UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ANTONIO BACHAALANI NACIF and WIES RAFI, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

ATHIRA PHARMA, INC., et al.,

Defendants.

C21-861 TSZ

ORDER

THIS MATTER comes before the Court on defendants' motion, docket no. 76, to dismiss the Consolidated Amended Complaint ("CAC"),[1] docket no. 74. Having reviewed all papers filed in support of, and in opposition to, the motion, the Court enters the following Order.

[1] By Order entered October 5, 2021, docket no. 60, the Court appointed as co-lead plaintiffs Antonio Bachaalani Nacif and Wies Rafi, and approved as lead counsel the firms of Labaton Sucharow LLP and Glancy Prongay & Murray LLP. Pursuant to the Minute Order entered October 28, 2021, docket no. 62, co-lead counsel, along with liaison counsel, Rossi Vucinovich, P.C., filed the Consolidated Amended Complaint that is the subject of the pending motion. Although the CAC identifies as plaintiffs only Nacif and Rafi, the caption of the CAC does not include them, but rather the putative class members who commenced these consolidated actions, namely Fan Wang, Hang Gao, Harshdeep Jawandha, Timothy Slyne, and Tai Slyne. The Clerk is DIRECTED to update the docket to reflect Nacif's and Rafi's status as the named plaintiffs, and all future filings shall bear the same caption as this Order.

**Background**

Athira Pharma, Inc. ("Athira") is a "late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal heath and stop neurodegeneration." Initial Public Offering ("IPO") Prospectus at 1, Ex. 2 to Roberts Decl. (docket no. 77-2). From 2013 until 2021, Leen Kawas, Ph.D. served as Athira's Chief Executive Officer ("CEO") and President. *See* CAC at ¶¶ 28 & 98 (docket no. 74). This litigation concerns statements made within Athira's IPO Prospectus and Second Public Offering ("SPO") Prospectus, as well as other filings with the U.S. Securities and Exchange Commission ("SEC"), which were not themselves false, but which are alleged to have been misleading because arguably material facts concerning Kawas's prior research were omitted.

Kawas obtained her pharmacology doctorate from Washington State University ("WSU") in 2011, after publishing a dissertation concerning the impact of Dihexa and/or its analogs (substances as to which WSU holds various patents) on the hepatocyte growth factor ("HGF") and Met system.[2] CAC at ¶¶ 31 & 35. The Consolidated Amended Complaint indicates that Athira's product known as "ATH-1017" either contains Dihexa as its active ingredient or is a "prodrug" that is used to transmit Dihexa. CAC at ¶¶ 1 & 29; *see id.* at ¶ 29 n.9 (defining a "prodrug" as "a biologically inactive compound that is

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[2] According to the Consolidated Amended Complaint, HGF activity is responsible for healthy brain function, and it is reduced in patients with neurodegenerative disorders like Alzheimer's Disease. CAC at ¶ 30. The CAC explains that Dihexa (N-hexanoic-L-tyrosine-L-isoleucine-(6)-aminohexanoic amide) either activates or mimics HGF activity at the c-Met receptor and might therefore improve cognitive function. *Id.*

used in lieu of the active compound to improve how the active compound is absorbed, distributed, or transmitted throughout the body"). The CAC further alleges that Kawas's dissertation was the "foundation" of her subsequent research and "the corresponding publications that directly relate to the development of ATH-1017." *Id.* at ¶ 40.

Between 2011 and 2015, Kawas co-authored the following six articles:

1. Leen H. Kawas, et al., *Mimics of the Dimerization Domain of Hepatocyte Growth Factor Exhibit Anti-Met and Anticancer Activity*, 339 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 509 (Nov. 1, 2011) **[hereinafter "Article 1"]**;

2. Leen H. Kawas, et al., *Development of Angiotensin IV Analogs as Hepatocyte Growth Factor/Met Modifiers*, 340 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 539 (Mar. 1, 2012) **[hereinafter "Article 2"]**;

3. Alene T. McCoy, et al., *Evaluation of Metabolically Stabilized Angiotensin IV Analogs as Procognitive/Antidementia Agents*, 344 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 141 (Jan. 1, 2013) **[hereinafter "Article 3"]**;

4. Leen H. Kawas, et al., *Nanoscale Mapping of the Met Receptor on Hippocampal Neurons by AFM and Confocal Microscopy*, 9 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY & MED. 428 (Apr. 2013) **[hereinafter "Article 4"]**;

5. Caroline C. Benoist, et al., *The Procognitive and Synaptogenic Effects of Angiotensin IV–Derived Peptides Are Dependent on Activation of the Hepatocyte Growth Factor/c-Met System*, 351 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 390 (Nov. 1, 2014) **[hereinafter "Article 5"]**; and

6. Phillip M. Uribe, et al., *Hepatocyte Growth Factor Mimetic Protects Lateral Line Hair Cells from Aminoglycoside Exposure*, 9(3) FRONTIERS IN CELLULAR NEUROSCIENCE (Jan. 28, 2015) (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4309183/) **[hereinafter "Article 6"]**.

CAC at ¶¶ 42, 50, 54, 60, 66, & 74 and nn.18, 22, 23, & 25.

Beginning in October 2014, comments about one or more of these articles started to appear on "PubPeer," which the operative pleading describes as "a website that allows users to discuss and review scientific research after publication." *See* CAC at ¶ 44 n.13. In its responses to "frequently asked questions," PubPeer indicates that it "accepts all types of comments about papers," but instructs that "[a]llegations of misconduct are forbidden." Ex. 4 to Sadler Decl. (docket no. 82-4 at 3 & 4). PubPeer further cautions that it "does not review comments scientifically," meaning that "comments conforming to [its] guidelines may still be wrong, misguided or unconvincing." *Id.* (docket no. 82-4 at 8). PubPeer "gives users control of their anonymity," and it has "no way of identifying anonymous commenters." *Id.* (docket no. 82-4 at 6 & 7). Some commenters use pseudonyms, which are "assigned randomly from the tree of life," *id.* (docket no. 82-4 at 10), while others voluntarily identify themselves in their posts, like Elisabeth M. Bik, a microbiologist who allegedly focuses on "image authenticity," *see* CAC at ¶ 94 (quoting Olivia Goldhill, *STAT News* (June 17, 2021)). PubPeer alerts authors via email when their papers receive comments. *See* Ex. 4 to Sadler Decl. (docket no. 82-4 at 5).

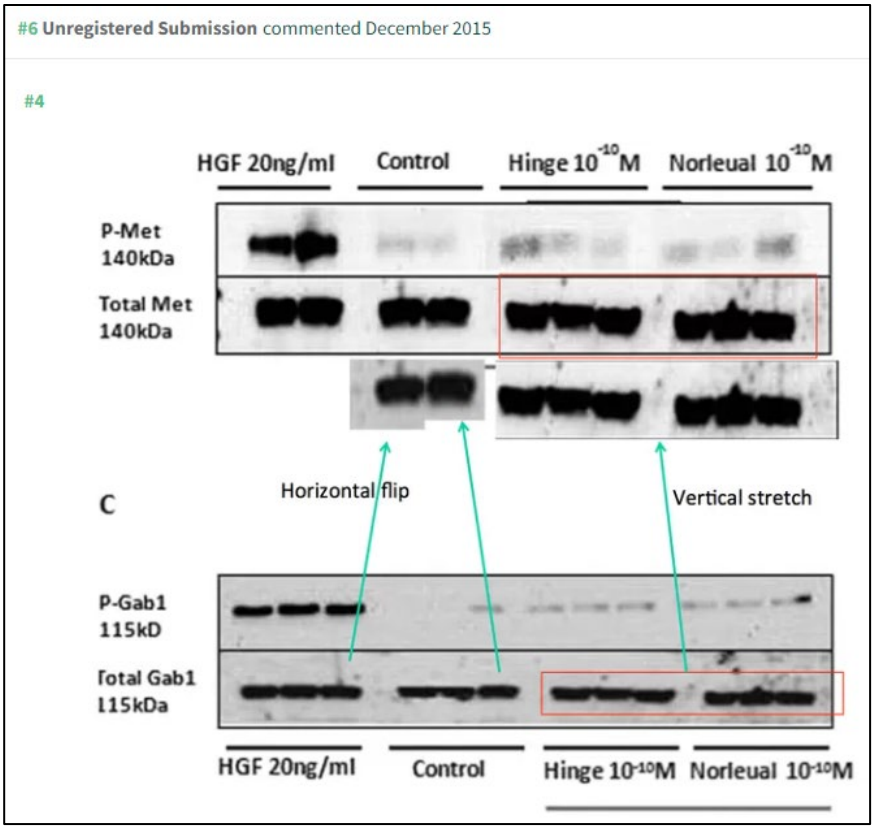
**A. Pre-IPO/SPO Comments on PubPeer**

Prior to Athira's IPO and SPO, only Articles 1, 4, and 5 were the subject of PubPeer postings. None of these PubPeer comments connected the figures in the publications to the images in Kawas's dissertation, and all of them were submitted anonymously. In October 2014, the following unregistered submission concerning Figure 2C in Article 5 appeared on PubPeer:

> **#1 Unregistered Submission** commented October 2014
>
> Multiple concerns about the image provided for the immunoblots in Figure 2c.
>
> http://jpet.aspetjournals.org/content/351/2/390/F2.large.jpg
>
> including the striking similarity between three of the bands in the lower row (P-Met) and the upper row (total Met), and several areas where the background shading changes at a 'hard edge'.
>
> If more experienced people at Pubpeer allay my concerns, or the authors provide the original images, then I will be very happy to withdraw my concern about this otherwise very interesting piece of work.

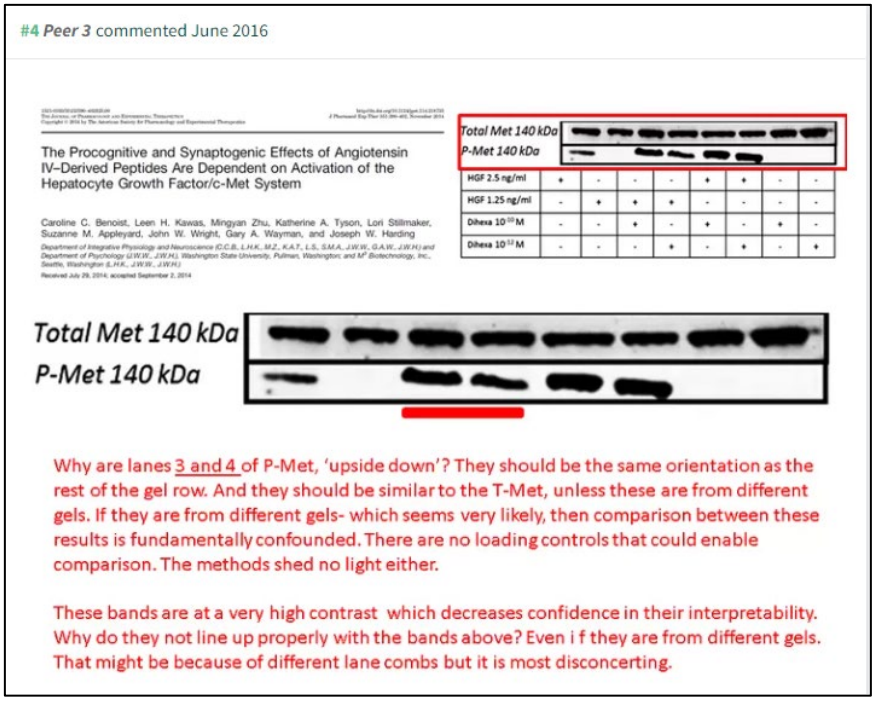
*See* https://www.pubpeer.com/publications/D5375331091A7EF887CDC02B813ACA (quoted in CAC at ¶ 68). Another PubPeer user disagreed, responding as follows: "I do not see concerning similarities between bands. Some bands are similar in shape, but there are not a lot of irregularities in shape or surrounding background, so it is hard to tell. I definitely do not see striking similarities between three bands." *Id.*

Article 1 was also the subject of comments in October 2014, but the operative pleading does not discuss those posts, presumably because, in January 2015, someone reported on PubPeer that "the authors have issued a correction that appears to address the query at the top of this thread." *See* https://www.pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE. In December 2015, a comment relating to Figures 3A and 3C of Article 1 was anonymously submitted to PubPeer, without any accompanying question or explanation. Plaintiffs have reproduced it in the Consolidated Amended Complaint, but without attribution, alleging that it "highlights the intentional nature" of Kawas's alleged misconduct. CAC at ¶ 47. The posting, which is shown on the next page and which cannot be understood without reference to the original (now unavailable without a subscription) article, makes no accusation of intentional misbehavior.




*See* https://www.pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE (included with modification in CAC at ¶ 47).

In June 2016, Article 5 was again questioned in a PubPeer post:

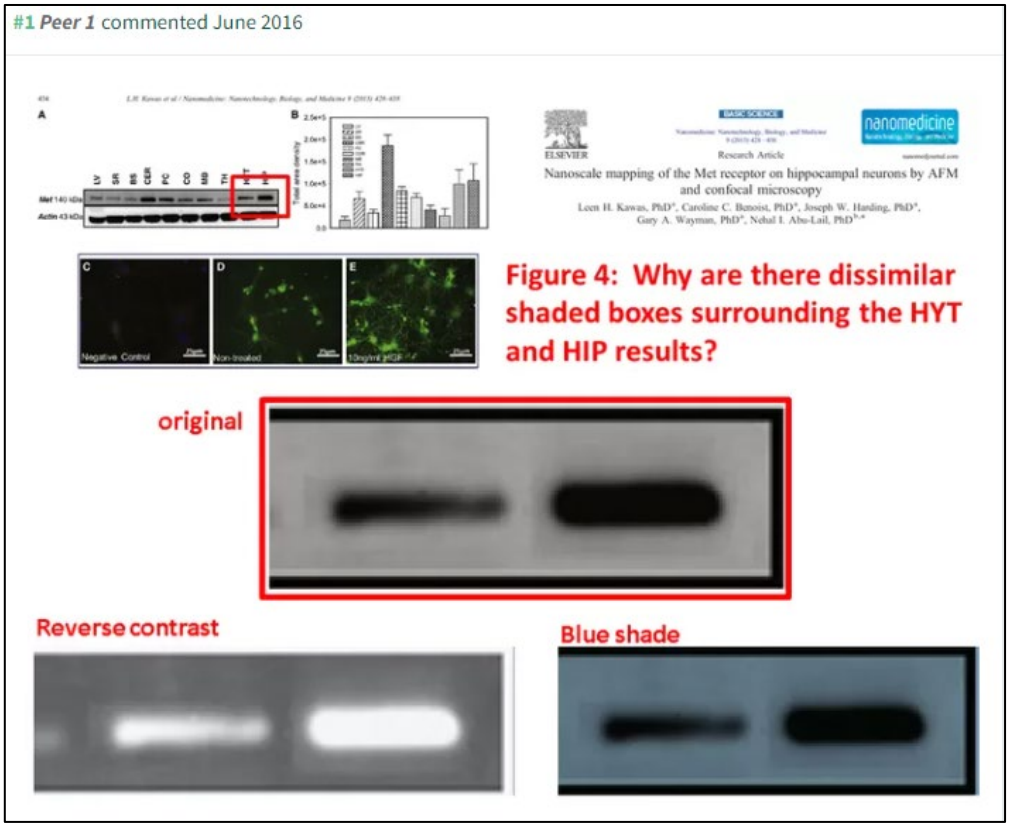


CAC at ¶ 69 (containing a screen shot from https://www.pubpeer.com/publications/D5375331091A7EF887CDC02B813ACA). The same commenter added:

> #5 *Peer 3* commented June 2016
>
> This research has been parlayed into a Biotechnology company called M3 led by one of the first authors of this study, Dr. Kawas. In the post-Holmes/Theranos environment, these and other concerns have added urgency.

*See* CAC at ¶ 70.

Around the same time, in June 2016, the following post about Article 4 appeared:




CAC at ¶ 62 (reproducing comment #1 at https://www.pubpeer.com/publications/36F84FDB31C718C8CF8F52C717D15C). No further comments about any of the six articles at issue were posted to PubPeer between June 2016 and May 2021.

In the meanwhile, in September 2020, Athira conducted an initial public offering of 12 million shares (at $17 per share) and netted roughly $186.4 million. CAC at ¶ 89. In October 2020, Athira's underwriters purchased almost 1.4 million shares (at $17 per share), netting Athira approximately $22.1 million. *Id.* Athira's second public offering of four million shares (at $22.50 per share) transpired in January 2021 and grossed $90 million. *Id.* at ¶ 90.

## B. Post-IPO/SPO Comments on PubPeer

In May 2021, comments about all six articles began surfacing, each from one of three PubPeer users. An individual with the pseudonym Actinopolyspora biskrensis submitted remarks about Articles 1, 2, 4, and 5. A person assigned the pseudonym Indigofera tanganyikensis made observations regarding Articles 1, 3, and 6. Elisabeth M. Bik offered opinions concerning certain figures in Articles 1, 2, and 5. These postings, organized by article, were as follows.

### 1. Article 1 – Kawas, et al. (Nov. 1, 2011)

#7 ***Actinopolyspora biskrensis*** commented May 2021

It appears that some of these figures were part of the December 2011 PhD dissertation of the first author, who seems now to be the CEO of a pharmaceutical company. I will add the email addresses of some of the co-authors in hopes that one of them will address these concerns. I will also alert the institution who may wish to investigate.

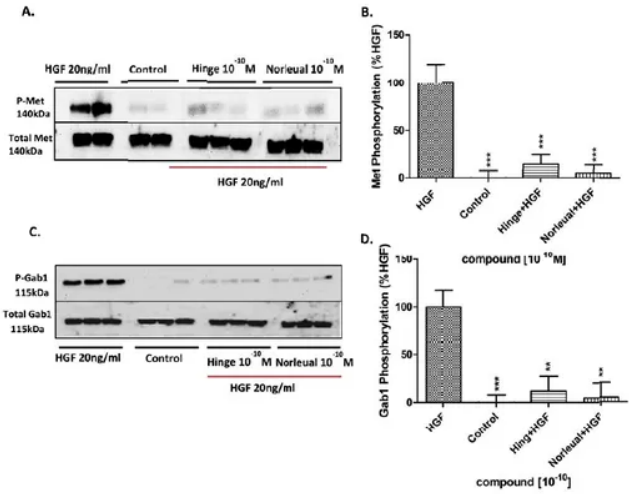


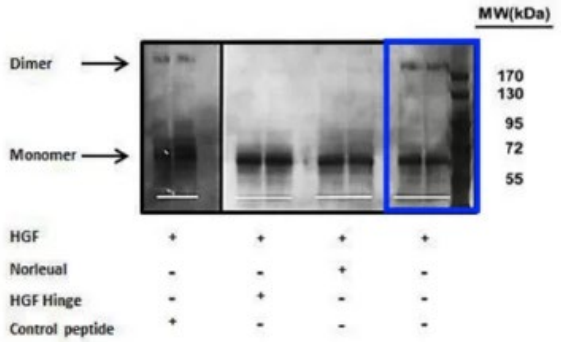

Figure 2.3: Norleual and the Hinge peptide inhibit HGF-dependent Met and Gab1 phosphorylation.

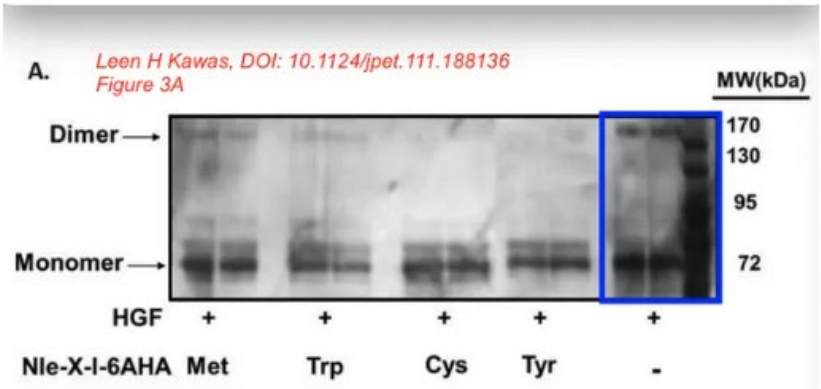
*See* CAC at ¶ 44 (quoting comment #7 at https://www.pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE). The CAC has omitted the next comment (#8), which was also from Actinopolyspora biskrensis and related to the remarks about Article 1 that were made in October 2014, but has included Elizabeth M. Bik's posting:

#9 **Elisabeth M Bik** commented June 2021

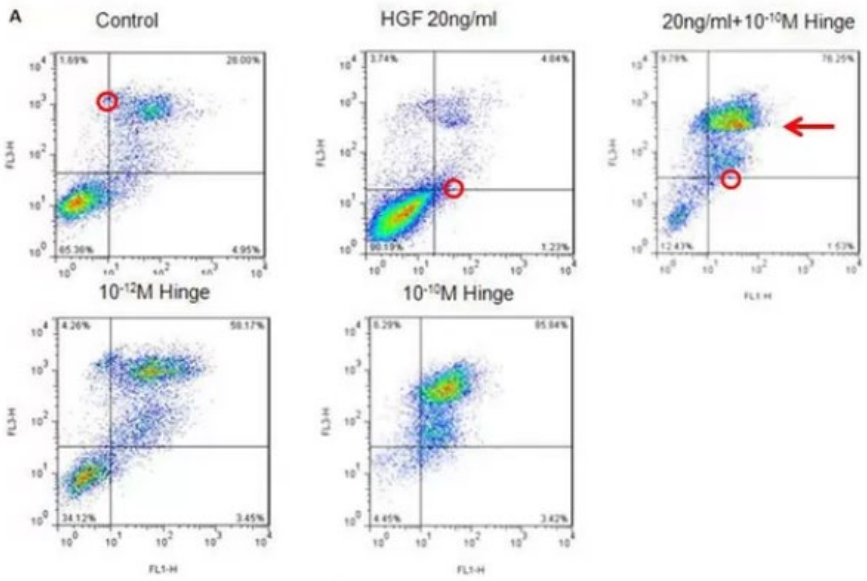
Blue boxes: Two lanes in Figure 2A of this paper appear to look similar to two lanes in Figure 3A in another paper by the same authors. That paper is: Leen H Kawas et al., DOI: 10.1124/jpet.111.188136, https://pubpeer.com/publications/01199F548BE82EE44C7D395568982B

Although the labels suggests these samples might have been treated similarly, it seems not quite good practice to include lanes from a different gel run on a different day. As can been seen from the comparison of the two gels, the 'monomer' bands form a single thick band in one gel, but run more like a double band in the second gel, suggesting the gel conditions might have been different. Can the authors please comment on the experimental conditions?



*See* CAC at ¶ 45 (quoting comment #9 at https://www.pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE). The last comment of interest about Article 1 was by Indigofera tanganyikensis:

> #10 ***Indigofera tanganyikensis*** commented June 2021
>
> I agree with the concerns raised in previous posts.
>
> The flow cyotmetry data presented in Figure 6A is also questionable.
>
> One of the dot plots show a unusal discontinuity (red arrow). In additon there are data points over the gating line, which is hard to explain since you always put the gating lines after the data is displayed...
>
> Kawas, L. H., Yamamoto, B. J., Wright, J. W., & Harding, J. W. (2011).
> *Mimics of the Dimerization Domain of Hepatocyte Growth Factor Exhibit Anti-Met and Anticancer Activity.*
> *Journal of Pharmacology and Experimental Therapeutics, 339(2), 509–518.* doi:10.1124/jpet.111.185694
>
> Figure 6A
>
> 
> 

*See* CAC at ¶ 46 (quoting comment #10 at https://www.pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE).

**2. Article 2 – Kawas, et al. (Mar. 1, 2012)**

The operative pleading asserts that "[t]he intentional nature of the alteration [to figures in Article 2] is apparent as the shaded box, the borders of which are identified by

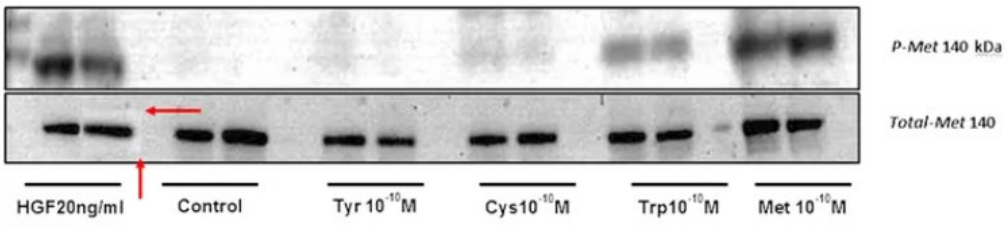
the red arrows below, confirms the image was intentionally manipulated." *See* CAC at ¶ 51. For support, the CAC cites to two PubPeer submissions by Actinopolyspora biskrensis, but neither posting makes any accusation about Kawas's intent.

**#2 *Actinopolyspora biskrensis*** commented May 2021

I came across this independently and agree with **#1**.

First author appears to now be CEO of a pharmaceutical company: https://www.athira.com/about-athira/#leadership

Contrast enhanced




**#3 *Actinopolyspora biskrensis*** commented May 2021

The figure in question appears to be from the PhD dissertation of the first author (page 102).

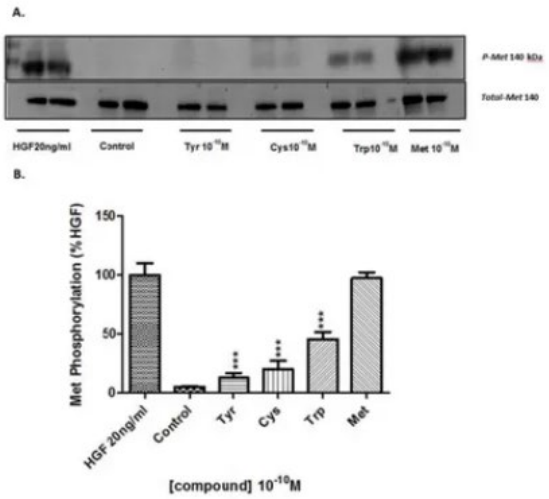



**Figure 3.4: Nle-X-Ile-(6) aminohexanoic amide analogs inhibition of Met phosphorylation.**

*See* https://www.pubpeer.com/publications/01199F548BE82EE44C7D395568982B.

Elisabeth M. Bik posted a comment about Article 2 that is almost identical to the opinion she had expresed about Article 1. The CAC does not reference the duplicative submission, a truncated version of which is reproduced on the left.

> **#4 Elisabeth M Bik** commented June 2021
>
> Blue boxes: Two lanes in Figure 3A of this paper appear to look similar to two lanes in Figure 2A in another paper by the same authors. That paper is: Leen H Kawas et al., DOI: 10.1124/jpet.111.185694, https://pubpeer.com/publications/51C554512CE22267B2E62172DF3DDE

**3. Article 3 – McCoy, et al. (Jan. 1, 2013)**[3]

Article 3 is among the publications referenced in U.S. Patent No. 11,021,514 (the "'514 Patent"), which was granted in June 2021 to Athira. *See* '514 Patent at p. 3; *see also* CAC at ¶¶ 57 & 82. According to the operative pleading, the '514 Patent covers "the composition of matter for ATH-1017." CAC at ¶ 82 (quoting an unidentified source). The CAC further alleges that the goal of the research summarized in Article 3 is "exactly the same goal that Athira has pursued since its founding." *Id.* at ¶ 56. In support of this assertion, the CAC quotes four sentences from a draft of Article 3, but the verbiage on which the operative pleading relies is preceded by an important disclaimer, highlighted in the following excerpt:

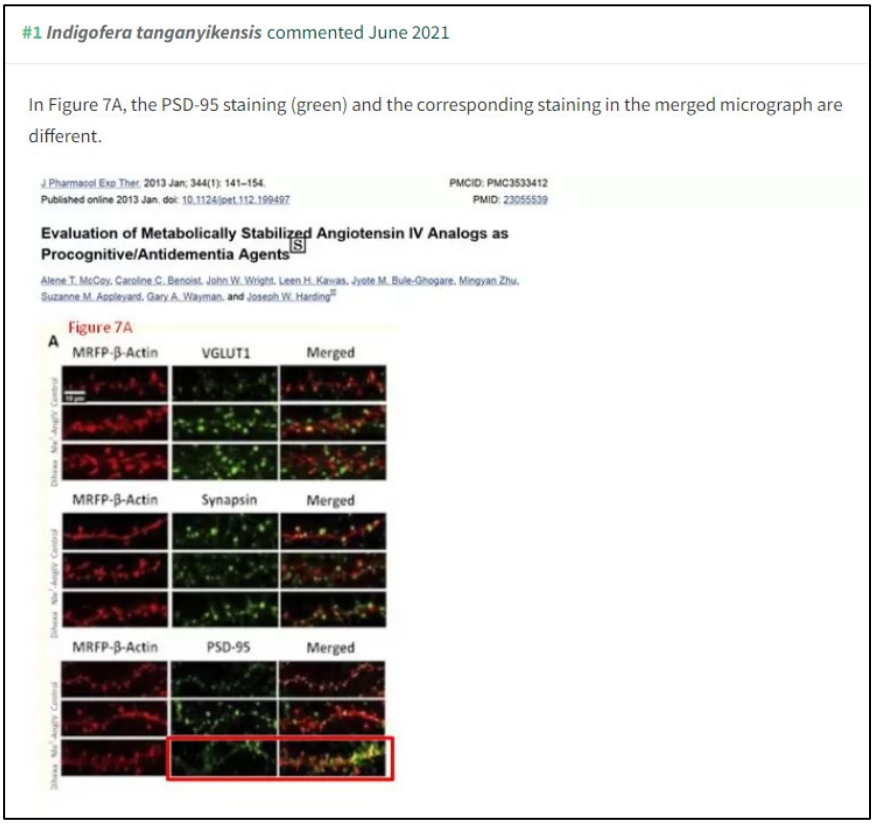
> **Although not the focus of this study** an obvious question relates to the identity of the molecular target responsible for the pro-cognitive and synaptogenic activity of dihexa and other AngIV-related compounds. Hints to the answer to this question can be found in four recent articles (Yamamoto et al., 2010; Kawas et al., 2011; Kawas et al., 2012, Wright et al., 2012),

[3] The operative pleading provides two different publication dates for Article 3, *see* CAC at ¶ 54 & n.18, but the abstract available at https://jpet.aspetjournals.org/content/344/1/141 indicates that Article 3 was accepted in early October 2012 and appeared in the January 2013 issue of the Journal of Pharmacology and Experimental Therapeutics.

> which clearly demonstrate that both the peripheral and CNS [central nervous system] actions of "$AT_4$ receptor" antagonists depend on their ability to inhibit the hepatocyte growth factor (HGF) / c-Met (HGF receptor) system by binding to and blocking HGF activation. *Conversely we (Benoist, Kawas, Wright, and Harding unpublished) have recently demonstrated that both Nle$^1$-AngIV and dihexa bind HGF leading to its activation and that the pro-cognitive and/or synaptogenic actions of these compounds are blocked by both HGF and c-Met antagonists. With this knowledge in hand a library of N-acyl-Tyr-Ile-(6) amino-hexanoic amide analogs was screened for their capacity to potentiate the biological activity of HGF. This screen identified the hexanoic N-terminal substituent as the most active compound.*
>
> *The ultimate goal of this project was to produce a clinically useful pharmaceutical for the treatment of dementia including Alzheimer's disease.* . . . **Among planned future studies**, designed to gage the clinical potential of dihexa, will be a direct comparison of dihexa to several approved anti-dementia therapeutics using rodent dementia models.

Draft of Article 3 at 37–38 (emphasis added) (italicized portion quoted in CAC at ¶ 55), JPET Fast Forward version (Oct. 10, 2012), available at https://jpet.aspetjournals.org/content/jpet/early/2012/10/10/jpet.112.199497.full.pdf (cited in CAC at ¶ 55 n.19).

The only PubPeer posting concerning Article 3 was submitted by Indigofera tanganyikensis:


#1 *Indigofera tanganyikensis* commented June 2021

In Figure 7A, the PSD-95 staining (green) and the corresponding staining in the merged micrograph are different.

J Pharmacol Exp Ther. 2013 Jan; 344(1): 141–154. PMCID: PMC3533412
Published online 2013 Jan. doi: 10.1124/jpet.112.199497 PMID: 23055539

**Evaluation of Metabolically Stabilized Angiotensin IV Analogs as Procognitive/Antidementia Agents**[S]

Alene T. McCoy, Caroline C. Benoist, John W. Wright, Leen H. Kawas, Jyote M. Bule-Ghogare, Mingyan Zhu, Suzanne M. Appleyard, Gary A. Wayman, and Joseph W. Harding[2]

Figure 7A

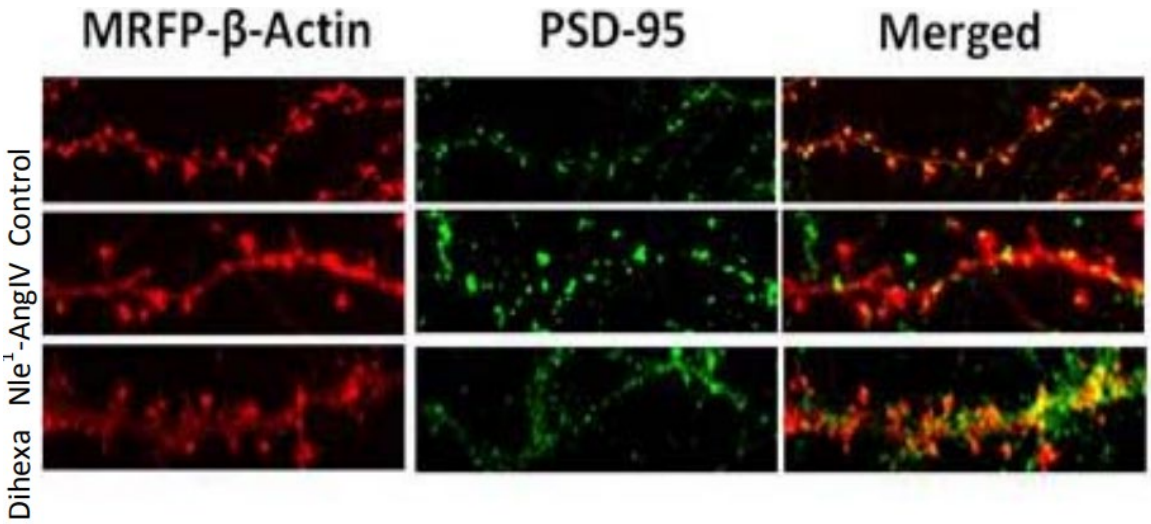
A

MRFP-β-Actin VGLUT1 Merged

MRFP-β-Actin Synapsin Merged

MRFP-β-Actin PSD-95 Merged

CAC at ¶ 58 (reproducing comment #1 at https://www.pubpeer.com/publications/4D8EFBD349D1A779627479FB694F7C). The operative pleading adds words to the end of the remark so that the sole sentence reads, "In Figure 7A, the PSD-95 staining (green) and the corresponding staining in the merged micrograph are different [from the other images]," *id.*, but the original observation was complete without the bracketed phrase. It concerned the two images at the intersections of the bottom row labeled "Dihexa" with the columns labeled "PSD-95" and "Merged," which are more visible in the following excerpt from the draft of Article 3:




Draft of Article 3 at Fig. 7-1, JPET Fast Forward version (Oct. 10, 2012), available at https://jpet.aspetjournals.org/content/jpet/early/2012/10/10/jpet.112.199497.full.pdf. Neither Indigofera tanganyikensis's June 2021 PubPeer comment nor the operative pleading connect Figure 7A of Article 3 with Kawas's dissertation.

**4. Article 4 – Kawas, et al. (Apr. 2013)**

With regard to Article 4, Actinopolyspora biskrensis posted three times in the May–June 2021 timeframe. The CAC quotes from two of Actinopolyspora biskrensis's

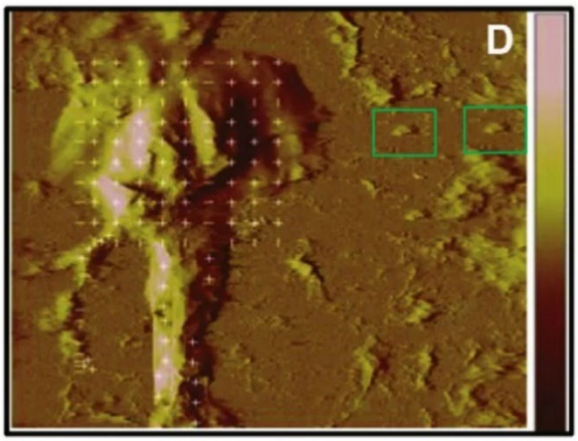
comments, which accuse the writers of manipulating (via a cut-and-paste method) a portion of Figure 2D, which "seem[s] to be pulled from the PhD dissertation of the first author," *see* CAC at ¶ 63, but the operative pleading omits the following observation by Actinopolyspora biskrensis:

> [T]he duplicated area noted in [comment] #2 does not seem to be part of the corresponding figure . . . in the dissertation. I suspect the duplication was done when labeling was redone for this published paper. If true, this certainly is not a best practice, ***but likely not done with any ill intent***.

*See* https://www.pubpeer.com/publications/36F84FDB31C718C8CF8F52C717D15C (emphasis added). The alleged duplications were demarcated in Actinopolyspora biskrensis's posts with green and magenta rectangles:

#2 ***Actinopolyspora biskrensis*** commented May 2021

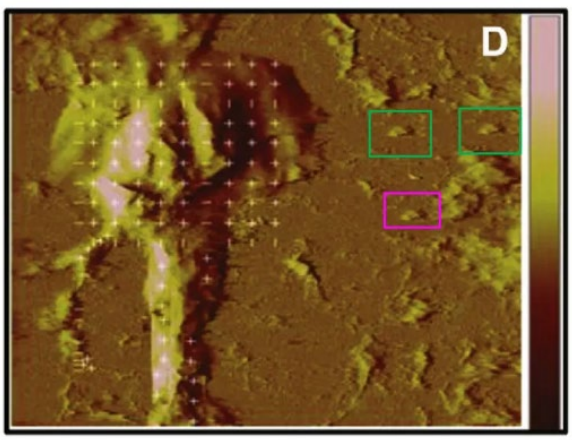
In addition to the concern in #1, with which I agree, there appears to be a region in Figure 2D that has been cut and pasted. The purpose of such manipulation is unclear, but it calls into question the veracity of the results.




#5 ***Actinopolyspora biskrensis*** commented June 2021

#2

A more careful reader spotted another possible occurrence of the apparently repeated figure (magenta box).




Actinopolyspora biskrensis also supplied the corresponding figure (Fig. 4.1C) from Kawas's dissertation:

#3 ***Actinopolyspora biskrensis*** commented May 2021

These figures seem to be pulled from the PhD dissertation of the first author (page 127), who appears to now be the CEO of a pharmaceutical company.

However, the duplicated area noted in #2 does not seem to be part of the corresponding figure 4.1 (below) in the dissertation. I suspect the duplication was done when labeling was redone for this published paper. If true, this certainly is not a best practice, but likely not done with any ill intent.

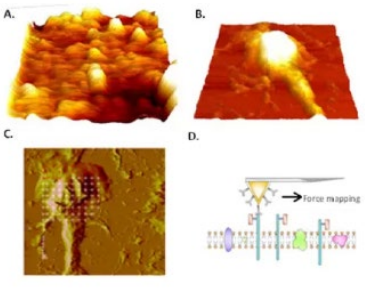
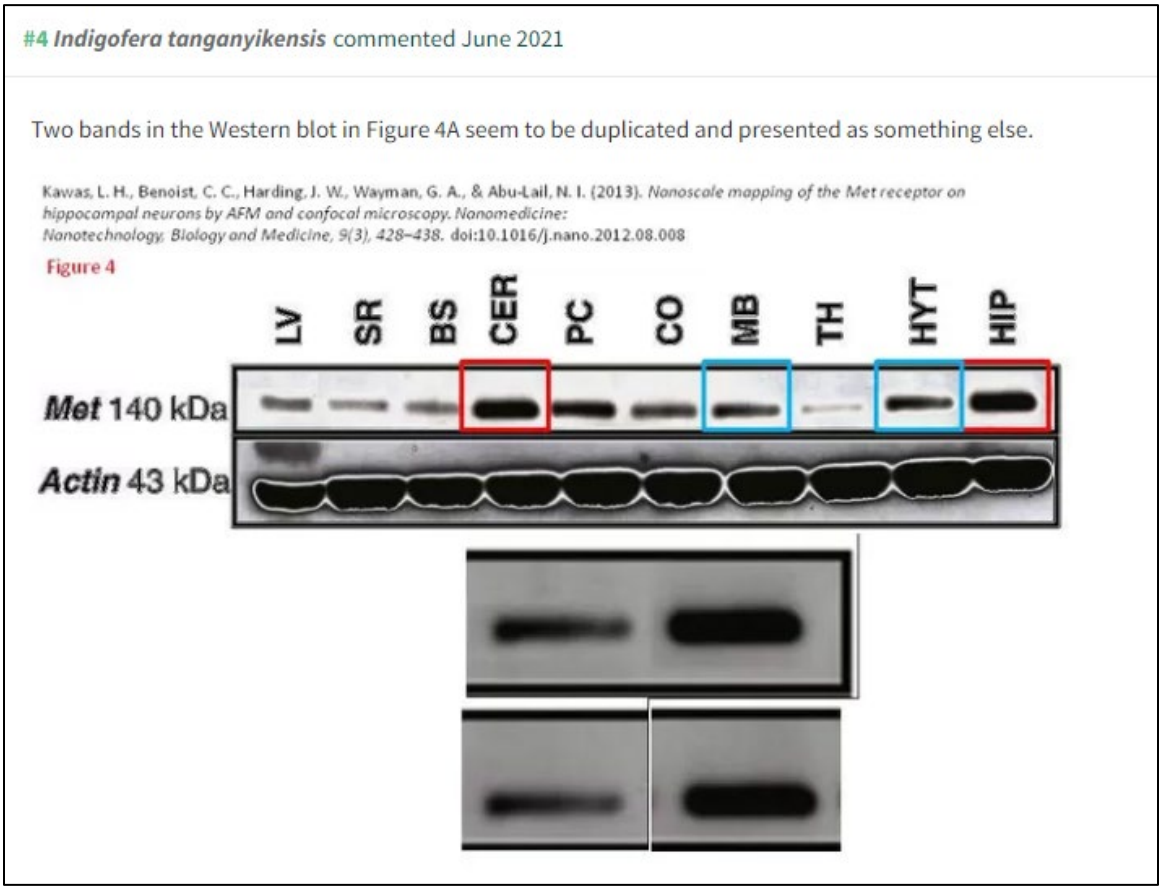



**Figure 4.1: Experimental setup: tip functionalization and force mapping.** (**A**) 3D high resolution TappingMode image of a COOH-activated Si3N4 disk with a monoclonal antibody against Met. The image is 500X500 $nm^2$ and 7.5 nm high. (**B**) 3D height Tapping Mode image of a hippocampal neuronal cell attached to poly-L-lysine coated coverslip. The image is 50X50$\mu m^2$ and 2.5 μm high (**C**) A representative example of how points are selected for force measurements. The image shows standard grid selection for locations on soma where force measurements were performed. (**D**) A schematic representation of how a Met receptor can be identified on hippocampal neurons cells membranes using a Met antibody-modified AFM tip.

Meanwhile, Indigofera tanganyikensis focused on Figure 4A in Article 4:

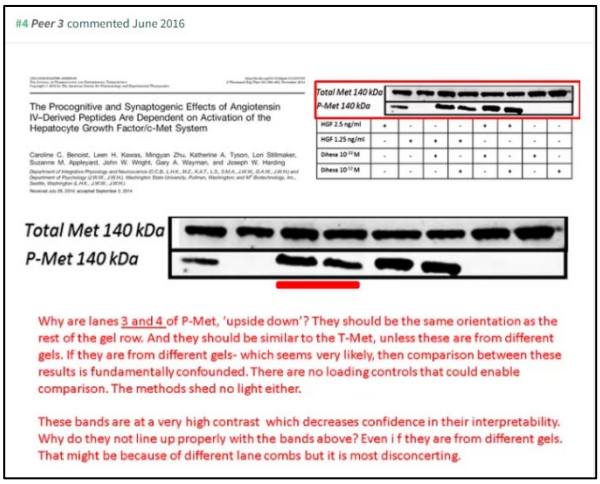


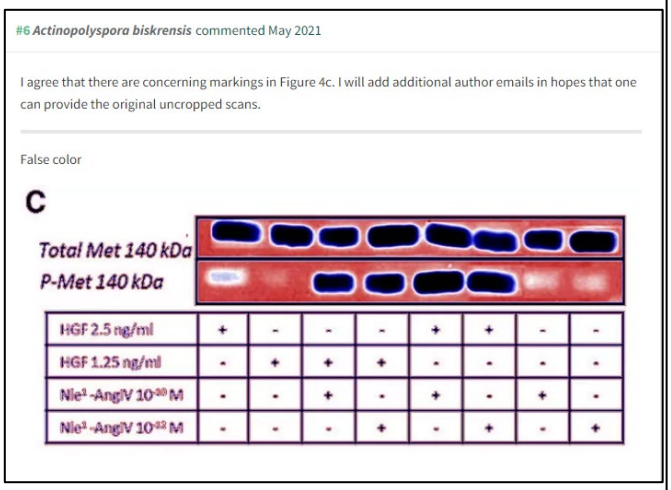

*See* CAC at ¶ 64 (quoting from comment #4 at https://www.pubpeer.com/publications/36F84FDB31C718C8CF8F52C717D15C). Unlike with Figure 2D, neither Indigofera tanganyikensis nor the operative pleading suggests that Figure 4A was replicated from Kawas's dissertation.

**5. Article 5 – Benoist, et al. (Nov. 2014)**

In May 2021, Actinopolyspora biskrensis stated agreement with the comments made on PubPeer in June 2016 about Figure 4C of Article 5. Both the anonymous comment made in June 2016 and Actinopolyspora biskrensis's submission in May 2021 are shown on the next page. In the May 2021 posting, Actinopolyspora biskrensis

indicated that "additional author emails" would be added "in hopes that one [of the writers] can provide the original uncropped scans." CAC at ¶ 71 (quoting comment #6 at https://www.pubpeer.com/publications/D5375331091A7EF887CDC02B813ACA). Based on Actinopolyspora biskrensis's remarks, the operative pleading alleges that Kawas and the other co-authors of Article 5 "received an email notification by at least May 2021, putting them on notice that the truth about the improperly altered research results was beginning to be revealed." *Id.* Any such notice, however, post-dated both the IPO and the SPO, the prospectuses related to which are the subject of this litigation.




June 2016 May 2021

In June 2021, Elisabeth M. Bik offered a montage of images from Articles 1, 2, and 5, to which she added yellow, pink, and blue boxes, and suggested that (i) Figure 1 of Article 5 contained "lanes" from the older papers, and (ii) the four "lanes" in the pink box "do not always appear to correspond to the same experiments." CAC at ¶ 72 (quoting comment #7 at https://www.pubpeer.com/publications/D5375331091A7EF887CDC02B813ACA). Bik's entire comment is reproduced on the next page.

#7 Elisabeth M Bik commented June 2021

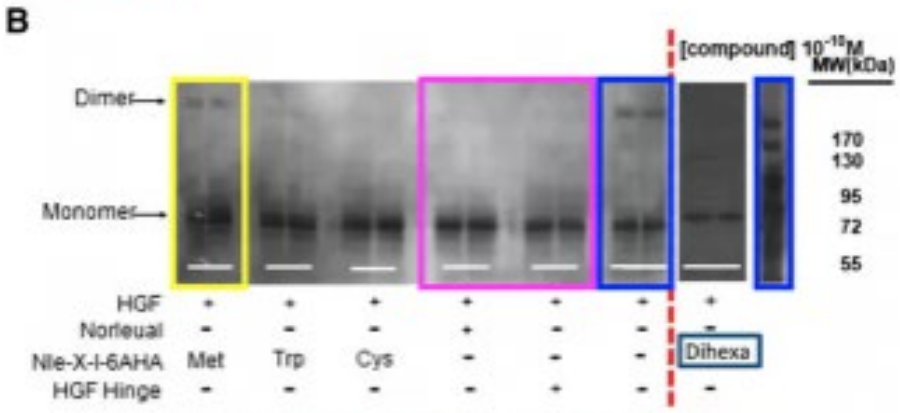
Figure 1

- Yellow, pink, and blue boxes highlight lanes also visible in two older paper by some of the same authors. The lanes do not always appear to correspond to the same experiments, in particular the four lanes marked with the pink box.

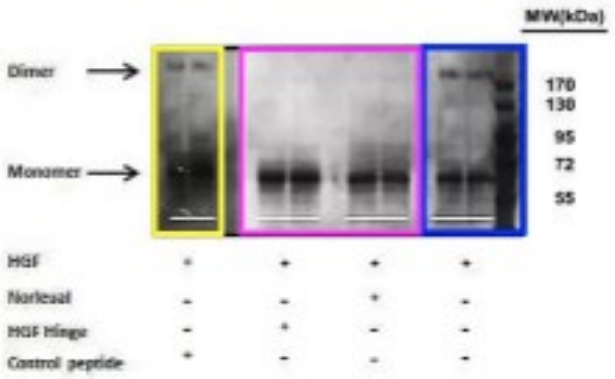
Could the authors please comment?

Those other two papers are Kawas et al., (2011), DOI: 10.1124/jpet.111.185694, https://pubpeer.com/publications/51C554512CE22267B2E621720F3DDE , and Kawas et al. (2012), DOI 10.1124/jpet.111.188136, https://pubpeer.com/publications/01199F548BE82EE44C7D3955689828 .

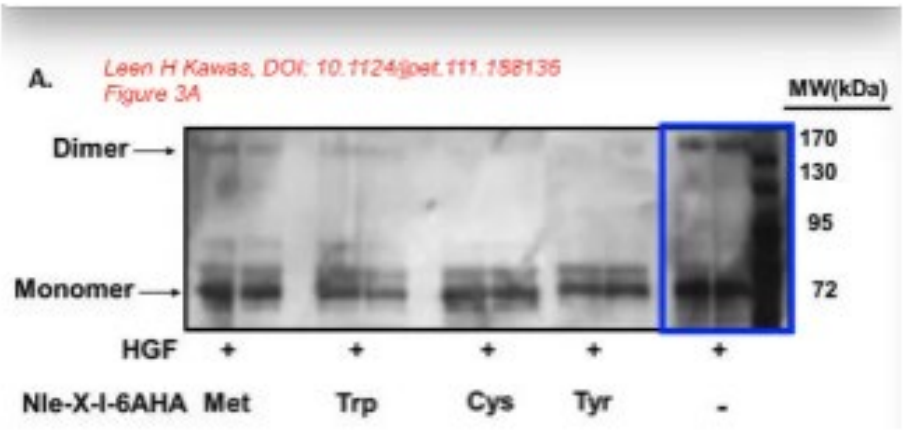
*Caroline C Benoist et al., DOI: 10.1124/jpet.114.218735*
*Figure 1*




*Leen H Kawas et al., DOI: 10.1124/jpet.111.185694*
*Figure 2A*




*Leen H Kawas, DOI: 10.1124/jpet.111.158136*
*Figure 3A*



**6. Article 6 – Uribe, et al. (Jan. 2015)**

Although Article 6 concerns experiments performed with Dihexa, it is not focused on neuronal heath, neurodegeneration, dementia, or Alzheimer's Disease. The scope of the study reported in Article 6 is described in its abstract as follows:

> Loss of sensory hair cells from exposure to certain licit drugs (e.g., aminoglycoside antibiotics, platinum-based chemotherapy agents) can result in permanent hearing loss. *Here we ask if allosteric activation of the hepatocyte growth factor (HGF) cascade via Dihexa, a small molecule drug candidate, can protect hair cells from aminoglycoside toxicity.* Unlike native HGF, Dihexa is chemically stable and blood-brain barrier permeable. As a synthetic HGF mimetic, it forms a functional ligand by dimerizing with endogenous HGF to activate the HGF receptor and downstream signaling cascades. *To evaluate Dihexa as a potential hair cell protectant*, we used the larval zebrafish lateral line, which possesses hair cells that are homologous to mammalian inner ear hair cells and show similar responses to toxins. . . . Our data suggest that Dihexa confers protection of hair cells through an HGF-mediated mechanism and that Dihexa holds clinical potential for mitigating chemical ototoxicity.

Phillip M. Uribe, et al., *Hepatocyte Growth Factor Mimetic Protects Lateral Line Hair Cells form Aminoglycoside Exposure*, 9(3) FRONTIERS IN CELLULAR NEUROSCIENCE (Jan. 28, 2015) (cited in CAC at ¶ 74 n.25, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4309183/) (emphasis added). The operative complaint attempts to link the research summarized in Article 6 to Athira by quoting from the conflict-of-interest statement and the acknowledgments, which disclose that "Leen H. Kawas is the CEO of M3 Biotechnology, Inc.," which "is developing HGF mimetics and antagonists for the treatment of various disorders including dementia," and that "[a]dditional funding for this project was provided by M3 Biotechnology, Inc." *Id.* (quoted in CAC at ¶ 76); *see also* CAC at ¶ 27 n.8 (indicating that Athira was founded as M3 Biotechnology, Inc.).

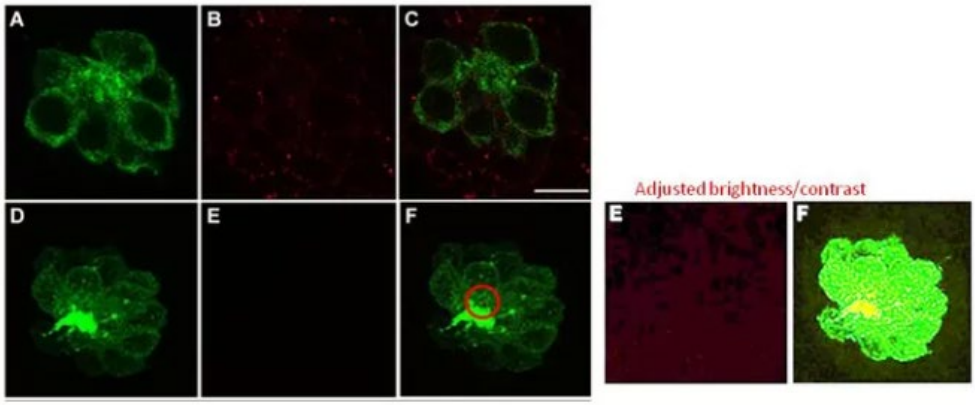
In June 2021, Indigofera tanganyikensis submitted the only comment on PubPeer concerning Article 6. It involved Figure 1 in Article 6, but did not reproduce the entire image or its labels, which are shown on the next page. The labels (and the surrounding text of Article 6) make clear that the samples pictured in Figures 1A–G are from zebrafish, as opposed to mice or rats, which appear to have been the test subjects for Kawas's and her colleagues' anti-dementia research. *See* U.S. Patents Nos. 8,598,118, 9,051,351, and 11,021,514. Neither Indigofera tanganyikensis nor the operative pleading connects Figure 1 of Article 6 with Kawas's dissertation, and the CAC draws no link between Article 6 and either ATH-1017 or Athira's work toward developing substances that might restore neuronal heath and/or stop neurodegeneration.

#1 ***Indigofera tanganyikensis*** commented June 2021

In Figure 1E,F the red staining (E) does not correspond with the merged picture (F). The micrograph in F show one red dot (red circle) which is not seen in E.

Hepatocyte growth factor mimetic protects lateral line hair cells from aminoglycoside exposure.
Uribe PM, Kawas LH, Harding JW, Coffin AB.
Front Cell Neurosci. 2015 Jan 28;9:3. doi: 10.3389/fncel.2015.00003.

Figure 1




*See* CAC at ¶ 77 (reproducing comment #1 at https://www.pubpeer.com/publications/D803673763EF5404FAE8CC546CC028).

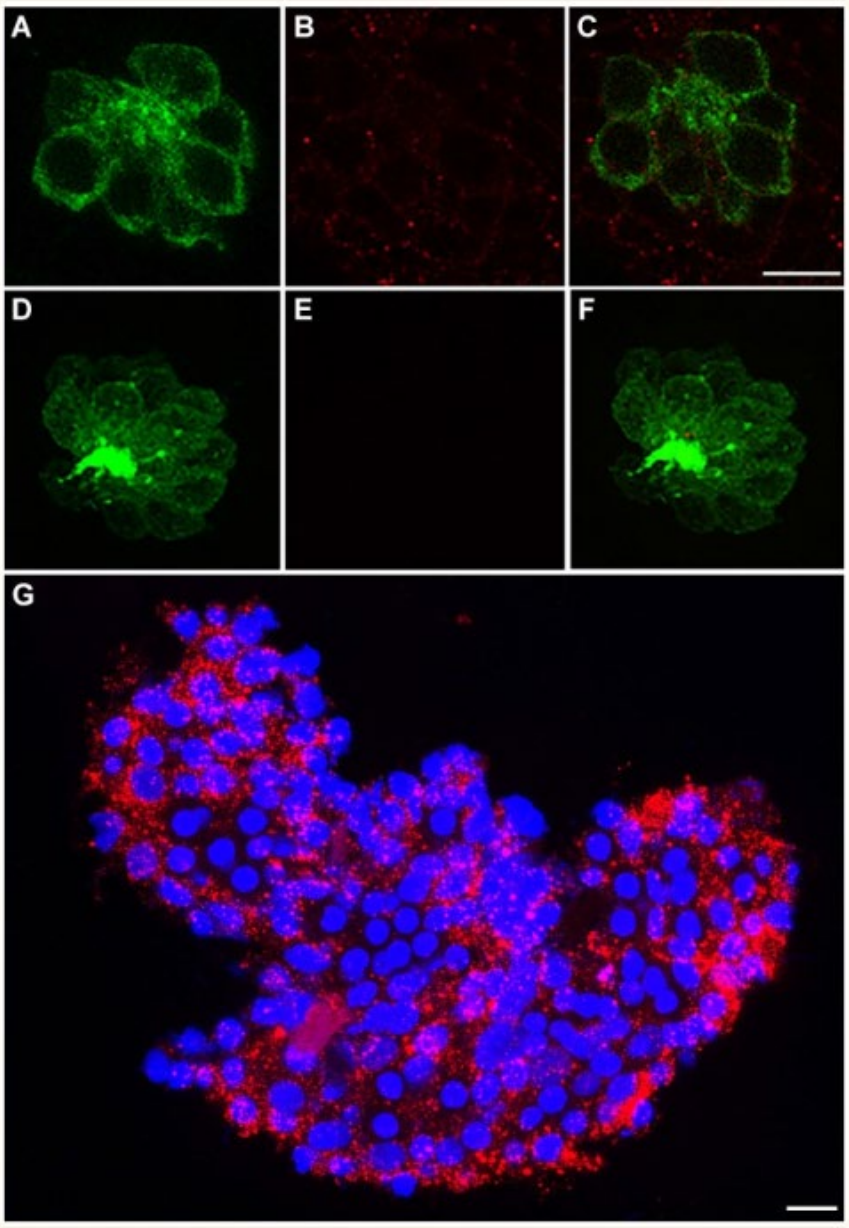



Figure 1

**c-Met is expressed in lateral line neuromasts. (A)** Neuromast of a Brn3c:mGFP transgenic zebrafish with clearly labeled hair cell boundaries. **(B)** Anti-c-Met labeling (red punctae) is present throughout the neuromast. **(C)** Merged image shows c-Met is present near the hair cell membrane and in surrounding cells. **(D–F)** Brn3c:mGFP larvae incubated with secondary antibody only show no c-Met labeling. **(G)** *AB adult liver tissue labeled with DAPI (blue) and anti-c-Met (red) demonstrates robust, punctate c-Met expression. Scale bar in **(C)** represents 5 μm and applies to images **(A–F)**. Scale bar in **(G)** represents 5 μm.

*See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4309183/ (cited in CAC at ¶ 74).

**C. Athira's Response**

On June 17, 2021, shortly after the PubPeer entries by Actinopolyspora biskrensis, Indigofera tanganyikensis, and Elisabeth M. Bik, Athira issued a press release indicating that Kawas had been placed on temporary leave "pending a review of actions stemming from doctoral research [she] conducted while at Washington State University." Ex. 3 to Roberts Decl. (docket no. 77-3). Athira further stated that an independent special committee had been formed to undertake the review. *Id.*; *see also* CAC at ¶ 91. The next day, on June 18, 2021, the price of Athira's stock fell $7.09 per share (nearly 40%) and closed at $11.15 per share. CAC at ¶ 96. In September 2021, the editors of the Journal of Pharmacology and Experimental Therapeutics, which published Articles 1, 2, 3, and 5, issued notices of concern about "possible image manipulation." CAC at ¶¶ 49, 53, 59, & 73. These concerns were shared with the authors and Washington State University, which began conducting its own investigation. *See*, *e.g.*, CAC at ¶ 49 & n.15 (citing Notice of Concern, https://jpet.aspetjournals.org/content/378/3/312.long); *see also* Ex. 5 to Sadler Decl. (docket no. 82-5).

On October 21, 2021, Athira issued a press release announcing that Kawas had resigned from her positions as Athira's CEO and President and as a member of the company's Board of Directors. Ex. 4 to Roberts Decl. (docket no. 77-4). The press release quoted Kelly A. Romano, Chair of the Board of Directors, as saying that "Dr. Kawas's actions at Washington State University took place many years ago and did not involve ATH-1017, Athira's lead development candidate." *Id.* The press release also released the primary finding of the independent special committee, namely that Kawas

"altered images in her 2011 doctoral dissertation and in at least four research papers that she co-authored while a graduate student at WSU, published from 2011 to 2014." *Id.* The press release further explained that (i) Athira's "lead development candidate, ATH-1017, is a novel small molecule in late-stage clinical development and not the subject of Dr. Kawas's doctoral research," (ii) in June 2021, "Athira was issued a patent in the U.S. covering ATH-1017," and (iii) "the special committee found that neither this patent nor the underlying patent application cites any of the papers the special committee found contained images altered by Dr. Kawas." *Id.* The operative pleading alleges that this last statement is demonstrably false.[4] CAC at ¶ 100.

In a resignation letter dated October 21, 2021, and addressed to "Athirians," Kawas wrote:

> *I regret that mistakes I made as a graduate student many years ago caused any distraction to Athira today. At the time, I was navigating an unfamiliar environment and did not fully comprehend the significance of my decision to enhance the images I used in my research.* I want to make clear that the enhancement to images was not a change to or manipulation of the underlying data. Even more importantly, it did not involve ATH-1017, Athira's lead development candidate. Regardless, I should have known better. I am confident that the relationships I have built, my dedication to patients and their families, and the potentially life-changing treatments we have developed, will be what defines me in the future.

[4] The only article co-authored by Kawas that was cited in Athira's '514 Patent was Article 3. *See* '514 Patent at 3. The only PubPeer comment about Article 3 did not link its concerns to Kawas's dissertation or other publications, and plaintiffs provide no basis for believing that the special committee found Article 3 to contain images altered by Kawas. Thus, plaintiffs have not pleaded facts showing that the special committee's press release was "demonstrably false."

CAC at ¶ 98 (quoting italicized portion); *see* Ex. 5 to Roberts Decl. (docket no. 88-1). Although the operative pleading repeatedly accuses Kawas of falsifying or fabricating the results of her studies, it makes no allegation that Kawas invented, altered, or manipulated the underlying data. In November 2021, WSU removed Kawas's dissertation from its archive. CAC at ¶ 41.

**D. Statements in the IPO and SPO Prospectuses, Forms 10-Q and 10-K, and Schedule 14A**

The operative complaint contains several statements challenged by plaintiffs. In their arguments for dismissal of plaintiffs' claims, defendants refer to each statement by number. In their response, plaintiffs embraced this approach. The Court will also adopt this method. The statements are as follows:

1. "Our leadership team includes experienced neuroscience biotech executives who have both developed and commercialized CNS drugs and founded successful companies. Dr. Leen Kawas, our founder and chief executive officer, has been essential in creating our innovative translational development strategy." CAC at ¶¶ 110 & 175 (quoting IPO Prospectus at 8 & 107, Ex. 2 to Roberts Decl. (docket no. 77-2 at 12 & 111)).

2. "Dr. Kawas earned a Ph.D. in molecular pharmacology from Washington State University in 2011 and a pharmacy degree from the University of Jordan in 2008. We believe Dr. Kawas's scientific and professional training, her instrumental role in building Athira Pharma, Inc., and her extensive understanding of our business, operations and strategy qualify her to serve on our board of directors." CAC at ¶¶ 111 & 176 (quoting IPO Prospectus at 151, Ex. 2 to Roberts Decl. (docket no. 77-2 at 155)).

3. "In December 2011, we entered into an exclusive license agreement with Washington State University Research Fund, or WSURF, which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with Washington State University, or WSU, in September of 2015. Under this agreement, WSU granted us an exclusive license to make, use, sell, and offer for sale licensed products and licensed processes that embody the licensed patents (including WSU's

rights to a patent jointly owned with Pacific Northwest Biotechnology, Inc.) and that form the underlying technology of the drug therapies we are developing." CAC at ¶¶ 113 & 178 (quoting IPO Prospectus at 91 & 140, Ex. 2 to Roberts Decl. (docket no. 77-2 at 95 & 144)).

4. "In December 2011, the Company entered into an exclusive license agreement with sublicensing terms with Washington State University Research Fund ('WSURF'), which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with sublicensing terms between the Company and Washington State University ('WSU') in 2015. Under this agreement, the Company has an exclusive license to make, use, sell, and offer for sale a chemical compound that forms the underlying technology of the drug therapies being developed by the Company." CAC at ¶ 117 (quoting Athira Form 10-Q (Nov. 12, 2020)).

5. Statements in the SPO materials that "repeated verbatim" the statements made in the IPO materials. *See* CAC at ¶¶ 120 & 181; *see also* SPO Prospectus, available at https://www.sec.gov/Archives/edgar/data/0001620463/000156459021001770/atha-424b4.htm.

6. "Leen Kawas, Ph.D., has served as our chief executive officer and as a member of our board of directors since January 2014. Previously, Dr. Kawas served as our vice president. Dr. Kawas serves on multiple boards, including the Washington Governor's Life Science Advisory Board, Scientific Review Board for the Alzheimer's Drug Discovery Foundation, and Alzheimer's Association – Washington Chapter Board. She also served as the co-chair of the International Alzheimer's Association Business Consortium. Dr. Kawas earned a Ph.D. in molecular pharmacology from Washington State University in 2011 and a pharmacy degree from the University of Jordan in 2008. We believe Dr. Kawas's scientific and professional training, her instrumental role in building Athira Pharma, Inc., and her extensive understanding of our business, operations and strategy qualify her to serve on our board of directors." CAC at ¶ 123 (quoting Athira Form 10-K for 2020 (Mar. 25, 2021)).

7. "Under this agreement, WSU granted us an exclusive license to make, use, sell, and offer for sale licensed products and licensed processes that embody the licensed patents (including WSU's rights to a patent jointly owned with Pacific Northwest Biotechnology, Inc.) and that form the underlying technology of the drug therapies we are developing. The term of the license begins on the effective date and continues until the earlier of the date in which no valid claim remains enforceable and the payment of royalties ceases for more than four consecutive quarters after such royalty

payments begin. . . . Under this agreement, the Company has an exclusive license to make, use, sell, and offer for sale a chemical compound that forms the underlying technology of the drug therapies being developed by the Company. . . . To keep in good standing, the agreement requires the Company to meet certain development milestones and pay an annual maintenance fee. All contractual requirements have been met as of December 31, 2020. During the year ended December 31, 2020, the Phase 2 clinical trial milestone had been reached and a payment of $50,000 to WSU was recorded." CAC at ¶ 125 (quoting Athira Form 10-K for 2020 (Mar. 25, 2021)).

8. "Nominee for Director Leen Kawas, Ph.D., has served as our chief executive officer and as a member of our board of directors since January 2014. Previously, Dr. Kawas served as our vice president. Dr. Kawas serves on multiple boards, including the Washington Governor's Life Science Advisory Board, Scientific Review Board for the Alzheimer's Drug Discovery Foundation, and Alzheimer's Association – Washington Chapter Board. She also served as the co-chair of the International Alzheimer's Association Business Consortium. Dr. Kawas earned a Ph.D. in molecular pharmacology from Washington State University in 2011 and a pharmacy degree from the University of Jordan in 2008. We believe Dr. Kawas's scientific and professional training, her instrumental role in building Athira Pharma, Inc., and her extensive understanding of our business, operations and strategy qualify her to serve on our board of directors." CAC at ¶ 128 (quoting Athira Schedule 14A (April 2021)).

9. "Considerations in Evaluating Director Nominees: Our nominating and corporate governance committee uses a variety of methods for identifying and evaluating potential director nominees. In its evaluation of director candidates, including the current directors eligible for re-election, our nominating and corporate governance committee will consider the current size and composition of our board of directors and the needs of our board of directors and the respective committees of our board of directors and other director qualifications. While our board has not established minimum qualifications for board members, some of the factors that our nominating and corporate governance committee considers in assessing director nominee qualifications include, without limitation, issues of character, professional ethics and integrity, judgment, business acumen, proven achievement and competence in one's field, the ability to exercise sound business judgment, tenure on the board of directors and skills that are complementary to the board of directors, an understanding of our business, an understanding of the responsibilities that are required of a member of the board of directors, other time commitments, diversity with respect to

professional background, education, race, ethnicity, gender, age and geography, as well as other individual qualities and attributes that contribute to the total mix of viewpoints and experience represented on our board." CAC at ¶ 129 (quoting Athira Schedule 14A (April 2021)).

10. "Our approach is designed to augment neuronal growth factor signaling through the hepatocyte growth factor/MET, or HGF/MET, a naturally occurring regenerative system. We believe enhancing HGF/MET signaling has the potential to protect existing neurons from damage, reduce inflammation, promote regeneration, and positively modulate brain activity. We anticipate that all of these characteristics may improve neuronal health and translate into clinical benefits. Our pipeline is built from our proprietary drug discovery platform, or ATH platform, and consists of a series of small molecules that are designed to target either (1) the central nervous system, or CNS, by crossing the blood brain barrier, or BBB, or (2) the peripheral nervous system." CAC at ¶ 132 (quoting Athira Form 10-Q (May 13, 2021)).

11. "In December 2011, the Company entered into an exclusive license agreement with sublicensing terms with Washington State University Research Fund ('WSURF'), which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with sublicensing terms between the Company and Washington State University ('WSU') in 2015. Under this agreement, the Company has an exclusive license to make, use, sell, and offer for sale a chemical compound that forms the underlying technology of the drug therapies being developed by the Company. To keep in good standing, the agreement requires the Company to meet certain development milestones and pay an annual maintenance fee. All contractual requirements have been met as of March 31, 2021. During the year ended December 31, 2020, the Phase 2 clinical trial milestone had been reached and a payment of $50,000 to WSU was recorded." CAC at ¶ 134 (quoting Athira Form 10-Q (May 13, 2021)).

Many of the statements are duplicative and will be grouped together for analysis as follows: (i) Statements 1, 2, 6, and 8 concerning Kawas's qualifications and Statement 9 about Athira's considerations in evaluating potential members of its Board of Directors; (ii) Statements 3, 4, 7, and 11 regarding Athira's licensing agreement with WSU; and (iii) Statement 10 describing Athira's drug-discovery approach. Statement 5, which

indicates that the SPO Prospectus contained language identical to the verbiage in the IPO Prospectus, will not be separately considered.

**E. Parties and Claims**

Plaintiff Antonio Bachaalani Nacif purchased and sold Athira stock on various dates between February 19, 2021, and June 16, 2021; as of June 17, 2021, Nacif still held 30,007 shares in one account and 19,000 shares in another account. *See* Exs. A & B to Townsend Decl. (docket nos. 41-1 & 41-2). Plaintiff Wies Rafi purchased 150 shares of Athira stock on October 20, 2020, and 6,450 shares on November 16, 2020; Rafi sold all shares on June 18, 2021 for a loss of $44,737.92. *See* Exs. B & C to Nivison Decl. (docket nos. 43-2 & 43-3). Nacif and Rafi sue on behalf of themselves and all others who "purchased Athira publicly traded securities during the period from September 17, 2020, through June 17, 2021, inclusive, and were damaged thereby." CAC at ¶ 215(a); *see also infra* note 5. They assert the following claims:

1. Violation of § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and of SEC Rule 10b-5, 17 C.F.R. § 240.10b-5;
2. Violation of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a);
3. Violation of § 11 of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. §§ 77k;
4. Violation of § 12(a)(2) of the Securities Act, 15 U.S.C. § 77l; and
5. Violation of § 15 of the Securities Act, 15 U.S.C. § 77o.

Plaintiffs' first, third, and fourth claims are asserted against all defendants, namely (a) Athira Pharma, Inc., (b) Leen Kawas, Ph.D., (c) Athira's Chief Financial Officer ("CFO") Glenna Mileson, (d) Athira's Board of Directors members Joseph Edelman,

John M. Fluke, Jr., and James A. Johnson (collectively "the Directors"), and (e) the underwriters for Athira's stock offerings, (i) Jefferies LLC, (ii) Goldman Sachs & Co. LLC, (iii) Stifel, Nicolaus & Company, Incorporated, and (iv) JMP Securities LLC (collectively, "the Underwriters"). The second and fifth claims are alleged against the individual defendants (Kawas, CFO Mileson, and the Directors). Defendants move to dismiss all claims.

**Discussion**

**A. Section 12(a)(2) of the Securities Act**

Defendants seek to dismiss the fourth claim under § 12(a)(2) of the Securities Act on the ground that neither Nacif nor Rafi purchased Athira stock in the IPO or SPO. *See* Mot. at 15 (docket no. 76). In response to defendants' motion, plaintiffs have withdrawn the § 12(a)(2) claim, *see* Resp. at 7 n.16 (docket no. 81), and the fourth claim is therefore DISMISSED with prejudice as to Nacif and Rafi.[5]

**B. Section 10(b) of the Exchange Act and SEC Rule 10b-5**

Although the operative pleading explicitly asserts the § 10(b) / Rule 10b-5 claim against "all Defendants," including the Underwriters, *see* CAC at ¶ 148, plaintiffs clarify in their response to defendants' motion to dismiss that they "allege Exchange Act claims as to all of the Defendants except for the Underwriter Defendants." Resp. at 16 n.27

[5] Nacif and Rafi had purported to represent a class of individuals and entities that "purchased or otherwise acquired Athira publicly traded common stock pursuant and/or traceable to Athira's September 2020 IPO or January 2021 SPO," CAC at ¶ 215(b), but they appear to concede that they could not, as to such class, meet the requirements of Federal Rule of Civil Procedure 23.

(docket no. 81). Defendants' motion to dismiss is therefore GRANTED in part, and plaintiffs' first claim against **the Underwriters** for violation of Exchange Act § 10(b) and Rule 10b-5 is DISMISSED with prejudice. The question now before the Court is whether the first claim is adequately alleged against the individual defendants and Athira.

Together, § 10(b) of the Exchange Act and SEC Rule 10b-5 prohibit, in connection with the purchase or sale of a security, making "any untrue statement of a material fact" or omitting "a material fact necessary" to make a statement "not misleading." *See* *Macomb Cnty. Emps.' Ret. Sys. v. Align Tech., Inc.*, No. 21-15823, --- F. 4th ---, 2022 WL 2525306, at *2 (9th Cir. July 7, 2022) (quoting 17 C.F.R. § 240.10b-5). A complaint alleging a violation of § 10(b) and Rule 10b-5 must meet the heightened pleading requirements for fraud claims that are set forth in Federal Rule of Civil Procedure 9(b), as well as the exacting standards of the Private Securities Litigation Reform Act ("PSLRA"). *Id.* (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007)). Rule 9(b) applies to all averments of "fraud or mistake," requires that a party "state with particularity the circumstances constituting fraud or mistake," and allows "conditions of a person's mind" (*e.g.*, malice, intent, knowledge) to be "alleged generally." Fed. R. Civ. P. 9(b). The PSLRA, however, mandates that, when asserting a claim under § 10(b) and Rule 10b-5, a pleading must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *See* 15 U.S.C. § 78u-4(b)(2)(A).

The requisite mental state for a § 10(b) / Rule 10b-5 claim is "scienter," which exists when an individual has an "intent to deceive, manipulate, or defraud." *Tellabs*, 551

U.S. at 319. The Supreme Court has also assumed, without deciding, that the scienter requirement may be satisfied by a showing of "deliberate recklessness." *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48 (2011). The Supreme Court has made clear, however, that a plaintiff cannot recover under § 10(b) for innocent or merely negligent misstatements or omissions. *See Merck & Co. v. Reynolds*, 559 U.S. 633, 648–49 (2010). The Ninth Circuit treats "deliberate recklessness" as proof of scienter, defining such recklessness as "an *extreme* departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the acter must have been aware of it." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (emphasis in original). The PSLRA's "strong inference" standard requires a plaintiff to "plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference." *Tellabs*, 551 U.S. at 328 (emphasis in original); *cf. id.* at 328–29 (observing that, at trial, a plaintiff must prove that a defendant *more likely than not* acted with scienter).

With respect to the individual defendants other than Kawas, plaintiffs have not sufficiently pleaded scienter. Plaintiffs have not asserted that, in connection with the challenged statements or alleged omissions, CFO Mileson or the Directors had an "intent to deceive, manipulate, or defraud." Instead, plaintiffs rely on the deliberate-recklessness theory, *see* Resp. at 21–23 (docket no. 81), but they have not alleged the requisite knowledge or obviousness of risk. CFO Mileson's corporate position since 2015 and previous experience at a biotechnology company do not give rise to any inference, let alone a "strong inference," that she was aware of flaws in Kawas's dissertation or other

publications. Similarly, the Directors' service on Athira's board and involvement in other biotechnology or pharmaceutical endeavors do not render plausible that they knew the images in Kawas's dissertation had been enhanced. Moreover, the CAC contains no factual allegation tending to show that any misconduct by Kawas while a graduate student was obvious at the time the challenged statements or alleged omissions were made. At most, the PubPeer postings that predated the IPO and SPO questioned certain figures in three articles co-authored by Kawas. These early PubPeer comments did not (and could not under PubPeer's rules) accuse Kawas of any wrongdoing, and they did not draw any link to Kawas's dissertation. The operative pleading offers no basis for believing that CFO Mileson or the Directors would have received notice of the PubPeer remarks or understood them to communicate any financial peril to Athira's potential shareholders. In sum, the CAC does not plead the type of "*extreme* departure from the standards of ordinary care" necessary to pursue a § 10(b) / Rule 10b-5 claim based on deliberate recklessness. With regard to **CFO Mileson and the Directors**, defendants' motion to dismiss is GRANTED in part, and plaintiffs' first claim under § 10(b) of the Exchange Act and SEC Rule 10b-5 against these defendants is DISMISSED without prejudice and with leave to amend.

As to Kawas, and by extension Athira, defendants contend that scienter is not sufficiently pleaded because the CAC does not establish that Kawas knew or should have known the consequences to investors of failing to disclose her actions while a graduate student at WSU. In essence, defendants' arguments focus on whether Kawas understood or should have understood the materiality, if any, of these omissions. Thus, to analyze

whether Kawas's scienter is adequately alleged, the Court must first consider materiality, which is an element of both the Exchange Act and Securities Act claims asserted in this litigation. For the sake of brevity and to avoid repetition, the subject will be addressed in Section D, after a discussion of the standards applicable to a Securities Act § 11 claim.

**C. Section 11 of the Securities Act**

To sell securities in interstate commerce, a company must file a registration statement with the SEC. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 178 (2015). If the registration statement, which often contains a prospectus, contains "an untrue statement of a material fact" or omits "a material fact . . . necessary to make" other statements "not misleading," then purchasers of the stock may sue certain entities enumerated in § 11 of the Securities Act, for example, the issuer and its directors at the relevant time, as well as any underwriters. *See id.* (citing 15 U.S.C. § 77k(a)); *see also Herman & MacLean v. Huddleston*, 459 U.S. 375, 381 & 382 n.13 (1983). Section 11 does not require a buyer to prove scienter, *see Omnicare*, 575 U.S. at 179, and absent allegations of fraud,[6] the standards of Federal Rules of Civil Procedure 8(a) and 12(b)(6) apply to a motion to dismiss. *See Callan v. Motricity Inc.*, No. C11-1340 TSZ, 2013 WL 195194, at *5 (W.D. Wash. Jan. 17, 2013).

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[6] In the operative pleading, plaintiffs assert that their § 11 claim is "based solely on strict liability and negligence," and not on "any knowing or reckless conduct" by any defendant, and they explicitly disclaim any allegation of fraud. CAC at ¶ 191; *see also* CAC at ¶¶ 163–73. Having conducted the requisite "close examination of the language and structure of the complaint," the Court concludes that plaintiffs have not alleged a "unified course of fraudulent conduct," and that their § 11 claim need not be viewed through the rigorous lens of Rule 9(b). *See In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 885–86 (9th Cir. 2012).

To comply with Rule 8(a) and overcome a Rule 12(b)(6) challenge, a complaint must offer "more than labels and conclusions," contain more than a "formulaic recitation of the elements of a cause of action," and indicate more than mere speculation of a right to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The factual allegations of a pleading must be accepted as true, but bald assertions, conclusory statements, and legal conclusions are not entitled to an assumption of truth. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–81 (2009). On a Rule 12(b)(6) motion, the question for the Court is whether the facts in the challenged complaint sufficiently state a "plausible" ground for relief. *Twombly*, 550 U.S. at 570. Plausibility is less than probability, but "more than a sheer possibility" that a defendant has engaged in misconduct; when a pleading provides "facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

Liability under § 11 for a security issuer extends to innocent misstatements and is "virtually absolute," while other types of defendants may escape responsibility if they exercised due diligence, but they bear the burden of proving such defense. *See Herman & MacLean*, 459 U.S. at 382 (citing 15 U.S.C. § 77k(b)). Given the strict nature of § 11, care must be exercised to avoid "conflat[ing] facts and opinions" set forth in registration statements. *See Omnicare*, 575 U.S. at 183. A fact is "a thing done or existing" or an "actual happening," whereas an opinion is "a belief," "view," or "sentiment which the mind forms of persons or things." *Id.* (citing WEBSTER'S NEW INT'L DICTIONARY 782 & 1509 (1927)). Unlike misrepresentations of material fact, an opinion expressed in a registration statement is generally not actionable under § 11; however, an opinion may

give rise to liability in one of three ways: (i) the professed belief was not actually held; (ii) a material supporting fact embedded in the opinion is not true (for example, stating that "I believe our TVs have the highest resolution available because we use a patented technology to which our competitors do not have access," when either no patent exists or a competitor has a license to practice the invention); or (iii) material facts are omitted that render the opinion misleading. *See id.* at 185–186 & 188–89. To proceed on the latter theory, a § 11 plaintiff must "identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id.* at 194. In *Omnicare*, the Supreme Court observed that pleading such level of detail "is no small task for an investor," *id.*, and offered a reminder that § 11 is not "an invitation to Monday morning quarterback an issuer's opinions." *Id.* at 186.

**D. Materiality**

Materiality is a mixed question of law and fact. *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976). Even when undisputed, the underlying objective facts are "merely the starting point for the ultimate determination of materiality." *See id.* The evaluation of materiality involves "delicate assessments of the inferences" that a reasonable investor would draw from a given set of facts and the significance of those inferences to him or her. *See id.* The question in analyzing materiality is whether the alleged misrepresentation or omission "would have misled a reasonable investor about the nature of his or her investment." *In re Daou Sys., Inc., Sec. Litig.*, 411 F.3d 1006,

1027 (9th Cir. 2005). With respect to omissions, the applicable standard is not one of completeness; regardless of how detailed and accurate the statements in a prospectus or other SEC-required filings might be, more information can likely be disclosed. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). To be actionable, an omission must "affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.*

**1. Kawas's Qualifications (Statements 1, 2, 6, 8, and 9)**

Of the various statements concerning Kawas's credentials and her selection as a member of Athira's Board of Directors, only Statements 1 and 2, which were included in the IPO Prospectus (and repeated in the SPO Prospectus) are actionable under § 11 of the Securities Act. *See Herman & MacLean*, 459 U.S. at 382 (a § 11 claim "must be based on misrepresentations or omissions in a registration statement"). Statements 6, 8, and 9 are challenged under § 10(b) of the Exchange Act and SEC Rule 10b-5. With the exception of Statement 9, these challenged statements summarized Kawas's education and/or professional experience. Statements 2, 6, and 8 also expressed an opinion that Kawas was qualified to serve on Athira's Board of Directors, and Statement 9 outlined Athira's considerations in selecting Board members. Plaintiffs do not contend that the factual contents of Statements 1, 2, 6, 8, and 9 were false; Kawas did indeed receive a pharmacy degree from the University of Jordan and a Ph.D. from WSU, she served on multiple boards, and she was at different times Athira's founder, vice president, and CEO. Moreover, plaintiffs do not dispute the accuracy of the director-nominee criteria articulated in Athira's April 2021 Schedule 14A and designated as Statement 9. Instead,

plaintiffs allege that information necessary to make the facts and opinions set forth in Statements 1, 2, 6, 8, and 9 "not misleading" was omitted.

Plaintiffs fail, however, to plead a plausible claim. According to plaintiffs, Athira's Prospectuses and other filings improperly omitted a statement that "the dissertation Kawas published in connection with obtaining her Ph.D. was obtained with falsified research." *See* CAC at ¶¶ 177 & 182; *see also id.* at ¶¶ 112, 121, 124, & 130. The operative pleading's accusation that Kawas's research or results was "falsified" is merely conclusory and not entitled, under Rule 12(b)(6) jurisprudence, to an assumption of accuracy or truth. *See Iqbal*, 556 U.S. at 680–81. Indeed, none of the PubPeer comments cited or reproduced in the CAC suggest that the underlying data was altered, let alone "falsified," and Kawas's resignation letter, which is the source of the only non-speculative facts set forth in the operative pleading on the subject, denied any manipulation of the research results, as opposed to the way in which they were illustrated. In sum, plaintiffs' claim that defendants were required to disclose Kawas's doctoral research was "falsified" is not supported by any factual allegations, and it has not crossed the threshold of plausibility; omission of "uncharged, unadjudicated [and unproven] wrongdoing" is not actionable under the securities laws. *See City of Pontiac Policemen's & Fireman's Ret. System v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014).

Plaintiffs further assert Athira's Prospectuses and other filings were misleading because they did not reveal that "Kawas's research publications regarding the compound underlying the Company's lead product contained altered images." CAC at ¶¶ 112, 121, 130, 177, & 182. Putting aside the doubts that the operative pleading itself raises

concerning whether Articles 1–6 relate to Athira's lead product,[7] plaintiffs' theory still falls short of alleging a plausible claim of omission. Even assuming that the enhanced images in Kawas's dissertation and subsequent journal articles were connected to ATH-1017, the actions taken by Kawas while a graduate student do not render misleading the *facts* set forth in Statements 1, 2, 6, 8, and 9. Neither Kawas's pharmacy degree nor her Ph.D. has been annulled and her professional experience has not somehow been erased. Moreover, non-disclosure of Kawas's conduct at WSU did not, with respect to the list of desired qualifications and demographics for members of Athira's Board, "affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *See Brody*, 280 F.3d at 1006.

As to the laudatory *opinions* about Kawas contained in Statements 1, 2, 6, and 8, namely that Kawas "has been essential in creating [Athira's] innovative translational development strategy," and that "Kawas's scientific and professional training, her instrumental role in building Athira . . . , and her extensive understanding of [Athira's] business, operations and strategy qualify her to serve on [Athira's] board of directors," plaintiffs must plead much more to show that the asserted omission rendered the opinions "misleading to a reasonable person reading the statement fairly and in context." *See*

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[7] The Consolidated Amended Complaint quotes a news article that acknowledged Athira had "moved on to a different molecule" than the one on which Kawas worked in connection with her dissertation and the publications at issue. *See* CAC at ¶ 93 (quoting Olivia Goldhill, *STAT News* (June 17, 2021)). Likewise, Athira's October 2021 press release, which is referenced in the operative pleading, *see* CAC at ¶ 97, distinguished between Kawas's previous research and Athira's "lead development candidate, ATH-1017." Ex. 4 to Roberts Decl. (docket no. 77-4).

*Omnicare*, 575 U.S. at 194. Plaintiffs do not allege that these opinions were not honestly held, and thus, they must plead "particular (and material) facts going to the basis for" the opinions, tending to show that the opinions were either provided without reasonable investigation or in conflict with then-known information. *See id.* The CAC's citation to PubPeer postings concerning a few images in certain antiquated articles does not meet this requirement. No rationale has been given as to why review of PubPeer remarks should have been part of the due diligence conducted in connection with the offering of securities. In addition, no allegation has been made that anyone other than Kawas would have known about these comments during the putative class period or that Kawas would have received notice of them prior to the IPO and SPO. Finally, to the extent these opinions are not mere puffery, and not actionable simply on that basis, nothing about Kawas's graduate work and publications more than six years before the IPO would negate her "essential" or "instrumental" role at Athira or her "extensive" understanding of Athira's business. Defendants' motion to dismiss is GRANTED in part, and the Securities Act § 11 claim against all defendants premised on Statements 1 and 2 is DISMISSED without prejudice and with leave to amend. Defendants' motion to dismiss is also GRANTED in part as to plaintiffs' Exchange Act § 10(b) and SEC Rule 10b-5 claim against Athira and Kawas based on Statements 1, 2, 6, 8, and 9, which is likewise DISMISSED without prejudice and with leave to amend.

**2. Athira's Licensing Agreement with WSU (Statements 3, 4, 7, and 11)**

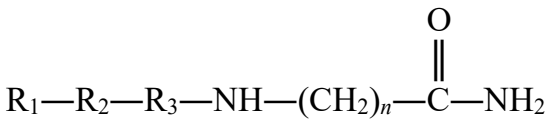
Within the second group of statements at issue, only Statement 3 appeared in the IPO (and SPO) Prospectus and is potentially actionable under § 11 of the Securities Act;

Statements 4, 7, and 11 are challenged under § 10(b) of the Exchange Act and SEC Rule 10b-5. Plaintiffs do not contend that the factual contents of Statements 3, 4, 7, and 11 were false. They do not dispute that (i) Athira entered into an agreement with Washington State University Research Fund, which was superseded by an agreement with WSU; (ii) WSU granted Athira an exclusive license relating to patents owned by WSU and/or Pacific Northwest Biotechnology, Inc. that disclose a "chemical compound" and/or "the underlying technology of the drug therapies" Athira is developing; (iii) the duration or term of the license was accurately summarized in the statements; or (iv) the contractual requirements (certain development milestones and annual fees) were met as of December 31, 2020, and March 31, 2021. Instead, plaintiffs allege that information necessary to make the facts set forth in Statements 3, 4, 7, and 11 "not misleading" was omitted, namely that (i) "the dissertation Kawas published in connection with obtaining her Ph.D. was obtained with falsified research," and (ii) "Kawas's research publications regarding the compound underlying the Company's lead product contained altered images." CAC at ¶¶ 179 & 182; *see also id.* at ¶¶ 114, 118, 121, 126, & 135. Again, the conclusory and unproven accusation of "falsified" research does not advance the omission claim through the gate of plausibility.

With regard to the other alleged omission, the operative pleading attempts to link Articles 1–6 to the patents licensed by WSU to Athira by broadly alleging that "[s]everal of those articles served as the basis for patents belonging to, or licensed by, Athira." CAC at ¶ 2. The Consolidated Amended Complaint lists five patents belonging to WSU, *see* CAC at ¶ 2 n.1 (citing U.S. Patents Nos. 8,598,118, 9,051,351, 9,066,901, 9,150,613,

and 9,475,854),[8] but it does not indicate which, if any, of these patents are licensed to Athira. At least three of these patents are unrelated to neuronal heath, neurodegeneration, dementia, or Alzheimer's Disease, which are Athira's areas of concern. *See* U.S. Patents Nos. 9,066,901 (claiming a "method for treating angiogenesis or obesity"), 9,150,613 (claiming a "method for treating melanoma"), and 9,475,854 (claiming a "method of treating or preventing hearing loss"). The Court will therefore focus on the other two patents referenced in the operative pleading, namely U.S. Patents Nos. 8,598,118 (the "'118 Patent") and 9,051,351 (the "'351 Patent").

The '118 Patent claims (i) a hepatocyte growth factor mimic having the formula:



or a composition comprising at least one such mimic; and (ii) N-hexanoic-L-tyrosine-L-isoleucine-(6)-aminohexanoic amide (a/k/a Dihexa) or a composition comprising Dihexa and a carrier. '118 Patent at 67:38–68:66 & Certificate of Correction (Dec. 3, 2013). In its specification, the '118 Patent cites to Articles 1 and 2, and both publications are listed in the references. *See* '118 Patent at 7:52, 40:39, 46:16–19, 50:9–12, 52:56, 53:18, 54:26, 55:53, & 61:29–38. The '351 Patent claims a "method for slowing progression of dementia associated with Alzheimer's disease or Parkinson's disease in a subject in need thereof comprising the step of administering to said subject a therapeutic amount of

[8] Joseph W. Harding is the first-named inventor on all but the last patent listed, as to which the lead inventor is Allison Coffin. Kawas is named as a co-inventor on each patent, all of which have been assigned to WSU.

hexanoic-tyrosine-isoleucine-(6)-amino-hexanoic amide." '351 Patent at 77:43–78:45. The '351 Patent incorporates the '118 Patent by reference, *id.* at 1:7–13, and cites to Article 1, *id.* at 43:25, 52:38–41, 55:17 & 46–47, but does not list in its "references" any of the articles co-authored by Kawas. Articles 3–6 are not mentioned in either patent.

Prior to the IPO and SPO, no PubPeer comment had been posted with respect to Article 2, and the only remarks about Article 1 were (i) addressed by a correction issued by the authors, or (ii) anonymously submitted without any accompanying question or explanation. Even if notice of these PubPeer postings was imputed to CFO Mileson, the Directors, and/or the Underwriters, which the facts pleaded by plaintiffs do not require, the PubPeer comments would not have caused a reasonable investor to doubt the validity of the patents apparently licensed to Athira, and their omission did not "affirmatively create" a misimpression about the status of the patents and exclusive license at issue. *See Brody*, 280 F.3d at 1006. Thus, defendants' motion to dismiss is GRANTED in part, and as to **CFO Mileson, the Directors, and the Underwriters**, plaintiffs' Securities Act § 11 claim based on Statement 3 is DISMISSED without prejudice and with leave to amend.

With regard to Kawas and Athira, the analysis under Securities Act § 11 is different. Kawas knew she had enhanced the images in her dissertation that were reproduced in subsequent publications, including the ones cited in the patents licensed to Athira. Section 11 does not require a showing of scienter, and plaintiffs need not plead facts from which Kawas's understanding about the potential significance of her previous actions to a reasonable investor could be inferred. As an issuer, Athira has strict liability under § 11. *See Feit v. Leasco Data Processing Equip. Corp.*, 332 F. Supp. 544, 575

(E.D.N.Y. 1971) ("Section 11 creates almost absolute liability in the issuer."). Thus, plaintiffs have pleaded a plausible claim that the failure to disclose Kawas's mistakes as a graduate student, while touting the exclusivity of a license for patents founded on Kawas's doctoral work, might have "misled a reasonable investor about the nature of his or her investment." *See In re Daou*, 411 F.3d at 1027. Defendants' motion to dismiss the § 11 claim against **Kawas and Athira** as to Statement 3 is therefore DENIED.

In contrast, defendants' motion to dismiss must be granted with respect to plaintiffs' § 10(b) / Rule 10b-5 claim against Kawas and Athira relating to Statements 3, 4, 7, and 11, which must meet the stringent standards of Rule 9(b) and the PSLRA. The operative pleading contains no facts suggesting that Kawas (or Athira) intended to "deceive, manipulate, or defraud" investors by discussing the WSU patents licensed by Athira, but withholding information about the enhancement of images in the underlying publications. According to plaintiffs, however, Kawas "***admitted*** that she falsified Athira's foundational research," and her "intentional falsification of her research supports a strong inference that she knew Athira's statements risked misleading investors." Resp. at 19–20 (docket no. 81) (emphasis in original). Plaintiffs' premise is not factual, but rather conclusory and argumentative, and the Consolidated Amended Complaint does not offer "facts rendering an inference of scienter *at least as likely as* any plausible opposing inference." *Tellabs*, 551 U.S. at 328 (emphasis in original).

Given that Kawas was only one of five inventors identified in the '118 and '351 Patents, only one of four co-authors of Article 1, and only one of five co-authors of Article 2, a plausible inference from the facts is that Kawas believed her work had been

amply vetted through the collaborative process and that the patents and publications would withstand scrutiny, despite the flaws about which she was undisputedly aware. This plausible inference is at least as and perhaps more likely than scienter, whether defined as intent or "deliberate recklessness," and thus, plaintiffs have not satisfied the pleading requirements of the PSLRA. Defendants' motion to dismiss is GRANTED in part, and as to **Kawas and Athira**, plaintiffs' § 10(b) / Rule 10b-5 claim concerning Statements 3, 4, 7, and 11 is DISMISSED for failure to adequately allege scienter, but without prejudice and with leave to amend.

**3. Athira's Drug-Discovery Approach (Statement 10)**

Pursuant to Exchange Act § 10(b) and SEC Rule 10b-5, plaintiffs challenge Statement 10, which was included in Athira's Form 10-Q filed in May 2021, on the theory that it "did not 'fairly align' with the fact that [Athira's approach] was based on falsified research." Resp. at 19 (docket no. 81). Again, plaintiffs' claim is built on bald assertions and argument, not facts. Statement 10 contains four sentences, two of which are factual: (i) Athira's "approach" is summarized as being "designed to augment neuronal growth factor signaling through the hepatocyte growth factor/MET, or HGF/MET, a naturally occurring regenerative system," and (ii) Athira's "pipeline" is described as "built from [its] proprietary drug discovery platform, or ATH platform," consisting of "a series of small molecules that are designed to target either (1) the central nervous system, or CNS, by crossing the blood brain barrier, or BBB, or (2) the peripheral nervous system." *See* CAC at ¶ 132. Plaintiffs do not contend that any of these representations are false.

The other two sentences in Statement 10 express opinions: (iii) "[w]e believe enhancing HGF/MET signaling has the potential to protect existing neurons from damage, reduce inflammation, promote regeneration, and positively modulate brain activity," and (iv) "[w]e anticipate that all of these characteristics may improve neuronal health and translate into clinical benefits." *Id.* Plaintiffs do not allege that these opinions were not honestly held. Instead, according to plaintiffs, Kawas and Athira should be held liable for not disclosing that "at least four studies with images . . . doctored by Kawas laid the biological groundwork for Athira's approach to treating Alzheimer's disease and other conditions." CAC at ¶ 133.

Defendants counter that the summary of Athira's "general scientific hypothesis," which is set forth in Statement 10, is not based on the research papers published by Kawas between 2011 and 2014, but rather on third-party studies and more recent clinical trials, which are described in the IPO Prospectus. *See* Mot. at 17–19 (docket no. 76); *see also* Ex. 2 to Roberts Decl. (docket no. 77-2 at 5, 92–93, 110, 116–17, & 127–35). Indeed, the IPO Prospectus does not cite to Kawas's dissertation or any of the articles that she co-authored. *See* Ex. 2 to Roberts Decl. (docket no. 77-2). Rather, it uses the phrase clinical trial or trials 463 times, and explains:

> Our lead candidate, ATH-1017, is a subcutaneous administered, BBB-penetrating, small molecule HGF/MET activator. In our Phase 1a and Phase 1b clinical trials, ATH-1017 for the treatment of Alzheimer's disease, or AD, was well tolerated with no serious adverse events. These clinical trials recruited 88 subjects, including 11 subjects with mild-to-moderate AD, who were assigned to treatment and control groups. . . .
>
> The primary focus of our Phase 1a and Phase 1b clinical trials of ATH-1017 for the treatment of AD was to establish safety and drug exposure levels.

> ATH-1017 was well tolerated at all tested doses, produced predictable pharmacokinetics with dose-linear exposures, and did not accumulate over the course of treatment. Pharmacodynamic measures evaluating brain penetration, target engagement, and brain function with electroencephalogram, or EEG, methods produced a strong suite of data, justifying further investigation of ATH-1017 in future clinical trials. Individuals with AD typically experience a general slowing of EEG, including a reduction in higher frequency waves, such as gamma. Gamma power is typically associated with learning, memory, and cognitive function. Administration of ATH-1017 increased high frequency gamma power activity with a single dose in both young healthy volunteers and elderly healthy volunteers. Gamma power also improved in AD subjects. P300 latency, a functional measure of working memory processing speed and executive function that highly correlates with cognition, was also substantially improved. After a single dose of ATH-1017, all AD subjects tested had improved P300 latency, and by the end of an 8-day treatment cycle, average P300 latency across the AD treatment group had improved by 73 milliseconds, a statistically significant change compared to placebo group that did not show any significant directional change. These results suggest that ATH-1017 has the potential to substantially improve synaptic connectivity and brain function in AD subjects.

IPO Prospectus, Ex. 2 to Roberts Decl. (docket no. 77-2 at 5). Given the promising results of clinical trials conducted with human subjects, plaintiffs have not proffered a plausible claim that any irregularity in the images relating to Kawas's nonclinical research, apparently performed on mice or rats, rendered misleading the facts and opinions set forth in Statement 10, particularly in light of the following warning in the IPO Prospectus:

> The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in nonclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans.

*Id.* (docket no. 77-2 at 27).

Moreover, for the reasons discussed earlier, the alleged facts do not give rise to the requisite "strong inference" of scienter on the part of Kawas and Athira. In addition to the comfort likely derived from knowing that colleagues had enough confidence in the work to put their names on the published papers, Kawas could have reasonably believed that Statement 10 was amply supported by more recent, clinical research, and that any misgivings about the images in her dissertation and earlier articles were immaterial. The nature of the risks assumed by purchasing Athira's stock were outlined in substantial detail in the IPO Prospectus,[9] and the operative pleading has not alleged facts justifying an inference that Kawas or Athira intended to "deceive, manipulate, or defraud" investors or acted with deliberate recklessness in omitting information about Kawas's actions while a graduate student. Defendants' motion to dismiss is GRANTED in part, and plaintiffs' claim under Exchange Act § 10(b) and Rule 10b-5 against Kawas and Athira relating to Statement 10 is DISMISSED without prejudice and with leave to amend.

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[9] The IPO Prospectus cautions *inter alia* that "[d]rug development is a highly uncertain undertaking and involves a substantial degree of risk." Ex. 2 to Roberts Decl. (docket no. 77-2 at 21). It makes clear that Athira had not yet "initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product candidate, arranged for a third party to do so on [its] behalf, or conducted sales and marketing activities necessary for successful product candidate commercialization." *Id.* The document further explained that Athira might "fail to or be unable to design and execute clinical trials to support marketing approval of ATH-1017 or any of [its] other product candidates," could not "guarantee [how] . . . the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities will interpret clinical trial results," and might be required to expend significant, (potentially unavailable) resources "to conduct additional clinical trials." *Id.* In addition, investors were told that, "[e]ven if regulatory approval is secured for any of [Athira's] product candidates, the terms of such approval may limit the scope and use of [the] product candidate, which may also limit its commercial potential." *Id.*

**E. Control Persons**

Because plaintiffs' claim under Exchange Act § 10(b) has been dismissed, plaintiffs' claim under Exchange Act § 20(a), which potentially imposes derivative liability on each person who controls a § 10(b) violator, must also be dismissed, albeit without prejudice and with leave to amend. Plaintiffs also pursue control person liability against the individual defendants under Securities Act § 15 for Athira's and/or Kawas's alleged violation of Securities Act § 11. Section 15 provides:

> Every person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77l of this title, shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, *unless the controlling person had no knowledge of or reasonable ground to believe in the existence of the facts by reason of which the liability of the controlled person is alleged to exist*.

15 U.S.C. § 77o(a) (emphasis added). For the same reasons that the operative pleading has failed to state a plausible claim that CFO Mileson and the Directors are personally liable under § 11, it has not adequately alleged that these defendants can be held vicariously liable as control persons. *See Laven v. Flanagan*, 695 F. Supp. 800, 808–09 (D.N.J. 1988) (observing that § 15 requires culpable (*i.e.*, knowing) participation, and "[t]o premise liability upon inaction, plaintiff must demonstrate that 'the aider-abettor *consciously* intended to assist in the perpetration of a wrongful act'" (emphasis in original)). Defendants' motion to dismiss is GRANTED in part, and plaintiffs' Securities Act § 15 claim against **CFO Mileson and the Directors** is DISMISSED without prejudice and with leave to amend. The § 15 claim remains pending against Kawas.

**Conclusion**

For the foregoing reasons, the Court ORDERS:

(1) Defendants' motion to dismiss, docket no. 76, is GRANTED in part and DENIED in part as follows:

(a) Plaintiffs' first claim for violation of Exchange Act § 10(b) and SEC Rule 10b-5 is DISMISSED with prejudice as to the Underwriters and without prejudice as to the individual defendants and Athira;

(b) Plaintiffs' second claim for violation of Exchange Act § 20(a) is DISMISSED without prejudice;

(c) Plaintiffs' third claim under Securities Act § 11 is DISMISSED in part without prejudice as to CFO Mileson, the Directors, and the Underwriters; with respect to Kawas and Athira, the third claim is also DISMISSED in part without prejudice as to Statements 1 and 2; the third claim remains pending against Kawas and Athira solely as to Statement 3;

(d) Plaintiffs' fourth claim under Securities Act § 12(a)(2) is DISMISSED with prejudice as to the named plaintiffs, Nacif and Rafi; and

(e) Plaintiffs' fifth claim under Securities Act § 15 is DISMISSED in part without prejudice as to CFO Mileson and the Directors; with respect to Kawas, the fifth claim is also DISMISSED in part without prejudice as to Statements 1 and 2; the fifth claim remains pending against Kawas solely as to Statement 3.

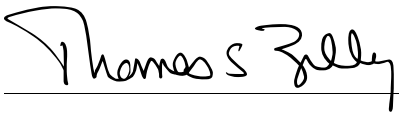
(2) Any amended pleading shall be filed within twenty-one (21) days of the date of this Order. Any responsive pleading or motion shall be filed within twenty-one (21) days thereafter.

(3) If no amended pleading is filed and/or no responsive motion is filed, then the parties shall file a Joint Status Report by September 15, 2022, proposing a schedule for this matter, including a deadline for completing discovery and a trial date. *See* Order at § II (docket no. 4).

(4) The Clerk is directed to send a copy of this Order to all counsel of record.

IT IS SO ORDERED.

Dated this 29th day of July, 2022.



Thomas S. Zilly
United States District Judge