UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 15-61631-CIV-COHN (consolidated with 15-62081-CIV-COHN)

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S
REPLY TO PLAINTIFFS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's Supplemental Scheduling Order of November 12, 2015 (D.E. 58, modified by D.E. 84, further modified by D.E. 88), Defendants Apotex Inc. and Apotex Corp. ("Apotex") hereby submit this Brief in reply to Plaintiffs' Responsive Claim Construction Brief (D.E. 83).

I. INTRODUCTION

Apotex's proposed constructions of the disputed claim terms of U.S. Patent No. 8,952,138 ("the '138 patent") and U.S. Patent No. 6,162,427 ("the '427 patent") are faithful to the intrinsic record. Indeed, one needs to go no further than the patents themselves and the respective prosecution histories to arrive at Apotex's proposed constructions. Further, the limitation "disease treating-effective amount" in the '427 patent is indefinite because, when viewed in light of the specification and the background knowledge of a person of ordinary skill in the art ("POSA"), it fails to inform, with reasonable certainty, those skilled in the art as to the scope of Amgen's alleged invention.

Meanwhile, Plaintiffs Amgen Inc. and Amgen Manufacturing Limited's ("Amgen") proposed constructions of the disputed claim terms improperly and unnecessarily add limitations to the claims and broaden the scope of the claims in a manner that is inconsistent with the intrinsic record. Accordingly, this Court should deny Amgen's litigation-based attempt to now modify the meaning of claim terms in the '138 patent that were relied upon by the United States Patent and Trademark Office ("Patent Office") to distinguish from the prior art. Indeed, Amgen's proposed constructions contradict the intrinsic record of both the '138 and '427 patents.

For the reasons stated herein, the Court should reject Amgen's proposed constructions of the disputed terms and instead adopt Apotex's proposed constructions, which follow the tenets of claim construction and are consistent with the intrinsic records of the patents.

II. ARGUMENT

A. The '138 Patent

1. "*a protein . . . present in a volume at a concentration of 2.0 g/L or greater*"

Both Apotex and Amgen agree that the subject matter of the purported invention of the '138 patent is refolding proteins at "high" concentrations. Nevertheless, claim 1 of the '138 patent never uses the word "high" anywhere in the claim. The reason for that is clear: the '138 patent clearly defines what the inventors believed was refolding proteins at "high"

concentrations—"*i.e.,* concentrations of 2.0 g/L and higher, ..." ('138 patent, col. 2, ll. 18-19.) Thus, claim 1 does not need to mention the word "high" when referring to the protein concentration because the '138 patent clearly informs a POSA what this term means.

Amgen and its expert, Dr. Richard C. Willson, III, would have this Court ignore the entire specification of the '138 patent and broaden the scope of claim 1 to cover methods of protein refolding at concentrations less than 2.0 g/L. Indeed, despite ample evidence in the '138 patent to the contrary, Amgen argues that protein refolding at concentrations of 2.0 g/L or greater is merely exemplary. That is incorrect and is contradicted by Dr. Willson's testimony. As Dr. Willson confirms, the '138 patent clearly defines refolding proteins at high concentrations as not merely exemplary, but as, in Dr. Willson's own words, "in effect," 2.0 g/L or greater. (1/18/16 Willson Dep. Tr. at 82:3 – 84:21 (excerpts of the deposition of Dr. Willson are attached hereto as "Exhibit A").) Specifically, the '138 patent states that "[u]ntil the present disclosure, these types of complex molecules could not be refolded at high concentrations, *i.e.,* concentrations of 2.0 g/L and higher, with any meaningful degree of efficiency on a small scale, and notably not on an industrial scale." ('138 patent, col. 2, ll. 17-21.) When reviewing this portion of the '138 patent, Dr. Willson admits that the '138 patent is defining refolding proteins at high concentrations as "in effect" at 2.0 g/L or greater. (Exh. A, 1/18/16 Willson Dep. Tr. at 82:3 – 84:21.) Anyone with common knowledge or a dictionary on hand would understand that "i.e." means "in effect" or "that is to say" or "in other words," it does not take a person of ordinary skill in the art to know that.[1] Thus, the '138 patent does not refer to "high" protein concentrations of 2.0 g/L or greater as merely one example in a broader range, but instead clearly defines protein refolding at concentrations of 2.0 g/L or greater as the key aspect of the claimed invention.

The '138 patent defines refolding proteins at a concentration of 2.0 g/L or greater in many other places too, not merely as an example. (*See*, *e.g.*, '138 patent at Abstract; col. 1, ll. 10-14; col. 2, ll. 52-55; col. 4, ll. 20-23, 35-38.) Thus, Dr. Willson's willingness to dismiss the Abstract of the '138 patent as an "outlier" compared to the rest of the patent's disclosure strains credibility. (Exh. A, 1/18/16 Willson Dep. Tr. at 74:13 – 77:25.)

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[1] *See, e.g.*, *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373-1374 (Fed. Cir. 2014)(noting that "i.e.," in contrast to "e.g.," can be used to "cast" a phrase as a definition and provide clarity in the specification).

Further, claim 1 of the '138 patent requires, "A method of refolding a protein . . . present in a volume . . . ." Therefore, the plain language of claim 1 clearly specifies a method of protein refolding performed in a volume. Those are the unambiguous words of the claim. Moreover, it is undisputed that the volume in which protein refolding occurs is a "refold mixture." (*Id.* at 93:4-9.) Nonetheless, Amgen and Dr. Willson argue that the term "volume" is never used to describe a "refold mixture." (D.E. 83, Exh. 1 at ¶¶ 17-19.) This is simply incorrect and contradicted by the specification of the '138 patent. Indeed, one need only look at the "Field of the Invention" to see that the '138 patent discusses a "volume" as including a refold mixture. Specifically, the '138 patent states, "[t]he present invention generally relates to refolding proteins at high concentrations, and more particularly to **refolding proteins in volumes** at concentrations of 2.0 g/L and above." ('138 patent at col. 1, ll. 10-14 (emphasis added).) Thus, the '138 patent clearly refers to a "volume" as including a refold mixture.

What is more, Amgen's proposed construction would render claim 1 of the '138 patent indefinite under 35 U.S.C. § 112, second paragraph. Specifically, under Amgen's construction, the term "volume" could refer to <u>any</u> volume containing the protein prior to forming a refold mixture. Indeed, Dr. Willson confirms that under Amgen's construction, "a protein . . . present in a volume at a concentration of 2.0 g/L or greater" is not specific to any volume; thus, the protein may be present in a volume at a concentration of 2.0 g/L or greater in one volume but not another volume. (D.E. 83, Exh. 1 at ¶¶ 18-19; *see also* Exh. A, 1/18/16 Willson Dep. Tr. at 97:5 – 103:2.) Thus, under Amgen's construction, a person of ordinary skill in the art would not know which volume must contain a protein at a concentration of 2.0 g/L or greater. This is the very definition of indefiniteness. *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 781 (Fed. Cir. 2010). Conversely, under Apotex's construction, a person of ordinary skill in the art would know exactly which volume must contain a protein at a concentration of 2.0 g/L or greater—the volume in which protein refolding occurs. There is no ambiguity in Apotex's construction; in fact, this construction is consistent with the plain language of claim 1 and the specification of the '138 patent.

Amgen also argues that "Apotex's characterization of the prosecution history is incorrect." (D.E. 83 at 5.) Indeed, both Amgen and Dr. Willson argue that in responding to the Patent Office's rejection, the applicants merely characterized the prior art as not disclosing

protein refolding at concentrations of 2.0 g/L or greater, but did not argue that this was a requirement for the claimed invention. (*Id.* at 5, Exh. 1 at ¶ 22.) This is a blatant misreading of the prosecution history. The applicants repeatedly distinguished the claims of the '138 patent from the prior art based on the purported novelty of protein *refolding* at concentrations of 2.0 g/L or greater. For example, the applicants stated throughout the prosecution, "[w]hile the recitation of refolding at a concentration of 2.0 g/L or greater is absent from the disclosure of the '370 patent, **it forms an element of each of applicants' pending claims**." (*See* D.E. 76, Exh. H at 7 (emphasis added).) Applicants continued, "[a]pplicants submit that the '370 patent does not teach **each and every element of the claimed invention, notably refolding proteins at concentrations of 2.0 g/L or greater** . . . ." (*See id.*, Exh. H at 7, Exh. I at 8 (emphasis added).) Thus, applicants clearly stated to the Patent Office that protein refolding at concentrations of 2.0 g/L or greater is required by the claims of the '138 patent, and indeed was one of the key elements that distinguished these claims from the prior art.

Finally, based on Amgen's questions at Dr. Anne Robinson's deposition, Amgen may argue that the "volume" recited in claim 1 cannot be limited to a refold mixture because claims 4 and 5 further limit "the volume" to include protein forms that are not present in a refold mixture. Therefore, according to Amgen, under Apotex's proposed construction claims 4 and 5 would be invalid under 35 U.S.C. § 112, fourth paragraph, for failing to specify a further limitation of the subject matter of claim 1. *See, e.g., Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006). To the extent Amgen makes such baseless arguments, they should be ignored.

First, Amgen has not asserted claims 4 and 5 of the '138 patent against Apotex and the parties have not asked the Court to construe these claims. Any attempt by Amgen to do so now would be improper. Second, to the extent that the Court considers the validity of claims 4 and 5 of the '138 patent in construing the terms of claim 1, Apotex's expert, Dr. Robinson, testified that a person of ordinary skill in the art would understand that claim 4 (and claim 5) merely refer to where the protein is derived from before adding it to the refold buffer. (1/20/16 Robinson Dep. Tr. at 129:18 – 130:5; 135:8-11 (excerpts of the deposition of Dr. Robinson are attached hereto as "Exhibit B").) Therefore, as understood by a person of ordinary skill in the art, nothing about claims 4 and 5 takes away from the fact that the "volume" referred to in claim 1 is the refold mixture. Further, as mentioned in Apotex's Responsive Brief, a refold mixture that has a

protein concentration of 2.0 g/L will logically have a protein concentration of over 2.0 g/L prior to being added to a refold buffer to form a refold mixture. Third, and finally, to the extent that this Court finds claims 4 and 5 invalid under Apotex's proposed constructions for the terms of claim 1, this is no reason to incorrectly construe claim 1 by adopting Amgen's proposed construction. It is not this Court's obligation to correct technical errors in claim drafting in order to preserve validity. *See Pfizer*, 457 F.3d at 1292 (citing *Rhine v. Casio, Inc*., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then . . . the claim is simply invalid.")).

Accordingly, the Court should reject Amgen's proposed construction and adopt Apotex's construction.

2. "*refold buffer*" *and "redox component"*

Amgen does not dispute that its proposed constructions for these terms are unnecessarily redundant and incorporate language already expressly recited in claim 1. Rather, Amgen contends that its "proposed construction was offered to identify precisely the elements that the refold buffer comprises." (D.E. 83 at 6; *see also id*., Exh. 1 at 9.) However, Amgen's argument fails to acknowledge that its construction for "refold buffer" would render the "redox component . . . and one or more of: (i) a denaturant; (ii) and aggregation suppressor; and (iii) a protein stabilizer" term a meaningless claim limitation that is simply duplicative of the claimed "refold buffer" itself. Likewise, Amgen fails to acknowledge that its construction for "redox component" would render the "redox component comprising a final thiol-pair ratio having a range of 0.001 to 100 and a redox buffer strength of 2mM or greater" term a meaningless claim limitation that is simply duplicative of the claimed "redox component" itself. Accordingly, the Court should reject Amgen's proposed constructions and adopt Apotex's constructions.

3. "*final thiol-pair ratio*" *and "redox buffer strength"*

Amgen spends much time arguing that considering the protein of interest, the concentration of the protein of interest, and chemicals carried over from the solubilization buffer into the "final thiol-pair ratio" and "redox buffer strength" would make calculation of these limitations imprecise. Amgen's argument misses the mark. The crux of the parties' disagreement centers on the correct "volume" that should be used to calculate the final-thiol pair

ratio and redox buffer strength. Amgen's expert, Dr. Willson, agrees that a person of ordinary skill in the art would readily know the volume of the refold mixture that could be used to calculate a "final thiol-pair ratio" and "redox buffer strength." (Exh. A, 1/18/16 Willson Dep. Tr. at 189:14 – 190:19.) Thus, Amgen's lengthy arguments about imprecise calculations should be discarded as irrelevant to the dispute at hand.

Further, it is Apotex's constructions for these terms, not Amgen's, which would be more precise and reliable. Indeed, the only "final thiol-pair ratio" and "redox buffer strength" that are relevant to the claimed method of protein refolding are those present in the final volume of the refold mixture, the only undisputed place where protein refolding occurs. The '138 patent supports this conclusion over and over again. (*See*, *e.g.*, '138 patent at col. 4, ll. 15-20; col. 8, ll. 19-36; col. 14, ll. 30-36.)

Accordingly, the Court should reject Amgen's proposed constructions and adopt Apotex's constructions.

4. "*2 mM or greater*"

Amgen argues that "Apotex's proposed construction improperly reads a limitation into the claim from certain portions of the specification and ignores the rest of its teachings." (D.E. 83 at 13.) Amgen, however, is wrong—the entirety of the specification, including the figures, provides support for an upper limit for the redox buffer strength as proposed by Apotex. (*See* '138 patent at col. 2, l. 67 through col. 3, l. 4; *id*. at col. 10, ll. 29-35, 54-65; *id*. at col. 11, ll. 16-21, 45-51; col. 3, ll. 4-5; Figures 1a-f.)

Amgen further argues that "[t]he examples in the specification repeatedly indicate that, during the initial testing to identify the optimal redox buffer strength, a sufficiently large range of redox buffer strengths may be tested." (D.E. 83 at 13 (citing '138 patent at col. 9, ll. 20-34; col. 10, l. 45 to col. 11, l.5; col. 11, ll. 54-63).) However, the disclosure cited by Amgen refers to testing "each component [i.e., thiol-pair ratios and redox buffer strength] . . . *over a range* of at least three concentrations." ('138 patent at col. 9, ll. 20-34 (emphasis added).) This disclosure does not refer to testing a "large range" of redox buffer strengths as Amgen would have this Court believe. What is more, Amgen's own citation includes the language "wherein the thiol-pair buffer strength [i.e. redox buffer strength] is effectively bounded at a maximum of 100 mM." (D.E. 83 at 13 (citing '138 patent at col. 10, l. 54 to col. 11, l. 5).)

Finally, Amgen fails to explain how its proposed construction would satisfy either the enablement or written description requirements of 35 U.S.C § 112, first paragraph. As explained in Apotex's Responsive Brief (D.E. 82), Amgen's proposed construction would provide a person of ordinary skill in the art with an *unlimited* range of redox buffer strengths to assess, *i.e.*, 2 mM *or greater*—the epitome of undue experimentation. What is more, the '138 patent specification does not show the inventors were in possession of a method of refolding a protein that would encompass the 2 mM or greater redox buffer strength limitation of the claims.

Accordingly, the Court should reject Amgen's proposed construction and adopt Apotex's construction.

5. "*refold mixture*"

Amgen contends that "[b]ecause the claimed method is directed to high protein concentration refolding, the dilution called for by the claim language must result in a concentration of protein in the refold mixture that remains high, and distinct from the dilute protein refolding conditions of the prior art." (D.E. 83 at 14.) Apotex does not disagree—the purported invention is indeed directed to protein refolding at "high" concentrations. Where the parties disagree, however, is whether a "high" protein concentration encompasses 1 g/L. As reflected in the specification and prosecution history of the '138 patent, it does not.

Instead, adopting Amgen's construction would place claim 1 squarely within what the inventors considered to be prior art. In the Background of the Invention, a section of the patent designed to inform a reader of the state of the prior art, the '138 patent states, "[t]ypical refold concentrations for complex molecules, such as molecules comprising two or more disulfides, are less than 2.0 g/L and more typically 0.01-0.5 g/L . . . ." ('138 patent, col. 1, ll. 52-55.) Curiously, Amgen's expert, Dr. Willson, acknowledges that protein refolding at concentrations of 0.01-0.5 g/L was in the prior art, citing this same portion of the '138 patent, but then chooses to ignore that the applicants also admit in the same sentence that protein refolding at concentrations less than 2.0 g/L is also in the prior art. When asked about his selective reading of this section of the '138 patent, Dr. Willson expressed confusion and said that he just does not read it that way. (*See* Exh. A, 1/18/2016 Willson Dep. Tr. at 45:2 – 69:24.) Thus, Amgen can only rely upon its expert's strained reading of what Apotex submits is a section of the '138 patent that could not be more clear. The inventors admitted that refolding proteins at both less

than 2.0 g/L and more typically at 0.01-0.5 g/L was prior art. Thus, adopting Amgen's construction of "refold mixture" by adding "[t]he refold mixture has a high protein concentration, where 'high protein concentration' is at or above about 1 g/L" would be improper based on the specification of the '138 patent and because it would place claim 1 squarely within what the inventors admitted was in the prior art.

Amgen further argues that "Apotex and Dr. Robinson completely ignore the disclosures in the specification that allow for a dilution of the protein concentration in the initial protein-containing volume to a concentration as low as 1 g/L in the refold mixture." (D.E. 83 at 4.) However, none of the disclosures cited by Amgen (*id.* at 4, 14 (citing '138 patent at col. 10, ll. 12-16; col. 12, ll. 44-49)) use the language "high protein concentration" when disclosing a range of protein concentrations which encompass 1 g/L or greater—a fact confirmed by Amgen's expert Dr. Willson. (Exh. A, 1/18/16 Willson Dep. Tr. at 71:14 – 73:8.) Thus, neither Apotex nor Dr. Robinson "ignored" these disclosures; instead, these disclosures were viewed as irrelevant to the purportedly inventive concept of refolding at "high" protein concentrations. Further, even a cursory review of the specification reveals that the patentees intended high protein concentrations to be 2.0 g/L or greater. (*See* '138 patent at Abstract; col. 1, ll. 11-14; D.E. 76, Exh. H at 6-7, Exh. I at 8.)

Accordingly, the Court should reject Amgen's proposed construction and adopt Apotex's construction.

B. The '427 Patent

1. "*chemotherapeutic agent*"

Amgen argues that "Apotex's proposed construction with its use of 'and/or' *confusingly* encompasses alternative and overlapping genuses." (D.E. 83 at 17 (emphasis added).) That is not true. Nothing about Apotex's proposed construction is "confusing;" rather, it represents the patentees' definition. (*See* D.E. 82 at 17 (citing '427 patent at col. 2, ll. 34-39).)

Amgen further argues that Apotex's proposed construction limits the chemotherapeutic agent to mobilizing stem cells by rendering the endothelial barrier permeable to stem cells. (D.E. 83 at 17-18.) Amgen is misrepresenting Apotex's position. Apotex is not arguing that the *only* method to mobilize stem cells is via opening the endothelial barrier. Rather, Apotex's definition encompasses this method of stem cell mobilization, which is expressly recited in the '427 patent,

while also encompassing the ability of chemotherapeutic agents to damage or destroy tumor cells. This construction is consistent with the specification, which makes clear to one skilled in the art that the '427 patent is using the term "chemotherapeutic agent" to describe *both* therapeutic agents that open the endothelial barrier to enhance stem cell mobilization and/or exogenous substances that damage or destroy microorganisms, parasites or tumor cells. Amgen cannot explain why it seeks to limit "chemotherapeutic agent" to only part of the definition provided in the specification.

Furthermore, both Apotex's and Amgen's proposed constructions rely on the functionality of the chemotherapeutic agents. Although Amgen argues that its proposed construction necessarily encompasses both functions of damaging or destroying microorganisms, parasites or tumor cells and opening the endothelial barrier, that argument is belied by Dr. Louis M. Pelus' testimony. (*See*, *e.g.*, 1/19/16 Pelus Dep. Tr. at 31:8 – 33:20 (excerpts of the deposition of Dr. Pelus are attached hereto as "Exhibit C").) Dr. Pelus acknowledges that the method described in the '427 patent encompasses administering a chemotherapeutic agent once to mobilize stem cells before the stem cells are collected, and a second time as part of the antitumor therapy (*i.e.*, damaging or destroying microorganisms, parasites or tumor cells) before the collected stem cells are transplanted back into the patient. (*See*, *e.g.*, *id.* at 25:25 – 26:12, 54:8 – 60:4.) Further, Dr. Pelus acknowledges that the dosage of chemotherapeutic agent given to mobilize stem cells may not be the same dosage of chemotherapeutic agent given as the antitumor therapy. (*Id.* at 25:25 – 27:6, 60:5 – 61:17.) Thus, Amgen's construction only encompasses the antitumor therapy part of the method, not the stem cell mobilization part.

For at least these reasons, the Court should reject Amgen's proposed construction and adopt Apotex's construction.

2. "***disease treating-effective amount***"

Amgen argues that "[c]ontrary to Apotex's argument, a [POSA] would understand that the specific amount of the chemotherapeutic agent would be one that was effective to enhance mobilization of stem cells for collection by leukapheresis." (D.E. 83 at 20.) Once again, as discussed above, Amgen's argument fails to acknowledge that the '427 patent specification also describes a second dose of a chemotherapeutic agent to damage or destroy tumor cells, *i.e.*, antitumor therapy, a fact acknowledged by Dr. Pelus. (*See* Exh. C, 1/19/16 Pelus Dep. Tr. at

25:25 – 27:6, 60:5 – 61:17.) Thus, it holds true that "disease treating-effective amount" in claim 1 could be talking about the amount to mobilize stem cells, the amount needed for antitumor therapy, or perhaps both. Accordingly, because the term "disease treating-effective amount" in claim 1 does not provide a person of ordinary skill in the art with reasonable certainty as to the scope of the invention, claim 1 is indefinite.

Amgen also argues that "[s]ince a [POSA] would understand *the purpose for which the chemotherapeutic agent was given (stem cell mobilization)* and could determine a disease treating-effective amount to enhance stem cell mobilization, the term 'disease treating-effective amount' is not indefinite." (D.E. 83 at 20 (emphasis added).) That argument is in stark contrast to Amgen's definition of chemotherapeutic agent. Indeed, Amgen itself proposes to define chemotherapeutic agent as an "[e]xogenous substance capable of damaging or destroying . . . tumor cells." (D.E. 77 at 12-13). Thus, based on Amgen's proposed construction of "chemotherapeutic agent," a "disease treating-effective amount" should be the amount of a chemotherapeutic agent capable of, *inter alia*, damaging or destroying tumor cells. This discrepancy between Amgen's proposed construction of "chemotherapeutic agent" and "disease treating-effective amount" further highlights the indefiniteness of this term.

What is more, Amgen fails to explain why the patentees used the phrase "stem cell mobilizing-effective amount" to modify G-CSF while using the phrase "disease treating-effective amount" to modify chemotherapeutic agent. If, as Amgen contends, "disease treating-effective amount" is limited to the amount "effective to enhance mobilization of stem cells" (D.E. 83 at 20), it is only logical that the patentees would have used "stem-cell mobilizing-effective amount" to modify "chemotherapeutic agent" rather than "disease treating-effective amount." But, tellingly, the patentees did not do so.

For at least these reasons, the Court should reject Amgen's proposed construction and find claim 1 of the '427 patent indefinite.

III. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Court reject Amgen's proposed constructions of the disputed terms and adopt Apotex's proposed constructions.

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Respectfully submitted

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of January, 2016, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached service list in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to electronically receive Notices of Electronic Filing.

Dated: January 27, 2016

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