UNITED STATES
PATENT AND TRADEMARK OFFICE

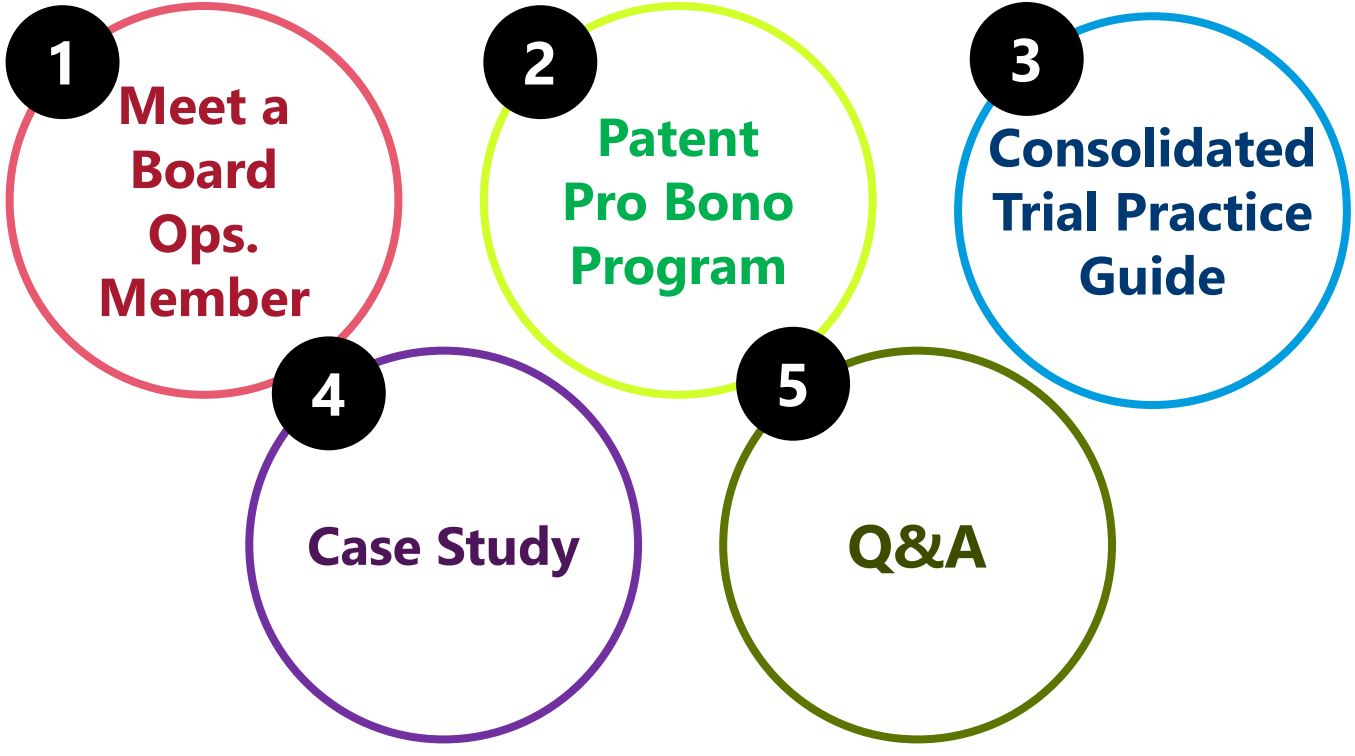
Patent Trial and Appeal Board
Inventor Hour Webinar: Episode 6

Grant Corboy, Staff Attorney - Patent Pro Bono Program Administrator
Ryan Flax, Administrative Patent Judge
Arthur Peslak, Administrative Patent Judge
Amee Shah, Administrative Patent Judge
Erica Swift, Chief Clerk of the Board

March 24, 2022

UNITED STATES
PATENT AND TRADEMARK OFFICE
uspto

Today's Agenda



Question/Comment Submission

To send in questions or comments about the presentation, please email:

PTABInventorHour@uspto.gov

Meet a Board Operations Division Member: Erica Swift, Chief Clerk of the Board

Erica Swift

Chief Clerk of the Board

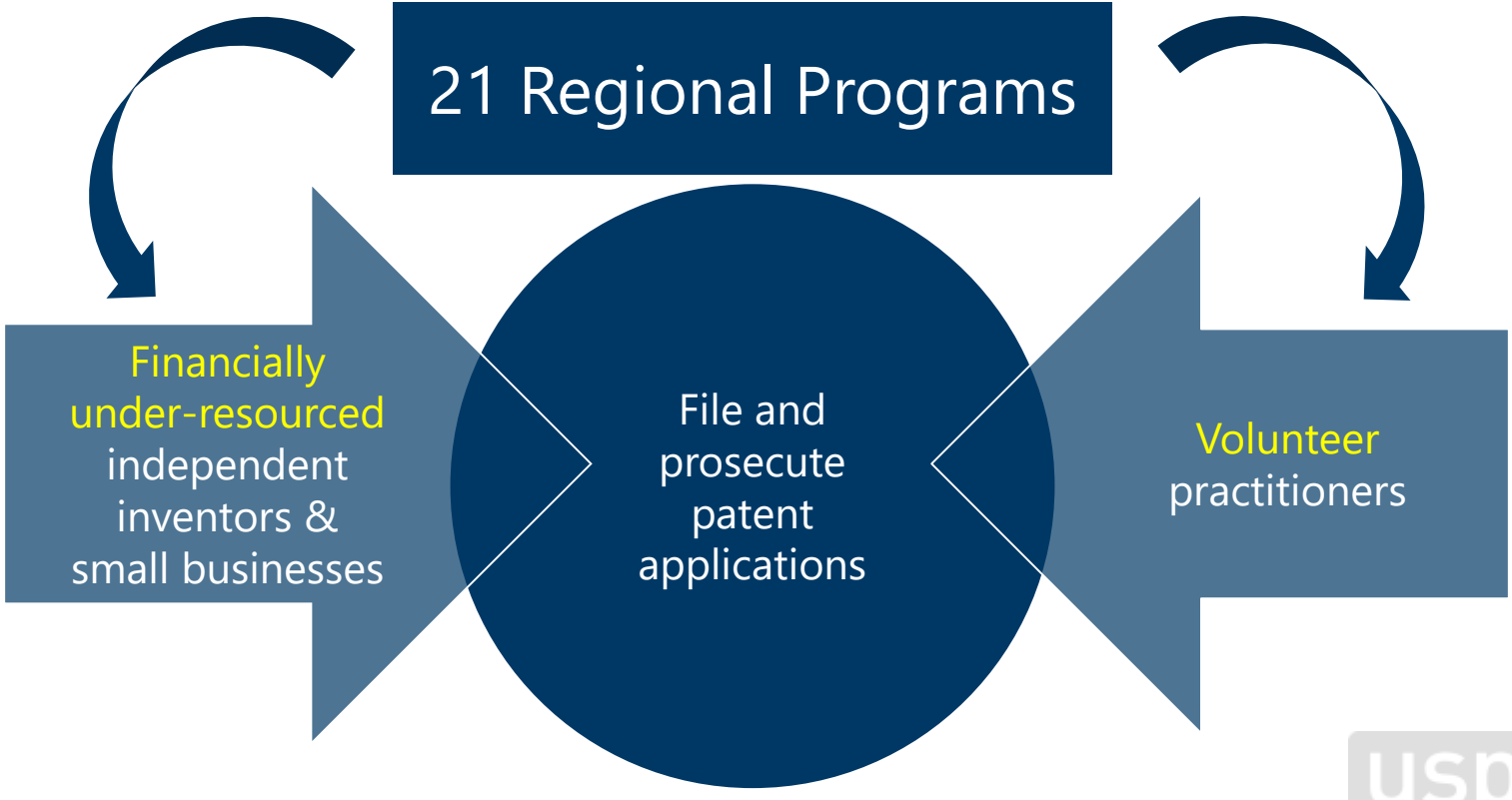
2022 National Medal of Technology and Innovation (NMTI)

- Nominations open through May 20
- Nation's highest honor for technological achievement, presented by President of the United States
- Find out more at: https://www.uspto.gov/learning-and-resources/ip-programs-and-awards/national-medal-technology-and-innovation-nmti

Grant Corboy, Staff Attorney - Patent Pro Bono Program Administrator
Office of Enrollment and Discipline, USPTO

An Overview of the Patent Pro Bono Program

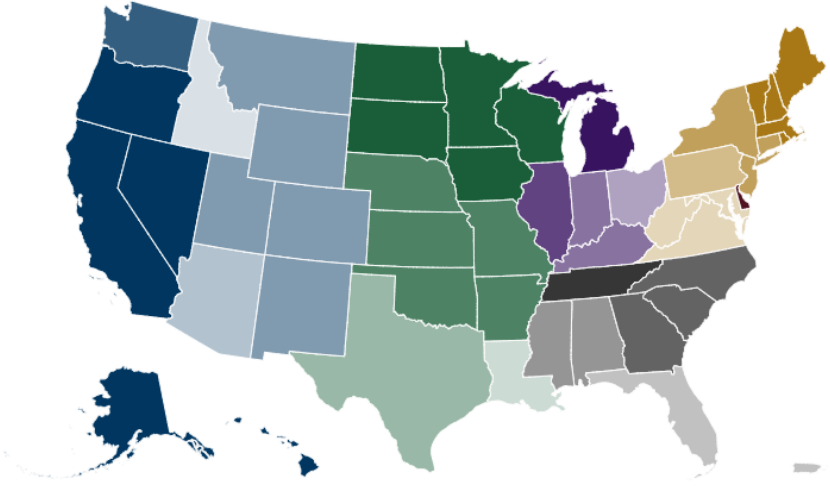
Patent Pro Bono Program



Benefits to USPTO & Inventors

- Impact for USPTO
  - Increased participation & patent application filings
  - Improved quality of patents
  - Supplements pro se (filing on your own) assistance efforts
- Impact for inventors
  - Work with experienced patent practitioners
  - > $26.5M legal services donated to inventors since 2015

Current Nationwide Coverage



- Washington Pro Bono Patent Network
- Idaho Patent Pro Bono
- California Inventors Assistance Program
- ProBoPat
- Arizona Public Patent Program
- LegalCORPS
- Georgia PATENTS
- Patent Pro Bono FL
- St. Louis U. Pro Bono Patent Program
- Texas Accountants and Lawyers for the Arts
- Louisiana Invents
- Chicago-Kent Patent Hub
- PatentConnect
- Ohio Invents
- Pro Bono Patent Project
- New England Program
- New York Tri State Program
- Delaware Program
- Federal Circuit Bar Assn.
- Philadelphia Volunteer Lawyers for the Arts
- Tennessee PATENTS
- BBVLP Patent Program

General Criteria for Inventors

- Gross household income
- Knowledge of the patent system:
  - Have filed provisional application or completed a certificate training course offered online by the USPTO (also available in Spanish)
- Invention (more than an idea)
  - Able to describe invention so someone could make and use it
- Responsible for all USPTO fees
  - Micro-entity status = ↓ 75% on most USPTO patent fees.
- Regional programs may have application fee ($25-$150) or other requirements

Matching with a Patent Practitioner

- Regional program provides practitioners with a brief description of you & invention
- No guarantee of matching, e.g.,
  - No practitioner with experience in technology
  - Conflicts
- Follow up periodically to verify your status
- Regional program will inform you if no practitioner is available
  - Regional program may provide you with other resources

Applying to the Patent Pro Bono Program

- To apply:
  - Apply directly with your regional program.
    - To find the regional program that serves you, see www.uspto.gov/probonopatents for a map of the United States and select your state.
- Email probono@uspto.gov if you have any questions.

Question/Comment Submission

To send in questions or comments about the presentation, please email:

PTABInventorHour@uspto.gov

Law School Clinic Certification Program

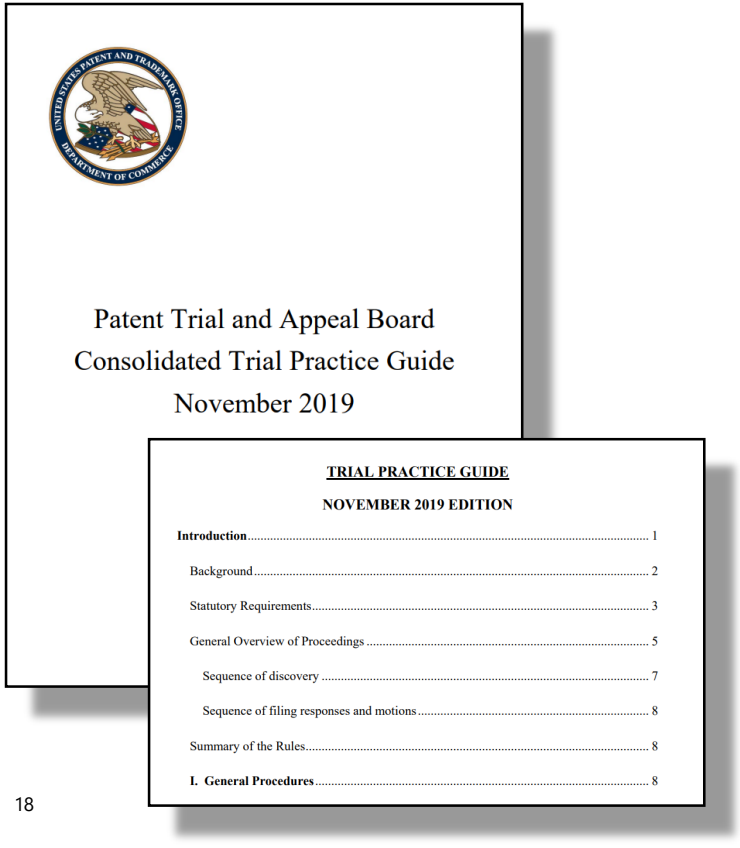
- Over 60 participating law school clinics
- Pro bono legal services to the public, including inventors, entrepreneurs, and small businesses
- Participating schools and contact information at: https://www.uspto.gov/learning-and-resources/ip-policy/public-information-about-practitioners/law-school-clinic-1

Arthur M. Peslak, Administrative Patent Judge

Trial Byte:

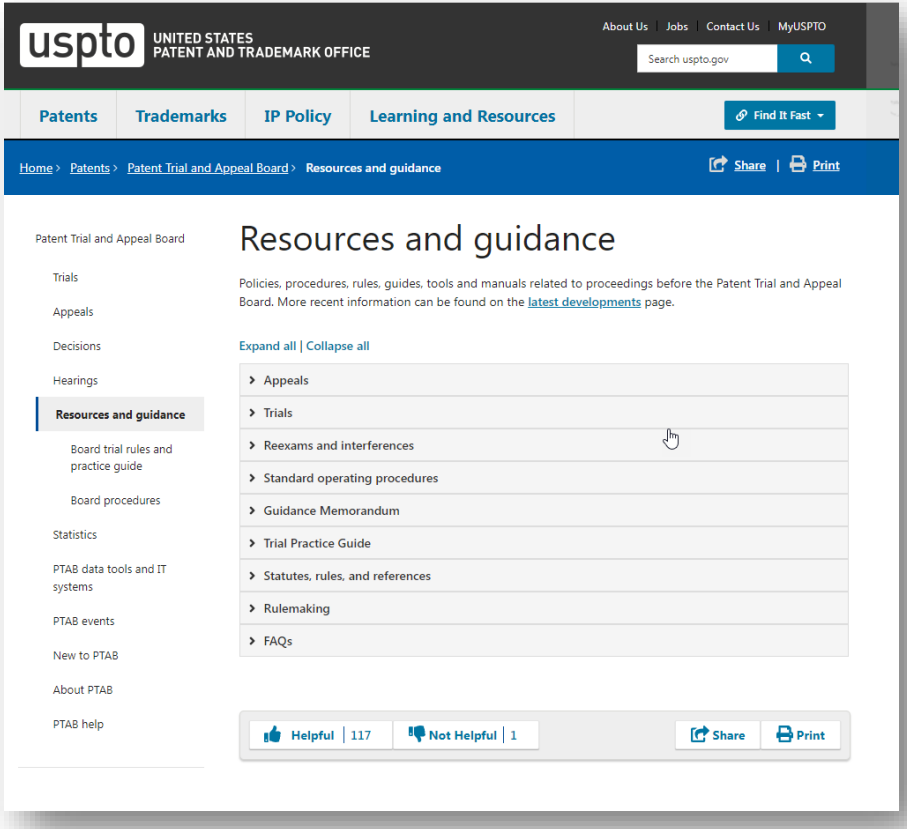
Consolidated Trial Practice Guide

What is the Consolidated Trial Practice Guide?



- Guidance on all procedure of AIA proceedings at the Board
- Covers everything from the Petition to the Final Written Decision
- Board also has formal rules at 37 C.F.R., Part 42
- *Compressed* Timeline

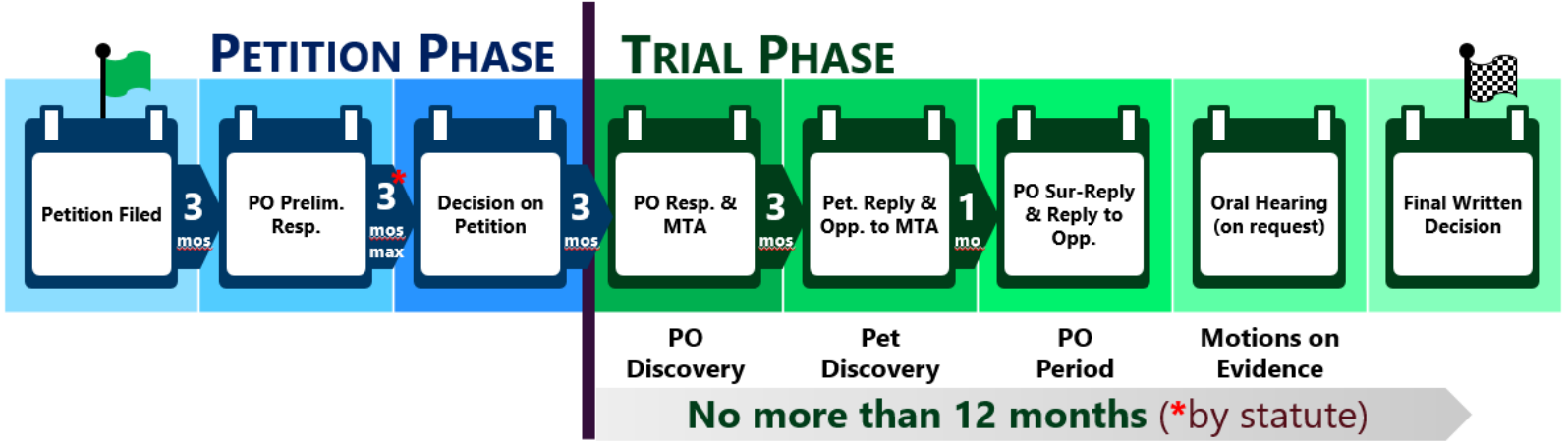
Where to find the Consolidated Trial Practice Guide?



Available at:

https://www.uspto.gov/patents/ptab/resources

Introduction
Timeline of AIA Trials



Some Important Parts of the Guide For Patent Owners

- Part II. C. Patent Owner Preliminary Response
  - After Petition is filed but before Decision on Institution
- Part II. F. Patent Owner Response
  - After Institution
  - Must include all arguments against the Petition including those made in the Preliminary Response
- Part II. G. Motion to Amend Patent Claims
  - After Institution

Some Important Parts of the Guide for Petitioners

- Part II. B. Petition
  - Requirements for Petition
- Part II. D. Institution of Trial
  - Matters Board Considers When Deciding to Institute
- Part II. I. Reply to Patent Owner Response
  - Requirements for Reply
  - Generally can't submit new evidence that should have been in the Petition

Useful Information During Trial

- Part I, F. Discovery
  - Routine Discovery
  - Initial Disclosures
  - Testimony
  - Cross-Examination
  - Expert Testimony
- Part II, K. Evidentiary Motions
  - Motions to Exclude Evidence
  - Must object during a deposition or within 5 business days of service of the evidence.

Part II. M. Oral Hearings

Parties Must Request Oral Hearing if desired

Patent Owner gets the last say

Question/Comment Submission

To send in questions or comments about the presentation, please email:

PTABInventorHour@uspto.gov

PTAB hearings

- Information regarding PTAB oral hearings including
  - Hearings schedule
  - Hearings guide
  - Hearings locations
  - Forms and samples (AIA trials and appeals)

  is available at:
  https://www.uspto.gov/patents/ptab/hearings

Amee Shah, Administrative Patent Judge

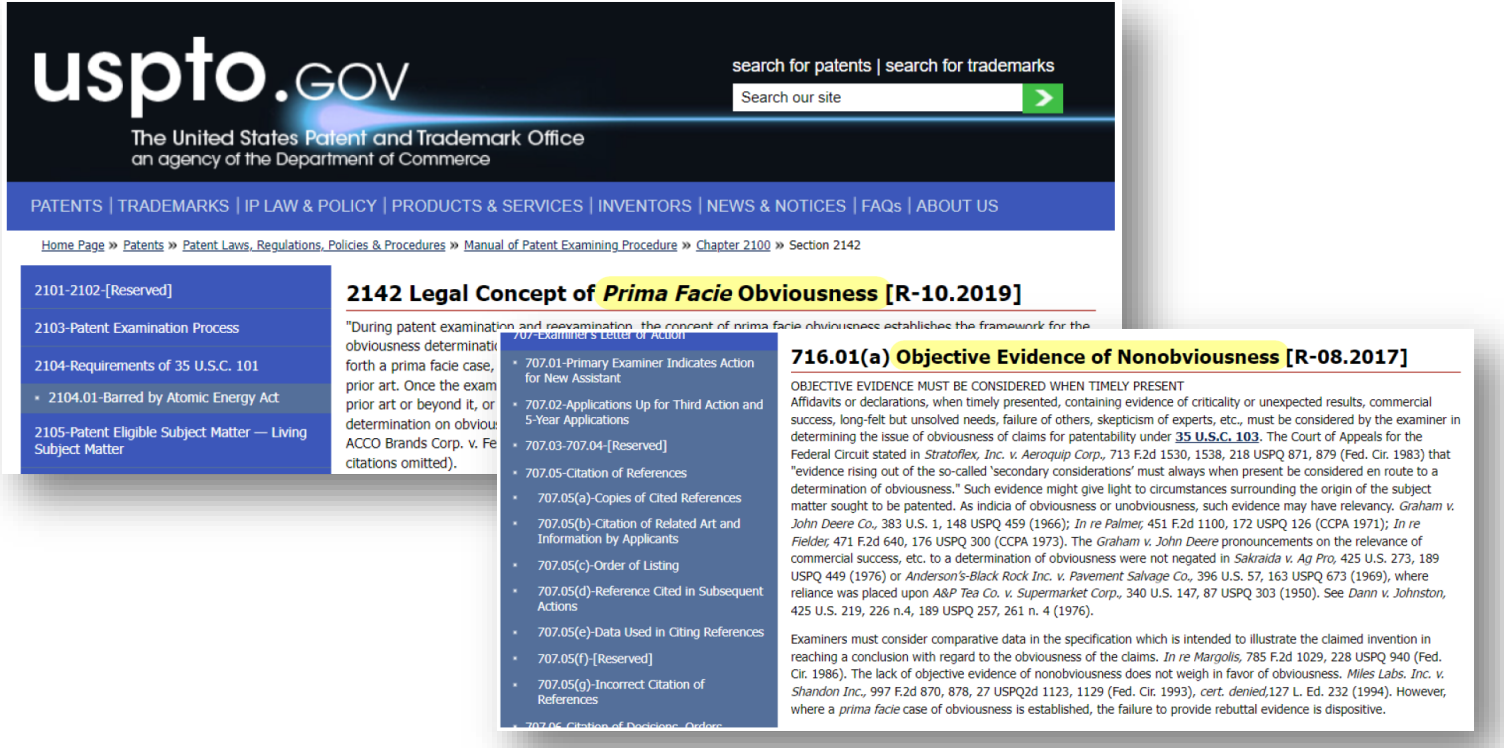
Case File:

Ex Parte Nazzal

Appeal Nos. 2017-001371 & 2019-006322

Prima Facie Case of Obviousness & Objective Indicia of Non-Obviousness

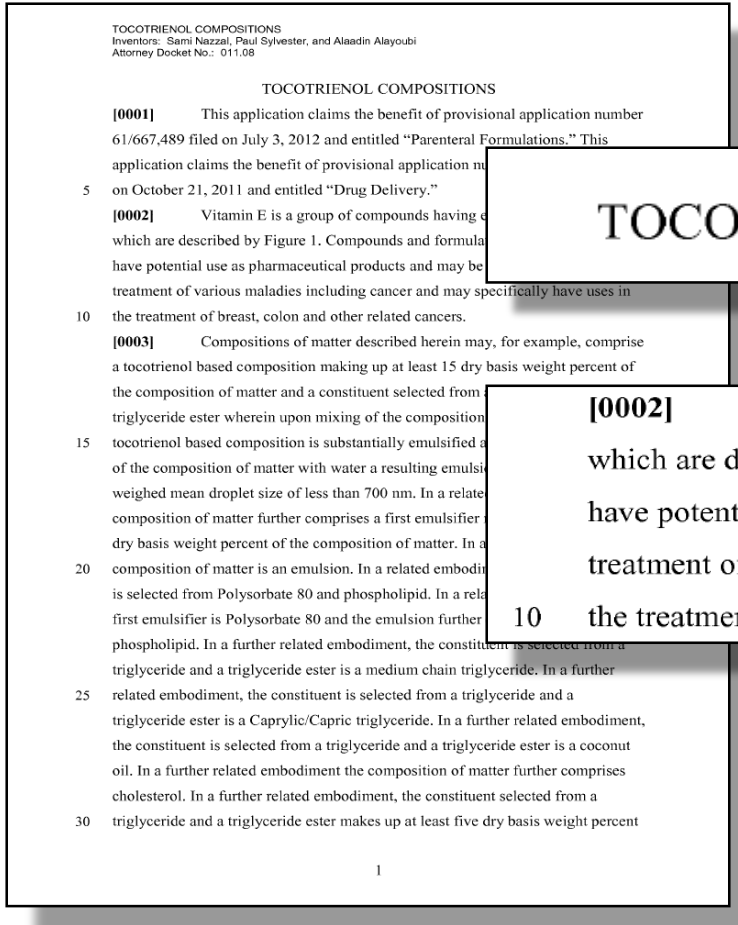
https://www.uspto.gov/web/offices/pac/mpep/



Goals

- Provide **insight** into patent prosecution
- Show how **objective indicia evidence** can overcome a prima facie case of obviousness
- Answer questions regarding PTAB's current **approach**

Application No. 13/656,573



TOCOTRIENOL COMPOSITIONS
Inventors: Sami Nazzal, Paul Sylvester, and Alaadin Alayoubi
Attorney Docket No.: 011.08

TOCOTRIENOL COMPOSITIONS

[0001] This application claims the benefit of provisional application number 61/667,489 filed on July 3, 2012 and entitled "Parenteral Formulations." This application claims the benefit of provisional application nu
on October 21, 2011 and entitled "Drug Delivery."

[0002] Vitamin E is a group of compounds having e
which are described by Figure 1. Compounds and formula
have potential use as pharmaceutical products and may be
treatment of various maladies including cancer and may specifically have uses in
the treatment of breast, colon and other related cancers.

[0003] Compositions of matter described herein may, for example, comprise a tocotrienol based composition making up at least 15 dry basis weight percent of the composition of matter and a constituent selected from
triglyceride ester wherein upon mixing of the composition
tocotrienol based composition is substantially emulsified a
of the composition of matter with water a resulting emulsi
weighed mean droplet size of less than 700 nm. In a relate
composition of matter further comprises a first emulsifier
dry basis weight percent of the composition of matter. In a
composition of matter is an emulsion. In a related embodi
is selected from Polysorbate 80 and phospholipid. In a rela
first emulsifier is Polysorbate 80 and the emulsion further
phospholipid. In a further related embodiment, the constituent is selected from a triglyceride and a triglyceride ester is a medium chain triglyceride. In a further related embodiment, the constituent is selected from a triglyceride and a triglyceride ester is a Caprylic/Capric triglyceride. In a further related embodiment, the constituent is selected from a triglyceride and a triglyceride ester is a coconut oil. In a further related embodiment the composition of matter further comprises cholesterol. In a further related embodiment, the constituent selected from a triglyceride and a triglyceride ester makes up at least five dry basis weight percent

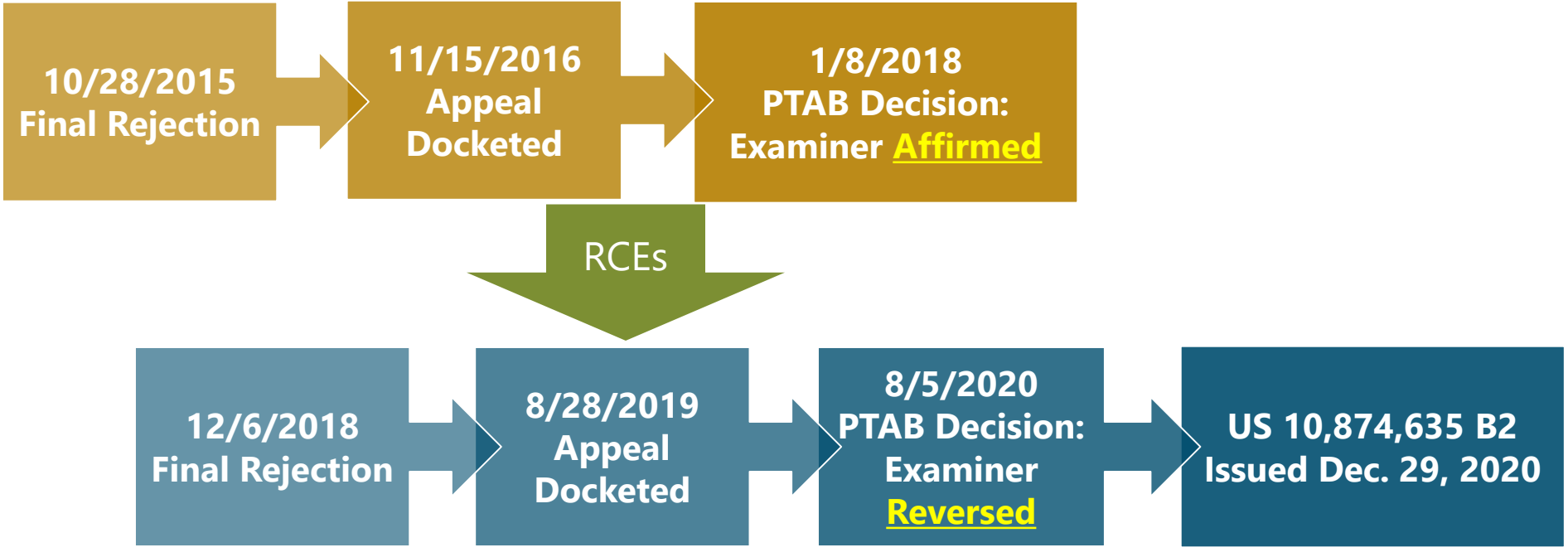
1

TOCOTRIENOL COMPOSITIONS

[0002] Vitamin E is a group of compounds having eight members, six of which are described by Figure 1. Compounds and formulations disclosed herein have potential use as pharmaceutical products and may be employed in the treatment of various maladies including cancer and may specifically have uses in the treatment of breast, colon and other related cancers.

Ex Parte Nazzal

Appeal Nos. 2017-001371 & 2019-006322



Representative Claims in the Appeals

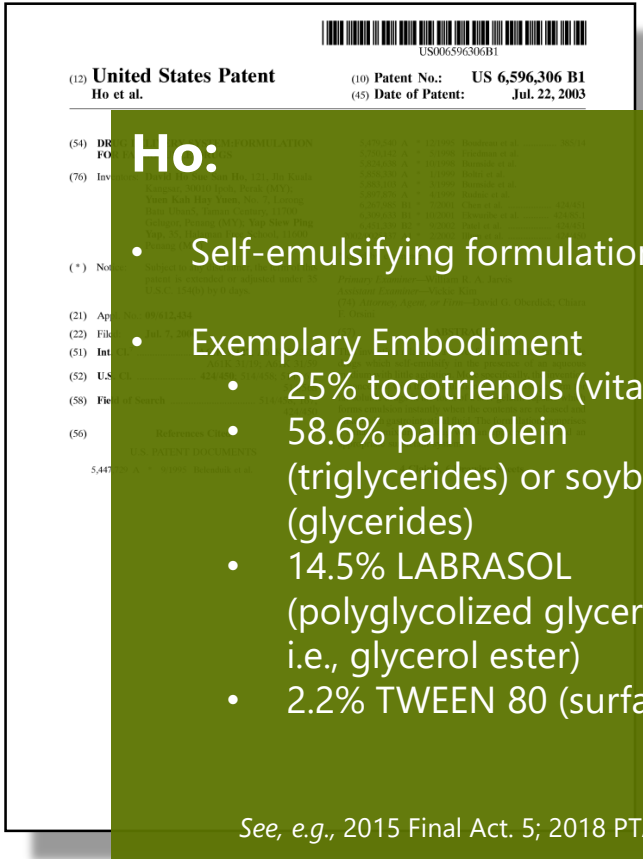
Appeal No. 2017-001371

56. A composition of matter comprising:
a. a quantity of vitamin E;
b. a glycerol ester; and
c. a polyoxyethylated triglyceride;
d. wherein the composition of matter is sufficiently homogenized to perform as a self-emulsifying drug delivery system;
e. wherein the quantity of vitamin E is at least 15 weight percent of the composition of matter; and
f. wherein the quantity of vitamin E is at most 55 weight percent of the composition of matter.

Appeal No. 2019-006322

56. A composition of matter comprising:
a. a quantity of vitamin E;
b. a glycerol ester; and
c. a polyoxyethylated triglyceride;
d. wherein the composition of matter is sufficiently homogenized to perform as a self-emulsifying drug delivery system;
e. wherein the quantity of vitamin E is at least 15 weight percent of the composition of matter;
f. wherein the quantity of vitamin E is at most 55 weight percent of the composition of matter;
g. wherein the composition of matter is configured such that it **completely emulsifies** upon dissolution in water; and
h. wherein the composition of matter is sufficiently homogenized to create an aqueous emulsion having an intensity-weighed **mean droplet size of less than 700 nm** upon dissolution in water**.**

Same Rejection in the Appeals:
Obviousness Over Ho & Lipari


US006596306B1

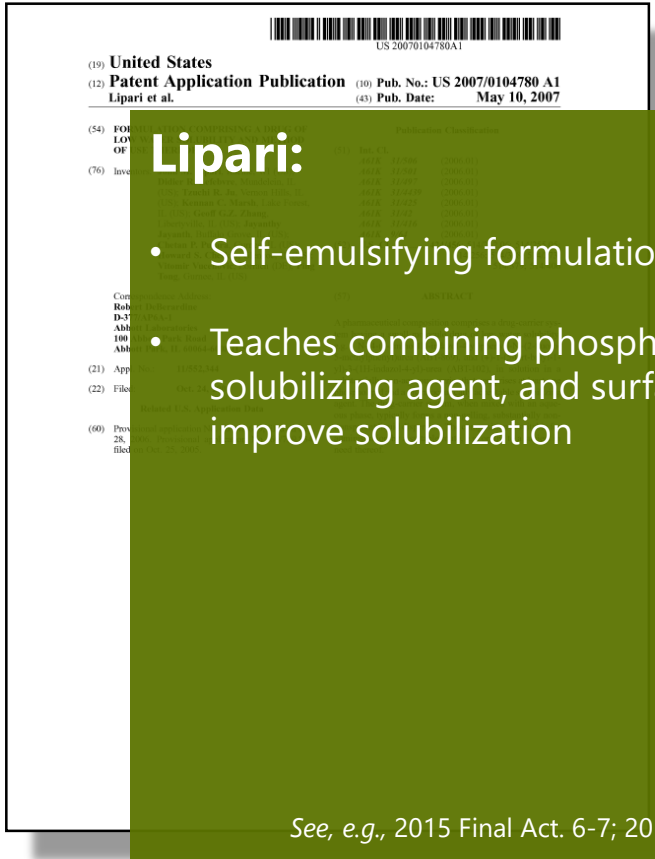
(12) **United States Patent**
Ho et al.

(10) **Patent No.: US 6,596,306 B1**
(45) **Date of Patent: Jul. 22, 2003**

Ho:

- Self-emulsifying formulations
- Exemplary Embodiment
  - 25% tocotrienols (vitamin E)
  - 58.6% palm olein (triglycerides) or soybean oil (glycerides)
  - 14.5% LABRASOL (polyglycolized glycerides, i.e., glycerol ester)
  - 2.2% TWEEN 80 (surfactant)

See, e.g., 2015 Final Act. 5; 2018 PTAB Dec. 2-3


US 20070104780A1

(19) **United States**
(12) **Patent Application Publication**
Lipari et al.

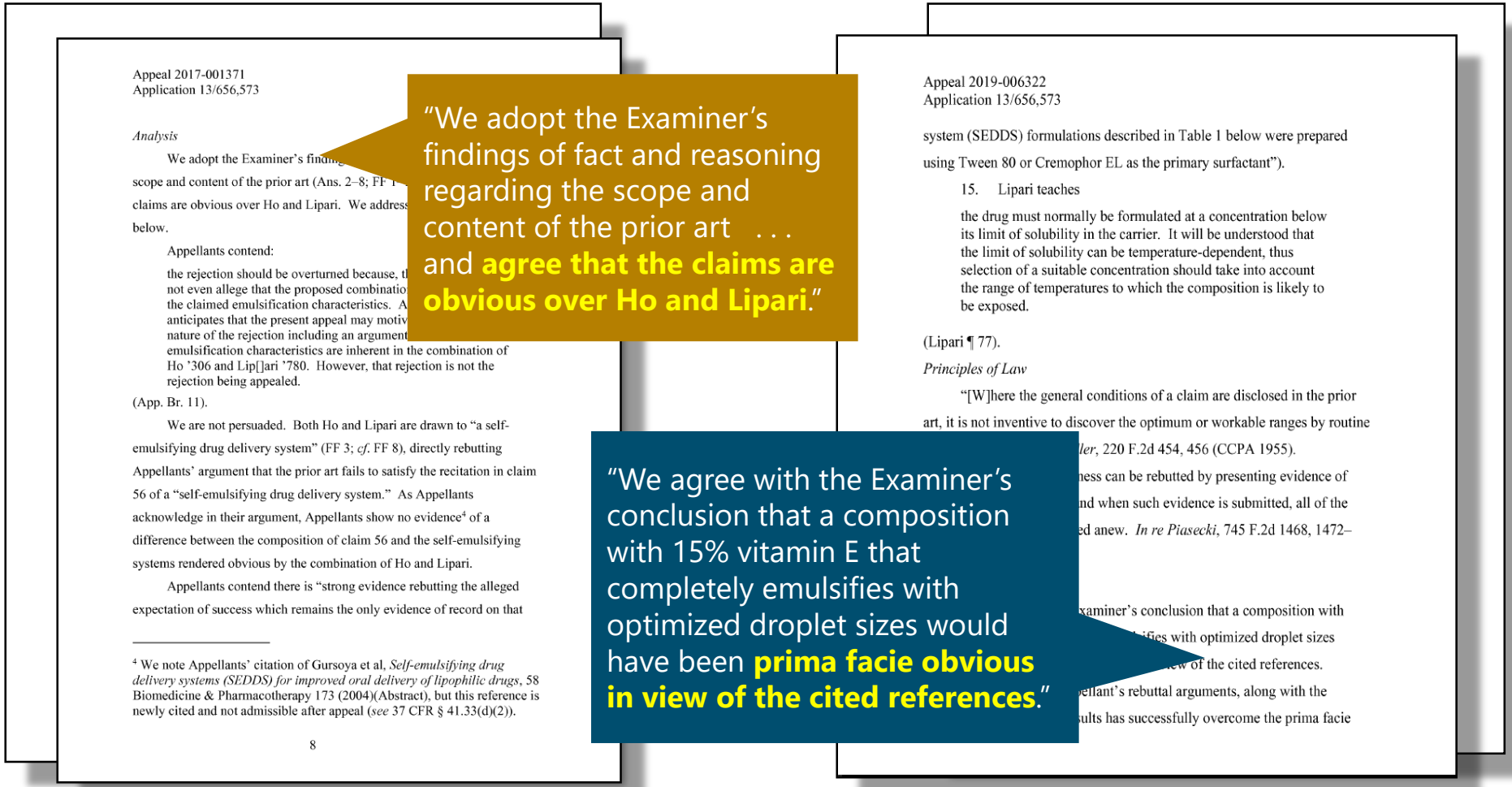
(10) **Pub. No.: US 2007/0104780 A1**
(43) **Pub. Date: May 10, 2007**

Lipari:

- Self-emulsifying formulations
- Teaches combining phospholipid, solubilizing agent, and surfactant to improve solubilization

See, e.g., 2015 Final Act. 6-7; 2018 PTAB Dec. 3

Prima Facie Obviousness



Appeal 2017-001371
Application 13/656,573

Analysis

We adopt the Examiner's findi
scope and content of the prior art (Ans. 2–8; FF 1
claims are obvious over Ho and Lipari. We address
below.

Appellants contend:

> the rejection should be overturned because, t
> not even allege that the proposed combinatio
> the claimed emulsification characteristics. A
> anticipates that the present appeal may motiv
> nature of the rejection including an argument
> emulsification characteristics are inherent in the combination of Ho '306 and Lip[]ari '780. However, that rejection is not the rejection being appealed.

(App. Br. 11).

We are not persuaded. Both Ho and Lipari are drawn to "a self-emulsifying drug delivery system" (FF 3; *cf.* FF 8), directly rebutting Appellants' argument that the prior art fails to satisfy the recitation in claim 56 of a "self-emulsifying drug delivery system." As Appellants acknowledge in their argument, Appellants show no evidence[4] of a difference between the composition of claim 56 and the self-emulsifying systems rendered obvious by the combination of Ho and Lipari.

Appellants contend there is "strong evidence rebutting the alleged expectation of success which remains the only evidence of record on that

[4] We note Appellants' citation of Gursoya et al, *Self-emulsifying drug delivery systems (SEDDS) for improved oral delivery of lipophilic drugs*, 58 Biomedicine & Pharmacotherapy 173 (2004)(Abstract), but this reference is newly cited and not admissible after appeal (*see* 37 CFR § 41.33(d)(2)).

8

"We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art . . . and **agree that the claims are obvious over Ho and Lipari**."

Appeal 2019-006322
Application 13/656,573

system (SEDDS) formulations described in Table 1 below were prepared using Tween 80 or Cremophor EL as the primary surfactant").

> 15. Lipari teaches
>
> the drug must normally be formulated at a concentration below its limit of solubility in the carrier. It will be understood that the limit of solubility can be temperature-dependent, thus selection of a suitable concentration should take into account the range of temperatures to which the composition is likely to be exposed.

(Lipari ¶ 77).

Principles of Law

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine
ler, 220 F.2d 454, 456 (CCPA 1955).
ness can be rebutted by presenting evidence of
nd when such evidence is submitted, all of the
ed anew. *In re Piasecki*, 745 F.2d 1468, 1472–

xaminer's conclusion that a composition with
ifies with optimized droplet sizes
ew of the cited references.
ellant's rebuttal arguments, along with the
sults has successfully overcome the prima facie

"We agree with the Examiner's conclusion that a composition with 15% vitamin E that completely emulsifies with optimized droplet sizes would have been **prima facie obvious in view of the cited references**."

Unexpected Results

components, surfactant system, and comb
7). Lipari teaches to select "a suitable tot
amount effective to solubilize the phospho
surfactant amounts can be selected within

Moreover, Ali, a prior art reference
that the person of ordinary skill in the art,
would have known that "[a]mong the criti
considered for the optimal in vitro
concentration, oil to surfactant
polarity of the emulsion, and droplet s
teaches "optimizing the ratio of primary a
are essential to produce SEDDS with desi
113, col. 1). Finally, Ali teaches "standard dissolution studies are suitable
for optimizing SEDDS formulations and for identifying critical formulation
variables" (Ali 113, col. 1). Thus, Ali evidences that the ordinary artisan
would have had assays to optimize SEDDS formulations and would have
optimized concentrations of components because these are critical
formulation variables. Appellants provide no evidence that such
optimization was anything other than routine.

Appellants contend they "developed a new SEDDS with unprecedented vitamin E loading and shown it to have exceptional emulsification performance" (Reply Br. 2).

We find this argument unpersuasive because Appellants identify no evidence supporting any unexpected results. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) ("It is well settled that unexpected results must be

"Appellants contend they 'developed a new SEDDS with unprecedented vitamin E loading and shown it to have exceptional emulsification performance" (Reply Br. 2).

We find this argument unpersuasive because **Appellants identify no evidence supporting any unexpected results**."

"Appellant's rebuttal arguments, along with the **evidence of unexpected results has successfully overcome the prima facie case of obviousness**."

system (SEDDS) formulations described in Table 1 below were prepared using Tween 80 or Cremophor EL as the primary surfactant").

15. Lipari teaches

> the drug must normally be formulated at a concentration below its limit of solubility in the carrier. It will be understood that the limit of solubility can be temperature-dependent, thus selection of a suitable concentration should take into account the range of temperatures to which the composition is likely to be exposed.

(Lipari ¶ 77).

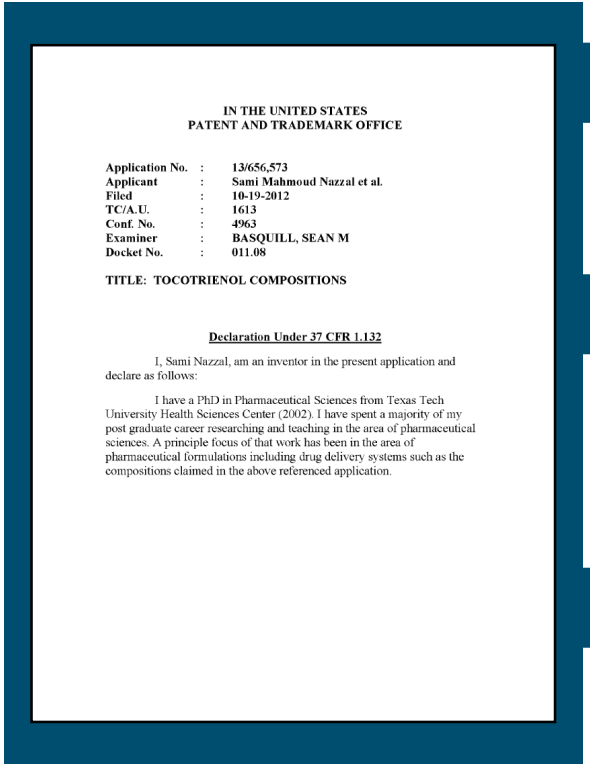
Principles of Law

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

ousness can be rebutted by presenting evidence of
ns and when such evidence is submitted, all of the
idered anew. *In re Piasecki*, 745 F.2d 1468, 1472–

Examiner's conclusion that a composition with
ulsifies with optimized droplet sizes
cie obvious in view of the cited references.
Appellant's rebuttal arguments, along with the
evidence of unexpected results has successfully overcome the prima facie

Nazzal Declaration



IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Application No.	:	13/656,573
Applicant	:	Sami Mahmoud Nazzal et al.
Filed	:	10-19-2012
TC/A.U.	:	1613
Conf. No.	:	4963
Examiner	:	BASQUILL, SEAN M
Docket No.	:	011.08

TITLE: TOCOTRIENOL COMPOSITIONS

Declaration Under 37 CFR 1.132

I, Sami Nazzal, am an inventor in the present application and declare as follows:

I have a PhD in Pharmaceutical Sciences from Texas Tech University Health Sciences Center (2002). I have spent a majority of my post graduate career researching and teaching in the area of pharmaceutical sciences. A principle focus of that work has been in the area of pharmaceutical formulations including drug delivery systems such as the compositions claimed in the above referenced application.

"[D]irectly tests the cited prior art, Ho, and shows that Ho does not satisfy the requirements of the claims."

2020 PTAB Dec. 9

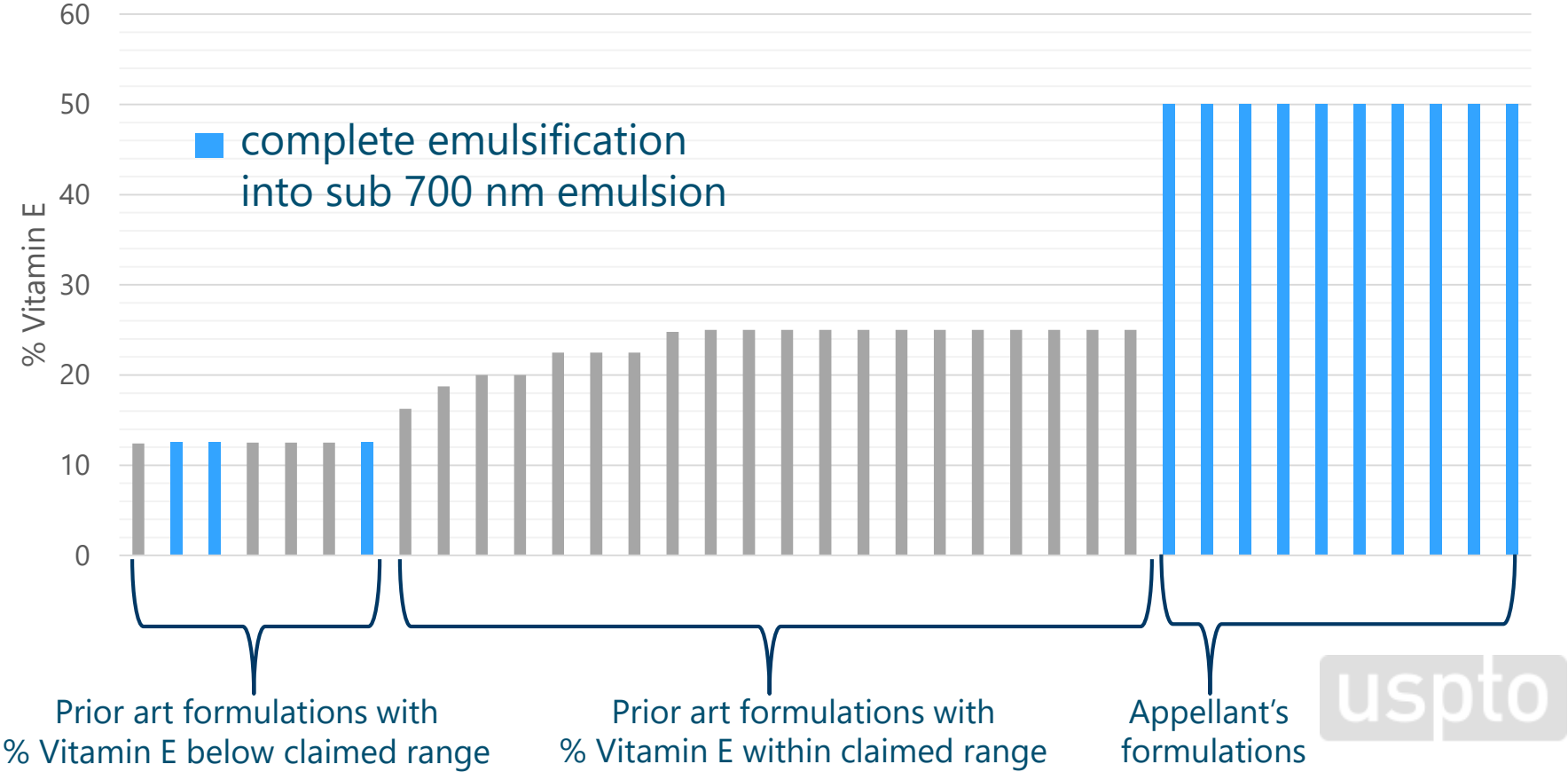
"[P]rovides analysis of other prior art [self-emulsifying] formulations."

2020 PTAB Dec. 10

"[S]tates 'based on the facts presented above and for the same reasons, at the time of the invention, the production of a > 15% vitamin E SEDDS capable of fully emulsifying into a sub 700nm emulsion was an unexpected results.'"

2020 PTAB Dec. 10

Analysis of Other Prior Art Formulations: Data from Nazzal Decl. Figure 3



Final Outcome

Appeal No. 2017-001371

"The evidence of record supports the Examiner's conclusion that **Ho and Lipari render claim 56 obvious**."

AFFIRMED

2018 PTAB Dec. 13

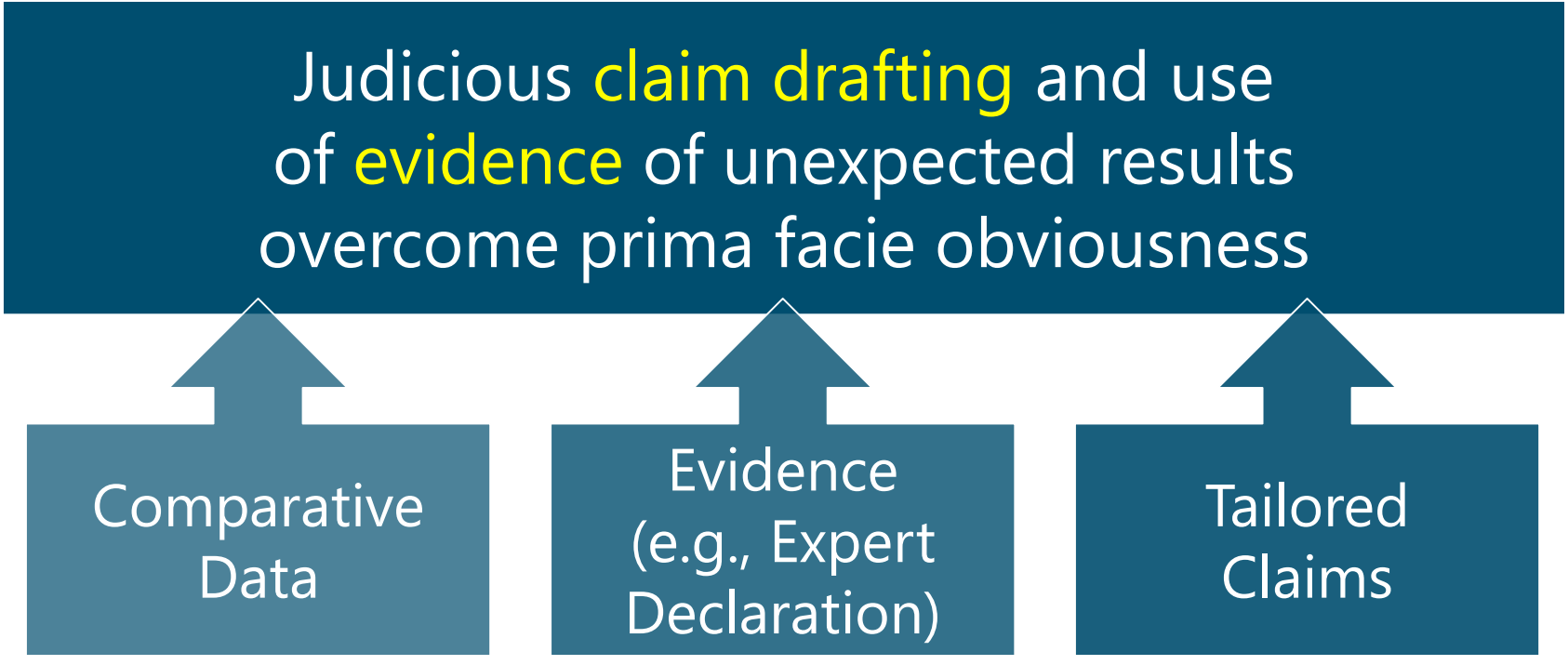
Appeal No. 2019-006322

"Appellant has provided substantial evidence that prior art formulations did not achieve a formulation containing . . . at least 15% vitamin E . . . that completely emulsified upon dissolution and resulted in droplet sizes of less than 700 nm . . . These results were **comparisons of the closest prior art** . . . and were **commensurate in scope with the very narrow claims at issue**, which also demonstrate a **difference in kind, not just degree** . . . . Thus, the evidence of record comports with the requirements necessary to **demonstrate unexpected results**."

REVERSED

2020 PTAB Dec. 11, 13

Takeaways


Judicious claim drafting and use of evidence of unexpected results overcome prima facie obviousness
Comparative Data
Evidence (e.g., Expert Declaration)
Tailored Claims

Question/Comment Submission

To send in questions or comments about the presentation, please email:

PTABInventorHour@uspto.gov

Next Inventor Hour webinar

- **April 28, 2022**, at noon to 1 p.m. ET
- Special hour-long presentation on the new PTAB Pro Bono Program

Future Inventor Hour webinars

- **April 28, 2022**, noon to 1 p.m. ET
- May 26, 2022 (same time)
- June 23, 2022 (same time)


UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE