IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA.

Plaintiffs,

C.A. No. 10-915-LPS

v.

WATSON LABORATORIES, INC. (NV) and EGIS PHARMACEUTICALS PLC,

Defendants.

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MEMORANDUM OPINION

November 14, 2012 Wilmington, Delaware STARK, U.S. District Judge:

Presently before the Court is Defendant's motion for summary judgment of no infringement under the doctrine of equivalents (D.I. 283) and Plaintiffs' motion for partial summary judgment on issue preclusion (D.I. 279). For the reasons discussed below, the Court will deny without prejudice Defendant's motion and deny in part and grant in part Plaintiffs' motion.

I. <u>BACKGROUND</u>

On October 26, 2010, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha ("AstraZeneca" or "Plaintiffs") filed a complaint alleging that Watson Laboratories, Inc. (NV)'s ("Watson" or "Defendant") New Drug Application ("NDA") No. 202172 infringes U.S. Patent No. RE37, 314 (the "'314 patent"). (D.I. 1) On November 23, 2011, Plaintiffs amended their complaint to add claims against Egis Pharmaceuticals PLC ("Egis" or collectively with Watson, "Defendants") for inducement of infringement. (D.I. 133)

The '314 patent is a reissue of U.S. Patent No. 5,260,440 (the "'440 patent") and is related to rosuvastatin in certain salt forms. On February 2, 2012, the Court construed the disputed claim term "a cation capable of forming a non-toxic pharmaceutically acceptable salt" to mean "an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein the ammonium ion is unsubstituted." (D.I. 214)

On June 1, 2012, Defendant filed a motion for summary judgment of no infringement under the doctrine of equivalents. (D.I. 283) On the same date, AstraZeneca filed a motion for partial summary judgment that issue preclusion bars Defendants from relitigating the validity and enforceability of the '314 patent. (D.I. 279) The Court heard oral argument on both motions on

September 24, 2012. (D.I. 370) ("Tr.")¹ Trial is scheduled to begin on December 12, 2012.

II. PERTINENT PROCEDURAL HISTORY

On December 11, 2007, AstraZeneca sued Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. (collectively, "Cobalt") alleging infringement of the '314 patent under 35 U.S.C. § 271(e)(2)(A) based on Cobalt's Abbreviated New Drug Application for Cobalt's rosuvastatin calcium. See C.A. No. 07-811-JJF (D. Del. 2010). Cobalt contended that the '314 patent was invalid due to obviousness, improper reissue, and lack of enablement,² and unenforceable based on inequitable conduct.

On March 27, 2009, Arrow Group International Limited ("Arrow") entered into an agreement with Egis to manufacture rosuvastatin zinc in Hungary and provide it to Arrow in the United States to sell through Cobalt. Arrow and Egis agreed that Arrow would conduct litigation relating to '314 patent and file an NDA for rosuvastatin zinc.

On December 2, 2009, Watson Pharmaceuticals, Inc. ("Watson's parent") acquired the Arrow Group, which included Cobalt. Watson's parent assumed control over Cobalt's rosuvastatin calcium litigation, Arrow's agreements with Egis, and work on rosuvastatin zinc products.

In June 2010, following trial, Judge Farnan rejected Cobalt's defense that the '314 patent was invalid and unenforceable. See In re Rosuvastatin Calcium Patent Litigation, 719 F. Supp.

¹The Court permitted the parties to file a joint letter following the hearing to address several issues. (D.I. 366, 367, 369)

²The 2010 calcium litigation in this Court involved eleven defendants in nine civil actions, all of which were consolidated, including for trial. See C.A. No. 08-md-1949-JJF (D. Del. 2010). Lack of enablement was not presented at trial.

2d 388, 410 (D. Del. 2010) (hereinafter the "2010 calcium litigation"). On August 10, 2010, the 2010 calcium litigation defendants filed their notices of appeal to the Federal Circuit.

On July 15, 2010, Watson filed its NDA for rosuvastatin zinc with the U.S. Food and Drug Administration. The instant litigation followed.

III. <u>LEGAL STANDARDS</u>

A grant of summary judgment is appropriate only where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). If the moving party has carried its burden, the nonmovant must then "come forward with 'specific facts showing that there is a genuine issue for trial." Id. at 587 (quoting Fed. R. Civ. P. 56(e)). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). If the Court is able to determine that "there is no genuine issue as to any material fact" and that the movant is entitled to judgment as a matter of law, summary judgment is appropriate. See Hill v. City of Scranton, 411 F.3d 118, 125 (3d Cir. 2005); see also Fed. R. Civ. P. 56(c).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; see also Podobnik v. U.S. Postal Serv., 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory

allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). Moreover, the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

IV. <u>DISCUSSION</u>

A. Motion for Summary Judgment of No Infringement Under the Doctrine of Equivalents

Watson seeks summary judgment on the ground that Plaintiffs cannot prove infringement under the doctrine of equivalents. Watson's primary contention is that because the patentees used narrow claim language, Plaintiffs are precluded from relying on the doctrine of equivalents to expand the patent's scope. In response, Plaintiffs argue that the doctrine of equivalents applies and protects patentees from infringers who make insubstantial changes to the claimed invention.

In order to protect the public notice function of patents, the Federal Circuit has articulated several rules of law that limit the application of the doctrine of equivalents. First, the doctrine cannot be used to expand a patentee's narrowly defined claim element. See Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1424 (Fed. Cir. 1997). Second, the doctrine cannot be used when a patent explicitly or implicitly excludes subject matter. See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345-47 (Fed. Cir. 2001). Finally, the

doctrine cannot be used to redefine, read out, or vitiate a claim limitation. See Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005).

In Sage, 126 F.3d at 1424, the Federal Circuit stated that "for a patentee who has claimed an invention narrowly, there may not be infringement under the doctrine of equivalents in many cases, even though the patentee might have been able to claim more broadly." The Court further noted that the doctrine of equivalents, when applied broadly, conflicts with the public notice function of patents. "[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed stricture." *Id.* at 1424-25. In analyzing the patent before it, the Court in Sage observed "clear structural limitations" in a relatively simple structure, no linguistic impediments to claiming a broader scope, and no subsequent changes in the art. See id. Thus, a skilled patent drafter would foresee the limiting nature of the chosen claim language, and infringement under the doctrine of equivalents was not proven. See id.

More recently, in *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1366 (Fed. Cir. 2012), the Court similarly concluded that a patentee could not expand the coverage of its patent through the doctrine of equivalents. The patentee, Cadbury Adams USA LLC ("Cadbury"), competed with the accused infringer, Wrigley Jr. Co. ("Wrigley"), in the chewing gum market. Cadbury's U.S. Patent No. 5,009,893 (the "'893 patent") claimed chewing gum that combined menthol and WS-3, an N-substituted-p-menthane carboxamide cooling agent. For its part, Wrigley owned U.S. Patent No. 6,627,233, which covered the combination of menthol and WS-23. It was undisputed that N-substituted-p-menthane carboxamide does not

cover WS-23. Instead, the parties' dispute was whether the term N-substituted-p-menthane carboxamide should be read to exclude all compounds other than N-substituted-p-menthane carboxamides.

On appeal, the Federal Circuit affirmed the District Court's conclusion that the '893 patent narrowly claimed N-substituted-p-menthane carboxamide and implicitly excluded other carboxamides, including WS-23. See id. at 1365-66. The invention "focuse[d] narrowly" on N-substituted-p-menthane carboxamide due its unexpected results when used with menthol. See id. The Court also noted that N-substituted-p-menthane carboxamide had a similar structure to menthol, whereas WS-23 did not. The Court further relied on the fact that the claims were narrowly drawn, only claiming a subset of carboxamide compounds. See id. at 1366. In ruling that the doctrine of equivalents could not expand the scope of Cadbury's patent, the Court emphasized that "the inventors were on notice of the potential interchangeability of WS-23 and WS-3, yet drafted the claims of the '893 patent narrowly to recite certain N-substituted-p-menthane carboxamides, not a broader category of carboxamides that would include WS-23."

Wrigley rejected Cadbury's reliance on Abraxis Bioscience, Inc. v. Mayne Pharma Inc., 467 F.3d 1370 (Fed. Cir. 2006). In Abraxis, the accused infringer, Mayne Pharma (USA), Inc. ("Mayne"), argued that the patentees had narrowly claimed their invention and could not rely on the doctrine of equivalents. See id. at 1379. Specifically, Mayne argued that because the patentees used the term "edetate" to claim their invention, they were precluded from relying on the doctrine of equivalents to accuse a compound, DTPA, a member of the broader class of polyaminocarboxylic acids, of which edetate is also a member. See id. at 1379 n.7. The Court

held that the patentees could rely on the doctrine of equivalents, noting that there was no evidence that the patentees had "clear[ly] and unmistakabl[y]" given up DTPA during prosecution. See id. at 1381. The Court found particularly persuasive the fact that DTPA had been unforeseeable at the time of invention. See id. Indeed, the Court cited Federal Circuit and Supreme Court precedent for the proposition that "[t]he doctrine of equivalents is designed to protect inventors from unscrupulous copyists and unanticipated equivalents." Id. at 1382 (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950)). By contrast, in Wrigley, WS-23, unlike DTPA, was a foreseeable and known equivalent at the time of invention. See 683 F.3d at 1366.

Wrigley cited two other Federal Circuit cases in affirming the finding of no infringement under the doctrine of equivalents. In Tanabe Seiyaku Co. v. Int'l Trade Comm'n, 109 F.3d 726, 732 (Fed. Cir. 1997), the Court held because Tanabe deliberately removed" subject matter from PTO examination, it could not thereafter utilize the doctrine of equivalents to recapture what it gave up in prosecution. Similarly, in Bicon, Inc. v. Straumann Co., 441 F.3d 945, 955 (Fed. Cir. 2006), the Court held that the doctrine of equivalents could not expand the scope of a claim containing a detailed description of a structure that "clearly excludes distinctly different and even opposite shapes."

In the instant case, Defendant relies primarily on Sage and Wrigley to contend that summary judgment is appropriate. In Watson's view, the patentees narrowly claimed and restricted their invention to the subset of alkaline metals, alkaline earth metals, and ammonium ions. Defendant asserts that there was no failure of language in claiming a broader group of cations capable of forming pharmaceutically acceptable salts. Rather, the patentees made a

deliberate decision to use narrow language in the specification to limit the potential cations to the three named subsets. Watson further argues that, at the time of the invention, zinc was a foreseeable cation known to be an appropriate pharmaceutically acceptable salt. (D.I. 284 at 15)³

Plaintiffs respond that Wrigley and Sage relied on several factors not present in this case. In Wrigley, in addition to narrow claim language, foreseeability of the equivalent, and the lack of linguistic impediments to claiming more broadly, the invention was narrowly focused on the N-substituted-p-menthane carboxamide, especially due to the unexpected results when combined with menthol. See 683 F.3d at 1365. The specification of Cadbury's patent also states that N-substituted-p-menthane carboxamide, and not carboxamides generally, was structurally similar to menthol. See id. Likewise, Plaintiffs argue that Sage is distinguishable because the patent there related to a simple structural device containing clear structural limitations, and the patentees had a clear opportunity to negotiate broader claims. Additionally, Plaintiffs argue that the patentees here never expressly criticized, disclaimed, or disclosed zinc in such a way that would support a conclusion that the claim language was "sharply restricted" or that certain cations were "clearly" excluded during prosecution. See generally AstraZeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (finding persuasive patentee's criticism of other solubilizers lacking specific feature of selected solubilizer); SciMed Life Sys., Inc. v. Advanced

³The prior art, U.S. Patent No. 4,444,784, cited in the '314 patent (D.I. 285 Ex. 2 at col. 1 l. 20), states that zinc is a pharmaceutically acceptable salt. (See also D.I. 285 Ex. 8 at col. 15 ll. 3-6)

⁴Plaintiffs cite Supreme Court and Federal Circuit authority for the proposition that the fact "[t]hat an element of an accused device already existed does not bar equivalency as to that element." Tr. at 35-38 (quoting Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1324 (Fed. Cir. 2000), and citing Warner-Jenkinson Co. v. Hilton Davis Chem., 520 U.S. 17, 25 (1997)).

Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-45 (Fed. Cir. 2001) (limiting catheters with coaxial lumens where written description emphasized coaxial lumens and criticized catheters using other types of lumens).

Having reviewed these authorities and the record, the Court has determined that the most appropriate course is to hear all of the evidence at trial and make a conclusion on the doctrine of equivalents thereafter. The Court is not, at this point, persuaded that Watson is entitled to judgment as a matter of law that the '314 claim language is so sharply narrowing as to require the exclusion of zinc under the doctrine of equivalents. See generally Pozen Inc. v. Par Pharm., Inc., 2012 WL 4465246, at *12-13 (Fed. Cir. Sept. 28, 2012) (stating that "absent more limiting language in the intrinsic record the doctrine of equivalents can be applied"). While the Court finds Sage and Wrigley relevant, the Court is unable to conclude at this point whether zinc was deliberately excluded and outside of the scope of the doctrine of equivalents. Rather, the Court concludes that the better course is to deny, without prejudice, Defendant's motion for summary judgment, which Defendant may renew following trial.

B. Motion for Partial Summary Judgment on Issue Preclusion

1. Validity As a Single Issue

AstraZeneca moves for partial summary judgment on the issue of validity and enforceability of the '314 patent under a theory of issue preclusion. Plaintiffs argue that validity is a single issue and new theories of invalidity are barred as a result of the 2010 calcium litigation ruling.

Issue preclusion applies where: "(1) the issue sought to be precluded is the same as that involved in the prior action; (2) that issue was actually litigated; (3) it was determined by a final

and valid judgment; and (4) the determination was essential to the prior judgment." Burlington N. R.R. v. Hyundai Merch. Marine Co., 63 F.3d 1227, 1231-32 (3d Cir. 1995).

In opposing summary judgment, Defendants rely heavily on this Court's decision in Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc., 763 F. Supp. 2d 671, 680 (D. Del. 2010). There, the undersigned Judge stated that defendant's "anticipation defenses were not 'actually litigated' and issue preclusion does not apply" because anticipation and obviousness have different requirements. See id. From this statement, Defendants conclude that this Court believes each theory on which a patent may be invalidated presents a separate issue for purposes of issue preclusion. However, in *Power Integrations* the question of whether invalidity is a single issue was not argued before the Court. Moreover, the parties there did not cite any authority in support of, or contrary to, Plaintiffs' proposition that validity is a single issue for purposes of issue preclusion. See, e.g., Roche Palo Alto LLC v. Apotex, Inc., 526 F. Supp. 2d 985, 995-96 (N.D. Cal. 2007) (holding validity is single issue); Meritor Transmission Corp. v. Eaton Corp., 2006 WL 3951711, at *5 (W.D.N.C. Sept. 26, 2006) (agreeing with "courts [holding] the validity of a patent is a single issue for purposes of collateral estoppel") (internal quotation marks omitted); Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp., 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006) (stating that "overwhelming weight of authority suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or individual pieces of evidence and arguments that may have been necessary to support the validity determination"); Advanced Display Sys., Inc. v. Kent State Univ., 2002 WL 1489555, at *10 (N.D. Tex. July 10, 2002) ("All the invalidity defenses raised by ADS have been rejected . . . [t]o the extent that any other defenses exist, ADS is precluded from litigating them under the doctrine of collateral estoppel."); Pall Corp. v. Fisher Scientific Co., 962 F. Supp. 210, 213 (D. Mass. 1997) (holding validity is single issue, so "[e]ven assuming that Fisher now seeks to invalidate the patent on different grounds than those asserted by MSI in the [prior action], the issue remains the same"); Zip Dee, Inc. v. Domestic Corp., 905 F. Supp. 535, 537-38 (N.D. Ill. 1995) (distinguishing between issues and arguments in support of issues).

Also persuasive is Plaintiffs' analogy to negligence law. According to the Restatement of Judgments 2d § 27 cmt. c, illus. 4 (1982), if A brought an action against B, asserting that B was negligent for speeding, and a court ruled in favor of B, A would be precluded from bringing another action against B for negligence based on another theory. Similarly, here, because Cobalt sought to invalidate the '314 patent under theories of obviousness and improper reissue in the 2010 calcium litigation, Cobalt is precluded from seeking to invalidate the '314 patent based on other theories of invalidity.

2. Watson Is Cobalt's Successor

Given that Cobalt is precluded from relitigating the issue of validity, Watson is also precluded as Watson is Cobalt's successor in interest. "Persons acquiring an interest in property that is a subject of litigation are bound by, or entitled to the benefit of, a subsequent judgement, despite a lack of knowledge." Golden State Bottling Co. v. NLRB, 414 U.S. 168, 179 (1973); see also Taylor v. Sturgell, 553 U.S. 880, 893-94 (2008) (identifying succeeding property ownership as exception to general rule against nonparty claim preclusion).

On June 16, 2009, Watson's parent entered into a Share Purchase Agreement to purchase the Arrow Group, subject to certain conditions. (D.I. 281 Ex. 2 ¶ 10) The Arrow Group

included Cobalt. (Id. ¶ 2) On December 2, 2009, Watson's parent acquired the Arrow Group. (Id. ¶ 14) As of the date of the acquisition, Watson's parent controlled Cobalt, including in the 2010 calcium litigation. (Id. ¶ 17) Additionally, Watson's parent controls Cobalt in the appeal of the 2010 calcium litigation. (Id. ¶¶ 29, 30) Moreover, the parties have stipulated that Watson's parent's "control" over Cobalt has the same meaning as set forth in Montana v. United States, 440 U.S. 147, 154 (1979), and Taylor v. Sturgell, 553 U.S. 880, 895 (2008) (stating that "a nonparty is bound by a judgment if she 'assume[d] control' over the litigation in which that judgment was rendered). (D.I. 281 Ex. 2 ¶ 31)

In *Montana*, 440 U.S. at 153-54, the Supreme Court stated that "[t]o preclude parties from contesting matters that they have had a full and fair opportunity to litigate protects their adversaries from the expense and vexation attending multiple lawsuits, conserves judicial resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions." The Court added that these interests also arise when non-parties assume control over litigation. *See id.* at 154. This is what has occurred here: Watson's parent assumed control over Cobalt's participation in the 2010 calcium litigation. The facts and stipulation indicate that Watson, through Watson's parent, had control and an interest in the prior 2010 calcium litigation, and therefore a full and fair opportunity to litigate. Thus, Watson, as Cobalt's successor in interest, is precluded from challenging the validity of the '314 patent. Accordingly, the Court will grant Plaintiffs' motion for partial summary judgment on issue preclusion as to Watson.

3. Egis is Not Watson's Proxy

A party "is not bound by a judgment to which [it] was not a party." *Taylor*, 553 U.S. at 898. "Extending the preclusive effect of a judgment to a nonparty runs up against the deep-

rooted historic tradition that everyone should have his own day in court." *Id.* at 881 (internal quotation marks omitted). However, preclusion may apply when a party "who did not participate in litigation later brings suit as the designated representative or agent of a person who was a party to the prior adjudication." *Id.*

Here, Plaintiffs contend Egis is precluded from litigating the validity of the '314 patent because Egis is Watson's proxy, so Egis, like Watson, should be precluded. The record does not support Plaintiffs. The July 31 Cooperation Agreement describing Arrow's relationship with Egis does not establish that Egis is a proxy. While that agreement states that

and

(D.I. 281 Ex. 30 at W0017573-74, § 5.1(ii)), it also states that

(id. at W0017587, § 15.3). Moreover, Egis moved to be dismissed from this case (D.I. 162), which would be odd conduct for a purported proxy (since Plaintiffs suggest Egis's role in this litigation is to press invalidity theories Watson itself is precluded from litigating). "[D]oubts about [collateral estoppel's] application should usually be resolved against its use." Witkowski v. Welch, 173 F.3d 192, 206 (3d Cir. 1999) (internal citations omitted); see also Taylor, 553 U.S. at 906 ("[C]ourts should be cautious about finding preclusion . . . [P]reclusion is appropriate only if the putative agent's conduct of the suit is subject to the control of the party who is bound by the prior adjudication."). Accordingly, the Court will deny Plaintiffs' motion

for partial summary judgment on issue preclusion as to Egis.⁵

V. <u>CONCLUSION</u>

Trial will proceed as scheduled. An appropriate Order follows.

⁵The Court's rulings with respect to enforceability are the same as those for invalidity: Watson is precluded from challenging the enforceability of the '314 patent, but Egis is not so precluded.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,

:

Plaintiffs,

C.A. No. 10-915-LPS

v.

WATSON LABORATORIES, INC. (NV) and EGIS PHARMACEUTICALS PLC,

:

Defendants.

ORDER

At Wilmington this 14th day of November, 2012, for the reasons set forth in the Memorandum Opinion issued this date, IT IS HEREBY ORDERED that:

- 1. Defendant's Motion for Summary Judgment of No Infringement Under the Doctrine of Equivalents (D.I. 283) is DENIED WITHOUT PREJUDICE.
- 2. Plaintiffs' Motion for Partial Summary Judgment that Issue Preclusion Bars
 Defendants from Relitigating the Validity and Enforceability of Claims 6 and 8 of the '314
 Patent (D.I. 279) is GRANTED with respect to Watson and DENIED with respect to Egis.

UNITED STATES DISTRICT JUDGE