UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and NEW YORK UNIVERSITY Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	)	Case No. 1:15-cv-10698-MLW

PLAINTIFFS' ASSENTED-TO MOTION FOR LEAVE TO FILE A SUPPLEMENTAL REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTIONS FOR A PRELIMINARY AND PERMANENT INJUNCTION

Pursuant to Local Rule 7.1(B)(3) of the United States District Court for the District of Massachusetts, plaintiffs Janssen Biotech, Inc. and New York University move for leave to file a Supplemental Reply Memorandum in support of their pending Motions for a Preliminary and Permanent Injunction. The proposed Reply Memorandum is attached as Exhibit A. In support of this motion, Plaintiffs state as follows:

1. On April 8, 2015, Plaintiffs filed a motion for partial summary judgment and a preliminary and permanent injunction. [Dkt. No. 34.]

2. On April 29, 2015, Defendants opposed that motion and cross-moved for partial summary judgment. [Dkt. Nos. 50-51.]

3. On May 20, 2015, Plaintiffs opposed Defendants' cross motion for partial summary judgment and a preliminary and permanent injunction. [Dkt. No. 60.]

4. On June 15, 2015, Defendants submitted a reply in support of their cross-motion for partial summary judgment. [Dkt. No. 67]

5. After Plaintiffs' motion and Defendants' cross-motion were fully briefed, the Federal Circuit issued a decision in *Amgen Inc. v. Sandoz Inc.*, 749 F.3d 1347 (Fed. Cir. July 21, 2015) interpreting certain provisions of the Biologics Price Competition and Innovation Act ("BPCIA").

6. The parties agreed that *Amgen* is directly applicable to the issues raised in Plaintiffs' motion and Defendants' cross-motion.

7. On August 13, 2015, in light of the *Amgen* decision, the parties filed a Joint Motion for a Proposed Scheduling Order for supplemental briefing on Plaintiffs' motion for partial summary judgment and a preliminary injunction and Defendants' cross-motion for partial summary judgment. [Dkt. No. 71]

8. On September 14, 2015, the parties filed an Amended Joint Motion for a Proposed Scheduling Order which slightly altered proposed event deadlines. [Dkt. No. 77]

9. Pursuant to the Amended Joint Motion for a Proposed Scheduling Order, the accompanying Supplemental Reply Brief responds to Defendants' oppositions in order to address, among other things, arguments made by Defendants not addressed in Plaintiff's opening briefs.

10. Defendants have no objection to the relief sought by this motion.

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY,

By their attorneys,

/s/ Alison C. Casey

Heather B. Repicky (BBO # 663347)
hrepicky@nutter.com
Alison C. Casey (BBO # 688253)
acasey@nutter.com
NUTTER MCCLENNEN & FISH LLP

Seaport West
155 Seaport Boulevard
Boston, MA 02210
(617) 439-2000

Dianne B. Elderkin (*pro hac vice*)
delderkin@akingump.com
Barbara L. Mullin (*pro hac vice*)
bmullin@akingump.com
Angela Verrecchio (*pro hac vice*)
averrecchio@akingump.com
Jason Weil (*pro hac vice*)
jweil@akingump.com
AKIN GUMP STRAUS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103
(215) 965-1200

Gregory L. Diskant (*pro hac vice*)
gldiskant@pbwt.com
Irena Royzman (*pro hac vice*)
iroyzman@pbwt.com
Aron Fischer (*pro hac vice*)
afischer@pbwt.com
Andrew D. Cohen (*pro hac vice*)
acohen@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Dated: September 28, 2015

LOCAL RULE 7.1 CERTIFICATION

Pursuant to Local Rule 7.1(A)(2), I certify that plaintiffs' counsel conferred with defendants' counsel on the subject of this motion, and was advised that defendants do not oppose or object to this motion.

/s/ Alison C. Casey

CERTIFICATE OF SERVICE

I certify that on September 28, 2015 this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing.

/s/ Alison C. Casey

2895142

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1:15-cv-10698**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

PLAINTIFFS' SUPPLEMENTAL REPLY MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTIONS FOR
A PRELIMINARY AND PERMANENT INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Plaintiffs Janssen Biotech, Inc. ("Janssen") and New York University ("NYU") submit this Supplemental Reply Memorandum of Law in support of their pending motion for a preliminary and permanent injunction against Defendants Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (together "Celltrion") and Hospira, Inc.

I. Introduction

In their initial opposition to Plaintiffs' pending motion, Defendants observed that "[t]he issue here is whether, under 42 U.S.C. § 262(*l*)(8)(A) ["paragraph (*l*)(8)(A)"], a biosimilar applicant must wait until *after* it receives FDA approval of its product before providing 180-days' notice of commercial marketing." Dkt. No. 51 at 1 (emphasis in original). As Defendants now concede, *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), resolved this issue in Plaintiffs' favor: a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." *Id*. at 1357 (emphasis added).

Shifting gears, Defendants now argue that the timing of a notice of commercial marketing is actually *not* the issue. Now Defendants contend that they are not required to give *any* notice at any time. This is supposedly because, unlike the defendant in *Amgen*, Defendants did not "*completely fail*[]," Dkt. No. 78 *passim* (emphasis added by Defendants), to comply with an altogether different provision of the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262(*l*)(2)(A) ("paragraph (*l*)(2)(A)"). Paragraph (*l*)(2)(A) required Defendants to provide Janssen with a copy of their abbreviated biological license application ("aBLA") and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." To be clear, Defendants *did* fail to comply with paragraph (*l*)(2)(A); they provided their aBLA, but no "other information" about their manufacturing processes. Defendants' argument rests entirely on the Federal Circuit's single use of the adverb "*completely*" to describe Sandoz's violation of the law. *Amgen*, 794 F.3d

at 1360 (emphasis added). Defendants repeat the phrase "completely fails" twenty-five times in their brief, five times in italics. Dkt. No. 78 *passim*; *see also* Dkt. No. 78 at 11 n.2.[1]

Repetition does little to advance this argument. Contrary to Defendants' contention, *Amgen* did not hold that a notice of commercial marketing is optional unless a biosimilar applicant fails to comply with paragraph (*l*)(2)(A), completely or otherwise. Rather, *Amgen* "conclude[d]" that a notice of commercial marketing "is mandatory." *Amgen*, 794 F.3d at 1359. Although the Court observed that Sandoz did fail to comply with paragraph (*l*)(2)(A), that was only one of multiple reasons why the statute was mandatory – and nothing at all turned on the fact that Sandoz *completely* failed to comply, rather than merely failed to comply (as Defendants did here). Instead, *Amgen* explained that paragraph (*l*)(8)(A) is mandatory because it is a "standalone provision" whose "purpose . . . is clear: requiring notice of commercial marketing be given to allow the RPS ["reference product sponsor" or innovator] a period of time to assess and act upon its patent rights" once a final biosimilar product has been approved. *Id.* at 1359-60. This has nothing to do with whether the applicant failed (or "completely" failed) to comply with paragraph (*l*)(2)(A).

Defendants also dispute that *Amgen* imposed an automatic 180-day injunction to enforce the notice of commercial marketing requirement, contending that the Federal Circuit tacitly applied the four-factor preliminary injunction test from *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). But whether *Amgen* imposed an automatic statutory injunction or applied *eBay sub silentio*, it granted an injunction to enforce paragraph (*l*)(8)(A) on facts that are indistinguishable from this case. This Court should grant the same injunction here.

[1] Citations to Defendants' supplemental brief (Dkt. No. 78) will be to pages of the pdf document, as the body of the brief is not paginated.

II. Under *Amgen*, a Notice of Commercial Marketing Is Mandatory

The core problem with Defendants' position is that the Federal Circuit granted Amgen the same 180-day injunction that Plaintiffs seek here on virtually identical facts. Defendants' argument that this injunction should be denied to Plaintiffs rests entirely a short passage in *Amgen*, where the majority *rejected* Sandoz's contention that paragraph (*l*)(8)(A) was optional because another provision of the statute, 42 U.S.C. § 262(*l*)(9)(B) ("paragraph (*l*)(9)(B)"), purportedly sets forth the sole consequence for noncompliance with the statutory notice. *See Amgen*, 794 F.3d at 1359-60. Paragraph (*l*)(9)(B) provides that if a biosimilar applicant fails to comply with paragraph (*l*)(8)(A) (among other provisions), then the innovator may seek a declaratory judgment on patents that were identified through the pre-litigation procedures of the BPCIA, which begin with paragraph (*l*)(2)(A). The Federal Circuit noted that paragraph (*l*)(9)(B) did "not apply in this case" because "Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.* at 1359. But the Federal Circuit's *rejection* of Sandoz's argument does not imply the opposite. Neither the Court's holding nor its interpretation of paragraph (*l*)(8)(A) depends upon whether an applicant fails to comply with paragraph (*l*)(2)(A) – much less "completely" fails to do so.

A. *Amgen* Holds That Paragraph (*l*)(8)(A) Is a "Mandatory," "Standalone" Provision That Does Not Depend on Compliance With Paragraph (*l*)(2)(A)

Defendants' contention that they do not have to provide a notice of commercial marketing is directly contrary to the *Amgen* decision. *Amgen* stated that "[a] question exists, however, concerning whether . . . paragraph (*l*)(8)(A) is mandatory. We conclude that it is." *Id.* If the court had intended to hold that paragraph (*l*)(8)(A) is sometimes optional and sometimes mandatory, it could not possibly have written those sentences. Defendants do not even attempt to explain how this passage can be squared with their reading of *Amgen*.

Defendants' argument that compliance with paragraph (*l*)(8)(A) depends on compliance with paragraph (*l*)(2)(A) begins with a miscitation. Defendants describe *Amgen* as holding that "the BPCIA's 'shall' provision . . . cannot be read in isolation." Dkt. No. 78 at 9. This is citation to other parts of the *Amgen* opinion that discuss other provisions of the BPCIA. When it came to the notice provision, the Court took a different tack: "[p]aragraph (*l*)(8)(A) is a *standalone* notice provision" so that "*nothing* in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Amgen*, 794 F.3d at 1359-60 (emphases added). Thus, paragraph (*l*)(8)(A) can and should be read in isolation. Defendants fail to explain how compliance with a "standalone notice provision" imposing a "notice requirement" that is *not* "condition[ed] . . . on paragraph (*l*)(2)(A)" is actually conditioned on paragraph (*l*)(2)(A).

Defendants place great emphasis on a subsequent sentence in the opinion: "We therefore conclude that where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." *Id*. at 1360. Defendants give this sentence more weight than it can bear. This sentence cannot be read to make compliance with paragraph (*l*)(8)(A)'s notice provision *depend* on compliance with paragraph (*l*)(2)(A). Such a reading would erase the preceding sentences of the opinion, which explicitly reject such a conditional reading of the notice provision. Properly read, the sentence simply states the facts of the case and reiterates one of the majority's grounds for rejecting the argument that paragraph (*l*)(8)(A) is optional. It does not purport to contradict the prior conclusion that paragraph (*l*)(8)(A) is a "mandatory," "standalone provision" that does *not* depend on compliance with paragraph (*l*)(2)(A).

Defendants point to the dissenting opinion of Judge Chen, who stated that "nothing in the

majority opinion suggests" that paragraph (*l*)(8)(A) is mandatory where the biosimilar applicant has complied with paragraph (*l*)(2)(A). *Id.* at 1371 (Chen, J., dissenting on the issue here); *see* Dkt. No. 78 at 7, 14. Although Judge Chen acknowledged this was a "peculiar" and "uncomfortable" reading of the statute, *Amgen*, 794 F.3d at 1371, Defendants note that "the majority did not dispute that reading." Dkt. No. 78 at 7, 14. But the Court had no obligation to address an odd misreading of its opinion by a dissenting judge. *See* Dkt. No. 72 at 8 n.3; *see also, e.g.*, *Clark v. Dugger,* 901 F.2d 908, 914 n.4 (11th Cir. 1990) ("The concerns of a dissenting justice do not, however, control the meaning of a majority opinion . . . ."). In any event, Judge Newman, one of the two judges in the majority, stated without ambiguity that the notice of commercial marketing was mandatory and she read the Court's opinion exactly as we do: "I agree with the court that notice of issuance of the FDA license is mandatory . . . ." *Amgen*, 794 F.3d at 1362 (Newman, J., concurring on the issue here). Judge Newman did not join, and the majority did not issue, a "peculiar" opinion holding that paragraph (*l*)(8)(A) is sometimes mandatory and sometimes optional. Rather, the majority "conclude[d]" that it was "mandatory." *Id.* at 1359 (majority opinion).

B. The Purpose of Paragraph (*l*)(8)(A), as Explained in *Amgen*, Compels the Conclusion that a Notice of Commercial Marketing Is Mandatory

Beyond its explicit holding, the reasoning of *Amgen* makes clear that a paragraph (*l*)(8)(A) notice of commercial marketing is mandatory. As Plaintiffs explained in their opening brief, *Amgen*'s holding that notice must be given after licensure was not based solely on the language of the statute, but also on what "Congress intended." *Id*. at 1358. Congress's intent, *Amgen* explained, was to require notice at time when "the product, its therapeutic uses, and its manufacturing processes are fixed" in order to "ensure[] the existence of a fully crystallized controversy regarding the need for injunctive relief" during the statutory 180-day period for

bringing a preliminary injunction motion. *Id.* Because a product, its therapeutic uses, and its manufacturing processes are *never* fixed before licensure, this purpose requires notice to be given after FDA licensure in every case. *See* Dkt. No. 72 at 10-11.

Defendants' only response is to deny that the Federal Circuit said what it said. Defendants argue that "neither the statute nor the *Amgen* decision supports [the] view" that "the purpose of the notice provision is to provide a post-approval, pre-launch 'statutory window' for assessing the need for a preliminary injunction based on a 'fully crystallized' product." Dkt. No. 78 at 19. But those are direct quotes from the court's opinion: "Requiring that a product be licensed before notice of commercial marketing ensures the existence of a ***fully crystallized controversy*** regarding the need for injunctive relief. It provides a ***defined statutory window*** during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." *Amgen*, 794 F.3d at 1358 (emphases added). Defendants cannot simply wish away the reasoning of *Amgen*.

Continuing to read *Amgen* with blinders, Defendants contend that "the notice provision is relevant only in [the] subset of cases" where the parties have chosen to litigate in two stages under the BPCIA. Dkt. No. 78 at 17. As Plaintiffs previously pointed out, this is the exact same argument that Defendants' made it in support of their now-rejected position that a notice of commercial marketing could be provided prior to licensure. *See* Dkt. No. 72 at 11-12; Dkt. No. 51 at 9-10. It is true that *if* a notice of commercial marketing could be given before licensure, it would serve no purpose other than to trigger the second stage of BPCIA litigation and would be irrelevant when the parties agreed to litigate in a single stage. But in holding that notice must be given *after* licensure, the Federal Circuit rejected that reading of the statute. The "defined statutory window" for assessing the need for injunctive relief prior to launch is always relevant.

Amgen, 794 F.3d at 1358. And it is particularly relevant here, given the numerous uncertainties about Plaintiffs' need for injunctive relief that that will not be resolved until Defendants' product is licensed. Dkt. No. 34-1 at 15-17. If the notice of commercial market were not mandatory, the statutory purpose of ensuring a "fully crystallized controversy regarding the need for injunctive relief" would be thwarted. *Amgen*, 794 F.3d at 1358.

C. The BPCIA Provides No Adequate Remedy for Failure to Give Notice of Commercial Marketing

Defendants insist that Janssen's sole remedy is a declaratory judgment action under paragraph (*l*)(9)(B). The *Amgen* Court rejected such an action as meaningless on the facts of that case, and it is equally meaningless on the facts of this case. A declaratory judgment action after a biosimilar applicant launches without notice does not address the irreparable injury of launch and is, in any event, unnecessary because the launch is itself an act of direct infringement. As in *Amgen*, a declaratory judgment action on these facts is a meaningless remedy. Defendants do not really dispute that; rather, they offer arguments verging from irrelevant to incoherent.

Defendants argue first that Janssen's grievance lies with Congress for failing to provide a remedy, not with this Court. Dkt. No. 78 at 20-21. But the same could be said of Amgen's complaint, and the *Amgen* Court found that a remedy already existed in the BPCIA – a mandatory pre-launch notice period. Next Defendants argue that the remedy is not meaningless because Janssen can in any event seek a preliminary injunction whenever it wishes. *Id.* at 21. But that is not the point. The question is whether the statute requires a mandatory pre-launch notice period to allow Janssen to assess the need for and seek such relief, and the *Amgen* Court held that the BPCIA does provides such a statutory window. Finally, straining to find some occasion when a declaratory judgment might be a useful remedy for a failure to give notice of commercial launch, Defendants imagine what they admit is a "hypothetical and highly

speculative situation." *Id.* at 21-22. That is a sorry basis to construe the BPCIA to deny Janssen an actual remedy on the facts of this case. But even Defendants' speculative hypothetical does not work. Defendants conjure an action for declaratory relief based on the applicant's "inten[t]" to launch without notice; but the statute provides that remedy only upon an *actual* launch without notice. *See* 42 U.S.C. § 262(*l*)(9)(B). In any scenario, a declaratory judgment action is a meaningless remedy.

In sum, under the holding of *Amgen* and under its reasoning, Defendants must provide Janssen with 180 days' notice after FDA approval of their biosimilar and before launch.

III. Because Defendants Failed to Comply With Paragraph (*l*)(2)(A), The Notice Is Mandatory Under Any Reading of *Amgen*

Even if *Amgen* could be read to mean that a notice of commercial marketing is mandatory only where the biosimilar applicant fails to comply with paragraph (*l*)(2)(A), it would still be mandatory here since Defendants failed to comply with paragraph (*l*)(2)(A). Paragraph (*l*)(2)(A) requires a biosimilar applicant to disclose not only its aBLA, but also "*such other information* that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A) (emphasis added). Here, Defendants provided Plaintiffs a copy of their aBLA, but they refused to provide any "other information" about their manufacturing processes. *See* Dkt. No. 34-2 ¶ 10; Dkt. No. 37 ¶ 11 and Exs. A & B.

Defendants argue that a biosimilar applicant must "completely" fail to comply with paragraph (*l*)(2)(A) before the notice of commercial marketing is mandatory, and they do not meet this test because their failure was not complete. Dkt. No. 78 at 11 n.2, 15-17. This is untenable. The Federal Circuit observed that Sandoz had "completely fail[ed] to provide its aBLA and the required manufacturing information" to Amgen. *Amgen*, 794 F.3d at 1360. Nothing in the Court's reasoning turns on its use of the adverb "completely." There is no reason

to believe the result would be any different if Sandoz had, as in this case, violated the statute by providing only its aBLA, while completely failing to provide "the required manufacturing information." *Id.* Indeed, elsewhere in the opinion, the Court states that "Sandoz did not comply with paragraph (*l*)(2)(A)" and that Sandoz chose "not to comply with paragraph (*l*)(2)(A)," without using the word "completely." *Id.* at 1359-60.

The reason *Amgen* considered Sandoz's failure to comply with paragraph (*l*)(2)(A) relevant was that Sandoz's failure to provide information deprived Amgen of the ability to create a patent list under the BPCIA on which declaratory relief could be sought, and instead forced Amgen to sue pursuant to 35 U.S.C. § 271(e)(2)(C)(ii), which makes it a technical act of infringement for a biosimilar applicant to fail to make paragraph (*l*)(2)(A) disclosures. *See id.* at 1358-59; *see id*. at 1355. Because Defendants here completely failed to provide "the required manufacturing information," *id.* at 1360, Janssen similarly had to assert its manufacturing patents under 35 U.S.C. § 271(e)(2)(C)(ii). This put Janssen in the exact same position as Amgen.

Defendants also contend that they did not violate paragraph (*l*)(2)(A) because the only information they withheld was "third-party data" which they had no statutory obligation to disclose. Dkt. No. 78 at 17. In fact, however, Defendants cited this data in their own BPCIA disclosures, which clearly indicates that it was in their possession and control for purposes of the BPCIA. *See* Dkt. No. 37 Ex. E, at 52-53. In any event, the Court need not decide whether Defendants violated paragraph (*l*)(2)(A) by withholding the specific information that Plaintiffs requested; they unequivocally violated it by completely failing to provide *any* manufacturing information that was not in their aBLA. Because Defendants failed to comply with paragraph (*l*)(2)(A), they are required to provide a notice of commercial marketing, even under the narrowest conceivable reading of *Amgen*.

IV. Janssen Is Entitled to an Injunction

Finally, Defendants argue that even if paragraph (*l*)(8)(A) imposes a mandatory 180-day notice requirement, they should not be ordered to comply with this requirement under *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 394 (2006). Dkt. No. 78 at 22-24. *Amgen* granted a 180-day injunction without discussion of the *eBay* factors. Defendants argue, however, that because Amgen relied on the traditional injunction factors in its application for a stay pending appeal, and because the Federal Circuit kept that injunction in place rather issuing a new one, the Federal Circuit should be understood as having applied *eBay.*

Defendants' argument goes nowhere. Plaintiffs have submitted extensive evidence in support of their motion for an injunction under the *eBay* factors. *See* Dkt. No. 35; Dkt. No. 36. Even if the *Amgen* majority could be understood as having tacitly applied *eBay* rather than issuing an automatic statutory injunction, the fact remains that it granted an injunction without further discussion after determining that Amgen should prevail on the merits of the paragraph (*l*)(8)(A) claim. Notably, Defendants do not even attempt to argue that this case is distinguishable from *Amgen* with respect to the *eBay* factors. On the contrary, in its motion for a temporary injunction, Amgen made arguments that closely track those of the Plaintiffs here, contending that price erosion, loss of patent certainty, and harm to goodwill and customer relationships constituted irreparable harm. *See* Amgen's Emergency Motion for an Injunction Pending Appeal 16-19, *Amgen, Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Apr. 17, 2015) (Dkt. No. 55). The Federal Circuit's holding that Amgen was entitled to a 180-day injunction calls for the same conclusion here. That is true regardless whether the basis for Federal Circuit's injunction was *eBay* or the BPCIA itself.

Dated: September 28, 2015

Respectfully submitted,

/s/ Alison C. Casey

Heather B. Repicky (BBO # 663347)
hrepicky@nutter.com
Alison C. Casey (BBO #688253)
acasey@nutter.com
NUTTER MCCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210
617-439-2000
FAX: 617-310-9192

Of Counsel:
Dianne B. Elderkin (admitted *pro hac vice*)
delderkin@akingump.com
Barbara L. Mullin (admitted *pro hac vice*)
bmullin@akingump.com
Angela Verrecchio (admitted *pro hac vice*)
averrecchio@akingump.com
Jason Weil (admitted *pro hac vice*)
jweil@akingump.com
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
215-965-1200
FAX: 215-965-1210

Gregory L. Diskant (admitted *pro hac vice*)
gldiskant@pbwt.com
Irena Royzman (admitted *pro hac vice*)
iroyzman@pbwt.com
Aron Fischer (admitted *pro hac vice*)
afischer@pbwt.com
Andrew D. Cohen (admitted *pro hac vice*)
acohen@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212-336-2000
FAX: 212-336-2222

Attorneys for Janssen Biotech, Inc. and New York University

CERTIFICATE OF SERVICE

I certify that on September 28, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Alison C. Casey

2895185