely noticed an appeal in the United States Court of Appeals for the Eleventh Circuit. The Eleventh Circuit transferred the appeal to us because it raises a claim arising under an Act of Congress relating to patents. See 28 U.S.C. § 1295(a)(1); ECF No. 11 (letter of transfer from the Eleventh Circuit).

II

We exercise exclusive jurisdiction “of an appeal from a final decision of a district court of the United States . . . in any civil action arising under . . . any Act of Congress relating to patents.” 28 U.S.C. § 1295(a)(1). Because Ms. Winfrey’s complaint before the district court alleged that the USPTO improperly denied two patent applications and wrongfully deemed the applications to be abandoned, we have exclusive jurisdiction over this appeal.

opportunity to litigate the issue in the earlier proceeding.

SAppx. 1007 (quoting *Miller’s Ale House, Inc. v. Boyton Carolina Ale House, LLC*, 702 F.3d 1312, 1318 (11th Cir. 2012)).

III

The court applies regional circuit law to “procedural questions that are not themselves substantive patent law issues.” *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1272 (Fed. Cir. 2001). When applying Eleventh Circuit law, “we review the dismissal under Rule 12(b)(6) de novo, accepting the complaint’s allegations as true and construing them in the light most favorable to the plaintiff.” *ABB Turbo Sys. AG v. TurboUSA, Inc.*, 774 F.3d 979, 984 (Fed. Cir. 2014) (citing *Speaker v. U.S. Dep’t of Health & Hum. Servs.*, 623 F.3d 1371, 1379 (11th Cir. 2010)).

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain sufficient factual allegations to “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face “when the plaintiff pleads sufficient facts to allow the court to draw the reasonable inference that the defendant is liable for the alleged misconduct.” *Equal Emp. Opportunity Comm’n v. STME, LLC*, 938 F.3d 1305, 1313 (11th Cir. 2019) (quoting *Boyle v. City of Pell City*, 866 F.3d 1280, 1286 (11th Cir. 2017)).

IV

On appeal, Ms. Winfrey does not challenge the district court’s application of the law. Instead, Ms. Winfrey only argues that the district court’s decision was factually incorrect. On review of the record, we affirm the district court’s dismissal for the reasons stated below.

A

In Ms. Winfrey’s complaint, she sought monetary damages from the USPTO for the alleged “pillaging and unethical practices that have taken place within Patent Office walls.” Appellant’s Informal Br. at 5. The district court dismissed Ms. Winfrey’s claim for money damages after concluding that she failed to exhaust administrative remedies

required by the FTCA. Although Ms. Winfrey challenges the district court's dismissal, nowhere in any of her extensive filings before this court do we find evidence that Ms. Winfrey filed the requisite administrative claim to bring a claim for money damages against the USPTO. Nor does Ms. Winfrey contend that she filed any such claim. We therefore affirm the district court's dismissal of her claim for money damages.

B

Ms. Winfrey's complaint also alleges that the USPTO improperly denied her '542 patent application and wrongfully deemed the application to be abandoned. The district court, noting that Ms. Winfrey's same APA claim was dismissed in *Winfrey II* for failing to exhaust administrative remedies, dismissed the claim as barred by collateral estoppel. Although on appeal Ms. Winfrey challenges the USPTO's determination that the '542 application was abandoned, she does not challenge the district court's application of collateral estoppel. Nor does Ms. Winfrey point this court to any evidence that she properly petitioned for review of the USPTO's abandonment determination.

In *Winfrey II*, the district court dismissed Ms. Winfrey's APA claim relating to the '542 patent application abandonment determination after concluding she failed to exhaust administrative remedies. Subsequently, the district court in *Winfrey III* and the district court in this case both determined that because of the dismissal in *Winfrey II*, Ms. Winfrey was collaterally estopped from raising the same APA claim. On review of the record, we too conclude that Ms. Winfrey's claim against the USPTO relating to the abandonment of the '542 patent application is barred by the doctrine of collateral estoppel. See *Miller's Ale House*, 702 F.3d at 1318 (providing the four conditions for collateral estoppel). We therefore affirm the district court's dismissal of her APA claim relating to the '542 patent application's abandonment determination.

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C

Ms. Winfrey's complaint also alleges that the USPTO improperly denied her '395 patent application and wrongfully deemed the application to be abandoned. The district court dismissed the APA claim after concluding that Ms. Winfrey did not exhaust the administrative remedies required to revive the patent application "after the USPTO deemed it abandoned." SAppx. 1009. On appeal, Ms. Winfrey challenges the facts relating to the USPTO's determination that she legally abandoned the '395 patent application. However, as with her APA claim for the '542 patent application, Ms. Winfrey fails to present any evidence that she filed a petition with the USPTO to revive her application or challenge its abandonment determination. Nor does Ms. Winfrey contend that she filed any such petition. Accordingly, there is no evidence in the record that Ms. Winfrey exhausted her administrative remedies. Because Ms. Winfrey failed to exhaust her administrative remedies, we affirm the district court's dismissal of her APA claim relating to the '395 patent application.

V

We have considered Ms. Winfrey's remaining arguments and find them unpersuasive. For the reasons stated above, we affirm the district court's Rule 12(b)(6) dismissal of Ms. Winfrey's action for failure to state a claim upon which relief can be granted.

AFFIRMED

COSTS

No costs.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

EULA WINFREY,

*

Plaintiff,

*

vs.

*

CASE NO. 3:22-CV-83 (CDL)

UNITED STATES DEPARTMENT OF
COMMERCE,

*

*

Defendant.

*

O R D E R

Eula Winfrey alleges that the United States Patent and Trademark Office improperly denied her two patent applications and wrongfully deemed the applications to be abandoned. The Government construes Winfrey's pro se complaint as asserting claims under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706, and the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 2671-2680. The Government moves to dismiss Winfrey's action because (1) Winfrey did not file an administrative claim as required for her FTCA claims, (2) one of her APA claims is barred by collateral estoppel, and (3) the other APA claim fails because she did not show that she exhausted administrative remedies. For the reasons set forth below, the Court grants the motion to dismiss (ECF No. 8).

MOTION TO DISMISS STANDARD

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual

matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The complaint must include sufficient factual allegations "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. In other words, the factual allegations must "raise a reasonable expectation that discovery will reveal evidence of" the plaintiff's claims. *Id.* at 556. But "Rule 12(b)(6) does not permit dismissal of a well-pleaded complaint simply because 'it strikes a savvy judge that actual proof of those facts is improbable.'" *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007) (quoting *Twombly*, 550 U.S. at 556).

FACTUAL BACKGROUND

Winfrey's pro se complaint seeks "relief for the issue of two pillaged patents." Compl. 1, ECF No. 1. Winfrey asserts that she submitted patent application 09/422,542 for a "step up diaper" on October 19, 1999 and that she is the true inventor of Huggies "Pull-Ups" diapers. Winfrey appears to allege that the United States Patent and Trademark Office ("USPTO") wrongfully rejected her patent claims and then deemed the '542 application to be abandoned in 2002. Winfrey claims that she "sought after an appeal and investigation within the patent office itself by filing an

appeal in 2006 which went ignored," then she "began to file" court actions against the USPTO and others in 2008. *Id.* at 2.

Winfrey's first court action was against Kimberly-Clark Corporation and the USPTO in the United States District Court for the Northern District of Georgia.¹ *Compl., Winfrey v. Kimberly-Clark Corp.*, 1:08-cv-01678-TWT (N.D. Ga. May 8, 2008), ECF No. 1. Winfrey alleged that the USPTO denied her patent for the "step up diaper" and that Kimberly-Clark began selling diapers like the "step up diaper" in 2001. Winfrey's claims against Kimberly-Clark were dismissed as time-barred. Order at 4, *Winfrey*, 1:08-cv-01678-TWT (N.D. Ga. July 31, 2008), ECF No. 20. Her claims against the USPTO were dismissed without prejudice because Winfrey failed to serve them in the manner required by law. Order, *Winfrey*, 1:08-cv-01678-TWT (N.D. Ga. Aug. 28, 2008), ECF No. 25.

Winfrey filed a second action in the Northern District regarding the "step up diaper" against Kimberly-Clark Corporation, the USPTO, and two USPTO employees. *Compl., Winfrey v. Kimberly-Clark Corp. (Winfrey II)*, 1:08-cv-02817-TWT (N.D. Ga. Sept. 9, 2008), ECF No. 1. The court dismissed Winfrey's claims against Kimberly-Clark based on *res judicata*, it dismissed her claims

¹ The Court may take judicial notice of these court filings, which Winfrey referenced in her Complaint. See Fed. R. Evid. 201(b); see also *United States v. Jones*, 29 F.3d 1549, 1553 (11th Cir. 1994) (noting that "a court may take notice of another court's order . . . for the limited purpose of recognizing the 'judicial act' that the order represents or the subject matter of the litigation").

against the USPTO for failure to exhaust administrative remedies, and it dismissed her claims against the USPTO employees for lack of personal jurisdiction. Order, *Winfrey II*, 1:08-cv-2817-TWT (N.D. Ga. Dec. 5, 2008), ECF No. 11.²

Winfrey filed a third action in the Northern District regarding the "step up diaper" against Kimberly-Clark Corporation and the USPTO. Compl., *Winfrey v. Kimberly-Clark Corp. (Winfrey III)*, 1:09-cv-02597-TWT (N.D. Ga. Sept. 22, 2009), ECF No. 1. The court dismissed Winfrey's claims against Kimberly-Clark based on res judicata and granted Kimberly-Clark's motion for sanctions. Order, *Winfrey III*, 1:09-cv-02597-TWT (N.D. Ga. Nov. 19, 2009), ECF No. 14; Order at 1, *Winfrey III*, 1:09-cv-02597-TWT (N.D. Ga. Dec. 23, 2009), ECF No. 20. The court dismissed Winfrey's claims against the USPTO as barred by collateral estoppel because the court had previously concluded in a prior action that Winfrey failed to exhaust her administrative remedies before filing her action. Order, *Winfrey III*, 1:09-cv-02597-TWT (N.D. Ga. Jan. 25, 2010), ECF No. 24.

² The Northern District's one-paragraph order did not provide a statement of the reasons for its decision. The USPTO's motion to dismiss, which was granted by the court, explained the statutory and regulatory process for challenging a determination of abandonment by the USPTO, and it included evidence demonstrating that although Winfrey successfully petitioned to revive her abandoned patent application in 2004, the USPTO again determined in 2007 that Winfrey abandoned the '542 patent application, and Winfrey did not file another petition to revive the '542 patent application. USPTO Mot. to Dismiss 6, *Winfrey II*, 1:08-cv-2817-TWT (N.D. Ga. Nov. 10, 2008), ECF No. 10-1.

In addition to her present claims about the "step up diaper," Winfrey alleges that she submitted another patent application to the USPTO regarding a "stroller buddy perambulatory connecting device." Winfrey filed provisional patent application 62/600,707 regarding the "stroller buddy" on February 28, 2017. She later filed non-provisional patent application 15/932,395 on February 23, 2018. Although Winfrey's complaint does not contain clear factual allegations about what happened with the '395 patent application, the USPTO presented evidence that a patent examiner rejected Winfrey's claims in April 2020. USPTO Mot. to Dismiss Ex. B, Letter from M. Barlow to E. Winfrey 2 (Apr. 7, 2020), ECF No. 8-2. The USPTO later determined that Winfrey had abandoned the '395 application. USPTO Mot. to Dismiss Ex. C, Letter from M. Barlow to E. Winfrey 2 (Nov. 18, 2020), ECF No. 8-3.

DISCUSSION

Winfrey's pro se complaint does not clearly articulate what claims she is asserting, but the Government construes Winfrey's complaint as asserting claims against the USPTO under the FTCA and the APA. The Government argues that Winfrey's FTCA claims fail because she did not present the required administrative claim to the USPTO before filing this action, that her APA claims based on the '542 step up diaper application are barred by collateral estoppel, and that her APA claims based on the '395 stroller buddy

application are barred because she did not exhaust administrative remedies. The Court addresses each argument in turn.

I. Winfrey's Tort Claims

Winfrey seeks damages from the USPTO, claiming that the USPTO wrongfully denied her two patent applications and allowed her ideas to be "pillaged" by others who reduced them to practice and took them to market. The Government construes these allegations as asserting tort claims against the USPTO. The FTCA provides an exclusive remedy for injury or loss of property "arising or resulting from the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment." 28 U.S.C. § 2679(b)(1). But before a person may bring an action against the United States under the FTCA, she must "have first presented the claim to the appropriate Federal agency," and that claim must have been "finally denied by the agency" or not finally disposed of by the agency within six months. 28 U.S.C. § 2675(a). Winfrey does not allege that she submitted an administrative claim to the USPTO under the FTCA regarding her damages claims for the "pillaging" of her patent applications. Winfrey also did not respond to the Government's assertion that she failed to present an FTCA claim to the USPTO. For these reasons, the Court finds that Winfrey's tort claims

should be dismissed for failure to exhaust administrative remedies under the FTCA.³

II. Winfrey's APA Claims Based on the '542 Application

The Government asserts that Winfrey's present APA claims based on the '542 step up diaper application are barred by collateral estoppel. Collateral estoppel "bars 'successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment.'" *Kordash v. United States*, 51 F.4th 1289, 1294 (11th Cir. 2022) (quoting *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008)). The doctrine applies when "(1) the issue at stake is identical to the one involved in the prior litigation; (2) the issue was actually litigated in the prior suit; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding." *Id.* (quoting *Miller's Ale House, Inc. v. Boynton Carolina Ale House, LLC*, 702 F.3d 1312, 1318 (11th Cir. 2012)).

All four conditions are met here. First, the issue in this action is the same as it was in the Northern District actions—

³ Winfrey argues that her damages claims should be allowed because "her claims have not only been stated but PROVEN." Pl.'s Resp. to Def.'s Mot. to Dismiss 4, ECF No. 9. This argument does not mention the FTCA's administrative claim requirement, and Winfrey did not establish or allege that she made such a claim.

Winfrey sought relief under the APA based on the '542 patent application, and a key question was whether Winfrey satisfied the APA's threshold exhaustion requirement. Second, the exhaustion issue was actually litigated in the second Northern District Action. See Order, *Winfrey II*, 1:08-cv-2817-TWT (N.D. Ga. Dec. 5, 2008), ECF No. 11 (dismissing Winfrey's APA claim for failure to exhaust administrative remedies). Third, the Northern District's determination that Winfrey failed to exhaust administrative remedies was critical and necessary to the dismissal of that action. And fourth, Winfrey had a fair opportunity to litigate this issue during the second Northern District action. Moreover, when Winfrey tried to bring another APA action in the Northern District based on the '542 patent application, the Northern District found that her claims were barred by collateral estoppel. Order, *Winfrey III*, 1:09-cv-02597-TWT (N.D. Ga. Jan. 25, 2010), ECF No. 24. For all these reasons, Winfrey's present APA claims arising out of the USPTO's decisions regarding the '542 application are dismissed based on the collateral estoppel doctrine.

III. Winfrey's APA Claims Based on the '395 Application

The Government argues that Winfrey's APA claims based on the '395 stroller buddy patent application should be dismissed because Winfrey did not exhaust her administrative remedies to challenge the USPTO's decision to reject the '395 application and deem it abandoned. A party aggrieved by a *final* federal agency action can

obtain judicial review under the APA. 5 U.S.C. § 704; accord *Canal A Media Holding, LLC v. U.S. Citizenship & Immigr. Servs.*, 964 F.3d 1250, 1255 (11th Cir. 2020). To be considered "final," the agency action "must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature." *Canal A Media Holding*, 964 F.3d at 1255. Thus, an agency decision is not "final" until the aggrieved party "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993).

The Government contends that Winfrey did not exhaust all administrative remedies to revive the '395 stroller buddy patent application after the USPTO deemed it abandoned, so the USPTO's abandonment decision was not "final." Under the applicable regulations, when a patent examiner rejects a patent application's claims in an Office action, the applicant must reply within the regulatory time frame, or the application will become abandoned. 37 C.F.R. §§ 1.134-1.135(a) (2023). If the application becomes abandoned for failure to reply to the Office action, the applicant may file a petition to revive the application. *Id.* § 1.137. Here, Winfrey does not allege that she exhausted administrative remedies for the '395 application before filing this action, and she did not clearly respond to the Government's contention that she never filed a petition to revive the '395 patent after the USPTO deemed

it abandoned. Thus, there are no factual disputes in the present record regarding whether Winfrey exhausted administrative remedies for the '395 application; the present record establishes that she did not.⁴ Winfrey's APA claims based on the '395 application are dismissed for failure to exhaust administrative remedies.

CONCLUSION

For the reasons set forth above, the Court grants the Government's motion to dismiss (ECF No. 8).

IT IS SO ORDERED, this 20th day of July, 2023.

S/Clay D. Land

CLAY D. LAND

U.S. DISTRICT COURT JUDGE

MIDDLE DISTRICT OF GEORGIA

⁴ The Government pointed to evidence of what happened to the '395 application, and Winfrey did not refute this evidence or even argue that there are fact disputes on this issue. The Court may thus consider the evidence. See *Tillery v. U.S. Dep't of Homeland Sec.*, 402 F. App'x 421, 424 (11th Cir. 2010) (per curiam) (finding that a district court did not err in considering evidence outside the pleadings regarding exhaustion of a Title VII claim where the plaintiff had an opportunity to develop the record through a response). The USPTO sent Winfrey an Office Action Summary stating that her claims in the '395 patent application were rejected. Letter from M. Barlow to E. Winfrey 2 (Apr. 7, 2020). Winfrey does not allege or assert that she responded to that Office action by the deadline. The USPTO later determined that Winfrey had abandoned the '395 application. Letter from M. Barlow to E. Winfrey 2 (Nov. 18, 2020). Winfrey does not allege or assert that she filed a petition to revive the '395 application, and the USPTO presented evidence that its records do not contain such a petition. Kim Decl. ¶ 3, ECF No. 8-7. Winfrey did not clearly respond to this argument or present any evidence to contradict the USPTO's evidence that she never filed a petition to revive the '395 application. Accordingly, based on the present record, the Court finds that Winfrey did not exhaust all administrative remedies for the '395 patent application, and the Court thus dismisses her APA claim regarding the '395 application.

**Additional material
from this filing is
available in the
Clerk's Office.**