

**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

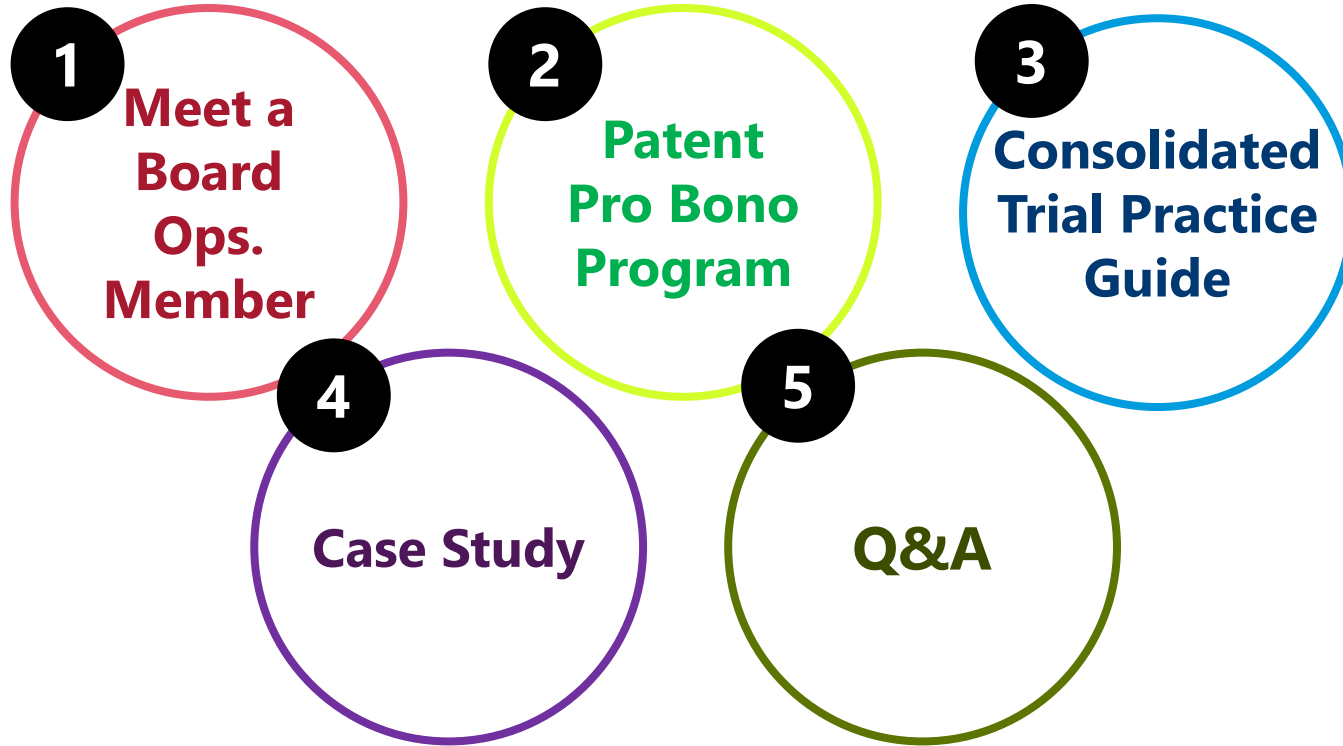
Erica Swift, Chief Clerk of the Board

March 24, 2022

UNITED STATES
PATENT AND TRADEMARK OFFICE



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

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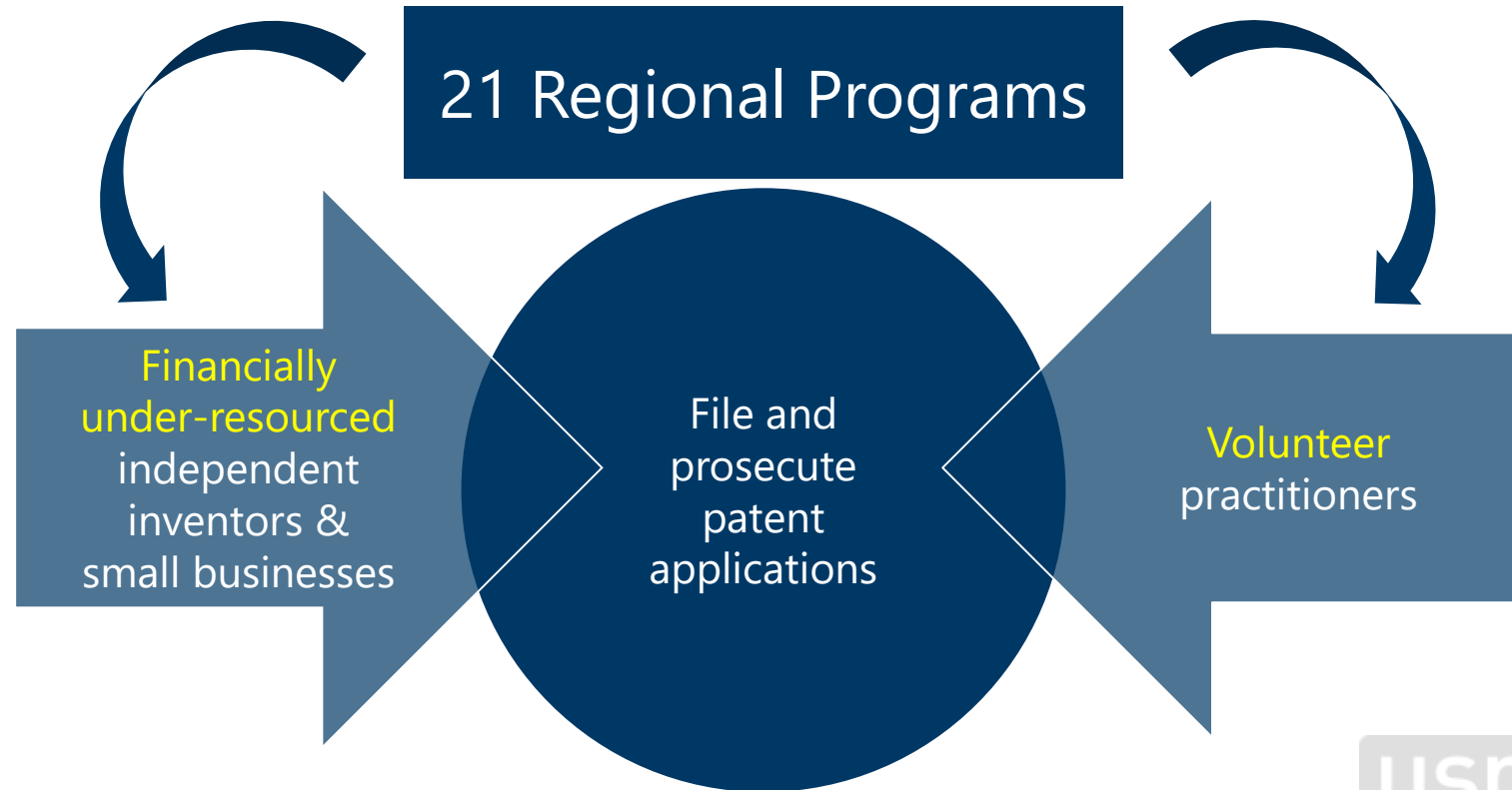


Grant Corboy, Staff Attorney - Patent Pro Bono Program Administrator
Office of Enrollment and Discipline, USPTO



An Overview of the Patent Pro Bono Program

Patent Pro Bono Program



Benefits to USPTO & Inventors



Impact for USPTO

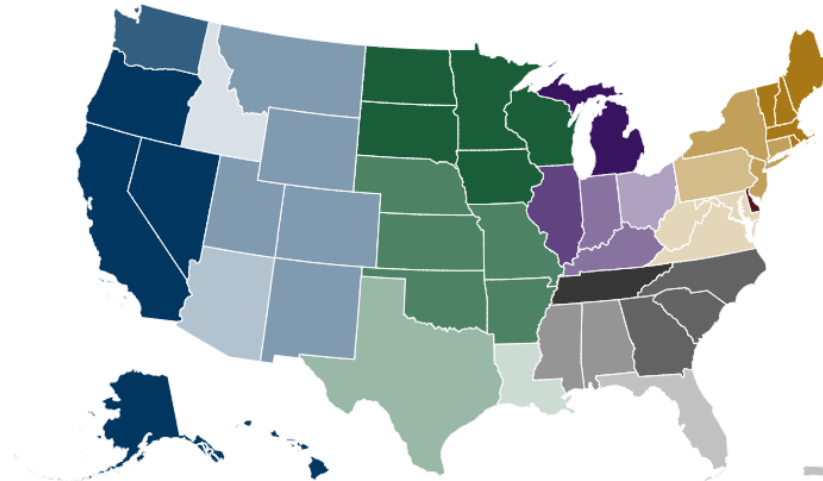
- Increased participation & patent application filings
- Improved quality of patents
- Supplements pro se (filing on your own) assistance efforts



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

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

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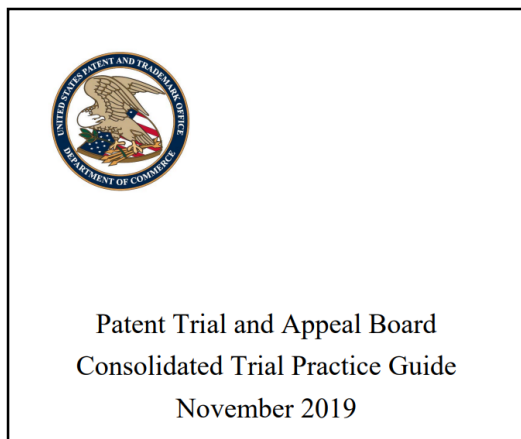


Arthur M. Peslak, Administrative Patent Judge



Trial Byte: **Consolidated Trial Practice Guide**

What is the Consolidated Trial Practice Guide?



<u>TRIAL PRACTICE GUIDE</u>	
NOVEMBER 2019 EDITION	
Introduction.....	1
Background.....	2
Statutory Requirements.....	3
General Overview of Proceedings	5
Sequence of discovery	7
Sequence of filing responses and motions.....	8
Summary of the Rules.....	8
I. General Procedures.....	8



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?

The screenshot shows the USPTO website interface. At the top, the USPTO logo and 'UNITED STATES PATENT AND TRADEMARK OFFICE' are visible. A search bar contains 'Search uspto.gov'. Below the navigation bar, the 'Patents' tab is selected. The breadcrumb trail reads 'Home > Patents > Patent Trial and Appeal Board > Resources and guidance'. The main content area is titled 'Resources and guidance' and includes a description: 'Policies, procedures, rules, guides, tools and manuals related to proceedings before the Patent Trial and Appeal Board. More recent information can be found on the [latest developments](#) page.' A list of resources is displayed with expandable arrows: Appeals, Trials, Reexams and interferences, Standard operating procedures, Guidance Memorandum, Trial Practice Guide, Statutes, rules, and references, Rulemaking, and FAQs. At the bottom of the page, there are feedback buttons for 'Helpful' (117) and 'Not Helpful' (1), along with 'Share' and 'Print' options.

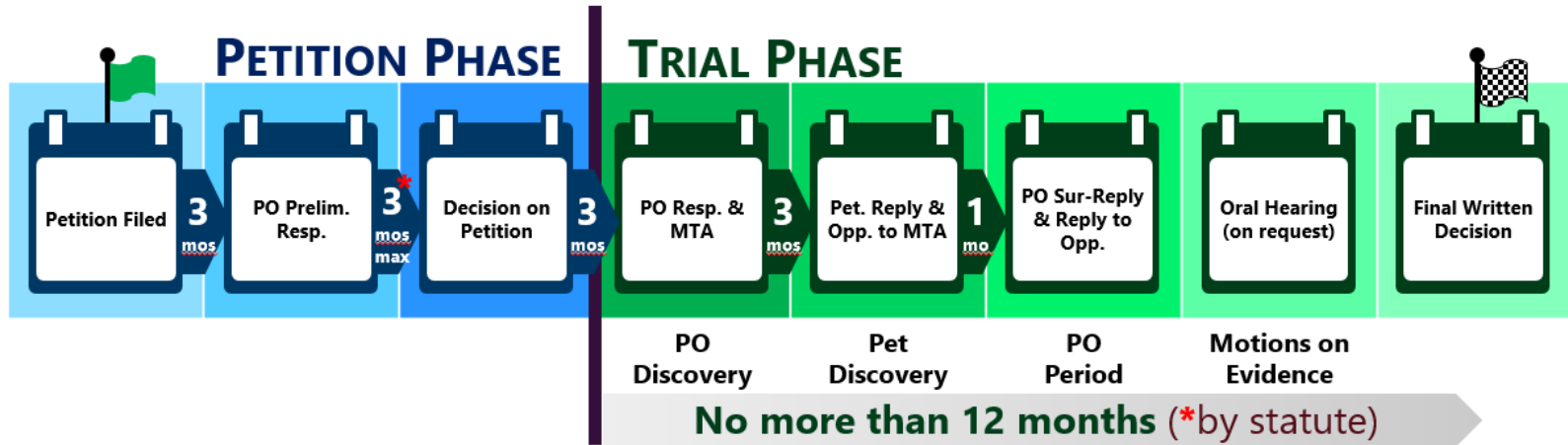
Available at:

<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:

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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/>

The screenshot shows the USPTO website interface. At the top, the logo 'uspto.GOV' is displayed alongside search options for patents and trademarks. Below the logo, the text identifies the USPTO as an agency of the Department of Commerce. A navigation bar lists various categories such as Patents, Trademarks, and IP Law & Policy. The main content area is titled '2142 Legal Concept of **Prima Facie Obviousness** [R-10.2019]'. It includes a table of contents on the left with items like '2101-2102-[Reserved]', '2103-Patent Examination Process', '2104-Requirements of 35 U.S.C. 101', and '2105-Patent Eligible Subject Matter'. The main text explains that during patent examination, the concept of prima facie obviousness establishes the framework for obviousness determinations. It also lists a table of contents for 707-Examiner's Letter of Action, with item 716.01(a) 'Objective Evidence of Nonobviousness [R-08.2017]' highlighted. This section states that objective evidence must be considered when timely presented and contains evidence of criticality or unexpected results. It references several court cases, including *Graham v. John Deere Co.*, *In re Palmer*, *In re Fielder*, *Graham v. John Deere*, *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, *Dann v. Johnston*, and *Miles Labs. Inc. v. Shandon Inc.*

2142 Legal Concept of *Prima Facie* Obviousness [R-10.2019]

"During patent examination and reexamining, the concept of prima facie obviousness establishes the framework for the obviousness determination. 707-Examiner's Letter of Action

obviousness determination for a prima facie case, prior art. Once the examiner has determined that the prior art or beyond it, or determination on obviousness. ACCO Brands Corp. v. Fe (citations omitted).

- 707.01-Primary Examiner Indicates Action for New Assistant
- 707.02-Applications Up for Third Action and 5-Year Applications
- 707.03-707.04-[Reserved]
- 707.05-Citation of References
 - 707.05(a)-Copies of Cited References
 - 707.05(b)-Citation of Related Art and Information by Applicants
 - 707.05(c)-Order of Listing
 - 707.05(d)-Reference Cited in Subsequent Actions
 - 707.05(e)-Data Used in Citing References
 - 707.05(f)-[Reserved]
 - 707.05(g)-Incorrect Citation of References
 - 707.05-Citation of Decisions, Orders

716.01(a) Objective Evidence of Nonobviousness [R-08.2017]

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHEN TIMELY PRESENT

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under **35 U.S.C. 103**. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1976) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective evidence of nonobviousness does not weigh in favor of obviousness. *Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), cert. denied, 127 L. Ed. 232 (1994). However, where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence is dispositive.

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 Nazzari, 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 number 61/667,489 filed on October 21, 2011 and entitled "Drug Delivery."

[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.

[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 a triglyceride ester wherein upon mixing of the composition of matter with water a resulting emulsion has a weighed mean droplet size of less than 700 nm. In a related embodiment, the composition of matter further comprises a first emulsifier in an amount of at least 10 dry basis weight percent of the composition of matter. In a further related embodiment, the composition of matter is an emulsion. In a related embodiment, the emulsion is selected from Polysorbate 80 and phospholipid. In a related embodiment, the first emulsifier is Polysorbate 80 and the emulsion further comprises a 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

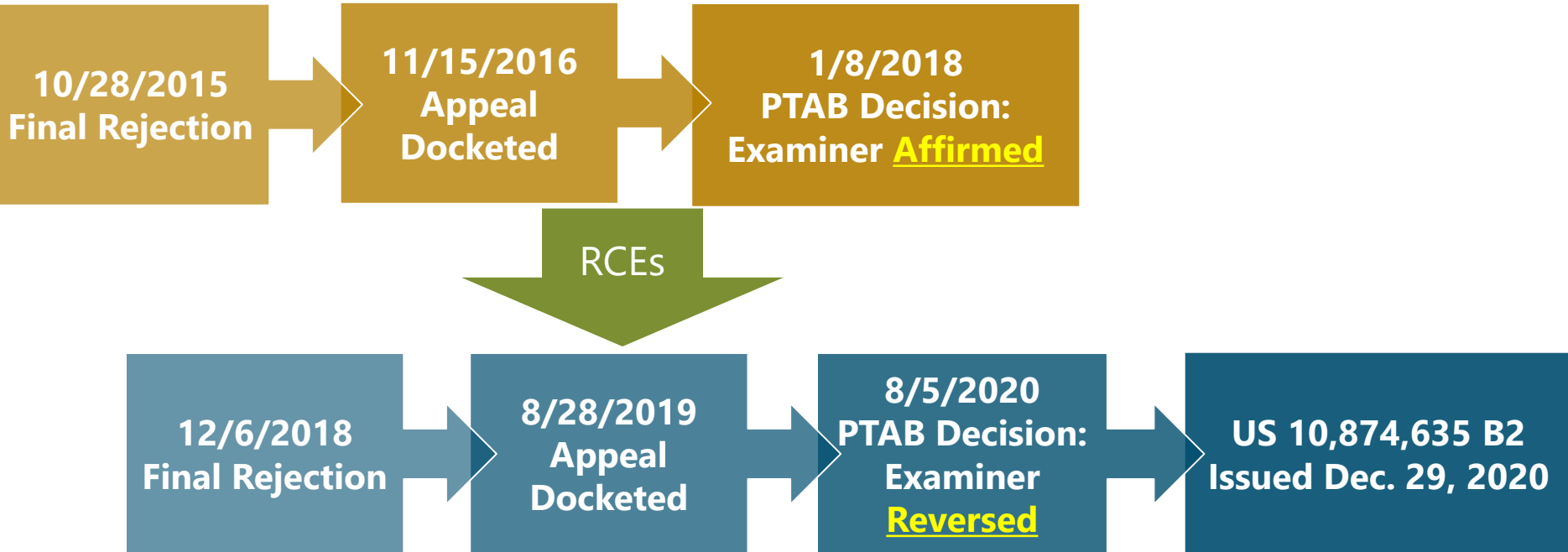
of the composition of matter and a constituent selected from a triglyceride ester wherein upon mixing of the composition of matter with water a resulting emulsion has a weighed mean droplet size of less than 700 nm. In a related embodiment, the composition of matter further comprises a first emulsifier in an amount of at least 10 dry basis weight percent of the composition of matter. In a further related embodiment, the composition of matter is an emulsion. In a related embodiment, the emulsion is selected from Polysorbate 80 and phospholipid. In a related embodiment, the first emulsifier is Polysorbate 80 and the emulsion further comprises a 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

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:
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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-weighted **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

(54) DR
FO
(76) Inv
(*) No
(21) Ap
(22) Fil
(51) Int
(52) US
(58) Fi
(59)

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 2007/0104780 A1

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

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

(54) FO
LO
OP
(76) Inv
Com
Rev
D-3
Abb
100
Abb
(21) App
(22) Fil
(60) Pro
28,
filed

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 findings regarding the scope and content of the prior art (Ans. 2-8; FF 1-4). The claims are obvious over Ho and Lipari. We address the Appellants' arguments below.

Appellants contend:

The rejection should be overturned because, the Appellants do not even allege that the proposed combination of the claimed emulsification characteristics. A person of ordinary skill in the art anticipates that the present appeal may motivate a rejection including an argument that the emulsification characteristics are inherent in the combination of Ho '306 and Lipari '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 evidence⁴ 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)).

"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."

"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."

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

experimentation." *In re Fisher*, 220 F.2d 454, 456 (CCPA 1955).

Obviousness can be rebutted by presenting evidence of unexpected results, and when such evidence is submitted, all of the evidence must be considered anew. *In re Piasecki*, 745 F.2d 1468, 1472-1473 (CA-9, 1984).

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.

The Appellants' rebuttal arguments, along with the evidence presented, has successfully overcome the prima facie

Unexpected Results

Appeal 2017-001371
Application 13/656,573

components, surfactant system, and combi
7). Lipari teaches to select “a suitable tota
amount effective to solubilize the phospho
surfactant amounts can be selected withi

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 size

teaches “optimizing the ratio of primary a
are essential to produce SEDDS with desi

113, col. 1). Finally, Ali teaches “standar
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
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We find this argument
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“Appellant’s rebuttal
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Appeal 2019-006322
Application 13/656,573

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(Lipari ¶ 77).

Principles of Law

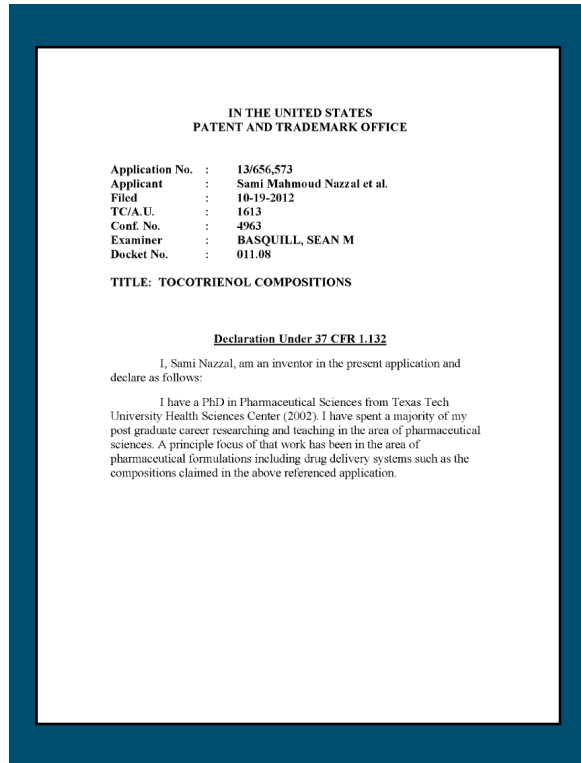
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Examiner’s conclusion that a composition with
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ere obvious in view of the cited references.

Appellant’s rebuttal arguments, along with the
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Nazzal Declaration



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

2020 PTAB Dec. 9

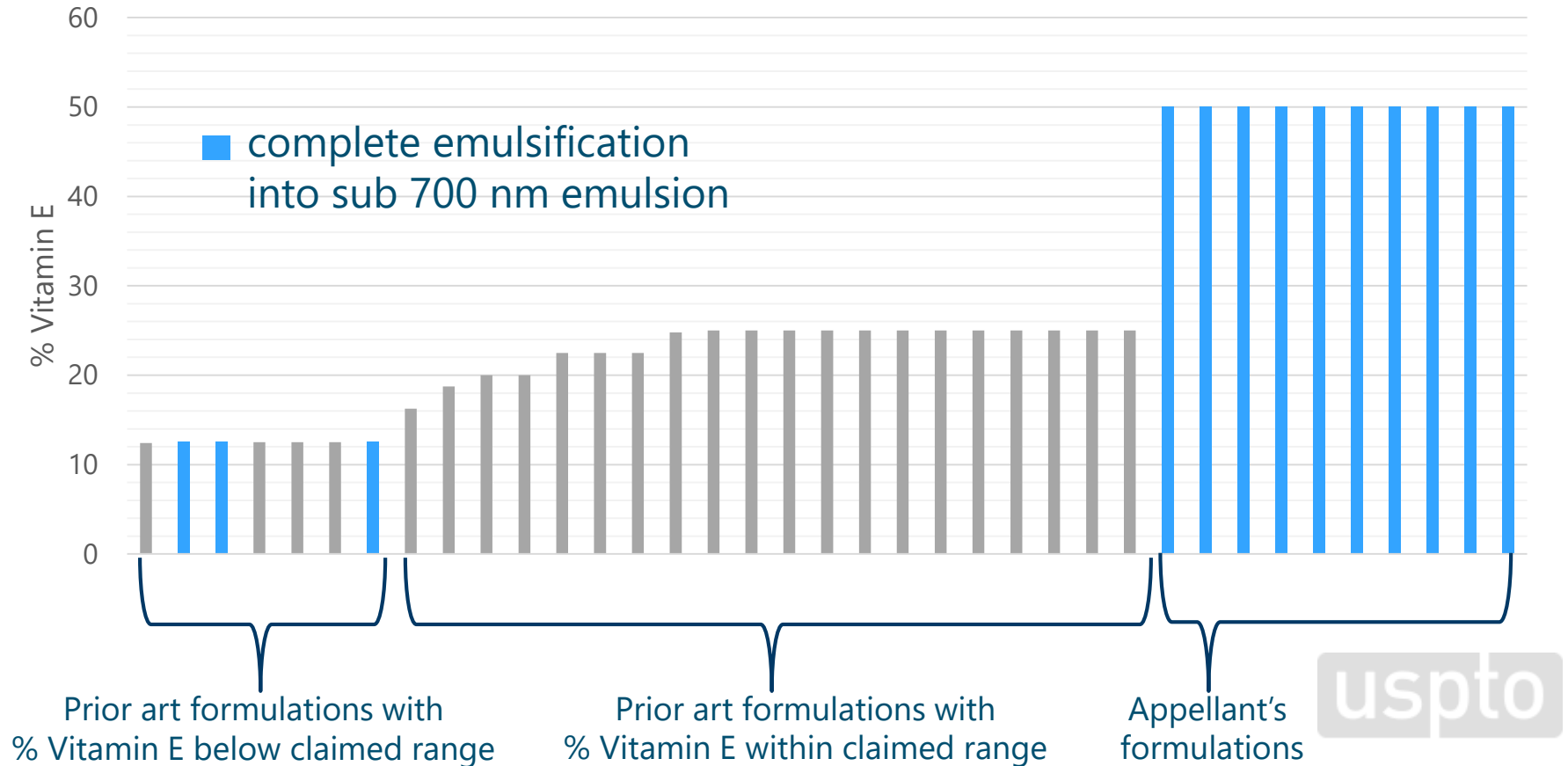
"[P]rovides analysis of other prior art [self-emulsifying] formulations."

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

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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)



