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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

AMARIN PHARMA, INC., *et. al.*, Plaintiffs, v. HIKMA PHARMACEUTICALS USA, INC., *et. al.*, Defendants,	Case No.: 2:16-cv-02525-MMD-NJK (Consolidated with 2:16-cv-02562-MMD-NJK) **INTERVENOR EPADI II'S MOTION TO VACATE JUDGMENT PURSUANT TO FED. R. CIV. P. 60** **ORAL ARGUMENT REQUESTED TELEPHONICALLY OR VIA ZOOM**

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Intervenor EPA Drug Initiative II ("EPADI II"), by and through its attorneys of record, hereby moves pursuant to Rule 60 of the Federal Rules of Civil Procedure, to vacate the Judgment entered on March 30, 2020 ("the Judgment"). This Motion is made and based upon the pleadings and papers on file herein, the below Memorandum of Points and Authorities, the Declaration of Michael S. Kasanoff filed contemporaneously with this Motion, as well as any argument of counsel the Court may allow at any hearing on this Motion.

MEMORANDUM OF POINTS AND AUTHORITIES

PRELIMINARY STATEMENT

Misinterpretation and abuse of statistical tests, confidence intervals, and statistical power have been decried for decades, yet remain rampant. Statisticians and others have been sounding the alarm about these matters for decades to little avail.[1]

The central function of a trial is to discover the truth. *Portuondo v. Agard*, 529 U.S. 61, 73, 120 S.Ct. 1119, 1127, 146 L.Ed.2d 47 (2000). Indeed, "cases should be decided upon their merits whenever possible." *Westchester Fire Ins. Co. v. Mendez*, 585 F.3d 1183, 1189 (9th Cir. 2009).

Unfortunately, this case was not decided on the merits. In lieu of the truth, the Judgment invalidating Amarin's patents on grounds of obviousness was premised upon **multiple fatal statistical errors** in analyzing and interpreting the prior art.

The Court relied upon the conclusion in Mori that the increase in LDL-C with DHA was statistically significant while the increase with EPA was not. *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA, Inc.*, 449 F.Supp.3d 967, 1007 (D. Nev.), *aff'd,* 819 Fed. Appx. 932 (Mem) (Fed. Cir. 2020). The Court's reliance upon Mori was mistaken, because the Mori authors made a **common statistical mistake** in failing to conduct the obvious and necessary direct comparison of the change in LDL-C between the EPA and DHA treatment groups. Mori et. al. did not include this critical comparison necessary to determine whether the effects of DHA and EPA on LDL cholesterol change were truly "differential".

[1] Dr. Gavin E. Jarvis Expert Report, Kasanoff Decl., Exh. "A", at 8, ¶22.

The Court also mistakenly relied upon Defense Expert Dr. Heinecke's disingenuous interpretation of Kurabayashi in reaching the erroneous conclusion that in "light of the statistically-significant differential effects reported between the EPA and control groups, a POSA would have attributed the reduction in Apo B to EPA." *Id.* at 990. The Court's conclusion as well as its reliance upon Kurabayashi was mistaken because Dr. Heinecke's interpretation of Kurabayashi (on which the Court relied) contained a **fatal statistical error**, which, if identified, would have contravened the erroneous conclusion that the lowering of Apo B was already demonstrated as obvious.

The Court's decision is not only mistaken, but is also tainted with the stench of fraud, because the Court relied upon a "cropped" version of Kurabayashi Table 3, which omitted supplying critical material information to this Court. Defendants' Proposed Findings of Fact at 71, ¶280 (Feb. 14, 2020) (ECF No. 373). In fact, it is the *same* cropped table which the Court copied directly from Defendants' Proposed Findings of Fact before pasting it verbatim into the Court's Opinion. *Amarin Pharma,* 449 F.Supp.3d at 990.

In order to appreciate the devious nature of Defendants' misrepresentation, one need only compare the cropped Table in the Court's Opinion (*Id.*), with the identical cropped Table in Defendants' Proposed Findings of Fact at 71, ¶280 (Feb. 14, 2020) (ECF No. 373), with the uncropped original Kurabayashi Table. Kasanoff Decl., Exh. "F", at 3. Defendants intentionally cropped the Table to disingenuously corroborate Dr. Heinecke's misleading expert testimony which was diametrically opposed to Kurabayashi's stated conclusion regarding their own statistical analysis of the data.

Accordingly, Intervenor EPADI II now moves pursuant to Rule 60(b) of the Federal Rules of Civil Procedure, to vacate the Judgment in this case on grounds of mistake, fraud, misrepresentation, and unclean hands. *Bayview Loan Servicing, LLC v. Trejo*, 2019 WL 6134471 at *1 (D. Nev. 2019). EPADI II further moves to vacate the Judgment based upon Defendants' fraud on the court. Fed. R. Civ. P. 60(d)(3). The relief requested by this Motion, as well as the basis for that relief can be reduced to a singular evidentiary equation:

Judgment invalidating Amarin's patents on grounds of prima facie obviousness

minus Mori

minus Kurabayashi

equals Vacation of said Judgment due to a lack of clear and convincing proof of prima facie obviousness.

ARGUMENT

POINT I

AS A THRESHOLD MATTER, JURISDICTION LIES WITH THIS COURT AND THIS FILING IS TIMELY

This Court is undoubtedly vested with jurisdiction to adjudicate this Motion. *Standard Oil Co. of California v. United States*, 429 U.S. 17, 19, 97 S.Ct. 31, 32, 50 L.Ed.2d 21 (1976).[2] This Court's jurisdiction vested on September 3, 2020 after the Federal Circuit issued its mandate. *Gould v. Mut. Life Ins. Co. of New York*, 790 F.2d 769, 773 (9th Cir. 1986).

Further, this Motion is timely. EPADI II's requests for relief under Fed. R. Civ. P. 60(b)(1) and 60(b)(3), are being filed within one-year after the entry of the original Judgment. Fed. R. Civ. P. 60(c)(1). EPADI II's requests for relief under the other provisions of Rule 60, are not subject to the one-year time limit. *United States v. Sierra-Pacific Indus, Inc.*, 862 F.3d 1157, 1167 (9th Cir. 2017).

[2] *See Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA, Inc.*, 819 Fed. Appx. 932 (Mem) (Fed. Cir. 2020).

POINT II

PURSUANT TO RULE 60(b)(1), THE JUDGMENT SHOULD BE VACATED ON GROUNDS OF MISTAKE DUE TO THE COURT'S ERRONEOUS RELIANCE UPON MORI TO ESTABLISH PRIMA FACIE OBVIOUSNESS

A. Curfman, et. al. Statistically Eviscerate Mori as a Viable Basis for Finding Clear and Convincing Evidence of Prima Facie Obviousness

Several months after entry of the Judgment, three highly credentialed[3] scholars authored a peer-reviewed paper concluding: (1) that a key piece of the prior art which was central to this case (Mori), reached an incorrect conclusion based upon a **common statistical error**; and (2) that prior art which is **scientifically incorrect**, does not provide a rational basis for invalidating patents on grounds of obviousness. Curfman, G., Bhatt[4], D.L. & Pencina, M., Federal Judge Invalidates Icosapent Ethyl Patents But Based on a Common Statistical Mistake, *Nat. Biotehcnol* 38, 939-941(2020). Kasanoff Decl., Exh. "C", at 1.[5] This is the first time that this pivotal paper has been presented to any court at any level in connection with this case.

Mori's fundamental flaw is that it did not address the *differential* effects of DHA and EPA on LDL cholesterol levels. *Id.* at 2. Mori did not include a "critical comparison necessary to determine whether the effects of DHA and EPA on LDL-C change were truly differential." *Id.* Had the appropriate statistical test been conducted, it would have shown that there is no plausible

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[3]Dr. Curfman among other things, is Deputy Editor at the Journal of the American Medical Association, former Executive Editor of the New England Journal of Medicine, and a Professor at Harvard Medical School. Dr. Bhatt is the Executive Director of Interventional Cardiovascular Programs at Brigham & Women's Hospital, and is also a Professor at Harvard Medical School. Dr. Pencina is Professor of Biostatistics and Bioinformatics at Duke University, and served as Director of Biostatistics at Duke Clinical Research Institute.

[4]Dr. Bhatt's REDUCE-IT STROKE abstract just received the prestigious Paul Dudley White International Scholar Award recognizing the authors with the highest ranked abstract across the United States at the International Stroke Conference 2021. *See* http://www.globenewswire.com/news-release/2021/03/17/2194773/0/en/VASCEPA-Icosapent-Ethyl-Found-in-Prespecified-and-Post-Hoc-Analyses-to-Significantly-Reduce-Stroke-in-At-Risk-Patients-in-Analyses-of-Landmark-REDUCE-IT-Study-Presented-at-Internat.html

[5]Because the paper was published well after the Judgment, it likewise could be considered as newly discovered evidence justifying relief under Fed. R. Civ. P. 60(b)(2).

statistically significant difference in the effects of DHA and EPA on LDL-C. *Id*.

The Court's reliance on Mori as the prior art was mistaken because the "presence of a statistically significant difference in one arm combined with the absence of a difference within the other arm does not imply a statistically significant difference between the arms." *Id*. If Mori had conducted the appropriate statistical test, it would **not** have been possible to claim that it was obvious that there were differential effects of DHA and EPA on LDL-C. *Id*. at 2-3.[6]

B. Intervenor's Expert, Dr. Gavin E. Jarvis, Statistically Eviscerates Mori as a Viable Basis for Finding Clear and Convincing Evidence of Prima Facie Obviousness

Intervenor's expert, Dr. Gavin E. Jarvis, verifies and concurs with these conclusions. Kasanoff Decl., Exh. "A", at 22, ¶72. Dr. Jarvis scrutinizes Dr. Heinecke's statement that Mori's reporting that "[s]erum LDL cholesterol increased significantly with DHA (by 8%; P = 0.019), but not with EPA (by 3.5%; NS)", "strongly suggesting that these two Omega-3 fatty acids could have distinct effects on LDL cholesterol levels." Kasanoff Decl., Exh. "A", at 11, ¶34.

Dr. Jarvis highlights three words of note: "strongly", "suggesting", and "could". *Id*. at 11, ¶35. He goes on, "To **suggest** (rather than confirm, demonstrate or prove) that something **could** (rather than does or will) be true is hardly a compelling statement of scientific conviction. It is couched in conditionals and supposition. The addition of the word "strongly" serves merely as a rhetorical distractor." *Id*.

Dr. Jarvis then asks, "How does one quantify the strength of a suggestion of a possibility?" *Id*. Dr. Jarvis answers, "It is a tortured statement that falls well short of describing normal standards of scientific proof. This may be because Heinecke recognizes that the logic leading to the conclusion that DHA and EPA have "differential effects" is statistically flawed. It is, at best, a suggestion." *Id*.

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[6] Defendants may contend that the Curfman et. al., paper is inadmissible hearsay. Defendants would be wrong as it is admissible under the Learned Treatise Exception. Fed. R. Evid. 803(18). Furthermore, the paper's statistical conclusions are subject to judicial notice. Fed. R. Evid. 201; Fed. R. Evid. 803(18)(B).

1 Dr. Jarvis explains that the main problem with Mori is that the stated objective, conclusion
2 and title all shepherd the reader towards believing that there is a difference in effect between EPA
3 and DHA, but **none of the reported analyses directly address this hypothesis**. *Id*. at 13, ¶41.
4 Rather, in the case of LDL-c, the claim about a differential effect appears to arise from the reported
5 significant effect of DHA and non-significant effect of EPA.[7] *Id*.
6 Dr. Jarvis then explains that **Mori** provides a further excellent illustration of why the
7 interpretations 'significant = real effect' and 'non-significant = no real effect' are logically doomed
8 to failure. *Id*. at 13, ¶42. Dr. Jarvis asks the reader to assume that the data had been appropriately
9 analyzed, and the outcomes showing the effects of olive oil, EPA and DHA were as follows: EPA
10 vs olive oil, not significant; DHA vs oil, significant; EPA vs DHA, not significant.[8] *Id.*
11 If it is the case that 'significant = real effect' and 'non-significant = no real effect', then Dr.
12 Jarvis asks, "How can the conclusion that EPA does not differ either from oil or DHA be reconciled
13 with the conclusion that DHA does differ from oil?" *Id*. Dr. Jarvis answers, "It makes no sense. This
14 approach to interpreting data and statistical results can be dismissed even before looking at any
15 data." *Id*.
16 In sum, as Dr. Jarvis points out, "any firm conclusions drawn about differential effects of
17 EPA and DHA based on **Mori** are unwarranted for several reasons:
18 a. No **direct statistical comparison** of EPA and DHA was performed by **Mori**.
19 b. Based on the data and analyses available, the power of any analysis that *might* have
20 been performed comparing EPA to DHA would almost certainly be too low.
21 c. A conclusion that there is a difference between EPA and DHA, because one is significantly different from olive oil and the other is not, is profoundly flawed, as
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23 [7]This is precisely the same **flawed inferential logic** encountered in Heinecke's interpretation
24 of the ApoB data in **Kurabayashi** and debunked in detail by Bland & Altman in their two articles.
Id. Indeed, the existence of this approach in **Mori**, a peer-reviewed paper, supports Bland &
25 Altman's wearied assertion that "[t]his practice is widespread". Notwithstanding its prevalence, it
is still wrong. *Id*.
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27 [8]As noted by Dr. Jarvis, "Of course, this latter analysis is missing, and this is the principal
problem with **Mori**'s analysis." *Id*.
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already stated."

Id. at 14, ¶46.

C. The Statistical Evisceration of Mori Mandates Vacating the Judgment on Grounds of Mistake Pursuant to Rule 60(b)(1)

A District Court has the discretion to correct a judgment for mistakes made by the judge. *Fid. Fed. Bank, FSB v. Durga Ma Corp.*, 387 F.3d 1021, 1024 (9th Cir. 2004); *Kingvision Pay-Per-View Ltd. v. Lake Alice Bar*, 168 F.3d 347, 350 (9th Cir. 1999); *Bayview Loan Servicing, LLC v. Trejo*, 2019 WL 6134471 at *1 (D. Nev. 2019); *Finley v. Nevada*, 2015 WL 8490928 at *1 (D. Nev. 2015). This includes both mistakes of law, and mistakes of fact. *San Luis & Delta-Mendota Water Auth. v. U.S. Dep't of Interior*, 624 F. Supp. 2d 1197, 1208 (E.D. Cal. 2009), *aff'd sub nom. San Luis & Delta-Mendota Water Auth. v. United States*, 672 F.3d 676 (9th Cir. 2012). A mistake warranting vacation of a judgment occurs "where the court changes its mind because it made a legal or factual mistake in making its original determination." *U.S. ex rel. Guardiola v. Renown Health*, 2017 WL 6886075 at *1 (D. Nev. 2017) (*quoting Blanton v. Anzalone*, 813 F.2d 1574, 1576 n.2 (9th Cir. 1987)).

Here, the Court's reliance on Mori as the prior art was mistaken because the "presence of a statistically significant difference in one arm combined with the absence of a difference within the other arm does not imply a statistically significant difference between the arms." *Curfman, et. al., supra*. Because the Court made this critical mistake, Intervenor respectfully requests that the Court reverse its decision, by concluding that Mori does not support the Court's previous determination of prima facie obviousness.

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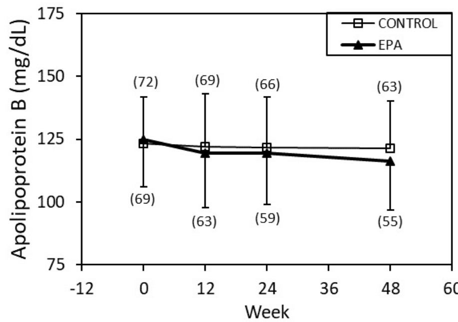
POINT III

PURSUANT TO RULE 60(b)(1), 60(b)(3), 60(b)(6), AND 60(d)(3), THE JUDGMENT SHOULD BE VACATED ON GROUNDS OF MISTAKE, FRAUD, MISREPRESENTATION, UNCLEAN HANDS, AND FRAUD ON THE COURT DUE TO THE COURT'S ERRONEOUS RELIANCE UPON KURABAYASHI TO ESTABLISH PRIMA FACIE OBVIOUSNESS

A. Kurabayashi Edited to Misrepresent: Statistical Analytical Mistakes and the Cropped Table

In the Defendants' Post-Trial Proposed Findings of Fact, they quote their expert witness, Dr. Jay W. Heinecke , "In light of the statistically-significant differential effects reported between the EPA and control groups, a person of ordinary skill in the art would have attributed the reduction in Apo B to EPA." (ECF No. 373) at 71, ¶280. The Court literally inserted Dr. Heinecke's false conclusion into its Opinion verbatim. *Amarin Pharma,* 449 F.Supp.3d at 990. However, this statement "and the flawed logic that it betrays **has no place in a peer-reviewed scientific journal**." Kasanoff Decl., Exh. "A", at 23, ¶75. (Emphasis in the original).

Dr. Jarvis explains that the figure below presents the data from Kurabayashi Table 3 in graphical form (data are a mean ± standard deviation with N numbers in brackets):



Using the Student's *t* tests, for ApoB, there was no significant difference between E3/E-EPA and E3 groups at any time point. Kasanoff Decl., Exh. "A", at 5, ¶14-¶15. **Kurabayashi** reports this as "NS" in Table 3, meaning "not significant" (see key in Table 1). *Id*. This means that the *P* value obtained with the test was greater than 0.05 ("Differences with a P value below .05 were considered statistically significant."). *Id*. This is a widely used threshold. *Id*.

They do not report the actual *P* values, although it is simple to reproduce these from the means, standard deviations and n values reported in Table 3. *Id*. For the ApoB data, the *P* values at each time point are: Baseline, $P = 0.66$; Week 12, $P = 0.50$; Week 24, $P = 0.53$; Week 48, $P = 0.13$. *Id*. Clearly, these are all greater than 0.05 and **therefore cannot be considered significant**. *Id*.

Dr. Heinecke's erroneous testimony and the Court's unwitting embrace of that testimony transpired despite being expressly contradicted by the stated conclusions of Kurabayashi, "The apolipoprotein B level in the eicosapentaenoic acid group was significantly lower at week 48 compared with the baseline level, but there was **no significant difference** between the groups." Kasanoff Decl., Exh. "A", at 5, ¶16; Kasanoff Decl., Exh. "F", at 3. Hence the necessity for the cropped Table.

Moreover, the Kurabayashi authors explicitly state **how** they compare groups to establish this conclusion of **no** difference between groups: "The significance of differences between the two groups was determined using Student unpaired test and that of differences in changes over time was determined by one-way repeated-measures analysis of variance. The statistical significance of intergroup differences was evaluated by two-way factorial analysis of variance followed by Fisher least significant difference method for multiple comparisons." Kasanoff Decl., Exh. "F", at 2.

It was this intergroup statistic that was **non-significant** in the ApoB analysis of Table 3 (See legend of "**NS**" for all time points between control and EPA arms illustrated below as $p^{\dagger}$). *Id*. The significance of the ANOVA variation in ApoB across time points within the EPA group was misrepresented to mean a difference in effects *between* EPA and control on ApoB. This is exactly the error Dr. Heinecke advanced, which this Court then accepted as fact.

Defendants cropped the table to exclude the descriptive legend which clearly states that the NS refers to a comparison *between* the EPA and control arms, which renders Heinecke's statement scientifically false. (ECF No. 373) at 71, ¶280. By doing so, Defendants have hidden the fact that Dr. Heinecke's conclusion is diametrically opposed to the Kurabayashi's stated statistical analysis.

The legend describing the lack of intergroup difference by student unpaired t-test for each time point was deliberately omitted, because it contradicted the erroneous statistical analysis of Dr. Heinecke's testimony. The legend should have been appended as the full Kurabayashi table includes the key intergroup difference statistic--the Students unpaired t-tests at each time point that definitively showed at every time point (**NS**) that "there was no significant difference between the groups". Kasanoff Decl., Exh. "F", at 3.

What motivated Defendants to crop the Table and hide the legend? Defendants and Dr. Heinecke both knew or should have known that to make a statement on the EPA effect on ApoB, there needed to be an honest representation of the full Table including the critical descriptive statistical legend. This Court was misled by a deliberate misrepresentation of the scientific truth, hidden behind a cropped table with a critically omitted legend, and an erroneous fabricated statistical construct.

When Dr. Heinecke was deposed regarding the proper methodology for statistical analysis, and was asked in reference to the same ApoB cohort, how to interpret the LDL changes between EPA and the Estrogen groups in Kurabayashi (both of which showed a decrease over time), he revealingly asks to review the comparative statistic for *between* group differences. It is readily evident that Dr. Heinecke clearly understood the need for such a **between** group comparison, but was *disingenuous* in not using the same comparative statistic for his analysis of Apo-B effects from the same group of patients in Table 3 Kurbayashi. Excerpts from Transcript of July 17, 2019 Deposition of Dr. Heinecke at 9 (Sept. 13, 2019) (ECF No. 264-3). In this context, we see *why* the Table was cropped as Dr. Heinecke and Defendants both knew this methodology of presentation was erroneous and deceptive.

When asked at his deposition whether there was a difference in the LDL cholesterol effects of EPA and control groups, Dr. Heinecke acknowledged that he needed an intergroup comparison test–meaning the full Table with descriptive legend and statistical comparisons, *not* the cropped one–to determine if there is a statistically significant, meaningful difference between the two groups. *Id*.

This is exactly the same reasoning demanding the application of the intergroup statistical comparison test for assessing the differential ApoB effects of EPA versus control in Table 3. Regarding ApoB, Heinecke conveniently abandoned the comparison because it did not suit Defendants' arguments. Defendants then cropped out this non-significant statistical comparison (ECF No. 373) at 71, ¶280, to ensure that the Court accepted at face value the narrative supported by the Cropped Table in rendering its decision. *Amarin Pharma,* 449 F.Supp.3d at 990.

B. Intervenor's Expert, Dr. Gavin E. Jarvis, Statistically Eviscerates Kurabayashi as a Viable Basis for Finding Clear and Convincing Evidence of Prima Facie Obviousness

Dr. Jarvis exposes the interpretative use of the statistical results in **Kurabayashi** employed by Dr. Heinecke and accepted de facto by this Court, as an example of a common misinterpretation and statistical abuse that has been decried for decades by academics. Kasanoff Decl., Exh. "A", at 8, ¶24. Here, Dr. Heinecke appears to be making an inference, not by comparing two (or more) sets of data with one *P* value addressing the relevant hypothesis, but by comparing two *P* values obtained separately, one from each group. *Id*.

Unfortunately, neither *P* value is addressing the relevant hypothesis about the effect of E-EPA. *Id*. His rationale regarding the ApoB data in Table 3 appears to run as follows:

(A) the change in ApoB over time with E3/E-EPA is significant ($P < 0.001$), therefore this is a real change;

(B) the change in ApoB over time with E3 is not significant (NS), therefore there is no real change;

(C) since there is a real change with E3/E-EPA and there is no real change with E3, this indicates a real difference between the two groups;

(D) the only difference is the use of E-EPA, therefore the reduction in ApoB must be caused by E-EPA.

Of these logical steps, (A) and (B) are most concerning. *Id*.

This exact scenario exemplified by Dr. Heinecke's interpretation of **Kurabayashi** is described in Bland and Altman, Comparisons within randomised groups can be very misleading. *BMJ*, 2011; 342: d561, the Statistics Treatise cited by Dr. Jarvis:

> *Rather than comparing the randomised groups directly, however, researchers sometimes look at the change in the measurement between baseline and the end of the trial; they test whether there was a significant change from baseline,* ***separately in each randomised group****. They may then report that this difference is significant in one group but not in the other, and conclude that this is evidence that the groups, and hence the treatments, are different.*

Kasanoff Decl., Exh. "A", at 9, ¶26. This description precisely matches how Dr. Heinecke interprets the data on ApoB from Table 3 of **Kurabayashi**. *Id.* Continuing:

> *The essential feature of a randomised trial is the comparison between groups. Within group analyses do not address a meaningful question: the question is not whether there is a change from baseline, but whether any change is greater in one group than the other.* ***It is not possible to draw valid inferences by comparing P values***", and further: "*Even when there is a clear benefit of one treatment over the other,* ***separate P values are not the way to analyse such studies****.*
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> **
>
> *Using separate paired tests against baseline and interpreting only one being significant as indicating a difference between treatments is a frequent practice.* ***It is conceptually wrong, statistically invalid, and consequently highly misleading.*** *When the null hypothesis between groups is true, the Type I error can be as high as 50%, rather than the nominal 5%, and even higher when more than two groups are compared.*
>
> **
>
> *Tests comparing the final measurement with baseline are useless in most cases. We cannot conclude that a treatment has effect because a before vs. after test is significant, because of natural changes over time and regression towards the mean.* ***We need a direct comparison with a randomised control.***
>
> **
>
> *Why do researchers do this? We know of no statistics text books which advocate this approach and ours explicitly warn against it.* ***To anybody who understands what "not significant" means, it should be obvious that within-group testing is illogical.*** *It should also appear so to anyone who has attended an introductory research methods course, which would have mentioned the importance and use of a control group.*

Id.

In sum, based upon universally accepted statistical canon, Dr. Jarvis concludes that Dr. Heinecke's interpretation of Kurabayashi's reported data on ApoB is so conceptually wrong, statistically invalid, and highly misleading, that it should be stricken from the record. *Id*. Once again, the statement, "In light of the statistically-significant differential effects reported between the EPA and control groups, a POSA would have attributed the reduction in Apo-B to EPA", and "the flawed logic that it betrays **has no place in a peer-reviewed scientific journal**." *Id*. at 23, ¶75. (Emphasis in the original). Such flawed logic likewise has no place in determining obviousness in a court of law.

The ability to withstand peer-review is the key to admissibility, credibility and reliability. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593, 113 S.Ct. 2786, 2797, 125 L.Ed.2d 469 (1993)(*Daubert I*). The Court unquestionably stands in the role of "gatekeeper" tasked with ensuring that expert testimony such as that of Dr. Heinecke, and the science relied upon in formulating scientific conclusions, has a **reliable** foundation. *Id*., 509 U.S. at 597, 113 S.Ct. at 2798-99.

An expert's blanket assurance of validity is insufficient. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (1995)(*Daubert II*). Instead, it must be shown that the expert's findings are predicated upon sound science, which requires some objective, independent validation of the expert's methodology. *Id*.

Intervenor respectfully submits that the Court needs to reevaluate its position as an evidentiary gatekeeper in view of its prior unwitting acceptance of the scientifically and logically flawed statement, "In light of the statistically-significant differential effects reported between the EPA and control groups, a POSA would have attributed the reduction in Apo-B to EPA." As confirmed by Dr. Jarvis, this statement has no place in a peer-reviewed scientific journal. If that scientifically and logically flawed statement cannot withstand scientific peer-review, then it is certainly a mistake to invalidate Amarin's patents based upon the invalid concepts underlying that flawed statement.

C. The Court's Reliance Upon Kurabayashi was a Mistake, Justifying Relief Under Rule 60(b)(1)

The Court mistakenly concluded that in "light of the statistically-significant differential effects reported between the EPA and control groups, a POSA would have attributed the reduction in Apo B to EPA." *Amarin Pharma,* 449 F.Supp.3d at 990. The Court's mistaken conclusion was directly contradicted by Kurabayashi: "The apolipoprotein B level in the eicosapentaenoic acid group was significantly lower at week 48 compared with the baseline level, but there was no significant difference between the groups." Kasanoff Decl., Exh. F", at 2. Kasanoff Decl., Exh. "A", at 5, ¶16.

Importantly, a District Court has the discretion to correct a judgment for mistakes made by the judge. *See POINT IIC, supra*. The Court's mistaken reliance upon Kurabayashi, qualifies as a mistake within the meaning of Rule 60(b)(1), and supports vacation of the Judgment on grounds of mistake pursuant to Rule 60(b)(1).

D. The Cropped Table and Dr. Heinecke's Scientific Deception Encompass Fraud, Misrepresentation, and/or Misconduct on the Part of Defendants, Justifying Relief Under Rule 60(b)(3)

Fraud perpetrated upon a party, as compared to a fraud which defiles the Court, is addressed by Rule 60(b)(3). *Toscano v. C.I.R.*, 441 F.2d 930, 933 (9th Cir. 1971). Proving fraud, misrepresentation and/or misconduct under Rule 60(b)(3), is a lesser burden than proving fraud on the court under Rule 60(d)(3). *Sierra-Pacific Indus, Inc.*, *supra.* Establishing fraud, misrepresentation and/or misconduct under Rule 60(b)(3) does not require proof of "nefarious intent or purpose" as relief under Rule 60(b)(3) can be granted even for accidental omissions. *Rembrandt Vision Technologies, L.P. v. Johnson & Johnson*, 818 F.3d 1320, 1328 (Fed. Cir. 2016).

Defendants cropped the table to exclude the descriptive legend that clearly states that the **NS** refers to a comparison between the EPA and control arms, which renders Heinecke's statement scientifically false. (ECF No. 373) at 71, ¶280. By doing so, Defendants have *hidden* the fact that Dr. Heinecke's conclusion is diametrically opposed to the stated conclusions of the Kurabayashi authors regarding their own statistical analysis, as exemplified by the Cropped Table Legend.

Defendants and Dr. Heinecke both knew or should have known that to make a statement on the EPA effect on ApoB, there needed to be an honest representation of the full Table including the critical statistical legend. This Court was misled by a deliberate misrepresentation of the scientific truth, hidden behind a cropped Table and a deliberately omitted legend.

Dr. Heinecke's scientifically disingenuous testimony and the cropping of the Table, was undoubtedly material to the Court's voiding of Amarin's patents on grounds of prima facie obviousness. *Rembrandt*, 818 F.3d at 1327. Amarin was substantially prejudiced by Dr. Heinecke's scientifically erroneous and disingenuous testimony and the cropping of the Table, which undermines the entire basis of the Judgment. Relief pursuant to Rule 60(b)(3) is therefore appropriate.

E. The Cropped Table and Dr. Heinecke's Scientific Deception Give Rise to Unclean Hands on the Part of Defendants, Justifying Relief Under Rule 60(b)(6)

Rule 60(b)(6) is distinct from the other Rule 60 subsections, in that relief under Rule 60(b)(6) must be for some reason other than the grounds expressly enumerated in the first five subsections. *Bayview Loan Servicing, supra*, at *3 n.2.[9] When parties such as Defendants set the judicial machinery in motion, but violated conscience, good faith, or other equitable principle in their prior conduct, the doors of the courthouse are shut to those parties, as courts will refuse to interfere on their behalf, acknowledge their rights, or award them any remedies. *Aptix Corp. v. Quickturn Design Systems, Inc.,* 269 F.3d 1369, 1375 (Fed. Cir. 2001).

In patent cases, where, as here, a party has engaged in egregious, **intentional misconduct** designed to mislead the court, the Federal Court has employed the "unclean hands doctrine" to remedy such egregious misconduct. *Therasense, Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011)(En Banc); *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 719 F.3d 1346, 1358 (Fed. Cir. 2013). Where, as here, the misconduct is particularly egregious, it

[9] A close reading of the "unclean hands" cases cited herein, indicates that none of them cite to Rule 60(b)(3) or Rule 60(d)(3). Hence we assert "unclean hands" pursuant to Rule 60(b)(6). We do so while recognizing that reasonable minds may differ as to whether "unclean hands" falls within Rule 60(b)(3). Either way, we submit that the doctrine should be applied to vacate the Judgment.

speaks for itself, and need not even be material. *Theresasense*, 649 F.3d at 1287.

An adjudication of unclean hands may occur when the misconduct of a party has "immediate and necessary relation to the equity that he seeks in respect of the matter in litigation", and/or "for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court. *Gilead Sciences, Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018). The unclean hands doctrine "necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant." *Id.*[10]

Such misconduct is an issue of substantial importance, as tampering with the administration of justice involves far more than an injury to a single litigant. *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238, 246, 64 S.Ct. 997, 1001, 88 L.Ed. 1250 (1944). Defendants have wronged this Court as an institution, where such fraud cannot be complacently tolerated. *Id.*

Public policy demands that eminent institutions of public justice such as this Court "be not so impotent that they must always be mute and helpless victims of deception and fraud." *Id.* This is so even if Amarin did not exercise the highest degree of diligence in uncovering the fraud. *Id. See Pumphrey v. K.W. Thompson Tool Co.*, 62 F.3d 1128, 1133 (9th Cir. 1995) (Even assuming that the victim was not diligent in uncovering the fraud, the court is still empowered to set aside the verdict where the court itself was the victim of the fraud).

Moreover, fraud in patent cases is a matter of public concern extending beyond the parties to the litigation. *Fraige v. American-National Watermatress Corp.*, 996 F.2d 295, 298 (Fed. Cir. 1993)(*citing Hazel-Atlas*, *supra*). Indeed, such misconduct is especially troubling in patent cases as "patent law is a field where so much depends upon familiarity with specific problems and principles not usually contained in the general storehouse of knowledge and experience." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 328, 135 S.Ct. 831, 838, 190 L.Ed.2d 719 (2015).

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[10]There is no difference between Ninth Circuit and Federal Circuit law governing the determination of "unclean hands." *Id.* at 1239 n.2.

For reasons already stated, Dr. Heinecke's scientifically disingenuous testimony and the deliberate cropping of the Table imbue Defendants with unclean hands. As a result of Defendants' unclean hands, the doors of the courthouse should be shut to Defendants, and they should be stripped of previously granted remedies through vacation of the Judgement pursuant to Rule 60(b)(6). *Aptix Corp.*, *supra*.

F. The Cropped Table and Dr. Heinecke's Scientific Deception Constitute a Fraud on the Court, Justifying Relief Under Rule 60(d)(3)

Fraud on the court encompasses the types of fraud seeking to defile the court itself, or perpetrated by officers of the court, so that the court cannot perform impartially. *United States v. Estate of Stonehill*, 660 F.3d 415, 444 (9th Cir. 2011). Fraud on the court transpires when the misconduct harms the integrity of the judicial process, irrespective of whether the party victimized by the fraud was prejudiced, as the perpetrator of the fraud cannot dispute the effectiveness of the fraud after the fact. *Dixon v. C.I.R.*, 316 F.3d 1041, 1046 (9th Cir. 2003).

The power to vacate a judgment based upon fraud on the court, is to be exercised with restraint, and should be used only when the fraud upon the court is established by clear and convincing evidence. *FTC v. Johnson*, 2015 WL 7069292 at *1 (D. Nev. 2015). Unlike fraud/misrepresentation under Rule 60(b)(3), fraud on the court under Rule 60(d)(3) must be an "intentional, material misrepresentation." *Sierra-Pacific Indus, Inc.*, *supra*, at 1168.

Standing alone, perjury or nondisclosure of evidence will not constitute a fraud upon the court "unless that perjury or nondisclosure was so fundamental that it undermined the workings of the adversary process itself. *Estate of Stonehill*, *supra*, at 445. Perjury may be adjudged a fraud on the court where it involves or is suborned by an officer of the court. *Sierra-Pacific Indus, Inc.*, *supra*. Such is the case here with the **deliberately** cropped Table.

Taken together, Dr. Heinecke's scientifically disingenuous testimony and the cropping of the Table constitute a fraud upon this Court within the meaning of Rule 60(d)(3). As a result, the Court has the inherent power to vacate the Judgment and formulate the appropriate remedy. *Dixon*, *supra.*, at 1047.

POINT IV

DR. HEINECKE'S DISINGENUOUS SCIENTIFICALLY FRAUDULENT RELIANCE UPON THE CLAIM CONSTRUCTION ORDER CONSTITUTES YET ANOTHER INSTANCE OF MISTAKE, FRAUD, MISREPRESENTATION AND INEQUITABLE CONDUCT JUSTIFYING RULE 60 RELIEF

Claim construction commences with the language of the claims. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1304 (Fed. Cir. 2015). When analyzing claim language, courts look to the intrinsic record, which includes the specification and prosecution history. *Id*.

Dr. Heinecke fraudulently and *deliberately* misapplied the Claim Construction Order (Aug. 10, 2018)(ECF 135) to commit a scientific fraud upon this Court. Dr. Heinecke falsely states in his Reply Expert Report that, "none of the asserted claims as construed requires an actual comparison to a second patient in a control group." (Aug. 9, 2019)(ECF 234-12) at 16 ¶201. By doing so, Dr. Heinecke deliberately ignored the plain language of Claim 8 of '677 Patent which states, "The method of claim 1, comprising administering to the subject about 4g of the pharmaceutical composition daily for the period of at least about 12 weeks to effect a reduction in apolipoprotein B ***compared to placebo control***." (Aug. 30, 2019)(ECF 235-15) at 3 (emphasis added).

The fundamental error that is falsely justified by erroneous application of the claim construction is the same in Kurabayashi as in Mori: The presence of a statistically significant difference in one arm combined with the absence of a difference within the other arm does not imply a statistically significant difference between the arms. This is exactly the scientifically false narrative that Dr. Heinecke advances, and that the Court was misdirected into accepting as fact when it mistakenly concluded, "Mori found that EPA did not raise LDL-C levels and Kurabayashi suggested that EPA reduced Apo B levels." *Amarin Pharma,* 449 F.Supp.3d at 1013.

Dr. Heinecke essentially implies that the Court's ruling on claim construction allows him to state that "compared to" imputes that comparison of a variable to itself can be construed to be equivalent to "comparison with placebo or control". This is clearly erroneous by all accepted statistical and analytical standards, and constitutes flagrant statistical and scientific misrepresentation.

This Court unambiguously clarified the meaning of the terms "compared to" (ipso facto "compared with") in its claim construction ruling which addressed the plain and ordinary meaning of "compared to" by defining it as follows: "By performing a comparison between what happens when the treatment is administered versus what would **otherwise happen to a second subject**, "compared to" defines the magnitude of the lipid effect or avoidance of the undesirable lipid effects..." Claim Construction Order (Aug. 10, 2018)(ECF 135) at 13.

This Court has made clear that the comparison is made **between two different subjects** where one is given the treatment, and the other has not been given the treatment. This Court did NOT sanction erroneous scientific analysis where statistically invalid comparisons of p-values of individual treatment group effects (baseline to post therapy), is used to impute differences in "between group" EPA effects. Otherwise, any random change while on therapy could be used to impute biological effect.

No scientific comparison can impute a real treatment effect without first comparing changes *between* a control group and a comparator group. This is the established **gold standard** of statistical analysis of all treatment effects.

Given his credentials and experience, Dr. Heinecke knew or should have known that his conclusions are scientifically and statistically untenable. But instead of acknowledging this fact, Dr. Heinecke advances a scientific and statistical fraud through abuse of the Claim Construction Order, "I understand that the Court construed this language as 'not a claim limitation' and that 'the claimed effect can be compared to the expectation if the subject did not receive purified ethyl-EPA.'" (Aug. 9, 2019)(ECF 234-12) at 15 ¶197. Dr. Heinecke goes on to say, "All asserted claims recite methods of treatment 'comprising' certain steps, and I understand that the transitional phrase means that other elements may be added and still form a construct within the scope of the claim." *Id.* at 16 ¶199.

Such conclusory, unsupported assertions by Dr. Heinecke as to the definition of a claim term, and how it determines the analysis of scientific prior art, are misleading, and not useful to the Court in reaching its judgment. *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1361 (Fed. Cir. 2013); *Gen. Protecht Grp., Inc. v. Int'l Trade Comm'n*, 619 F.3d 1303, 1310–11

(Fed. Cir. 2010). Extrinsic evidence such as Dr. Heinecke's expert report opinions, is not reliable in determining how to read claim terms. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318–19 (Fed. Cir. 2005)(en banc).

To the extent that Dr. Heinecke's testimony merely provides his opinion as to claim construction, it is to be accorded no weight. *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1289 (Fed. Cir. 2008). Expert testimony at odds with the intrinsic evidence must be disregarded. *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005).

Thus the Claim Construction Order provides neither a justification nor a safe harbor for Dr. Heinecke's scientific and statistical fraud. The Court made an unwitting mistake by according any weight to Dr. Heinecke's statisically erroneous and scientifically fraudulent testimony. Further, Dr. Heinecke's misrepresentation likewise constitutes fraud, fraud on the court, and inequitable conduct justifying vacation of the Judgment.

POINT V

PURSUANT TO RULE 60, THE JUDGMENT SHOULD BE VACATED BECAUSE WITHOUT THE BENEFIT OF MORI AND KURABAYASHI, DEFENDANTS CANNOT MEET THEIR BURDEN OF CLEARLY AND CONVINCINGLY PROVING PRIMA FACIE OBVIOUSNESS

Patents enjoy a presumption of validity which can only be rebutted by clear and convincing evidence. *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 971 (Fed. Cir. 2014). As noted by this Court, the party seeking to invalidate patents on grounds of obviousness, must clearly and convincingly prove "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Amarin Pharma,* 449 F.Supp.3d at 1005. Such clear and convincing evidence must produce in the mind of the trier of fact, "an abiding conviction that the truth of the factual contentions is highly probable." *Allergan*, *supra.*

While the Court may have had an abiding conviction that there was clear and convincing evidence at the time the Court entered the Judgment invalidating Amarin's patents on grounds of prima facie obviousness, we respectfully submit that the grounds for such an abiding conviction no longer exist once the scientific misrepresentation of the prior art is taken into account. Accordingly, pursuant to Rule 60, the Court should vacate the Judgment invalidating Amarin's prima facie obviousness. Simply stated, without Mori and without Kurabayashi, Defendants cannot meet their burden of proof.

CONCLUSION

Sunlight is said to be the best of disinfectants; electric light the most efficient policeman. *Buckley v. Valeo*, 424 U.S. 1, 67, 96 S.Ct. 612, 658, 46 L.Ed.2d 659 (1976). For the reasons above, Intervenor EPADI II respectfully requests that the Court vacate the Judgment and enter Judgment in favor of Amarin, or if the Court is not inclined to do so at this time, the Court should at least vacate the Judgment and schedule further proceedings narrowly focused on the issues raised in this Motion.

Dated: March 19, 2021

/s/ *Michael S. Kasanoff*

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