

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SPECTRUM PHARMACEUTICALS, INC.	)	
and UNIVERSITY OF STRATHCLYDE,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 12-260-RGA-CJB
	)	
INNOPHARMA, INC., MYLAN TEORANTA,	)	
MYLAN INSTITUTIONAL LLC, and MYLAN	)	
INSTITUTIONAL INC.,	)	
	)	
Defendants.	)	
_____	)	

**REPORT AND RECOMMENDATION**

Pending before the Court in this patent infringement action are three summary judgment motions. Defendants Mylan Teoranta, Mylan Institutional LLC, and Mylan Institutional Inc. (collectively, “Defendants”) filed a Motion for Summary Judgment of Noninfringement of Claims 5 through 14 of U.S. Patent No. 6,500,829 (the “’829 patent”) (“Defendants’ Non-infringement Motion”), (D.I. 197), and a Motion for Summary Judgment of Invalidity of Claims 1 and 2 of the ’829 Patent (“Defendants’ Invalidity Motion”), (D.I. 196). Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and the University of Strathclyde (collectively, “Plaintiffs”) filed a single motion, entitled Motion for Summary Judgment that Rees 1986 Does Not Invalidate the ’829 Patent (“Plaintiffs’ Validity Motion”), (D.I. 204). During the pendency of these motions, a parallel District of Nevada action on the ’829 patent proceeded to trial, involving the same Plaintiffs and similar accused products, and the District of Nevada held that certain claims of the ’829 patent are invalid or not infringed. (*Spectrum Pharms., Inc. v. Sandoz Inc.*,

Civil Action Number 12-111-GMN-RJJ (D. Nev.) (the “Nevada Action”), D.I. 313, 365) In light of that development, both Plaintiffs and Defendants have submitted letter briefs arguing that the pending motions cannot be heard on their merits, and that the Court must instead resolve this action on collateral estoppel grounds. (*See* D.I. 263, 264, 266, 267) For the reasons that follow, the Court recommends that Defendants’ Non-infringement Motion be GRANTED on collateral estoppel grounds as to claims 5-9 of the '829 patent and DENIED as moot with regard to claims 10-14 of the '829 patent, that Defendants’ Invalidity Motion be GRANTED on collateral estoppel grounds, that Plaintiff’s Validity Motion be DENIED as moot, and that judgment be entered in favor of Defendants.

## **I. BACKGROUND**

### **A. The Patent-in-Suit**

Plaintiffs assert infringement of the '829 patent, entitled “Substantially Pure Diastereoisomers of Tetrahydrofolate Derivatives[.]” (D.I. 1, ex. A) The patent issued on December 31, 2002. (*Id.*) At the time of its issue, the '829 patent was assigned to the University of Strathclyde, who subsequently issued an exclusive license to Spectrum. (D.I. 100 at ¶ 13)

The present invention centers on 5-formyltetrahydrofolic acid, a chemical compound commonly known as leucovorin. ('829 patent, col. 1:28-29) The leucovorin compound is composed of equal amounts of two diastereoisomers, referred to as the “(6S)” and “(6R)” diastereoisomers. (D.I. 47 at 2; D.I. 52 at 1) The '829 patent asserts, however, that a report from 1981 found that only the (6S) diastereoisomer—also known as levoleucovorin—is responsible for leucovorin’s beneficial clinical effects. ('829 patent, col. 1:57-61; D.I. 52 at 2) Other reports suggested that the (6R) diastereoisomer might actually inhibit the beneficial effects of the (6S)

diastereoisomer. ('829 patent, cols. 1:62-2:12) Accordingly, the present invention relates to the preparation of a substantially pure form of the desired (6S) diastereoisomer from leucovorin.

(*Id.*, Abstract; *id.*, Fig. 4; *see also* D.I. 52 at 3)

**B. The Co-Pending Nevada Action**

On January 20, 2012, prior to filing the present action, Plaintiffs brought an action for infringement of the '829 patent against Sandoz Inc. (“Sandoz”) in the District of Nevada (the “Nevada Action”). (Nevada Action, D.I. 1 at ¶¶ 1, 22, 24) The Nevada Action has since proceeded through summary judgement, (Nevada Action, D.I. 313), and a bench trial, culminating in a judgment in favor of Sandoz, (Nevada Action, D.I. 365). The Nevada District Court held that claims 5-9 of the '829 patent were not infringed by Sandoz, (Nevada Action, D.I. 313 at 25), and that claims 1-2 of the '829 patent are invalid as obvious, (Nevada Action, D.I. 365 at 44-45). The Nevada Action is currently on appeal to the United States Court of Appeals for the Federal Circuit. (D.I. 270)

**C. The Present Motions**

This action was referred to the Court by Judge Richard G. Andrews on May 23, 2012, to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. Briefing on the pending motions for summary judgment was completed on December 9, 2014, (D.I. 242, 243, 245), and oral argument was requested on December 12, 2014, (D.I. 246). The Court held oral argument on the pending motions on March 10, 2015. Subsequent to the hearing, at the request of the parties, (D.I. 262), the Court issued an oral order allowing them to submit supplemental letter briefing regarding the issue of collateral estoppel in light of the

decisions in the Nevada Action.<sup>1</sup>

## II. STANDARD OF REVIEW

### A. Summary Judgment

A grant of summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). 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, 585-86 (1986). If the moving party meets this burden, the nonmovant must then “come forward with specific facts showing that there is a *genuine issue for trial*.” *Id.* at 587 (emphasis in original) (internal quotation marks omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, 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).

However, in order to defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586-87; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal

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<sup>1</sup> Plaintiffs have also filed a Motion for Leave to File a Reply regarding the collateral estoppel issue, (D.I. 268), and Defendants have responded to that motion, (D.I. 269).

quotation marks and citation omitted). The “mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are “material,” and a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials”; or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B).

**B. Collateral Estoppel**

The issue of collateral estoppel in a patent action in this district is governed by the law of the United States Court of Appeals for the Third Circuit, unless the determination involves substantive issues of patent law. *See Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citation omitted). The Third Circuit’s articulation of the collateral estoppel standard has varied, but it applies the general rule set forth in the Second Restatement of Judgments: ““When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is

conclusive in a subsequent action between the parties, whether on the same or a different claim.”<sup>2</sup> *Jean Alexander Cosmetics, Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (quoting Restatement (Second) of Judgments § 27 (1982)). The Third Circuit has articulated a set of requirements for the application of collateral estoppel, including that: “(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action.” *Id.* (internal quotation marks and citations omitted); *see Raytech Corp. v. White*, 54 F.3d 187, 190 (3d Cir. 1995) (setting forth the four-factor test). In addition, that Court has also considered “whether the party being precluded had a full and fair opportunity to litigate the issue in question in the prior action, and whether the issue was determined by a final and valid judgment[.]” *Jean Alexander Cosmetics*, 458 F.3d at 249 (internal quotation marks and citations omitted); *see Haize v. Hanover Ins. Co.*, 536 F.2d 576, 579 (3d Cir. 1976) (quoting Restatement of Judgments § 68(1) (1942)). The doctrine of collateral estoppel applies to relitigation of both issues of fact and issues of law. *U.S. v. Stauffer Chem. Co.*, 464 U.S. 165, 170-71 (1984) (citation omitted).<sup>2</sup>

With regard to patent issues specifically, collateral estoppel prevents a patentee from relitigating a determination of invalidity or non-infringement. *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 350 (1971); *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1381-82 (Fed. Cir. 2013). The application of collateral estoppel does not require the claims or accused products to be identical to those at issue in the prior proceeding.

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<sup>2</sup> The pendency of an appeal is not a barrier to applying collateral estoppel. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999); *Galderma Laboratories v. Amneal Pharm.*, 921 F. Supp. 2d 278, 281 (D. Del. 2012).

*See Ohio Willow Wood*, 735 F.3d at 1342 (holding that collateral estoppel prevented a patentee from asserting claims that are “substantially similar” to claims that had previously been held invalid); *Aspex Eyewear, Inc.*, 713 F.3d at 1381-82 (holding that plaintiff’s infringement allegation was precluded by collateral estoppel where the accused products in the instant suit were “materially identical” to another entity’s products previously held not to infringe the asserted patent).

### **III. DISCUSSION**

#### **A. The Motions for Summary Judgment**

In their letter briefs, Defendants ask the Court to resolve their pending motions on the basis of collateral estoppel, as opposed to reaching the merits of the motions.<sup>3</sup> (D.I. 264 at 3; D.I. 267 at 1-3) Plaintiffs do not dispute that collateral estoppel applies. (D.I. 263 at 1) The only remaining dispute is how, procedurally, to resolve the case. Defendants ask this Court to grant their summary judgment motions, (D.I. 264 at 3), whereas Plaintiffs seek entry of judgment in favor of Defendants, and for this Court to deny Defendants’ summary judgment motions as moot. (D.I. 263 at 1) The Court will address each of the three pending summary judgment motions in turn.

First, regarding Plaintiffs’ Validity Motion, neither party asks the Court to grant the

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<sup>3</sup> Defendants asserted, in their opening letter brief, that they still sought summary judgment on the merits of their motions, in addition to seeking summary judgment based on collateral estoppel. (D.I. 264 at 3 (“Accordingly, we ask that Mylan’s summary judgment motions be granted not only for the reasons discussed at oral argument on March 10, 2015, but also for the reason that collateral estoppel requires judgment in Mylan’s favor.”)) Defendants later clarified that they now seek judgment solely on collateral estoppel grounds. (D.I. 269 at 1 (“[Defendants] no longer seek judgment based on the grounds discussed at the March 10 oral argument, but only on collateral estoppel grounds”))

motion at this time; both parties agree that the motion should be denied. (*See* D.I. 263 at 1 (arguing that the Plaintiffs’ Validity Motion should be denied as moot); D.I. 267 at 1 n.1 (asserting that the Plaintiffs’ Validity Motion must be denied because it “conflicts with the Nevada decision holding claims 1 and 2 *invalid*”)) As such, and in light of the nature of the resolution of the remaining motions, the Court recommends that the District Court deny Plaintiffs’ Validity Motion as moot.

Second, with regard to Defendants’ Non-infringement Motion, the parties agree that the non-infringement bases presented in the Nevada Action are factually identical to the non-infringement bases presented in this action, and that the remaining requirements for collateral estoppel are met as to claims 5-9 of the '829 patent.<sup>4</sup> (*See* D.I. 263 at 2 (“there is no dispute that those [non-infringement] issues were actually litigated” in the Nevada Action); D.I. 264 at 2 (stating that “the identical issue was previously litigated”)) The only remaining dispute is whether this Court should grant the motion (Defendants’ position) or deny it as moot (Plaintiffs’ position). Defendants ask the Court to grant the motion, rather than entering judgment and denying the motion as moot, because they seek to preserve their ability to make arguments on appeal:

If the Court issues an order consistent with Spectrum’s request [to deny Defendants’ summary judgment motions as moot], Spectrum might have no reason to appeal this Court’s decision, but instead,

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<sup>4</sup> The present non-infringement motion, as submitted, also seeks summary judgment on claims 10-14 of the '829 patent, which were not at issue in the Nevada Action. (D.I. 197; D.I. 199 at 1, Nevada Action D.I. 313 at 13) At oral argument, however, Plaintiffs clarified that they are no longer asserting that claims 10-14 of the '829 patent are infringed by Defendants. (Oral Argument Transcript (“Tr.”) at 67-68; *see also* D.I. 264 at 3 n.1) In light of Plaintiffs’ statements during oral argument, the Court recommends Defendants’ Non-infringement Motion be denied as moot with regard to claims 10-14 of the '829 patent.

might simply hope to vacate the final judgment under Fed. R. Civ. P. 60(b)(5) in the event the Federal Circuit reverses the Nevada Court. Under that scenario, Mylan might be deprived of the opportunity to participate in appellate arguments on the merits of its invalidity and noninfringement arguments.

(D.I. 267 at 2)

In the end, Plaintiffs offer no meaningful argument that summary judgment is inappropriate with regards to Defendants' Non-infringement Motion. Under these circumstances, Defendants are "legally entitled" to have their motion granted, and the Court may do so without addressing its merits or the merits of the Nevada Court's decision. *See DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, — F. Supp. 3d —, CIVIL ACTION NO. 2:12-cv-00764-WCB-RSP (LEAD CASE), 2014 WL 4961992, at \*1-3, \*6 (E.D. Tex. Oct. 3, 2014) (Bryson, J., sitting by designation) (granting summary judgment motion on collateral estoppel grounds after another court held that the patent-in-suit was not subject-matter eligible). Such a resolution would at least allow for the possibility that, if Plaintiffs appeal the grant of summary judgment, Defendants could make their own arguments on appeal to the Federal Circuit as to why the grant of the non-infringement motion is well taken, arguments that may be different than those put forward by Sandoz. *Id.* at \*6; (*see also* D.I. 267 at 3). As such, the Court recommends that the District Court grant Defendants' Non-infringement Motion on collateral estoppel grounds.

Lastly, Defendants' Invalidity Motion involves a somewhat different question. That motion seeks a determination of invalidity of claims 1 and 2 of the '829 patent. (D.I. 251 at 1) Unlike Defendants' Non-infringement Motion, the particular grounds of this motion were not adjudicated in the prior case.

By way of background, Defendants' Invalidity Motion seeks summary judgment on the grounds that claims 1 and 2 of the '829 patent are obvious in light of a combination of two references: a commercial pharmaceutical composition called "Wellcovorin[,]" which consisted of a "50-50% mixture of the (6S) and (6R) diastereoisomers of leucovorin[,]" combined with a prior invention of substantially pure (6S) leucovorin by a U.S.-based researcher named Dr. Donna Cosulich. (D.I. 251 at 1-4) Defendants allege that Dr. Cosulich's invention was described in several scientific publications, as well as in a patent, which the Court will refer to collectively as the "Cosulich References." (D.I. 251 at 3) According to Defendants, "it would have been obvious to substitute that substantially pure (6S) leucovorin [created by Dr. Cosulich] for the less pure mixture being used in the [Wellcovorin] commercial pharmaceutical composition[,]" which would result in a product that meets all of the elements of claims 1 and 2. (*Id.* at 1)

The Nevada Court, however, found that claims 1 and 2 of the '829 patent were rendered obvious on different grounds. (Nevada Action, D.I. 365 at 37-44) There, the Court held that:

[A] person of ordinary skill knew in September 1986 that leucovorin existed as a mixture of desired (6S) and undesired (6R) isomers, and that its therapeutic usefulness derives wholly from the (6S) isomer. . . . These facts alone make the composition of claims 1 and 2 of the '829 patent prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified.

(*Id.* at 38 (internal quotation marks and citations omitted)) That determination was based only in part on a reference authored by Dr. Cosulich (submitted at trial as exhibit PTX 14); the Court also cited numerous other references and trial exhibits in support of its obviousness finding. (*Id.* at 17, 38) The Court also found, without any further consideration of PTX 14, that: (1) the prior

art “provided an explicit teaching to purify the (6S) isomer[.]” (2) “the desired (6S) isomer previously had been isolated and was in the prior art[.]” and (3) the objective indicia of nonobviousness at issue did not render the claims nonobvious. (*Id.* at 38-44) Thus, it was only after consideration of a number of other references that the Court concluded that claims 1 and 2 were invalid as obvious. (*Id.* at 37-44)

Nonetheless, the parties agree that collateral estoppel applies, based on the Nevada Court’s ultimate determination that the claims are invalid. (*See* D.I. 263 at 2 (stating that “[v]alidity is treated as a single issue for purposes of collateral estoppel”); D.I. 264 at 2) The question, though, is how to address Defendants’ Invalidation Motion procedurally.

Plaintiffs ask the Court to deny the motion as moot. But in doing so, they appear to suggest that otherwise, a grant of the motion would amount to a “substantive” determination that “no questions of fact remain on [the asserted prior art references at issue in this case.]” (D.I. 263 at 2-3) They argue that such a determination would be improper because issues of fact do indeed remain as to those references. (*Id.*)

Defendants, however, have since clarified that they do not seek judgment on the merits. (D.I. 269 at 1) As such, the Court interprets Defendants’ collateral estoppel argument as putting forward an alternate basis for the grant of their motion—rather than as an argument that no issues of fact remain and Defendants are entitled to judgment as a matter of law as to the specific grounds of the motion (i.e., a determination that the combination of the Wellcovorin reference and the Cosulich References render the claims obvious). In that case, any differences between the arguments presented by the motion and those addressed by the Nevada Court are irrelevant. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999)

("[I]t is clear from the case law that has developed since *Blonder-Tongue* that an inappropriate inquiry is whether the prior finding of invalidity was correct; instead, the court is only to decide whether the patentee had a full and fair opportunity to litigate the validity of his patent in the prior unsuccessful suit.") (quoting *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983)) (alteration in original); *Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp.*, No. A-03-CA-754-SS, 2006 WL 1544621, at \*5 (W.D. Tex. May 31, 2006) ("[T]he 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 the individual pieces of evidence and arguments that may have been necessary to support the validity determination."). The Court therefore recommends that the District Court grant Defendants' Invalidity Motion on collateral estoppel grounds. *See Apeldyn Corp. v. Sony Corp.*, — F. Supp. 3d —, 2015 WL 1534347, at \*8 (D. Del. Apr. 2, 2015) (granting summary judgment due to collateral estoppel, and in doing so, noting that the Court did not consider the moving party's alternative argument seeking summary judgment of non-infringement on the merits).

Because the decisions set out above resolve all issues in this case,<sup>5</sup> the Court recommends

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<sup>5</sup> The final remaining motion is Plaintiffs' Motion for Leave to File a Reply, (D.I. 268). In that motion, Plaintiffs allege that "Mylan's responsive letter brief set forth for the first time its argument as to why it is entitled to a decision *on the merits* of its pending summary judgment motions, which has been disputed since this issue was raised prior to oral argument on summary judgment." (D.I. 268 at 1 (emphasis in original)) Plaintiffs' argument fails because Defendants disclosed this argument in their opening brief, and Plaintiffs had an opportunity to respond in their answering brief. (*See* D.I. 264 at 3 (Defendants stating that "we ask that Mylan's summary judgment motions be granted not only for the reasons discussed at oral argument on March 10, 2015, but also for the reason that collateral estoppel requires judgment in Mylan's favor")) In any event, as noted above, Defendants have since stated that they do not seek judgment on the merits. (D.I. 269 at 1) As such, the Court will not consider Plaintiffs' reply

that the District Court enter judgment in favor of Defendants.<sup>6</sup>

#### IV. CONCLUSION

For the reasons set forth above, the Court recommends that Defendants' Non-infringement Motion be GRANTED on collateral estoppel grounds as to claims 5-9 of the '829 patent and DENIED as moot as to claims 10-14 of the '829 patent, that Defendants' Invalidity Motion be GRANTED on collateral estoppel grounds, and that Plaintiffs' Validity Motion be DENIED as moot. The Court also DENIES Plaintiffs' Motion for Leave to File a Reply.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1) and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>.

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brief, and the Court hereby DENIES Plaintiffs' Motion for Leave to File a Reply, (D.I. 268).

<sup>6</sup> In their opening letter brief, Plaintiffs ask the Court to enter judgment with a provision that final judgment be vacated if the Federal Circuit reverses or vacates the judgment in the Nevada Action. (D.I. 263 at 3) The Court recommends that the District Court decline to enter such a provision, because it is unnecessary. In the event that the Federal Circuit reverses or vacates the Nevada Action, Plaintiffs may file a Federal Rule of Civil Procedure 60(b)(5) motion for relief from the judgment.

Dated: May 22, 2015

  
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Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE