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
Today’s Agenda

1. Meet a Board Ops. Member
2. Patent Pro Bono Program
3. Consolidated Trial Practice Guide
4. Case Study
5. Q&A
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
An Overview of the Patent Pro Bono Program

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

21 Regional Programs

File and prosecute patent applications

Financially under-resourced independent inventors & small businesses

Volunteer practitioners
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
- BAVLP 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

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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
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

**PETITION PHASE**
- Petition Filed
- PO Prelim. Resp.
- Decision on Petition

**TRIAL PHASE**
- PO Resp. & MTA
- Pet. Reply & Opp. to MTA
- PO Sur-Reply & Reply to Opp.
- Oral Hearing (on request)
- Final Written Decision

**No more than 12 months** (*by statute*)
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

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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
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 Nozad, Paul Sylvester, and Aladin Alayubi
Attorney Docket No.: 011.08

[0001] This application claims the benefit of provisional application number 61/607,849 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 triglyceride ester wherein mixing of the composition of matter with water a resulting emulsion with a mean droplet size of less than 700 nm. In a related embodiment the composition of matter further comprises a first emulsifier making up at least 5 dry basis weight percent of the composition of matter. In a further embodiment the composition of matter is an emulsion. In a related embodiment the constituent is selected from Polysorbate 80 and phospholipid. In a related embodiment the first emulsifier is Polysorbate 80 and the emulsion further comprises phospholipid. In a further related embodiment, the constituent is selected from a triglyceride ester is a medium chain triglyceride. In a further related embodiment, the constituent is selected from a triglyceride ester is a Caprylic/Capric triglyceride. In a further related embodiment, the constituent is selected from 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 ester makes up at least five dry basis weight percent.
Ex Parte Nazzal
Appeal Nos. **2017-001371** & **2019-006322**

- **10/28/2015** Final Rejection
- **11/15/2016** Appeal Docketed
- **1/8/2018** PTAB Decision: Examiner **Affirmed**
- **8/5/2020** PTAB Decision: Examiner **Reversed**
- **US 10,874,635 B2** Issued Dec. 29, 2020
Representative Claims in the Appeals

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.
Same Rejection in the Appeals: Obviousness Over Ho & Lipari

**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

**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
"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."
"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."
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 13/665,973
Applicant : Semi Mahmoud Nazzal et al.
Filed : 18-19-2012
TC/AU : 1613
Conf. No. : 4900
Examiner : BASQUILL, SEAN M
Docket No. : 011.08

TITLE: TOTOCRIENOL COMPOSITIONS

Declaration Under 37 CFR 1.132

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

I have a PhD in Pharmaceutical Sciences from Texas Tech University Health Science 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.

2020 PTAB Dec. 9

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

2020 PTAB Dec. 10

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

- Prior art formulations with % Vitamin E below claimed range
- Prior art formulations with % Vitamin E within claimed range
- Appellant's formulations

- Complete emulsification into sub 700 nm emulsion
Final Outcome

Appeal No. 2017-001371

“The evidence of record supports the Examiner’s conclusion that Ho and Lipari render claim 56 obvious.”

AFFIRMED

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

2018 PTAB Dec. 13

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)