

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATOSSA THERAPEUTICS, INC.,
Petitioner

v.

JINA PHARMACEUTICALS, INC.,
Patent Owner

PGR2026-00015
Patent 12,245,997

**DECLARATION OF MAURICIO TOHEN MD, DrPH IN SUPPORT OF
PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO.
12,245,997**

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I, Dr. Mauricio Tohen, hereby declare under penalty of perjury:

I. INTRODUCTION

1. I have been retained by Groombridge, Wu, Baughman & Stone LLP, on behalf of Atossa Therapeutics, Inc. (“Atossa”) to provide opinions regarding U.S. Patent No. 12,245,997 (“the ’997 patent”). Specifically, I have been asked to consider the validity of claims 1-10 of the ’997 patent (the “Challenged Claims”). Except as otherwise indicated, I have personal knowledge of the facts and opinions set forth in this declaration, and believe them to be true. If called upon to do so, I would testify competently thereto.
2. I am being compensated for my time at my standard consulting rate. I will be reimbursed for the expenses that I incur in the course of this work. My compensation is not contingent upon the results of my analysis, the substance of my opinions, or the outcome of any proceeding involving the Challenged Claims. I have no financial interest in the outcome of this matter or in the pending matters involving Jina Pharmaceuticals, Inc. (“Jina” or “Patent Owner”) or Atossa.

II. BACKGROUND AND QUALIFICATIONS

3. I offer statements and opinions on behalf of Atossa, generally regarding the written description, enablement, indefiniteness, novelty, prior art, and understanding of a person of ordinary skill in the art as it relates to the ’997 patent.

4. My extensive background, training and research endeavors in the field of bipolar disorder are relevant to the subjects of this declaration.
5. In 1976, I earned a Doctor of Medicine from the National University of Mexico in Mexico City, Mexico. In 1982, I completed a Psychiatry Residency at the University of Toronto, Clarke Institute of Psychiatry. In 1985, I completed a Clinical Fellowship in Psychopharmacology at the Harvard Medical School McLean Hospital, Mailman Research Center. In 1984, I earned a Master of Public Health at the Harvard School of Public Health. In 1988, I earned a Doctorate in Public Health at the Harvard School of Public Health. And in 2000, I earned a Master in Business Administration at Indiana University, Kelley School of Business.
6. After earning my doctorate degree, I taught at Harvard Medical School, where I was an Associate Professor in both the Department of Psychiatry and Department of Epidemiology and I remain affiliated with McLean Hospital at Harvard Medical School. I then served as the Aaron & Bobbie Elliott Krus Endowed Chair in the Department of Psychiatry at The University of Texas Health Science Center in San Antonio, Texas. I presently serve as University Distinguished and Regents Professor and Chairman of the Department of Psychiatry & Behavioral Sciences at The University of New Mexico, Health Sciences Center in Albuquerque, New Mexico.

7. I have received numerous awards and recognitions throughout my career. In 2014, I was recognized by Thomson Reuters's "The World's Most Influential Scientific Minds, 2014," which recognizes scientists who ranked in the top 1 percent by citations of their published work in 21 fields between 2002 and 2012. In 2017, I was recognized by Expertscape as having the top 0.12% expertise in bipolar disorder worldwide based on citations of published articles between 2007-2017. In 2020, I was awarded University Distinguished Professor by the University of New Mexico, which is an award given to individuals who have demonstrated outstanding achievements and are nationally and internally recognized as scholars. In 2024, I was awarded the American Society of Hispanic Psychiatry – Lifetime Achievement Award. In 2025 I was named Regents Professor at the University of New Mexico, a special title bestowed on selected senior faculty members who, in the judgment of the Dean and on the advice of a faculty selection committee, merit recognition of their accomplishments as teachers, scholars and leaders both in University affairs and in their national/international professional communities.
8. I am a fellow of the American College of Neuropsychopharmacology and a distinguished fellow of the American Psychiatric Association. I was a trustee on the Board of Trustees for the Bowden Foundation for Advanced Interventions Research in Mood and Anxiety Disorders. I previously served as the President

of the American Society of Hispanic Psychiatry and the President of the International Society of Bipolar Disorders (ISBD). I continue to be actively involved in ISBD and have published a number of impactful publications that have emerged from ISBD task forces on the treatment of bipolar disorders.

9. I have co-edited four books, including Bipolar Disorder: Comorbidity in Affective Disorders and Bipolar Psychopharmacotherapy. I have authored more than 400 research papers related to bipolar disorder and other psychiatric disorders. Further, I am currently an Editorial Board Member on the following journals: Bipolar Disorders; Journal of Affective Disorders; Early Intervention in Psychiatry; World Journal of Psychiatry; and The International Journal of Bipolar Disorders. I have continually conducted clinical research including conducting clinical trials in bipolar disorders since I completed my doctoral degree in Public Health with a focus in Epidemiology at the Harvard School of Public Health in 1988. In my clinical practice for the last 30+ years, I primarily have provided care to patients living with bipolar disorders.
10. Attached hereto as **Appendix A** is a true and correct copy of my Curriculum Vitae describing my background and experience and includes a list of my publications and presentations.

III. PRIORITY DATE AND ONE OF ORDINARY SKILL

11. I understand that a person of ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to have known the relevant art at the time of the invention. I understand that POSITA is also a person of ordinary creativity, who in many cases will be able to fit the teachings of multiple patents or printed publications together. I further understand that the factors that may be considered in determining the level of ordinary skill in a particular field of art include (1) the level of education and experience of those working in the field, (2) the types of problems encountered in the field, and (3) the sophistication of the technology at the time of the invention, which I understand to be as early as April 10, 2020. I understand this date is sometimes referred to as the “priority date” or “earliest filing date” of the patent. I understand that not every factor may be present in every case. I understand that POSITA is not a specific real person, but rather is a hypothetical person having the qualities reflected by the above-discussed factors. I further understand that POSITA would have knowledge from the teachings of the prior art, including the art cited herein.

12. I understand that a person of ordinary skill in the art with respect to the ’997 patent is a person with an advanced degree—either a Ph.D. or an M.D.—and three to five years of experience treating and/or researching psychiatric conditions including bipolar disorder.

13. Well before the claimed April 10, 2020 priority date of the '997 patent, my level of skill in the art was at least that of POSITA. I am qualified to provide opinions concerning what such POSITA would have known or understood as of that time. Unless otherwise stated, my analysis and conclusions provided herein are from the perspective of POSITA as of that date.

IV. MATERIALS RELIED UPON

14. In reaching the conclusions described in this declaration, I have relied on the documents and materials cited in this Declaration and those identified in **Appendix B**. These materials are patents, related documents, and printed publications. Each of these is a type of document that experts in my field would reasonably rely upon when forming their opinions.

15. My opinions are also based on my education, training, knowledge, and personal and professional experience.

V. BACKGROUND ON THE STATE OF THE ART

16. The prior art disclosed methods for using endoxifen to treat bipolar I disorder, including, specifically, in the phase II trial described in Ahmad, A., et al., "Endoxifen, a New Treatment Option for Mania: A Double-Blind, Active-Controlled Trial Demonstrates the Antimanic Efficacy of Endoxifen," Clin Transl Sci 9:252-259 (2016) ("Ahmad 2016") (EX1004), in which patients treated with 4 mg or 8 mg of endoxifen citrate for 21 days experienced significant

clinical improvement across multiple symptoms of bipolar mania, with the 8 mg dose providing improvements similar to divalproex, an FDA-approved treatment for acute mania. EX1004 (Ahmad 2016), 1-3.

17. It was also well-known long before the April 10, 2020 priority date that patients experiencing breakthrough or recurring symptoms of bipolar I disorder should optimize the dose of their existing medication, and monitor the response to that change in treatment, prior to administering any additional medication, such as rescue medication as defined in the '997 patent. EX1005 (Hirschfeld), 8-9.

18. Further, it was well known in the prior art that—due to the risk of significant side effects, particularly in certain populations like elderly, immunocompromised, or pregnant individuals—administration of additional medication for the treatment of bipolar I disorder, such as rescue medications for breakthrough or recurring symptoms, should be avoided. EX1005 (Hirschfeld), 14 (“cognitive impairment,” “extrapyramidal side effects and tardive dyskinesia,” “orthostatic hypotension,” and “greater risks of falls and hip fractures”); *see id.* at 3 (“each additional medication generally increases the side effect burden and the likelihood of drug-drug interactions or other toxicity”). Rather than immediately administer a new additional medication, the prior art taught that prescribers should first optimize the dose of the existing medication and monitor the patient after that adjustment before considering additional medication, in order to avoid

drug/drug toxic interactions, additional side effects, or an increase to non-adherence to pharmacological treatment. *See* EX1005 (Hirschfeld), 3, 14.

19. The prior art also taught that several patients treated with either 4 mg or 8 mg of endoxifen for bipolar I disorder in Ahmad 2016 did not require a rescue medication for at least 21 days after treatment began. EX1004 (Ahmad 2016), 3.
20. The prior art additionally disclosed methods for treating each of the bipolar I disorder patient sub-populations identified in claims 2-5 and 7-10—*i.e.*, patients having manic episodes with mixed features; manic episodes without mixed features; or depression or depressive episodes. For example, the phase II trial described in Ahmad 2016 involved treatment of patients having both manic and mixed episodes. EX1004 (Ahmad 2016), 1, 3. Ahmad 2016 explains that patients in the study “were diagnosed of BPD I and [as] having displayed an acute manic or mixed episode (with or without psychotic features) according to DSM-IV-TR as judged by the investigator.” EX1004 (Ahmad 2016), 2. When patients experience symptoms of depression while also experiencing mania, the patients are experiencing episodes with “mixed features.” Patients with mania can also present without mixed features (depressive symptoms) and vice versa. Ahmad 2016 measured improvements in the patients’ Young Mania Rating Scale—an indicator of patients having manic episodes—and the Montgomery-Asberg Depression Rating Scale (MADRS), which measures severity of depressive

symptoms, which can be present in episodes of mania or depression. EX1004 (Ahmad 2016), 1-5.

21. The prior art also taught that prescribers should closely monitor patients' clinical symptoms, and that prescribers should monitor their blood concentrations, when the technology is available, to determine if those blood levels correlate with dose and with response to treatment or emergence of side effects. EX1005 (Hirschfeld), 8-9, 12, 20-21, 24. For example, in the clinical study described in Ahmad 2016, patients' clinical symptoms and blood concentrations were monitored periodically throughout the 21-day treatment period. EX1004 (Ahmad 2016), 1, 3, 4.

A. Ahmad 2016

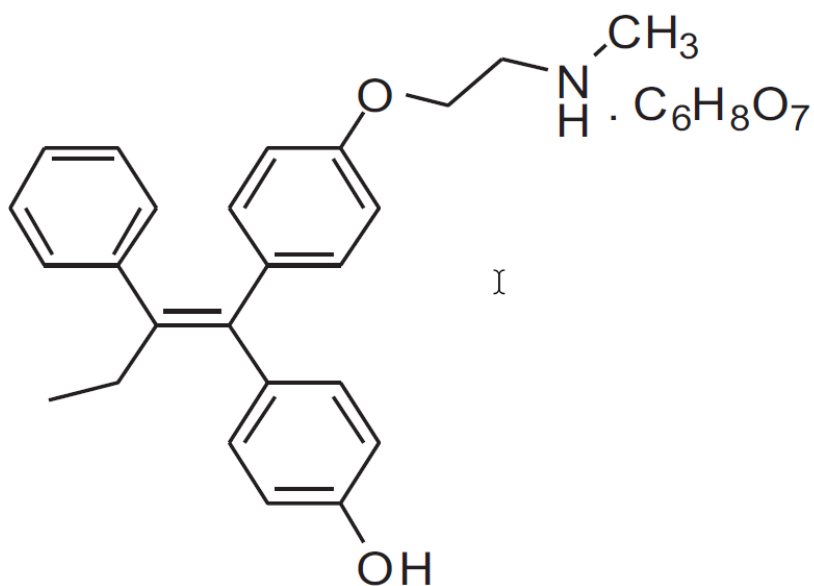
22. I understand that Ahmad 2016, published June 27, 2016, is prior art under at least 35 U.S.C. § 102(a)(1). EX1004 (Ahmad 2016), 1.

23. I have been aware of Ahmad 2016 since soon after its publication, because endoxifen is an active metabolite of tamoxifen, a prior-art bipolar disorder treatment. Further, Ahmad 2016 cites 3 publications where I am the lead author.

24. I have been aware of Clinical and Translational Science, the journal Ahmad 2016 was published in, since the 2010s, as a result of my involvement in conducting and designing clinical trials in bipolar disorder. The journal is an open access journal of the American Society for Clinical Pharmacology and Therapeutics. It

publishes original research including laboratory research and treatment of medical conditions including psychiatric. Its impact of 2.8 would be considered good.¹ In my opinion Clinical and Translational Science is a well-known and regularly published journal that clinical researchers in my field were aware of before 2020.

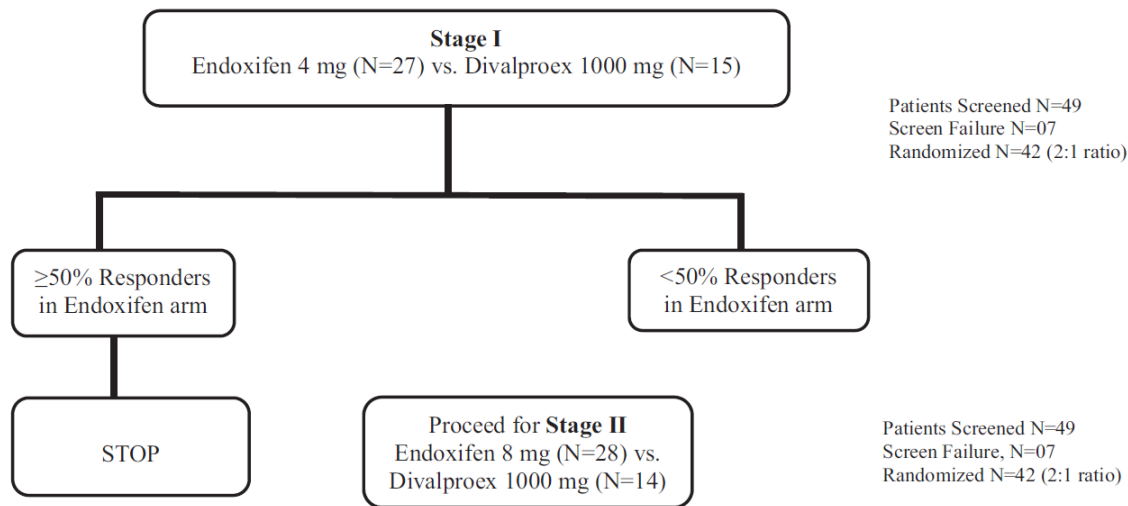
25. Ahmad 2016 describes a phase II clinical trial that studied the effects of fixed doses of endoxifen. EX1004 (Ahmad 2016), 1. Ahmad 2016 discloses the following chemical structure for endoxifen citrate:



¹ Impact factor is the average number of cited publications over the last 2 years. In Medicine, a number higher than 3 is considered good, higher than 10 is considered very good.

EX1004 (Ahmad 2016), Figure 1.

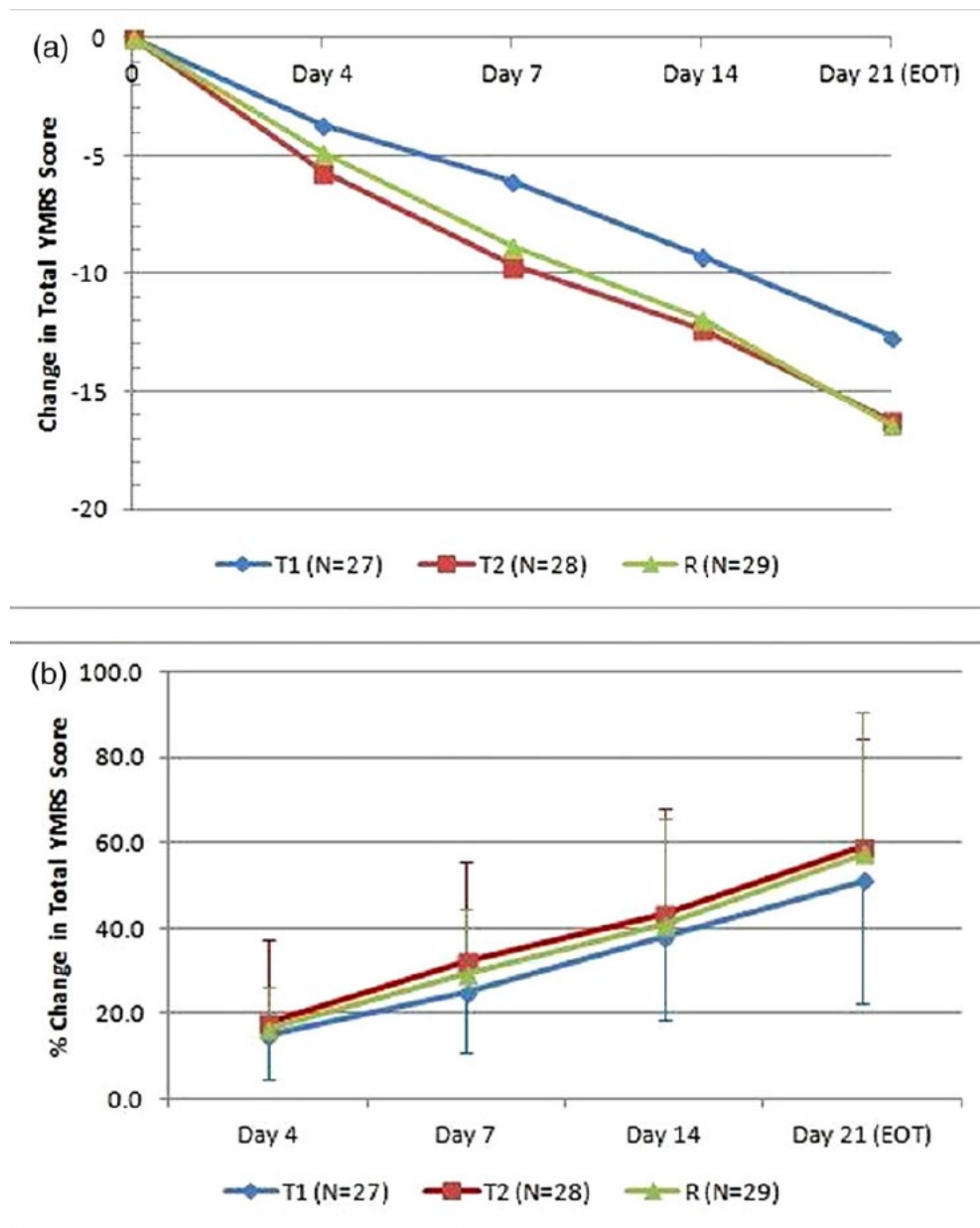
26. Patients in Ahmad 2016 received either 4 mg or 8 mg of endoxifen citrate in enteric-coated tablets or 1000 mg of divalproex for a 3-week period. EX1004 (Ahmad 2016), 1, 3.



EX1004 (Ahmad 2016), 3.

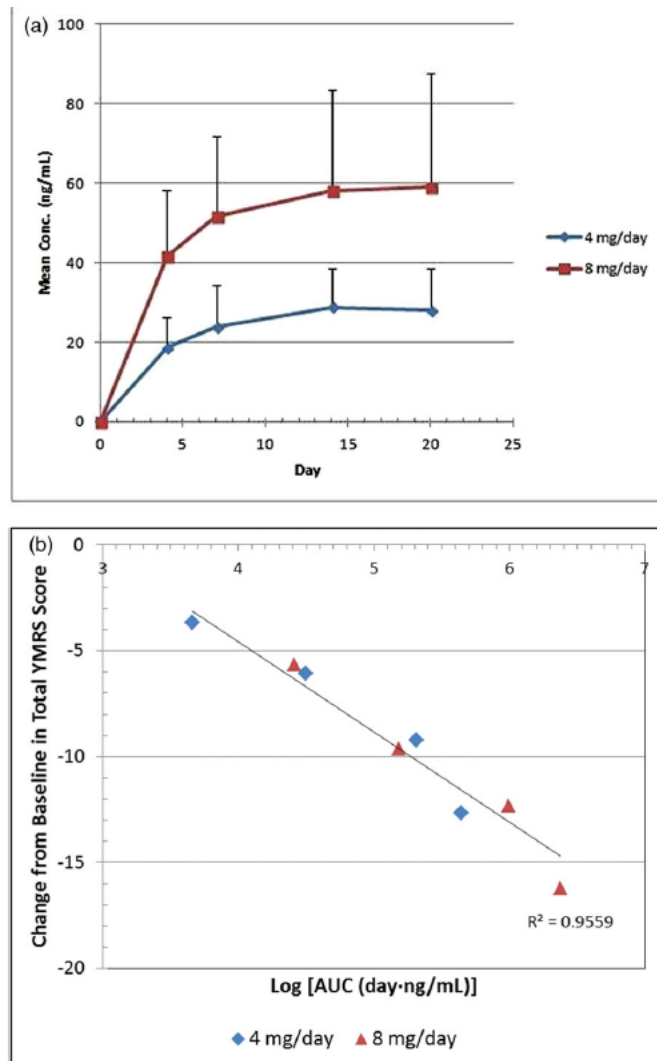
27. Patients in Ahmad 2016 discontinued all psychotropic medications at least 2 days prior to randomization, except for benzodiazepines, which were discontinued no later than 10 days into treatment with endoxifen or divalproex. EX1004 (Ahmad 2016), 3. Patients also did not receive benzodiazepines within 12 hours of scheduled mania ratings to avoid “efficacy or safety overlap.” EX1004 (Ahmad 2016), 3. Other studies assessing antimanic agents have had a similar approach to the allowance of the use of benzodiazepines. *See, e.g.*, EX1006 (Ahmad 2020), 3.

28. The primary end point in Ahmad 2016 was the proportion of responders in each arm on Day 21 based on change in the Young Mania Rating Scale (YMRS) total score. EX1004 (Ahmad 2016), 3. Secondary end points included mean change from baseline to the end of treatment in the Montgomery–Asberg Depression Rating Scale (MADRS) total score. EX1004 (Ahmad 2016), 3.



EX1004 (Ahmad 2016), Figs. 3(a),(b).

29. Ahmad 2016 also describes monitoring endoxifen plasma level concentrations at days 4, 8, 14 and 20 for both the 4 mg and 8 mg doses. Ahmad 2016 reports that the response in the 8 mg group was better than in the 4 mg group. EX1004 (Ahmad 2016), Fig.4(a). Ahmad 2016 notes a difference in the plasma concentration of patients receiving 4 mg per day versus 8 mg per day, disclosing “that the doubling of dose from 4 mg to 8 mg once daily result[ed] in ~2-fold increase in plasma AUC.” EX1004 (Ahmad 2016), 5-6.



EX1004 (Ahmad 2016), Figs. 4(a),(b).

30. Ahmad 2016 discloses that the most common side effects in the trial were psychiatric in nature, and that 15 patients in the endoxifen treatment groups (out of a total of 55), and 12 patients in the divalproex treatment group (out of a total of 28) experienced an adverse event. Psychiatric side effects are frequently related to lack of efficacy response, and in Ahmad 2016 more psychiatric side effects were reported in the 4 mg group, where patients had lesser improvements

in efficacy endpoints compared to patients in the 8 mg group. Ahmad 2016 thus discloses that at least 40 patients in the endoxifen treatment groups did not experience a psychiatric adverse event, such as breakthrough or recurring symptoms of bipolar disorder, and therefore these 40 patients did not require any additional medication, such as a rescue medication, during the study.

Table 2 Incidence of treatment related adverse events in BPD I patients

Adverse event	Endoxifen, 4 mg (N = 27)		Endoxifen, 8 mg (N = 28)		Divalproex, 1 gm (N = 28)	
	N	%	N	%	N	%
Patients with at least one AE	8	29.63	7	25	12	41.38
Nausea	1	3.7	1	3.57	5	17.24
Headache	2	7.4	3	10.71	3	10.34
Insomnia	1	3.7	2	7.14	5	17.24

EX1004 (Ahmad 2016), Table 2.

B. Ahmad 2020

31.Ahmad 2020 (“Endoxifen: A new, protein kinase C inhibitor to treat acute and mixed mania associated with bipolar I disorder”), published December 25, 2020, describes a Phase III clinical study testing 8 mg endoxifen. EX1006 (Ahmad 2020). I have been asked to assume that Ahmad 2020 is not prior art because it was published after the priority date. However, I understand that I may use it to, for example, determine if the claims were enabled as of the priority date. It is clear Ahmad 2020 describes the *same* clinical study summarized in the ’997 patent’s specification. **First**, both share overlapping inventors/authors, and a sponsor: the ’997 patent lists Ateeq Ahmad, Imran Ahmad and Saifuddin Sheikh among the named inventors, with Jina Pharmaceuticals Inc. as the original

assignee. Ahmad 2020 similarly lists Ateeq Ahmad, Imran Ahmad, and Saifuddin Sheikh as co-authors, and states they are affiliated with Jina Pharmaceuticals Inc. **Second**, the trial design, dose, and active control described in the patent are identical to those in Ahmad 2020. Ahmad 2020 describes “a Phase III prospective, multicenter, randomized controlled trial (1:1), double-blind, double-dummy,” comparing “a daily dose of 8 mg endoxifen” with “1000 mg divalproex” (extended-release), in patients with “Bipolar I Disorder (BPD I).” EX1006 (Ahmad 2020), 1-3. The ’997 patent likewise describes “a multicenter, randomized, double-blind, double-dummy, active controlled, parallel study to assess the efficacy and safety of endoxifen enteric coated tablet 8 mg and divalproex sodium extended release tablet 1000 mg in patients of bipolar I disorders.” EX1001, 4:50-54. **Third**, the patient population and conduct of the study are also identical. Ahmad 2020 reports “[a] total of **228** adult patients (18-65 years) diagnosed with BPD I experiencing current manic episodes with/without mixed features” randomized in an inpatient setting. EX1006 (Ahmad 2020), 3. The ’997 patent states a “[t]otal **228** patients were enrolled in the study. All 228 patients were qualified for safety trial.” EX1001, 4:55-56. The clinical study was conducted “in patients of bipolar I disorders,” in the same 8 mg vs 1000 mg design. *Id.*, 4:50-54. **Fourth**, the study durations are the same. Ahmad 2020 identifies the primary endpoint as the mean change in Young Mania

Rating Scale (YMRS) total score at **day 21**. EX1006 (Ahmad 2020), 3. The '997 patent also states that the study treatment was “at least **21** days” and “[a]t the EOT, none of the patient required rescue medications, no rescue medications were administered to any of the patients, and none of the patient discontinue from the study.” EX1001, 4:57-59.

32. But contrary to the alleged summary of the study in the '997 patent's specification, Ahmad 2020 discloses that the same reported study allowed and actually used what the '997 patent defines as rescue medication. For example, Ahmad 2020 discloses that lorazepam and diazepam (both benzodiazepines) were “allowed” to control events like agitation or akathisia, and such benzodiazepines were “allowed but avoided within 12 hours of scheduled mania ratings.” EX1006 (Ahmad 2020), 3. Ahmad 2020 further reports that lorazepam and diazepam were not only “allowed” but were, in fact, used: “Lorazepam was given to 10 out of 116 patients in the endoxifen arm and 13 out of 112 patients in the divalproex arm.” EX1006 (Ahmad 2020), 5. Ahmad 2020's Table 3 also confirms that lorazepam and diazepam were administered to patients in both arms. EX1006 (Ahmad 2020), Table 3. While Ahmad 2020 itself did not refer to them as “rescue medications,” lorazepam and diazepam are benzodiazepines, which are included in the '997 patent's definition of “rescue medications.” EX1001, 3:44-46 (“For present disclosure, the rescue medications are selected

from the group of lithium, valproate, lamotrigine, *benzodiazepines*, anticholinergics and like thereof.”).

C. Hirschfeld 2002 (APA Bipolar Treatment Guideline)

33.I understand that Hirschfeld 2002 (“Practice Guideline for the Treatment of Patients With Bipolar Disorder (Revision)”), published April 2002, is prior art under at least 35 U.S.C. § 102(a)(1). EX1005, 1. Those in my field, including POSITA, would have been aware of Hirschfeld 2002 as of its publication and would have been aware of and looking for papers from the American Journal of Psychiatry. In addition, I have been aware of Hirschfeld 2002 since soon after its publication, due to my work on bipolar disorder clinical trials, and because it cites papers where I am an author. Hirschfeld 2002 is a practice guideline for the treatment of patients with bipolar issued by the American Psychiatric Association’s (“APA”) Working Group on Bipolar Disorder. The APA practice guidelines provide teachings regarding the state of the art for the treatment of bipolar, including standards of treatment for patients with bipolar disorder that POSITA would have been aware of as of the April 10, 2020 priority date of the ’997 patent. For example, Hirschfeld 2002 provides teachings regarding the use of additional medication for breakthrough or recurring symptoms as part of methods of treatment for bipolar I disorder, or what the ’997 patent defines as “rescue medication.” Hirschfeld 2002 explains that for many patients,

monotherapy (*i.e.*, therapy with a single drug, such as lithium, valproate, or an antipsychotic such as olanzapine) may be sufficient. EX1005 (Hirschfeld), 1. Hirschfeld 2002 further explains that if patients experience a manic or mixed episode (*i.e.*, a “breakthrough” or recurrence in symptoms), the first-line intervention should be to optimize the dose of the existing medication, and not to immediately administer an additional medication. EX1005 (Hirschfeld), 8. Hirschfeld further teaches that optimization of dosage entails ensuring that the blood level of the treatment medication is in the therapeutic range and, in some cases, achieving a higher serum level (although one still within the therapeutic range) by adjusting the dose. EX1005 (Hirschfeld), 8.

34. Hirschfeld also states that caution should be exercised when combining medications, especially in certain populations such as the elderly, immunocompromised, or pregnant individuals, who may be at increased risk of adverse side effects. EX1005 (Hirschfeld), 12-14. Hirschfeld further states that undesirable side effects associated with the administration of rescue medication in, *e.g.*, the elderly, include cognitive impairment, slowed or excessive unwanted movement, tardive dyskinesia, orthostatic hypotension, and greater risks of falls and hip fractures, which can be life-threatening. EX1005 (Hirschfeld), 14. Hirschfeld makes clear that each additional medication increases the side effect burden and the likelihood of drug-drug interactions or other toxicity, and thus

any potential addition should be approached with caution. EX1005 (Hirschfeld), 4, 14.

35. Hirschfeld also describes the standard of care for monitoring the doses administered to patients. Hirschfeld explains that when optimizing a first-line treatment to address patient's breakthrough or recurring symptoms the prescriber should monitor the patient to ensure that the serum drug level is in the therapeutic range and, in some cases, monitor to ensure the patient achieves a higher serum level. EX1005 (Hirschfeld), 8-9. Hirschfeld further explains that certain patient populations should be monitored periodically, for example, patients taking certain medications with potentially dangerous side effects, such as lithium, and patients who are elderly or pregnant. EX1005 (Hirschfeld), 8-9, 12, 20.

VI. THE '997 PATENT

36. I assume an April 10, 2020 priority date for the purposes of my opinions herein and reserve the right to supplement my opinions should Jina assert an earlier priority date.

A. Overview of the '997 Patent

37. The '997 patent is titled "Endoxifen for the Treatment of Bipolar I Disorder."

EX1001. Claim 1 recites:

A method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder, said method comprising:
administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for up to 21 days,
wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.

38. The '997 patent does not fully describe the invention that the patent claims. For example, while the patent defines “therapeutically effective concentration” as “a concentration of endoxifen in plasma which is sufficient to decrease or prevent or cure the symptoms [of bipolar disorder],” the patent merely repeats the phrase “maintaining a therapeutically effective concentration” without further insight into, *e.g.*, what that level would be, how it could be achieved, how long it would take to achieve that concentration (and using what dose), and even whether the concentration is dose dependent. Rather, the patent concedes that “[t]he exact mechanism by which endoxifen exerts its therapeutic effects ***have not been established*** in bipolar disorder” and hypothesizes that “the efficacy of endoxifen ***could*** be mediated through PKC [protein kinase C].” EX1001, 2:29-32.

39. Additionally, the '997 patent's specification recites a broad range of doses that one might try but only provides one example of administering any dose within

that range (8 mg). EX1001, 4:50-54. Though the '997 patent describes that a “[c]linical study... was carried out by administering to the patient doses of 2 mg to 16 mg,” the next paragraph only discloses that an 8 mg dose was administered in the study. This description of the single clinical trial administering 8 mg does not describe the full range of a “therapeutically effective concentration” of endoxifen citrate and there is no example in the specification of a study that actually utilized any other dose in the claimed 2 mg to 16 mg range of endoxifen citrate doses. EX1001, 4:44-54.

40. The '997 patent also describes that an object of the disclosure is to “provide a method... wherein the patient *does not require* rescue medication.” EX1001, 4:21-28. During prosecution, to overcome the prior art, the claims were amended, instead, to require “wherein the method does not include a rescue medication for the treatment of bipolar I disorder.” EX1001, cl.1. The '997 patent defines “rescue medications” as including benzodiazepines. EX1001, 3:42-46.

41. The '997 patent's claim 6 recites the same limitations as claim 1, but additionally requires “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient.” EX1001, cl.6. The '997 patent's specification never refers to “monitoring the dose” or any other monitoring or measurement of plasma concentrations including its frequency.

Rather, the '997 specification provides that “[t]argeting the PKC signalling pathway for bipolar disorder can improve the patient compliance, when the therapeutic dose monitoring is not required in patient...” EX1001, 1:60-62.

42.I have considered the Challenged Claims (claims 1-10) of the '997 patent, which read as follows:

Claim 1

[1.pre] A method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder, said method comprising:

[1.a] administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for up to 21 days,

[1.b] wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.

Claim 2

[2] The method of claim 1, wherein the patient has manic episodes with mixed features.

Claim 3

[3] The method of claim 1, wherein the patient has manic episodes without mixed features.

Claim 4

[4] The method of claim 1, wherein the patient has depression.

Claim 5

[5] The method of claim 1, wherein the patient has depressive episodes.

Claim 6

[6.pre] A method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder, said method comprising:

[6.a] administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for up to 21 days; and

[6.b] monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient;

[6.c] wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.

Claim 7

[7] The method of claim 6, wherein the patient has manic episodes with mixed features.

Claim 8

[8] The method of claim 6, wherein the patient has manic episodes without mixed features.

Claim 9

[9] The method of claim 6, wherein the patient has depression.

Claim 10

[10] The method of claim 6, wherein the patient has depressive episodes.

B. Overview of the '997 Patent Prosecution History

43. The application leading to the '997 patent was filed on April 9, 2021 and claims priority to an April 10, 2020 provisional application. EX1002, 1. The Examiner issued multiple office actions, including 102 and 103 rejections of the then-pending claims 1-4 as anticipated by "Endoxifen, a New Treatment Option for

Mania: A Double-Blind, Active-Controlled Trial Demonstrates the Antimanic Efficacy of Endoxifen” by Ahmad et al. (primary reference “Ahmad 2016” (EX1004), published in 2016). EX1002, 167-69; 216-20; 268-73; 317-21; 387-91.

44. Initially claim 1 required that “the patient is not administered rescue medication during the said treatment” with endoxifen. EX1002, 14. The Examiner rejected this and other claims, among other rejections, for anticipation by Ahmad 2016, finding that Ahmad 2016 taught that “concomitant medications...have been discontinued before treatment and thus meet the instant claim limitation.” EX1002, 167-174. In response, Patent Owner changed (amended) pending claim 1 to include “wherein no rescue medication is administered to the patient during the said treatment of the bipolar I disorder by maintaining the therapeutically effective concentration of endoxifen in the patient.” EX1002, 200. Patent Owner argued that “[a]s per the claimed invention, the inventors found that there is no need to administer other medications (i.e., lorazepam) during a period of the treatment of the bipolar I disorder by maintaining the therapeutically effective concentration of endoxifen in the patient.” EX1002, 202. Patent Owner distinguished Ahmad 2016 by arguing that Ahmad 2016 “allows to administer benzodiazepines to the patient to whom endoxifen is administered, up to 10 days from starting administering of endoxifen.” EX1002, 200-02.

45. The Examiner then rejected the claims again as anticipated and/or obvious over Ahmad 2016. EX1002, 216-220. The Examiner observed Ahmad 2016 “teaches concomitant medications such as lorazepam have been discontinued before treatment and thus meet the instant claim limitation” and that benzodiazepines may be used “only as needed,” making it “obvious... to administer only endoxifen without any other medications.” EX1002, 218-19.
46. In response, Patent Owner again changed claim 1 from “no rescue medication is administered” to “no rescue medication is required to be administered” and added “wherein the rescue medicine is at least one medicine selected from a group consisting of lithium, valproate, lamotrigine, benzodiazepines, and anticholinergics.” EX1002, 239. Patent Owner argued that Ahmad 2016 disclosed that “benzodiazepines (i.e., lorazepam/diazepam) were allowed to be administered as concomitant medicines.” EX1002, 241. Patent Owner identified Ahmad 2016’s disclosure “that the investigator is allowed to administer concomitant medicines (as rescue medicines) if the patient showed undue excitement.” EX1002, 241. Patent Owner argued that “[t]his implies that the investigator had to monitor the patients continuously to investigate whether the rescue medication would be required for each and every patient undergoing the treatment according to Ahmad’s study.” EX1002, 241.

47. Patent Owner again changed claim 1 to state “wherein no rescue medication is required for the treatment of the bipolar I disorder” and deleted the prior list of specific drugs. EX1002, 304. Patent Owner argued Ahmad 2016 “**allowed... concomitant medicines if the patient showed undue excitement**” and contrasted that with a claimed method in which “no rescue medication is required to the patient during the treatment of the bipolar I disorder....” EX1002, 305, 306 (emphasis original).

48. The Examiner rejected the pending claims again. EX1002, 317-321. The Examiner explained that the “no rescue medication is required” language “imply[d] that the presence of a rescue medication is not positively eliminated from the instant treatment.” EX1002, 320. “Rather, the term ‘not required’ imply[d] that the rescue medication is optional, left to one’s choice or discretion, and not mandatory.” EX1002, 320. The Examiner stated that Ahmad 2016 “suggests one can include benzodiazepines only as needed and therefore it is not necessary to administer benzodiazepines during the administration of endoxifen.” EX1002, 320.

49. Patent Owner again changed claim 1 to require “wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.” EX1002, 350. Patent Owner cited “the last paragraph on page 4 of the specification as filed,” which defined “rescue medication” as “an additional medication necessary

to treat breakthrough or recurring symptoms” and includes a list of drugs. EX1002, 11, 351. Patent Owner argued that the claim as amended now required that the “method involves the complete removal of a rescue medication.” EX1002, 351. Patent Owner contrasted this from Ahmad 2016, which “include[s] benzodiazepines... **whenever necessary.**” EX1002, 351 (emphasis original); *see also* EX1002, 362 (Examiner stating “that the proposed amendment positively excludes a rescue medication from the claimed method”).

50. The Examiner again rejected the pending claims and viewed Ahmad 2016 as teaching a design that “does not require... additional rescue medication,” and pointed to Ahmad 2016’s use of benzodiazepines only as “as needed.” EX1002, 387-90. After PO amended the claims, as described below, the Examiner subsequently accepted Patent Owner’s interpretation of the amended language. EX1002, 397. The Examiner stated, regarding an interview, that “Applicants argue that [the] instant claims now exclude the administration of rescue medication during the treatment of bipolar I disorder, because the claims recite ‘that the method does not include a rescue medication.’” EX1002, 397, 434.

51. Patent Owner amended the pending claims again, adding new independent claim 6 and dependent claims 7-10. EX1002, 418-19. Claim 6 introduced a new requirement (limitation) of “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient.”

Patent Owner cited no support for this amendment in the specification and asserted that “[n]o new matter ha[d] been added.” EX1002, 420.

52. The Examiner issued a Notice of Allowance for the pending claims 1-10. EX1002, 434. The Examiner stated that the prior art did not disclose “wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.” EX1002, 434. The Examiner characterized Ahmad 2016’s method as “requir[ing]... benzodiazepines as adjunct medication, thus teaching away from the limitation.” EX1002, 434. The Examiner’s Notice of Allowance, however, did not rely on the new monitoring limitation to support allowance of the pending claims. Rather, the Examiner’s rationale for allowing the pending claims focused on the “method does not include a rescue medication” language and the alleged distinction from Ahmad 2016’s design. EX1002, 434.

C. Claim Construction of the ’997 Patent Claims

53. I understand that patent claims terms are generally given their plain and ordinary meaning in light of the specification. I also have been advised that the plain and ordinary meaning may not apply where a patentee acts as his own lexicographer, meaning that the patentee sets out his own definition for the term or where the patentee disavows the full scope of the claim term either in the specification or during prosecution.

54.I have been asked to assume that, in the context of the '997 patent, the preamble

“[a] method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder” is limiting. I have applied this understanding in my analysis below.

55.I have also been asked to assume that “the method does not include a rescue medication for the treatment of the bipolar I disorder” as used in each of the Challenged Claims means the claims “positively exclude[] a rescue medication from the claimed method” such that the claims prospectively prohibit the use of any rescue medication for the treatment of bipolar I disorder at any time during the claimed endoxifen course (2-16mg once daily for up to 21 days). I have applied this understanding in my analysis below except as indicated with respect to my analysis of Ground 4 (Anticipation by Ahmad 2016).

56.I have also been asked to assume that “therapeutically effective concentration” is “a concentration of endoxifen in plasma which is sufficient to decrease or prevent or cure the symptoms associated with a medical condition or infirmity or to normalize body functions in disease or disorders that result in impairment of specific body functions.” I have applied this understanding in my analysis below.

57.I have also been asked to assume that “EOT” is “end of treatment.” I have applied this understanding in my analysis below.

58.I have also been asked to assume that “rescue medication” is “an additional medication necessary to treat breakthrough or recurring symptoms” and that rescue medications “are selected from the group of lithium, valproate, lamotrigine, benzodiazepines, anticholinergics and like thereof.”

59.I have also been asked to assume that “enteric coating” is “any pharmaceutically acceptable coating preventing the release of the active agent in the stomach and sufficiently disintegrating in the intestine tract (by contact with approximately neutral or alkaline intestine juices) to allow the resorption of the active agent through the walls of the intestinal tract. The enteric coating remains intact in the acidic environment of the stomach and then solubilize in the more alkaline environment of the small intestine.”

60.For all other terms, I have been asked to assume that they have their plain and ordinary meaning as they would have been understood by POSITA in light of the specification, and for each term I have applied that meaning in my analysis.

VII. THE CHALLENGED CLAIMS ARE INVALID

A. Legal standards

61.I understand that a patent claim is invalid under 35 U.S.C. § 112(a) if the patent does not contain an adequate written description of the claimed invention. I have been informed that the purpose of this written description requirement is to make sure that the scope of the exclusive patent rights, as set forth in the claims, does

not extend beyond the scope of the inventors' contribution to the art as described in the patent specification. I understand that compliance with the written description requirement involves both an assessment of the scope of the claims and the adequacy of the patent's disclosure to support claims of such scope.

62. I understand that for the specification of a patent to meet the written description requirement, the as-filed specification must describe the invention in sufficient detail such that a person of ordinary skill in the art could have concluded as of the filing date of the patent that the inventor possessed the claimed subject matter. I understand that the specification must convey with reasonable clarity to a person of ordinary skill in the art that the inventor had possession of the claimed subject matter at the earliest filing date of the patent application. I further understand that the disclosure in the specification is analyzed by looking objectively at the four corners of the specification i.e., what appears in the specification. I understand that disclosure that satisfies the written description requires more than simply repeating the language of the claims in the specification.

63. I understand that each claim limitation must be disclosed, and the written description analysis requires taking each claim as an integrated whole rather than a collection of independent limitations. I understand that the disclosure must describe the claimed invention with all its limitations. I further understand that it is not sufficient for purposes of the written description requirement that the

disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.

64. I understand that a claim limitation may be considered to contain a negative limitation when the claim provides an instruction to not take an action. I understand that the specification must describe a reason to exclude a relevant element to provide written description support for that the negative limitation.

65. I understand that for inventions in technological fields that are highly unpredictable more description may be required to show possession of the claimed invention.

66. I understand that written description is assessed as of the earliest filing date of the patent, which here is April 10, 2020. Evidence regarding the knowledge of a person of ordinary skill in the art after the earliest claimed filing date cannot be used to support an argument of adequate written description. I further understand that when the scope of a claim has been changed by amendment, the specification at the time of filing must describe and support the newly claimed subject matter to satisfy the written description requirement.

67. I understand that a patent claim is invalid under 35 U.S.C. § 112(a) if the full scope of the claim is not enabled as of the earliest filing date of the patent (i.e., April 10, 2020). I understand that a claim is not enabled if a person of ordinary

skill in the art would not have been able to make and use the full scope of the claimed invention without undue experimentation. I further understand that the specification must enable the full scope of the invention as defined by the language of the claims. I further understand that evidence dated after the earliest filing date of the patent may be used to determine if the claims were enabled as of that earliest filing date.

68. I understand that, for purposes of enablement, one way to determine whether the amount of experimentation is “undue” is to apply the so-called *Wands* factors, which include, but are not limited to: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. I understand that applying the *Wands* factors is one, but not the only, way to consider whether claims are enabled.

69. In assessing whether a person of ordinary skill in the art could practice the full scope of the claimed invention without undue experimentation, I have been instructed to account for the knowledge of a person of ordinary skill in the art at the time of the invention. I understand that the specification may call for a reasonable amount of experimentation to make and use a patented invention, but

that a person of ordinary skill in the art has to be able to recreate the invention with reasonable certainty. What is reasonable will depend on the nature of the invention and the underlying art. If the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention to be enabling.

70. I understand that a claim may be invalid under 35 U.S.C. § 112(b) as indefinite if the claim, when interpreted in view of the specification and the prosecution history, does not inform those skilled in the art about the scope of the invention with reasonable certainty. I understand that a patent claim must particularly point out and distinctly claim the subject matter of the invention. I understand that in instances where the claim language might mean several different things and no informed and confident choice is available, then the claim may be considered indefinite.

71. I understand that a claim may be invalid as anticipated under 35 U.S.C. § 102(a) if every limitation recited in a claim is found in an item of prior art, either expressly or inherently, and arranged in the item of prior art in the same way as it is claimed, so that the disclosure effectively puts the public in possession of the invention. I further understand where a prior art reference discloses multiple embodiments, each disclosed embodiment can be the basis for an invalidating disclosure.

72.I have been advised that an anticipatory reference is determined from the perspective of POSITA. Therefore, a reference discloses a claimed invention if POSITA could take its teachings in combination with their knowledge of the particular art and be in possession of the invention.

73.I understand that for post grant review, invalidity (also called unpatentability) must be shown under a preponderance of the evidence standard, which I understand means it must be proven to be more likely true than not true.

74.As set forth below, I have concluded that each of the Challenged Claims is invalid (and unpatentable) for lack of written description, enablement and indefiniteness and that claims 1-4 are anticipated by Ahmad.

B. Ground 1: Lack of Written Description

1. No Written Description of the Limitation “Wherein The Method Does Not Include a Rescue Medication” (Claims 1–10)

75. I have analyzed the limitation in independent claims 1 and 6 requiring “wherein the method does not include a rescue medication for the treatment of bipolar I disorder.” As discussed above, I understand that this limitation means the method positively excludes (i.e., prospectively prohibits) the use of any rescue medication for the treatment of bipolar I disorder at any time during the claimed endoxifen course (2-16 mg once daily for up to 21 days). I also understand from the prosecution history that in order to obtain allowance over Ahmad 2016, the

Patent Owner argued this limitation positively excludes (prospectively prohibits) the use of rescue medication throughout the course of the method.

76. The specification of the '997 patent, along with the originally filed claims, does not describe a method that positively excludes the use of any rescue medication for the treatment of bipolar I disorder at any time during the claimed endoxifen course. Instead, the specification repeatedly states that “the patient is *not required* to be administered rescue medication” and that “the patient *does not require* rescue medication.” EX1001, 1:11-12, 3:5-11, 3:17-19, 4:21-28, 4:35-36. POSITA would read those statements in the context of bipolar care as conveying that rescue medication may be unnecessary in some instances based on the patient’s status, not that rescue medication is positively excluded from the treatment method. For example, some patients may achieve sufficient symptom control on endoxifen alone such that they do not need additional rescue medication. This is consistent with the Examiner’s view during prosecution that “not required” means optional and does not prohibit administration. EX1002, 317. These statements in the specification do not describe, or even suggest, a study or treatment design in which the prescriber is prohibited from administering rescue medication if clinically indicated. Rather, they are consistent with the routine and desirable goal in bipolar treatment of minimizing the need for additional medications, without prohibiting the option to use such medications

when necessary to protect patient safety or relieve severe symptoms. EX1005 (Hirschfeld), 4, 8, 12-14.

77. As support for the amendment in which the Patent Owner added the “the method does not include a rescue medication” language, Patent Owner pointed only to “the last paragraph on page 4 of the specification as filed.” EX1002, 343 (corresponding to EX1001, 3:42-46). That cited paragraph is the patent’s definition of “rescue medication” and lists example drugs that fall within that definition. EX1002, 11 (“The term ‘rescue medication’ refers to an additional medication necessary to treat breakthrough or recurring symptoms. For present disclosure, the rescue medications are selected from the group of lithium, valproate, lamotrigine, benzodiazepines, anticholinergics and like thereof.”). In my opinion, that paragraph does not provide written description support for a method that positively excludes (prospectively prohibits) rescue medications. The patent’s definition of “rescue medication” does not itself convey to POSITA a method that prohibits the use of any of drugs the patent defines with that term. For example, there is no discussion in the specification of a clinical rationale for excluding rescue medications, no articulation of disadvantages of rescue medications in this endoxifen citrate context, and no safety management plan describing how investigators would handle breakthrough symptoms if rescue medications were positively excluded.

78. The only passage in the specification that mentions the actual conduct of a study states retrospectively that “[a]t the EOT, none of the patient required rescue medications, no rescue medications were administered to any of the patients, and none of the patients discontinue from the study.” EX1001, 4:57-59.
79. In my opinion, POSITA would not have understood this statement to describe positively excluding (prospectively prohibiting) rescue medication. As noted above, the specification does not identify any inclusion or exclusion criterion in the protocol that would have prevented investigators from administering rescue medications if clinically indicated. Rather, POSITA would have understood this statement as an observed outcome of what allegedly happened in that particular study. It is not a description that the study design positively excluded rescue medications. And the ’997 patent does not address whether “rescue medications” in the reported trial were defined in the same way as they are in the ’997 patent itself.
80. Therefore, in my opinion, the ’997 patent fails to provide adequate written description for the limitation “wherein the method does not include a rescue medication for the treatment of bipolar I disorder.”

2. No Written Description of “Maintaining a Therapeutically Effective Concentration...With a Dose in a Range from 2 mg to 16 mg” (Claims 1–10)

81.I have analyzed the preambles and limitations of independent claims 1 and 6 that recite “maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder” by “administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate.” As discussed above, I have been asked to assume the preamble is limiting. I further understand the ’997 patent defines a “therapeutically effective concentration” as “a concentration of endoxifen in plasma which is sufficient to decrease or prevent or cure the symptoms associated with a medical condition or infirmity or to normalize body functions in disease or disorders that result in impairment of specific body functions.” EX1001, 3:36-41.

82.In my opinion, the ’997 patent specification fails to describe the full scope of the claimed requirement that the method “maintain[s] a therapeutically effective concentration of endoxifen in the patient” using “a dose in a range from 2 mg to 16 mg” for patients with bipolar I disorder. The specification does not provide any actual plasma concentrations that were achieved, nor does it identify any threshold level that POSITA could use as a benchmark for the claimed therapeutic effect. The only clinical example in the ’997 patent specification describes an 8 mg endoxifen dose (see discussion above), and even in that

example the patent does not provide any data, examples, figures, pharmacokinetic parameters, or discussion showing what endoxifen plasma concentrations are achieved at the claimed dosage ranges, what concentration thresholds would be “therapeutically effective,” how long it would take to reach those thresholds, or how those concentrations relate to treatment of the claimed patient populations.

83. In my opinion, POSITA would not read the recitation of a broad untested dose range to mean the inventors possessed the full breadth of the claimed method that successfully maintain therapeutic concentrations across the eight-fold range of doses. In the field of bipolar treatment, dose-response relationships vary across patients and conditions, and achieving and maintaining a therapeutically effective concentration is not predictable from a bare list of doses without accompanying pharmacokinetic data, plasma concentration levels, or dose-response studies. EX1005 (Hirschfeld), 25 (“[T]he relationships among dose, serum concentration, response, and side effects are variable. Therefore, the dose should be titrated upward according to response and side effects.”), 22 (“The “optimal” maintenance level may therefore vary somewhat from patient to patient.”). For example, the specification does not disclose whether doses as low as 2 mg would be sufficient to create a “therapeutically effective concentration of endoxifen” to begin with, let alone maintain it, or whether doses as high as 16 mg would be

tolerable or have adherence issues such that patients would continue to take such doses (such that a concentration would be “maintain[ed]”). Nor would POSITA assume that because an 8 mg dose purportedly showed efficacy in a single trial, a dose as low as 2 mg would achieve a therapeutically effective concentration, or that a dose as high as 16 mg would be tolerable or safe. Here, it is my opinion that POSITA would not have understood the named inventors to be in possession of the claimed invention based on the specification. Instead, POSITA would have needed to conduct their own scientific research to confirm that the full range of claimed doses would be suitable to maintain a therapeutically effective concentration of endoxifen for treatment of patients with bipolar I disorders, and to confirm that the untested doses in that range would not have the “significant issues with tolerability, efficacy, and attempt[ed] suicide or [] suicidal behavior” that the ’997 patent specification itself identifies as problematic in drugs approved for treating bipolar disorder (which are particularly relevant here given the claims’ prohibition on the administration of rescue medication that could address these “significant issues”). EX1001, 1:25-31, 1:40-42.

84. Therefore, in my opinion, the ’997 patent fails to provide adequate written description for the limitations “maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder” by

“administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate.”

3. No Written Description of Administering Endoxifen for “Up to 21 Days” (Claims 1–10)

85.I have analyzed the limitation of independent claims 1 and 6 requiring administering endoxifen citrate “once per day for up to 21 days.” The originally filed independent claim 1 required administering endoxifen citrate “once per day for *at least* 21 days” (EX1002, 14), and claim 1 was subsequently amended, along with later-added claim 6, to require administering endoxifen citrate “once per day for *up to* 21 days.” EX1002, 304.

86.In my opinion, the specification, along with the originally filed claims, fails to describe the full scope of this limitation. As originally filed, independent claim 1 required administering endoxifen citrate “once per day for *at least* 21 days”—a time period wholly different (and largely non-overlapping) from that in the final claim, and it was only when claim 6 was added in a subsequent amendment that the “up to limitation” was added to the claims. From a clinical perspective, the shift from “at least 21 days” to “up to 21 days” materially changes the claimed treatment duration. “[U]p to 21 days” encompasses substantially shorter treatment courses (e.g., from the outset of the method through 21 days) that are not described in the specification. Indeed, the specification contains no

description of administering endoxifen for any duration less than 21 days. Every mention of the treatment period in the specification, including the abstract, the general description, and the study summary, describes a duration of “at least 21 days.” EX1001, Abstract; *see also, e.g.*, EX1001, 4:44-48 (“Clinical study... was carried out by administering to the patient doses of 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for *at least* 21 days according to the present application.”), 1:6-11 (“once per day for *at least* 21 days”), 2:66-3:4 (same), 3:5-11 (same), 3:12-17 (same), 4:15-20 (same), 4:21-28 (same), 4:29-34 (same). Moreover, the words “up to” appear in the specification only three times: once in claim 1, again in claim 6, and in an unrelated passage discussing the number of people that suffer from bipolar disorder. EX1001, cl.1, cl.6, 1:18-19 (“Bipolar disorder is a chronic, debilitating illness that affects up to 3% of the US population.”).

87. There is no disclosure in the specification of a treatment course lasting less than 21 days. In clinical research on bipolar I disorder, the choice of treatment duration is not an arbitrary detail. It affects both efficacy and safety, particularly when a new agent is being used in place of established mood stabilizers and when rescue medications are purportedly excluded. EX1005 (Hirschfeld), 8 (“With adequate dosing and serum levels, medications for the treatment of mania generally exert some appreciable clinical effect by the 10th to the 14th day of

treatment.”), 3 (“Following remission of an acute episode, patients may remain at particularly high risk of relapse for a period of up to 6 months; this phase of treatment, sometimes referred to as continuation treatment...”), 10 (“Maintenance medication treatment is generally recommended following a single manic episode.... Primary goals of treatment include relapse prevention, reduction of subthreshold symptoms, and reduction of suicide risk”). A specification that consistently describes an “at least 21 days” treatment does not, in my opinion, demonstrate possession of a method in which treatment may be concluded at any time before 21 days while still “maintaining a therapeutically effective concentration” and meeting the overall treatment goals. There are no data indicating, for example, what would be the minimum number of days patients needed to be treated with endoxifen to ensure improvement of other outcomes such as rehospitalization, self-harm, or the ability to return to work or study. Further, there is no explanation for why a prescriber would elect for a shorter than 21 day treatment duration, no discussion of clinical criteria for earlier conclusion, and no example of efficacy when dosing stops before day 21.

88. Therefore, in my opinion, the '997 patent fails to provide adequate written description for the limitation requiring administering endoxifen citrate “once per day for up to 21 days.”

4. No Written Description of “Monitoring the Dose Administered to the Patient No Sooner Than 21 Days After Commencement of the Administering to the Patient” (Claims 6–10)

89. I have analyzed the limitation of independent claim 6 requiring “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient.” This limitation was added immediately prior to allowance. EX1002, 409. I understand that “no sooner than 21 days” means that the first such monitoring event occurs on or after the 21-day mark from the start of treatment. For example, if the endoxifen treatment lasts 21 days, that means that the monitoring begins on or after the 21st (and last) day of the endoxifen dosing.

90. In my opinion, the specification, along with the originally filed claims, provides no written description support for this limitation. The specification contains only two generic statements about any “monitoring,” both of which are in the background section, where the patent discusses prior art therapies such as divalproex and general PKC-targeted approaches. EX1001, 1:32-34, 1:60–63.

91. The first of these two statements reads: “Divalproex has a good tolerability but a high discontinuation rate. There is also a continuous need to observe the therapeutic dose monitoring in patients during the treatment.” EX1001, 1:32-34. POSITA would have understood this to be simply a description of standard practice with divalproex, a well-known mood stabilizer that requires therapeutic

dose monitoring. POSITA would also have understood this sentence to be limited to divalproex, and not as a teaching that is being imported into the claimed endoxifen method. The sentence does not refer to endoxifen at all, does not mention any particular dose or dosing range, and does not suggest that monitoring should occur “no sooner than 21 days” after treatment starts. To the contrary, the natural reading is that divalproex requires “continuous” therapeutic dose monitoring during treatment. Consistent with this interpretation, clinical guidelines recommend periodically monitoring patients’ blood levels, even in the absence of dose change, for example, lithium treatment where the guidelines recommend monitoring at least every six months. EX1005 (Hirschfeld), 20-21. In my view, that is the opposite of the late-added claim 6 language, which requires a monitoring event that occurs only after 21 days have elapsed from the commencement of dosing.

92. The second statement states: “Targeting the PKC signalling pathway for bipolar disorder can improve the patient compliance, when therapeutic dose monitoring is not required in patient, and such treatment can provide significant improvement in mania and depression.” EX1001, 1:60-63. Here again, the specification is speaking about PKC-targeted therapies in general and not about endoxifen in particular. The sentence does not identify any endoxifen dose or regimen, does not describe any clinical trial, and does not provide an example of a specific PKC-

targeting drug that has been shown to avoid therapeutic dose monitoring in bipolar I disorder. Further, the very next passage in the specification underscores how speculative that PKC statement is with respect to endoxifen itself. The patent admits that “[t]he exact mechanism by which endoxifen exerts its therapeutic effects have not been established in bipolar disorder. However, the efficacy of endoxifen could be mediated through PKC.” EX1001, 2:29-32. In my opinion, this language would signal to POSITA that any link between endoxifen and the PKC signaling pathway is hypothetical. If the mechanism of action of endoxifen in bipolar disorder has “not been established,” and its relationship to PKC is only that it “could be” mediated through PKC, then the earlier general statement about PKC-targeted treatments avoiding therapeutic dose monitoring cannot reasonably be read as describing a specific monitoring strategy for endoxifen. Moreover, this background passage describes a hypothetical situation in which “therapeutic dose monitoring is not required” at all (EX1001, 1:60-63), while claim 6 recites a method that affirmatively requires monitoring at some point after the dosing begins (“**monitoring**... no sooner than 21 days”). In my opinion, this is another reason POSITA would not read that PKC passage as providing written description support for the claim 6 requirement.

93. Apart from the two background sentences I discussed earlier, there is no other mention of any “monitoring” anywhere in the specification. Even the patent’s brief description of the endoxifen clinical trial, which spans only a few sentences, says nothing about whether patients were monitored clinically, whether the investigators verified that the medication was actually taken by the patient, whether serum drug levels were measured, or whether any particular monitoring schedule was followed. EX1001, 4:43-59.

94. In my opinion, this silence is particularly striking in light of the standard of care at the priority date. As I explained earlier in this declaration, and as reflected in bipolar treatment guidelines such as Hirschfeld, therapeutic dose monitoring and close clinical follow up were standard practice for medication adherence regardless of whether the treatment is a mood stabilizer or any other agent used to treat bipolar I disorder. EX1005 (Hirschfeld), 8-9, 12, 20. To the extent “therapeutic dose monitoring” means measuring plasma concentrations, that type of monitoring was the standard of care in many patients receiving treatment for bipolar I disorder and a requirement to delay “monitoring the dose... no sooner than 21 days” would be counter to that standard of care. POSITA reading the ’997 patent’s description of the endoxifen trial would therefore not have understood it to exclude therapeutic dose monitoring before day 21, and certainly would not infer a requirement that the prescriber refrain from “monitoring” for

the first 21 days and then begin monitoring only at or after day 21. The patent offers no explanation, data, or example suggesting why monitoring should first occur specifically at 21 days rather than earlier or after in treatment, and contains no reference at all to monitoring beginning 21 days after administration starts. Thus, in my opinion, the specification does not demonstrate to POSITA that the inventors were in possession of the full range of the claimed methods of treatment requiring “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient” as of the invention date.

95. Therefore, in my opinion, the '997 patent fails to provide adequate written description for the limitation of independent claim 6 requiring “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient.

5. No Written Description of Treating Patients with the Additional Conditions Described in the Dependent Claims (Claims 2–5 and 7–10)

96. I have analyzed dependent claims 2 through 5 and 7 through 10, which require the patient to have specific conditions such as “manic episodes with mixed features” (claims 2 and 7), “manic episodes without mixed features” (claims 3 and 8), “depression” (claims 4 and 9), and “depressive episodes” (claims 5 and 10).

97. In my opinion, the '997 patent does not provide an adequate written description for these patient subgroups recited in dependent claims 2-5 and 7-10. The specification does not indicate that the symptom amelioration had been stratified for patients with or without mixed features, such that POSITA would have understood that the inventors possessed methods of treatment that were effective across the various patient populations claimed in the dependent claims. Moreover, the only clinical example in the specification simply states that endoxifen citrate 8 mg was administered once daily "to patients [with] bipolar I disorders," without identifying whether any of those patients had mixed features, bipolar mania, or a current depressive episode (bipolar depression). EX1001, 4:50-54. The specification does not disclose any data, analyses, or examples directed at the subgroups recited in the dependent claims. The only mention of any of these symptoms anywhere in the specification is in its repeating of the claim language and the generic statement that "[t]argeting the PKC signalling pathway for bipolar disorder... can provide significant improvement in mania and depression." *E.g.*, EX1001, 1:60-64; *see also* 2:50-54, 2:55-59, 3:66-4:3, 4:4-8. As discussed above, that generic statement does not mention endoxifen, any particular dose, or any method tailored to patients with mixed features or current depressive episodes. *See* EX1001, 1:60-64. Therefore, the specification does not convey to POSITA that the inventors had actually possessed a method

of maintaining a therapeutically effective concentration of endoxifen for treating bipolar I disorder including bipolar mania and bipolar depression or presence or absence of mixed features as required by the dependent claims.

98. This lack of specific disclosure is particularly significant because bipolar I disorder patients with different symptom profiles often require different treatment strategies, and different dosing, and not all pharmacological agents treat both bipolar mania and bipolar depression. A treatment effective for bipolar mania may not be effective for patients with bipolar depression or with the presence of mixed features. EX1005 (Hirschfeld), 8 (“antidepressant monotherapy is not recommended, given the risk of precipitating a switch into mania”), 21 (“patients with prominent depressive symptoms during mania and with multiple prior mood episodes were more likely to respond to acute treatment with divalproex than with lithium”); EX1008 (Baldessarini)², 3-8 (describing

² EX1008 (“Bipolar Depression: Overview and Commentary”) published May 3, 2010 in a regularly published journal which those in my field, including POSITA would have been familiar with, looked to, and able to locate, and therefore I understand it is prior art under at least 35 U.S.C. § 102(a)(1). I have been aware of

various conditions treated by prior art drugs and providing table summarizing whether prior art drugs were known to be effective in treating bipolar depression versus bipolar mania). For example, patients who present with manic episodes with mixed features tend to be more treatment resistant and often require combinations of mood stabilizers and atypical antipsychotics, with careful avoidance or cautious use of antidepressants. EX1005 (Hirschfeld), 7-8 (“the first-line pharmacological treatment for patients with severe mania is the initiation of either lithium plus an antipsychotic or valproate plus an antipsychotic,” “antidepressant monotherapy is not recommended, given the risk of precipitating a switch into mania”), 28; EX1008 (Baldessarini), 3-8. By contrast, while some agents are particularly effective for acute mania, such as typical antipsychotics, there is no evidence of their efficacy in bipolar depression—in fact, these drugs can even worsen depressive symptoms if used in monotherapy. EX1008(Baldessarini), 6-8 (“olanzapine (Zyprexa®) has limited evidence of efficacy for short- or long-term treatment aimed at bipolar depression, although it is considered effective in recurrent mania,” “Emerging

EX1008 since its publication because I am the fourth listed author on the publication.

treatments... can be at least partially effective in the treatment or prevention of recurring bipolar depression. Less is known about their long-term effects on dysthymia or the dysphoria of mixed states.”). Moreover, the same dose of a given drug that controls acute mania may need to be higher than the dose required to treat depression. POSITA would have understood that “depressive episodes” (required by claim 5) refers to a patient who undergoes five or more symptoms of depression within the same two-week period. EX1009 (DSM-5), 9.³

99. The '997 patent does not provide any data, examples, or discussion showing that endoxifen at any dose, much less across the entire 2 mg to 16 mg range and at the schedule of doses claimed, is effective for each of these specific subgroups or that the inventors had developed dosing or management strategies tailored to these subgroups. Therefore, it is my opinion that the specification does not convey to POSITA that the inventors had actually possessed an effective method

³ American Psychiatric Association, “Diagnostic and Statistical Manual of Mental Disorders,” Fifth Edition (2013) (which was a well-known publication to those in my field, including POSITA, and a publication to which those in my field, including POSITA, would have looked) published 2013 and I understand it is prior art under at least 35 U.S.C. § 102(a)(1).

of treating each of the patient subpopulations claimed in the dependent claims. Therefore, in my opinion, the '997 patent fails to provide adequate written description for the limitations in dependent claims 2 through 5 and 7 through 10.

C. Ground 2: Lack of Enablement

1. No Enablement of “Maintaining a Therapeutically Effective Concentration of Endoxifen” By Administering a “Dose In a Range From 2 mg to 16 mg...For Up to 21 Days” With No “Rescue Medication” (Claims 1-10)

100. In my opinion, the '997 patent does not enable “maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder” across the claimed 2 mg to 16 mg dose range, administered once per day for up to 21 days, while positively excluding any use of rescue medications. The patent defines a “therapeutically effective concentration” in very general, functional terms as a concentration “sufficient to decrease or prevent or cure the symptoms” or “to normalize body functions,” but it does not give any actual examples of what concentration(s) are needed to achieve in an effective method of treatment with endoxifen for the claimed patient populations with the claimed doses or claimed dosing durations. EX1001, 3:36-41. There are no data or discussion of how POSITA would determine, without undue experimentation, that a particular endoxifen concentration has been reached and is being maintained. There is also no discussion of how such a concentration is to be

identified or achieved when the prescriber is not permitted to use rescue medications at all. As just one example, the specification tells POSITA nothing regarding to whether a 2mg dose of endoxifen (which is within the claimed 2-16mg range), administered for just two days (which is within the claimed “up to 21 days” range) would ever reach a “therapeutically effective concentration” (let alone be sufficient to maintain that concentration, as claimed) and would do so without the possibility of permitting the use of rescue medication. The same is true with respect to the at least hundreds, if not thousands, of other dose amount and duration combinations covered by the claims.

101. The specification instead contains only a single brief clinical example in which one dose, 8 mg of endoxifen citrate, was administered once daily for “at least” 21 days. EX1001, 4:44-59. Even in that example, the patent does not report any endoxifen plasma concentrations or PK parameters, does not describe the time course of symptom change, and does not state whether or how many patients had their symptoms decreased, prevented, or cured, or whether their “body functions” were normalized. And beyond that single 8 mg example, the ’997 patent provides no data or discussion at all about endoxifen pharmacokinetics, such as half-life, accumulation, or steady state, and no examples or studies at any other dose within the 2 mg to 16 mg range. There are no *in vitro* studies, no animal studies, and no human data showing what

concentrations are achieved at the untested doses, and certainly nothing linking those untested doses to both therapeutic effect, dosing schedule, and prohibition of any rescue medication, as required by the patent claims.

102. Moreover, the example simply states that at the end of treatment, “none of the patient required rescue medications, no rescue medications were administered to any of the patients.” EX1001, 4:57-59. As discussed above, POSITA would read that sentence as a retrospective observation for that particular study population, not as a description of a protocol in which rescue medications were positively excluded (prospectively forbidden from the outset). As also discussed above, Ahmad 2020, which describes the same trial, confirms that lorazepam and diazepam were allowed and in fact given in that study, and those benzodiazepines fall within the ’997 patent’s own definition of rescue medications. EX1006 (Ahmad 2020), 4; EX1001, 3:43-46. That reinforces my view that the patent does not enable a method in which rescue medications are positively excluded.

103. In my opinion, even if the brief description of the clinical study in the ’997 patent were treated as a valid working example, it would still fall short of supporting the breadth of the claimed methods. That study describes administering a single dose, 8 mg of endoxifen citrate, once daily for “at least 21 days” in a particular trial population of patients in the manic phase of bipolar disorder. EX1001, 4:44-59. And as disclosed in Ahmad 2020, that study

affirmatively included administering rescue medications as defined by the '997 patent. EX1006 (Ahmad 2020), 4; EX1001, 3:43-46. Moreover, Ahmad 2016 tested only two doses, 4mg and 8mg, and although it provided plasma concentrations for those two doses, it provided no information as to any threshold concentration that would be required to be “therapeutically effective” (particularly across the broad claimed patient population with different symptoms), Ahmad 2016 administered only for 21 days and no shorter durations within the claimed ranges, and Ahmad 2016 included administering rescue medications. EX1004, 3, 5-6. By contrast, the claims of the '997 patent cover the entire 2 mg to 16mg dose range, not merely 8 mg, and apply to “up to 21 days” of treatment, which encompasses shorter courses as well as longer ones, in all patients with bipolar I disorder, not just the specific population enrolled in the described trial, and to do so while positively excluding rescue medications entirely. Nothing in the specification ties the asserted “therapeutically effective concentration” and “no rescue medication” result to any particular dose, to any defined subset of patients, or to any specific treatment duration. Given this complete lack of information, POSITA would have needed to undertake substantial experimentation to identify which doses, in which patients, for which treatment durations, can actually maintain a therapeutically effective concentration of endoxifen monotherapy while prohibiting any rescue

medications. That experimentation would have included, for example, testing multiple doses within the 2 mg to 16 mg range, measuring endoxifen plasma levels over time, documenting clinical response, and not allowing additional medications. It would require separate clinical studies in different bipolar disorder patient subtypes including bipolar depression, and presence of mixed features.

104. In my opinion, application of the *Wands* factors further confirms that POSITA would have had to engage in undue experimentation to practice the full scope of the method of treatment claimed by the '997 patent. First, the quantity of experimentation required would be large—it would require multiple additional clinical studies. The claims require “maintaining a therapeutically effective concentration of endoxifen,” for all patients with bipolar I, by administering a 2 mg to 16 mg dose range, “up to 21 days,” while positively excluding the use of rescue medications. As discussed above, to determine which doses within that range, in which types of patients, and over what durations, would both maintain a “therapeutically effective concentration of endoxifen” monotherapy, POSITA would need, at a minimum, to design and conduct additional clinical trials at multiple dose levels, in multiple clinically distinct subpopulations, and with different treatment durations. That would also include, for example, careful

tracking of plasma concentrations, symptom response, adverse events, and not allowing rescue-medication.

105. Second, the amount of guidance in the specification is minimal. The '997 patent provides no actual endoxifen plasma concentration data for any dose, no threshold or duration that POSITA could use to determine whether the “therapeutically effective concentration” has been achieved or maintained, or when rescue medications can be excluded entirely across the full spectrum of patients with bipolar I and across the full range of claimed doses.

106. Third, regarding the presence or absence of working examples in the specification, there is only a brief description of a study of 8 mg endoxifen that does not provide any plasma-concentration data or pharmacokinetic data, does not show that a “therapeutically effective concentration” was reached or maintained, does not tie the reported retrospective absence of rescue medication usage to any particular dose, patient characteristics, or treatment duration, and does not indicate what factors would enable positively excluding rescue medications. EX1001, 4:44-59.

107. Fourth and fifth, the nature of the invention and the state of the art further weigh against enablement. The '997 patent itself acknowledges that the mechanism by which endoxifen might work in bipolar disorder was speculative at the time, stating that PKC “appears to have a role” in bipolar disorder, that

PKC was merely a “novel molecular target,” and that “the exact mechanism by which endoxifen exerts its therapeutic effects have not been established,” with efficacy only possibly mediated through PKC. EX1001, 1:46-47, 1:58-59, 1:60-63, 2:29-32. In my view, that is not the kind of understanding that would have permitted POSITA to reliably extrapolate from one or two dose levels to the entire 2 mg to 16 mg range. There was nothing in the prior art that would have allowed clinicians to predict, in the absence of specific clinical results, which endoxifen doses would be therapeutically effective for bipolar I disorder, let alone which would be effective in all patients without the option of rescue medications. And, as discussed above, Ahmad 2016 disclosed plasma concentrations at only 4mg and 8mg, did not disclose a threshold “therapeutically effective” concentration of endoxifen, and did not exclude rescue medications, thus providing no guidance to POSITA as to a therapeutically effective concentration of endoxifen that could treat bipolar I disorder in the absence of rescue medications. EX1004, 3, 5-6. Moreover, the “single-dose study” referenced in Ahmad 2016 tested only doses from 0.5 mg to 4.0 mg in “healthy human subjects” and thus also provides no guidance to POSITA as to a “therapeutically effective concentration” for treating bipolar I disorder (particularly across the broad claimed patient population with different

symptoms), and certainly not at the full range of claimed doses. EX1004, 6 & n.13.

108. Sixth and seventh, although the relative skill in the art may be high, the field of methods for successfully treating bipolar I disorder is unpredictable, particularly if POSITA were required to eliminate the possibility of administering any rescue medication from such methods. The '997 patent notes that existing treatments fail to benefit an estimated 40-50 percent of patients and that significant problems with tolerability, efficacy, and suicidal behavior remain. EX1001, 1:28-31, 1:40-42. For example, responses to mood stabilizers and antipsychotics may vary widely across patients, and it is possible to see good responses in some individuals and poor or intolerable responses in others with the same condition at the same nominal dose. EX1005 (Hirschfeld), 4-5 (“At other times in treatment, it may be necessary to discontinue a medication (e.g., because of intolerable side effects) or substitute one medication for another.”), 15 (“Older patients...may also have difficulty tolerating antipsychotic medications and are more likely to develop extrapyramidal side effects and tardive dyskinesia than younger individuals.”); EX1008, 3-8. The '997 patent also notes that clinicians must constantly balance efficacy and side effects such as sedation, weight gain, thrombocytopenia, and thyroid dysfunction., as well as adherence to treatment. is affected by these adverse effects. EX1001, 1:35-39.

Therefore, POSITA could not reasonably assume that all doses from 2 mg through 16 mg of endoxifen, in all patients with bipolar I, will be both safe and effective, and that they will allow the prescriber to eliminate even the possibility of using rescue medications. The idea that a broad, eight-fold dose range would uniformly permit a “no rescue medication” approach across the entire bipolar I population is not supported by any data in the patent or the prior art.

109. Eighth, the Challenged Claims broadly cover an eight-fold dose range, treatment “up to 21 days” that includes shorter courses, and all patients with bipolar I, including those with severe, mixed, or comorbid presentations, while affirmatively excluding the possibility of any administration of rescue medications. Yet the specification discloses at most a single 8 mg study in an unspecified bipolar I population, with no plasma concentration or detailed symptom data, and Ahmad 2020 shows that even in that study, benzodiazepine rescue medications were still used. EX1006 (Ahmad 2020), 4. There is no explanation in the patent for how to generalize from that limited and incomplete example to the full scope of the claims. It is thus my opinion that POSITA would have to undertake extensive, undue experimentation to practice the full scope of the claimed methods of treatment.

110. Therefore, in my opinion (and regardless of the consideration of Ahmad 2020), the '997 patent fails to enable, as claimed, maintaining a therapeutically

effective concentration of endoxifen monotherapy for treating bipolar I disorders at the full 2 mg to 16 mg range of claimed doses over the broad claimed duration, for any patient with bipolar I, without the possibility of using rescue medications.

D. Ground 3: Claims 6-10 Are Unpatentable as Indefinite

1. Indefiniteness of “Monitoring the Dose Administered to the Patient No Sooner than 21 days After Commencement...” (Claims 6-10)

111. In my opinion, the “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering” limitation in claim 6 is indefinite. The term “monitoring the dose administered” is not a term of art that has a single, well accepted meaning. As discussed above, the only references to “monitoring” in the specification are background comments about “therapeutic dose monitoring” in relation to divalproex and speculative PKC targeted therapies, which POSITA would have understood as prior art context rather than a description of the claimed endoxifen methods. EX1001, 1:32-34, 1:60-63. As a result, the specification gives no guidance that would allow POSITA to identify what acts satisfy “monitoring the dose administered.”

112. In my opinion, “monitoring the dose administered” could encompass a wide range of different activities. For example, it could refer to measuring plasma endoxifen concentrations at specific time points and adjusting the dose based on those levels and determining its effects on the presence or severity of symptoms

of bipolar I disorder as well on presence and severity of adverse events. It could mean checking pill counts at clinic visits or reviewing pharmacy refill histories to assess adherence to the prescribed dose. It could refer to asking the patient about what dose they are actually taking, or to adjusting the prescribed dose based on observed clinical response and side effects. It could also mean some combination of these activities. In practice, all of these are ways in which a clinician “monitors” a specific dose. The ’997 patent, however, does not select among these possibilities, does not specify any measurement, frequency or threshold, and does not tie the claimed “monitoring” to any particular clinical or laboratory activity. When claim 6 was added late in prosecution, Patent Owner did not cite any supporting passage in the specification. EX1002, 418-420. In my opinion, the ’997 patent’s specification, claims, and prosecution history leave POSITA without any basis to determine which of these activities, alone or in combination, satisfy the “monitoring the dose administered” requirement and which do not.

113. Therefore, in my opinion, the “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering” limitation renders claims 6-10 indefinite.

E. Ground 4: Claims 1-4 Are Anticipated By Ahmad 2016

114. As discussed above, Patent Owner obtained allowance of the '997 patent claims by arguing that the claim term “the method does not include a rescue medication for the treatment of the bipolar I disorder” means that, before the method of treatment with endoxifen citrate begins, the prescriber positively excludes the possibility of treatment with any rescue medication during the course of the method. And, as discussed above, it is my opinion that nothing in the specification demonstrates to POSITA that the inventors possessed efficacious methods of treatment with endoxifen citrate across the claimed dose range that did not include at least the possibility that a patient would need a rescue medication before at least 21 days after the method began. It is further my opinion that, if it were possible to practice such a method, it would require POSITA to undertake undue experimentation to identify, for example, the specific doses of endoxifen citrate from within the claimed range that would need to be administered, for what duration, and to which specific patient populations, such that the possibility of administering those patients a rescue medication could be positively precluded before the method begins and be carried out in clinical practice without the need for rescue medications. If, however, Patent Owner abandons the interpretation of the claim term “the method does not include a rescue medication for the treatment of the bipolar I disorder” that it argued for to

secure these patent claims, and asserts that “wherein the method does not *include* a rescue medication for the treatment of bipolar I disorder” instead means “wherein the patient does not *require* rescue medication,” then it is my opinion that, for the reasons discussed below, Ahmad 2016 discloses each and every element, and therefore anticipates, claims 1-4 of the ’997 patent.

115. Below I have set forth the basis for my opinion, explaining how the disclosures of Ahmad 2016 disclose each claim element, and together anticipate the claims.

1. Independent Claim 1

116. Independent claim 1 is reproduced below, with the labels added in brackets for the purpose of referencing the claim elements and limitations in the following analysis:

[1.pre]: A method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder, said method comprising:

[1.a]: administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for up to 21 days,

[1.b]: wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.

117. Element 1.pre is a preamble that recites “a method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder, said method comprising.” In my opinion, Ahmad 2016 discloses a method for maintaining a therapeutically effective concentration of endoxifen for treatment of a patient with bipolar I disorder. For example, Ahmad 2016 discloses that “[p]atients orally administered 4 mg/day or 8 mg/day endoxifen showed significant improvement in mania assessed by the Young Mania Rating Scale as early as 4 days. The effect remained significant throughout the 21-day period.” EX1004 (Ahmad 2016), Abstract; *see also id.*, 5, 6, Figs.3-4; *see also* EX1002, 168 (“Ahmad teaches antimanic properties of endoxifen in patients with bipolar I disorder (BP) with current manic or mixed episode.”), 169 (“Patients orally administered 4 mg/day or 8 mg/day endoxifen showed significant improvement in mania assessed by the Young Mania Rating Scale as early as 4 days... Ahmad teaches endoxifen has been shown as a promising novel antimanic or mood stabilizing agent, as seen by significantly improved YMRS scale at almost every treatment evaluation.”). Ahmad further explains that “[e]fficacy and safety assessments were done based on evaluation parameters on Days 4, 7, 14, and 21 (end of treatment)” and that “safety blood Clinical Global Impression of Improvement (CGI-I) was collected on Day 21 / discharge day from hospital.” EX1004 (Ahmad 2016), 3; *see* EX1002, 168-69

(“Further, the administration of endoxifen (4 mg and 8 mg) provides a steady state plasma concentration of endoxifen for 14 and also 20 days, and that doubling of the dose from 4 to 8 mg increases the plasma AUC by 2-fold (p 257), thus manifesting the anti-manic effect (which can be construed as without mixed episode) or mixed episodes patients of endoxifen (p 258)”), 218 (“Ahmad teaches that the plasma concentration of endoxifen is maintained at 14 and 20 days, indicating steady state of the endoxifen (fig.4).”), 219 (“with respect to maintaining the therapeutically effective concentration of endoxifen in the patient, Ahmad teaches that the concentration of endoxifen is maintained up to 21 days (Fig.3 and p 256-col. 2- pharmacokinetics and pharmacokinetic-pharmacodynamic (PK-PD) relation of endoxifen”).

118. Element 1.a recites “administering to the patient, a dose in a range from 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day for up to 21 days.” In my opinion, Ahmad 2016 discloses administering to the patient, a dose in a range from 2 mg to 16 mg (in particular, 4 mg and 8 mg) of endoxifen citrate in an enteric coated tablet once per day for up to 21 days (in particular, for 21 days).

119. First, Ahmad 2016 discloses administering to the patient a dose in a range of 2 mg to 16 mg of endoxifen in an enteric coated tablet once per day for up to 21 days. For example, Ahmad 2016 discloses that “[e]ndoxifen was given orally as

enteric coated tablets at two fixed doses (4 mg/day or 8 mg/day) to enhance the bioavailability,” and that “[e]fficacy and safety assessments were done based on evaluation parameters on Days 4, 7, 14, and 21 (end of treatment).” EX1004 (Ahmad 2016), 2, 3; *see also* EX1002, 399 (“Ahmad... et al teaches the efficacy of enteric coated endoxifen-citrate in claimed amounts, administered for claimed amount of time, for treating manic depression in BPD patients and also shows that the administration when measured on YMRS scale is safe and tolerable suggesting mood stability of the patients.”); EX1004, Abstract, 3-4, 6.

120. Second, it is my opinion that Ahmad 2016’s endoxifen is endoxifen citrate, and thus Ahmad 2016 discloses administering endoxifen citrate (including at doses of 4mg and 8mg). For example, the chemical structure depicted in Figure 1 of Ahmad 2016 matches with the structure described as endoxifen citrate in the ’997 patent. EX1001, 2:6-8 (“The empirical formula of endoxifen citrate is $C_{25}H_{27}NO_2 \cdot C_6H_8O_7$ ”); *see also* EX1002, 168 (“Ahmad teaches enteric coated endoxifen citrate salt (‘ $C_6H_8O_7$ ’ is citric acid, see figure 1 and page 253, col. 2-Methodology).”). In my opinion, the following structure disclosed in Ahmad 2016 is the citrate form of endoxifen.

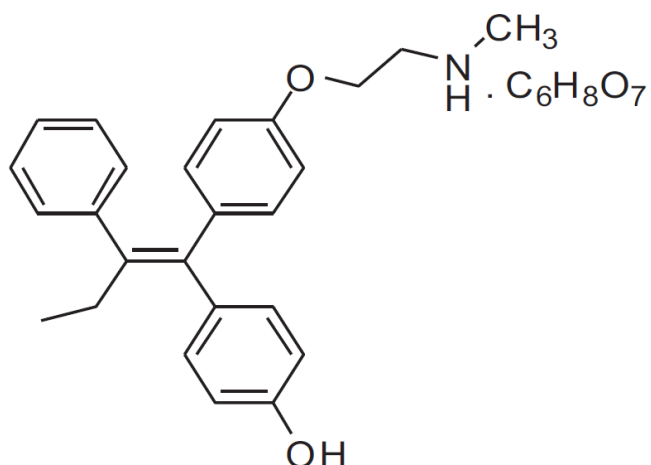


Figure 1 Chemical structure of endoxifen.

EX1004 (Ahmad 2016), Fig. 1.

121. Element 1.b recites, “wherein the method does not include a rescue medication for the treatment of the bipolar I disorder.” To the extent that Patent Owner argues (inconsistent with what it argued to obtain allowance during prosecution) that this limitation means “the patient does not *require* rescue medication,” instead of the interpretation of the limitation it argued for to gain allowance of the patent, under which rescue medication is positively excluded before the method begins, Ahmad 2016 discloses a method that does not include a rescue medication for the treatment of the bipolar I disorder. For example, Ahmad 2016 teaches that “[a]ll psychotropic medications except benzodiazepines (lorazepam/diazepam only) were discontinued at least 2 days before randomization,” and that “[b]enzodiazepines (lorazepam- /diazepam only) (up to 5 mg/day, preferably in divided doses) were allowed as adjunctive

medication as needed at the discretion of the investigator from 2 days prior to randomization but not beyond the first 10 days of investigational medicinal product dosing.” EX1004 (Ahmad 2016), 3; *see also* EX1002, 218 (“Ahmad teaches concomitant medications such as lorazepam have been discontinued before treatment... Ahmad also teaches monotherapy trials of drugs for the treatment of bipolar disorder (table 3 and 4b)), 219-20 (“Ahmad teaches a study design without any concomitant medication and yet providing endoxifen concentration for up to 21 days.”), 221 (“This is further evidenced from the study design (fig. 2) of Ahmad wherein the design does not include any benzodiazepines.”), 225 (“...Ahmad teaches concomitant medications such as lorazepam have been discontinued before treatment.”), 226 (“According to Ahmad treatment of bipolar disorder (BD), as described in Tables 3 and 4b, does not include any rescue medication.”), 271 (“Ahmad teaches all concomitant psychotropic medications except benzodiazepines (such as lorazepam) have been discontinued before treatment...”), 328 (“the second study design of Ahmad does not require any additional drug”), 390 (“Moreover, Ahmad does not require that additional rescue medication is evident from the study design (fig. 2), wherein the design does not include any benzodiazepines.”).

122. Ahmad 2016’s trial was to test “endoxifen alone,” and thus POSITA would have understood (*i.e.*, interpreted) this Ahmad 2016 language as disclosing that

patients discontinued treatment with all other psychotropic medications except benzodiazepines before the study began. EX1004 (Ahmad 2016), 3, 6, 7. It is my opinion that one reason why investigators discontinue treatment with other psychotropic medications except benzodiazepines before a study like the one in Ahmad 2016 begins is to control for the effects that those other drugs may have on the efficacy and safety outcomes for the drug being investigated. If patients are taking other psychotropic medications when the study begins, it may be unclear whether the improvements (or lack thereof) observed in patients in the study are due to the study drug or the study drug in combination with another medication. Similarly, if a patient experiences side effects, it may be unclear whether those side effects are attributable to the study drug, to the patients' prior medication, or the abrupt discontinuation of prior medications. EX1005 (Hirschfeld), 4 ("However, each additional medication generally increases the side effect burden and the likelihood of drug-drug interactions or other toxicity and therefore must be assessed in terms of the risk-benefit ratio to the individual patient."), 8, 12-14. It is my opinion that POSITA would thus have recognized Ahmad 2016 to be disclosing that patients would not have been taking any rescue medications except benzodiazepines when the study began.

123. It is also my opinion that Ahmad 2016 discloses that benzodiazepines were administered only "*as needed at the discretion of the investigator,*" which

POSITA would have recognized to be a disclosure that only patients experiencing an adverse event would be considered to have a need for discretionary treatment with benzodiazepines. EX1004 (Ahmad 2016), 3; *see also* EX1002, 219 (“Ahmad also teaches that benzodiazepines are allowed as adjunctive medication as needed at the discretion of the investigator (p 254). Thus, Ahmad suggests one can include benzodiazepines only as needed and therefore it is not necessary to administer benzodiazepines during the administration of endoxifen.”), 399 (“Ahmad suggests administering benzodiazepines only as needed during endoxifen treatment and do not include the same in the study design.”). It is my opinion that POSITA would have recognized Ahmad 2016’s teaching that benzodiazepines were administered only “as needed” and only “at the discretion of the investigator” to be an express disclosure that patients would have needed to report an adverse event such as akathisia before the investigator could exercise discretion in administering benzodiazepines to a patient in need thereof. Ahmad 2016’s disclosures are consistent with my experience of administering clinical trials for bipolar I disorder, where patients are required to report adverse events to clinical investigators prior to receiving any additional medication in a study such as Ahmad 2016. In my opinion prescribers would only administer benzodiazepines to patients experiencing an adverse event because those medications may have a confounding impact on the efficacy and safety outcomes

for the drug being investigated. Because of the risk of confounding the study results, a study investigator would consider administering a benzodiazepine only if a patient reported an adverse event that demonstrated that a patient was in need of a benzodiazepine. Consistent with this, Ahmad 2016 indicates that adverse events observed in the trial included those that were “psychiatric in nature,” a category which would include breakthrough or recurring symptoms of bipolar I disorder. For example, Ahmad 2016 discloses that adverse events in the study included insomnia and delusions, EX1004 (Ahmad 2016), 3, and POSITA would have recognized those adverse events as breakthrough or recurring symptoms of bipolar I disorder for which a benzodiazepine might be warranted.

124. Further, Ahmad 2016 discloses that only 15 patients in the 55-patient endoxifen treatment group experienced adverse events of any kind. EX1004 (Ahmad 2016), 3. In my opinion, POSITA would have understood this description of the results as disclosing that the 40 patients in the endoxifen treatment group who did not experience adverse events did not receive a benzodiazepine and therefore did not receive any benzodiazepine or other rescue medication. As discussed above, given the nature and design of the study in Ahmad 2016, it is my opinion that POSITA would have recognized that Ahmad 2016’s disclosure that all patients stopped all psychotropic medications other than benzodiazepines prior to starting the study as disclosing rescue medication

was not administered in that study unless a patient was experiencing an adverse psychiatric event. It is also my opinion that POSITA would have further recognized that the study investigators would have administered benzodiazepines only to patients who reported an adverse event during treatment for which benzodiazepine treatment might be warranted. Indeed, consistent with my interpretation, Ahmad 2016 reports that “[b]enzodiazepines were avoided within 12 h[ours] of scheduled mania ratings... [to] avoid **efficacy or safety overlap.**” EX1004 (Ahmad 2016), 3. It is thus my opinion that POSITA would thus have recognized that the disclosure in Ahmad 2016 that at least 40 patients in the endoxifen treatment did not experience adverse events to be a disclosure that at least those 40 patients also did not receive a benzodiazepine (or other rescue medication) because such medication would have been administered at an investigator’s discretion only after a patient experienced an adverse event.

125. Thus, in my opinion, Ahmad 2016 discloses each element of claim 1 and therefore renders claim 1 invalid as anticipated.

2. Dependent Claim 2

126. Dependent claim 2 recites “[t]he method of claim 1, wherein the patient has manic episodes with mixed features.” In my opinion, Ahmad 2016 discloses the method of claim 1 wherein the patient has manic episodes with mixed features. For example, Ahmad 2016’s study inclusion criteria included “patients who were

diagnosed of BPD I and having displayed an acute... mixed episode,” and Ahmad 2016 discloses that it “show[ed] for the first time the antimanic properties of endoxifen in patients with bipolar I disorder (BPD I)” with “mixed episode.” EX1004 (Ahmad 2016), Abstract, 2; *see also* EX1002, 168 (“Ahmad teaches antimanic properties of endoxifen in patients with bipolar I disorder (BP) with current... mixed episode”), 221 (“A skilled artisan would have been motivated because Ahmad teaches administering endoxifen 4 mg and 8 mg for alleviating depressive symptoms of mixed episode of BPD similar to that of divalproex, with a steady state plasma concentration of endoxifen for 14 and also 21 days, and that doubling of the dose from 4 to 8 mg increases the plasma AUC by 2-fold (p 257), thus manifesting the anti-manic effect or mixed episodes patients of endoxifen (p 258).”). POSITA would have recognized Ahmad 2016’s phrase “mixed episode” patients to mean patients having “manic episodes with mixed features” and thus recognized these to be disclosures that the methods of treatment disclosed in Ahmad 2016 were effective in treating patients having “manic episodes with mixed features” as required by claim 2. Indeed, Ahmad 2016 discloses that each patient enrolled in the study was diagnosed as having an “acute manic or mixed episode (with or without psychotic features)” as judged by the investigator, and it is my opinion that POSITA would have recognized this to be a disclosure that all 84 patients in the study had either an acute manic episode, or an acute mixed

episode, i.e., an acute episode with both symptoms of mania and depression. Consistent with this, Ahmad 2016 measured the “antimanic” efficacy of endoxifen in each patient using the YMRS, in addition to measuring the MADRS of all patients to assess improvements in depressive symptoms and because “switch to depression remains a concern in all treatment of bipolar mania.” EX1004 (Ahmad 2016), 5. Ahmad 2016 thus discloses that all 84 patients were experiencing symptoms of acute mania and that a number of these patients also experienced episodes of mixed symptoms or mania with depressive symptoms. It is thus my opinion that POSITA would have recognized Ahmad 2016’s disclosure that patients in the study included those having “acute... mixed episode” to be a disclosure of treating patients who are having “manic episodes with mixed features,” as required by claim 2.

127. Ahmad 2016 similarly teaches that “orally administered endoxifen at 4 mg/day or 8 mg/day in this phase II clinical trial was well tolerated and showed significant improvement in... mixed episodes patients.” EX1004 (Ahmad 2016), 7. For the same reasons I discuss above, POSITA would have understood this to be a disclosure of treating patients who are having “manic episodes with mixed features,” as required by claim 2.
128. In my opinion, Ahmad 2016 thus discloses each and every element of, and therefore anticipates, claim 2.

3. Dependent Claim 3

129. Dependent claim 3 recites “[t]he method of claim 1, wherein the patient has manic episodes without mixed features.” It is my opinion that Ahmad 2016 discloses the method of claim 1 wherein the patient has manic episodes without mixed features. For example, Ahmad 2016 discloses that “[i]n this study we show for the first time the antimanic properties of endoxifen in patients with bipolar I disorder (BPD I) with current manic” episode. EX1004 (Ahmad 2016), Abstract. POSITA would understand this disclosure (and ones like it in Ahmad 2016) to be referring to manic episodes *without* mixed features (as opposed to a “mixed episode” which would include manic episode *with* mixed features). EX1009 (DSM-5), 8-10, 12-13 (providing separate criteria for a “manic episode” and “manic or hypomanic episode, with mixed features,” namely that a manic or hypomanic episode, with mixed features requires that the criteria for a manic episode diagnosis in addition to at least three of the listed symptoms of depression). Ahmad 2016’s study inclusion criteria included “patients who were diagnosed of BPD I and having displayed an acute manic [episode].” EX1004 (Ahmad 2016), 2; EX1002, 169 (“Patients orally administered 4 mg/day or 8 mg/day endoxifen showed significant improvement in mania assessed by the Young Mania Rating Scale as early as 4 days.”). Ahmad 2016 teaches “orally administered endoxifen at 4 mg/day or 8 mg/day in this phase II clinical trial was

well tolerated and showed significant improvement in manic... patients.” EX1004 (Ahmad 2016), 7. And Ahmad 2016 explains that “[t]o the best of our knowledge, this is the first report that describes the findings of a randomized, double-blind, active-controlled clinical trial to evaluate efficacy and safety of endoxifen in BPD I patients with current **manic**... episode.” EX1004 (Ahmad 2016), 2. It is my opinion that POSITA would have understood these references to patients having simply “manic” episodes as disclosures of patients having manic episodes without mixed features. POSITA would have recognized that Ahmad 2016 distinguishes patients with “manic... episodes” from patients with “mixed episodes,” as separate patient populations. It is further my opinion that POSITA would have understood that “manic episode” patients are experiencing only manic symptoms at the time of assessment while “mixed episode” patients, by contrast, are experiencing manic and depressive symptoms. And as I discussed above, Ahmad 2016 discloses that patients in the study were diagnosed as having either “acute manic *or* acute mixed episode,” and it is my opinion that POSITA would have understood that this passage refers to two separate patient populations and that the former is patients who are only having an acute manic episode, i.e., not an episode with mixed features of mania and depression. Thus, it is my opinion that, in addition to disclosing methods of treating patients suffering from a “mixed” episode, POSITA would have recognized Ahmad 2016

as expressly disclosing methods of treating patients suffering from only a “manic... episode,” *i.e.*, those not experiencing a “mixed” or depressive episode. Indeed, the examiner made this finding during prosecution. *See* EX1002, 168-69 (“Further, the administration of endoxifen (4 mg and 8 mg)... [manifests] the anti-manic effect (**which can be construed as without mixed episode**)....”).

130. It is therefore my opinion that Ahmad 2016 discloses each and every element of, and thus anticipates, claim 3.

4. Dependent Claim 4

131. Claim 4 recites “[t]he method of claim 1, wherein the patient has depression.”

In my opinion, Ahmad 2016 discloses the method of claim 1, wherein the patient has depression. Ahmad 2016 teaches using its method in treating patients with depressive symptoms (*i.e.*, patients that have depression). For example, Ahmad 2016 teaches that “[t]he result demonstrated the effectiveness of endoxifen 4 mg and 8 mg in alleviating depressive symptoms of mixed episode of BPD similar to that of divalproex.” EX1004 (Ahmad 2016), 5; *see also* EX1002, 168 (“Ahmad teaches that a switch to depression remains a concern in all treatments of bipolar mania, depressive symptoms were assessed with the MADRS score throughout the trial. Ahmad teaches effectiveness of endoxifen 4 mg and 8 mg in alleviating depressive symptoms of mixed episode of BPD similar to that of divalproex (p 256, col.1 & Table 2) (claim 1).”). Ahmad 2016 further notes that

a secondary endpoint in the study was mean change from baseline to the end of treatment in the Montgomery–Asberg Depression Rating Scale (MADRS) total score. EX1004 (Ahmad 2016), 2. In my opinion POSITA would have recognized that one of the secondary endpoints measured in the study, namely Montgomery–Asberg Depression Rating Scale (MADRS), is a measurement of improvements and monitoring of symptoms in patients with depression. EX1010 (Quilty) 1-3 (“The Montgomery–Åsberg Depression Rating Scale (MADRS) is a widely used clinician-rated measure of depressive severity,” “The MADRS now follows the Ham-D as the most extensively used clinician-rated measure of depressive severity in clinical research”).⁴ In particular, it is my opinion that

⁴ Lena C. Quilty et al., “The Structure of the Montgomery–Åsberg Depression Rating Scale Over the Course of Treatment for Depression,” 22 Int’l J. Methods Psychiatry Rsch. 175 (2013) (which was published in a regularly published journal that was well-known to those in my field, including POSITA, and was a publication to which those in my field, including POSITA, would have looked), published August 19, 2013 and I understand it is prior art under at least 35 U.S.C. § 102(a)(1). Those in my field, including POSITA, would have been aware of

POSITA would have known and recognized that the Montgomery-Åsberg Depression Rating Scale is a scale that stratifies the severity and presence of depression and depressive episodes in adults with bipolar disorder. EX1010 (Quilty) 1-3. And it is further my opinion that POSITA would further have recognized the reference's disclosure that endoxifen was effective in "alleviating depressive symptoms" to be an express disclosure that patients with depression and experiencing depressive episodes were treated with endoxifen.

132. It is therefore my opinion that Ahmad 2016 discloses each and every element of, and thus anticipates, claim 4.

VIII. CONCLUSION

133. In summary, for the reasons described above, I have concluded that each of the Challenged Claims is invalid for lack of written description, lack of enablement, indefinite, and claims 1-4 are anticipated under 35 U.S.C. § 102(a) in light of the prior art reference discussed above and the knowledge of POSITA.

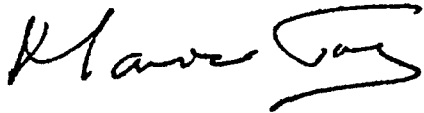
Quilty as of its publication and would have been aware of and looking for papers from the International Journal of Methods in Psychiatric Research.

134. Specifically, it is my opinion that Ground 1: Claims 1-10 Lack Written Description; Ground 2: Claims 1-10 Are Not Enabled; Ground 3: Claims 1-10 Are Indefinite; and Ground 4: Claims 1-4 Are Anticipated by Ahmad 2016.
135. To the extent it is argued that any further disclosure is required for any of the limitations in the Challenged Claims that I have identified herein as being disclosed, either explicitly or inherently, by the references listed in Appendix B, POSITA would certainly have found that limitation obvious to include based on the same explicit disclosure or inherent disclosures and analysis I have identified in my declaration.
136. I reserve the right to supplement by opinions in the future and to respond to any arguments that Patent Owner or its expert(s) may raise and to take into account any new information as it becomes available to me.
137. I have been warned that willful false statements and the like are punishable by fine or imprisonment, or both. I make this declaration of my own personal knowledge, and all statements made of my own knowledge are true. All statements made on information and belief are believed to be true. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

I declare under penalty of perjury that the foregoing is true and correct.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 10, 2025.

A handwritten signature in black ink, appearing to read "Mauricio Tohen". The signature is stylized with a large, sweeping "M" and a long, horizontal stroke at the end.

Mauricio Tohen MD, DrPH, MBA

APPENDIX A

December 8, 2025

Mauricio Tohen, MD, DrPH, MBA

Professional Address

University of New Mexico
Health Sciences Center
Department of Psychiatry and Behavioral Sciences
2400 Tucker Ave MSC 09 5030
Albuquerque, NM 87131

Licensure

01/2013 – Present	Medical License – New Mexico Medical Board, License # MD2013-0005
10/2010 – Present	Medical License – Texas Board of Medical Examiners, License # N7897
03/2009 – Present	Medical License – State of Florida, License # 103871

Certification

01/1984	Board Certification - American Board of Psychiatry and Neurology, Certificate #: 26530
01/1982	L.M.C.C. Examination - Licentiate of the Medical Council of Canada, Certificate # 54301
01/1982	Specialist in Psychiatry - Royal College of Physicians and Surgeons of Canada, F.R.C.P. (C), License # 2712
01/1980	FLEX certification, Massachusetts, Certificate #42580
01/1980	Specialist in Internal Medicine - National Autonomous University of Mexico
01/1980	Board Certification - Mexican Board of Internal Medicine
01/1980	P.L.A.B. Examination - United Kingdom General Medical Council Registration
01/1976	Medicine and Surgery - Ministry of Health, Mexico, Certificate # 10482
01/1976	Educational Commission for Foreign Medical Graduates, Certificate # 246-335-4

Educational History

1997 – 2000	MBA, Indiana University, Kelley School of Business, Indianapolis, IN, General Administration
1985 – 1988	DrPH, Doctorate in Public Health, Harvard School of Public Health, Boston, MA, Epidemiology
1985 – 1988	Harvard School of Public Health, Boston, MA, Teaching Fellowship in Epidemiology
1983 – 1984	MPH, Harvard School of Public Health, Boston, MA, Public Health
1982 – 1985	Harvard Medical School McLean Hospital, Mailman Research Center, Belmont, MA, Clinical Fellowship, Psychopharmacology
1982	DPsych, Department of Psychiatry, University of Toronto, Toronto, Canada, Psychiatric Research
1979 – 1982	University of Toronto, Clarke Institute of Psychiatry, Toronto, Canada, Psychiatry Residency

1976 – 1979	National University of Mexico, National Institute of Nutrition, Mexico City, Mexico, Internal Medicine Residency
1976	MD, National University of Mexico, Mexico City, Mexico, Medicine & Surgery

Employment History

Academic:

10/2025 – Present	Regents Professor, The University of New Mexico, Health Sciences Center
02/2013 – Present	University Distinguished Professor and Chairman, The University of New Mexico, Health Sciences Center, Department of Psychiatry and Behavioral Sciences, Albuquerque, NM
09/2011 – 02/2013	Professor with Tenure, The University of Texas Health Science Center at San Antonio, Department of Psychiatry, San Antonio, TX
09/2010 – 02/2013	Adjunct Professor of Epidemiology, The University of Texas Health Science Center at Houston, Houston, TX
02/2009 – 02/2013	Aaron & Bobbie Elliott Krus Endowed Chair, The University of Texas Health Science Center at San Antonio, Department of Psychiatry
02/2009 – 02/2013	Division Head, Mood & Anxiety Disorders, The University of Texas Health Science Center at San Antonio, Department of Psychiatry,
01/1994 – 12/1997	Psychiatrist, McLean Hospital, Belmont, MA
01/1997 – 01/2009	Clinical Associate Professor, Harvard Medical School, Department of Psychiatry, Boston, MA
01/1997 – Present	Consultant, McLean Hospital, Belmont, MA
01/1994 – 12/1997	Epidemiologist, McLean Hospital, Belmont, MA
01/1994 – 12/1997	Associate Professor, Harvard Medical School, Department of Psychiatry, Boston, MA
01/1994 – 12/1997	Associate Professor, Harvard School of Public Health, Department of Epidemiology, Boston, MA
01/1992 – 12/1994	Associate Epidemiologist, McLean Hospital, Belmont, MA
01/1991 – 12/1994	Assistant Professor, Harvard School of Public Health, Department of Epidemiology, Boston, MA
01/1991 – 12/1993	Assistant Professor, Harvard Medical School, Department of Psychiatry, Boston, MA

Non-Academic:

01/1997 – 12/2008	Leadership in the Pharmaceutical Industry- Led the team that successfully obtained the indication for Olanzapine for the treatment of Acute Mania and relapse prevention from the Food & Drug Administration (FDA) and the CPMP (European regulatory agency); the indication for bipolar depression for fluoxetine/olanzapine combination from the FDA; and the indication of Olanzapine for acute mania and bipolar depression from the Japanese regulatory Agency.
01/2004 – 12/2008	Distinguished Lilly Scholar, Lilly Research Laboratories, Indianapolis, IN
01/2003 – 01/2004	Led Zyprexa Product Team (100+ members)
01/2000 – 12/2003	Medical Director, Zyprexa Product Team, Lilly Research Laboratories, Indianapolis, IN
01/1997 – 12/2000	Medical Advisor, Lilly Research Laboratories, Indianapolis, IN

Professional Recognition, Honors, Etc.

10/2025	President- American Association of Chairs of Departments of Psychiatry
10/2025	Regents Professor, University of New Mexico, School of Medicine A special title bestowed on selected senior faculty members who, in the judgment of the Dean and on the advice of a faculty selection committee, merit recognition of their accomplishments as teachers, scholars and leaders both in University affairs and in their national/international professional communities
10/2024-10/2025	President-elect American Association of Chairs of Departments of Psychiatry
05/2024	American Society of Hispanic Psychiatry - Lifetime Achievement Award. This award honors individuals for their careers, lifetime service, dedication, outstanding community projects, clinical work, and/or education; that has impacted the lives of Hispanic/Latino families and patients with mental illness in US/Latin America/Globally.
07/2020	Named University Distinguished Professor - Individuals who have demonstrated outstanding achievements and are nationally and internationally renowned as scholars. This is the highest faculty title that UNM bestows and is used only for a few of its most prominent faculty members.
01/2017	Recognized by Expertscape as having the top % 0.12 expertise in bipolar disorder worldwide based on citations of published articles between 2007-2017
06/2016	The International Society for Bipolar Disorders Mogens Schou Award for Education and Teaching
05/2016	NAMI Exemplary Psychiatrist, 2016
07/2014	Thomson Reuter's "The World's Most Influential Scientific Minds, 2014" Honorees were the scientists who ranked in the top 1 percent by citations of their published work in 21 broad fields between 2002 and 2012. One of 100 scientists worldwide recognized in the Psychiatry/psychology category.
03/2011	American Psychiatric Association (APA), Simon Bolivar Award
01/1999	Lilly Research Laboratories President's Recognition Award
01/1995	FIRST Award: NIMH, 1995-2000
01/1992	Alfred Pope Award for Young Investigators
01/1991	NARSAD Young Investigator Award: 1991-1993
01/1985	NIMH Research Service Award in Psychiatric Epidemiology: Harvard Program in Psychiatric Epidemiology, 1985-1988

Memberships in Professional Societies

07/2020 - Present	Life time member Asociacion Psiquiatrica Mexicana
07/2013 - Present	American Association of Chairs of Departments of Psychiatry (ACDP)
01/2006 – Present	Fellow, American College of Neuropsychopharmacology (ACNP)
01/2003 – 2005	Member, American College of Neuropsychopharmacology (ACNP)
01/2000 – 12/2002	Associate Member, American College of Neuropsychopharmacology (ACNP)
01/1999 – Present	Member, Academia Nacional de Medicina (México)
01/1992 – 2011	Fellow, American College of Psychiatrists (ACP)

01/1982 – 01/1985	Royal College of Physicians and Surgeons of Canada Fellow Specialty of Psych
01/1981 – Present	American Psychiatric Association – Lifetime Distinguished Fellow

Other Extramural Professional Activities

Board of Directors or Trustees

02/2013 – 02/2015	Director, Board of Directors BioMedical Research Institute of New Mexico (BRINM), Albuquerque, New Mexico
03/2015 – 2017	Trustee, Board of Trustees for the Bowden Foundation for Advanced Interventions Research in Mood and Anxiety Disorders “B-FAIRMD, San Antonio, Texas

Editorial Board Memberships

06/2014 – 2019	Associate Editor, American Journal of Psychiatry
06/2014 – 2015	Editorial Board Member/Reviewer, Journal of Schizophrenia Research.
01/2012 – Present	Editorial Board Member, The International Journal of Bipolar Disorders
01/2012 – 2022	Regional Editor for North America, World Journal of Biological Psychiatry
11/2012 – 2022	Editorial Board Member, World Journal of Psychiatry
09/2011 – 2020	Editorial Board Member, International Journal of Neuropsychopharmacology, Official Publication of the International College of Neuropsychopharmacology (CINP)
01/2006 – Present	Editorial Board Member, Early Intervention in Psychiatry
01/2004 – Present	Editorial Board Member, Journal of Affective Disorders
01/2004 – 2014	Editorial Board Member, Current Psychiatry Reviews
01/2002 – 2012	Editorial Board Member, Trends in Evidence-Based Neuropsychiatry
01/2001 – 2021	Editorial Board Member, Journal of Clinical Psychiatry
01/2000 – Present	Editorial Board Member, Journal of Bipolar Disorders
01/1998 – 2000	Editorial Board Member, Harvard Review of Psychiatry

Data Safety Monitoring Boards (DSMB)

2018 – 2020	Member, Safety Advisory Board Minerva compound MIN-101, Negative Symptoms of Schizophrenia, A Multicenter, Randomized, Double-blind, Parallel-Group, Placebo-Controlled, Monotherapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of MIN-101 in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 40-Week Open-Label Extension
2015 – 2017	Member, Otsuka-Lundbeck, Long acting Intramuscular Aripiprazole for maintenance treatment in Bipolar Disorder
2013 – 2015	Member, Hoffman-La Roche Ltd, Roche Depression Study NP25620 – Antidepressant

Advisor for submissions to Regulatory Agencies

2019	Advisor, FDA advisory committees, Jansen and Jansen, FDA Advisory Committee meeting for Esketamine MDSI.2109
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Grant Reviews

10/2018	Reviewer, SERV (Mental Health Services Research Committee)
10/2017	Reviewer, NIMH standing committee, SERV (Mental Health Services Research Committee)

06/2017	Reviewer, NIMH Special Emphasis Panel ZMH1 ERB - K (06): Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34)
04/2015	Reviewer, NIMH ZMH1 ERB-D 02 R, Early Phase Clinical Trials
01/2013 – 2015	Member NIMH FAST (New Experimental Medicine Studies: Fast-Fail Trials)
01/1992 – 1996	Member NIMH Epidemiology and Genetics Review Committee

Administrative work with Professional Societies

10/2025- 09/2026	President American Association of Chairs of Departments of Psychiatry
10/2024- 09/2025	President-Elect American Association of Chairs of Departments of Psychiatry
10/2023- 09/2024	Secretary/Treasurer American Association of Chairs of Departments of Psychiatry
01/2014 – 01/2016	President, American Society of Hispanic Psychiatry
05/2013 – 05/2016	Member, Council on Research American Psychiatric Association
03/2010 – 03/2012	President, International Society of Bipolar Disorders
01/2009 – 12/2011	Council Member, International Society of Bipolar Disorders
01/1994 – 12/1997	Council Member, Research Council, American Psychiatric Association
01/1987 – 12/1997	Examiner, Part II American Board of Psychiatry and Neurology

Invited Lectures

12/2024	<u>Bipolar Disorder: Comorbid Conditions.</u> NH Psychiatry Grand Rounds. Virtual. (Invited Speaker)
04/2021	<u>First Episode Psychosis in Hispanic Youth.</u> 2nd Brazilian Congress of Psychiatry Online, Virtual (invited Speaker)
04/2021	<u>1st Episode Psychosis Care with a Focus in Minority Patients.</u> Grand Rounds at Department of Psychiatry of Queen's University in Kingston, ON. Virtual (Invited Speaker)
03/2021	A Shot for Bipolar I Disorder? Identifying Appropriate Patient Profiles for Maintenance Therapy with Long Acting Injectable Medications. Webinar for PsychU. Virtual (Invited Speaker)
03/2021	<u>Predictors of Outcomes in Bipolar Disorder.</u> Psychiatry Grand Rounds at U Penn, Penn Medicine Princeton Health, Plainsboro, NJ. Virtual (Invited Speaker)
02/2021	<u>Primer Episodio de Psicosis en la Comunidad Hispana en EEUU.</u> Constancia Conferencista 2º Curso Internacional de Actualización en Neuropsicofarmacología 2021. Virtual (Invited Speaker)
06/2018	<u>Outcomes in First Episode Psychosis/Mania.</u> Grand Rounds at Texas Tech University, Health Science Center, El Paso, Texas, US (Invited Speaker)
04/2018	<u>Outcomes in First Episode Psychosis/Mania.</u> Grand Rounds at University of Utah, Utah, US (Invited Speaker)
11/2017	<u>Academia, Investigación Y Docencia;</u> La Psiquiatría en la Salud Mental: Neurociencias, psiquiatría Clínica y Sociocomunidad, XXV Congreso Nacional y V Internacional de la Asociación Psiquiátrica Mexicana AC. Mérida, Yucatán, México (Invited Speaker)

11/2017 Lecciones Sobre el Primer Episodio del Trastorno Bipolar; La Psiquiatría en la Salud Mental: Neurociencias, psiquiatría Clínica y Sociocomunidad, XXV Congreso Nacional y V Internacional de la Asociación Psiquiátrica Mexican AC. Merida, Yucatan, Mexico (Invited Speaker)

05/2014 Clinical Epidemiology of Bipolar Disorder; Grand Rounds at University of Miami Health System, Miami, Florida (Invited Speaker)

02/2011 Outcomes in Bipolar Disorders; International Society for Bipolar Disorders, Munich, Germany (Invited Speaker)

11/2010 Outcomes in Bipolar Disorder; International Society for Bipolar Disorders, Tokyo, Japan (Invited Speaker)

10/2010 Outcomes in Bipolar Disorders; International Society for Bipolar Disorders, Mexico City, Mexico (Invited Speaker)

09/2010 Drug Development in Bipolar Disorders; 1st Meeting of East Asian Bipolar Forum and The Inaugural Meeting of the International Bipolar Disorders Society, International Bipolar Disorders Society, Korea (Keynote Speaker)

09/2010 Tratamiento De Mantenimiento Y Desenlace De Los Trastornos Bipolares; International Bipolar Disorders Society, Medellin, Columbia (Keynote Speaker)

09/2010 Novel Analysis in Outcomes in Bipolar Disorders; International Society for Bipolar Disorders, Budapest, Hungary (Invited Speaker)

09/2010 Outcomes in Bipolar Disorders; International Society for Bipolar Disorders, Seoul, South Korea, (Invited Speaker)

05/2010 Treatment in Bipolar Disorders; International Bipolar Disorders Society, Japan (Invited Speaker)

04/2010 Current Research and Future Perspectives in the Psychiatry/Mental Health Field; Pontificia Universidad Javerina Bogota Columbia Hospital, Bogota, Colombia (Invited Speaker)

03/2010 Nomenclature Course and Outcome in Bipolar Disorders; 2010 Annual Meeting International Society for Bipolar Disorders, San Pablo, Brazil (Keynote Speaker)

01/2010 Outcome in Bipolar Disorders; St. Patrick's Hospital, Dublin, Ireland, (Invited Speaker)

12/2009 Olanzapine in Bipolar Depression; American College of Neuropsychopharmacology (ACNP) Annual Meeting, Ft. Lauderdale, Florida (Invited Speaker)

11/2009 Treatment and Outcome in Bipolar Disorder; Turkish Psychiatric Association, Turkey (Invited Speaker)

11/2009 Conflict of Interest; Texas Psychiatric Society, Galveston, Texas (Invited Speaker)

11/2009 Treatment in Bipolar Mania; XV Reunion Annual Asociación Psiquiátrica Mexicana, Acapulco, Mexico (Invited Speaker)

10/2009 Outcome in Bipolar Disorders; XXV Annual Meeting, Mexican Institute of Psychiatry, Tlalpan, Mexico City, Mexico (Invited Speaker)

10/2009 Outcome in Manic Disorder; National Institute of Psychiatry, Buenos Aires, Argentina (Invited Speaker)

06/2009 Nomenclature Course and Outcome in Bipolar Disorder; International Conference of Bipolar Disorders, Pittsburgh, PA (Invited Speaker)

04/2009 Outcome in Mania; World Psychiatric Association International Congress, "Treatments in Psychiatry: A New Update", Florence, Italy (Invited Speaker)

01/2009	<u>Outcome and Treatment in Bipolar Disorder</u> ; International Society for CNS Clinical Trials and Methodology (ISCTM) IV Bipolar Symposium, Barcelona, Spain (Invited Speaker)
07/2008	<u>Maintenance Treatment of Bipolar Disorders</u> , East Asia Bipolar Symposium, Fukuoka, Japan (Keynote Speaker)
01/2008	<u>Nomenclature in Course and Outcome in Bipolar Disorders</u> ; 3rd Biennial Conference of the International Society for Bipolar Disorders, New Delhi, India.
2007	<u>Outcome and Maintenance Treatment in Bipolar Disorder</u> ; Australasian Society for Bipolar and Depressive Disorders Conference, Sydney, Australia.
2007	<u>Predictors of Syndromal and Functional Recovery in Patients with a First-episode of Mania</u> ; Australasian Society for Bipolar and Depressive Disorders Conference, Sydney, Australia.
08/2006	<u>Baseline Characteristics and Outcomes in First and Multiple Episode Patients with Acute Mania</u> ; 114 th Annual American Psychological Association Convention, New Orleans, Louisiana.
2006	<u>Update on the Treatment of Bipolar Disorders</u> ; Taiwan Society of Psych Annual Meeting.
10/1988	<u>Outcome in Bipolar Disorder</u> , Continuing Medical Education (CME) Lecture, Emerson Hospital, Concord, Massachusetts (Invited Speaker)
05/1988	<u>Psychiatric Epidemiology</u> , Continuing Medical Education (CME), Hampstead Hospital, Hampstead, New Hampshire (Invited Speaker)

Media Communications

03/2021	<u>One Year Later: A look back at the pandemic's impact on mental health</u> . KOB4 News Story. https://www.kob.com/new-mexico-news/one-year-later-a-look-back-at-the-pandemics-impact-on-mental-health/6038793/
03/2021	<u>Doctors hope to study long term mental health effects of COVID-19</u> . KOB4 News Story. https://www.kob.com/albuquerque-news/doctors-hope-to-study-long-term-mental-health-effects-of-covid-19/6041747/?cat=13516
05/2020	Tohen, M. (2020, May 21). First episode of psychosis in Hispanic American youth challenges during a pandemic [Video]. YouTube. https://www.youtube.com/watch?v=m74krqr5XKM
10/2022	<u>Bond seeks \$36M for new pediatric psychiatric center</u> . KOB4 News Story. https://www.kob.com/new-mexico/bond-seeks-36m-for-new-pediatric-psychiatric-center/

Narrative Description of Research, Teaching, and Service Interests

Mauricio Tohen, MD, DrPH, MBA, is a University Distinguished Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the University of New Mexico Health Science Center, Albuquerque NM. From 2009 to 2013 he was a Professor of Psychiatry and The Krus Endowed Chair in Psychiatry at the University of Texas Health Science Center at San Antonio. Dr. Tohen received his medical degree from the National University of Mexico and his Doctor of Public Health degree in Epidemiology from Harvard University. His postdoctoral training included a residency in Psychiatry at the University of Toronto, a clinical fellowship at McLean Hospital and Harvard Medical School, and a teaching fellowship in Epidemiology at the Harvard

School of Public Health. From 1988 to 1997, Dr. Tohen was the Clinical Director of the Bipolar and Psychotic Disorders Program at McLean Hospital. From 1997 to 2008 he was a member of Lilly Research Laboratories reaching the senior-most scientific level of Distinguished Lilly Scholar. In 2009 he joined the University of Texas Health Science Center at San Antonio as the Head of the Division of Mood and Anxiety Disorders. Dr. Tohen received a National Service Award in Psychiatric Epidemiology from the National Institute of Mental Health (NIMH) and Harvard University. He also received a FIRST award from the NIMH, the Pope Award from McLean Hospital, and a NARSAD Young Investigator Award and the Simon Bolivar Award from the American Psychiatric Association. In 2014 he was named by Thomson Reuter's "The World's Most Influential Scientific Minds, 2014". Honorees were the scientists who ranked in the Top 1 percent by citations of their published work in 21 broad fields between 2002 and 2012.

Dr. Tohen is one of 100 scientists worldwide recognized in the Psychiatry/psychology category. He has served on the Epidemiology and Genetics and the Clinical Centers and Special Projects Grant Member NIMH ZMH1 ERB-D 02 R, Early Phase Clinical Trials Member NIMH FAST (New Experimental Medicine Studies: Fast-Fail Trials) review group. Review committees at the NIMH. Dr. Tohen's research, supported by grants from the NIMH and the pharmaceutical industry, has focused on the epidemiology, outcome, and treatment of bipolar disorder. He was the President of the International Society for Bipolar Disorders (2010-2012) He was recently selected as President elect (2013-2015) of the American Society of Hispanic Psychiatry. Dr. Tohen has contributed more than 300 original publications. He has co-edited four books: Psychiatric Epidemiology (1995 first edition, 2002 second edition & 2011 third edition); Mood Disorders Across the Life Span (1996); Bipolar Disorder: Comorbidity in Affective Disorders (1999). The Upswing in Research and Treatment (2005); and Bipolar Psychopharmacotherapy, first edition (2006), second edition (2011). He also edited the book Comorbidity in Affective Disorders (1999). Clinical Trial Design Challenges in Mood Disorders (2015), first edition. In 2014 Dr Tohen was recognized in Thomson Reuter's "The World's Most Influential Scientific Minds, 2014". Honorees were the scientists who ranked in the top 1 percent by citations of their published work in 21 broad fields between 2002 and 2012. Dr. Tohen was one of 100 scientists worldwide recognized in the Psychiatry/psychology category.

In 2016 the International Society for Bipolar disorders awarded him the Mogens Schou award for Education and Teaching.

In 2017 and in 2021 Dr Tohen was Recognized by Expertscape as having the top % 0.12 expertise in bipolar disorder worldwide based on citations of published articles between 2007-2017 and between 2010-2021

In 2024 Dr Tohen's total citations added up to 40,814, with a D-Index of 106.

Scholarly Achievements

Abstracts:

1. Tohen M: Deprescribing (2025 June) American Association of Clinical Psychopharmacology. Phoenix, Arizona
2. **Tohen M.** Psychiatric Emergency visits for minor in New Mexico. (2025 March) CYBD's World Bipolar Day Research Symposium 2025. Toronto Canada.

3. McIntyre R S, **Tohen M**, Mattingly G, Vieta E , Citrome L , Clayton A H, Yu J, Nguyen H-B. Early Improvement of Symptoms in Bipolar I Depression Predicts Functional Remission and Recovery: A Post Hoc Analysis (2025 March). 2025 NP Institute Orlando Florida.
4. **Tohen M**, Sheinthal S, and KMW. Steering through Rough Waters: How to be Successful Agents of Change Management (2024) AACDP-AADPRT workshop 2024
5. Roger S. McIntyre, **Tohen M**, Gregory Mattingly, Eduard Vieta, Jun Yu, Huy-Binh Nguyen. Relationship Between Symptomatic and Functional Improvement During Cariprazine Treatment in Patients With Bipolar I Depression: Post Hoc Analysis of a Randomized, Placebo-Controlled Trial. (2024 Dec). 2024 ACNP.
6. **Tohen M**. Emergency psychiatry in New Mexico: advances and challenges. (2024 November) 24th World Congress of Psychiatry, Mexico City.
7. Castilla Puentes RC, Montano P, Tohen, Ng B, Colon-Rivera H. Latinx/Hispanic Communities and Mental Health: Identifying Barriers to Access and Potential Solutions During Unsettled Times. (2021 05). 2021 APA Annual Meeting, Virtual.
8. **Tohen M**, Friedman B, Crisanti A, Duran D. Characteristics of Hispanics Referred to Coordinated Specialty Care for First Episode of Psychosis and Factors Associated with Enrollment (poster P11-078). (2021 05). 2021 APA Annual Meeting, Virtual.
9. Salvatore P, Khalsa HK, **Tohen M**, Baldessarini RJ, Maggini C. Subjective experience disturbances and nuclear psychopathology among 258 mid-course schizophrenia-spectrum disorders subjects. (2020 01). McLean Research Day.
10. Tsai J, **Tohen M**, Pikalov A, Loebel A. Efficacy of Lurasidone in Bipolar Depression: Pooled Results of Two Adjunctive Studies with Lithium or Valproate. (2015). ASCP.
11. Khalsa HM-K, **Tohen M**., Baldessarini R.J., Salvatore P. Aggressive or Homicidal Ideation and Behavior in 500 Patients Hospitalized for a First-episode Psychotic Disorder: Relationship to Clinical Diagnosis (2015). Harvard Research Day. 2015
12. De La Garza II R, Ahmed A, Arango V, Bolanos-Guzman C, Deas D, Johnson B, Laje G, Lotrich F, **Tohen M**, Zarate C. The Minority Task Force of ACNP (2014). ACNP Meeting, 2014
13. Feldstein Ewing S, Montanaro E, **Tohen M**, Bryan A. Improving addictions treatment outcomes for Hispanic youth: Analyzing results from a brief intervention targeting alcohol and marijuana use. (2014) National Hispanic Science Network, El Paso, TX.
14. **Tohen M**. Fostering the Therapeutic Alliance Brainstorm Session. Parallel Sessions: Partnership Alliance Part II. Two Tracks: Consumer/Clinician Partnership Track: Answering the Tough Questions Together – Part II. Research Participant/Researcher Partnership Track: Opening Doors to New Research – Part II. June 15th, 2013. (Presented DBSA 2013 National Conference, Miami FL).
15. **Tohen M**, Brunner E, Osuntokun O, Landry J, Schroer R, Thase, M. Longer-term Efficacy and Safety of Olanzapine and Fluoxetine Combination Versus Fluoxetine Monotherapy Following Successful Combination Therapy of Treatment-resistant Depression 2012 Dec. (Presented ACNP 51st Annual Meeting).
16. Quinones J, Bowden CL, **Tohen M**, Gonzalez JM, Singh V, Thompson PM. Deconstructing the clinical effects of antidepressants in bipolar disorder using symptom

- domains derived from the bipolar inventory of signs and symptoms scale (BISS) 2012 Feb. p. 294-294. (Biological Psychiatry; vol. 71, no. 8S).
17. Katagiri H, **Tohen M**, McDonnell DP, Fujikoshi S, Case M, Kanba S, Takahashi M, Gomez JC. Long-term safety and efficacy of olanzapine in the treatment of Japanese patients with bipolar I disorder, depressed. June 3-7, 2012. (Presented at the 28th CINP World Congress of Neuropsychopharmacology Stockholm, Sweden).
 18. **Tohen M**. Olanzapine vs. Placebo in Bipolar Depression 2011 Jun. (9th International Conference on Bipolar Disorders (ICBD), Pittsburgh, PA).
 19. Ketter TA, Leon AC, Calabrese JR, Kemp DE, Thase ME, Bowden CL, **Tohen M**, Friedman, ES, Kocsis JH, Shelton, RC, McInnis MG, McElroy SL, Reilly-Harrington, NA, Sylvia LG, Deckersbach T, Nierenberg AA. Bipolar Clinical and Health Outcomes Initiative in Comparative Effectiveness (Bipolar CHOICE): Rationale and Design 2011. (Presented at the ACNP in 2011).
 20. Bowden CL, Mintz J, **Tohen M**, Calabrese J, Davis J. Development of Novel Integrative Multistate Measures of Efficacy, Tolerability and Functional Status in Maintenance Clinical Trials for Bipolar Disorder 2011. (Presented at the ACNP in 2011).
 21. **Tohen M**, Mintz J, Bowden CL, Calabrese J, Davis J. Use of the Functional Adjusted Clinical States in Bipolar Disorder Methodology in the Lamotrigine Registration Studies in Bipolar Disorder 2011. (Presented at the ACNP in 2011).
 22. **Tohen M**, Frank E, Bowden C, Colom F, Ghaemi NS, Yatham LM. International Society of Bipolar Disorders (ISBD) task force of the nomenclature of course and outcome in bipolar disorders 2010 Apr. p. S14-S15. (Journal of Affective Disorders; vol. 122, no. 1).
 23. Calabrese JR, Ganocy S, Brecher M, Carlson B, Edwards S, Eudicone J, Evoniuk, Jansen W, Kemp D, McQuade R, Millen B, Minkwitz M, Owen R, Pikalov A, Szegedi A, **Tohen M**, Vester-Biokland E, van Willigenburg A. Early Improvement as a Predictor of Response and Remission from 10 Placebo-Controlled Acute Bipolar I or II Depression Trials 2008. (3rd Biennial Conference of the International Society for Bipolar Disorders, New Delhi, India).
 24. Cruz N, Goikolea JM, **Tohen M**, Baldessarini RJ, Vieta E. Placebo Response in Placebo-Controlled Trials 2008. (3rd Biennial Conference of the International Society for Bipolar Disorders, New Delhi, India).
 25. Yatham LN, **Tohen M**, Wang W. Developed and Non-Developed Countries: Is There a Difference in Active Treatment and Placebo Response in Patients with Bipolar Depression 2008 Jan. (3rd Biennial Conference of the International Society for Bipolar Disorders, New Delhi, India).
 26. Calabrese JR, Ganocy S, Brecher M, Carlson B, Edwards S, Eudicone J, Evoniuk, Jansen W, Kemp D, McQuade R, Millen B, Minkwitz M, Owen R, Pikalov A, Szegedi A, **Tohen M**, Vester-Biokland E, van Willigenburg A. Early Improvement as a Predictor of Response and Remission from 10 Placebo-Controlled Acute Bipolar I or II Depression trials 2008. (3rd Biennial Conference of the International Society for Bipolar Disorders, New Delhi, India).

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28. Severus E, Lipkovich I, Young AH, **Tohen M**. Do lithium levels to prevent depressive episodes differ from those to prevent manic/mixed episodes in bipolar disorder? 2007. (7th International Conference on Bipolar Disorder, Pittsburgh, PA).
29. **Tohen M**, Sutton V. Maintenance treatment of mixed mania in patients who remitted after acute treatment with olanzapine: a double-blind, placebo-controlled study 2007. (7th International Conference on Bipolar Disorder, Pittsburgh, PA).
30. **Tohen M**, Bowden CL, Smulevich A, Kryzhanovskaya L, Osuntokun O, Wang WV, Martenyi F. Olanzapine plus Carbamazepine Vs. Carbamazepine in the Treatment of Mania: A 6-week, Double-blind, Randomized Trial 2007. (7th International Conference on Bipolar Disorder, Pittsburgh, PA).
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33. **Tohen M**, Kryzhanovskaya L, Carlson G, DelBello M, Wozniak J, Kowatch R, Wagner K, Findling R, Lin D, Robertson-Plouch C, Xu W, Huang X, Dittman R, Biederman J. Olanzapine in the Treatment of Acute Mania in Adolescents with Bipolar I Disorder: A 3-Week Randomized Double-Blind Placebo-Controlled Study 2006. (Biol Psychiatry; vol. 59, no. 387).
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35. Kryzhanovskaya L, Schulz C, McDougale C, Frazier J, Dittman R, Robertson-Plouch C, Bauer T, Xu W, Wang WV, Carlson J, **Tohen M**. A Double-Blind, Placebo-Controlled Study of Olanzapine in Adolescents with Schizophrenia 2006. (Biol Psychiatry; vol. 59, no. 733).
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37. Kryzhanovskaya L, Schulz C, McDougale C, Frazier J, Dittman R, Robertson-Plouch C, Bauer T, Xu W, Wang WV, Carlson J, **Tohen M**. A Double-Blind, Placebo-Controlled Study of Olanzapine in Adolescents with Schizophrenia 2006. p. S104-105. (European Psychiatry; vol. 21, no. Supp1).
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43. Kryzhanovskaya L, Schulz C, McDougale C, Frazier J, Dittman R, Robertson-Plouch C, Bauer T, Xu W, Wang WV, Carlson J, **Tohen M**. A Double-Blind, Placebo-Controlled Study of Olanzapine in Adolescents with Schizophrenia 2006. (APA).
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47. **Tohen M**. Analyses of Treatment Efficacy in Subtypes of Adolescent Patients with Bipolar Disorder Treated with Olanzapine for Acute Mania: A 3-Week Randomized Double-Blind Placebo-Controlled Study 2006. (NCDEU 46th Annual Meeting).
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51. **Tohen M**, Kryzhanovskaya L, Carlson G, DelBello M, Wozniak J, Kowatch R, Wagner K, Findling R, Lin D, Robertson-Plouch C, Xu W, Dittmann R, Biederman J. Efficacy of Olanzapine for the Treatment of Acute Mania in Subtypes of Adolescent Patients: A 3-Week Randomized Double-Blind Placebo-Controlled Study 2006. (2nd Biennial Conference of the International Society for Bipolar Disorders).

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53. Vieta E, Panicali F, Goetz I, Reed C, Comes M, **Tohen M**. Olanzapine in the Treatment of Mania: 12-Week Results from the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM) Observational Study 2006.
54. **Tohen M**, Bowden CL, Smulevich A, Kryzhanovskaya L, Bergstrom R, Quinlan T, Osuntokun O, Wang WV, Martenyi F. Olanzapine Plus Carbamazepine Vs. Carbamazepine in the Treatment of Mania: A 6-week, Double-blind, Randomized Trial (Abstract #59) 2006. (Neuropsychopharmacology; vol. 31-S1, no. S221).
55. Corya S, Keck P, Vieta E, Niswander J, Xu W, **Tohen M**, Risser R. Olanzapine/Fluoxetine and Olanzapine Treatment for Bipolar Depression: Open-Label Continuation in Rapid Cycling Patients 2005. (5th International Review of Bipolar Disorders).
56. Yurgelun-Todd D, Gruber SA, Risser R, Briggs SD, **Tohen M**. Neurocognitive Function after Treatment with Lithium or Olanzapine: A Double-Blind Study 2005. (Biological Psychiatry, 6th Annual Convention and Scientific Program).
57. Ketter TA, Houston JP, Risser R, Adams DH, Meyers A, Williamson D, **Tohen M**. Olanzapine and Lithium Prophylaxis of Bipolar Disorder and Episode History 2005. (Biological Psychiatry, 6th Annual Convention and Scientific Program; vol. 57, no. 8S).
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65. Salvatore P, Baldessarini RJ, **Tohen M**, Khalsa H-M K, Hennen J, Gonzalez-Pinto A, Baethge C. Morbidity from onset in First-episode Bipolar I Disorder Patients: The Bipolar International 300 Study 2005. (6th International Conference of Bipolar Disorder; vol. 7, no. 2).
66. Berk M, Vieta E, Yatham L, **Tohen M**. Moving the field forward: The impact of research driven educational initiatives on bipolar patients and providers 2005. (Symposium 12, International Society for Bipolar Disorders).
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73. Keck P, Calabrese JR, Corya SA, Andersen S, Gillig M, Baker RW, **Tohen M**. Olanzapine/fluoxetine combination in the treatment of rapid-cycling bipolar depression 2004. (Int'l Society for Bipolar Disorders 1st Regional Group Conference (poster)).
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86. **Tohen M**. Predictors of Outcome in 52 cases of psychotic nonaffective disorders 2004. (APA (American Psychiatric Association) Annual Meeting).
87. **Tohen M**, Risser R, Detke H, Forrester T, Corya S. Time in Euthymia for bipolar patients receiving olanzapine or lithium maintenance treatment (Poster No.67) 2004. (NCDEU 44th Annual Meeting).
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93. **Tohen M**, Bowden CL, Calabrese J, Sachs G, Risser RC, Detke HC, Shen H. Predictors of time to relapse in bipolar I disorder 2004. (Int'l J of Neuropsychopharmacology, XXIV CINP Congress).
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104. Corya S, Case M, Briggs SD, **Tohen M**. Olanzapine/fluoxetine combination for treatment-resistant depression 2004. (World Psychiatric Association International Congress).
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Presentations:

1. 2025 Vumedi Week. Virtual. Tips for Treating Bipolar Disorder. **Tohen. M**. Presentend Virtually Aug. 25-29, 2025.
2. 2025 ASCP Annual Meeting. Scottsdale Arizona. Practical Considerations for Deprescribing Psychiatric Medication. **Tohen M**. Presented in Person May 29th, 2025.
3. CYBD's World Bipolar Day Research Symposium 2025. Toronto Canada. Psychiatric Emergency visits for minor in New Mexico. **Tohen M**. Presented in person March 27th, 2025.
4. 24th World Congress of Psychiatry. Emergency psychiatry in New Mexico: advances and challenges. **Tohen. M** Presented in Person November 17th, 2024.
5. Long-Acting Injectables & Bipolar Disorder. **Tohen. M** Presented Virtually Jun 27, 2024.
6. ECHO Mental Health Central America Telementoring Series: Bipolar Disorder. **Tohen. M** Presented April 18th, 2024.
7. First episode psychosis in the Hispanic population. **Tohen M**. Plenary Lecture Presentation for American Society of Hispanic Psychiatry Annual Meeting; Critical Research Issues In Latinx Mental Health 2024, Presented in New York City May 3, 2024.
8. Social Determinants of Mental Health. **Tohen. M** Presented in person May 21st – 25th, 2022.

9. Latinx/Hispanic Communities and Mental Health: Identifying Barriers to Access and Potential Solutions During Unsettled Times. Castilla Puentes RC, Montano P, **Tohen M**, Ng B, Colon-Rivera H. Poster presented at the 2021 APA Annual Meeting, Virtual, May 3, 2021.
10. . Characteristics of Hispanics Referred to Coordinated Specialty Care for First Episode of Psychosis and Factors Associated with Enrollment (poster P11-078). **Tohen M**, Friedman B, Crisanti A, Duran D. Poster presented at the 2021 APA Annual Meeting, Virtual, May 3, 2021.
11. Implications for Latinos with Serious Mental Illness (SMI) During a Pandemic. **Tohen M**. Presentation for National Hispanic and Latino MHTTC, Virtual, May 21, 2021.
12. First episode of psychosis in Hispanic American youth challenges during a pandemic **Tohen M**. Presentation for National Hispanic and Latino MHTTC, Virtual, May 21, 2021. <https://www.youtube.com/watch?v=m74krqr5XKM>
13. A Clinicians Guide to First Episode Psychosis for Latinx Youth. Tohen M, Friedman B, Halperin D. Presentation for National Hispanic and Latino MHTTC, Virtual, February 26, 2021.
14. Long-term Morbidity in Major Affective & Schizoaffective Disorders Following Hospitalization in First Psychotic Episodes. Salvatore P, Khalsa H-MK, Tohen M & RJ Baldessarini, McLean International Consortium for Mood & Psychotic Disorders. Virtually presented at McLean Hospital Research Day (January 2021) and Harvard Medical School Psychiatry Research Day (April 2021).
15. Predicting long-term Morbidity in Major Affective & Schizoaffective Disorders with Psychotic Features. Salvatore P, Baldessarini RJ, Khalsa H-MK & Tohen M, McLean International Consortium for Mood & Psychotic Disorders. Virtually presented at McLean Hospital Research Day (January 2021) and Harvard Medical School Psychiatry Research Day (April 2021).
16. Basic Bipolar Disorder. Psychiatric Nurse Practitioner Program, University of New Mexico, Health Sciences Center, Albuquerque, NM, October 2, 2020.
17. Lost revenue and subsequent documentation improvement strategy in the department of psychiatry. Earl D, Gaudiot C, Cruz M, Corbin J, Sigl D, Montgomery L, Foley K, Hazelwood S, Nguyen J, Richardson E, **Tohen M**. Poster presented at UNM QIPS Conference, ABQ, NM March 2020.
18. 1st Episode Psychosis. September 20, 2019. Presented at 2019 Houston Mood Disorders Conference, Houston, TX.
19. Primer Episodio Psicótico: Las Patologías de Alta Frecuencia. July 1, 2019. Presented at XXII Symposium Internacional, Colegio Chileno de Neuropsicofarmacología.
20. Efficacy of Cariprazine in Patients With Bipolar Depression: Results From 3 Randomized, Double-Blind, Placebo-Controlled Trials. March 2019. Presented at 21st Annual ISBD Conference in Sydney, Australia.
21. Atopic-allergic-inflammatory-autoimmune diseases (AAIA) comorbidity and suicide in antecedent phases of first-psychotic episodes among 263 Bipolar-I Disorder patients. January 30, 2019. Presented at McLean Research Day.
22. Efficacy of Lurasidone in Preventing Recurrence of Bipolar Disorder: Results of a Multistate Outcome Analysis of Treatments (MOAT). December 2, 2017. ACNP Annual

- Meeting, Poster Session II. Presented as poster at ACNP Annual Meeting, Palm Springs, CA.
23. Outcome in First Episode Non-affective Psychosis. May 30, 2016. ASCP, NIA Workshop.
 24. Nomenclature in Course and Outcome in Bipolar Disorders 2007. (7th International Conference on Bipolar Disorder, Pittsburgh, PA).
 25. Manic/Hypomanic Symptoms During Depression. The Spectrum of Mixed States: A Bipolar CHOICE Study. May 31st, 2013. (Presented NCDEU 53rd Annual Meeting, Hollywood, FL).
 26. Defining Mood Stabilizers 2007. (2nd International symposium on Bipolar Disorders).
 27. Baseline Characteristics and Outcomes in First and Multiple Episode Patients with Acute Mania 2006. (APA).
 28. Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness): A Pragmatic Trial of Lithium vs. a Second Generation Antipsychotic for Bipolar Disorder. *Atlantic 1*. ASCP Annual Meeting, Hollywood, FL, June 2014.
 29. Shesler LW, Nierenberg AA, Sylvia LG, Kinrys G, McInnis M, Shelton R, McElroy SL, Kocsis JH, Friedman E, **Tohen M**, Bowden C, Ketter T, Calabrese J, Thase M, Reilly Harrington NA, Rabideau D, Deckersbach T. Clinical and Demographic characteristics Related to Quality of Life and Functioning in Bipolar Disorder: Findings from the Bipolar CHOICE study. Poster accepted to the 2013 Meeting of the Association for Behavioral and Cognitive Therapies, Nashville, TN.
 30. **Tohen M**, McIntyre R, Arsenault J. OLZ Efficacy on BP Dep with Mixed Features. 26th ECNP Congress, Barcelona, Spain.
 31. Katagiri H, **Tohen M**, McIntyre RS, Fujikoshi S, Kanba S. Efficacy of olanzapine monotherapy in the treatment of bipolar mania with mixed features as defined by DSM5. Presented as a poster at 29th CINP World Congress of Neuropsychopharmacology; June 22 – 26, 2014. Vancouver, Canada.
 32. Fostering the Therapeutic Alliance Brainstorm Session. Parallel Sessions: Partnership Alliance Part II. Two Tracks: Consumer/Clinician Partnership Track: Answering the Tough Questions Together – Part II. Research Participant/Researcher Partnership Track: Opening Doors to New Research – Part II, DBSA 2013 National Conference, Miami FL. June 2013. (Panelist Member).
 33. Manic/Hypomanic Symptoms During Depression. The Spectrum of Mixed States: A Bipolar CHOICE Study, International Conference on Bipolar Disorders, Miami Beach, FL. June 2013.
 34. The Spectrum of Mixed States: A Bipolar CHOICE Study, Manic/Hypomanic Symptoms During Depression, NCDEU 53rd Annual Meeting Sponsored by American Society of Clinical Psychopharmacology (ASCP), Hollywood, FL. May 2013.
 35. First Steps in Helping Patients With First-Episode Psychosis, Two year stability of diagnosis in First-Episode psychosis: The importance of close observation early in the course of the condition, American Psychiatric Association, San Francisco, California. May 2013.
 36. Investigacion en Latinoamerica sobre el transtorno bipolar, 15th World congress of Psychiatry, World Psychiatric Association, Buenos Aires, Argentina. September 2012.

37. Latest Research Findings & Implications on Mood Disorders, Annual PBRN convocation Agenda, South Texas Psychiatric Network/VA Mental Health Network, San Antonio, TX. October 2011.
38. Olanzapine vs. Placebo in Bipolar Depression, 9th International Conference on Bipolar Disorder (ICBD), Pittsburgh, PA. June 2011.
39. New Approaches to Somatic Treatment, 9th International Conference on Bipolar Disorder (ICBD), Pittsburgh, PA. June 2011.
40. International Society for Bipolar Disorder (ISBD) Task Force Reports, 9th International Conference on Bipolar Disorder (ICBD), Pittsburgh, PA. June 2011.
41. Outcome and maintenance treatment in Bipolar Disorders, 4th International Forum INNOPSY 11, Implications for Treatment, New Clinical and Bio-Pathogenetic Models in Psychopathology., Milan, Italy. May 2011.
42. Transforming Mental Health Through Leadership, Discovery, and Collaboration: From Clinical Epidemiology to Clinical Trials in Bipolar Disorder, Grand Rounds, Department of Psychiatry, The University of Texas Health Science Center at Houston, Houston, TX. May 2011.
43. Placebo use in bipolar clinical trials, International Society for Bipolar Disorders, Budapest, Hungary. March 2011.
44. Current Research and Future Perspectives in the Psychiatry/Mental Health Field of, 2010 Annual Meeting, American Psychiatric Association, New Orleans, LA. May 2010.
45. Interactive: What constitutes "evidence" in medicine?, The International Review of Bipolar Disorders, IRBD, Lisboa, Portugal (Co-Presenter) Details: Lisbon Symposium on Bipolar Disorders 09. May 2009.
46. The development role of antipsychotics in bipolar disorders: mania, mixed state and maintenance studies, The International Review of Bipolar Disorders, Lisbon Symposium on Bipolar Disorders 09, IRBD, Lisboa, Portugal. May 2009.
47. The 2008 Career Development Institute for Bipolar Disorder, Launching and Maintaining a Career in Bipolar Disorder Research, Department of Psychiatry, Biomedical science Tower, South Conference Center, The University of Pittsburgh. April 2008.
48. The International Society for Bipolar Disorders Task Force on the Nomenclature of Course and Outcome in Bipolar Disorders, Delhi, India. January 2008.
49. The International Society for bipolar Disorders Task Force on the Nomenclature of Course and Outcome in Bipolar Disorders, Agra, India. January 2008.
50. Career Development, Seminar Series, School of Medicine, Indiana University, Indianapolis, IN. October 2007.
51. Defining Mood Stabilizers, 2nd International Symposium, Bipolar Disorders, Budapest, Hungary. September 2007.
52. Predictors of syndromal and functional recovery in patients with a first-episode of mania, 2007 Conference, Australasian Society for Bipolar Disorders, Sydney, Australia. September 2007.
53. Nomenclature in Course and Outcome in Bipolar Disorders, 7th International Conference on Bipolar Disorder, Pittsburgh, PA. June 2007.
54. Comparison of Olanzapine response for teens and adults, AACAP, San Diego, CA. October 2006.

55. Analyses of Treatment Efficacy and Safety in Adolescents Compared to Adults with Bipolar Disorder Treated with Olanzapine for Acute Mania, 2006 Research Forum, American Academy of Child and Adolescent Psychiatry. October 2006.
56. Protective and Risk Factors for Pediatric Bipolar Disorder: Predicting Outcomes, 2006 Research Forum, American Academy of Child and Adolescent Psychiatry. October 2006.
57. Olanzapine in Adult and Adolescent Mania: A Summary of Two RCT, 5th Conference on Bipolar Disorder, European Stanley, Barcelona, Catalonia, Spain. October 2006.
58. Outcomes in Bipolar Disorders, Grand Rounds, University of Colorado, CO. September 2006.
59. Outcomes in Bipolar Disorders, School of Medicine, Indiana University, Indianapolis, IN. September 2006.
60. The McLean Harvard First Episode Mania Study, 2nd Biennial Conference, International Society for Bipolar Disorders, Edinburgh, Scotland, United Kingdom. August 2006.
61. Relapse Prevention in Bipolar Disorder, ISCTM, Chicago, IL. July 2006.
62. Outcomes in Bipolar Disorder, 9th Annual, Mental Health Symposium, Indianapolis, IN. June 2006.
63. Mood Stabilizers: Clinical Evidences of Efficacy from Acute to Maintenance Phase, XV congresso, Nazionale Della Societa Italiana Di Neuropsicofarmacologia, Genoa, Italy. June 2006.
64. Analyses of Treatment Efficacy in Subtypes of Adolescent Patients with Bipolar Disorder Treated with Olanzapine for Acute Mania: A 3-Week Randomized Double-Blind Placebo-Controlled Study, 46th Annual Meeting, NCDEU, Boca Raton, FL. June 2006.
65. Moving the field forward: The impact of research driven educational initiatives on bipolar patients and providers, Symposium 13, International Society of Affective Disorders, Lisbon, Portugal. March 2006.
66. Pharmacological treatment for mania, 15th Annual Meeting, Society of Clinical Neuropsychopharmacology, Tokyo, Japan. October 2005.
67. Moving the field forward: The impact of research driven educational initiatives on bipolar patients and providers, Symposium 13, International Society for Bipolar Disorders, Philadelphia, PA. June 2005.
68. Predictors of time to relapse in bipolar I disorder, XXIV CINP Congress, Paris, France. June 2005.
69. Predictors of time to relapse in bipolar I disorder, International Congress, World Psychiatric Association, Florence, Italy. November 2004.
70. El proyecto de primeros episodios de trastornos del espectro bipolar del Hospital McLean, 2nd National Meeting, Early Phases of Mental Illness: The Bipolar Spectrum Disorder, Santander, Spain. November 2004.
71. Nuevas fronteras en el trastorno bipolar, Tratamiento farmacologico en depresion bipolar y prevención de recaídas, 11th Congreso Internacional de Psiquiatría, Buenos Aires, Argentina. October 2004.
72. 05/2004, Predictors of Outcome in 52 cases of psychotic nonaffective disorders, Annual Meeting, CME Syllabus & Proceedings Summary, APA, New York, NY. May 2004.

73. Prediction of recovery and recurrence in patients with first episode mania, 2nd Biennial Conference, ISAD, Cancun, Mexico. March 2004.
74. Use of Olanzapine in Mania, SOPSI 2001, Rome, Italy. February 2001.
75. The Course of Mania and Schizobipolar Variants, International Conference, Coming of Age of the Bipolar Spectrum, San Diego, CA. November 2000.
76. Use of Antipsychotics in Bipolar Disorder. Bipolar Disorder: From Biological Mechanisms to Treatment, 50th Annual Meeting, Canadian Psychiatric Association, Victoria, British Columbia, Canada. October 2000.
77. Olanzapine versus Divalproex Sodium for the Treatment of Acute Mania, Conference on Bipolar Disorder, European Stanley Foundation, Amsterdam, Netherlands. September 2000.
78. The McLean First Episode Project: Two year syndromal and functional recovery in 219 cases of major affective disorders with psychotic features, 2nd Annual Conference on Bipolar Disorder, Stanley Foundation, Amsterdam, Netherlands. September 2000.
79. Il Disturbo Bipolare: Clinica E Terapia, Parma, Italy. June 2000.
80. Use of Antipsychotics in Mania, Annual Meeting, Israel Psychiatric Association, Jerusalem, Israel. April 2000.
81. Treatment of Acute Mania, Annual Meeting, Italian Psychiatric Association, Rome, Italy. February 2000.
82. Outcome Studies in Bipolar Disorder, 50 Years of Treatments for Bipolar Disorder: A Celebration of John Cade's Discovery, Sydney, Australia. December 1999.
83. Novel Antipsychotics and Mania, Simposio Internazionale dedicato a I 100 Anni Della "Follia Maniaco Depressiva" Di Emil Kraepelin, Rome, Italy. November 1999.
84. The Psychiatric Hospital in the Next Millennium, Regional Meeting, World Psychiatric Association, Buenos Aires, Argentina. October 1999.
85. New Pharmacological Interventions in the Treatment of Schizophrenia and Bipolar Disorders, 49th Annual Meeting, Canadian Psychiatric Association, Westin Harbour Castle, Toronto, Canada. September 1999.
86. Current and Emerging Clinical Data with Atypical Antipsychotics in the Treatment of Bipolar Disorder, 49th Annual Meeting, Canadian Psychiatric Association, Westin Harbour Castle, Toronto, Canada. September 1999.
87. New advancements in the management of bipolar disorder, 12th Congress, European College of Neuropsychopharmacology, London, United Kingdom. September 1999.
88. McLean Harvard First Episode Study, Grand Rounds, University of Illinois, Chicago, IL. September 1999.
89. Use of antipsychotics in bipolar disorder, Third International Conference on Bipolar Disorder, Pittsburgh, PA. June 1999.
90. The McLean First-Episode Project: Two-Year Syndromal and Functional Recovery in 219 Cases of Major Affective Disorders with Psychotic, Features Third International Conference on Bipolar Disorder, Pittsburgh, PA. June 1999.
91. What Works: Services for People with Dual Diagnosis, Annual Convention, NAMI, Washington, DC. June 1995.
92. Predictors of Outcome After a First-Episode of Psychosis Recovery from Psychiatric Disability, State House, Boston, MA. May 1995.

93. New Management Options in Bipolar Disorder, Grand Rounds, St. Vincent Hospital. October 1994.
94. Bipolar Disorder, MDDA Meeting, McLean Hospital, Belmont, MA. October 1994.
95. Mood Disorders Throughout the Lifespan, Satellite Symposium, 44th Annual Meeting, Canadian Psychiatric Association, Ottawa, Ontario, Canada. September 1994.
96. New Management Options in Bipolar Disorder, Annual Staff Meeting, Pharma-Care, Inc., Princeton, NJ. September 1994.
97. Bipolar Disorder, MDDA of Southern Massachusetts, Pembroke Hospital, Pembroke, MA. July 1994.
98. Psychiatric Epidemiology, Comprehensive Update in Psychiatry, McLean Hospital, Belmont, MA. March 1994.
99. Course and Outcome in Mania, Grand Rounds, University of Cincinnati, Cincinnati, OH. October 1993.
100. Diagnosis and Treatment of Bipolar Disorder, Universidad de Nuevo Leon, Monterrey, Mexico. October 1993.
101. Outcome in Mania, Universidad de Monterrey, Monterrey, Mexico. October 1993.
102. Preventing Recurrence of Affective Disorders, Mood Disorders, The Ontario College of Family Physicians, Toronto, Ontario, Canada. June 1993.
103. Psychiatric Epidemiology, Comprehensive Update in Psychiatry, McLean Hospital, Belmont, MA. March 1993.
104. The McLean First-Episode Mania Project, Grand Rounds, Psychopharmacology, Cambridge Hospital, Cambridge, MA. March 1993.
105. Manic Depressive Illness, "Talk About the Mind", hosted by Dr. J. Dreyfus, Milton Cable System, Milton, MA. February 1993.
106. The McLean First Episode Psychosis/Mania Project, Lecture Series, Massachusetts Mental Health Center Psychopharmacology, MA. February 1993.
107. New Directions in Assessment of Psychiatric Outcome, (Faculty), Department of Postgraduate and Continuing Education, McLean Hospital, Belmont, MA. December 1992.
108. First-Episode Psychosis, Grand Rounds, Worcester State Hospital, Worcester, MA. November 1992.
109. Course of Mania, Grand Rounds, Sunnybrook Hospital, University of Toronto, Toronto, Canada. June 1992.
110. Outcome in Mania, The First Annual Alfred Pope Award for Young Investigators, McLean Hospital, Belmont, MA. June 1992. Details: Four Year Prospective Follow Up of 75 Patients Utilizing Survival Analysis. Mauricio Tohen, MD, DrPH, recipient
111. Latest Advances in Research and Medications Workshop, Tenth Annual State Convention, Alliance of the Mentally Ill of Massachusetts, Boston Park Plaza Hotel, Boston, MA. May 1992.
112. Outcome in Mania, Grand Rounds, Lahey Clinic, Burlington, MA. May 1992.
113. Outcomes in Mania, Grand Rounds, University of Massachusetts, Worcester, MA. April 1992.
114. Psychiatric Epidemiology, McLean Hospital Comprehensive Review and Update in Psychiatry, McLean Hospital, Belmont, MA. March 1992.

115. Mania, Benefit, NARSAD, Belmont, MA. March 1992.
116. Psychiatric Epidemiology Lecture, PGII-III Residents, University of Massachusetts, MA. November 1991.
117. Psychotic Disorders, Comprehensive Update in Clinical Psychiatry, McLean Hospital, Belmont, MA. October 1991.
118. Outcome in Mania, Manic Depressive and Depressive Association of Worcester, University of Massachusetts, Worcester, MA. September 1991.
119. Outcome of Research in Mania, Manic Depressive and Depressive Association of Boston (MDDA Boston), Boston, MA. June 1991.
120. Psychiatric Epidemiology Lecture, MD-MPH Program, Tufts University, Medford, MA. April 1991.
121. Mental Illness: Myths and Realities. "Friend-Raising", Local Civic Leaders, McLean Hospital, Belmont, MA. April 1991.
122. Psychiatric Epidemiology, Comprehensive Update in Psychiatry, Hyatt Regency Hotel, McLean Hospital, Cambridge, MA. March 1991.
123. Psychotic Disorders, McLean Hospital Comprehensive Update in Clinical Psychiatry, McLean Hospital, Cambridge, MA. November 1990.
124. Mania in Old Age, Psychopharmacology Lunch Program, McLean Hospital, Belmont, MA. November 1990.
125. Bias in Outcome Research, Advances in Psychopharmacology and Behavioral Neurobiology, 1990 seminar series, Massachusetts General Hospital, MA. April 1990.
126. Differential Diagnosis in Psychotic Disorders, CME Lecture, Waltham-Weston Hospital, Waltham, MA. January 1990.
127. Psychotic Disorders. Comprehensive Clinical Update in Psychiatry, McLean Hospital, Belmont, MA. October 1989.
128. Outcome in Mania, Psychiatric Epidemiology Colloquium, Harvard Program in Psychiatric Epidemiology, Boston, MA. October 1989.
129. Predicting Outcome in Manic Depressive Patients, Psychiatry Grand Rounds, Mount Auburn Hospital, Cambridge, MA. April 1989.
130. Comprehensive Review and Update in Psychiatry, Psychiatric Epidemiology, McLean Hospital, Belmont, MA. March 1989.
131. Outcome in Bipolar Disorder, CME Lecture, Hampstead Hospital, Hampstead, NH. March 1989.
132. Outcome in Bipolar Disorder, Psychopharmacology Lecture Series, Massachusetts Mental Health Center, MA. February 1989.
133. Outcome in Bipolar Disorder, Academic Conference, McLean Hospital, Belmont, MA. December 1988.
134. Outcome in Bipolar Disorder, Mailman Research Center Academic Conference, McLean Hospital, Belmont, MA. September 1988.
135. Comprehensive Review and Update in Psychiatry, Psychiatric Epidemiology, McLean Hospital, Belmont, MA. April 1988.
136. Discussant for: Mortality and Causes of Death in Schizophrenia and Manic Depression, 26th Annual Conference, Boston Society of Neurology and Psychiatry, Boston, MA. September 1987. (Panel) Details: Speaker: Dr. Ming T. Tsuang

Original research or scholarly articles in refereed journals:

1. Goldberg JF, Swartz HA, Mago R, McIntyre RS, Malhi GS, Rosenblat JD, Freeman MP, Vieta E, Thase ME, **Tohen M**, Citrome L. (June 2025) What Is Meant by the Term "Deprescribing," and Does It Belong in Our Lexicon? J Clin Psychiatry. 2025 Jun 2;86(4):25ac15936. doi: 10.4088/JCP.25ac15936.PMID: 40488722
2. Salvatore P, Khalsa HK, Baldessarini RJ, **Tohen M**. (Apr. 2025) Suicide Attempts in First Episodes of Major Psychiatric Disorders With Psychotic Features. J Nerv Ment Dis. 2025 Apr-May 01;213(4):108-116. doi: 10.1097/NMD.0000000000001828.PMID: 40272938
3. Fountoulakis KN, Karakatsoulis G, Abraham S, Adorjan K, Ahmed HU, Alarcón RD, Arai K, Auwal SS, Berk M, Levaj S, Bobes J, Bobes-Bascaran T, Bourgin-Duchesnay J, Bredicean CA, Bukelskis L, Burkadze A, Abud IIC, Castilla-Puentes R, Cetkovich M, Colon-Rivera H, Corral R, Cortez-Vergara C, Crepin P, De Berardis D, Delgado SZ, De Lucena D, De Sousa A, Stefano RD, Dodd S, Elek LP, Elissa A, Erdelyi-Hamza B, Erzin G, Etchevers MJ, Falkai P, Farcas A, Fedotov I, Filatova V, Fountoulakis NK, Frankova I, Franza F, Frias P, Galako T, Garay CJ, Garcia-Álvarez L, García-Portilla MP, Gonda X, Gondek TM, González DM, Gould H, Grandinetti P, Grau A, Groudeva V, Hagin M, Harada T, Hasan TM, Razali S, Hilbig J, Hossain S, Iakimova R, Ibrahim M, Iftene F, Ignatenko Y, Irrarazaval M, Ismail Z, Ismayilova J, Jakobs A, Jakovljević M, Jakšić N, Javed A, Kafali HY, Karia S, Kazakova O, Khalifa D, Khaustova O, Koh S, Kopishinskaia S, Kosenko K, Vadon NB, Lalljee A, Liewig J, Majid A, Malashonkova E, Malik K, Malik NI, Mammadzada G, Mandalia B, Marazziti D, Marčinko D, Martinez S, Matiekus E, Mejia G, Memon RS, Martínez XEM, Mickevičiūtė D, Milev R, Mohammed M, Molina-López A, Morozov P, Muhammad NS, **Tohen M**, Tsapakis Marie E, Tukhvatullina D., Irfan Ullah, Ratnaraj Vaidya, Johann M Vega-Dienstmaier, Jelena Vrublevska, O. Vukovic, O. Vysotska, N. Widiastih, A.Yashikhina, D. Smirnova. (2025) Treatment and long- term outcome of mental disorders: The grim picture from a quasi-epidemiological investigation in 54,826 subjects from 40 countries. Psychiatry Res. 2025
4. Kumar P, Moomtaheen F, Malec SA, Yang JJ, Bologa CG, Schneider KA, Zhu Y, **Tohen M**, Villarreal G, Perkins DJ, Fielstein EM, Davis SE, Matheny ME, Lambert (2025 Feb) Detecting Opioid Use Disorder in Health Claims Data With Positive Unlabeled Learning. CG.IEEE J Biomed Health Inform. 2025 Feb;29(2):750-757. doi: 10.1109/JBHI.2024.3515805. Epub 2025 Feb 10.PMID: 40030473
5. Barans S, Saavedra JL, Lardier DT, **Tohen M**, Lenroot R, Bustillo J, Halperin D, Friedman B, Loewy R, Murray-Krezan C, McIver S, Crisanti (2025 Jan) Characteristics Associated with Engagement in the Early Detection Cascade of Care for Psychosis at a College Counseling Center. AS.Community Ment Health J. 2025 Jul;61(5):913-922. doi: 10.1007/s10597-024-01430-z. Epub 2025 Jan 5.PMID: 39757309.
6. Bell Lynum KS, Castro CF, Zhang Z, Patel M, **Tohen M**. (2024 Oct) Aripiprazole once-monthly for the treatment of adult patients with earlier-stage bipolar I disorder: a post

- hoc analysis of data from a double-blind, placebo-controlled, 52-week randomized withdrawal trial. *Int J Bipolar Disord*. 2024 Oct 27;12(1):37. doi: 10.1186/s40345-024-00358-
7. Vieta E, **Tohen M**, McIntosh D, Kessing LV, Sajatovic M, McIntyre RS. (2024 Oct) Early use of long-acting injectable antipsychotics in bipolar disorder type I: An expert consensus. *Bipolar Disord*. 2025 Feb;27(1):7-16. doi: 10.1111/bdi.13498. Epub 2024 Oct 22.
 8. Wrobel, M. Turner, O. M. Dean, M. Berk, L. G. Sylvia, M. E. Thase, T. Deckersbach, **M. Tohen**, M. G. McInnis, J. H. Kocsis, R. C. Shelton, M. J. Ostacher, D. V. Iosifescu, S. L. McElroy, A. Turner, A. A. Nierenberg. (2024 Dec) Understanding the relationship between childhood abuse and affective symptoms in bipolar disorder: New insights from a network analysis. *Psychiatry Research* 342 (2024) 116197 doi 10.1016/j.psychres.2024.116197. Epub 2024 Dec.
 9. **M. Tohen**, J. Yu, K. Kramer, H-B Nguyen. (2024 Oct) Early improvement with cariprazine as a predictor of antidepressant, anxiolytic, and antimanic response in bipolar I mania and depression: A pooled post hoc analysis of randomized cariprazine trials. *Journal Affective Disorder*. 1:362:194-200. doi: 10.1016/j.jad.2024.06.100. Epub 2024 Jun 26.
 10. Fountoulakis KN, Vrublevska J, Abraham S, Adorjan K, Ahmed HU, Alarcón RD, Arai K, Auwal SS, Berk M, Bjedov S, Bobes J, Bobes-Bascaran TB, Bourgin-Duchesnay J, Bredicean CA, Bukelskis L, Burkadze A, Cabrera Abud II, Castilla-Puentes R, Cetkovich M, Colon-Rivera H, Corral R, Cortez-Vergara C, Crepin P, De Berardis D, Delgado SZ, De Lucena D, De Sousa A, Di Stefano R, Dodd S, Elek LP, Elissa A, Erdelyi-Hamza B, Erzin G, Etchevers MJ, Falkai P, Farcas A, Fedotov I, Filatova V, Fountoulakis NK, Frankova I, Fianza F, Frias P, Galako T, Garay CJ, Garcia-Álvarez L, García-Portilla MP, Gonda X, Gondek TM, González DM, Gould H, Grandinetti P, Grau A, Groudeva V, Hagin M, Harada T, Hasan TM, Hashim NA, Hilbig J, Hossain S, Iakimova R, Ibrahim M, Iftene F, Ignatenko Y, Irarrazaval M, Ismail Z, Ismayilova J, Jacobs A, Jakovljević M, Jakšić N, Javed A, Kafali HY, Karia S, Kazakova O, Khalifa D, Khaustova O, Koh S, Kosenko K, Koupidis SA, Lalljee A, Liewig J, Majid A, Malashonkova E, Malik K, Malik NI, Mammadzada G, Mandalia B, Marazziti D, Marčinko D, Martinez S, Matiekus E, Mejia G, Memon RS, Meza Martínez XE, Mickevičiūtė D, Milev R, Mohammed M, Molina-López A, Morozov P, Muhammad NS, Mustač F, Naor MS, Nassieb A, Navickas A, Okasha T, Pandova M, Panfil AL, Panteleeva L, Papava I, Patsali ME, Pavlichenko A, Pejuskovic B, Pinto Da Costa MP, Popkov M, Popovic D, Raduan NJN, Ramírez FV, Rancans E, Razali S, Rebok F, Rewekant A, Reyes Flores EN, Rivera-Encinas MT, Saiz P, Sánchez de Carmona M, Saucedo Martínez D, Saw JA, Saygili G, Schneiderreit P, Shah B, Shirasaka T, Silagadze K, Sitanggang S, Skugarevsky O, Spikina A, Sira Mahalingappa SS, Stoyanova M, Szczegieliński A, Tamasan SC, Tavormina G, Tavormina MGM, Theodorakis PN, **Tohen M**, Tsapakis EM, Tukhvatullina D, Ullah I, Vaidya R, Vega-Dienstmaier JM, Vukovic O, Vysotska O, Widiastih N, Yashikhina A, Smirnova D. (2024 May 1) Non-binary gender, vulnerable populations and mental health during the COVID-19 pandemic: Data from the COVID-19 Mental health inTernational for the

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Review Articles

1. Sagman D, **Tohen M**. Comorbidity in Bipolar Disorder the Complexity of Diagnosis and Treatment *Psychiatric Times* 2012 Jun;XXIX(6)
2. **Tohen M**, Treuer T. Clinical Usefulness of Olanzapine in Bipolar Disorder-A Developer's Insight Touch Briefings 2009
3. **Tohen M**. Olanzapine use in bipolar disorder *Actas Españolas de Psiquiatría* 2008;36(Sup1):61-63.
4. **Tohen M**. Antipsychotic-induced EPS in bipolar disorder and schizophrenia. *Psych Times* 2003;20(54)
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7. **Tohen M**. The prognosis of bipolar disorder: Recent findings and informed speculation. *Currents in Affective Disorders* 1993;12:5-13.
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2. **Tohen M.** Depression y Ritmo Circadiano (Dissertation for specialty in Internal Medicine) 1979. 101 p.

Editorial

1. **Tohen M.** Need for Better Understanding of and Approach to Bipolar Disorder The Mainichi Medical Journal 2008 Jul;4(7):541-628.
2. **Tohen M.** Nomenclature in Bipolar Disorder. Clin Approaches in Bipolar Disorders 2006;5(35)
3. **Tohen M.** Classical Neuroleptics Are Still Relevant for Mania, Con J Bip Disorders 2005;IV(2)
4. **Tohen M.** Bipolar disorder is a lifelong condition Paradigm Mag 1996

Other

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3. **Tohen M.** In memoriam--Vivek Singh. *J Affect Disord*. 2016 Mar 15;193:144. doi: 10.1016/j.jad.2015.12.028.
4. Haro JM, Reed C, Gonzalez-Pinto A, Novick D, Bertsch J, Vieta E; **EMBLEM Advisory Board**. (2011 April). 2-Year course of bipolar disorder type I patients in outpatient care: factors associated with remission and functional recovery. *European Neuropsychopharmacology*, 21(4):287-93. doi: 10.1016/j.euroneuro.2010.08.001. Epub 2010 October 16.
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8. Vieta E, Angst J, Reed C, Bertsch J, Haro JM; **EMBLEM advisory board**. (2009 November). Predictors of switching from mania to depression in a large observational study across Europe (EMBLEM). *Journal of Affective Disorders*, 118(1-3):118-23. doi: 10.1016/j.jad.2009.02.007. Epub 2009 March 9.

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12. van Rossum I, Boomsma M, Tenback D, Reed C, van Os J; **EMBLEM Advisory Board**. (2009 January). Does cannabis use affect treatment outcome in bipolar disorder? A longitudinal analysis. *Journal of Nervous and Mental Disorders*, 197(1):35-40. doi: 10.1097/NMD.0b013e31819292a6.
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17. **Tohen M**, Risser R, Grundy SL. Reply to "Jagadheesan K. Olanzapine in acute bipolar mania" *Arch Gen Psych* 2002;59(2):188
18. **Tohen M**. Book Review: Understanding Depression: what we know and what you can do about it 2002:304
19. **Tohen M**. Course of mania and schizobipolar variants *Audio-Digest Psychiatry* 2001;30(4)
20. **Tohen M**. Manic illness drugs: patient responses *The Wall Street Journal* 2000 Dec
21. **Tohen M**, Grundy S. The use of mood stabilizers for treating psychotic disorders in acute mania *J Clin Psych, Audiograph Series* 1998;1(6)
22. **Tohen M**. Innovative approaches to treatment-resistant psychiatric disorders. *Psychiatric Annals*. 1998;28(11):616.
23. **Tohen M**. Racial-Differences In Leukocyte Counts - Reply *American Journal of Psychiatry*, 1996;153(4):587
24. **Tohen M**. Reply to Gordon MA: Carbamazepine associated thrombocytopenia *J Clin Psych* 1992;53:378-379.
25. Baldessarini R (English to Spanish translation by: **Tohen M**). Las bases biomedicas de la Depresion y su tratamiento (Original title: Biomedical Aspects of Depression and its Treatment) 1986.

26. **Tohen M**, Young D. San Fernando Hospital Case Study. Pew Curriculum Center for Health Policy and Management Harvard School of Public Health, President and Fellows of Harvard College 1983;3.

Research

Current Grant and Contract Funding:

- Title:** Feasibility of an Early Detection Program for Early Psychosis on a College Campus
Grant Number: 1 R34 MH120777-01
Principal Investigator: Annette S. Crisanti, Ph.D.
Role if not PI: **Co-Investigator**
Funding Organization: National Institute of Mental Health (NIMH)
Dates: August 15th, 2019 – May 31st, 2022
Amount Awarded: \$675,871.00
- Title:** The McLean First-Episode Psychosis Project
Role: Principal Investigator
Effort: 5%
Funding Agency: Atlas Foundation
Period: 01/2007 - 01/2020
Total Costs: \$250,000.00
Grant Detail: The primary goal of this study is to conduct follow up first episode psychosis/mania patients and to determine predictors of outcome. This study is conducted in collaboration with investigators at McLean Hospital and has been funded by a private foundation.

Past Grant and Contract Funding:

- Title:** Optimizing Outcomes in Bipolar illness Interventions in Hispanic Communities
Role: Co-Investigator
Effort: 10%
Funding Agency: National Institute of Mental Health (NIMH)
Period: 09/2011 - 06/2013
Total Costs: \$3,376,390.00
Grant Detail: An Advanced Center for Interventions and/or Service Research was established to conduct research that will personalize community based treatment of bipolar disorders to improve outcomes. We will investigate interactions of cultural factors, adherence and engagement, behavioral domains and biological factors with outcomes, thereby providing a model that can transform current diagnostic and treatment paradigms for bipolar disorder. A major aim of this proposal is to better develop our understanding of bipolar disorder in the Hispanic American population, in particular the impact of acculturation on adherence to treatment programs. These efforts will equip us to serve as a national resource to advance the NIMH mission of reducing the burden of bipolar illness and improve outcomes through the efforts of research about treatments and their acceptability to patients, and broadly disseminate this

research for the purposes of improving clinical care, public education and public health planning.

- **Title:** Improving Diabetes Risk Factors in Persons with Schizophrenia or Bipolar disorder by Switching to Ziprasidone
Role: Principal Investigator
Effort: 5%
Funding Agency: Pfizer
Period: 04/2007 - 12/2010
Total Costs: \$382,800.00
Grant Detail: Study addresses whether switching to Ziprasidone improved diabetes risk factors in patients with schizophrenia.
- **Title:** Analyses of Registration Bipolar Prophylaxis Trials to Develop New Study Designs
Role: Principal Investigator
Effort: 20%
Funding Agency: NIMH
Period: 09/2009 - 09/2011
Total Costs: \$723,678.00
Grant Detail: To provide methodologies which can facilitate the development of new evidence based interventions and to improve overall outcomes and reduce adverse effect burdens, the investigators plan novel research on data sets from 11 completed large, randomized, blinded, placebo controlled maintenance trials. To validate concepts on remission, recovery, response, relapse, recurrence, subsyndromal symptoms and mood switch the investigators shall test whether the concepts provide meaningful prediction of time to relapse/recurrence. Second, to test statistical techniques and outcome variables that incorporate different degrees of recovery, tolerability, adverse effects and functional status into integrated measures of bipolar outcomes, the investigators will develop measures that integrate results on efficacy, safety and function. Third, this research will identify illness characteristics which predict response to individual drugs and classes of drugs
- **Title:** Administrative Supplement to Bipolar Illness Intervention in Hispanic Communities
Role: Co-Investigator
Effort: 10%
Funding Agency: NIMH
Period: 09/2009 - 04/2011
Total Costs: \$172,943.00
Grant Detail: The purpose of this proposal is to upgrade the data management and data base components of our Developing Center for Interventions and Service Research in Bipolar Disorders (DCISR) and utilize the data base developed through the several activities of the DCISR to conduct an analysis with broad public health significance. We will re-engineer and expand the functions of the data base management system including: front end entry, data storage, web based entry from extramural sites and more

effective querying procedures. These advances will serve participating investigators, public sector clinicians and lay individuals who may thereby learn about research results and improve their effective knowledge about bipolar recognition and treatment.

- **Title:** Preventing morbidity in first episode schizophrenia
Role: Co-Investigator
Effort: 10%
Funding Agency: Feinstein Institute for Medical Research
Period: 07/2009 - 02/2013
Total Costs: \$112,563.00
Grant Detail: This study compares risperidone with aripiprazole for treatment of first episode schizophrenia.

- **Title:** P20 Developing Center for Bipolar Illness Interventions in Hispanic Communities
Role: Co-Investigator
Effort: 5%
Funding Agency: NIMH
Period: 08/2004 - 04/2009
Total Costs: \$2,470,727.00
Grant Detail: This program establishes a Developing Center for Interventions and Service Research (DCISR) that will forge an academic-community partnership to conduct interdisciplinary interventions research that will improve care of bipolar disorders, study moderators and mediators in the community that affect outcomes and participation in clinical research, and be of particular relevance to Hispanic Americans. The DCISR will enable the applicants to expand and develop their research capabilities, and contribute to greater alignment of research outcomes with community needs.

- **Title:** Longitudinal study of first-episode mania
Role: Principal Investigator
Effort: 50%
Funding Agency: NIMH FIRST Award MH51948-01A2
Period: 01/1995 - 12/2000
Total Costs: \$508,000.00

- **Title:** Predictors of Outcome After a First-Episode of Psychosis: Follow-up study of first-episode psychotic patients
Role: Principal Investigator
Effort: 50%
Funding Agency: NIMH MH 04844
Period: 01/1991 - 12/1994
Total Costs: \$103,000.00

- **Title:** Training in Psychiatric Epidemiology
Role: Trainee

Effort: 100%

Funding Agency: NIMH-T-32

Period: 01/1985 - 12/1988

- **Title:** DSM-5 Field Trial in Academic Institutions
Role: Principal Investigator
Effort: 20%
Funding Agency: American Psychiatric Association (APA)
Period: 09/2010 - 05/2011
Total Costs: \$183,250.00
Grant Detail: Field trials for depression, bipolar disorder, schizophrenia, and attenuated psychotic syndrome of proposed DSM-5 diagnostic criteria, for major academic sites, cross-cutting dimensional measures and diagnostic-specific severity measures. The objective is to assure that these proposed changes are subjected to rigorous and empirically sound field trials before DSM is released for general clinical and research use.
- **Title:** Seroquel vs. standard treatment cost effectiveness study
Role: Principal Investigator
Funding Agency: Zeneca Pharmaceuticals
Period: 01/1996 - 12/1997
Total Costs: \$138,000.00
- **Title:** Lamotrigine vs. placebo in the treatment of bipolar depression
Role: Principal Investigator
Funding Agency: Glaxo-Wellcome
Period: 01/1996 - 12/1997
Total Costs: \$286,000.00
- **Title:** Gabapentin vs. placebo as an adjunct treatment of bipolar mania
Role: Principal Investigator
Funding Agency: Parke-Davis
Period: 01/1996 - 12/1997
Total Costs: \$138,000.00
- **Title:** MDL 100, 907 in the treatment of schizophrenia
Role: Principal Investigator
Funding Agency: Dawes
Period: 01/1996 - 12/1997
- **Title:** Cost-effectiveness study of Valproate vs. Lithium
Role: Principal Investigator
Funding Agency: Abbott Pharmaceutical
Period: 01/1995 - 12/1996

Total Costs: \$174,000.00

- **Title:** Olanzapine vs. Risperidone in the treatment of schizophrenia
Role: Principal Investigator
Funding Agency: Lilly Research Laboratories
Period: 01/1995 - 12/1996
Total Costs: \$287,000.00
- **Title:** Sertindole vs. risperidone in treatment resistant schizophrenia
Role: Principal Investigator
Funding Agency: Abbott Laboratories
Period: 01/1995 - 12/1996
Total Costs: \$162,000.00
- **Title:** Different Industry Funds
Role: Principal Investigator
Funding Agency: McLean Hospital Pharmacoepidemiology Fund
Period: 01/1994 - 12/1997
- **Title:** Risperidone QD vs. BID dosing schizophrenia
Role: Principal Investigator
Funding Agency: Janssen Pharmaceutical Inc.
Period: 01/1994 - 12/1996
Total Costs: \$168,000.00
- **Title:** A 52-week, open extension study evaluation (ziprasidone)
Role: Principal Investigator
Funding Agency: Pfizer, Inc.
Period: 01/1994 - 12/1996
Total Costs: \$160,000.00
- **Title:** Forty week double-blind study evaluating the safety and efficacy of two dose regimens of ziprasidone in maintenance treatment of outpatients with schizophrenia and schizoaffective disorders
Role: Principal Investigator
Funding Agency: Pfizer, Inc.
Period: 01/1994 - 12/1996
Total Costs: \$268,000.00
- **Title:** Dose-response study in the treatment of Bipolar mania
Role: Principal Investigator
Funding Agency: The UpJohn Co.
Period: 01/1994 - 12/1995
Total Costs: \$35,000.00

- **Title:** Olanzapine vs. Haloperidol in the treatment of schizophrenia and other psychotic disorders
Role: Principal Investigator
Funding Agency: Lilly Research Laboratories
Period: 01/1993 - 12/1995
Total Costs: \$216,000.00
- **Title:** Open study of Risperidone in Bipolar Mania (investigator-initiated study)
Role: Principal Investigator
Funding Agency: Janssen Pharmaceutical Research Foundation
Period: 01/1993 - 12/1995
Total Costs: \$64,000.00
- **Title:** Efficacy and Tolerability of Ascending Doses of OPC-14597 compared to placebo and Haloperidol in acutely relapsing psychosis
Funding Agency: Otsuka America Pharmaceutical Inc.
Period: 01/1993 - 12/1994
Total Costs: \$150,000.00
- **Title:** DSM-IV field trial in Psychotic Disorders
Role: Principal Investigator
Funding Agency: John D. and Catherine T. MacArthur
Period: 01/1991 - 12/1994
Total Costs: \$10,000.00
- **Title:** First Episode Psychosis
Role: Principal Investigator
Funding Agency: NARSAD Young Investigator Award
Period: 01/1991 - 12/1994
Total Costs: \$50,000.00

Pending Grant and Contract Funding:

- **Title:** Once-weekly D-Cycloserine in Schizophrenia
Role: Co-Investigator
Effort: 2%
Funding Agency: Massachusetts General Hospital (The General Hospital Corp)
Period: 12/2011 - 11/2016
Total Costs: \$572,551.00
- **Title:** Comparative Effectiveness of a Second Generation Antipsychotic or a Mood Stabilizer
Role: Co-Investigator
Effort: 20%

Funding Agency: AHRQ, Subcontract w/Massachusetts General Hospital

Period: 08/2010 - 08/2013

Total Costs: \$146,954.00

Grant Detail: A 10-site, 6-month comparative effectiveness study is proposed of the prototypical second generation antipsychotic mood stabilizer quetiapine and the prototypical classic mood stabilizer lithium for 480 participants with bipolar disorder. In addition to randomized medications, each group will have adjunctive personalized treatment to manage specific mood states and comorbid conditions.

- **Title:** Evidence Based Biomarkers to Select Personalized Treatment in Bipolar Disorder
Role: Co-Investigator
Effort: 10%
Funding Agency: Subcontract w/Massachusetts General Hospital
Period: 08/2010 - 08/2013
Total Costs: \$328,264.00
Grant Detail: The overall aim of this proposal is to personalize treatment of bipolar disorder. To accomplish this aim, the NIMH Bipolar Trials Network proposes a 10-site study that uses an innovative synthesis of a comparative effectiveness study with an evidence-based biomarker study. We propose to determine the differential effectiveness of 6 months of treatment with the prototypical second generation antipsychotic mood stabilizer quetiapine vs. the prototypical classic mood stabilizer lithium and the predictive and moderating effects of calcium metabolism and pharmacogenomics using selected evidence-based single nucleotide polymorphisms.
- **Title:** Biomarkers of Risk in Adolescent Offspring of Bipolar and Unipolar Adults
Role: Co-Investigator
Effort: 5%
Funding Agency: NIMH
Period: 10/2009 - 09/2011
Total Costs: \$335,656.00
Grant Detail: This proposal describes an innovative study investigating how mood disorder risk in conjunction with HPA axis activity influence brain anatomy, brain function and ultimately the expression of a mood disorder. In this application, we propose to expand our ongoing, funded research that is investigating biomarkers of risk for unipolar affective disorders in adolescents to consider biomarkers of risk for bipolar disorder (BD).
- **Title:** The South Texas Adolescent Risk Trajectories (START) Study
Role: Co-Investigator
Effort: 20%
Funding Agency: National Institute of Mental Health
Period: 10/2009 - 09/2011
Total Costs: \$12,998,682.00

Grant Detail: The goals of this application are twofold: First, to repeat the comprehensive baseline neuroimaging protocol at the two-year follow-up to examine developmental changes in neural phenotypes including structural MRI, functional MRI tapping emotion regulation and reward dependence, development of white matter tracts using diffusion tensor imaging, and resting blood flow via a pulsed arterial spin labeling sequence. We also propose to comprehensively quantify genome-wide expression patterns at baseline, one-year, and two-year follow-ups to track developmental changes in gene expression mediated by exposure to stress and to examine their impact on changes in neural phenotypes and behavior. The second goal of this proposal is to extend the efforts of our longitudinal research examining risk for depression and alcohol use disorders to examine initial risk trajectories in adolescence more broadly by adding 1,300 adolescents aged 12 to 18 years irrespective of their familial risk.

Teaching/Education

Masters Student Mentoring:

- 09/1993 – 05/1994 Advisor, Patrick Stapleton for Master of Health Care Administrator, Simmons College. Thesis: "The Impact of Managed Care on a Free-Standing Psychiatric Hospital", Simmons College
- 09/1989 – 05/1998 Thesis Advisor, Alexis Henry for the degree of Doctor of Philosophy. Boston University School of Occupational Therapy Thesis: "Functional Recovery in Acute Psychosis." Obtained NARSAD Young Investigator Award
- 09/1983 – 05/1985 Thesis Advisor, George Dion for the degree of Doctor of Science, Boston University, Sargent College of Allied Professions. Thesis: "Parameters and Predictors of Functional Outcome in Bipolar Patients Hospitalized for a Manic Episode: Results of Two and Six Month Follow Ups"

Undergraduate Medical Student Mentoring:

- 09/1985 – 05/1988 Clinical Instructor; 5 hours/week, 2 Students, Psychiatry, McLean Hospital, Harvard Medical School

Classroom, Laboratory teaching, and tutoring (courses or blocks taught or team-taught):

- 09/2012 – 02/2013 Supervisor PGY2 rotation Bipolar clinic 6 month rotation 4 hrs/week, One Student, University of Texas Health Science Center at San Antonio
- 02/2010 – 12/2012 Clinical Instructor for medical students, Pharmacy students, Psychiatric Residents 4 hrs/5 days/week, Ten Students, University of Texas Health Science Center at San Antonio
- 07/2008 – 12/2008 Founding Co-Director, Indiana University/Lilly Research Laboratory Psychopharmacology Fellow, One Student
- 01/1997 – Present Lecturer, Part-time, Harvard Medical School, Harvard University Faculty of Medicine

01/1997 – Present	Seminar on Outcome and Treatment of Bipolar Disorder, Residents; 6 week, 10 Students, McLean Hospital, Harvard Medical School
09/1992 – 05/1997	Instructor, Graduate Level, Diagnosis of Major Psychotic Disorders in a Clinical Setting (EPI 290), Harvard School of Public Health, Preparation Hrs: 20
09/1992 – 05/1997	Instructor, Graduate Level, The Epidemiology of Major Psychiatric Disorders (EPI 217a), Harvard School of Public Health, Preparation Hrs: 24
09/1990 – 05/1997	Instructor, Graduate Level, Research in Psychiatric Epidemiology (EPI 3502), Harvard School of Public Health, Advisor to students conducting research
09/1990 – 05/1992	Co-Course Director, Graduate Level, Risk Factors in Psychiatric Epidemiology (EPI 218b), Harvard School of Public Health, Preparation Hrs: 20; Associate Director (Course Director: Professor Ming Tsuang)
09/1989 – 05/1993	"Psychopathology of Psychotic Disorders", Seminar Director; 8 hours/year, 10 Students, Harvard School of Public Health, McLean Hospital
09/1987 – 05/1990	Instructor, Graduate Level, Introduction to Clinical Psychiatry (Psychiatry 700), Harvard Medical School, Preparation Hrs: 4 ; Instructor and lecturer
09/1987 – 05/1988	Tutor; 10 hours/year, The New Pathway Clerkship in Psychiatry, Harvard Medical School, 2 Students
09/1986 – 05/1997	Co-Course Director, Resident Level, Psychiatry 501M.10b, Harvard Medical School, Associate Course Director (Course Director: Professor Ross J. Baldessarini): Advanced Clinical Clerkship in Diagnosis and Treatment of Major Psychosis, McLean Hospital Advisor for research projects
09/1986 – 05/1988	"Research Methods and Critical Reading of the Literature" for Residents in Psychiatry, Seminar developer and director; 10 hours/year, 10 Students, McLean Hospital
09/1986 – 05/1987	Teaching Assistant, Graduate Level, Assessment Methods in Psychiatric Epidemiology (EPI 219d), Harvard School of Public Health, Preparation Hrs: 20 ; Course developer (with Professor Gerald L. Klerman and Jane Murphy, Ph.D.)
09/1985 – 05/1988	Biogenetic Aspects in Personality Disorders and Epidemiology of Schizophrenia, Lecturer; 2 hours/year, 8 Students, McLean Hospital Residency Training Program in Psychiatry
09/1985 – 05/1986	Teaching Assistant, Graduate Level, Epidemiologic Reasoning and Practice (EPI 202b), Harvard School of Public Health, Preparation Hrs: 40
09/1985 – 05/1986	Teaching Assistant, Graduate Level, Introduction to Biostatistics (B10 201ab), Harvard School of Public Health, Preparation Hrs: 40
09/1984 – 05/1987	Teaching Assistant, Graduate Level, Epidemiology of Mental Disorders (EPI 216bc), Harvard School of Public Health, Preparation Hrs: 20
09/1984 – 05/1985	Teaching Assistant, Graduate Level, Epidemiology and Public Health (EPI 201a), Harvard School of Public Health, Preparation Hrs: 40

Resident and fellow teaching and mentoring:

07/2014 – 07/2015 Advisor, Leslie Chavez MD, Resident, Department of Psychiatry & Behavioral Sciences, University of New Mexico Health Sciences Center, Albuquerque, New Mexico

04/2010 – 02/2013 Advisor, Robert Gonzalez, MD, Fellow, Mood & Anxiety Disorders, The University of Texas Health Science Center at San Antonio

03/2009 – 02/2013 Advisor, Marlon Quinones, MD, Resident, Junior Faculty Mood & Anxiety Disorders, The University of Texas Health Science Center at San Antonio

09/2008 – 08/2009 Advisor, Nuria Cruz, MD, PhD, Fellow in the McLean/Harvard First Episode Project, University of Barcelona, Mclean Harvard

09/2005 – 05/2006 Advisor, Jesus Perez MD, Fellow in the McLean/Harvard First Episode project – Established First Episode Project in Cambridge, England, McLean/Harvard

09/2003 – 05/2004 Advisor, Christopher Baethge MD, Fellow in the McLean/Harvard First Episode Project, McLean Hospital

01/2002 – 12/2002 Advisor, Harkaitz Imaz MD, Fellow in the McLean/Harvard First Episode Project, McLean Hospital

09/2001 – 05/2003 Advisor, Robert Irvin MD, Lilly/McLean Fellow in Bipolar disorder, McLean Hospital

09/2001 – Present Advisor, Paola Salvatore MD, Fellow in the McLean/Harvard First Episode Project: Obtained NARSAD Young Investigator Award (2003, 2006), McLean/Harvard

09/1994 – 05/1997 Advisor, Carlos Zarate, M.D.: Obtained Dupont-Warren and Livingstone Award, McLean Hospital: NARSAD Young Investigator Award: APA Minority Fellowship, McLean Hospital

09/1993 – 05/1994 Primary Supervisor, James Hegarty, M.D., Chief Resident of Bipolar and Psychotic Disorders Program, McLean Hospital: obtained American Psychiatric Association Research Award: Lily/APA Award: Loughlin Award and Alfred Pope Award, McLean Hospital

09/1992 – 05/1994 Advisor, German Baraibar, M.D., Research Fellow in Psychiatry, Harvard Medical School

09/1992 – 05/1993 Advisor to Graduate student in Epidemiology; 1 hour/week, Jose Castillo, M.D., Harvard School of Public Health

09/1992 – 05/1993 Advisor, Jong-Won Kim, M.D., Research Fellow, Harvard Medical School

09/1991 – 05/1994 Advisor, Jose Castillo, M.D., Research Fellow in Psychiatry, Harvard Medical School

09/1991 – 05/1992 Preceptor and Primary Supervisor, Stephen Strakowski, M.D., Chief Resident in Psychiatry, McLean Hospital: obtained Loughlin Award by American College of Psychiatrists, McLean Hospital

09/1990 – 05/1993 Preceptor and Primary Supervisor, Michael Banov, M.D. Resident in Psychiatry, McLean Hospital: obtained Loughlin Award by American

College of Psychiatrists, and Best Resident Poster at Department of Psych Res Day, McLean Hospital

09/1990 – 05/1991 Primary Supervisor, Andrew Stoll, M.D., Chief Resident of Psychotic Disorders Program, McLean Hospital: obtained American Psychiatric Association Research Award, McLean Hospital

09/1989 – 05/1992 Preceptor, Elyse Dubo, M.D., Resident in Psychiatry, McLean Hospital

09/1989 – 05/1990 Primary Supervisor, Shelly Greenfield, M.D., Chief Resident of Psychotic Disorders Program, McLean Hospital

Mentoring of Faculty in Education:

09/2013 – Present Advisor, Annette Crisanti PhD, Assistant Professor, Department of Psychiatry & Behavioral Sciences, University of New Mexico Health Sciences Center, Albuquerque NM

09/2010 – 09/2012 Advisor, Nancy Diazgranados, MD, Assistant Professor, Mood & Anxiety Disorders, The University of Texas Health Science Center at San Antonio

Other Teaching and Student Mentoring Activities:

07/2013 – 12/2013 Advisor, Lorena Bordes MD JJ Fellowship ISBD Mexico, from Instituto Mexicano de Psiquiatría. Observership, Department of Psychiatry & Behavioral Sciences, University of New Mexico Health Sciences Center, Albuquerque NM

10/2012 – 10/2012 Advisor, Dr. Maria Yoldi JJ Fellowship ISBD Mexico from National University of Mexico on an Observer-ship, The University of Texas Health Science Center at San Antonio

09/2012 – 09/2012 Advisor, Dr. Hideaki Katagiri visited for 2 weeks on an Observer-ship application w/UHS from Eli Lilly Japan KK, The University of Texas Health Science Center at San Antonio

12/2011 – 02/2012 Advisor, Dr. Ivan Vargas Cardoso from AstraZeneca, The University of Texas Health Science Center at San Antonio

07/2011 – 12/2011 Advisor, Dr. Ulises Montero *JJ Fellowship ISBD Mexico*, The University of Texas Health Science Center at San Antonio

07/2011 – 10/2011 Advisor, Dr. Salvador Garfias Garcia, Short-term Scholar from Mexico, The University of Texas Health Science Center at San Antonio

Service

Past Patient Care Activities:

09/2010 – 09/2012 Mentor to Nancy Diazgranados, MD, The University of Texas Health Science Center at San Antonio

05/2010 – 02/2013 Clinician, Inpatient Psychiatric Unit, University Hospital, San Antonio, TX

04/2010 – 02/2013 Mentor to Robert Gonzalez, MD, The University of Texas Health Science Center at San Antonio

05/2009 – 02/2013 Mentor to Marlon Quinones, MD, The University of Texas Health Science Center at San Antonio

Administrative Duties at University/Institute of Higher Learning:

02/2013 – Present Chairman, Department of Psychiatry & Behavioral Sciences, University of New Mexico, Health Sciences Center, Albuquerque, NM

03/2009 – 02/2013 Division Head, Division Head, Mood & Anxiety Disorders, The University of Texas Health Science Center at San Antonio

07/1988 – 12/1996 Clinical Director, Bipolar & Psychotic Disorders Program, McLean Hospital, Harvard Medical School, Belmont MA

Departmental Committees at University/Institute of Higher Learning:

09/2009 – 02/2013 Committee Member, Promotion, Tenure and Appointments Committee, The University of Texas Health Science Center at San Antonio

03/2009 – 02/2013 Committee Member, Grand Rounds Committee, The University of Texas Health Science Center at San Antonio

01/1994 – 12/1997 Committee Member, Research Committee, McLean Hospital

01/1994 – 12/1994 Member, Qing Liang, M.S., Doctor of Science degree Candidate in Biostatistics, Member Examination Committee, Harvard, Public Health

01/1993 – 01/1993 Coordinator, Founding Coordinator, Harvard University Research Day-Department of Psychiatry

01/1993 – 12/1993 Member, Bei Chang, M.S., Doctor of Science degree Candidate in Biostatistics, Member Examination Committee, Harvard, Public Health

01/1992 – 12/1997 Board Member, Institutional Review Board, McLean Hospital

01/1990 – 12/1997 Committee Member, Pharmacy Committee, McLean Hospital

01/1990 – 12/1994 Committee Member, Rate Review Committee, McLean Hospital

01/1989 – 12/1997 Representative, Neal Alan Myself Fund Committee, McLean Hospital Representative

01/1989 – 12/1991 Representative, Ethel-Dupont-Warren Fellowship Award Committee, McLean Hospital Representative

01/1989 – 12/1990 Committee Member, General Director's Vision of Excellence Award Committee, McLean Hospital

01/1988 – 12/1997 Committee Member, Residents Selection Committee, McLean Hospital

01/1987 – 12/1997 Committee Member, Residents Education Committee, McLean Hospital

01/1987 – 12/1997 Committee Member, Quality Assurance Committee, McLean Hospital, Department of Psychiatry

01/1987 – 12/1993 Committee Member, Medical Records Committee, McLean Hospital

01/1987 – 12/1988 Committee Member, Clinical Case Conference Committee, McLean Hospital

01/1984 – 12/1987 Coordinator, Developer and Coordinator, Doctoral Students Research Group, Harvard Program in Psychiatric Epidemiology

01/1981 – 12/1982 Vice President, Psychiatric Residents, Association of Toronto

01/1980 – 12/1981 Representative, Clarke Institute of Psychiatry - Pharmacy Committee

01/1980 – 12/1981 Representative, Research Committee, University of Toronto, Department of Psychiatry

Local, State, Regional, National Committees:

02/2013 – Present	Director, Biomedical Research Institute of New Mexico, BRINM'S Board of Directors (State)
04/2012 – 04/2012	Invited speaker, ACNP Annual Meeting, FACS-BD: A New Analysis Methodology for Maintenance Studies in Bipolar Disorder.
01/2010 – 01/2012	Committee Member, Scientific Committee, The International Society of CNS Clinical Trials and Methodology
01/2009 – 12/2011	Committee Member, Credential Committee, American College of Neuropsychopharmacology (National)
01/2006 – 12/2009	Committee Member, Psychiatric Treatment Committee, American Psychiatric Association
01/2006 – 12/2009	Committee Member, Membership Committee, American College of Psychiatrists (National)
01/2006 – 12/2006	Chair, Committee on Nomenclature on Outcome in Bipolar Disorder, International Society of Bipolar Disorders
01/2005 – 12/2008	Committee Member, Liaison Committee with Government and Industry, American College of Neuropsychopharmacology (National)
01/2003 – 12/2006	Committee Member, History Committee, American College of Neuropsychopharmacology
01/2003 – Present	Fellow, American College of Psychiatrists
01/2003 – Present	Fellow, American Psychopathological Association
01/2003 – Present	Fellow, Distinguished Fellow, American Psychiatric Association
01/2001 – 12/2002	Co-Chair, Clinical Research Committee (CRC), Lilly Research Laboratories
01/2000 – 12/2003	Committee Member, Committee on the Award for Research in Mood Disorders, American College of Psychiatrists (National)
01/1998 – 12/1999	Committee Member, Health Services Research Committee, American Psychiatric Association (National)
01/1997 – 12/2001	Committee Member, Clinical Centers and Special Projects Review Committee, National Institute of Mental Health (National)
01/1996 – 12/1999	Committee Member, Committee on the Dean Award, American College of Psychiatrists
01/1995 – 12/1997	Committee Member, Hispanic Committee, American Psychiatric Association
01/1994 – 12/1994	Fellow, American Psychiatric Association (National)
01/1992 – 12/1996	Committee Member, Epidemiology Review Committee, National Institute of Mental Health (National)
01/1991 – 12/1992	Coordinator, Field Trial Coordinator, Diagnostic and Statistical of Mental Disorders, Fourth Edition (National)
01/1990 – 12/1997	Coordinator, Psychopharmacology Update Coordinator, Massachusetts Psychiatric Society (State)
01/1990 – 12/1993	Chair, Neal Alan Myself Fund Committee
01/1990 – 12/1993	Committee Member, Nominating Committee, Massachusetts Psychiatric Society (State)

APPENDIX B

Exhibit	Description
EX1001	U.S. Patent No. 12,245,997
EX1002	U.S. Patent No. 12,245,997 File History
EX1004	A. Ahmad et al., <i>Endoxifen, a New Treatment Option for Mania: A Double-Blind, Active-Controlled Trial Demonstrates the Antimanic Efficacy of Endoxifen</i> , 9 CLINICAL TRANSLATIONAL SCI. 252 (2016)
EX1005	Robert M.A. Hirschfeld et al., <i>Practice Guideline for the Treatment of Patients with Bipolar Disorder (Revision)</i> , 159 AM. J. PSYCHIATRY 1 (2002)
EX1006	Ateeq Ahmad et al., <i>Endoxifen: A New, Protein Kinase C Inhibitor to Treat Acute and Mixed Mania Associated with Bipolar I Disorder</i> , 23 BIPOLAR DISORDERS 595 (2020)
EX1008	Ross J. Baldessarini et al., <i>Bipolar Depression: Overview and Commentary</i> , HARV. REV. PSYCHIATRY 143 (2010)
EX1009	DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-5), (5th ed. 2013)
EX1010	Lena C. Quilty et al., <i>The Structure of the Montgomery-Åsberg Depression Rating Scale Over the Course of Treatment for Depression</i> , 22 INT'L J. METHODS PSYCHIATRY RSCH. 175 (2013)