OTSUKA PHARMACEUTICAL CO., LTD. v. ZYDUS PHARMACEUTICALS USA INC. et al Doc. 240

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
MYLAN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TORRENT PHARMACEUTICALS LIMITED, INC., TORRENT PHARMA INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., PRINSTON PHARMACEUTICAL INC., and SOLCO HEALTHCARE U.S., LLC,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
AJANTA PHARMA LIMITED, AJANTA PHARMA USA INC., and AUROBINDO PHARMA LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TEVA PHARMACEUTICALS USA, INC.,
Defendant.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TEVA PHARMACEUTICALS USA, INC.,
Defendant.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos.
14-3168 (JBS/KMW)
14-4508 (JBS/KMW)
14-4671 (JBS/KMW)
14-5537 (JBS/KMW)
14-5876 (JBS/KMW)
14-5878 (JBS/KMW)
14-6398 (JBS/KMW)
14-7105 (JBS/KMW)
14-7252 (JBS/KMW)
14-8074 (JBS/KMW)
14-8077 (JBS/KMW)
15-1585 (JBS/KMW)
15-161 (JBS/KMW)

MEMORANDUM OPINION REGARDING OTSUKA'S UNOPPOSED MOTIONS FOR CERTIFICATION OF THE STIPULATED JUDGMENTS OF NONINFRINGEMENT ON THE '350 PATENT

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OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. LUPIN LIMITED, LUPIN ATLANTIS HOLDING SA, LUPIN PHARMACEUTICALS, INC., and HETERO LABS LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS USA and CADILA HEALTHCARE LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. APOTEX CORP., APOTEX INC., APOTEX PHARMACHEM INC., and HETERO LABS LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SCIEGEN PHARMACEUTICALS INC., BACTOLAC PHARMACEUTICAL, INC., and HETERO LABS LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS INDA PVT. LTD., Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. HETERO DRUGS LIMITED, HETERO LABS LIMITED, and HETERO USA, INC., Defendants.

SIMANDLE, Chief Judge:

In these related patent infringement actions, Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") advances its position that Defendants' abbreviated new drug applications (hereinafter, "ANDAs") to market generic

aripiprazole products infringe the compound and method of use patents covering Otsuka's aripiprazole product, Abilify®.[1]

As relevant here, on November 16, 2015, this Court construed the phrase "a/the pharmaceutical composition" / "in combination with," as it appears in the asserted claims of U.S. Patent No. 8,759,350 (hereinafter, "the '350 patent"), to mean "a single dosage form, or 'pharmaceutical composition,' containing at least two active ingredients: aripiprazole and at least one of citalopram, escitalopram and salt thereof." Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 7195222, at *22 (D.N.J. Nov. 16, 2015) (hereinafter, the "Markman decision"). In light of this construction, and Defendants' representations concerning the single-ingredient nature of their ANDA products, stipulated judgments of noninfringement on Otsuka's '350 patent claims have been entered in each of these thirteen related actions. [See, e.g., Docket Item 206 in 14-3168; Docket Item 143 in 14-4508; Docket Item 201 in 14-4671; Docket Item 155 in 14-5537; Docket Item 156 in 14-5876; Docket Item 209 in 14-5878; Docket Item 208 in 14-6398; Docket Item 131 in 14-7105; Docket Item 164 in 14-7252; Docket Item 225 in 14-8074; Docket Item 119 in 14-8077; Docket Item 116 in 15-1585; Docket Item 146 in 15-161.]

[1] The patents asserted in these related infringement actions generally include: U.S. Patent Nos. 5,006,528 ("the '528 patent"), 7,053,092 ("the '092 patent"), 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,600 ("the '600 patent"), and 8,642,760 ("the '760 patent").

Although these stipulated judgments resolve only a fraction of these complex infringement actions, Otsuka now seeks certification of the stipulated judgments under Rule 54(b), Fed. R. Civ. P., on the grounds that the now-resolved '350 patent infringement claims presented issues severable from and not intertwined with the remaining infringement claims and counterclaims raised in these actions.[2] [See, e.g., Docket Item 212 in 14-3168; Docket Item 142 in 14-4508; Docket Item 204 in 14-4671; Docket Item 145 in 14-5537; Docket Item 144 in 14-5876; Docket Item 213 in 14-5878; Docket Item 210 in 14-6398; Docket Item 129 in 14-7105; Docket Item 170 in 14-7252; Docket Item 222 in 14-8074; Docket Item 110 in 14-8077; Docket Item 115 in 15-1585; Docket Item 145 in 15-161.] For that reason, and in light of "the intensity of the parties' disagreement on ... core issue[s] concerning the '350 patent," Otsuka takes the view that appellate review of the Markman decision would, despite the pendency of ongoing litigation relative to the remaining patents-in-suit, benefit all parties "from certainty as to the proper construction of the '350 patent." (Otsuka's Br. at 1-2, 5-9.) Defendants,[3] however, initially opposed certification, on the grounds that certification would result in a piecemeal appellate process, and would improperly reward Otsuka for its otherwise inordinate delay in seeking appellate

[2] Otsuka filed a single brief in all of these related actions.
[3] Although Defendants seek to market generic aripiprazole products under different ANDAs, they jointly briefed the request for certification at issue here.

review of this Court's '350 patent claim construction.[4] (See Defs.' Opp'n at 4-16.)

In the aftermath of the parties' briefing, on March 30, 2016, this Court entered final judgments of noninfringement in three cases in which Otsuka had asserted only the '350 Patent, Otsuka v. Accord, et al., Civil Action No. 14-6158, Otsuka v. Aurobindo, et al., Civil Action No. 14-6890, and Otsuka v. Alembic, Civil Action No. 14-7405 (hereinafter, "the Standalone '350 patent cases"). See Otsuka Pharm. Co. v. Intas Pharm. Ltd., Nos. 14-6158, 14-6890, 14-7405, 2016 WL 1251032 (D.N.J. Mar. 30, 2016). In other words, Otsuka may, at least in the three Standalone '350 patent cases, take an immediate appeal of the relevant portion of the Markman decision, since a final judgment has been entered in each.[5] As a result of these judgments, Defendants withdrew their opposition to certification on April 7, 2016.[6] [See, e.g., Docket Item 237 in 14-3168.]

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[4] Prior to the Markman decision, on April 16, 2015, the Court preliminary construed the claim phrase "a/the pharmaceutical composition" / "in combination with," as recited in the asserted claims of the '350 patent, in connection with Otsuka's request for injunctive relief against defendants in thirteen related cases. See Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., 99 F. Supp. 3d 461, 478-83 (D.N.J. 2015) (hereinafter, "the TRO opinion").

[5] Based upon Otsuka's consistent representations concerning its appellate intentions (and the pendency of the certification motions), the Court anticipates that Otsuka will shortly file notices of appeal in the Standalone '350 patent cases.

[6] Despite the absence of opposition, the Court must still proceed through the certification inquiry, because Federal Circuit law

Against that contextual backdrop, the Court addresses Otsuka's certification request. For the reasons that follow, Otsuka's unopposed motions for certification will be granted, and the Court will certify the stipulated judgments of noninfringement as final pursuant to Federal Rule of Civil Procedure 54(b).

The Court finds as follows:

1. **Factual and Procedural Background**. For purposes of the pending motions, the Court need not retrace the lengthy factual and procedural background of these related infringement actions. Rather, it suffices to note that these pharmaceutical actions principally concern two distinct series of related patents: three directed at Otsuka's aripiprazole polymorph patents (the '615, the '796, and the '760 patents), and one addressed at a specific method of using Otsuka's aripiprazole product (the '350 patent). More specifically, the '615, the '796, and the '760 patents disclose a "Low Hygroscopic

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requires an express discussion of the reasons justifying "departure from the general rule that all issues by the district court should be resolved in a single appeal of a final judgment." iLOR, LLC v. Google, Inc., 550 F.3d 1067, 1072 (Fed. Cir. 2008) (declining to consider certification, based upon the district court's failure to cite Rule 54(b) or to "set[] forth the circumstances justifying immediate appeal of the decision"); see also L.A. Gear, Inc. v. Voit Sports, Inc., 42 F.3d 1409 (Fed. Cir. 1994) (generally taking issue with a district court's failure to expressly discuss the circumstances supporting certification).

Aripiprazole Drug Substance and Processes for the Preparation Thereof."[7] (See, e.g., '615 patent at 1:45-52.) In other words, these polymorph patents "claim novel forms of anhydrous aripiprazole" with "low hygroscopicity." Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222, at *3. "The '350 Patent, by contrast, generally relates to a method of treating major depressive disorders through the adjunctive use of aripiprazole in conjunction with certain serotonin reuptake inhibitors (hereinafter, 'SRIs'), and specifically discloses a 'Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders.'" Id. at *4.

2. In the Markman decision, this Court construed the phrases "a/the pharmaceutical composition" and "in combination with," as they appear in all asserted claims of the '350 patent, to mean "a single dosage form, or 'pharmaceutical composition,' containing at least two active ingredients: aripiprazole and at least one of citalopram, escitalopram and salt thereof." See Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222, at *22. In other words, for a drug product to infringe the asserted claims of the '350 patent, as construed, that product must contain a single dosage form with two active pharmaceutical

[7] As explained in the Markman decision, the '615, the '796, and the '760 patents share a common specification. See Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222, at *3 n.9.

ingredients, aripiprazole and either citalopram or escitalopram, or salts thereof. See Otsuka Pharm. Co., 2016 WL 1251032, at *2. Defendants here, though, have consistently advanced the position that their ANDA products cannot, as a matter of law, directly infringe any claim of the '350 patent, because their proposed aripiprazole products contain only a single active ingredient, aripiprazole, and not the multi-component pharmaceutical composition (consisting of aripiprazole in addition to either citalopram and/or escitalopram) disclosed by the '350 patent. See id.

3. For that reason, the parties have, in each of these related infringement actions, stipulated to the entry of judgments finding Defendants' ANDA products noninfringing of the '350 patent, on account of the fact that they do not contain the two active ingredients required by the construed '350 patent. [See, e.g., Docket Item 2016 in 14-3168 (stipulating that "Defendants' accused products do not infringe the '350 patent ... based on the Court's current construction of 'a/the pharmaceutical composition' and 'in combination with'").]

4. **Standard for Rule 54(b) Certification**.[8] "Ordinarily the proceedings in a district court must be final as to [ ] all

[8] Although Federal Circuit decisions would ordinarily govern patent law-related determinations in these patent infringement actions, the parties (and other courts throughout this District) rely upon Third Circuit's distillation of the standard for

causes of action and parties for a court of appeals to have jurisdiction over an appeal under 28 U.S.C. § 1291."[9] Morton Int'l, Inc. v. A.E. Staley Mfg. Co., 460 F.3d 470, 476 (3d Cir. 2006) (citations omitted). Federal Rule of Civil Procedure 54(b), however provides a mechanism for rendering a partial final judgment as to some, but not all, parties or claims in a single action. See Enercon Indus. Corp. v. Pillar Corp., 105 F.3d 1437, 1439 (Fed. Cir. 1997) (citation omitted) (explaining that Rule 54(b) "allows 'a district court to sever an individual claim that has been finally resolved'"). Rule 54(b), Fed. R. Civ. P., specifically provides as follows: "[w]hen an action presents more than one claim for relief—whether as a claim, counterclaim, crossclaim, or third-party claim—or when multiple parties are involved, the court may direct entry of a final

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certification under Federal Rule of Civil Procedure 54(b). See, e.g., Church & Dwight Co. v. Abbott Labs., No. 05-2142, 2007 WL 1101446, at *2 (D.N.J. Apr. 11, 2007) (explaining Third Circuit law on a certification request in a patent infringement action). Despite the parties' position, this Court looks, as it must, to Supreme Court and Federal Circuit authority relative to certification. See Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 830 (Fed. Cir. 2003) (explaining that Federal Circuit law generally governs Rule 54(b) certification); State Contracting & Eng'g Corp. v. State of Fla., 258 F.3d 1329, 1334 (Fed. Cir. 2001) (same); but see Golan v. Pingel Enter., Inc., 310 F.3d 1360, 1366 n.3 (Fed. Cir. 2002) (explaining that regional circuit law governs the Rule 54(b) determination).

[9] 28 U.S.C. § 1291 specifically provides that, "the court of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction over appeals from all final decisions of the district courts of the United States..."

judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay." In other words, Rule 54(b) permits the district court to separate out final decisions from non-final decisions in multiple party and/or multiple claim litigation in order to allow immediate appeal. See iLOR, LLC, 550 F.3d at 1072 (explaining the purposes of Rule 54(b) certification)

5. A certification decision under Rule 54(b) involves two separate determinations: (1) there has been a final judgment on the merits, i.e., an ultimate disposition on a cognizable claim for relief; and (2) there is "no just reason for delay." Curtiss–Wright Corp. v. General Elec. Co., 446 U.S. 1, 7–8 (1980). In addressing the "no just reason for delay" aspect of the certification inquiry, the Federal Circuit requires that a district court's certification decision provide "sound reason[s] to justify departure from the general rule that all issues ... be resolved in a single appeal of a final judgment." iLOR, LLC, 550 F.3d at 1072; see also Aug. Tech. Corp. v. Camtek, Ltd., 542 F. App'x 985, 993 (Fed. Cir. 2013) (citing iLOR, LLC for the same premise). In applying this standard, district courts, in turn, look to (1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court

might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim which could result in a setoff against the judgment to be made final; and (5) other factors, such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense. See, e.g., Curtiss–Wright Corp., 446 U.S. at 8; W.L. Gore & Assocs., Inc. v. Int'l Med. Prosthetics Research Assocs., Inc., 975 F.2d 858, 861 (Fed. Cir. 1992) (citations omitted) (setting forth the same general framework).

6. Despite the flexibility of the inquiry, certification constitutes "the exception, not the rule, to the usual course of proceedings in a district court" and "should not be entered routinely or as a courtesy or accommodation to counsel." Panichella v. Pa. R.R. Co., 252 F.2d 452, 455 (3d Cir. 1958); see also Pause Tech. LLC v. TiVo Inc., 401 F.3d 1290, 1294 n.2 (Fed. Cir. 2005) (citation omitted) (explaining Rule 54(b) as "an exception to the common law rule"). Rather, the Rule "should be used only in the infrequent harsh case as an instrument for the improved administration of justice and the more satisfactory disposition of litigation in the light of the public policy indicated by statute and rule." Panichella, 252 F.2d at 455; see also City Select Auto Sales, Inc. v. David/Randall Assocs., Inc., ___ F. Supp. 3d ____, 2015 WL 6507142 (D.N.J. Oct. 26, 2015) (same). Thus, despite the

parties' consent to Rule 54(b) certification, the Court has undertaken an independent examination of the certification standards as applied to these related cases.

7. **Discussion**. Application of these principles here readily support certification of the stipulated judgments as final. Indeed, the first inquiry – the existence of a final judgment on the merits – requires no lengthy inquiry, because the stipulated judgments of noninfringement left no litigable issues relative to the '350 patent. Stated differently, these stipulated judgments fully disposed of Otsuka's infringement claims directed at the '350 patent in Defendants' favor.[10] See Ultra-Precision Mfg. Ltd. v. Ford Motor Co., 338 F.3d 1353, 1357 (Fed. Cir. 2003) (citation omitted) (explaining finality for purposes of Rule 54(b) as an "'ultimate disposition of an

[10] In light of the stipulated judgments, Otsuka requests that Defendants' counterclaims concerning the '350 patent, to the extent any remain, be dismissed without prejudice. All of the stipulated judgments provided for the dismissal of counterclaims concerning the '350 patent without prejudice, except for the judgment entered in Otsuka v. Apotex, et al., Civil Action No. 14-8074 (hereinafter, "the Apotex Defendants"). Nevertheless, given the stipulated judgments and in order to similarly orient these related infringement actions, the Court will dismiss the Apotex Defendants' counterclaims directed at the '350 patent without prejudice to reinstatement in the event the Federal Circuit reverses or remands this case back to this Court. See, e.g., Nystrom v. Trex Co., Inc., 339 F.3d 1347, 1351 (Fed. Cir. 2003) (citation omitted) (explaining the discretion of district courts "to dismiss a counterclaim ... as moot where [the court] finds no infringement"); see also See Otsuka Pharm. Co., 2016 WL 1251032, at *2 (dismissing counterclaims concerning the '350 patent without prejudice).

individual claim entered in the course of a multiple claims action'").

8. Turning then to the "no just reason for delay" inquiry, the Court observes, at the outset, Otsuka's delay in seeking appellate review of this Court's construction of the '350 patent. Indeed, in the event Otsuka took early issue with the Court's '350 patent construction, Otsuka could have appealed pursuant to 28 U.S.C. § 1292(b) the Court's April 16, 2015 decision denying Otsuka's motions for injunctive relief. See generally Otsuka Pharm. Co., 99 F. Supp. 3d 461. Similarly, Otsuka could have sought summary judgment and certification in the **immediate** aftermath of the Markman decision. See generally Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222. Instead, however, Otsuka waited to voice its certification position until nine months after the TRO opinion, and nearly two months after the Markman decision. A delay of that magnitude, in turn, gives some support to the view that the time to seek appellate attention to this Court's '350 patent construction has passed.

9. The Court, however, will not ignore the distinctiveness of the issues concerning the '350 patent from the (as-of-yet unresolved) issues related to Otsuka's aripiprazole polymorph patents. Indeed, the specification of the '350 patent differs from the otherwise identical

specifications of the polymorph patents, and the ’350 patent addresses itself to a conceptually severable invention (an allegedly novel method of use, rather than a specific polymorphic form). In other words, the infringement case relative to the ’350 patent has, from inception of these related actions, presented and required different inquiries from those the Court continues to confront on Otsuka’s aripiprazole polymorph patents. Indeed, the claim phrase that motivated the stipulated judgments - “a/the pharmaceutical composition” and “in combination with” – finds its roots only in the asserted claims of the ’350 patent. With that, the review requested here does not raise the risk of successive appeals on the same issue, nor does it target an issue that future developments might resolve. See W.L. Gore & Assocs., Inc., 975 F.2d at 861.

10. Despites these circumstances, Defendants initially opposed certification,[11] based upon the fact that the claim term “anhydrous aripiprazole crystals B” can be found in the asserted claims of the ’350, ’796, and ’615 patents. (See Defs.’ Opp’n at 7-8.) The presence of common claim terms leaves unchanged the separateness of these patents, however, because the

[11] Defendants, as explained above, withdrew their opposition to certification following the entry of summary judgments in the Standalone ’350 patent cases. [See, e.g., Docket Item 237 in 14-3168.] Nevertheless, this Court must still determine whether the circumstances presented here warrant certification.

stipulated judgments hinged upon the separate phrases "a/the pharmaceutical composition" and "in combination with." [See, e.g., Docket Item 2016 in 14-3168 (stipulating that "Defendants' accused products do not infringe the '350 patent ... based on the Court's current construction of "a/the pharmaceutical composition" and "in combination with").] In that way, the proposed appeal solely concerns the correctness of the Court's construction of the phrase "a/the pharmaceutical composition" and "in combination with" for purposes of the '350 patent, and not the unconnected claim term "anhydrous aripiprazole crystals B."

11. More critically, this Court has, as recounted above, already entered final judgments of noninfringement in the Standalone '350 patent cases, Otsuka v. Accord, et al., Civil Action No. 14-6158, Otsuka v. Aurobindo, et al., Civil Action No. 14-6890, and Otsuka v. Alembic, Civil Action No. 14-7405. In that way, the avoidance of a piecemeal appeals process no longer constitutes an attainable goal in the cascade of related actions concerning Otsuka's aripiprazole patents. See W.L. Gore & Assocs., Inc., 975 F.2d at 861 (citations omitted) (explaining that appellate courts "having historically disfavored piecemeal litigation and permitted appeals from complete and final judgments only"); City Select Auto Sales, Inc., ___ F. Supp. 3d ____, 2015 WL 6507142, at *5 (denying certification in order to

avoid a "piecemeal appeal process"). Stated differently, whether or not this certification motion is granted, there will already be appeals of right in the three Standalone '350 patent cases involving exactly this same issue of claim construction.

12. Thus, although the Court recognizes the Federal Circuit's general reluctance to take "appeals from claim construction decisions," Canon, Inc. v. GCC Int'l Ltd., 263 F. App'x 57, 61 (Fed. Cir. 2008), the finality derived from the stipulated judgments on the '350 patent claims, together with the reality that the Standalone '350 patent cases are already appealable as final judgments, call for certification of the stipulated judgments as final. Indeed, the unique factual and procedural circumstances presented here, rise to the unusual level in which final certification becomes appropriate.

13. Certification of the '350 patent non-infringement judgments in the captioned cases will itself avoid piecemeal appeals of the same constructions, enhancing judicial efficiency. The various defendants have shown a facility for cooperation in the briefing and argument of common issues, and it would be surprising if that does not continue on appeal for both groups of cases – the three Standalone '350 patent cases and the above-captioned Rule 54(b)-certified summary judgment '350 patent cases. This factor also counsels in favor of Rule 54(b) certification.

14. For all of these reasons, Otsuka's unopposed motions for certification will be granted, and the Court will certify the stipulated judgments of noninfringement as final pursuant to Federal Rule of Civil Procedure 54(b). An accompanying certification Order will be entered in each of these related actions.

April 12, 2016
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge