

**IN UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

MARIO J.A. SAAD, MD PhD)	CIVIL ACTION NO.:
)	
Plaintiff,)	
)	
v.)	
)	
AMERICAN DIABETES)	
ASSOCIATION)	
)	
Defendant.)	

VERIFIED COMPLAINT

Mario J. A. Saad, MD, PhD (“Dr. Saad”) commences this litigation seeking injunctive relief and damages against the American Diabetes Association (“ADA”), which has wrongfully published a digital expression of concern, will publish a hard-copy expression of concern and may ultimately retract four of Dr. Saad’s peer reviewed articles currently published in the ADA’s *Diabetes* journal, where the articles have been published since 2011, 2007, 2006 and 1997 respectively. Dr. Saad seeks: (1) an Order requiring the ADA to remove the digital expression of concern which was published on February 2, 2015 on the ADA’s *Diabetes* website regarding Dr. Saad’s four articles; (2) a permanent injunction enjoining the ADA from publishing the hard-copy expression of concern regarding Dr. Saad’s four articles in the March issue of *Diabetes* which releases on February 24, 2015; and (3) a permanent injunction enjoining the ADA from retracting Dr. Saad’s four articles from *Diabetes*.

In support of these claims, Dr. Saad alleges the following:

PARTIES

1. Plaintiff Dr. Saad is a citizen of Brazil residing in São Paulo, Brazil.
2. Defendant ADA is an Ohio corporation with its principal place of business in Alexandria, Virginia.
3. Defendant ADA has at least one Massachusetts office [330 Congress Street, Boston, MA and 10 Speen Street, 2nd Floor, Framingham, MA] and has a registered agent located in Boston, Massachusetts [Corporation Service Company, 84 State Street, Boston, MA].

JURISDICTION AND VENUE

4. This court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.
5. Venue is proper pursuant to 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

6. Dr. Saad is currently employed by the State University of Campinas, in the Department of Internal Medicine, which is located in São Paulo, Brazil (“University”).
7. Dr. Saad became Associate Professor of Medicine in 1996 and Professor of Medicine in 2003 at the University. Dr. Saad was coordinator of the PhD program of the Internal Medicine Department and subsequently the coordinator of the PhD program of the Medical School. [See Dr. Saad’s current C.V. attached hereto as **EXHIBIT A**]
8. Dr. Saad was the Dean of the Medical School at the University from 1998 to 2002 and was a member of the committees of two research support agencies. He is Editor of the Brazilian Journal of Medical and Biological Research for the area of Clinical

Investigation and a member of the Editorial Board of the journals *Endocrinology*, the *American Journal of Physiology and Metabolisms*. [See **EXHIBIT A**]

9. Dr. Saad has supervised 55 undergraduate students in research programs; 17 Masters degrees, 22 PhDs and 18 Postdoctoral fellowships. [See **EXHIBIT A**]

10. The ADA has several professional publications including: *Diabetes*, *Diabetes Care*, *Clinical Diabetes*, *Diabetes Spectrum*, *Standards of Medical Care in Diabetes*, *Scientific Sessions Abstract Book*, and *BMJ Open Diabetes Research and Care*.¹

11. *Diabetes*, the ADA's flagship research publication is the highest ranked journal devoted exclusively to diabetes research. *Diabetes* is a peer-reviewed journal that publishes original research articles on the physiology and pathophysiology of diabetes and its complications.²

12. Dr. Saad has published over 237 articles in scholarly journals that have been cited over 10,000 times. [See **EXHIBIT A**]

13. In 2011 the ADA published Dr. Saad's article in *Diabetes, Physical Exercise Reduces Circulating Lipopolysaccharide and TLR4 Activation and Improves Insulin Signaling in Tissues of DIO Rats*. *Diabetes*, 2011; 60:784–796. ("2011 Article") [Article attached hereto as **EXHIBIT B**].

14. In 2007 the ADA published Dr. Saad's article in *Diabetes, Loss-of-Function Mutation in Toll-Like Receptor 4 Prevents Diet-Induced Obesity and Insulin Resistance*.

¹ The Journals of the ADA are self-described as, "counted among the most prominent publications in the field of endocrinology and metabolism. With more than 60 years of publishing experience, ADA journals continue to be the authoritative source for the latest in diabetes research." Information found at www.diabetesjournals.org, last accessed 2/3/2015

² Information found at www.diabetesjournals.org, last accessed 2/3/2015

Diabetes 2007; 56:1986–1998. (“2007 Article”) [Article attached hereto as **EXHIBIT C**].

15. In 2006 the ADA published Dr. Saad’s article in *Diabetes, Exercise Improves Insulin and Leptin Sensitivity in Hypothalamus of Wistar Rats*. *Diabetes* 2006; 55:2554–2561. (“2006 Article”) [Article attached hereto as **EXHIBIT D**].

16. In 1997 the ADA published Dr. Saad’s article in *Diabetes, Effect of Captopril, Losartan, and Bradykinin on Early Steps of Insulin Action*. *Diabetes* 1997;46:1950–1957. (“1997 Article”) [Article attached hereto as **EXHIBIT E**].

17. By electronic mail (“e-mail”) dated March 10, 2014 the ADA through Christian Kohler, staff liaison of the ADA’s Subcommittee on Ethical Scientific Publications (“ESP”)³ contacted Dr. Saad and informed him that two of his articles (2011 and 2007 Articles) “...appear to contain instances of image manipulation and duplication that violate the journal’s publication policies”. Mr. Kohler requested that Dr. Saad respond to the specific issues raised by ESP by March 25, 2014.⁴

18. By e-mail dated March 24, 2014 Dr. Saad responded to Mr. Kohler and provided responses related to the concerns raised in Mr. Kohler’s March 10th correspondence.⁵

19. By e-mail dated April 9, 2014 Mr. Kohler responded to Dr. Saad and stated: “I regret to inform you that after careful review and much discussion, the ESP has concluded that your response and explanations do not adequately address the concerns

³ According to Mr. Kohler the ADA’s ESP works on behalf of the ADA journal editors to review cases of potential scientific/academic misconduct in manuscripts submitted to or articles published in ADA journals.

⁴ Note that this notice was given 3 and 7 years, respectively, after the original publication of these peer-reviewed articles.

⁵ Dr. Saad noted that it would be difficult to find the original materials (specifically the blots) because the Article in question was over 7 years old and Dr. Saad’s standard practice, as recommended by National Institute of Health (“NIH”) is to maintain the original data of research for only 5 years.

outlined in my letter dated March 10. The ESP still has serious concerns about the reliability of the reported data.”

20. In the April 9th e-mail Mr. Kohler informed Dr. Saad that he will contact the University, specifically President Jose Tadeu Jorge, Vice President for Research Glauca Maria Pastore, and the Committee of Research Ethics to request the initiation of the appropriate investigation regarding the accuracy, reliability, and integrity of the data reported in the 2011 and 2007 Articles. [Correspondence attached hereto as **EXHIBIT F**].

21. On April 22, 2014 the University appointed an Inquiry Commission (“I.C.”) to meet and hear Dr. Saad and collaborating researchers on the issues as requested by Mr. Kohler on behalf of the ADA in the March 10th correspondence.

22. On May 13, 2014 Dr. Saad and fellow researchers presented their materials and explanations to the I.C.

23. On June 9, 2014 the I.C. gathered and concluded that after inspecting and talking with Dr. Saad and fellow researchers, the general results of the research presented in the 2011 and 2007 Articles are valid. The I.C. also found no evidence of dishonesty on behalf of Dr. Saad and the researchers. In addition, the I.C. concluded that mistakes had occurred in the treatment of the digital images, identification methods, storage and manipulation of the laboratory images.

24. The I.C. ultimately concluded that the scientific results presented in the 2011 and 2007 Articles are valid, the results were not compromised by the mistakes cited in Mr. Kohler’s March 10th correspondence, and the Commission highlighted that the articles

are extensively mentioned by literature (73 quotes in Scopus databases on June 13, 2014⁶).

25. By letter dated August 12, 2014 the I.C. wrote the Attorney General (“Provost”) and informed the Attorney General that the investigated mistakes did not compromise the results of publications under analysis (2011 and 2007 Articles). The Commission went on to state that “[i]t is therefore considered that no infringement was committed whatsoever to justify the opening of administrative and disciplinary proceedings, or the application of penalties and thus recommends the filing of the records.” [Correspondence attached hereto as **EXHIBIT G**].

26. The University subsequently provided the ADA with the final investigation report.. [Report attached hereto as **EXHIBIT H**].

27. By e-mail dated October 12, 2014 Mr. Kohler informed Dr. Saad that the ADA’s ESP is reviewing the investigation report from the University. Additionally, Mr. Kohler informed Dr. Saad that the editors of *Diabetes* were recently informed of two other articles (2006 and 1997 Articles) for which Dr. Saad was listed as a co-author that appear to contain instances of inappropriate image duplication. Mr. Kohler requested a response to the new allegations regarding the 2006 and 1997 Articles by October 27, 2014.⁷

28. By email dated October 27, 2014 Dr. Saad responded to Mr. Kohler’s October 12th e-mail regarding the new allegations surrounding the 2006 and 1997 Articles.

⁶ “Scopus is the largest abstract and citation database of peer-reviewed literature: scientific journals, books and conference proceedings. Delivering a comprehensive overview of the world's research output in the fields of science, technology, medicine, social sciences, and arts and humanities, Scopus features smart tools to track, analyze and visualize research.” Information found at: <http://www.elsevier.com/online-tools/scopus>, last accessed 2/3/2015.

⁷ Mr. Kohler did not inform Dr. Saad who or what entity was providing information to the ADA regarding Dr. Saad’s articles (2011, 2007, 2006 or 1997).

29. By e-mail dated December 2, 2014 Mr. Kohler informed Dr. Saad that the ADA's ESP completed its review of the University's report regarding the 2011 and 2007 Articles as well as Dr. Saad's and Dr. Carvalheirais⁸ recent responses related to the 1997 and 2006 Articles.

30. In the December 2nd correspondence Mr. Kohler informed Dr. Saad that based on the ESP's review and recommendations, *Diabetes* will publish a digital expression of concern online on December 15, 2014⁹ and the expression of concern will appear in the March print issue of *Diabetes*, which releases on February 24, 2015.

31. In the December 2nd correspondence Mr. Kohler informed Dr. Saad that the ADA's ESP will ask the University to *reinvestigate*¹⁰ the data published in the 2011 and 2007 Articles and the information presented in Dr. Saad's point by point response.¹¹

32. Most detrimental, the ADA stated that it will not consider, for publication in *any ADA journal*¹² *any submissions* authored by any of the faculty of the University until

⁸ Jose B.C. Carvalheirais was contacted by the ESP to inform him of the concerns related to the 2006 and 1997 Articles (Dr. Carvalheirais is listed as the corresponding author on these Articles) requesting an explanation for the issues raised in Mr. Kohler's October 12, 2014 e-mail.

⁹ Notably that the ADA did not publish the digital expression of concern on December 15, 2014, but rather on February 2, 2015. The ADA published the digital expression of concern after counsel for the Plaintiff reached out to Mr. Kohler on January 26, 2015 requesting that the ADA refrain from publishing the expression of concern (digital or hard-copy) until the parties have an opportunity to discuss the matter. Mr. Kohler responded to Plaintiff's counsel on Friday, January 29, 2015 and stated that the digital expression of concern will be linked online to the Articles as of Monday, February 2, 2015. As of February 5, 2015 Mr. Kohler has failed to return the telephone call of Plaintiff's counsel.

¹⁰ In December 2014 and January 2015 the President of the University contacted Mr. Kohler and informed him that the University was assembling a new I.C. to be composed of recognized scientists in the area of endocrinology and diabetes (two members from outside of Brazil – one member from the United States and one member from Belgium) and the meeting was to be held on the only workable dates of March 9th and 10th 2015. This meeting is to be convened to reevaluate 2011 and 2007 Articles and to evaluate the 2006 and 1997 Articles.

¹¹ The ADA called for a primary investigation into the 1997 and 2006 Articles and called for a secondary investigation into the 2007 and 2011 Articles, yet hastily published an expression of concern after the University found in favor of Dr. Saad regarding the 2007 and 2011 Articles and the University has yet to undergo and investigation into the 1997 and 2006 Articles.

the issues described in the expression of concern have been appropriately reviewed and addressed by the University. [Correspondence attached hereto as **EXHIBIT I**]

33. By letter dated January 26, 2015 Dr. Saad's counsel wrote to Mr. Kohler and requested that the ADA not publish the expression of concern (digital or otherwise) until the parties had an opportunity to discuss the matter. [Correspondence attached hereto as **EXHIBIT J**]¹³.

34. Without waiting for the investigatory report of the March 9th and 10th 2015 I.C. (established to reevaluate 2011 and 2007 Articles and to evaluate the 2006 and 1997 Articles), the ADA posted the digital expression of concern on February 2, 2015, imposed a hard deadline of February 24, 2015, at which time it will publish a hard-copy expression of concern in the March issue of *Diabetes* and the ADA may at any time act unilaterally and retract Dr. Saad's articles currently published in *Diabetes*. [February 2, 2015, Expression of Concern attached hereto as **EXHIBIT L**]

35. The ADA's digital (currently posted) expression of concern, soon to be published hard-copy expression of concern and potential retraction of the articles have and will continue to severely damage Dr. Saad's professional reputation.

COUNT I
(Defamation)

36. Dr. Saad repeats and incorporates by reference the allegations of Paragraphs 1 through 35 of the complaint.

¹² ADA publications include: *Diabetes*, *Diabetes Cares*, *Clinical Diabetes*, *Diabetes Spectrum*, *Standards of Medical Care in Diabetes*, *Scientific Sessions Abstract Book*, and *BMJ Open Diabetes Research and Care*.

¹³ Mr. Kohler responded to Plaintiff's Counsel's January 26th letter on January 29th. [Correspondence attached hereto as **EXHIBIT K**]

37. The ADA has posted a digital expression of concern that is available for any individual with internet access to view.

38. The ADA will publish a hard-copy expression of concern that will appear in the March print issue of *Diabetes*, which releases on February 24, 2015.

39. The ADA may retract Dr. Saad's articles from the ADA, and has already demonstrated that it does not value the findings of the University's I.C. Retraction of the articles will cause Dr. Saad to suffer irreparable harm to his professional reputation.

40. *Diabetes* is an internationally recognized and influential peer-reviewed research journal with an *Impact Factor* of 8.5¹⁴ and is the highest ranked journal with a focus on original diabetes research.

41. The ADA reaches over 51,000 health care professionals through its online and print publications and is widely circulated to the top research universities.

42. Should the ADA retain the digital expression of concern regarding Dr. Saad's articles, this will be the independent and voluntary action of the ADA.

43. As a direct and proximate result of the ADA's publishing of the expression of concern and potential retraction of Dr. Saad's articles from *Diabetes*, Dr. Saad has and will continue to suffer foreseeable harm and damage including, but not necessarily limited to, irreparable harm to his professional reputation.

¹⁴ An impact factor can be defined as "[a] measure reflecting the average number of citations to recent articles published in a particular journal publication... Calculation of an impact factor is based upon the average number of citations received per paper published in a particular journal during the preceding two years." Information found at <http://www.impactfactorsearch.com/IF.html> , last accessed 2/3/2015

WHEREFORE, Plaintiff Dr. Saad respectfully requests that the Court enter an Order finding in his favor and, on Count I, by way of equitable relief, order the ADA to remove the digital expression of concern, permanently enjoin the ADA from publishing the hard-copy expression of concern in the March issue of *Diabetes* and permanently enjoin the ADA from retracting the Plaintiff's article from the ADA; and further, that the Court grant such other relief as it deems just and proper.

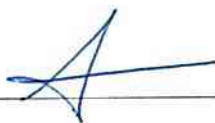
**THE PLAINTIFF HEREBY DEMANDS A TRIAL BY JURY
ON ALL COUNTS SO TRIABLE.**

VERIFICATION

I, Mario J.A. Saad, have read the above Verified Complaint and affirm that the information provided in the Verified Complaint and attached exhibits are true to my belief or knowledge based on my personal knowledge.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY THIS __ DAY OF
FEBRUARY 2015.

Mario J.A. Saad



Respectfully submitted,
MARIO J.A. SAAD
By his attorneys,

/s/ Steven J. Brooks

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