

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

JANSSEN BIOTECH, INC., and  
NEW YORK UNIVERSITY

Plaintiffs,

v.

CELLTRION HEALTHCARE CO., LTD.,  
CELLTRION, INC., and  
HOSPIRA, INC.

Defendants.

**Civil Action No. 1:15-cv-10698  
Civil Action No. 1:16-cv-11117**

REQUEST FOR ORAL ARGUMENT

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION *IN LIMINE*  
NO. 4: TO PRECLUDE EVIDENCE AND ARGUMENT FROM JANSSEN  
CONCERNING CHANGE TO MEDIA COMPOSITIONS FROM SINGAPORE**

**I. INTRODUCTION**

To support its claim for induced infringement, Janssen seeks to use evidence of measures to “avoid further infringement” taken during the pendency of this lawsuit to “support[] an inference of knowing infringement.” Dkt. 281 at 16; Dkt. 305 at 11. But any such evidence is inadmissible based on the plain language of Federal Rule of Evidence 407, which states that “[w]hen measures are taken that would have made an earlier injury or harm less likely to occur,” *i.e.*, measures are taken to “avoid” the alleged injury or harm, “evidence of the subsequent measures is not admissible to prove...culpable conduct.” Fed. R. Evid. 407.

Janssen’s only argument is that Rule 407 does not apply to patent cases, based on the notion that the rule is allegedly limited to cases involving “steps [taken] in furtherance of added safety.” Dkt. 305 at 12. Janssen is wrong. Rule 407 is “not limited to products liability cases,” *Gilanian v. City of Boston*, 431 F. Supp. 2d 172, 177 (D. Mass. 2006), or to other cases in the traditional personal injury context. Numerous courts—including the Federal Circuit—have

applied Rule 407 outside these scenarios, including in multiple patent cases, where multiple courts have held that the Rule “bars evidence of subsequent remedial action in proving culpability for a prior act or event.” *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1221 (Fed. Cir. 1995) (patent case). Under Rule 407, therefore, Janssen may not attempt to persuade the jury that steps taken to “avoid further infringement” demonstrate “culpability for...prior act[s]” of infringement that Janssen alleges in this case. Dkt. 281 at 16; *Pall Corp.*, 66 F.3d at 1221.

## II. ARGUMENT

Previously, the accused products—powdered compositions that Celltrion uses to make cell culture media in South Korea, to grow cells that produce infliximab antibody—were manufactured by GE HyClone<sup>1</sup> in Logan, Utah. No. 16-11117 Dkt. 1 at 2. Because the accused products were made “in the United States,” Janssen claims that they “infringe claims of Janssen’s 083 patent.” *Id.* Janssen also alleges that Celltrion is vicariously liable for the alleged direct infringement by GE HyClone, and that Celltrion and Hospira are liable for inducing it. *Id.* at 23-27.

During this case, Celltrion began purchasing media compositions from GE HyClone’s facility in Singapore, with the Logan, Utah manufacturing facility only available in the unlikely event a backup is ever needed. Dkt. 282 ¶ 87. Because a claim of direct infringement based on the making of a product is limited to products made “within the United States,” 35 U.S.C. § 271(a), the conduct alleged to infringe the ’083 patent has ceased. There can be no vicarious liability where there is no infringement, of course, and “there can be no inducement of

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<sup>1</sup> HyClone is now a subsidiary of GE Healthcare. To avoid confusion, the entity is referred to herein as “GE HyClone.”

infringement without direct infringement.” *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002).

Because Janssen’s claim of “[i]nduced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement,” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011), Janssen asserts that evidence of the change in media product manufacturing locations is circumstantial “evidence supporting an inference of knowing infringement.” Dkt. 305 at 10-11. As Janssen puts it, Celltrion is “fleeing the jurisdiction.” Dkt. 281 at 16; Ex. 1, 12/21/16 Hear. Tr. at 131:23.

Janssen’s argument is squarely prohibited by Rule 407. “When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove...culpable conduct.” Fed. R. Evid. 407. The Rule “bars evidence of subsequent remedial action in proving culpability for a prior act or event.” *Pall Corp.*, 66 F.3d at 1221. As explained above, there can be no claim of infringement now that Celltrion purchases the media products from outside the United States. Janssen’s argument that Celltrion’s change to sourcing media products from Singapore “avoid[s] further infringement” makes it a subsequent remedial measure—that is, a “measure[.]...taken that would have made an earlier injury or harm less likely to occur.” Dkt. 281 at 16; Fed. R. Evid. 407. Because induced infringement “requires evidence of culpable conduct,” *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006), Rule 407 prohibits exactly what Janssen seeks to do here: use the change to prove the “culpable conduct” that is “require[d]” for induced infringement. Fed. R. Evid. 407.

Janssen argues Rule 407 does not have “anything to do with” this case because one of the reasons for the Rule is a “social policy of encouraging people to take, or at least not discouraging

them from taking, steps in furtherance of added safety.” Dkt. 305 at 12 (quoting Fed. R. Evid. 407 Adv. Comm. Notes); Ex. 1, 12/21/16 Hear. Tr. at 131:20. That is not true. Nothing in the language of Rule 407 limits it to cases involving “injury or harm” that is personal or physical in nature.

Indeed, Rule 407 has been applied in many contexts outside personal injury. *See, e.g., PLC Med. Sys., Inc. v. Eclipse Surgical Techs., Inc.*, 976 F. Supp. 89, 90 (D. Mass. 1997) (revision of FDA protocol in light of copyright infringement suit); *S. E. C. v. Geon Indus., Inc.*, 531 F.2d 39, 52 (2d Cir. 1976) (regulations enacted to prevent securities violations); *R.M. Perlman, Inc. v. N.Y. Coat, Suit, Dresses, Rainwear & Allied Workers’ Union Local 89-22-1, I.L.G.W.U., AFL-CIO*, 33 F.3d 145, 156 (2d Cir. 1994) (modifications to clause challenged as unlawful under National Labor Relations Act); *Reynolds v. Univ. of Pa.*, 483 F. App’x 726, 733 (3d Cir. 2012) (changes to a website in breach of contract case); *Dennis v. Cty. of Fairfax*, 55 F.3d 151, 154 (4th Cir. 1995) (Title VII discrimination case); *Pastor v. State Farm Mut. Auto. Ins. Co.*, 487 F.3d 1042, 1045 (7th Cir. 2007) (revisions to a contract); *Lust v. Sealy, Inc.*, 383 F.3d 580, 585 (7th Cir. 2004) (evidence related to employment discrimination); *Ford v. Schmidt*, 577 F.2d 408, 410–11 (7th Cir. 1978) (evidence in Section 1983 suit challenging prison policy); *Higginbotham v. Baxter Int’l, Inc.*, 495 F.3d 753, 760 (7th Cir. 2007) (changes to financial controls in securities litigation); *Hickman v. GEM Ins. Co.*, 299 F.3d 1208, 1214 (10th Cir. 2002) (changes in practices related to the interpretation of insurance policy); *Specht v. Jensen*, 863 F.2d 700, 701 (10th Cir. 1988) (evidence in action to recover under Section 1983 for illegal search).

No logical reason supports Janssen’s artificial limitation on Rule 407. In fact, the Federal Circuit has specifically recognized that Rule 407 applies in patent cases. In *Pall Corp.*, the district court had found that the defendant infringed, and enhanced damages for sales of the

accused product, nylon 66, after the defendant partially switched to a non-infringing alternative, nylon 46. *Pall Corp.*, 66 F.3d at 1221. The Federal Circuit noted that Rule 407 “bars evidence of subsequent remedial action in proving culpability for a prior act or event.” *Id.* While in that case the Rule had not been violated, the Federal Circuit assumed without question that Rule 407 applied. *Id.* This is not surprising, since the Federal Circuit recognizes that “[p]atent infringement is a tort.” Dkt. 344 at p. 2 (citing *Wordtech Sys., Inc. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010)); No. 16-1117 Dkt. 1 at 25-27; *see also Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33 (1931) (“Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee.”)).

Many district courts have applied Rule 407 to patent cases too. The Northern District of Illinois, for instance, refused to permit discovery into efforts to modify an accused product after awareness of the asserted patent, holding such evidence “falls squarely within the prohibition of Fed. R. Evid. 407.” *Vardon Golf Co. v. BBMG Golf Ltd.*, 156 F.R.D. 641, 652 (N.D. Ill. 1994). In *Vardon*, the court recognized that “culpable conduct” under Rule 407 “has a broader scope than just negligent conduct, and we think its scope is broad enough to reach patent infringement actions.” *Id.* The *Vardon* court held that allowing such evidence “would create a disincentive for [defendant] to discontinue the infringing conduct.” *Id.* Numerous other courts agree that Rule 407 applies to patent cases.<sup>2</sup>

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<sup>2</sup> *E.g.*, *Mikkelsen Graphic Eng’g Inc. v. Zund Am., Inc.*, No. 07-0391, 2011 WL 1330782, at \*11 (E.D. Wis. Apr. 7, 2011), *aff’d in part, vacated in part*, 541 F. App’x 964 (Fed. Cir. 2013) (evidence of removal of search function inadmissible); *Deflecto, LLC v. Dundas \* Jafine Inc.*, No. 13-0116, 2015 WL 9413148, at \*2 (W.D. Mo. Dec. 22, 2015) (“[I]ntroducing the Modified ProMax to prove that Defendant knew the Original ProMax allegedly infringed Plaintiff’s patents is precisely the type of evidence [Rule] 407 is designed to preclude”); *Tyco Healthcare Grp. LP v. Applied Med. Res. Corp.*, No. 09-176, 2011 WL 7563868, at \*3 (E.D. Tex. Sept. 23, 2011) (prohibiting argument that “recent replacement of the pleated skirt shield in the accused trocars is evidence that the pleated skirt shield trocars infringes the Smith patents”);

The only decision Janssen has identified, and Defendants have found, declining to apply Rule 407 in the patent context did so based on a misreading of another case. In *Kowalski v. Anova Food, LLC*, the court stated that “[c]ourts have held in patent infringement cases that the design changes are not ‘subsequent remedial measures’ within the meaning of Fed. R. Evid. 407.” *Kowalski v. Anova Food, LLC*, No. 11-795, 2015 WL 1119411, at \*3 (D. Haw. Feb. 18, 2015) (citing *Duhn Oil Tool, Inc. v. Cameron Int’l Corp.*, No. 05-1411, 2011 WL 121547, at \*1 (E.D. Cal. Jan. 13, 2011)). But the case *Kowalski* cites, *Duhn Oil Tool*, actually reaches the opposite conclusion. In *Duhn Oil Tool*, the court granted in part and denied in part the defendant’s motion *in limine*, stating that “Duhn Oil may offer evidence of the design changes Cameron made to its mandrels, on the issue of willful infringement **but cannot argue** that these design changes are ‘subsequent remedial measures’ within the meaning of Fed. R. Evid. 407.” *Duhn Oil Tool*, 2011 WL 121547, at \*1 (emphasis added). The *Duhn Oil Tool* court did apply Rule 407: “Duhn Oil may not argue that Cameron’s mandrel design changes in any way evidence Cameron’s belief that its earlier designs were infringing the ’925 patent.” Ex. 2, *Duhn Oil Tool, Inc. v. Cameron Int’l Corp.*, No. 05-1411, Dkt. 652 at ii-iii (E.D. Cal. Jan. 26, 2011).

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*Datatreasury Corp. v. Wells Fargo & Co.*, No. 06-72, 2010 WL 11468934, at \*27 (E.D. Tex. Oct. 5, 2010) (“[E]vidence of deactivation of encryption...cannot be used to prove culpability, e.g., willfulness, of pre-deactivation activity.”); *Plew v. Ltd. Brands, Inc.*, No. 08-3741, 2012 WL 379933, at \*8 (S.D.N.Y. Feb. 6, 2012) (allowing evidence of discontinuation of accused product for limited purpose “of showing the duration of the sales...consistent with Rule 407”); *ABT Sys., LLC v. Emerson Elec. Co.*, No. 11-00374, 2013 WL 468501, at \*2 (E.D. Mo. Feb. 7, 2013) (granting motion *in limine* “to prevent the admission of evidence or testimony regarding subsequent remedial measures to show an admission of infringement”); Tentative Rulings on...Motions in Limine, Dkt. 512 at 10-11, *Interactive Health, LLC v. King Kong USA, Inc.*, No. 06-1902 (C.D. Cal. July 24, 2008) (excluding evidence of defendants’ “sale of different products in lieu of the original accused models...to the extent the Plaintiffs attempt to introduce such evidence to demonstrate culpability”); *see also cf. Gen. Motors Corp. v. Keystone Auto. Indus., Inc.*, 453 F.3d 351, 357 n.1 (6th Cir. 2006) (excluding evidence of removal of trademarked design).

Finally, Janssen may not use evidence of the switch to Singapore media products as “impeachment” evidence. Dkt. 281 at 16; Fed. R. Evid. 407. Janssen claims it will “impeach[]” the Defendants’ “defense of good faith”—*i.e.*, the defense to inducement that there was a good faith basis for noninfringement of the ’083 patent. Dkt. 281 at 16. First, impeachment is a witness-by-witness inquiry depending on the testimony, so the Court can address this issue only in the context of the actual trial. But more importantly, the impeachment exception to Rule 407 cannot be allowed to swallow the rule, and “in effect enable [the proponent] to impeach” in a way that uses the subsequent remedial measure in exactly the way Rule 407 is supposed to guard against. *Harrison v. Sears, Roebuck & Co.*, 981 F.2d 25, 31–32 (1st Cir. 1992) (affirming exclusion of impeachment evidence under Rule 403 where “evidence would have prejudiced Appellees contrary to the intent of Rule 407.”). “The leading commentators have noted the difficulty associated with applying the impeachment exception to Rule 407” because it can be “used as a loophole” for bringing in the evidence the Rule bars. *Id.* (“If the evidence was admitted to impeach Hyde, Appellants’ argument to the jury could have closely paralleled an argument that the subsequent measure could be seen as proof that Appellees were negligent.”). Accordingly, “[t]o guard against the impeachment exception being used as a loophole...trial judges should not abandon their discretionary authority under Federal Rule of Evidence 403 to exclude the use of such evidence.” *Id.* (citing Wright & Graham, Federal Practice and Proc. § 5289, at 148 (1980)). To “impeach” an assertion of a good faith belief in noninfringement by attempting to use the remedial measure to show a belief in infringement would be to do exactly what Rule 407 prohibits, and thus any efforts to do so must be prevented under Rule 403.

### **III. CONCLUSION**

For the foregoing reasons, Defendants respectfully request that the Court grant Defendants' motion *in limine* to preclude evidence and argument from Janssen concerning change to media compositions from Singapore.



Dated: January 12, 2017

Defendants Celltrion Healthcare Co., Ltd.,  
Celltrion, Inc., and Hospira, Inc.

By: /s/Andrea L. Martin

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**CERTIFICATE OF SERVICE**

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 12, 2017.

/s/Andrea L. Martin, Esq.  
Andrea L. Martin, Esq.

**Defendants' Motion *in Limine* No. 4**  
**Exhibit 1**

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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JANSSEN BIOTECH, INC.,	)	
and NEW YORK UNIVERSITY,	)	
	)	
Plaintiffs,	)	
	)	Civil Action
v.	)	No. 15-CV-10698-MLW
	)	
CELLTRION HEALTHCARE CO.,	)	
LTD, CELLTRION, INC., and	)	
HOSPIRA, INC.,	)	
	)	
Defendants.	)	
	)	

BEFORE THE HONORABLE MARK L. WOLF  
UNITED STATES DISTRICT JUDGE

MOTION HEARING

December 21, 2016  
1:33 p.m.

John J. Moakley United States Courthouse  
Courtroom No. 10  
One Courthouse Way  
Boston, Massachusetts 02210

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Peter Lawson, Patterson Belknap, Webb &amp; Tyler LLP

1 limited as however Your Honor thinks is appropriate, no need  
2 for attorneys to testify, but the evidence is admissions and  
3 should come in.

4           Lastly, the Singapore option. We can have argument.  
5 They told us just a few weeks ago, actually, October -- now  
6 slide 61 -- that Celltrion intends to source HyClone products  
7 from Singapore, but it wants to retain the ability to source  
8 HyClone media from Logan if necessary. And should that be  
9 admissible, is that a subsequent remedial measure? We can  
10 argue about it at the appropriate time.

11           THE COURT: I think, assuming we get that far, there  
12 are going to be two issues: One, should it be excluded under  
13 Rule 407. Second, does it have sufficient probative value as  
14 consciousness of guilt. Then there would be a Rule 403  
15 analysis.

16           MR. DISKANT: I understand. If I can just have a  
17 nanosecond to say our point on it.

18           THE COURT: Sure.

19           MR. DISKANT: First, we don't think that 407,  
20 subsequent remedial measures, has anything to do with this.  
21 It's like discovering you have a contaminated shipment of  
22 yogurt and shipping it to India to sell. I don't think, you  
23 know, fleeing the jurisdiction is what this rule is about.

24           I think in terms of its probative value, I think in  
25 any case where you're not going to get the confession or you're

1 going to get the kind of heated arguments that we're going to  
2 get, it will be significantly probative.

3 THE COURT: Yeah. That's a generally applicable  
4 principle. In a range of cases like employment discrimination  
5 cases, judges are urged not to grant summary judgment on the  
6 issue of discriminatory intent because frequently there's not  
7 direct evidence. You have to rely on circumstantial evidence,  
8 admonished to be careful.

9 MR. DISKANT: That would be our point of view. And  
10 I'm content to rest on that if Your Honor wishes.

11 THE COURT: It's now 5:25. I hoped to be further  
12 along, but this has been very valuable. I'm going to take the  
13 two issues that you argued under advisement. I'm ordering you  
14 to come back at 10:00 tomorrow morning. I'll apologize in  
15 advance if I'm still trying to figure this out at 10:00, and  
16 I'll let you know when I'm finished. But I may be able to  
17 decide these two matters that you've argued.

18 Let me ask you this question, though. Is there any  
19 practical significance to Hospira being in this case? In other  
20 words, you said you were going to try this case in two weeks.  
21 I don't think we can finish these arguments in two weeks, but  
22 you'll be -- you won't hear from me when you're before the jury  
23 while the jury is there.

24 But I mean, what's the practical significance of  
25 Hospira being in the case? Is there a way to prevail against

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CERTIFICATE OF OFFICIAL REPORTER

I, Kelly Mortellite, Registered Merit Reporter and Certified Realtime Reporter, in and for the United States District Court for the District of Massachusetts, do hereby certify that pursuant to Section 753, Title 28, United States Code that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Dated this 28th day of December, 2016.

/s/ Kelly Mortellite

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Kelly Mortellite, RMR, CRR

Official Court Reporter



**Defendants' Motion *in Limine* No. 4**  
**Exhibit 2**

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18 UNITED STATES DISTRICT COURT

19 EASTERN DISTRICT OF CALIFORNIA

20 DUHN OIL TOOL, INC.,

21 Plaintiff/Counterclaim-Defendant,

22 vs.

23 CAMERON INTERNATIONAL  
CORPORATION,

24 Defendant/Counterclaim-Plaintiff.  
25

Case No. 1:05-cv-01411-OWW-GSA

**ORDER RE DEFENDANT CAMERON'S  
MOTIONS *IN LIMINE*  
(DOCKET NOS. 528 and 531)**

**Hon. Oliver W. Wanger**

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Pending before this Court are Defendant Cameron’s Motions *in Limine* filed December 14, 2010 (Docket Nos. 528 and 531). The Court having considered all of the parties’ respective moving and opposition papers and related documents, and oral argument, finds as follows:

**1. Cameron’s Motion *in Limine* No. 1, Reference to the Macando Prospect or Gulf of Mexico Oil Spill.**

Cameron’s Motion *in Limine* No. 1 is Granted.

**2. Cameron’s Motion *in Limine* No. 2, Duhn Oil’s Reasons for Terminating Mr. John Rogers.**

Cameron’s Motion *in Limine* is Granted in part and denied in part. Duhn Oil may offer evidence as to reasons for John Rogers’ termination, but limited to the reasons set out in the following documents: D096730, D096731, D096732 and D096736-37.

**3. Cameron’s Motion *in Limine* No. 3, Asserting an Advice of Counsel Defense Regarding Duhn Oil’s Intent for Inequitable Conduct.**

Cameron’s Motion *in Limine* No. 3 is Denied without prejudice.

**4. Cameron’s Motion *in Limine* No. 4, Subsequent Remedial Measures.**

Cameron’s Motion *in Limine* No. 4 is Granted in part and Denied in part. The parties may offer evidence of the changes that Cameron made to its mandrels, but these design changes shall not be considered “subsequent remedial measures” within the meaning of FRE 407. Duhn Oil may not argue that Cameron’s mandrel design changes in any way evidence Cameron’s belief that its earlier designs were infringing the ‘925 patent, or that Cameron’s mandrel

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design changes evidence that earlier Cameron mandrel designs were infringing the '925 patent.

**5. Cameron's Motion in Limine No. 5, Financial State of Cameron.**

Cameron's Motion in Limine No. 5 is Granted.

**6. Cameron's Motion in Limine No. 6; Reference to Motions in Limine.**

Cameron's Motion in Limine No. 6 is Granted.

**7. Cameron's Motion in Limine No. 7; Reference to Denied Summary Judgment Motions.**

Cameron's Motion in Limine No. 7 is Granted.

**8. Cameron's Motion in Limine No. 8, Request for Stipulation and Documents.**

Cameron's Motion in Limine No. 8 is Granted and neither party shall make such requests in the presence of the jury.

**9. Cameron's Motion No. 9 regarding any Reference to Objections during the Reading of Deposition Testimony.**

Cameron's Motion in Limine No. 9 is Granted.

**10. Cameron's Motion in Limine No. 10, The Nature of Any Fact Witness's Preparation for Trial or for Deposition Testimony with that Witness's Counsel.**

Cameron's Motion in Limine No. 10 is Denied without prejudice.

**11. Cameron's Motion in Limine No. 11 in Reference to Courtroom Attendees.**

Cameron's Motion in Limine No. 11 is Granted.

**12. Cameron's Motion in Limine No. 12 regarding Connections to California.**

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IT IS SO ORDERED.

Dated: January 25, 2011

/s/ Oliver W. Wanger  
UNITED STATES DISTRICT JUDGE