

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,
Patent Owner

Case IPR2025-00799

Patent No. 11,261,151

**EXPERT DECLARATION OF WILLIAM MAYO, Ph.D., ADOPTING THE
OPINIONS OF STEVEN MILLER, Ph.D.**

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I, William Mayo, Ph.D., do hereby declare:

I. Introduction

1. I have been retained to provide my expert opinions on behalf of Intas Pharmaceuticals, Limited, in support of a petition for *inter partes* review of claims 1-21 of U.S. Patent No. 11,261,151 (“the 151 Patent”; Ex. 1001), which challenges the validity of the 151 patent. I have been asked to provide this declaration adopting the opinions of Dr. Miller, who is no longer available to participate in these proceedings. Dr. Miller’s report is attached as Appendix 1. I have maintained the paragraphs of Dr. Miller’s declaration and have only modified the language as necessary to reflect the change from Dr. Miller to myself. I have not been asked to, and have not, provided any new opinions. The only additions I have offered are my own Education and Professional Background at the conclusion of this declaration. A redline showing the changes from Dr. Miller’s declaration is attached as Appendix 2.

2. The opinions set out by this declaration are based on my education, knowledge and experience. I have considered the materials and items identified in this declaration, as well as Dr. Miller’s declaration.

II. Dr. Miller’s Education and Professional Background

3. I understand Dr. Miller’s qualifications and credentials to testify as an expert in this case were set forth in his curriculum vitae (attached as Appendix A).

4. I understand Dr. Miller has significant experience in materials characterization, specifically in regards to analyzing samples through spectroscopic techniques and analyzing the physical structure of molecules using techniques such as X-ray diffraction and spectroscopy. I understand Dr. Miller has more than 20 years of academic and industrial materials development and characterization experience. I understand Dr. Miller's research has resulted in more than 15 publications in refereed journals.

5. I understand Dr. Miller obtained a B.A., in Physics, from Rutgers University in 2004 and then obtained an M.S. and then a Ph.D. in Materials Science and Engineering, also from Rutgers. I understand that while at Rutgers, Dr. Miller worked as a teaching assistant, research assistant, post-doctoral assistant, and research associate. I also understand that Dr. Miller conducted research with the nano-materials and devices group and the composite and optical materials center.

6. Since 2014 Dr. Miller has been the president/owner of H&M Analytical Services, which is a full-service x-ray diffraction and analysis testing lab, which also provides a wide range of other testing and material characterization services. Polymorph identification of pharmaceuticals is a substantial portion of the testing performed by H&M Analytical Services.

7. I also understand that since 2018, Dr. Miller has been an Adjunct Professor at Rutgers, teaching Advanced Materials Characterization.

III. Dr. Miller's Compensation

8. I understand Dr. Miller was compensated for the time he spent on this matter at his ordinary rate of \$500 per hour for expert services. I understand Dr. Miller was reimbursed for his reasonable expenses incurred in connection with my work on this matter. I further understand Dr. Miller's compensation does not depend on the opinions I offer or on the outcome of this proceeding or any other proceeding.

IV. Scope of Dr. Miller's Engagement

9. I understand Dr. Miller was asked by counsel to perform certain experiments to determine the x-ray power diffraction ("XRPD") patterns of crystals synthesized by Dr. Ron Bihovsky according to the methods taught in International Application No. WO 2017/070651 ("Liu"). I understand Dr. Miller also compared the XRPD patterns of the crystals synthesized by Dr. Bihovsky to the disclosure and claims of the 151 patent.

10. I understand that some of the claims are directed to compositions for use as a pharmaceutical and methods for treating a subject. I understand that Dr. Miller is not an expert in pharmaceutical formulations or treating patients, and was not asked to offer any opinions outside of his expertise or concerning the ultimate issues of validity of the claims.

V. Background

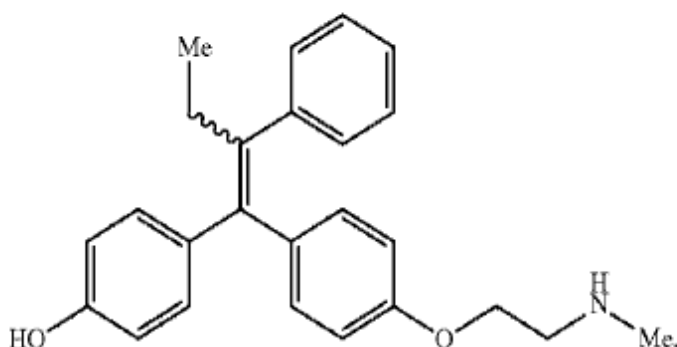
11. The claims of the 151 patent are directed to compositions comprising a crystalline form of endoxifen that is at least 90% by weight (Z)-endoxifen having a

crystalline Form I, characterized by an x-ray powder diffraction pattern comprising certain peaks.

12. Endoxifen (4-hydroxy-N-desmethyltamoxifen) is a nonsteroidal selective estrogen receptor modulator. I understand that Intas sells endoxifen in India under the brand name Zonalta for the treatment of manic depressive disorder. See Ex. 1015.

13. Endoxifen can be depicted as the below chemical structure, which is referred to as Formula (III) in the 151 patent:

Formula (III)



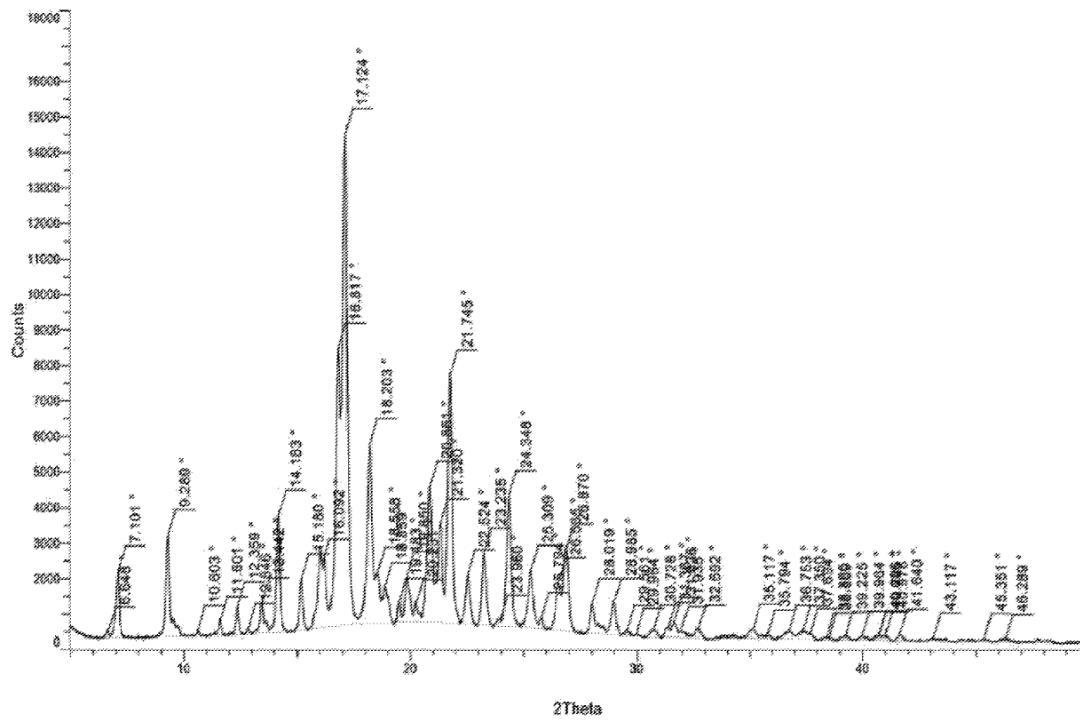
See, e.g., Ex. 1001 at 3:1-15.

VI. The 151 Patent

14. The 151 patent is entitled “Methods for Making and Using Endoxifen.” Ex. 1001 at Cover. I understand that the 151 patent is a U.S. National Phase Application of International Application No. PCT/US2018/050272, filed September 10, 2018 and claims priority to Provisional Application No. 62/556,799, dated September 11, 2017. *Id.* Thus, I have been instructed to use September 11, 2017 as

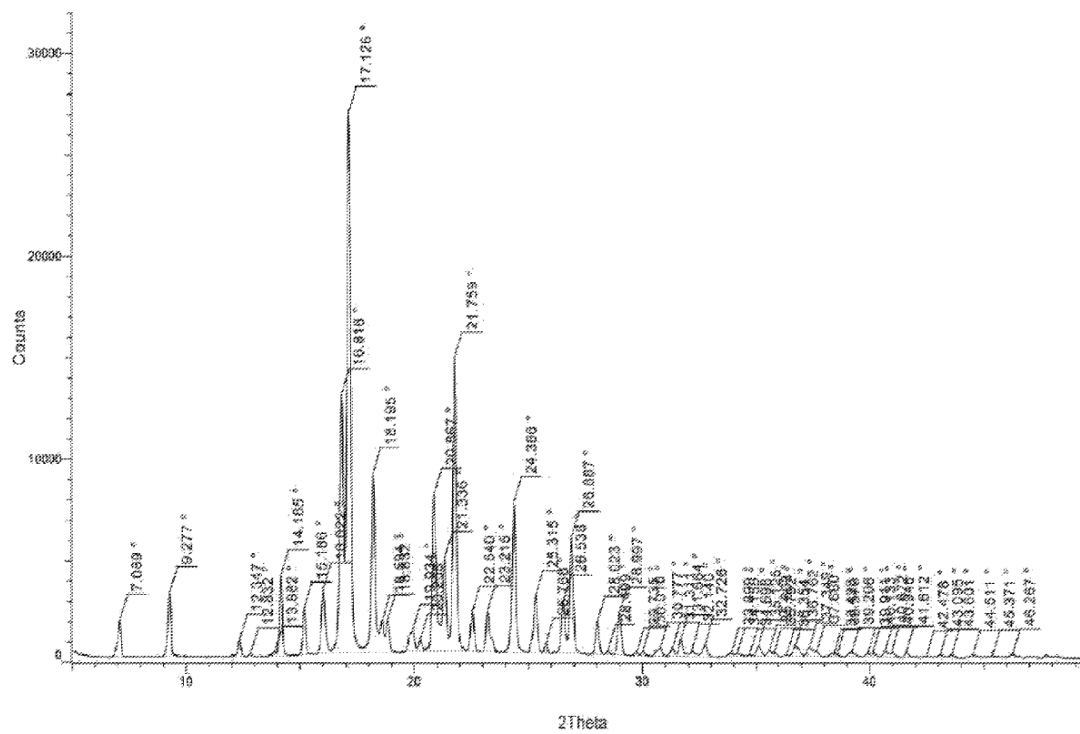
the time of invention, and to consider my opinions from the perspective of a person of skill at that time.

15. The 151 patent is directed to compositions of endoxifen that are at least 90% by weight of (Z)-endoxifen in a particular crystalline form (*i.e.*, Form I) and methods of administering such formulations. The 151 patent characterizes Form I by its XRPD pattern. In particular, the 151 patent states that Form I “may be characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta, and optionally further comprising at least one peak selected from $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$ and $26.5\pm0.3^\circ$ two theta. In some embodiments, the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.” *Id.* at 3:20-28. The 151 patent further states that Form I “is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.” *Id.* at 3:32-34. Figures 9 and 10 of the 151 patent are reproduced below.



Id. at

Figure 9.



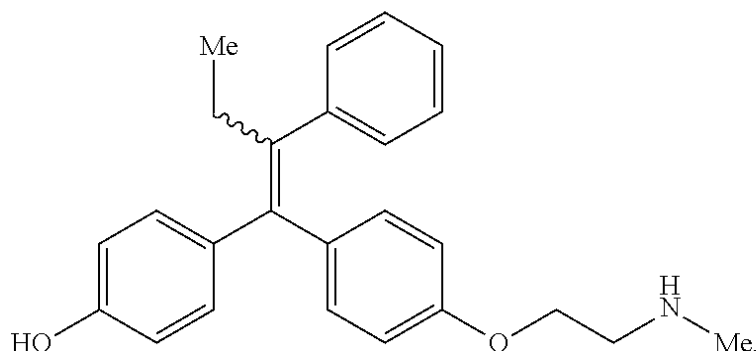
Id. at Figure 10.

16. I understand that the 151 patent contains the following 21 claims:

Independent Claim 1 and Dependent Claims 2-15 and 21

1. A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and $26.5 \pm 0.3^\circ$ two theta.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3 \pm 0.3^\circ$, $28.0 \pm 0.3^\circ$ and $29.0 \pm 0.3^\circ$ two theta.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3 \pm 0.3^\circ$, $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$, $26.5 \pm 0.3^\circ$, $28.0 \pm 0.3^\circ$ and $29.0 \pm 0.3^\circ$ two theta.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

6. The composition of claim 1, wherein greater than 90% by weight of the (Z)-isomer in the composition is crystalline Form I.
7. The composition of claim 1, further comprising a pharmaceutically acceptable carrier or diluent.
8. The composition of claim 7, wherein the composition is formulated for oral, parenteral, topical, or intraductal delivery.
9. The composition of claim 7, wherein the composition is formulated for oral delivery as a tablet, a caplet, a capsule, or a pill.
10. The composition of claim 7, wherein a mean half-life of the compound of Formula (III) in a subject treated with the composition is between 30 hours to 60 hours.
11. The composition of claim 1, formulated as an oral dosage form comprising 1 mg to 200 mg per unit dose of the composition, and wherein daily administration of the oral dosage form achieves in a subject treated with the composition one or more of:
 - a steady state plasma level of the compound of Formula (III) within 7 to 21 days;
 - a steady state plasma level of the compound of Formula (III) ranging from 25 nM to 300 nM;
 - a steady state plasma level of the compound of Formula (III) greater than 30 nM; or
 - maximal plasma levels of the compound of Formula (III) within 2 to 10 hours after administering.
12. The composition of claim 11, wherein a mean half-life of the compound of Formula (III) in the subject is between 40 hours to 55 hours.
13. The composition of claim 11, wherein the oral dosage form is formulated as an enteric tablet, an enteric caplet, an enteric capsule, a delayed-release tablet, a delayed-release caplet or a delayed-release capsule.

14. The composition of claim 11, wherein at least 80% of the compound of Formula (III) in the oral dosage form is released in the intestines of the subject.

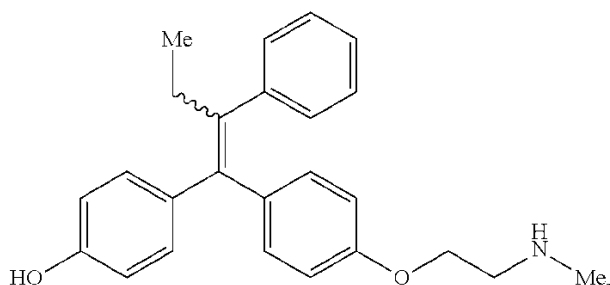
15. The composition of claim 11, having a mean area under the curve extrapolated to time infinity ($AUC_{0-\infty}$) of the compound of Formula (III) of 200 hr*ng/mL to 10000 hr*ng/mL.

21. The composition of claim 1, wherein the composition is stable for at least 9 months at 5° C. and 60% relative humidity or at 25° C. and 60% relative humidity.

Independent Claim 16 and Dependent Claims 17-20

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

17. The method of claim 16, wherein the subject has prostate cancer and wherein the subject further has or is at risk of having gynecomastia.

18. The method of claim 16, wherein the subject has tamoxifen-refractory or tamoxifen resistant hormone-dependent breast disorder or hormone-dependent reproductive tract disorder.

19. The method of claim 16, wherein the composition comprises 0.01 mg to 200 mg of the (Z)-isomer.

20. The method of claim 16, wherein a steady state plasma level of the compound of Formula (III) is achieved within 7 to 21 days of the first administration of the composition to the subject, and wherein the steady state plasma level of the compound of Formula (III) in the subject is greater than 30 nM.

VII. Person of Ordinary Skill in the Art

17. I understand that the content of a patent (including its claims) and prior art should be interpreted the way a person of ordinary skill in the art (or “POSA”) would have interpreted the material at the time of the alleged invention. In my opinion, a POSA for purposes of the 151 patent has a graduate degree in organic chemistry, material science, medicinal chemistry, pharmaceutical chemistry, or a related field, and four to six years of experience in the synthesis, purification, analysis, design, and/or formulation of pharmaceutical compounds and derivatives. A POSA would have worked with a team of professionals with training in related disciplines, such as pharmacology, pharmacokinetics, formulation, drug discovery and/or drug development as of the date of the claimed inventions.

18. I base my opinion on my review of the 151 patent, the problems the 151 patent was attempting to solve, the prior art discussed below, and my general experience with pharmaceutical compounds and the people working in the field. I meet and/or exceed the definition of a POSA. I also note that my opinions would not change if the level of skill in the art were found to be lower.

VIII. Claim Construction

19. I understand that terms should be given their plain and ordinary meaning to a person of skill at the time of invention. I have applied this principle to all terms in the 151 patent addressed below.

IX. Summary of the Prior Art

A. WO 2017/070651 (“Liu”)

20. I understand that International Application No. WO 2017/070651 (“Liu”) was filed on October 24, 2016, and published on April 27, 2017 and is therefore prior art to the 151 patent. Ex. 1003 at Cover.

21. Liu teaches methods for synthesizing and purifying (Z)-endoxifen with a 99% isomeric purity. *See, e.g., id.* at [0076]. In particular, Liu discloses two methods of preparing highly pure (Z)-endoxifen: i) synthesis followed by sequential recrystallizations (“Liu’s Recrystallization Procedure”), *id.*, [0021]-[0045], and (ii) synthesis followed by isomerization and sequential recrystallizations (“Liu’s Isomerization and Recrystallization Procedure”). *Id.*, [0046]-[0055]. Liu does not report any XRPD data of the compounds Liu synthesized. Thus, Liu does not report whether its compounds exhibited the XRPD pattern recited in the claims of the 151 patent (*i.e.*, Form I). However, as I discuss in more detail below, I have confirmed that Liu’s procedure provides (Z)-endoxifen that exhibits an XRPD pattern consistent with Form I as claimed in the 151 patent.

B. General X-Ray Powder Diffraction Art

22. XRPD is a method of exposing a crystalline form of a compound to X-rays, generating a pattern as a function of the scattering angle. Bunaciu, A. et al., *X-ray Diffraction: Instrumentation and Applications*, 45 CRITICAL REVIEWS IN ANALYTICAL CHEM. 289-99 (May 21, 2015) (“Bunaciu”) discloses that XRPD can be used to identify a specific polymorph structure. Ex. 1011 at 289. For example, Bunaciu explains that “[i]n the drug design, discovery, development, and formulation process, X-ray powder diffraction can help to establish a formulation by discovering the morphology and the degree of crystallinity, providing unique polymorph identification, and determining the quantity of each in mixture.” *Id.* Thus, the same (or substantially similar) XRPD patterns for different samples of a substance indicate that the samples have the same polymorph structure. *Id.*

X. Dr. Miller’s X-Ray Powder Diffraction of (Z)-Endoxifen Synthesized in Accordance with Liu’s Procedures

23. Dr. Bihovsky followed the procedures outlined in Liu to obtain highly pure (Z)-endoxifen. I understand Dr. Miller then tested the highly pure (Z)-endoxifen synthesized by Dr. Bihovsky according to Liu to obtain the XRPD patterns of the crystals. I also understand Dr. Miller analyzed the resulting XRPD patterns. I understand the experimental test and analysis conditions used for the

XRPD testing was intended to be attached to Dr. Miller's declaration as Appendix B.

24. The results of Dr. Miller's XRPD testing for the resulting (Z)-endoxifen crystals from both Liu's Recrystallization Procedure and Liu's Isomerization and Recrystallization Procedure are below. The tables below provide the measured peak positions (*e.g.*, $^{\circ}2\text{-theta}$), the d-spacing, and the intensity of each measured peak for each solid (*e.g.*, the solids made by Liu's recrystallization procedure and the solids made by Liu's isomerization and recrystallization procedure).

**XRPD Results of Liu's
Recrystallization Procedure**

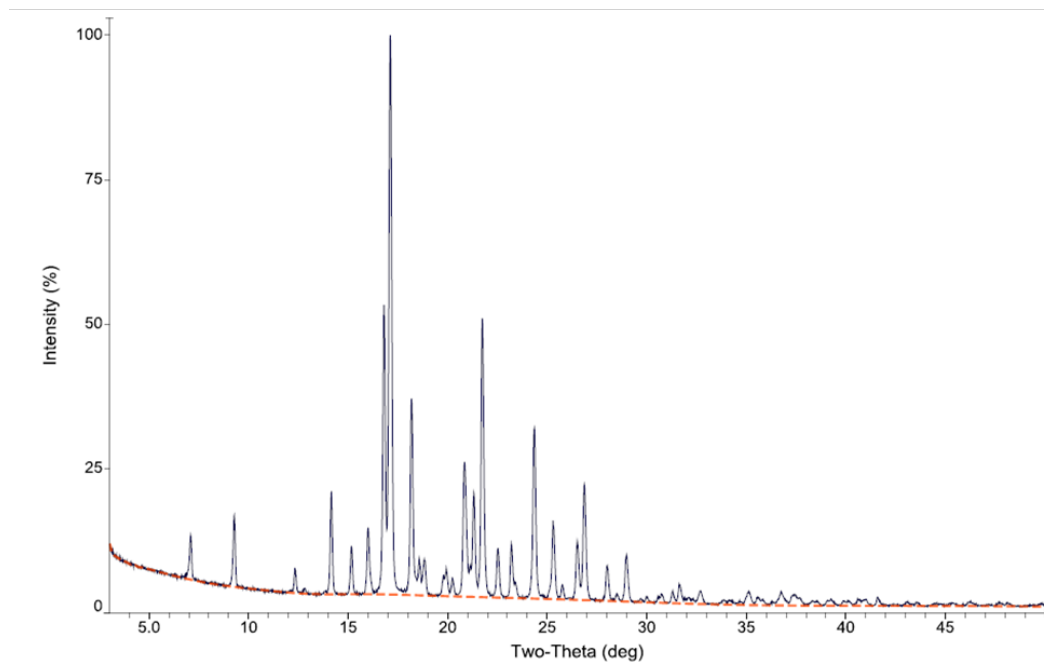
2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

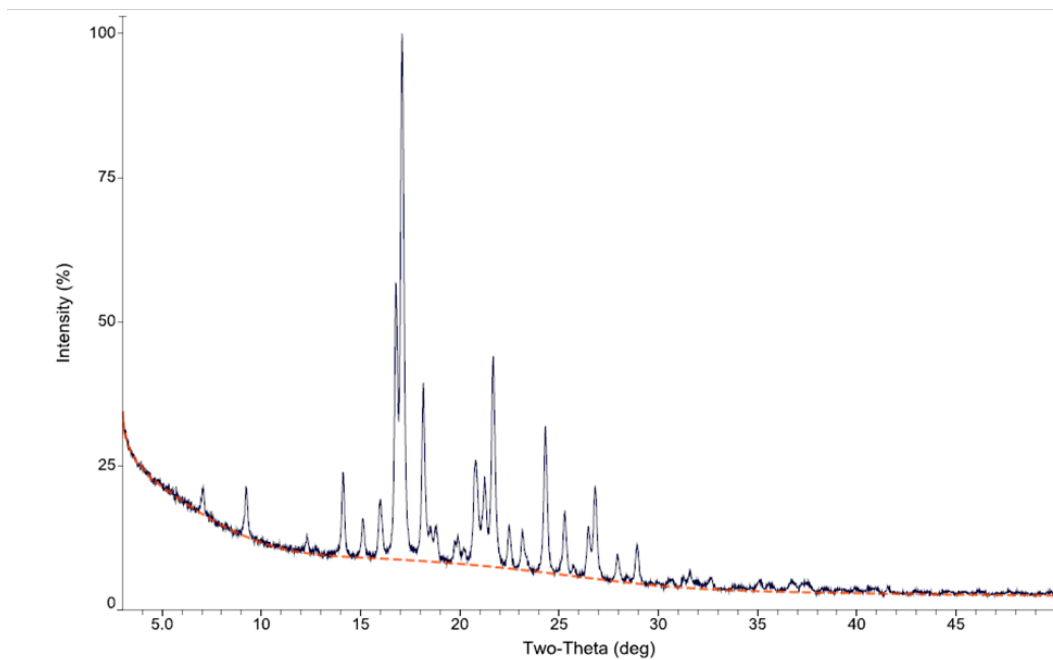
2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

25. The graphs below also provide the results of the XRPD testing of the resulting (Z)-endoxifen crystals from Dr. Bihovsky. The graphs below provide the XRPD patterns in °2-theta as a function of intensity for each of the solids made by Liu's recrystallization procedure and the solids made by Liu's isomerization and recrystallization procedure.

**XRPD Results of Liu's
Recrystallization Procedure**



**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**



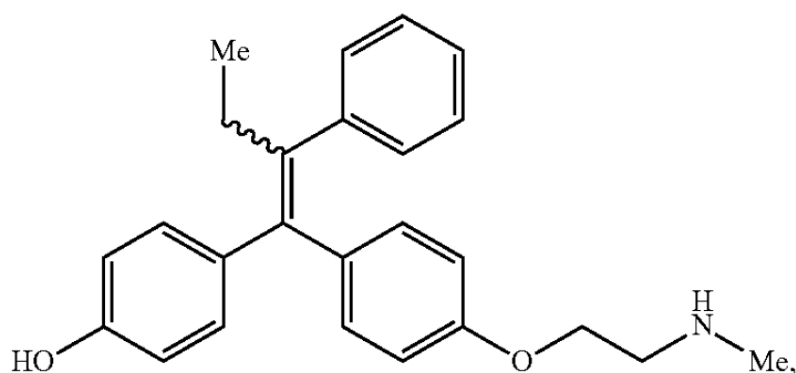
XI. Claims 1-5 and 16 in View of Liu

26. I incorporate by reference Dr. Bihovsky's discussion of the claims in in view of Liu.

A. Independent Claim 1

A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer

27. Formula (III) recited in the claims is endoxifen (including E- and/or (Z)-endoxifen). See Ex. 1001 at 8:15-16. As described in the 151 patent, Formula (III) can include the polymorphic salt, free base, co-crystal, and/or solvate forms of (Z)-endoxifen. See *id.* at 12:48-52.

28. Liu teaches “a process for preparing (Z)-endoxifen” with “a ratio of (Z)-endoxifen (1) to (E)-endoxifen (2) greater than 20:1.” Ex. 1003 at Abstract. Thus, Liu teaches a composition comprising a crystalline form of a compound of

Formula (III) wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer.

wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta.

29. Liu does not disclose that the (Z)-endoxifen created is the claimed “Form I” or provide an XRPD characterization of the resulting crystalline solids. However, as discussed above, Dr. Bihovsky reproduced Liu, and sent the resulting crystals to Dr. Miller for XRPD testing.

30. “[T]he X-ray diffraction pattern is the fingerprint of periodic atomic arrangements in a given material.” Ex. 1011 at Abstract; *see also* Ex. 1031 at 1 (“Every crystalline phase of a given substance produces a characteristic X-ray diffraction pattern.”). As such, an XRPD pattern can be used to identify a particular form of a crystal structure. Therefore, as shown below, the results of Dr. Miller’s XRPD testing confirm that the resulting (Z)-endoxifen from both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are the claimed Form I, characterized by the claimed XRPD peaks. *See* Ex. 1031 at 9 (“The agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form . . .”).

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

31. Thus, Liu inherently teaches that the crystalline form of the (Z)-isomer obtained is Form I, characterized by an XRPD comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta.

B. Dependent Claim 2

32. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 2 are similarly present in Liu’s resulting crystalline solids.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and 26.5 ± 0.3 two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

C. Dependent Claim 3

33. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 3 are similarly present in Liu's resulting crystalline solids.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

D. Dependent Claim 4

34. As discussed above, “[t]he agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 4 are similarly present in Liu's resulting crystalline solids.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3\pm0.3^\circ$, $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$, $26.5\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

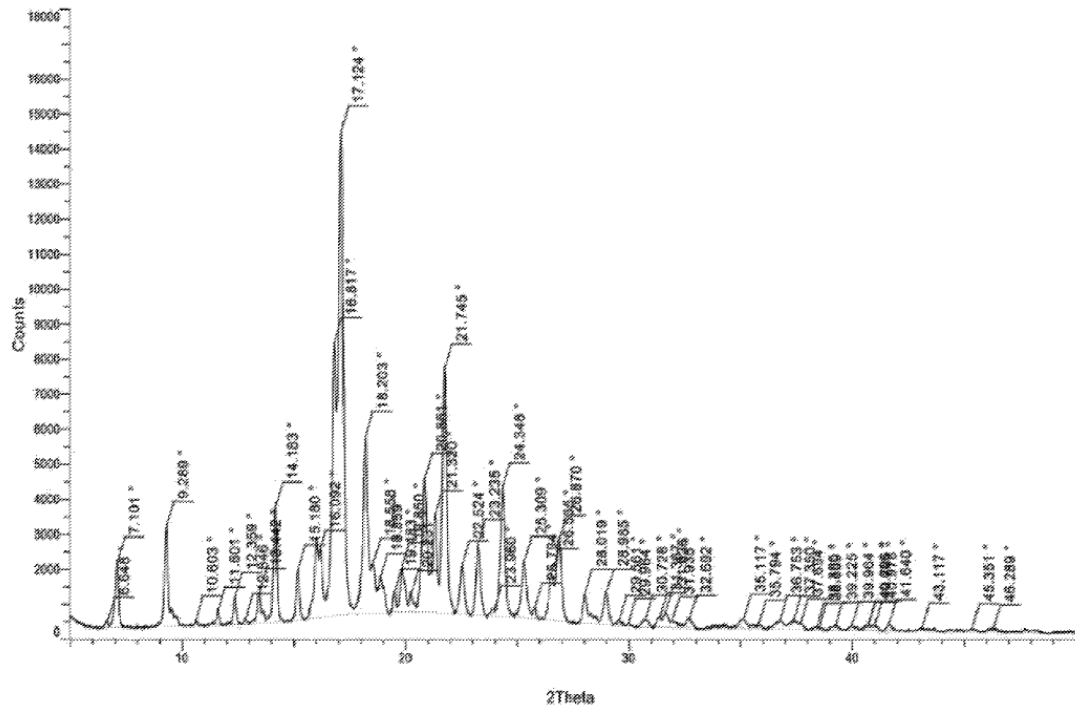
E. Dependent Claim 5

35. As discussed above, “[t]he agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

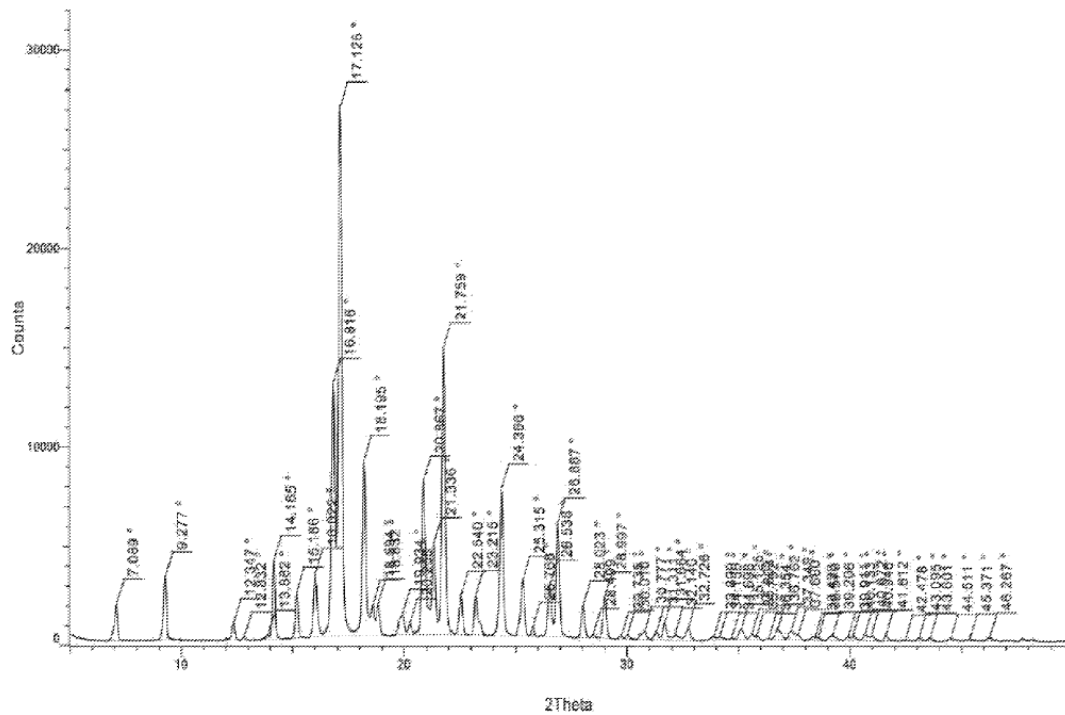
by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 5 are similarly present in Liu's resulting crystalline solids.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

36. The 151 patent's Figures 9 and 10 are reproduced below. Also below is a figure illustrating the XRPD patterns of the crystalline solids obtained by Dr. Bihovsky following Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures arranged for comparison with a stick pattern of the XRPD pattern data reported at Table 8 of the 151 patent (shown in blue), which corresponds to the XRPD patterns shown in Figures 9 and 10.

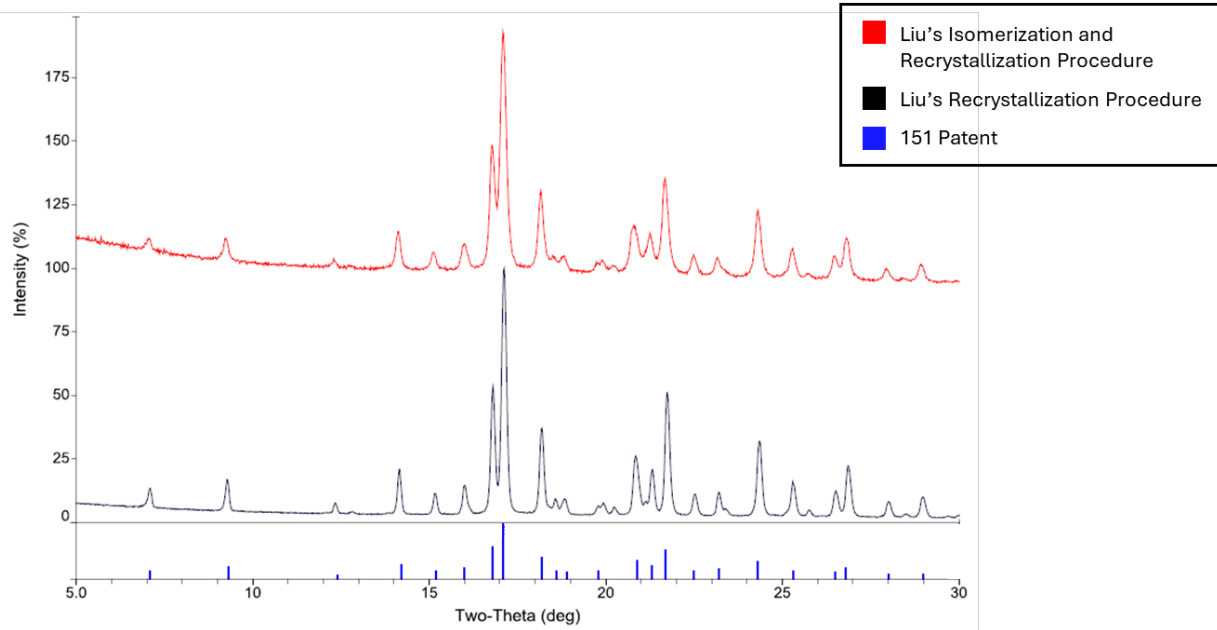


Ex. 1001, Figure 9.



Id., Figure 10.

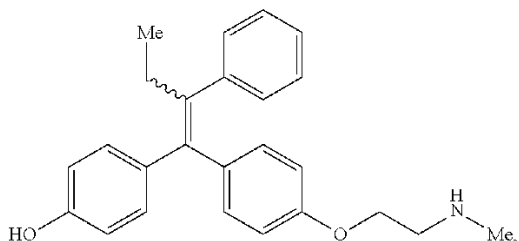
**XRPD Results of Liu's Procedures
Compared to the 151 Patent**



F. Independent Claim 16

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

37. Liu teaches that (Z)-endoxifen may be used to treat hormone-dependent breast disorders. For example, Liu explains that (Z)-endoxifen is more active at the estrogen receptor, and therefore may be used to treat breast cancer. Ex. 1003 at [0002]-[0004]. Therefore, Liu discloses a method of using highly pure (Z)-endoxifen to “treat[] a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in the subject” as recited in claim 16.

38. And as discussed with respect to claim 1, the (Z)-endoxifen obtained by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures exhibit the claimed XRPD patterns. Thus, Liu inherently discloses (Z)-endoxifen in the claimed Form 1.

XII. Education and Professional Background of William E. Mayo, Ph.D.

39. A copy of my *Curriculum Vitae* is included as Appendix 3, which details my educational, professional, research and employment credentials. A condensed summary focusing on my 50+ years of experience with characterization of structural polymorphs (such as those that occur in pharmaceuticals) appears below.

40. I hold a B.S. degree in Physics from Carnegie-Mellon University (1971), an M.E. in Metallurgy and Materials Science from Carnegie-Mellon University (1974), and a Ph.D. in Mechanics and Materials Science from Rutgers University (1982). Following my doctoral work, I was a post-doctoral fellow at Bell Labs in Murray Hill, NJ, specializing in the development of x-ray diffraction characterization tools.

41. Before joining academia, I worked in the private and government sectors for several years at Harry Diamond Labs (1971-72), Olin Metals Research (1974-77) and TRW (1977-78).

42. From 1978 to 2008, I was employed by Rutgers University, where I successively held the titles of Research Assistant, Assistant Professor, Associate Professor, Professor and Emeritus Professor. I have taught numerous courses during that time, including courses in material characterization, x-ray diffraction, phase transformations and thermodynamics at the undergraduate, graduate, and

professional levels. I supervised numerous research projects funded at more than \$20,000,000 dealing with phase transformations and phase identification by X-ray diffraction.

43. While at Rutgers, I taught more than 2,000 students in undergraduate and graduate material science courses. I have taught and supervised graduate students at the MS, Ph.D. and post-graduate levels with a primary emphasis on phase transformations, material characterization, and X-ray Diffraction.

44. In 1997, I was the co-founder of H&M Analytical Services ('H&M') and served as its Chief Scientist through 2012 when I sold the company. H&M's primary emphasis during that time was the use of various analytical tools such as XRPD, SEM, TEM, DSC, TGA, PSA, XRF and FTIR to characterize a wide range of materials, including organic and inorganic solids such as pharmaceuticals, excipients, polymers, minerals, alloys, ceramics, glasses, pigments, composites, and so forth.

45. I founded the company NanoPac in 1999 to commercialize my research into phase transformations of metastable materials to create bi-continuous nano-nano composites.

46. Throughout much of my career and through a company that I co-founded (Xstream Systems and successor), I have also worked on the development of a novel 3-D tomographic energy dispersive X-ray diffraction technique to detect

contraband such as explosives hidden in checked baggage, counterfeit drugs in sealed containers, and most recently, opioids such as fentanyl being smuggled through international mail.

47. Through my work at H&M and Xstream Systems, I have investigated thousands of pharmaceuticals and excipients, especially with regard to structural characterization, phase identification, polymorphic transformations and environmental stability.

48. In 2006, I was awarded the title of *Fellow* of the International Centre for Diffraction Data ('ICDD'). At various times working with the ICDD, I was the Editor for the *Metals Index of the Powder Diffraction File* (18 yrs); the Assistant Editor for New Diffraction Data for the *Powder Diffraction* journal (9 yrs); Chair of the Grant-In-Aid Committee (2 yrs); an Editor for the *PDF-4 Relational Database* (4 yrs); an Editor for *The Blue Book* (4 yrs); and an Assistant Editor for *Metals Index of the Powder Diffraction File* (5 yrs). Also, from 1998 to 2001, I was Assistant Editor for the *Nanostructured Materials* journal. I have authored, edited, or contributed to 39 books/electronic databases and published 136 refereed articles.

49. I am an expert in the fields of material characterization, polymorphism, X-ray diffraction analysis, phase identification, crystal growth, crystal engineering, and phase transformations. I have consulted widely for industry, particularly in the fields of pharmaceutical polymorphism and phase identification.

XIII. Compensation for Dr. William Mayo

50. I am being compensated for the time that I spend on this matter at my ordinary rate of \$450 per hour. I am also being compensated for any reasonable expenses incurred in relation to my work in this matter. My compensation does not depend on the opinions that I offer or on the outcome of this proceeding.

XIV. Relationship Between Dr. William Mayo and Dr. Steven Miller/H&M

51. Dr. Miller was a student of mine while he was a graduate student and Post-Doctoral Fellow at Rutgers and he would have taken two X-ray diffraction courses that I taught. Dr. Miller also studied electron diffraction techniques taught by others. While a graduate student working on his Ph. D. thesis, Dr. Miller and I occasionally would work together on diffraction problems related to his research. However, I was not his Ph.D. thesis advisor.

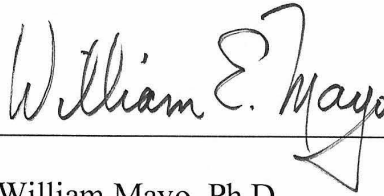
52. When I started to think about retiring from H&M Analytical Services, I contacted Dr. Miller in 2010 to see if there was any interest in working with me and eventually acquiring my business. Based on my interactions with him at Rutgers and his experience with various material characterization techniques, I was confident that Dr. Miller had the requisite knowledge and skills to run the laboratory.

53. In 2011, Dr. Miller was hired to work at H&M on a one-year trial basis and in mid-2012, the deal to purchase H&M was finalized. During the trial period, I continued to supervise the laboratory and train Dr. Miller in all aspects of the

business. Since Dr. Miller already had the requisite experience in XRPD, we focused on expansion of the business and the implementation of H&M's Quality Program. At that time, I also implemented the various protocols to qualify the business for FDA certification including establishing standards under 21CFR Part 11 for electronic records and electronic signatures. I trained Dr. Miller in these protocols before he completely took over the lab's operation.

54. In mid-2012, the contract to purchase H&M was executed and as per terms of the agreement, I reduced my workload to become an occasional consultant. That arrangement slowly phased out and I completed the separation in 2016.

55. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



William Mayo, Ph.D.

12/29/25
Date

MAYO

APPENDIX 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,

Petitioner

v.

ATOSSA THERAPEUTICS, INC.,

Patent Owner

Case IPR2025-00799

Patent No. 11,261,151

EXPERT DECLARATION OF STEVEN MILLER, Ph.D.

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I, Steven Miller, Ph.D., do hereby declare:

I. Introduction

1. I have been retained to provide my expert opinions on behalf of Intas Pharmaceuticals, Limited, in support of a petition for *inter partes* review of claims 1-21 of U.S. Patent No. 11,261,151 (“the 151 Patent”; Ex. 1001), which challenges the validity of the 151 patent.

2. The opinions set out by this declaration are based on my education, knowledge and experience. I have considered the materials and items identified in this declaration.

II. Education and Professional Background

3. My qualifications and credentials to testify as an expert in this case are set forth in my curriculum vitae (attached as Appendix A).

4. I have significant experience in materials characterization, specifically in regards to analyzing samples through spectroscopic techniques and analyzing the physical structure of molecules using techniques such as X-ray diffraction and spectroscopy. I have more than 20 years of academic and industrial materials development and characterization experience. My research has resulted in more than 15 publications in refereed journals.

5. I obtained a B.A., in Physics, from Rutgers University in 2004. I then obtained an M.S. and then a Ph.D. in Materials Science and Engineering, also from

Rutgers. While at Rutgers, I worked as a teaching assistant, research assistant, post-doctoral assistant, and research associate. I conducted research with the nano-materials and devices group and the composite and optical materials center.

6. Since 2014 I have been the president/owner of H&M Analytical Services, which is a full-service x-ray diffraction and analysis testing lab, which also provides a wide range of other testing and material characterization services. Polymorph identification of pharmaceuticals is a substantial portion of the testing performed by H&M Analytical Services.

7. Since 2018 I have been an Adjunct Professor at Rutgers, teaching Advanced Materials Characterization.

III. Compensation

8. I am being compensated for the time I spend on this matter at my ordinary rate of \$500 per hour for expert services. I am reimbursed for my reasonable expenses incurred in connection with my work on this matter. My compensation does not depend on the opinions I offer or on the outcome of this proceeding or any other proceeding.

IV. Scope of Engagement

9. I was asked by counsel to perform certain experiments to determine the x-ray power diffraction (“XRPD”) patterns of crystals synthesized by Dr. Ron Bihovsky according to the methods taught in International Application No. WO

2017/070651 (“Liu”). I also compared the XRPD patterns of the crystals synthesized by Dr. Bihovsky to the disclosure and claims of the 151 patent.

10. I understand that some of the claims are directed to compositions for use as a pharmaceutical and methods for treating a subject. I am not an expert in pharmaceutical formulations or treating patients, and I have not been asked to offer any opinions outside of my expertise or concerning the ultimate issues of validity of the claims.

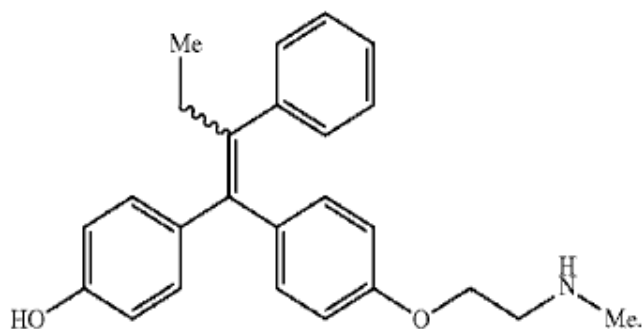
V. Background

11. The claims of the 151 patent are directed to compositions comprising a crystalline form of endoxifen that is at least 90% by weight (Z)-endoxifen having a crystalline Form I, characterized by an x-ray powder diffraction pattern comprising certain peaks.

12. Endoxifen (4-hydroxy-N-desmethyltamoxifen) is a nonsteroidal selective estrogen receptor modulator. I understand that Intas sells endoxifen in India under the brand name Zonalta for the treatment of manic depressive disorder. *See* Ex. 1015.

13. Endoxifen can be depicted as the below chemical structure, which is referred to as Formula (III) in the 151 patent:

Formula (III)



See, e.g., Ex. 1001 at 3:1-15.

VI. The 151 Patent

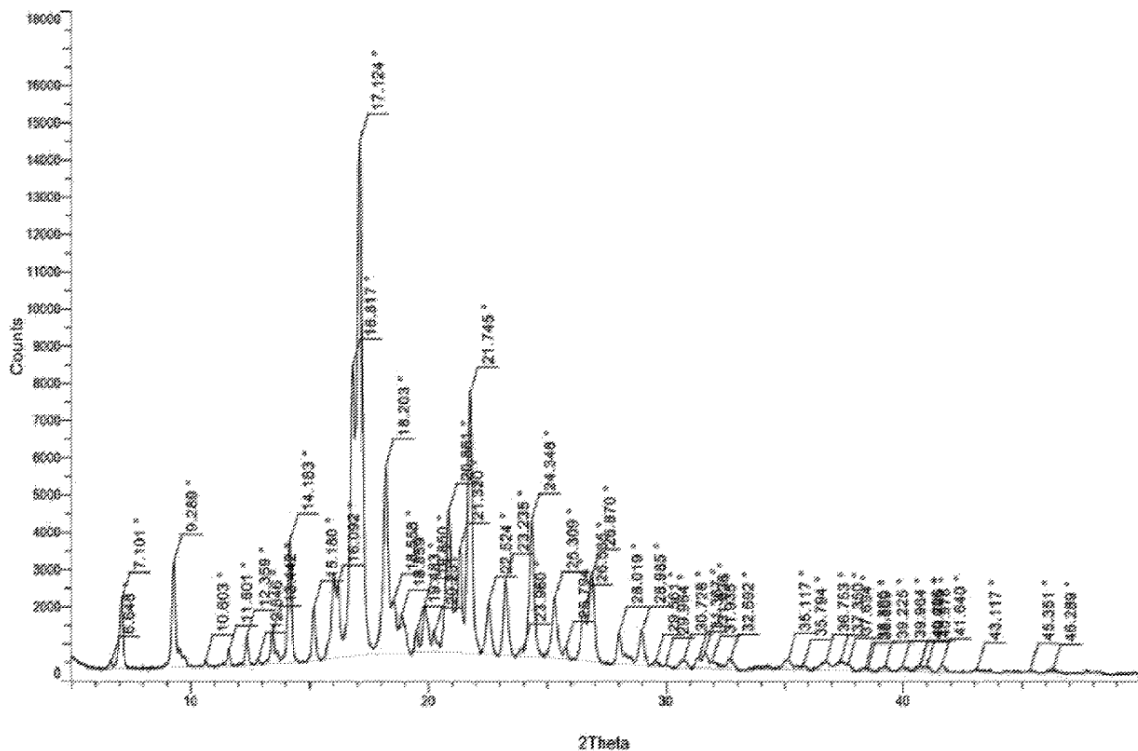
14. The 151 patent is entitled “Methods for Making and Using Endoxifen.” Ex. 1001 at Cover. I understand that the 151 patent is a U.S. National Phase Application of International Application No. PCT/US2018/050272, filed September 10, 2018 and claims priority to Provisional Application No. 62/556,799, dated September 11, 2017. *Id.* Thus, I have been instructed to use September 11, 2017 as the time of invention, and to consider my opinions from the perspective of a person of skill at that time.

15. The 151 patent is directed to compositions of endoxifen that are at least 90% by weight of (Z)-endoxifen in a particular crystalline form (*i.e.*, Form I) and methods of administering such formulations. The 151 patent characterizes Form I by its XRPD pattern. In particular, the 151 patent states that Form I “may be characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, and optionally further comprising at

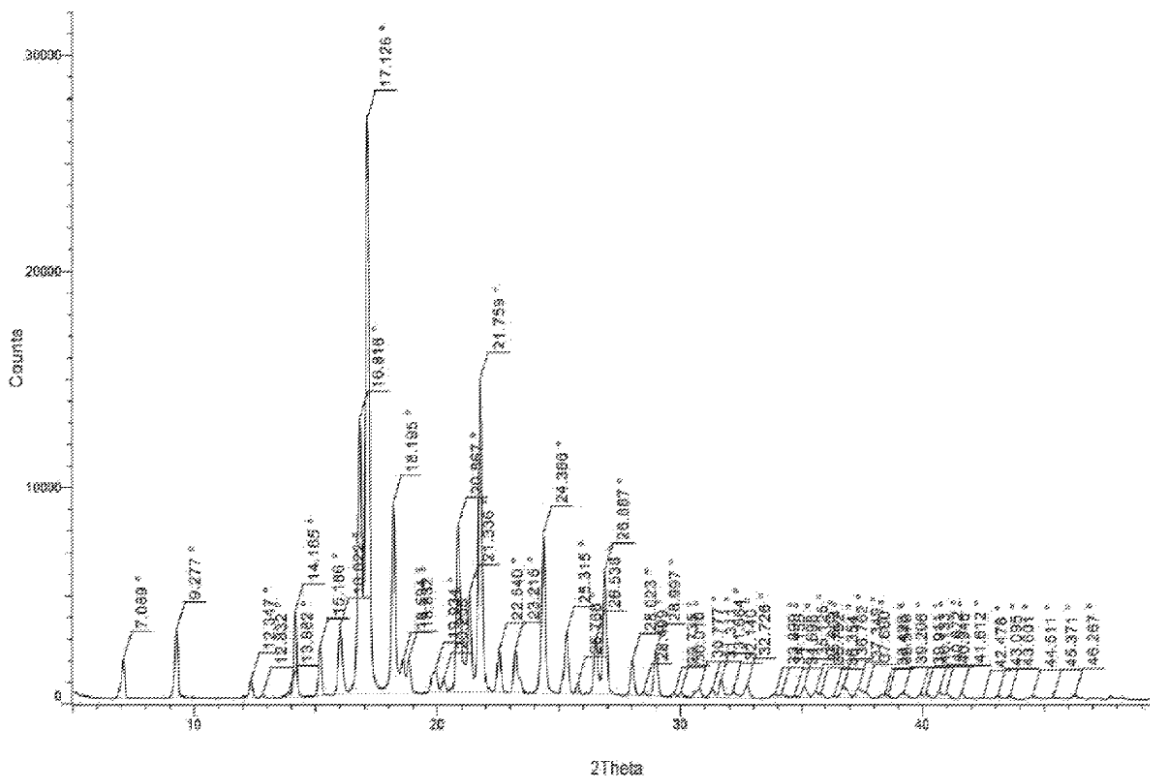
least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and $26.5 \pm 0.3^\circ$ two theta. In some embodiments, the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3 \pm 0.3^\circ$, $28.0 \pm 0.3^\circ$ and $29.0 \pm 0.3^\circ$ two theta.” *Id.* at 3:20-28.

The 151 patent further states that Form I “is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.” *Id.* at 3:32-34.

Figures 9 and 10 of the 151 patent are reproduced below.



Id. at Figure 9.



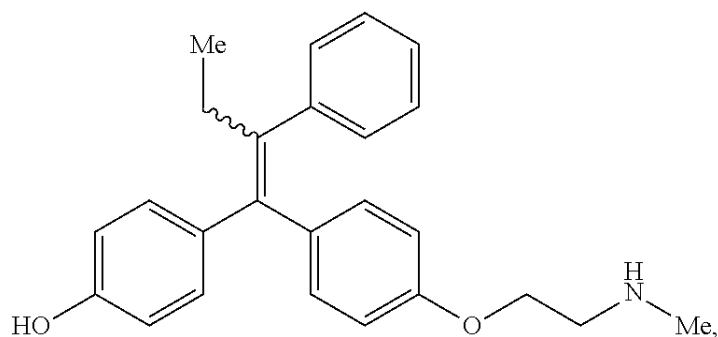
Id. at Figure 10.

16. I understand that the 151 patent contains the following 21 claims:

Independent Claim 1 and Dependent Claims 2-15 and 21

1. A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$ and $26.5\pm0.3^\circ$ two theta.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3\pm0.3^\circ$, $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$, $26.5\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

6. The composition of claim 1, wherein greater than 90% by weight of the (Z)-isomer in the composition is crystalline Form I.

7. The composition of claim 1, further comprising a pharmaceutically acceptable carrier or diluent.

8. The composition of claim 7, wherein the composition is formulated for oral, parenteral, topical, or intraductal delivery.

9. The composition of claim 7, wherein the composition is formulated for oral delivery as a tablet, a caplet, a capsule, or a pill.

10. The composition of claim 7, wherein a mean half-life of the compound of Formula (III) in a subject treated with the composition is between 30 hours to 60 hours.

11. The composition of claim 1, formulated as an oral dosage form comprising 1 mg to 200 mg per unit dose of the composition, and

wherein daily administration of the oral dosage form achieves in a subject treated with the composition one or more of:

a steady state plasma level of the compound of Formula (III) within 7 to 21 days;

a steady state plasma level of the compound of Formula (III) ranging from 25 nM to 300 nM;

a steady state plasma level of the compound of Formula (III) greater than 30 nM; or

maximal plasma levels of the compound of Formula (III) within 2 to 10 hours after administering.

12. The composition of claim 11, wherein a mean half-life of the compound of Formula (III) in the subject is between 40 hours to 55 hours.

13. The composition of claim 11, wherein the oral dosage form is formulated as an enteric tablet, an enteric caplet, an enteric capsule, a delayed-release tablet, a delayed-release caplet or a delayed-release capsule.

14. The composition of claim 11, wherein at least 80% of the compound of Formula (III) in the oral dosage form is released in the intestines of the subject.

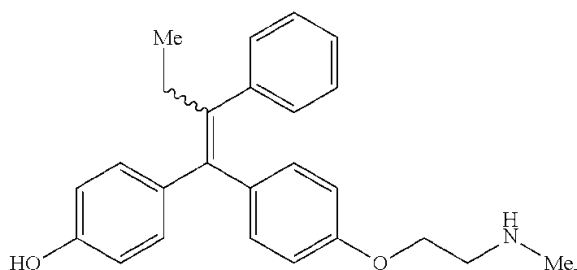
15. The composition of claim 11, having a mean area under the curve extrapolated to time infinity ($AUC_{0-\infty}$) of the compound of Formula (III) of 200 hr*ng/mL to 10000 hr*ng/mL.

21. The composition of claim 1, wherein the composition is stable for at least 9 months at 5° C. and 60% relative humidity or at 25° C. and 60% relative humidity.

Independent Claim 16 and Dependent Claims 17-20

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

17. The method of claim 16, wherein the subject has prostate cancer and wherein the subject further has or is at risk of having gynecomastia.

18. The method of claim 16, wherein the subject has tamoxifen-refractory or tamoxifen resistant hormone-dependent breast disorder or hormone-dependent reproductive tract disorder.

19. The method of claim 16, wherein the composition comprises 0.01 mg to 200 mg of the (Z)-isomer.

20. The method of claim 16, wherein a steady state plasma level of the compound of Formula (III) is achieved within 7 to 21 days of the first administration of the composition to the subject, and wherein the steady state plasma level of the compound of Formula (III) in the subject is greater than 30 nM.

VII. Person of Ordinary Skill in the Art

17. I understand that the content of a patent (including its claims) and prior art should be interpreted the way a person of ordinary skill in the art (or “POSA”) would have interpreted the material at the time of the alleged invention. In my opinion, a POSA for purposes of the 151 patent is a graduate degree in organic

chemistry, material science, medicinal chemistry, pharmaceutical chemistry, or a related field, and four to six years of experience in the synthesis, purification, analysis, design, and/or formulation of pharmaceutical compounds and derivatives. A POSA would have worked with a team of professionals with training in related disciplines, such as pharmacology, pharmacokinetics, formulation, drug discovery and/or drug development as of the date of the claimed inventions.

18. I base my opinion on my review of the 151 patent, the problems the 151 patent was attempting to solve, the prior art discussed below, and my general experience with pharmaceutical compounds and the people working in the field. I meet and/or exceed the definition of a POSA. I also note that my opinions would not change if the level of skill in the art were found to be lower.

VIII. Claim Construction

19. I understand that terms should be given their plain and ordinary meaning to a person of skill at the time of invention. I have applied this principle to all terms in the 151 patent addressed below.

IX. Summary of the Prior Art

A. WO 2017/070651 (“Liu”)

20. I understand that International Application No. WO 2017/070651 (“Liu”) was filed on October 24, 2016, and published on April 27, 2017 and is therefore prior art to the 151 patent. Ex. 1002 at Cover.

21. Liu teaches methods for synthesizing and purifying (Z)-endoxifen with a 99% isomeric purity. *See, e.g., id.* at [0076]. In particular, Liu discloses two methods of preparing highly pure (Z)-endoxifen: i) synthesis followed by sequential recrystallizations (“Liu’s Recrystallization Procedure”), *id.*, [0021]-[0045], and (ii) synthesis followed by isomerization and sequential recrystallizations (“Liu’s Isomerization and Recrystallization Procedure”). *Id.*, [0046]-[0055]. Liu does not report any XRPD data of the compounds Liu synthesized. Thus, Liu does not report whether its compounds exhibited the XRPD pattern recited in the claims of the 151 patent (*i.e.*, Form I). However, as I discuss in more detail below, I have confirmed that Liu’s procedure provides (Z)-endoxifen that exhibits an XRPD pattern consistent with Form I as claimed in the 151 patent.

B. General X-Ray Powder Diffraction Art

22. XRPD is a method of exposing a crystalline form of a compound to X-rays, generating a pattern as a function of the scattering angle. Bunaciu, A. et al., *X-ray Diffraction: Instrumentation and Applications*, 45 CRITICAL REVIEWS IN ANALYTICAL CHEM. 289-99 (May 21, 2015) (“Bunaciu”) discloses that XRPD can

be used to identify a specific polymorph structure. Ex. 1011 at 289. For example, Bunaciu explains that “[i]n the drug design, discovery, development, and formulation process, X-ray powder diffraction can help to establish a formulation by discovering the morphology and the degree of crystallinity, providing unique polymorph identification, and determining the quantity of each in mixture.” *Id.* Thus, the same (or substantially similar) XRPD patterns for different samples of a substance indicate that the samples have the same polymorph structure. *Id.*

X. X-Ray Powder Diffraction of (Z)-Endoxifen Synthesized in Accordance with Liu’s Procedures

23. Dr. Bihovsky followed the procedures outlined in Liu to obtain highly pure (Z)-endoxifen. I then tested the highly pure (Z)-endoxifen synthesized by Dr. Bihovsky according to Liu to obtain the XRPD patterns of the crystals. I also analyzed the resulting XRPD patterns. The experimental test and analysis conditions used for the XRPD testing is attached to this declaration as Appendix B.

24. The results of my XRPD testing for the resulting (Z)-endoxifen crystals from both Liu’s Recrystallization Procedure and Liu’s Isomerization and Recrystallization Procedure are below. The tables below provide the measured peak positions (*e.g.*, °2-theta), the d-spacing, and the intensity of each measured peak for each solid (*e.g.*, the solids made by Liu’s recrystallization procedure and the solids made by Liu’s isomerization and recrystallization procedure).

**XRPD Results of Liu's
Recrystallization Procedure**

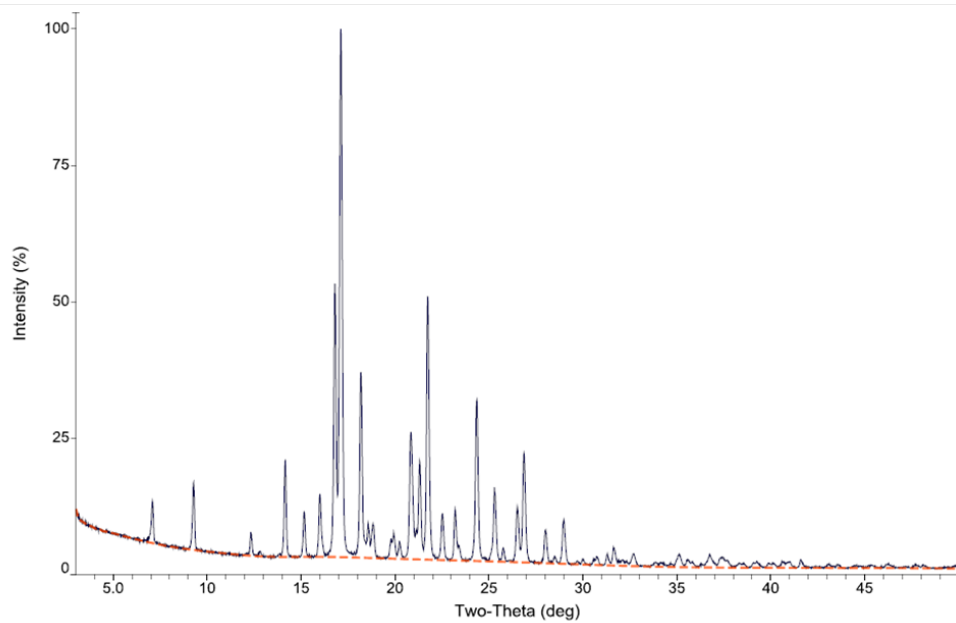
2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

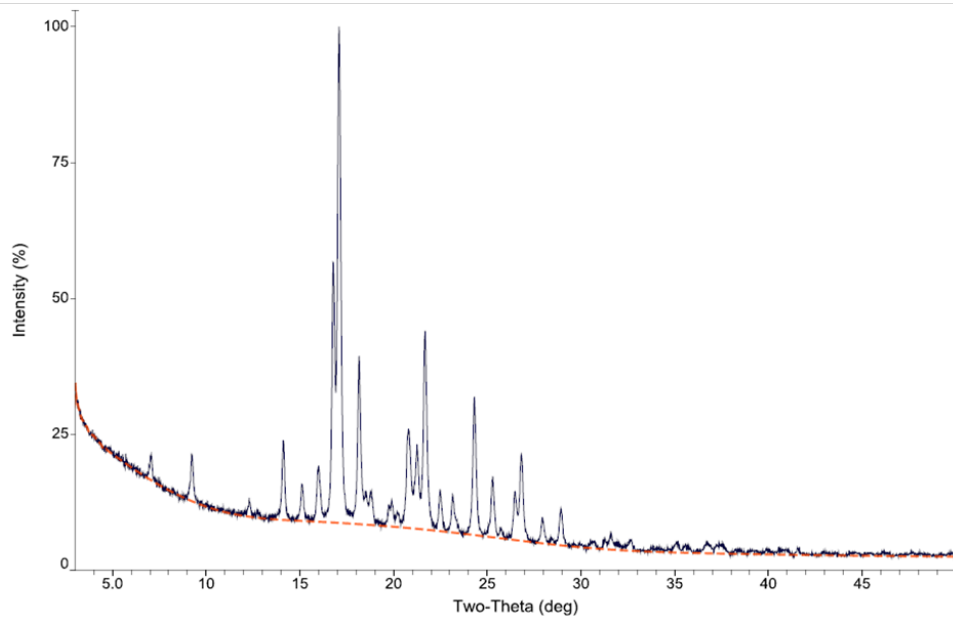
2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

25. The graphs below also provide the results of the XRPD testing of the resulting (Z)-endoxifen crystals from Dr. Bihovsky. The graphs below provide the XRPD patterns in °2-theta as a function of intensity for each of the solids made by Liu's recrystallization procedure and the solids made by Liu's isomerization and recrystallization procedure.

**XRPD Results of Liu's
Recrystallization Procedure**



**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**



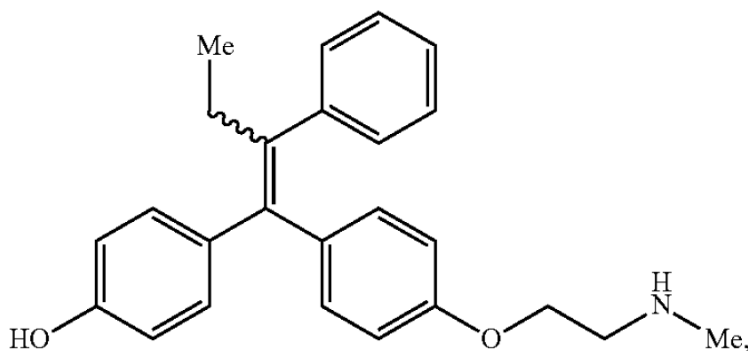
XI. Claims 1-5 and 16 in View of Liu

26. I incorporate by reference Dr. Bihovsky's discussion of the claims in in view of Liu.

A. Independent Claim 1

A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer

27. Formula (III) recited in the claims is endoxifen (including E- and/or (Z)-endoxifen). *See* Ex. 1001 at 8:15-16. As described in the 151 patent, Formula (III) can include the polymorphic salt, free base, co-crystal, and/or solvate forms of (Z)-endoxifen. *See id.* at 12:48-52.

28. Liu teaches “a process for preparing (Z)-endoxifen” with “a ratio of (Z)-endoxifen (1) to (E)-endoxifen (2) greater than 20:1.” Ex. 1003 at Abstract. Thus, Liu teaches a composition comprising a crystalline form of a compound of

Formula (III) wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer.

wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta.

29. Liu does not disclose that the (Z)-endoxifen created is the claimed “Form I” or provide an XRPD characterization of the resulting crystalline solids. However, as discussed above, Dr. Bihovsky reproduced Liu, and sent the resulting crystals to me for XRPD testing.

30. “[T]he X-ray diffraction pattern is the fingerprint of periodic atomic arrangements in a given material.” Ex. 1011 at Abstract; *see also* Ex. 1031 at 1 (“Every crystalline phase of a given substance produces a characteristic X-ray diffraction pattern.”). As such, an XRPD pattern can be used to identify a particular form of a crystal structure. Therefore, as shown below, the results of my XRPD testing confirm that the resulting (Z)-endoxifen from both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are the claimed Form I, characterized by the claimed XRPD peaks. *See* Ex. 1031 at 9 (“The agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form . . .”).

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

31. Thus, Liu inherently teaches that the crystalline form of the (Z)-isomer obtained is Form I, characterized by an XRPD comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta.

B. Dependent Claim 2

32. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” *See* Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 2 are similarly present in Liu’s resulting crystalline solids.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and 26.5 ± 0.3 two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

C. Dependent Claim 3

33. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” *See* Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 3 are similarly present in Liu's resulting crystalline solids.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3 \pm 0.3^\circ$, $28.0 \pm 0.3^\circ$ and $29.0 \pm 0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

D. Dependent Claim 4

34. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 4 are similarly present in Liu's resulting crystalline solids.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3\pm0.3^\circ$, $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$, $26.5\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

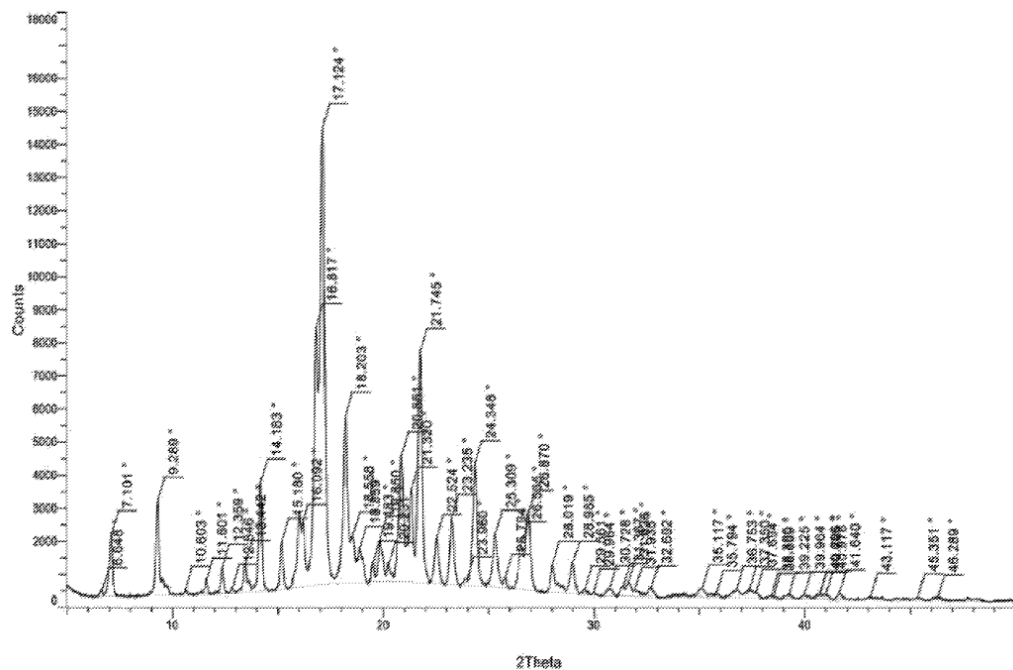
E. Dependent Claim 5

35. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” *See* Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

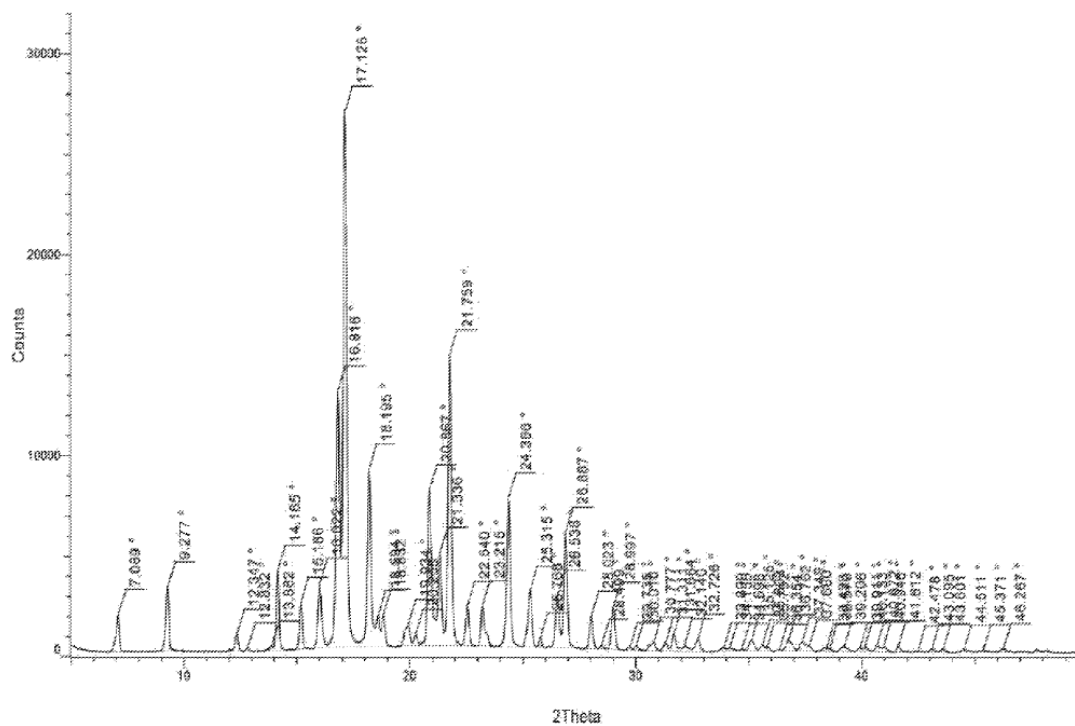
by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 5 are similarly present in Liu's resulting crystalline solids.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

36. The 151 patent's Figures 9 and 10 are reproduced below. Also below is a figure illustrating the XRPD patterns of the crystalline solids obtained by Dr. Bihovsky following Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures arranged for comparison with a stick pattern of the XRPD pattern data reported at Table 8 of the 151 patent (shown in blue), which corresponds to the XRPD patterns shown in Figures 9 and 10.

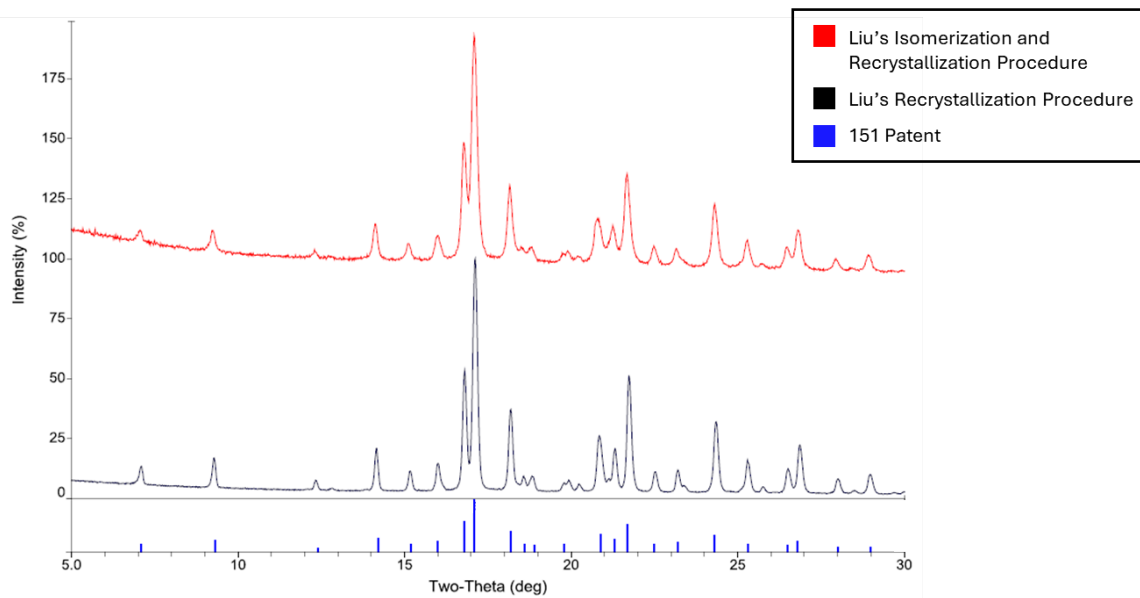


Ex. 1001, Figure 9.



Id., Figure 10.

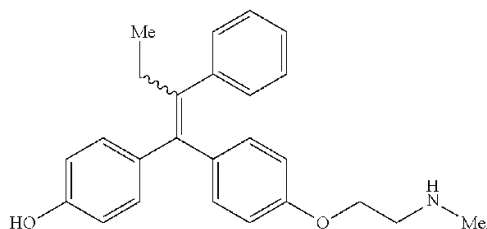
XRPD Results of Liu's Procedures
Compared to the 151 Patent



F. Independent Claim 16

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

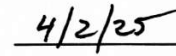
37. Liu teaches that (Z)-endoxifen may be used to treat hormone-dependent breast disorders. For example, Liu explains that (Z)-endoxifen is more active at the estrogen receptor, and therefore may be used to treat breast cancer. Ex. 1003 at [0002]-[0004]. Therefore, Liu discloses a method of using highly pure (Z)-endoxifen to “treat[] a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in the subject” as recited in claim 16.

38. And as discussed with respect to claim 1, the (Z)-endoxifen obtained by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures exhibit the claimed XRPD patterns. Thus, Liu inherently discloses (Z)-endoxifen in the claimed Form 1.

39. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

A handwritten signature in cursive script, appearing to read "Steven Miller", is written over a horizontal line.

Steven Miller, Ph.D.

A handwritten date "4/2/25" is written over a horizontal line.

Date

APPENDIX A

Dr. Steven L. Miller, PhD, MBA

H&M Analytical Services
1301 Whitehorse Mercerville Rd., Suite 101
Hamilton, NJ 08619
(609) 758-5700
steve@h-and-m-analytical.com

- Education:** Ph.D., Materials Science and Engineering, *Rutgers University, 2008.*
Thesis Title: "Towards Room Temperature Processed and Completely Flexible Organic Photovoltaics", Thesis Advisor: Prof. Manish Chhowalla
M.S., Materials Science and Engineering, *Rutgers University, 2006.*
B.A., Physics (minor: Mathematics), *Rutgers University, 2004.*
M.B.A., Finance/Accounting, *University of California, Irvine, 1991.*
B.A., Economics, *University of California, Irvine, 1987.*
- Technical Experience:**
- | | |
|--------------|--|
| 2014-Current | President/Owner, H&M Analytical Services, Cream Ridge, NJ |
| 2018-Current | Adjunct Professor, Rutgers University, School of Engineering
Course taught: Advanced Materials Characterization |
| 2012-2014 | Scientist, H&M Analytical Services, Cream Ridge, NJ |
| 2009-2012 | Research Associate, Ceramic, Composite and Optical Materials Center, Materials Science and Engineering, Rutgers University, Piscataway, NJ. |
| 2008-2009 | Post Doctoral Assistant, Ceramic, Composite and Optical Materials Center, Materials Science and Engineering, Rutgers University, Piscataway, NJ. |
| 2004-2007 | Graduate Research Assistant, Nano-Materials and Devices Group, Materials Science and Engineering, Rutgers University, Piscataway, NJ. |
| 2004-2008 | Teaching Assistant, Materials Science and Engineering, Rutgers University, Piscataway, NJ.
Courses: - Materials Processing I
- Photonic, Electronic and Magnetic Applications of Nanostructures and Nanomaterials
- Electron Microscopy |
- Business Experience:** Summary – *Almost twenty years of experience in finance and accounting, including high level management positions. Extensive experience managing budgets, people and projects. Significant achievements/projects included:*
- *Initial public offering for medical equipment leasing company.*
 - *Developed and implemented quality control and peer review standards for the public accounting profession.*
 - *Designed and managed financial reporting system for a start-up company.*
 - *Designed and developed a production planning system for a printed circuit board manufacturing facility.*
- | | |
|-----------|---|
| 2000-2004 | Technical Manager, American Institute of Certified Public Accountants, Jersey City, NJ. |
| 1998-1999 | Audit Manager, Ernst & Young LLP, Iselin, NJ. |
| 1996-1997 | Chief Accounting Officer, Rockford Industries, Inc. Santa Ana, CA. |
| 1991-1996 | Audit Manager, Deloitte & Touche LLP, Costa Mesa, CA. |
| 1990-1991 | Finance Manager, Conservation Technologies, Inc., Irvine, CA. |
| 1985-1988 | Financial Analyst, Xerox Corp., El Segundo, CA. |

- Publications:** A. Chikkam, M. Zamanzadeh, S. Pulagam, P. Mortel, B. Murali, S. Miller, S. Mercurio, "Corrosion Deposits Database - X-Ray Diffraction Analysis of Deposits from Oil and Gas Upstream Well/Production Systems," *AMPP Conference Proceedings*, C2024-20831 (2024)
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M. Jitianu, J.K. Ko, S. Miller, C. Rohn, R. A. Haber,” Controlled Processing of Bulk Assembling of Nanoparticles of Titania,” *Ceramic Transactions* **223**, (2009)

C. Mattevi, G. Eda, S. Agnoli, S. Miller, K. A. Mkhoyan, O. Celik, D. Mastrogiovanni, G. Granozzi, E. Garfunkel, and M. Chhowalla, "Evolution of Electrical, Chemical, and Structural Properties of Transparent and Conducting Chemically Derived Graphene Thin Films," *Advanced Functional Materials* **19**, 1 (2009)

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G. Fanchini, S. Miller, B. Parekh, and M. Chhowalla, “Optical anisotropy in transparent and conducting single-walled carbon nanotube thin films,” *Nano Letters* **8**, 2176 (2008)

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S. Miller, G. Fanchini, Y. Lin, C. Li, C. Chen, W. Su, and M. Chhowalla, “Investigation of nanoscale morphological changes in organic photovoltaics during solvent vapor annealing,” *Journal of Materials Chemistry* **18**, 306 (2008).

D. Slusark, M.V. Demirbas, A. Portune, S. Miller, R. Haber, R. Brennan, W. Green, E. Chin, and J. Campbell, “Nondestructive Evaluation (NDE) of Sintered Silicon Carbide and its Correlation to Microstructure and Mechanical Properties,” *Proceedings of the Army Science Conference*, Orlando FL, December 2008.

A. Du Pasquier, S. Miller, and M. Chhowalla, “On the use of Ga-In eutectic and halogen light source for testing P3HT-PCBM organic solar cells,” *Solar Energy Materials and Solar Cells* **90**, 1828 (2006).

A. Du Pasquier, H.E. Unalan, A. Kanwal, S. Miller, and M. Chhowalla, “Conducting and transparent single-wall carbon nanotube electrodes for polymer-fullerene solar cells,” *Applied Physics Letters* **87**, 203511 (2005).

Synergistic activities, memberships and awards:

- Founded the Materials Research Society Student Chapter at Rutgers University.
- Former member of the Materials Research Society, American Physical Society, American Association for the Advancement of Science, and Sigma Xi.
- Awarded the Betty Skuze Thompson Prize in physics.
- Supervised/assisted with undergraduate and graduate research projects.
- Established laboratory and protocols for general photovoltaic research at Rutgers University.
- Established TEM sample preparation laboratory and procedures.
- Established and maintained Rutgers FESEM laboratory.

Skills:

Transmission Electron Microscopy, Scanning Electron Microscopy, Electron Energy Loss Spectroscopy, Energy Dispersive Spectroscopy, Wavelength Dispersive Spectroscopy, Optical Microscopy, Atomic Force Microscopy, X-ray Diffractometry, Raman Spectroscopy, UV-Vis Spectroscopy, Fourier Transform Infra-Red Spectroscopy, Thermo Gravimetric Analysis, Profilometry, Electrical Characterization

MAYO

APPENDIX 2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,

Petitioner

v.

ATOSSA THERAPEUTICS, INC.,

Patent Owner

Case IPR2025-00799

Patent No. 11,261,151

EXPERT DECLARATION OF WILLIAM MAYO, Ph.D., ADOPTING THE
OPINIONS OF STEVEN MILLER, Ph.D.

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Declaration of ~~Steven Miller~~William Mayo, Ph.D.

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I, ~~Steven Miller~~William Mayo, Ph.D., do hereby declare:

I. Introduction

1. I have been retained to provide my expert opinions on behalf of Intas Pharmaceuticals, Limited, in support of a petition for *inter partes* review of claims 1-21 of U.S. Patent No. 11,261,151 (“the 151 Patent”; Ex. 1001), which challenges the validity of the 151 patent. I have been asked to provide this declaration adopting the opinions of Dr. Miller, who is no longer available to participate in these proceedings. Dr. Miller’s report is attached as Appendix 1. I have maintained the paragraphs of Dr. Miller’s declaration and have only modified the language as necessary to reflect the change from Dr. Miller to myself. I have not been asked to, and have not, provided any new opinions. The only additions I have offered are my own Education and Professional Background at the conclusion of this declaration. A redline showing the changes from Dr. Miller’s declaration is attached as Appendix 2.

2. The opinions set out by this declaration are based on my education, knowledge and experience. I have considered the materials and items identified in this declaration, as well as Dr. Miller’s declaration.

II. Dr. Miller's Education and Professional Background

3. MyI understand Dr. Miller's qualifications and credentials to testify as an expert in this case arewere set forth in myhis curriculum vitae (attached as Appendix A).

4. I-haveI understand Dr. Miller has significant experience in materials characterization, specifically in regards to analyzing samples through spectroscopic techniques and analyzing the physical structure of molecules using techniques such as X-ray diffraction and spectroscopy. I-haveI understand Dr. Miller has more than 20 years of academic and industrial materials development and characterization experience. MyI understand Dr. Miller's research has resulted in more than 15 publications in refereed journals.

5. I understand Dr. Miller obtained a B.A., in Physics, from Rutgers University in 2004. I and then obtained an M.S. and then a Ph.D. in Materials Science and Engineering, also from Rutgers. WhileI understand that while at Rutgers, Dr. Miller worked as a teaching assistant, research assistant, post-doctoral assistant, and research associate. I also understand that Dr. Miller conducted research with the nano-materials and devices group and the composite and optical materials center.

6. Since 2014 I-haveDr. Miller has been the president/owner of H&M Analytical Services, which is a full-service x-ray diffraction and analysis testing lab,

which also provides a wide range of other testing and material characterization services. Polymorph identification of pharmaceuticals is a substantial portion of the testing performed by H&M Analytical Services.

7. ~~Since~~I also understand that since 2018 ~~I have~~, Dr. Miller has been an Adjunct Professor at Rutgers, teaching Advanced Materials Characterization.

III. Dr. Miller's Compensation

8. I ~~am being~~understand Dr. Miller was compensated for the time ~~I spend~~he spent on this matter at ~~my~~his ordinary rate of \$500 per hour for expert services. ~~I am~~I understand Dr. Miller was reimbursed for ~~my~~his reasonable expenses incurred in connection with my work on this matter. ~~My~~I further understand Dr. Miller's compensation does not depend on the opinions I offer or on the outcome of this proceeding or any other proceeding.

IV. Scope of Dr. Miller's Engagement

9. ~~I~~ understand Dr. Miller was asked by counsel to perform certain experiments to determine the x-ray power diffraction ("XRPD") patterns of crystals synthesized by Dr. Ron Bihovsky according to the methods taught in International Application No. WO 2017/070651 ("Liu"). ~~I~~ understand Dr. Miller also compared the XRPD patterns of the crystals synthesized by Dr. Bihovsky to the disclosure and claims of the 151 patent.

10. I understand that some of the claims are directed to compositions for use as a pharmaceutical and methods for treating a subject. I ~~am~~understand that Dr. Miller is not an expert in pharmaceutical formulations or treating patients, and I ~~have~~was not ~~been~~ asked to offer any opinions outside of ~~my~~this expertise or concerning the ultimate issues of validity of the claims.

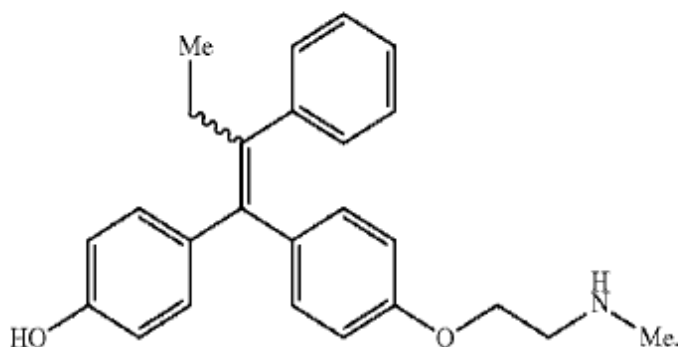
V. Background

11. The claims of the 151 patent are directed to compositions comprising a crystalline form of endoxifen that is at least 90% by weight (Z)-endoxifen having a crystalline Form I, characterized by an x-ray powder diffraction pattern comprising certain peaks.

12. Endoxifen (4-hydroxy-N-desmethyltamoxifen) is a nonsteroidal selective estrogen receptor modulator. I understand that Intas sells endoxifen in India under the brand name Zonalta for the treatment of manic depressive disorder. See Ex. 1015.

13. Endoxifen can be depicted as the below chemical structure, which is referred to as Formula (III) in the 151 patent:

Formula (III)



See, e.g., Ex. 1001 at 3:1-15.

VI. The 151 Patent

14. The 151 patent is entitled “Methods for Making and Using Endoxifen.” Ex. 1001 at Cover. I understand that the 151 patent is a U.S. National Phase Application of International Application No. PCT/US2018/050272, filed September 10, 2018 and claims priority to Provisional Application No. 62/556,799, dated September 11, 2017. *Id.* Thus, I have been instructed to use September 11, 2017 as the time of invention, and to consider my opinions from the perspective of a person of skill at that time.

15. The 151 patent is directed to compositions of endoxifen that are at least 90% by weight of (Z)-endoxifen in a particular crystalline form (*i.e.*, Form I) and methods of administering such formulations. The 151 patent characterizes Form I by its XRPD pattern. In particular, the 151 patent states that Form I “may be characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, and optionally further comprising at

least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and $26.5 \pm 0.3^\circ$ two theta. In some embodiments, the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3 \pm 0.3^\circ$, $28.0 \pm 0.3^\circ$ and $29.0 \pm 0.3^\circ$ two theta.” *Id.* at 3:20-28. The 151 patent further states that Form I “is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.” *Id.* at 3:32-34. Figures 9 and 10 of the 151 patent are reproduced below.

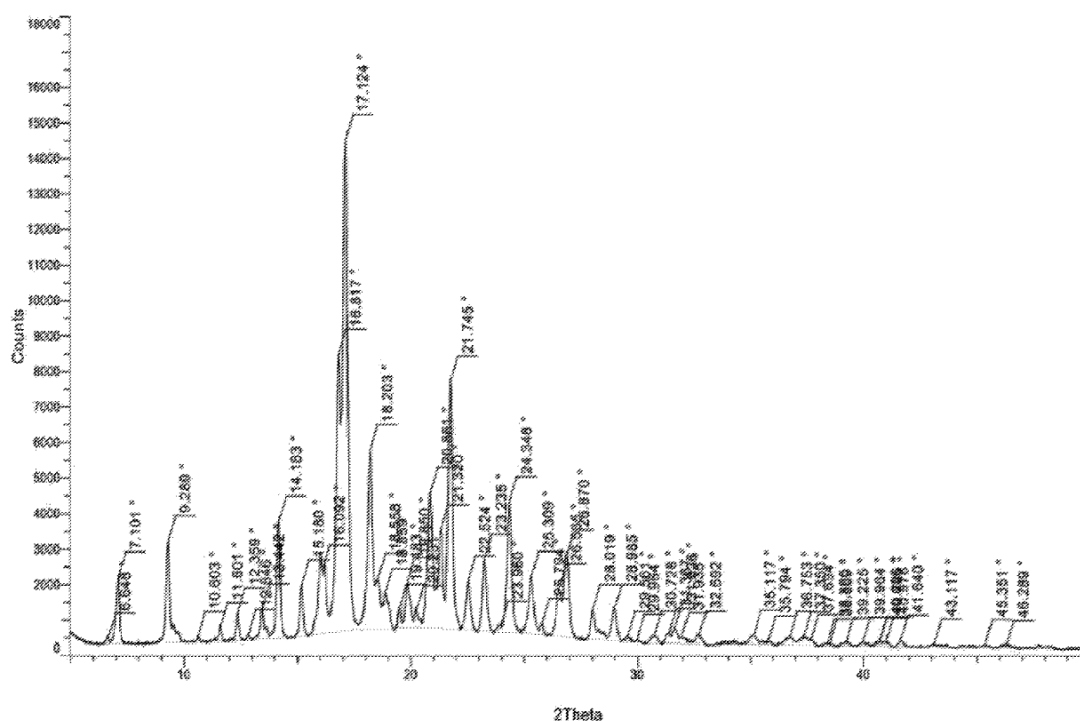
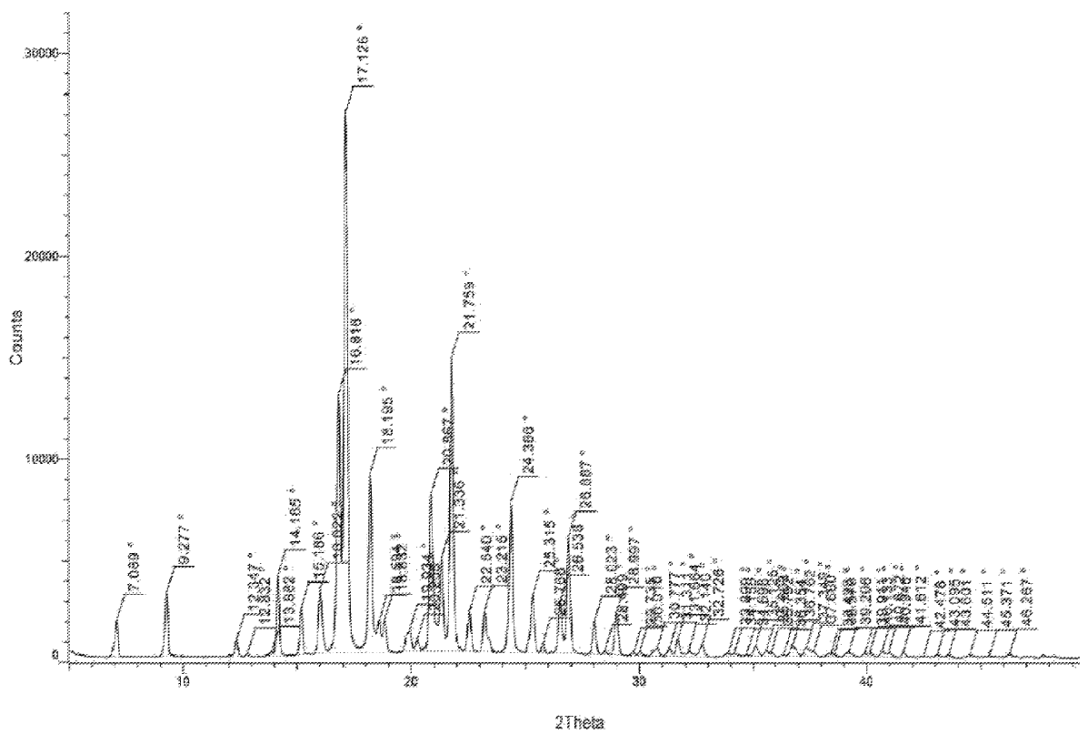


Figure 9.



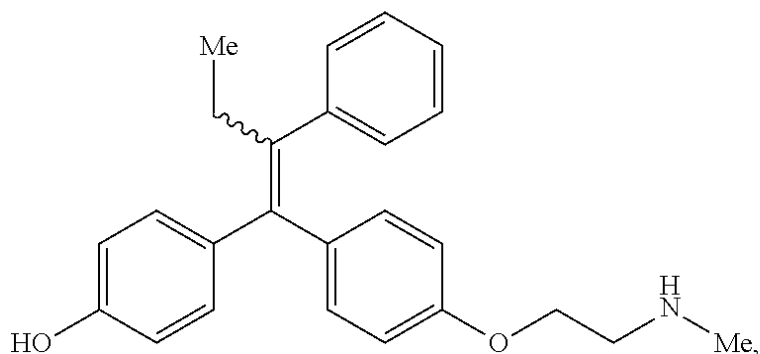
Id. at Figure 10.

16. I understand that the 151 patent contains the following 21 claims:

Independent Claim 1 and Dependent Claims 2-15 and 21

1. A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the

(Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$ and $26.5\pm0.3^\circ$ two theta.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3\pm0.3^\circ$, $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$, $26.5\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

6. The composition of claim 1, wherein greater than 90% by weight of the (Z)-isomer in the composition is crystalline Form I.

7. The composition of claim 1, further comprising a pharmaceutically acceptable carrier or diluent.

8. The composition of claim 7, wherein the composition is formulated for oral, parenteral, topical, or intraductal delivery.

9. The composition of claim 7, wherein the composition is formulated for oral delivery as a tablet, a caplet, a capsule, or a pill.

10. The composition of claim 7, wherein a mean half-life of the compound of Formula (III) in a subject treated with the composition is between 30 hours to 60 hours.

11. The composition of claim 1, formulated as an oral dosage form comprising 1 mg to 200 mg per unit dose of the composition, and wherein daily administration of the oral dosage form achieves in a subject treated with the composition one or more of:

a steady state plasma level of the compound of Formula (III) within 7 to 21 days;

a steady state plasma level of the compound of Formula (III) ranging from 25 nM to 300 nM;

a steady state plasma level of the compound of Formula (III) greater than 30 nM; or

maximal plasma levels of the compound of Formula (III) within 2 to 10 hours after administering.

12. The composition of claim 11, wherein a mean half-life of the compound of Formula (III) in the subject is between 40 hours to 55 hours.

13. The composition of claim 11, wherein the oral dosage form is formulated as an enteric tablet, an enteric caplet, an enteric capsule, a delayed-release tablet, a delayed-release caplet or a delayed-release capsule.

14. The composition of claim 11, wherein at least 80% of the compound of Formula (III) in the oral dosage form is released in the intestines of the subject.

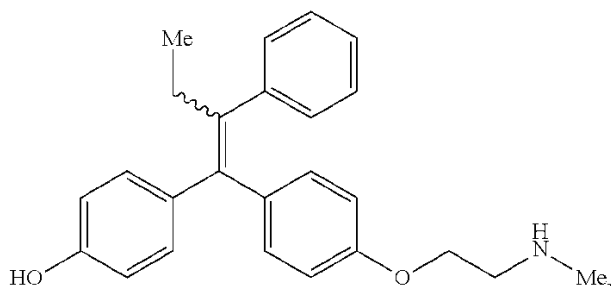
15. The composition of claim 11, having a mean area under the curve extrapolated to time infinity ($AUC_{0-\infty}$) of the compound of Formula (III) of 200 hr*ng/mL to 10000 hr*ng/mL.

21. The composition of claim 1, wherein the composition is stable for at least 9 months at 5° C. and 60% relative humidity or at 25° C. and 60% relative humidity.

Independent Claim 16 and Dependent Claims 17-20

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

17. The method of claim 16, wherein the subject has prostate cancer and wherein the subject further has or is at risk of having gynecomastia.

18. The method of claim 16, wherein the subject has tamoxifen-refractory or tamoxifen resistant hormone-dependent breast disorder or hormone-dependent reproductive tract disorder.

19. The method of claim 16, wherein the composition comprises 0.01 mg to 200 mg of the (Z)-isomer.

20. The method of claim 16, wherein a steady state plasma level of the compound of Formula (III) is achieved within 7 to 21 days of the first administration of the composition to the subject, and wherein the steady state plasma level of the compound of Formula (III) in the subject is greater than 30 nM.

VII. Person of Ordinary Skill in the Art

17. I understand that the content of a patent (including its claims) and prior art should be interpreted the way a person of ordinary skill in the art (or “POSA”) would have interpreted the material at the time of the alleged invention. In my opinion, a POSA for purposes of the 151 patent [is has](#) a graduate degree in organic

chemistry, material science, medicinal chemistry, pharmaceutical chemistry, or a related field, and four to six years of experience in the synthesis, purification, analysis, design, and/or formulation of pharmaceutical compounds and derivatives. A POSA would have worked with a team of professionals with training in related disciplines, such as pharmacology, pharmacokinetics, formulation, drug discovery and/or drug development as of the date of the claimed inventions.

18. I base my opinion on my review of the 151 patent, the problems the 151 patent was attempting to solve, the prior art discussed below, and my general experience with pharmaceutical compounds and the people working in the field. I meet and/or exceed the definition of a POSA. I also note that my opinions would not change if the level of skill in the art were found to be lower.

VIII. Claim Construction

19. I understand that terms should be given their plain and ordinary meaning to a person of skill at the time of invention. I have applied this principle to all terms in the 151 patent addressed below.

IX. Summary of the Prior Art

A. WO 2017/070651 (“Liu”)

20. I understand that International Application No. WO 2017/070651 (“Liu”) was filed on October 24, 2016, and published on April 27, 2017 and is therefore prior art to the 151 patent. Ex. ~~1002~~1003 at Cover.

21. Liu teaches methods for synthesizing and purifying (Z)-endoxifen with a 99% isomeric purity. *See, e.g., id.* at [0076]. In particular, Liu discloses two methods of preparing highly pure (Z)-endoxifen: i) synthesis followed by sequential recrystallizations (“Liu’s Recrystallization Procedure”), *id.*, [0021]-[0045], and (ii) synthesis followed by isomerization and sequential recrystallizations (“Liu’s Isomerization and Recrystallization Procedure”). *Id.*, [0046]-[0055]. Liu does not report any XRPD data of the compounds Liu synthesized. Thus, Liu does not report whether its compounds exhibited the XRPD pattern recited in the claims of the 151 patent (*i.e.*, Form I). However, as I discuss in more detail below, I have confirmed that Liu’s procedure provides (Z)-endoxifen that exhibits an XRPD pattern consistent with Form I as claimed in the 151 patent.

B. General X-Ray Powder Diffraction Art

22. XRPD is a method of exposing a crystalline form of a compound to X-rays, generating a pattern as a function of the scattering angle. Bunaciu, A. et al., *X-ray Diffraction: Instrumentation and Applications*, 45 CRITICAL REVIEWS IN ANALYTICAL CHEM. 289-99 (May 21, 2015) (“Bunaciu”) discloses that XRPD can

be used to identify a specific polymorph structure. Ex. 1011 at 289. For example, Bunaciu explains that “[i]n the drug design, discovery, development, and formulation process, X-ray powder diffraction can help to establish a formulation by discovering the morphology and the degree of crystallinity, providing unique polymorph identification, and determining the quantity of each in mixture.” *Id.* Thus, the same (or substantially similar) XRPD patterns for different samples of a substance indicate that the samples have the same polymorph structure. *Id.*

X. Dr. Miller’s X-Ray Powder Diffraction of (Z)-Endoxifen Synthesized in Accordance with Liu’s Procedures

23. Dr. Bihovsky followed the procedures outlined in Liu to obtain highly pure (Z)-endoxifen. I understand Dr. Miller then tested the highly pure (Z)-endoxifen synthesized by Dr. Bihovsky according to Liu to obtain the XRPD patterns of the crystals. I also understand Dr. Miller analyzed the resulting XRPD patterns. The I understand the experimental test and analysis conditions used for the XRPD testing is was intended to be attached to ~~this~~ Dr. Miller’s declaration as Appendix B.

24. The results of [myDr. Miller's](#) XRPD testing for the resulting (Z)-endoxifen crystals from both Liu's Recrystallization Procedure and Liu's Isomerization and Recrystallization Procedure are below. The tables below provide the measured peak positions (*e.g.*, °2-theta), the d-spacing, and the intensity of each measured peak for each solid (*e.g.*, the solids made by Liu's recrystallization procedure and the solids made by Liu's isomerization and recrystallization procedure).

**XRPD Results of Liu's
Recrystallization Procedure**

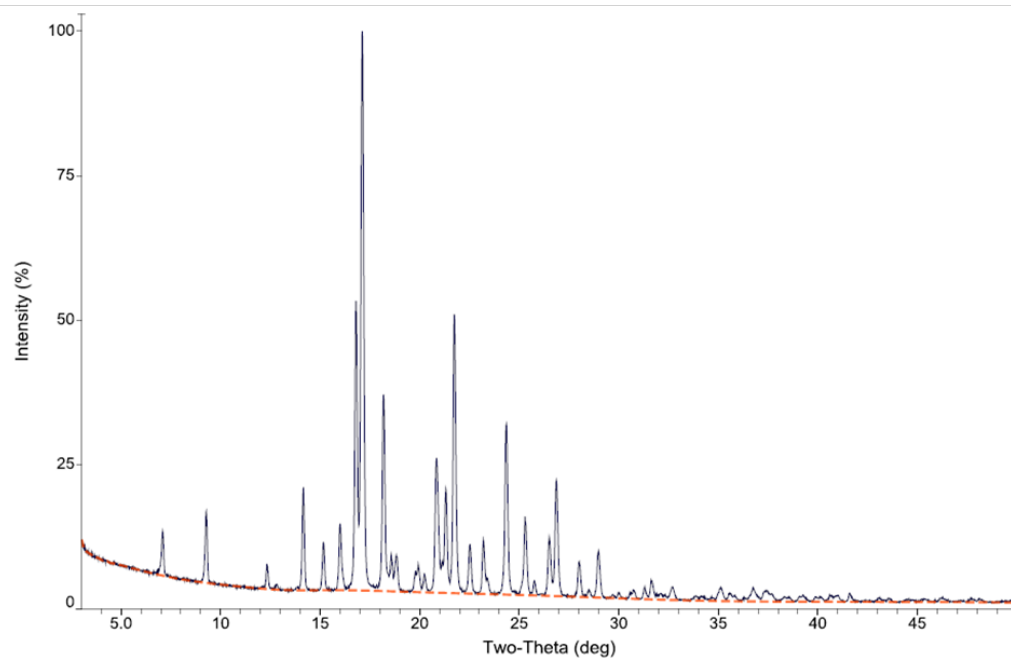
2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

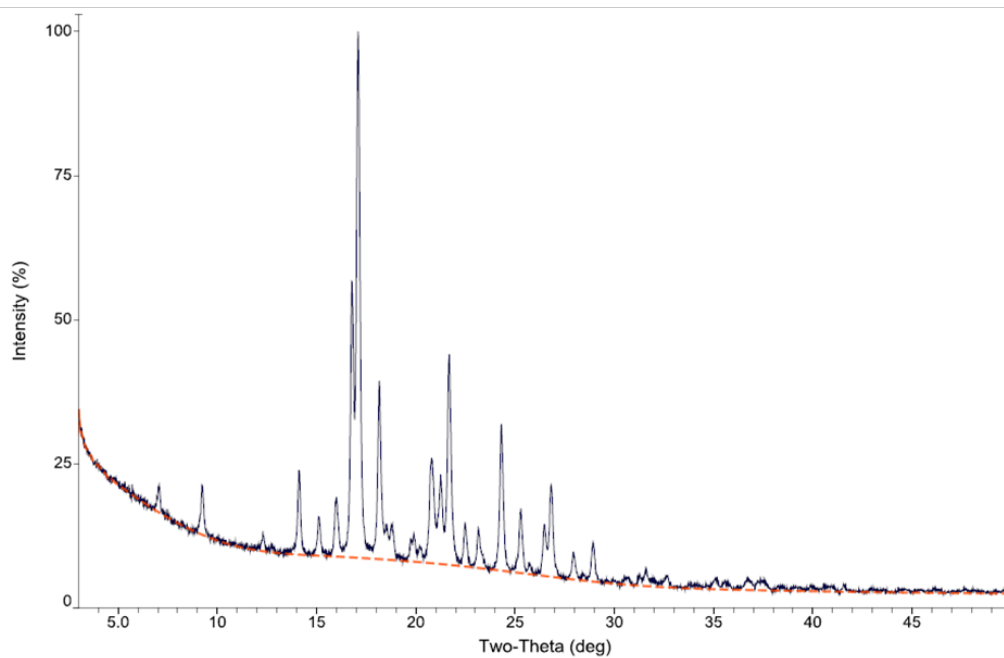
2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

25. The graphs below also provide the results of the XRPD testing of the resulting (Z)-endoxifen crystals from Dr. Bihovsky. The graphs below provide the XRPD patterns in °2-theta as a function of intensity for each of the solids made by Liu's recrystallization procedure and the solids made by Liu's isomerization and recrystallization procedure.

**XRPD Results of Liu's
Recrystallization Procedure**



**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**



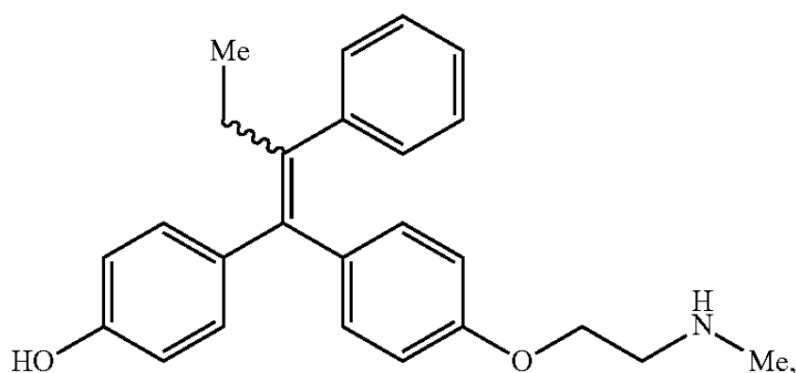
XI. Claims 1-5 and 16 in View of Liu

26. I incorporate by reference Dr. Bihovsky's discussion of the claims in in view of Liu.

A. Independent Claim 1

A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer

27. Formula (III) recited in the claims is endoxifen (including E- and/or (Z)-endoxifen). See Ex. 1001 at 8:15-16. As described in the 151 patent, Formula (III) can include the polymorphic salt, free base, co-crystal, and/or solvate forms of (Z)-endoxifen. See *id.* at 12:48-52.

28. Liu teaches “a process for preparing (Z)-endoxifen” with “a ratio of (Z)-endoxifen (1) to (E)-endoxifen (2) greater than 20:1.” Ex. 1003 at Abstract. Thus, Liu teaches a composition comprising a crystalline form of a compound of

Formula (III) wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer.

wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8\pm0.3^\circ$, $17.1\pm0.3^\circ$ and $21.8\pm0.3^\circ$ two theta.

29. Liu does not disclose that the (Z)-endoxifen created is the claimed “Form I” or provide an XRPD characterization of the resulting crystalline solids. However, as discussed above, Dr. Bihovsky reproduced Liu, and sent the resulting crystals to [meDr. Miller](#) for XRPD testing.

30. “[T]he X-ray diffraction pattern is the fingerprint of periodic atomic arrangements in a given material.” Ex. 1011 at Abstract; *see also* Ex. 1031 at 1 (“Every crystalline phase of a given substance produces a characteristic X-ray diffraction pattern.”). As such, an XRPD pattern can be used to identify a particular form of a crystal structure. Therefore, as shown below, the results of [myDr. Miller’s](#) XRPD testing confirm that the resulting (Z)-endoxifen from both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are the claimed Form I, characterized by the claimed XRPD peaks. *See* Ex. 1031 at 9 (“The agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form . . .”).

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

31. Thus, Liu inherently teaches that the crystalline form of the (Z)-isomer obtained is Form I, characterized by an XRPD comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta.

B. Dependent Claim 2

32. As discussed above, “[t]he agreement in the 2θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 2 are similarly present in Liu’s resulting crystalline solids.

2. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $16.0 \pm 0.3^\circ$, $18.8 \pm 0.3^\circ$ and 26.5 ± 0.3 two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
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15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

C. Dependent Claim 3

33. As discussed above, “[t]he agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 3 are similarly present in Liu's resulting crystalline solids.

3. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises at least one peak selected from $12.3\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

D. Dependent Claim 4

34. As discussed above, “[t]he agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 4 are similarly present in Liu's resulting crystalline solids.

4. The composition of claim 1, wherein the x-ray powder diffraction pattern further comprises peaks at $12.3\pm0.3^\circ$, $16.0\pm0.3^\circ$, $18.8\pm0.3^\circ$, $26.5\pm0.3^\circ$, $28.0\pm0.3^\circ$ and $29.0\pm0.3^\circ$ two theta.

**XRPD Results of Liu's
Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.092	12.454	7.80%
9.282	9.520	12.90%
12.329	7.173	4.30%
14.160	6.250	18.30%
15.167	5.837	8.50%
16.002	5.534	11.60%
16.803	5.272	51.70%
17.120	5.175	100.00%
18.189	4.873	34.60%
18.576	4.773	3.60%
18.827	4.710	6.60%
19.795	4.481	3.20%
19.929	4.452	4.40%
20.236	4.385	2.60%
20.848	4.258	23.90%
21.133	4.201	5.60%
21.315	4.165	15.40%
21.735	4.086	49.90%
22.532	3.943	8.60%
23.204	3.830	9.60%
23.386	3.801	2.80%
24.355	3.652	30.50%
25.296	3.518	13.70%
25.762	3.455	2.30%
26.513	3.359	10.30%
26.864	3.316	20.80%
28.016	3.182	6.30%
28.501	3.129	1.40%
28.984	3.078	8.30%
30.017	2.975	1.00%
30.577	2.921	1.20%
30.755	2.905	1.50%
31.303	2.855	1.90%
31.633	2.826	2.90%
32.709	2.736	2.10%
35.119	2.553	2.10%
35.617	2.519	1.40%
36.742	2.444	2.10%
37.426	2.401	1.60%
37.690	2.385	1.20%
39.262	2.293	1.20%
40.633	2.219	1.00%
40.984	2.200	1.20%
41.602	2.169	1.40%

**XRPD Results of Liu's Isomerization
and Recrystallization Procedure**

2-Theta	d(Å)	Intensity (%)
7.0596	12.5113	5.3%
9.2221	9.5818	9.6%
12.2968	7.1921	3.3%
14.1140	6.2699	16.1%
15.1034	5.8613	7.4%
15.9991	5.5351	10.5%
16.7726	5.2815	52.0%
17.0879	5.1848	100.0%
18.1572	4.8818	32.8%
18.4964	4.7930	2.6%
18.8126	4.7132	2.4%
19.7344	4.4951	3.9%
19.8949	4.4592	4.8%
20.1986	4.3928	2.3%
20.7968	4.2678	19.3%
21.2492	4.1779	10.2%
21.6815	4.0956	39.9%
22.4860	3.9508	7.7%
23.1546	3.8382	7.5%
24.3068	3.6588	28.3%
25.2900	3.5188	12.1%
25.7163	3.4614	1.7%
26.4785	3.3635	9.3%
26.8135	3.3222	18.1%
27.9493	3.1897	5.2%
28.9206	3.0848	7.1%
30.7185	2.9082	1.3%
31.2886	2.8565	1.8%
31.6080	2.8284	3.0%
32.5985	2.7446	1.9%
35.0858	2.5556	1.6%
35.1753	2.5493	2.2%
35.6552	2.5160	1.1%
36.7208	2.4454	1.7%
37.5069	2.3960	1.6%

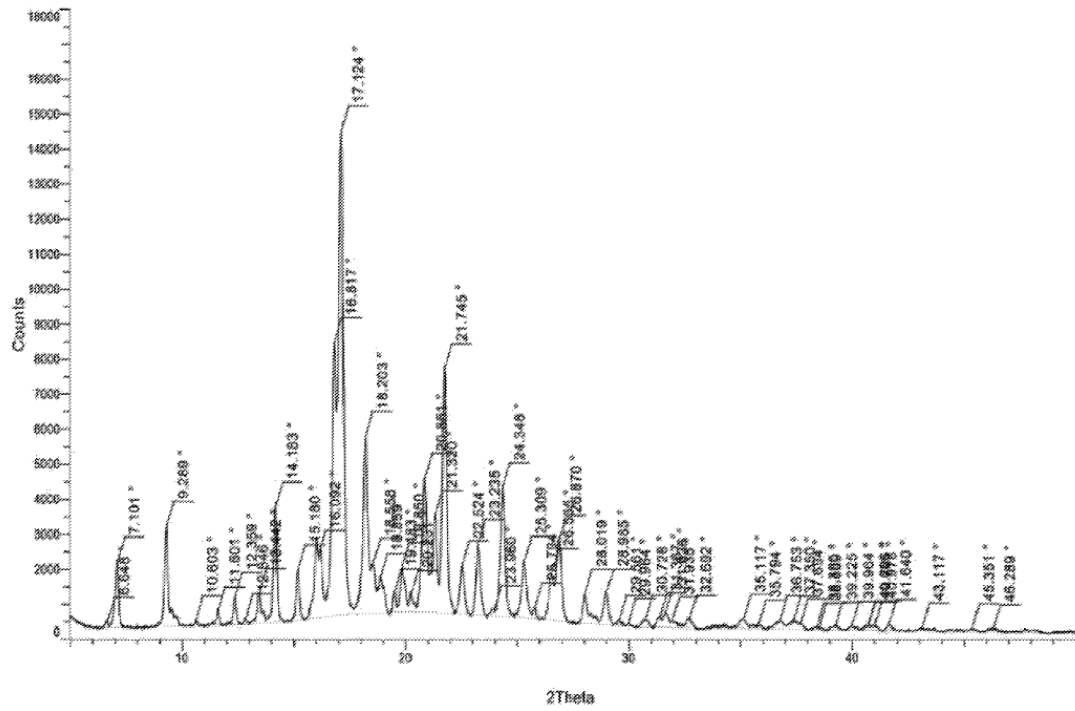
E. Dependent Claim 5

35. As discussed above, “[t]he agreement in the 2Θ diffraction angles between specimen and references is expected to be within 0.2° for the same crystal form.” See Ex. 1031 at 9. The results of the XRPD testing of the crystalline solids of (Z)-endoxifen obtained via Dr. Bihovsky’s synthesis of highly pure (Z)-endoxifen

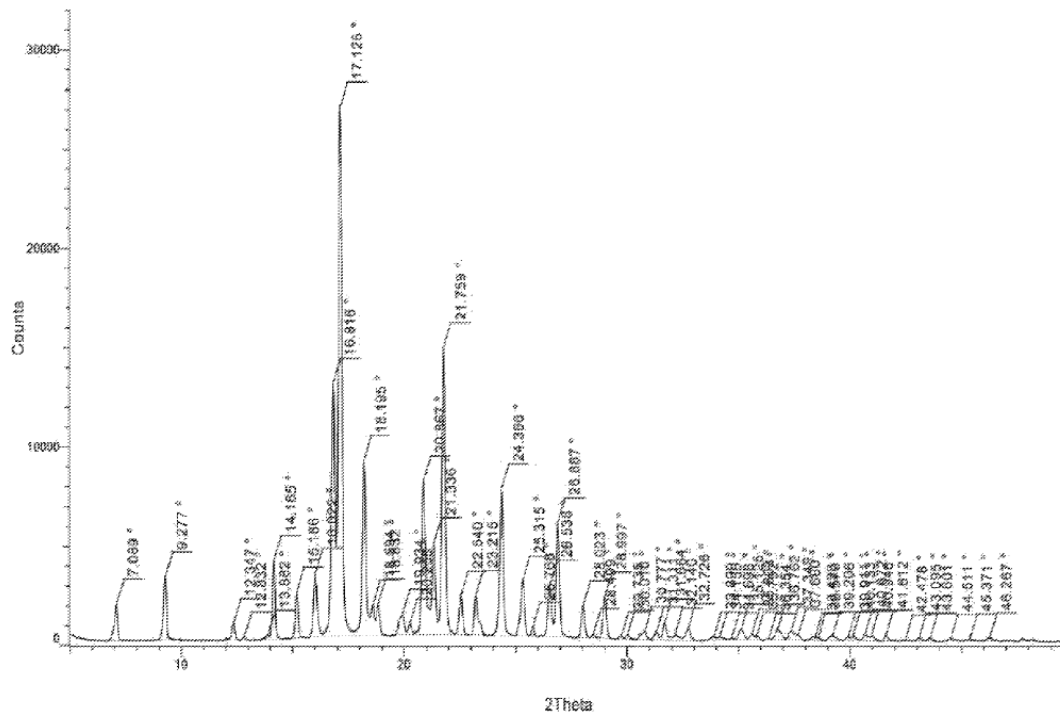
by following both Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures are within 0.2° of the values disclosed in the 151 patent. Therefore, the XRPD testing confirms that the peaks recited in dependent claim 5 are similarly present in Liu's resulting crystalline solids.

5. The composition of claim 1, wherein the crystalline form of the (Z)-isomer is characterized by an x-ray powder diffraction pattern substantially as set forth in FIG. 9 or FIG. 10.

36. The 151 patent's Figures 9 and 10 are reproduced below. Also below is a figure illustrating the XRPD patterns of the crystalline solids obtained by Dr. Bihovsky following Liu's Recrystallization and Liu's Isomerization and Recrystallization Procedures arranged for comparison with a stick pattern of the XRPD pattern data reported at Table 8 of the 151 patent (shown in blue), which corresponds to the XRPD patterns shown in Figures 9 and 10.

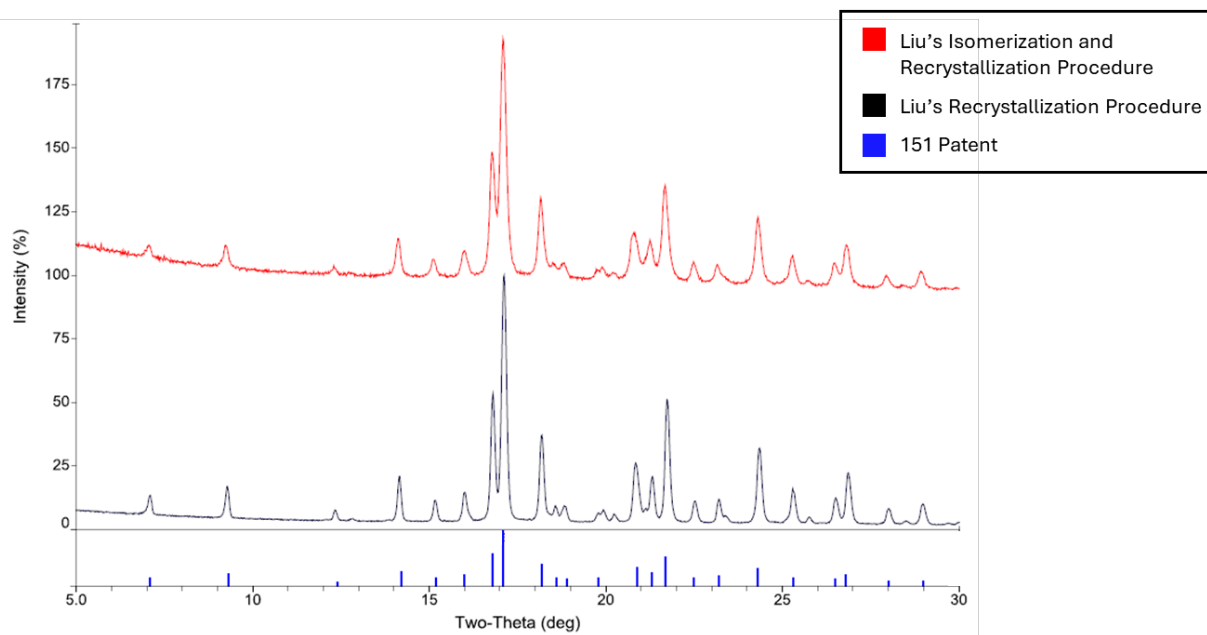


Ex. 1001, Figure 9.



Id., Figure 10.

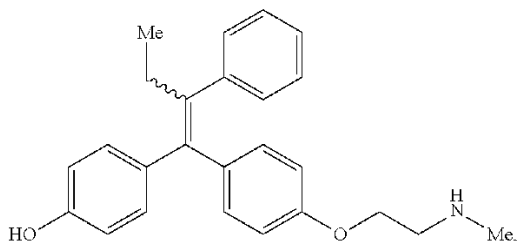
**XRPD Results of Liu's Procedures
Compared to the 151 Patent**



F. Independent Claim 16

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at $16.8 \pm 0.3^\circ$, $17.1 \pm 0.3^\circ$ and $21.8 \pm 0.3^\circ$ two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

37. Liu teaches that (Z)-endoxifen may be used to treat hormone-dependent breast disorders. For example, Liu explains that (Z)-endoxifen is more active at the estrogen receptor, and therefore may be used to treat breast cancer. Ex. 1003 at [0002]-[0004]. Therefore, Liu discloses a method of using highly pure (Z)-endoxifen to “treat[] a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in the subject” as recited in claim 16.

38. And as discussed with respect to claim 1, the (Z)-endoxifen obtained by following both Liu’s Recrystallization and Liu’s Isomerization and Recrystallization Procedures exhibit the claimed XRPD patterns. Thus, Liu inherently discloses (Z)-endoxifen in the claimed Form 1.

XII. Education and Professional Background of William E. Mayo, Ph.D.

39. A copy of my Curriculum Vitae is included as Appendix 3, which details my educational, professional, research and employment credentials. A condensed summary focusing on my 50+ years of experience with characterization of structural polymorphs (such as those that occur in pharmaceuticals) appears below.

40. I hold a B.S. degree in Physics from Carnegie-Mellon University (1971), an M.E. in Metallurgy and Materials Science from Carnegie-Mellon University (1974), and a Ph.D. in Mechanics and Materials Science from Rutgers University (1982). Following my doctoral work, I was a post-doctoral fellow at Bell Labs in Murray Hill, NJ, specializing in the development of x-ray diffraction characterization tools.

41. Before joining academia, I worked in the private and government sectors for several years at Harry Diamond Labs (1971-72), Olin Metals Research (1974-77) and TRW (1977-78).

42. From 1978 to 2008, I was employed by Rutgers University, where I successively held the titles of Research Assistant, Assistant Professor, Associate Professor, Professor and Emeritus Professor. I have taught numerous courses during that time, including courses in material characterization, x-ray diffraction, phase transformations and thermodynamics at the undergraduate, graduate, and

professional levels. I supervised numerous research projects funded at more than \$20,000,000 dealing with phase transformations and phase identification by X-ray diffraction.

43. While at Rutgers, I taught more than 2,000 students in undergraduate and graduate material science courses. I have taught and supervised graduate students at the MS. Ph.D. and post-graduate levels with a primary emphasis on phase transformations, material characterization, and X-ray Diffraction.

44. In 1997, I was the co-founder of H&M Analytical Services ('H&M') and served as its Chief Scientist through 2012 when I sold the company. H&M's primary emphasis during that time was the use of various analytical tools such as XRPD, SEM, TEM, DSC, TGA, PSA, XRF and FTIR to characterize a wide range of materials, including organic and inorganic solids such as pharmaceuticals, excipients, polymers, minerals, alloys, ceramics, glasses, pigments, composites, and so forth.

45. I founded the company NanoPac in 1999 to commercialize my research into phase transformations of metastable materials to create bi-continuous nano-nano composites.

46. Throughout much of my career and through a company that I co-founded (Xstream Systems and successor), I have also worked on the development of a novel 3-D tomographic energy dispersive X-ray diffraction technique to detect

contraband such as explosives hidden in checked baggage, counterfeit drugs in sealed containers, and most recently, opioids such as fentanyl being smuggled through international mail.

47. Through my work at H&M and Xstream Systems, I have investigated thousands of pharmaceuticals and excipients, especially with regard to structural characterization, phase identification, polymorphic transformations and environmental stability.

48. In 2006, I was awarded the title of *Fellow* of the International Centre for Diffraction Data ('ICDD'). At various times working with the ICDD, I was the Editor for the *Metals Index of the Powder Diffraction File* (18 yrs); the Assistant Editor for New Diffraction Data for the *Powder Diffraction* journal (9 yrs); Chair of the Grant-In-Aid Committee (2 yrs); an Editor for the *PDF-4 Relational Database* (4 yrs); an Editor for *The Blue Book* (4 yrs); and an Assistant Editor for *Metals Index of the Powder Diffraction File* (5 yrs). Also, from 1998 to 2001, I was Assistant Editor for the *Nanostructured Materials* journal. I have authored, edited, or contributed to 39 books/electronic databases and published 136 refereed articles.

49. I am an expert in the fields of material characterization, polymorphism, X-ray diffraction analysis, phase identification, crystal growth, crystal engineering, and phase transformations. I have consulted widely for industry, particularly in the fields of pharmaceutical polymorphism and phase identification.

XIII. Compensation for Dr. William Mayo

50. I am being compensated for the time that I spend on this matter at my ordinary rate of \$450 per hour. I am also being compensated for any reasonable expenses incurred in relation to my work in this matter. My compensation does not depend on the opinions that I offer or on the outcome of this proceeding.

XIV. Relationship Between Dr. William Mayo and Dr. Steven Miller/H&M

51. Dr. Miller was a student of mine while he was a graduate student and Post-Doctoral Fellow at Rutgers and he would have taken two X-ray diffraction courses that I taught. Dr. Miller also studied electron diffraction techniques taught by others. While a graduate student working on his Ph. D. thesis, Dr. Miller and I occasionally would work together on diffraction problems related to his research. However, I was not his Ph.D. thesis advisor.

52. When I started to think about retiring from H&M Analytical Services, I contacted Dr. Miller in 2010 to see if there was any interest in working with me and eventually acquiring my business. Based on my interactions with him at Rutgers and his experience with various material characterization techniques, I was confident that Dr. Miller had the requisite knowledge and skills to run the laboratory.

53. In 2011, Dr. Miller was hired to work at H&M on a one-year trial basis and in mid-2012, the deal to purchase H&M was finalized. During the trial period, I continued to supervise the laboratory and train Dr. Miller in all aspects of the

business. Since Dr. Miller already had the requisite experience in XRPD, we focused on expansion of the business and the implementation of H&M's Quality Program. At that time, I also implemented the various protocols to qualify the business for FDA certification including establishing standards under 21CFR Part 11 for electronic records and electronic signatures. I trained Dr. Miller in these protocols before he completely took over the lab's operation.

54. In mid-2012, the contract to purchase H&M was executed and as per terms of the agreement, I reduced my workload to become an occasional consultant. That arrangement slowly phased out and I completed the separation in 2016.

39.55. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Steven Miller William Mayo, Ph.D.

Date

MAYO

APPENDIX 3

Curriculum Vitae

William Edward Mayo
648 Kensington Place
Wilton Manors, FL 33305
billm02127@gmail.com

Summary

- PhD in Material Science with over 45 years of experience in academia and industry
- Expert in X-ray diffraction (XRD) analysis of organic and inorganic materials
- Fellow of the International Centre for Diffraction Data
- Former editor of XRD database and journals
- Founder of XRD service laboratory and consulting service
- Inventor of XRD system for counterfeit pharmaceutical detector
- Author/coauthor of 135+ published articles
- Expert in material analysis and patent infringement litigation

Education

- | | |
|------|--|
| 1982 | Post Doctoral Fellow , Bell Labs, Murray Hill NJ - Major areas of study: XRD characterization of III-V thin films. |
| 1982 | Ph.D. (Mechanics and Materials Science), Rutgers University, Piscataway NJ - Major areas of study: structural and failure analysis of materials deformed by fatigue and stress corrosion cracking; development of computerized x-ray testing methods; modeling of hardening mechanisms and phase transformations. |
| 1974 | M.E. (Metallurgy and Materials Science) Carnegie-Mellon University, Pittsburgh PA., - Major areas of study: metal processing methods and semiconductor characterization. |
| 1971 | B.S. (Physics) Carnegie-Mellon University, Pittsburgh PA. |

Post Graduate Training

- | | |
|-----------|--|
| 2013-2016 | Current Good Manufacturing Practices (cGMP) – Classroom training in FDA required aspects of pharmaceutical testing. |
| 2003 | Advanced Rietveld Analysis – Georgia Tech University, Atlanta, GA |
| 2000 | Rietveld Analysis – Universität Bayreuth, Bayreuth, Bavaria, Germany |

Academic Employment

2008- pres	Emeritus Professor , Rutgers University, Piscataway NJ, Material Science and Engineering Dept.
1998-2008	Professor , Rutgers University, Piscataway NJ, Ceramic and Materials Engineering Department (now <i>Materials Science & Engineering Dept.</i>).
1995-1998	Associate Professor , Rutgers University, Piscataway NJ, Ceramic and Materials Engineering Department.
1988-1995	Associate Professor , Rutgers University, Piscataway NJ, Dept. of Mechanics and Materials Science.
1982-1988	Assistant Professor , Rutgers University, Piscataway NJ, Dept. of Mechanics and Materials Science.
1978-1982	Research Assistant , Rutgers University, Piscataway NJ, Dept. of Mechanics and Materials Science.

Non-Academic Employment

1997-2015	H&M Analytical Services , Allentown NJ, (Co-Founder and Chief Scientist).
2011-pres	Veracity Network , Vero Beach FL, (Co-founder/Science Advisor) - formerly Xstream Systems.
2004-2011	Xstream Systems , Vero Beach FL, (Co-founder/Science Advisor).
1999-2001	Nanopac , New Brunswick NJ, (Co-founder)
1977-1978	TRW (Reda Pump Division), Bartlesville OK, Materials Engineering Section, (Metallurgist).
1974-1977	Olin Metals Research Laboratory , New Haven CT, Physical Metallurgy Section, (Metallurgist).
1970-1972	Harry Diamond Research Laboratory , Washington, DC, Microminiature Branch, (Physicist).

Honors

2019	Finalist . Opioid Challenge (DHS, USPS, NASA)
2006	Fellow , International Centre for Diffraction Data, Newtown Square PA.
1982	Post-Doctoral Fellow , Bell Laboratories, Murray Hill, NJ

Editorial Positions

1994-2007	Editor , <i>Metals Index of the Powder Diffraction File</i> , ICDD
1998-2007	Assistant Editor for New Diffraction Data , <i>Powder Diffraction</i> (Journal)
1998-2001	Assistant Editor , <i>Nanostructured Materials</i> (Journal)
1996-2000	Editorial Staff , <i>PDF-4 Relational Database</i> , ICDD
1997-1998	Editorial Staff , <i>The Blue Book</i> , ICDD
1987-1988	Chair, Editorial Board , TMS/AIME Conference on High Temperature Superconductors, Rutgers University
1985-1986	Member, Editorial Board , TMS/AIME Conference on Semiconductor Defects, Bell Labs
1979-1984	Assistant Editor , <i>Metals Index of the Powder Diffraction File</i> , ICDD
1982-1983	Member, Editorial Board , US/France Cooperative Meeting, Snowmass, CO

Technical Society Memberships (past 10 years)

American Ceramic Society
American Crystallographic Association
International Centre for Diffraction Data
Materials Research Society
Sigma Xi Honorary Society

Teaching (Courses Taught)

150:254	Laboratory II (X-ray diffraction and X-ray fluorescence)
150:206	Thermodynamics
150:309	Analytical Techniques in Ceramics
150:408	Analytical Techniques for Ceramics Research
150:520	X-ray Diffraction and Spectroscopy in Ceramics
150-521	X-ray Diffraction and Spectroscopy Laboratory
150-524	Advanced Characterization
150:532	Kinetics: Diffusion, Phase Transformations and Sintering
150:563	Advanced X-ray Diffraction
440-127	Introduction to Computing for Engineers
440-407	Mechanical Properties of Materials

655-351	Metallurgical Engineering
655-551	Physical Metallurgy I
655-552	Physical Metallurgy II
635-553	Mechanical Behavior of Metals
655-561	Computer Aided Experimentation
655-595	Advanced Physical Metallurgy I
655-601	Kinetics of Metal Systems
655-xxx	X-ray Diffraction (unaccredited course)

Teaching (Courses Developed)

150:254	Laboratory II (X-ray diffraction and X-ray fluorescence)
150:520	X-ray Diffraction and Spectroscopy in Ceramics
150:521	X-ray Diffraction and X-ray Spectroscopy Laboratory
440-125	Introduction to FORTRAN
655-561	Computer Aided Experimentation
655-553	Mechanical Behavior of Metals
655-601	Kinetics in Metal Systems

Teaching (Courses Supervised)

440-125	1990 - 1996 (Average of 125 students/year)
440-127	1982 - 1996 (Average of 900 students/year)
655-221	1990 - 1991 (Approximately 750 students)
655-222	1990 - 1991 (Approximately 400 students)

Personnel Supervised

Ph.D. Students	Christian Pinzone, Ph.D. 2006
	Chandrusekhar Reddy Gorla, Ph.D. 1999
	Yu Chi Wang, Ph.D. 1998
	Matthew Schurman, Ph.D. 1998
	Shih-Chieh Liao, Ph.D. 1996
	Chiao-Yi Hwang, Ph.D. 1995
	Ganjiang Feng, Ph.D. 1992

	Jhong Wah Lee, Ph.D., 1992
	Shyam Rao, Ph.D., 1992
	Chi-Fung Lo, Ph.D., 1989
	Hidehiko Kamide (1986-88)
	Nagabusham Patibandla (1989-90)
Post-Docs	Ping Lu (1993-95)
	B S Sywe (1994-95) (w/ Y. C. Lu)
	Shih Chieh Liao (1997-99)
	James Colaizzi (1999-00)
Visiting Professors	Masanori Kurita (1988-89), Nagaoka Technological University, Japan
	Zwi Kalman (1989-2001), Hebrew University, Jerusalem, Israel

University Service

	Hub Computer Committee (1994-1998)
	Common Purposes (Executive Committee) (1994-95)
University	Search Committee for VP for Computing (1991-92)
	Radiation Safety Committee (1984-90)
	Freshman Computing Committee (1983-96)
	Freshman Computer Course Coordinator (1983-96)
College	College Planning Committee (1989-1994)
	Health and Safety Committee (1986-1991)
	Grievance Committee (1991-94)
	Committee on Strategic Plan (1993)
	Seminar Series Organizer (1983-84, 1992)
Department	Safety Officer (1983-91)
	Space Committee (1991-93)
	Computer Course Coordinator (1982-1996)
	X-ray Laboratory Supervision (1983- 2008)

Scholarly Service Activities

	Eastern Analytical Society (2014)
	Sintering 99 Conference (1999)
	Victims of PanAm 103 (1996)
	American Civil Liberties Union (1996)
	Carnegie Institute (1995)
	Congressional Office of Technology Assessment (1995)
	Bureau of Alcohol, Tobacco and Firearms (1995)
	Denver X-Ray Conference (1995)
Invited Speaker	International Centre for Diffraction Data (1993)
	National Academy of Sciences (1991)
	Congressional Office of Technology Assessment (1991)
	Naval Weapons Laboratory (1991)
	Johns Hopkins University (1990)
	Stevens Institute of Technology (1988)
	Columbia University (1987)
	Session Chairman at MRS/AIME Conference (1986)
	Jet Propulsion Laboratory (1983)
	ASM Meeting, US Steel Fairless Works (1982)
Visiting Lecturer	Shanghai Technical College, Shanghai, PRC (1986)
	JCPDS/ICDD Education Subcommittee (1991-pres)
	JCPDS/ICDD Metals Subcommittee (1991-pres)
	TMS (NJ Chap) Program Committee (1986-89)
Technical Societies	TMS (NJ Chap) Student Affairs Committee (1983-91)
	TMS (NJ Chap) Coordinator, Student Paper Contest (1990)
	Metals Science Club (NY) Membership Committee (1986)
	Metals Science Club (NY) Program Committee (1984)
	ICDD Grant in Aid (Chair) (2005-07)
	ICDD Editor for Metals and Alloys (1994-2008)
Journal Referee	Applied Physics Letters
	Corrosion
	Journal of the American Ceramic Society
	Journal of Applied Physics

Journal of Applied Crystallography
 Journal of Electronic Materials
 Journal of Materials Research
 Metallurgical Transactions
 Material Science and Engineering
 Nanostructured Materials
 Powder Diffraction
 Scripta Materiala
 Transactions of ASME

Reviewer National Science Foundation
 Department of Energy
 State of Connecticut/DEPSCOR (DOD)
 NSF Small Business Innovative Research

Research Centers

1997 - 2002 **Associate Director** of Advanced Coating Technology Development Program funded by the ONR for the period 6/97 to 6/02. This program is a consortium of 5 Universities, 1 Government Lab, and 9 Industrial partners. Total funding for this program and its associated DUSTP program exceeds \$7,300,000.

1983 - 1986 **Co-Chair** of Steering Committee 1983-1986 for Rutgers Surface Modification Research Center. During tenure as Co-Chair, almost \$1,000,000 in external research support and matching funds were generated.

1982 - 1984 **Director** of Centralized X-Ray Facilities for the NJ Sponsored Advanced Technology Center for Surface Engineered Materials (ATC-SEM). Responsible for fund raising (\$330,000), construction and supervision of new user facility used jointly by Rutgers, Princeton, Stevens, NJIT and Sarnoff Labs.

Research Grants

DHS/CBP/ USPS Opioid Detection Challenge (\$100,000) (3/19-10/19)

DARPA Development of Hi-performance Ceramic Armor (\$150,000) (5/13- 5/16)

DHS Development of Explosive Simulants (\$499,500) (1/05-9/06)

L-3 CXRS/CT Hybrid Explosives Detection Technology (\$4,930,000) 10/02 – 9/1/03)

ONR Lightweight Ceramic Materials and Survivability Technologies (\$700,000) (9/01-

8/07)

UDelaware (AFOSR)	Processing of Nanoscale Ceramic Metamaterials (\$200,000) (7/01-6/05)
ARL	Advanced Ceramic Armor (\$520,000) (2/01-1/06)
NIST	Nanoceramic Cutting Tools - Phase II (\$300,000) (9/00-8/02)
BMDO	Ceramic Nano-composites (\$65,000) (5/00-10/00)
NJ-TTCP	Commercialization of Nanosctructured Ceramics (\$240,000) (4/00-3/01)
NSF	Nanostructured Ceramic Composites (\$100,000) (1/00-5/00)
NIST	Nanoceramic Cutting Tools (\$70,000) (7/99-1/00)
NSF	High Resolution X-Ray Diffractometer (w/Riman) (\$108,797) (9/99-8/00)
ONR	Thermal Sprayed Nanostructures: A New Generation of High Performance Ceramic Coatings (co-PI w/Kear) (\$5.570,000) (6/97-6/02)
ONR	Thermal Spray Nanostructured Ceramic Coatings for Dual Use Applications (co-PI w/ Kear) (\$1,793,800) (9/97-9/00)
Rutgers	Grant to Obtain a Grant (\$2,000) (9/95-5/96)
SMI/BDO	Conductive Hard Ceramic Coatings (\$16,000) (7/95-1/96)
RUICI	Undergraduate Computing Facility (\$582,000) (9/94)
DOE/Pyro	High Temperature Reflectivity of Materials (\$25,086) (8/94-9/94)
SDIO/SMI	Quantum Si Dots (\$208,656) (9/93-8/95)
Emcore	Hybrid MOCVD/ALE Growth of GaN (\$164,804) (7/94-12/95)
AFURI	Nondestructive Evaluation of Corroded Structures (\$99,668) (9/93-8/96)
FAA	Development of Explosives Detection Method (\$4,450,138) (8/91-7/93)
EPRI	Orientation Dependence of Carbide Growth (\$160,143) (7/93-12/94)
Kodak	Equipment Request for MOCVD System (\$317,622) (2/93)
NSF	Two Station Thin Film Diffractometer (\$60,000) (6/91- 11/91)
NJ	Centralized X-Ray Facility (\$330,000) (6/91-11/92)
EPRI	Orientation Dependence of SCC (\$58,501) (6/90-8/91)
Ford	Residual Stresses in E-Beam Weldments (\$22,010) (6/90-2/91)
GE	Ceramic Composites (\$50,000) (3/90-2/91)
FAA	Feasibility Study for Explosives Detection (\$26,655) (10/89-10/90)
GE	CVD Deposition of Ceramic Composites (\$42,814) (4/89-3/90)
MEA	Strain Analysis of C-Rings (\$10,000) (1/89-6/89)
NSF	Computer Grinding Model (\$212,874) (9/88-8/91)
EPRI	Role of Carbides in SCC (\$45,567) (7/88-6/89)

NSF	Supercomputer Time (\$50,000) (3/88-2/89)
ASM	Travel Award (\$1,200) (3/88)
NJ	Conference Organization (\$5,000) (3/88-6/88)
Rutgers	Defect Mapping in Semiconductors (\$1,135) (6/86-5/87)
NSF	Grinding & Residual Stresses (\$149,889) (8/85-8/87)
EPRI	Surface Induced Microplasticity During SCC (\$229,059) (9/84-9/87)
NJ	RBS Equipment Grant (\$50,000) (6/84)
Rutgers	Surface Initiated Fatigue Failures (\$2,500) (6/84-5/85)
Rutgers	Strains in Thin Films (\$3,500) (6/83-5/84)
Rutgers	Al-Li Alloy Development (\$3,150) (6/82-5/83)

Publications

PhD Dissertation

Studies of Microscopic Strain Distributions in Metal Systems, Directed by Sigmund Weissmann and Thomas Tsakalakos, Rutgers University (1982)

Published Books (authored)

Introduction to Computing for Engineers, William E. Mayo and Martin Cwiakala, (1997) ISBN 0-390-14579-3, McGraw-Hill/Primis Division, 437pp

Introduction to Programming with FORTRAN 90 , William E. Mayo and Martin Cwiakala, (1995) ISBN 0-07-041156-5, McGraw-Hill/Schaum's Division, 448pp.

Introduction to Programming with FORTRAN 77, William E. Mayo and Martin Cwiakala (1994) ISBN 0-07-041155-7, McGraw-Hill/Schaum's Division, 346pp.

Introduction to Computing for Engineers, William E. Mayo and Martin Cwiakala (1992), ISBN 0-390-11790-0, McGraw-Hill/Primis Division, 772pp

Introduction to Computing for Engineers, William E. Mayo and Martin Cwiakala, (1992), ISBN 0-07-041139-5, McGraw-Hill, 580pp.

Introduction to Computing for Engineers, William E. Mayo and Martin Cwiakala, (1992), ISBN 0-07-10832-2 (International ed.), McGraw-Hill

The FORTRAN 90 Workbook, William E. Mayo and Martin Cwiakala, (1992) ISBN 0-07-041148-4, McGraw Hill, 176pp

Solutions Manual to Accompany Introduction to Computing for Engineers, William E. Mayo, Martin Cwiakala, and Jack Yu, (1992) ISBN 0-07-041140-9, McGraw-Hill, 316pp.

Published Books (edited)

Powder Diffraction File Set 58 (on CD-ROM), 2008, ICDD, CD-ROM

Powder Diffraction File Set 57 (on CD-ROM), 2007, ICDD, CD-ROM

Powder Diffraction File Set 56 (on CD-ROM), 2006, ICDD, CD-ROM

Powder Diffraction File Set 55 (on CD-ROM), 2005, ICDD, CD-ROM

Powder Diffraction File Set 54 (on CD-ROM), 2004, ICDD, CD-ROM

Powder Diffraction File Set 53 (on CD-ROM), 2003, ICDD, CD-ROM

Powder Diffraction File Set 52 (on CD-ROM), 2002, ICDD, CD-ROM

Metals Relational Database, 2003, ICDD, CD-ROM

Powder Diffraction File Set 51 (on CD-ROM), 2001, ICDD, CD-ROM

Powder Diffraction File Set 50 (on CD-ROM), 2000, ICDD, CD-ROM

Powder Diffraction File Set 49 (on CD-ROM), 1999, ICDD, CD-ROM

Powder Diffraction File Set 48 (on CD-ROM), 1998, ICDD, CD-ROM

Powder Diffraction File Set 47 (On CD-ROM), 1997, ICDD, CD-ROM

Powder Diffraction File Set 46 (On CD-ROM), 1996, ICDD, CD-ROM

Powder Diffraction File Set 45 (On CD-ROM), 1995, ICDD, CD-ROM

Powder Diffraction File Set 44 (On CD-ROM), 1994, ICDD, CD-ROM

Metals and Alloys Indexes Search Manual, (1993), ICDD, 672pp.

Processing and Applications of High T_C Superconductors: Status and Prospects, William E. Mayo (1988), The Metallurgical Society, 431pp.

Semiconductor-Based Heterostructures: Interfacial Structure and Stability, M.L. Green, J.E.E. Baglin, G.Y. Chin, H.W. Deckman, W.E. Mayo, and D. Narasinhham (1986), The Metallurgical Society, 431pp

Powder Diffraction File Set 32 (On CD-ROM), 1982, ICDD, CD-ROM

Powder Diffraction File Set 31 (On CD-ROM), 1981, ICDD, CD-ROM

Powder Diffraction File Set 30 (On CD-ROM), 1980, ICDD, CD-ROM

Powder Diffraction File Set 29 (On CD-ROM), 1979, ICDD, CD-ROM

Powder Diffraction File Set 28 (On CD-ROM), 1978, ICDD, CD-ROM

Chapters in Books

Applications of X-Ray Topographic Methods to Materials Science, Sigmund Weissmann and William E. Mayo, pp. 311-323, Plenum Press, 1984

Nondestructive Evaluation: Application to Material Processing, Sigmund Weissmann and William E. Mayo, in Nondestructive Evaluation, edited by R.L. Green, pp. 129-136, Plenum Press, 1984

Nondestructive Evaluation: Application to Material Processing, Sigmund Weissmann and William E. Mayo, in Nondestructive Evaluation, edited by R.L. Green, pp. 185-196, Plenum Press, 1984

X-Ray Measurements of Long-Range Strains: A Bridge Between Micromechanics and Macromechanics, S. Weissmann, Z.H. Kalman, J. Chaudhuri, R. Yazici and W. Mayo in Residual Stress and Stress Relaxation, Edited by E. Kula and V. Weiss, pp. 501-517, Plenum Press, 1982

Instructional Text Notebooks

Mechanical Properties of Metals and Mechanically Induced Failures, W. E. Mayo and Thomas Tsakalakos (1988), Center for Professional Advancement

Making and Shaping of Metals, W. E. Mayo and T. Tsakalakos (1988), Center for Professional Advancement

X-ray Diffraction Laboratory Handbook, W.E. Mayo (2005), Rutgers

Published Articles

Characterization of Melt-blended Graphene-poly(etheretherketone) Nanocomposite, A. Tewatia, J. Hendrix, Z. Dong, M. Taghon, S. Tse, G. Chiu, W.E. Mayo, B. Kear, T. Nosker and J. Lynch, *Material Sci &*

Engineering Part B, 216 (2017) 41-49.

Observations of Nanocrystalline Cubic Boron Nitride Formed by Plasma Spraying, K. M. Reddy, C. Hwang, M. Ornek, S.L. Miller, W.E. Mayo, A. Burgess, R.A. Haber, *Acta Materialia*, 116 (2016) 155-165.

c-BN Seeding Effect on the Phase Transition of a-BN(OC) Compound, C. Hwang, M. Ornek, V. Domnick, W. Mayo, S.L. Miller and R.A. Haber, *Adv in Ceramic Armor XI* (2015) Ch. 8.

Using Layered Manufacturing to Create Textured Microstructures in Si₃N₄ Ceramics, S. Rangarajan, B. Harper, R. McCuiston, A. Safari, Z. Kalma, W. Mayo, *Mater. Res. Soc. Proc.*, 625 (2011) 179.

The Possible Roles of Stoichiometry, Microstructure and Defects on the Mechanical Behavior of Boron Carbide, R. McCuiston, J. Lasalvia, J. McCauley and W.E. Mayo, *Ceramic Eng. And Sci Proc.*, 29(2009) 153-162.

On the Processing of Nanostructured Ceramics, B.H. Kear & W.E. Mayo, *Mater. Sci. Forum*, 437-438 (2003) 399-402.

Infrared Microscopic Imaging of Bone: Spatial Distribution of CO₃²⁻, H. Ou-Yang, E.P. Paschalls, W. Mayo, A.L. Boskey and R. Mendelsohn, *Journal of Bone Mineral Res.*, 16 (2001) 893-900.

Dense Nanoscale Single- and Multi-phase Ceramics Sintered by Transformation Assisted Consolidation, J. Colaizzi, W.E. Mayo, B.H. Kear, and S-C Liao, *Int. J of Powder Met*, 37 (2001) 45-54 (*Outstanding Paper Award*)

Reduced Pressure Requirements for Production of Nanoceramic Composites, J. Colaizzi, W.E. Mayo, B.H. Kear, and X-Z Zhou, *APMI Annual Meeting*, New Orleans, (2001)

Far-Infrared Investigation of C60 High Pressure/High-Temperature Polymers & Dimer, V.C. Long, J.L. Musfeldt, K. Kamaras, Y.Iwasa, W.E. Mayo, *Ferroelectrics*, 249 (2001) pp. 135-144.

On the Processing of Nanocrystalline and Nanocomposite Ceramics, B.H. Kear, J. Colaizzi, W.E. Mayo, and S.C. Liao, *Scripta. Mater.* 44(2001) 2065-2068.

X-ray diffraction analysis of LaC₂, W. E. Mayo, *Powder Diffraction File*, 51-1172 (2001).

X-ray diffraction analysis of HoH₂, W. E. Mayo, *Powder Diffraction File*, 51-1171 (2001).

X-ray diffraction analysis of Sm, W. E. Mayo, Powder Diffraction File, 51-1170 (2001).

X-ray diffraction analysis of Ni₃Ti, W. E. Mayo, Powder Diffraction File, 51-1169 (2001).

X-ray diffraction analysis of GeS, W. E. Mayo, Powder Diffraction File, 51-1168 (2001).

X-ray diffraction analysis of CaC₂, W. E. Mayo, Powder Diffraction File, 51-1167 (2001).

X-ray diffraction analysis of Na₃As, W. E. Mayo, Powder Diffraction File, 51-1166 (2001).

X-ray diffraction analysis of La, W. E. Mayo, Powder Diffraction File, 51-1165 (2001).

X-ray diffraction analysis of Ag₂O₂, W. E. Mayo, Powder Diffraction File, 51-0945 (2001).

X-ray diffraction analysis of BiF₃, W. E. Mayo, Powder Diffraction File, 51-0944 (2001).

X-ray diffraction analysis of Fe₂P, W. E. Mayo, Powder Diffraction File, 51-0943 (2001).

X-ray diffraction analysis of MnP, W. E. Mayo, Powder Diffraction File, 51-0942 (2001).

X-ray diffraction analysis of W₅Si₃, W. E. Mayo, Powder Diffraction File, 51-0941 (2001).

X-ray diffraction analysis of MoB, W. E. Mayo, Powder Diffraction File, 51-0940 (2001).

X-ray diffraction analysis of WC, W. E. Mayo, Powder Diffraction File, 51-0939 (2001).

Structure and Interface-controlled Growth Kinetics of ZnAl₂O₄ Formed at the (11-2) ZnO/(10-12) Al₂O₃ Interface, C.R. Gorla, W.E. Mayo, S. C. Liang, Y. Lu, J. Appl. Phys., 87 (2000) 3736-3743.

Thermal Sprayed Nanostructured WC/Co Hardcoatings, B.H. Kear, R.K. Sadanji, M. Jain, R. Yao, Z. Kalman, G. Skandan, and W.E. Mayo, J. Thermal Spray Tech, 9 (2000) 399-406

Plasma Sprayed Nanostructured Al₂O₃/TiO₂ Powders and Coatings, B.H.

Kear, Z. Kalman, R.K. Sadangi, G. Skandan, J. Colaizzi, and W. Mayo, Acoustics, Speech and Signal Processing IEEE., 9 (2000) 483-487.

Refinement of Nanoscale Grain Structure in Bulk Titania via a Transformation Assisted Consolidation (TAC) Method, S. C. Liao, J. Colaizzi, Y. Chen, B.H. Kear, W.E. Mayo, Am. Cer. Soc., 83 (2000) 2163-2169.

Far-infrared Vibrational Properties of High-pressure/high-temperature C60 Polymers and C60 Dimer, V.V. Long, J.L. Musfeldt, K. Kamarás, G.B. Adams, J.B. Page, Y. Iwasa, and W. Mayo, Phys. Rev. B, 61(2000) 13191-13201.

Breaking the Nanograin Barrier in Sintered Ceramics, J. Colaizzi, B.H. Kear, and W.E. Mayo, ICAMP 2000, New Zealand, November 2000.

Using Layered Manufacturing to Create Textured Microstructures in Si₃N₄ Ceramics, S. Rangarajan, B. Harper, R. McCuiston, A. Safari, Z. Kalman, W. Mayo, S.C. Danforth, and C. Gasdaska, MRS Proceedings 625(2000) 179.

Synthesis and Consolidation of Nanocrystalline Cubic ZrO₂, Z. Zhou, W.R. Cannon, J. Colaizzi, B.H. Kear, and W.E. Mayo, Nano2000, Sendai, Japan (2000).

Dense Ceramic Nano-nano Composites Produced by Transformation Assisted Consolidation, J. Colaizzi, W.E. Mayo, and B.H. Kear, American Ceramic Society Annual Meeting, St. Louis, (2000).

Thermal Sprayed Nanostructured Hard Coatings, B. H. Kear and W.E. Mayo, NATO Science Series, 78 (2000) 113-129.

Breaking the Nanoscale Barrier in Bulk, Sintered Ceramics, J. Colaizzi, B.H. Kear, and W.E. Mayo, Nano2000, Sendai, Japan (2000).

Dense Nanoscale Single- and Multi-phase Ceramics Sintered by Transformation Assisted Consolidation, J. Colaizzi, W.E. Mayo, B.H. Kear and S. C. Liao, Int. Conf. Powder Met. And Part. Mater., New York City (2000).

Transformation-Assisted Consolidation of Bulk Nanocrystalline TiO₂, S.C. Liao, Y.J. Chen, W.E. Mayo and B.H. Kear, Nanostructured Mater., 11 (1999) 553-557.

In_{0.5}(Al_xGa_{1-x})_{0.5} HEMTs for High-efficiency low-voltage Power Amplifiers: design, fabrication, and device results, Y. C. Wang, J.M. Kuo, F. Ren, J.R. Lothian, H.S. Tsai, J.S. Weiner, H.C. Kuo, C.H. Lin, Y.K. Chen and W.E.

Mayo, IEEE Trans. On Microwave Theory Tech., 47 (1999) 1404-1412.

Structural, Optical, and SAW Properties of Epitaxial ZnO Films Grown on (012) Sapphire by MOCVD, C.R. Gorla, S. Liang, W.E. Mayo, Y. Lu, M. Wraback, and H. Shen, J. Appl. Phys., 85 (1999) 2595-2602.

Structure-Property Relations in Mesoscopic BaTiO₃ and PbTiO₃, E.K. Akdogan, W. Mayo, A. Safari, C.J. Rawn, and E.A. Payzant, Ferroelectrics 223 (1999) 11-18.

Micro- and Nano-scaled Composites via Decomposition of Plasma Sprayed Ceramics, J. Colaizzi, B.H. Kear, W.E. Mayo, R. Shropshire, R.W. Rigney, and S. Brunhouse, (Proc. Int. Powder Federation Meeting), 1999

Far-infrared Investigation of C₆₀ Dimer and High-Pressure/High-Temperature Polymers, V.C. Long, J.L. Musfeldt, K. Kamaras, Y. Iwasa, and W.E. Mayo, Proc. LEES99, Budapest (1999).

Thermal Sprayed Nanosctructred WC/Co Hardcoatings, B. H. Kear, Z. Kalman, R. Sadangi, R. Yao, G. Skandan, and W.E. Mayo, (Proceedings of Thermal Spray Processing of Nanoscale Materials II, Quebec, Canada (1999)

High Pressure Polymerization of Single Wall Nanotubes, O. A. Voronov, G.S. Tompa, B. H. Kear, S.C. Liao, R. Livi, and W.E. Mayo, Joint International Meeting of the Electrochemical Society, Hawaii (1999).

High Pressure Sintering of Fullerine Soot, O. A. Voronov, G.S. Tompa, B. H. Kear, R. Livi, R.O. Lautfy, and W.E. Mayo, Joint International Meeting of the Electrochemical Society, Hawaii (1999).

Bulk Nanocrystalline Ceramics via High Pressure/Low Temperature Sintering, J. Colaizzi, Y.J. Chen, W.E. Mayo, and B.H. Kear, Second International Conf. On Science, Technology, and Applications of Sintering, State College PA, (1999).

Bulk Nanocrystalline Ceramics via High Pressure/Low Temperature Sintering, S.C. Liao, Y.J. Chen, B.H. Kear, and W.E. Mayo, Proc. Of Metal Powder Industry Conference, Vancouver, B.C., Canada (1999)

Improving the Powder Diffraction Files Metals, Alloys, and Related Materials Subfile, P. L. Wallace, J.N. Dann, H. Jones, W.E. Mayo, and A. C. Roberts, Proc. of Denver X-ray Conference, Steamboat Springs, Co (1999)

Epitaxial Growth of (1120) ZnO on (0112) Alumina by MOCVD, S. Liang, C.R. Gorla, N. Emanetoglu, Y. Liu, W.E. Mayo, and Y. Lu, J. Elec. Mat.,

27(1998) L72-L76.

High Pressure/Low Temperature Sintering of Nanocrystalline Alumina, S.C. Liao, Y.J. Chen, B.H. Kear, and W.E. Mayo, *Nanostructured Materials*, 10(1998) 1063-1079.

An $In_{0.5}(Al_{0.3}Ga_{0.7})_{0.5}P/In_{0.2}Ga_{0.8}As$ Power HEMT With 65.2% Power-Added Efficiency Under 1.2V Operation, Y. C. Wang, J.M. Kuo, J. R. Lothian, F. Ren, H.S. Tsai, J.S. Weiner, J. Lin, A. Tate, Y.K. Chen, and W.E. Mayo, *IEEE Electron Device Letters*, 34 (1998) 594-595.

Schottky Barrier Heights of $In_{0.5}(Al_xGa_{1-x})_{0.5}P$ ($0 < x < 1$) Lattice Matched to GaAs, Y. C. Wang, J.M. Kuo, F. Ren, J.R. Lothian, and W.E. Mayo, *Solid State Electronics*, 42 (1998) 1045-1048.

Epitaxial ZnO Piezoelectric Films for RF Filters, N.W. Emanoglu, W. Nuri, Y. Lu, C. Gorla, Y. Liu, S. Liang, W.E. Mayo, *Mat. Res. Soc.*, 445 (1998) 353-357.

Optimization of Aluminum Composition in $In_{0.5}(Al_xGa_{1-x})_{0.5}P/In_{0.2}Ga_{0.8}As$ HEMTs for Power Applications, J.M. Kuo, Y.C. Wang, J.R. Lothian, H.S. Tsai, Y.K. Chen, and W.E. Mayo, *J. Vac. Sci. Technol.*, B16 (1998) 1404-1407.

High Pressure/Low Temperature Sintering of Nanocrystalline Ceramics: Processing Issues and Emerging Applications, S.C. Liao, Y.J. Chen, B.H. Kear, and W.E. Mayo, *Fine, Ultrafine and Nanopowders*, New York, NY (1998).

Growth and SAW Properties of Epitaxial ZnO Thin Films, N. W. Emanetoglu, C. R. Gorla, S. Liang, Y. Lu, W.E. Mayo, and T. Kosinski, *Proc. 1998 IEEE International Freq. Control Symp.*, (1998) 790-795.

Single- and Double-Heterojunction Pseudomorphic $In_{0.5}(Al_{0.3}Ga_{0.7})_{0.5}P/In_{0.2}Ga_{0.8}As$ High Electron Mobility Transistors Grown by Gas Source Molecular Beam Epitaxy, Y. C. Wang, J. M. Kuo, F. Ren, J.R. Lothian, J.S. Weiner, J. Lin, W.E. Mayo, and Y.K. Chen, *IEEE Electron Device Letters*, 18 (1997) 550-553

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Silicon and Germanium Nanoparticle Formation in an Inductively Coupled Plasma Reactor, C.R. Gorla, S. Liang, G. Tompa, W.E. Mayo, Y. Lu, *J. Vac. Sci. & Tech.*, 15 (1997) 860-864.

Epitaxial ZnO Piezoelectric Films for RF Filters, N. Emanetoglu, Y. Liu, S. Liang, C. Gorla, W.E. Mayo, and Y. Lu, *Mat. Res. Soc. Symp. Proc.*, 495(1997) 353-357.

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