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PATENT PROTECTION OVERVIEW

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Notice

This content is for informational purposes only and is not legal advice.

Please consult with your counsel and appropriate sources for legal authority and guidance on these matters.

Four Categories of Intellectual Property

- **Patents**
  - Patent Prosecution
  - Post Patent Grant Proceedings at the USPTO (Quasi-Litigation)
  - Patent Litigation
  - Pharmaceutical Patents
- Trade Secrets
- Trademark/Trade Dress
- Copyrights

Distinct Patent Areas:
Patent Prosecution And Patent Litigation

Patent Prosecution

- File patent application at USPTO
- Correspond with patent examiner
- Conducted by inventor (pro se) or patent attorney/patent agent
  - PTO barred – Pass patent bar
- https://oedci.uspto.gov/OEDCI/practitionerSearchEntry

Patent Issued

Patent Litigation

- Enforcing/defending against patents
- US District Court or International Trade Commission
- US Court of Appeals for the Federal Circuit
- US Supreme Court
- PTO barred not required
  - Member of state bar

Patent Prosecution: Obtaining A Patent

UNITED STATES
PATENT AND TRADEMARK OFFICE

uspto

- Alexandria, VA (many Examiners work remotely)
- Manual of Patent Examining Procedure (MPEP)
  - “Bible” of patent prosecution
  - https://www.uspto.gov/web/offices/pac/mpep/index.html

Three Types Of US Patents

- Utility Patent
  - Machine – bike, car, medical device
  - Manufacture – a part (e.g., a circuit, screw, bolt)
  - Composition of matter – chemical compound, drug formulation
  - Process – Method of making an item, method of treatment
- Design Patent
  - Ornamental design – the configuration and shape of an article
- Plant Patent
  - Asexually reproduced new variety of plant

Provisional Patent Application

- Provisional application – a placeholder
  - Not reviewed, not published, claims not required
  - Importance → filing date = priority date
    - First to file system (no longer first to invent system)
    - Protects against later publications/disclosures
  - Expires after 1 year – file a non-provisional application or lose priority date
  - Does not start patent term clock
  - Application numbers in the 60s (e.g., 61/376,568)

Non-Provisional Patent Application

- US non-provisional application
  - Assigned to an Examiner for examination
  - Published after 18 months
  - Application numbers in the teens (e.g., 13/817,448)
- International – PCT application (Patent Cooperation Treaty)
  - More than 150 countries
  - File in PCT member patent office (US common e.g., PCT/US2011/048422)
  - Published after 18 months
  - Pick countries to enter in national phase – costs v. benefits

Utility Non-Provisional Application Requirements

- In English with a description and at least one claim (often includes drawings)
- Oath/declaration from each inventor
- Fees
- Filing requirements are met → filing receipt and examination

	Fee	Small entity	Micro entity
Basic Filing	350.00	140.00	70.00
Each independent claim in excess of 3	600.00	240.00	120.00
Each claim in excess of 20	200.00	80.00	40.00
Search	770.00	308.00	154.00
Examination	880.00	352.00	176.00
Issue	1,290.00	516.00	258.00

https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule

Patent Claims Define The Invention

We claim:

1. A drug delivery system for use with a dry powder for inhalation, comprising:

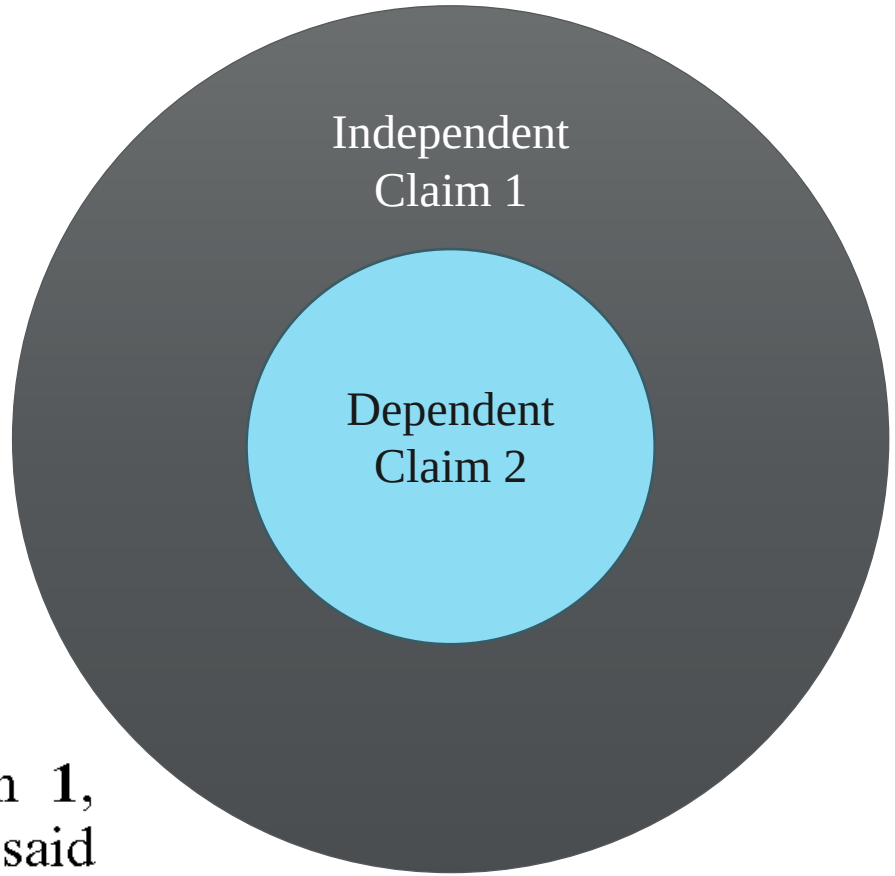
a unit configured to hold or support the dry powder;

an aerosol delivery port;

a flow passage configured for air flow between said unit and said aerosol delivery port; and

a three-dimensional rod array disposed in said flow passage comprising a plurality of rows, wherein each of said plurality of rows has a plurality of unidirectional rods, wherein said rows are spaced apart along a primary direction of air flow in said flow passage, and wherein the rods have a size in the range of 0.375 mm to 0.5 mm.

2. The drug delivery system as claimed in claim **1**, wherein successive rows of said plurality of rows in said primary direction of air flow are staggered.



Possible Actions During Patent Prosecution

- Submission of Prior Art (IDS)
- Restriction Requirement
- Office Action Rejecting Claims
  - Non-final if first or new basis
  - Final if basis for rejection maintained
- Applicant Response
  - Claim amendments
  - Declaration
- Examiner Interview
- Requests for Continued Examination (RCE)
- Appeal to the Patent Trial and Appeal Board (PTAB)
- Notice of Allowance

101 Rejection: Is Invention Patent Eligible?

- Eligible subject matter

  35 USC § 101 – Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- Not patentable – products of nature, mathematical equations, abstract ideas
- Traditionally low bar
- Most biotech inventions eligible
  - Pharmaceuticals, drug formulations, medical devices
  - Health apps (methods tied to computers) and diagnostic tests may raise issues

102/103 Rejections: Is Invention Already Known?

- Very common
- 35 USC § 102 – Anticipated by the prior art
  - Claimed invention described in single prior art reference
- 35 USC § 103 – Rendered obvious by the prior art
  - Claimed invention described in combination of prior art references
  - *Graham* factors
    - Scope and content of the prior art, differences between the invention and the prior art, level of ordinary skill in the art, secondary considerations of non-obviousness
- 102/103 rejections
  - Independent claim 102 rejection/dependent claim 103 rejection

112 Rejection: Is Invention Clear And Supported?

- **35 USC § 112**
  - Indefiniteness
    - Claims must clearly and precisely inform person of ordinary skill in the art of the boundaries of the invention
  - Lack of enablement
    - Disclosure when filed must contain sufficient information to enable a person of ordinary skill in the art to make and use the claimed invention
  - Lack of a written description
    - Specification must describe the claimed invention in sufficient detail that a person of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention

Appeal To The PTAB

- Appeal an adverse examiner decision Patent Trial and Appeal Board (PTAB)
  - Notice of Appeal
  - Appeal Brief
  - Examiner’s Answer
  - Oral Hearing if requested
  - Decision by the Board (affirmed, affirmed-in-part, reversed)
- Oct. 2024 – Apr. 2025
  - 64.5% affirmed (agreed with the Examiner)
  - 8.4% affirmed-in-part
  - 26.0% reversed
  - 1% Dismissed or Remand

Success! USPTO Issues A United States Patent

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Michelle K. Lee

Director of the United States Patent and Trademark Office

- Expiry (utility patent) – 20 years from earliest US filing date (non-provisional or PCT)
- Patent Term Adjustment
  - Additional days due to delays by the PTO
- Terminal Disclaimer
  - Shortens the patent term
  - Overcomes obviousness double patenting
- Patent Term Restoration
  - Maximum 5-year extension from FDA approval process
  - Applies to first permitted commercial marketing

US Patent Maintenance Fees	Fee	Small Entity	Micro Entity
Due 3.5 years	2,150.00	860.00	430.00
Due 7.5 years	4,040.00	1,616.00	808.00
Due 11.5 years	8,280.00	3,312.00	1,656.00

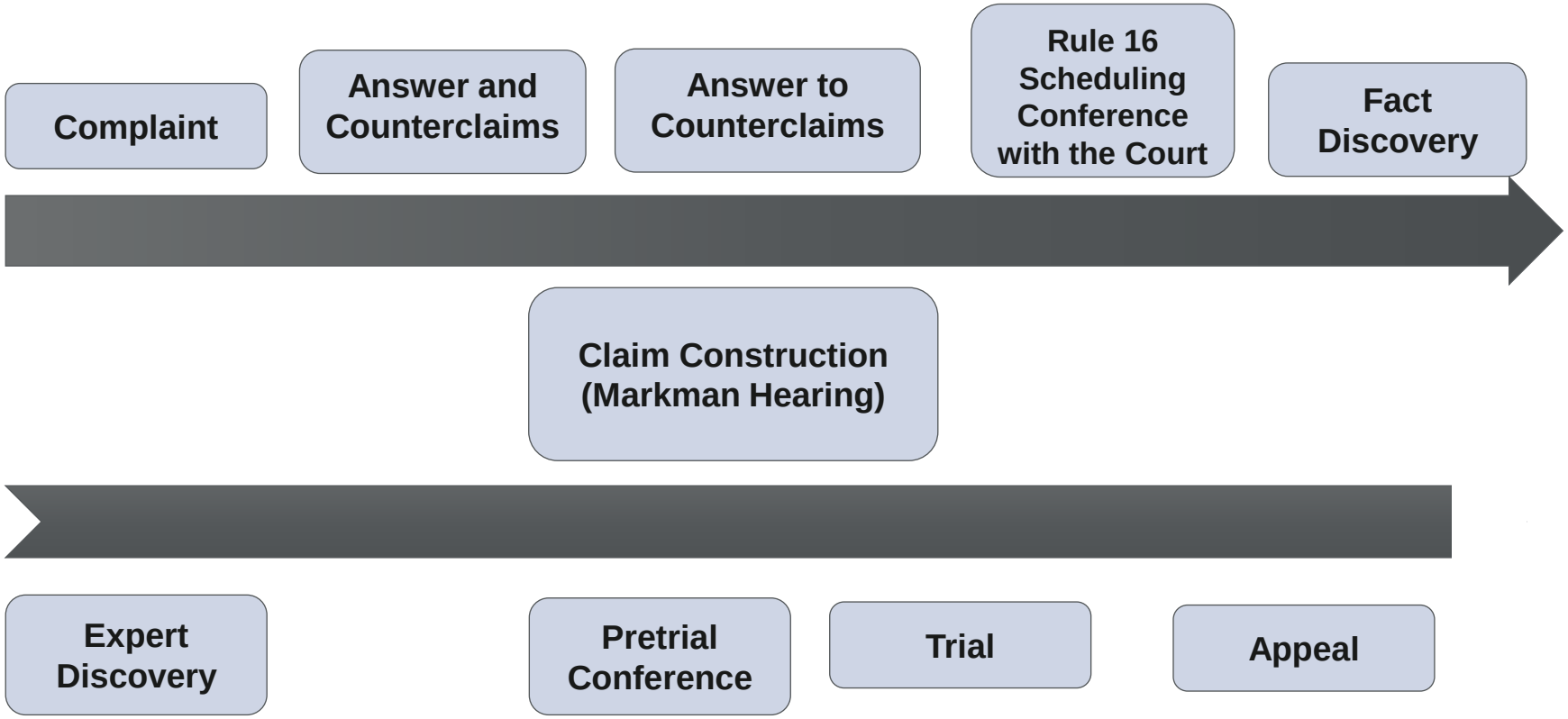
Post Patent Grant Proceedings At USPTO

- AIA – America Invents Act enacted September 16, 2011
- Post Grant Review (PGR) and Inter Partes Review (IPR)
- Challenge to patent validity at USPTO instead of federal courts
  - Patent Trial and Appeal Board (PTAB)
  - Appeal to United States Court of Appeals for the Federal Circuit
  - Less involved and less costly than district court litigation
- Less likely pharma patents challenged
  - Fiscal Year 2024 total petitions filed – 1,288
  - Electrical/Computer 69%, Mechanical/Business Methods 22%, Bio/Pharma 6%, Chemical 3%
  - Bio/Pharma petitions instituted – 73% (61 of 84)

Patent Litigation – Enforcing And Defending

- Patentees (plaintiffs) suing alleged infringers (defendants)
- Exclusively federal courts
  - Federal subject matter jurisdiction
  - United States District Court
  - United States Court of Appeals for the Federal Circuit
  - United States Supreme Court
- US District Court
  - District court with jurisdiction over alleged infringer
  - Majority of small molecule pharma cases filed in DE and NJ

General Timeline
District Court Patent Litigation



- Hatch-Waxman litigation – approx. 2 years to trial
- EDVa Rocket Docket – typically 4 to 6 months to trial
- Federal Circuit Appeal – from notice of appeal to decision ~ 1.2 years

Hatch-Waxman Orange Book
Small Molecule Drugs

- New Drug Application (NDA) – brand
- Abbreviated New Drug Application (ANDA) – generic
- Brand lists patents in Orange Book (OB)
  - Patent claims covering API, drug product, or approved method of use
  - https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
- Generic certifies to each OB patent
  - PIV certification – OB patent invalid/not infringed
- Generic sends notice letter to patent owner/NDA holder
- Brand sues within 45 days of notice letter receipt
  - 30 month stay of FDA approval of generic

Orange Book Patent Leverage For Brand

- Number of OB patents/latest expiring OB patent
  - Non-expired OB patents trigger 30 month stay
  - Raise costs – generic fighting multiple fronts/needs win on all asserted claims
  - Settlement date in view of OB patent expiry dates
- API patent – strong patent position
  - No non-infringement
  - Difficult to invalidate
  - But first to expire – later OB expiring patents extends timeline
- Other patents – strength varies
  - Approvable formulation outside patent claims
  - Section viii carve-out of approved indication
  - Ability to use different polymorph

BPCIA
Biologics and Biosimilars

- Biologics Price Competition and Innovation Act
  - Part of Patient Protection and Affordable Care Act (Obama Care)
  - Abbreviated approval pathway for biosimilars
  - Abbreviated Biologics License Application (aBLA) or 351k application
  - Reference Product Sponsor (RPS)
- Purple Book
  - Biologic information
  - Biosimilar/interchangeable products
  - Reference product/interchangeable product exclusivity periods
  - Patent information if disclosed to aBLA filer (patent dance)
  - https://purplebooksearch.fda.gov/

BPCIA Patent Dance

- Not mandatory
- aBLA applicant and RPS exchange patent information
  - aBLA applicant sends aBLA to RPS within 20 days of FDA acceptance
  - RPS and aBLA applicant exchange patent lists
  - Negotiate list of patents in infringement case
  - First wave and second wave litigations
- Entire dance up to 245 days
- https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2022/12/Patent-Dance-Guide-December-2022.pdf

US Patent Prosecution Histories Publicly Available

https://patentcenter.uspto.gov/

- **US Pat. No. 10,004,682**

Date	Action
2/17/13	Application filing of and preliminary amendment
2/28/13	PTO sends notice of missing parts
5/28/13	Inventors' oath filed
6/6/13	Filing receipt from PTO
3/24/14	Applicants file an IDS and submits references
8/12/15	Non-final rejection **(2.5 years from filing to substantive office action)**
10/20/15	Amendment/response by applicants
2/1/16	Final rejection
6/20/16	Applicant files RCE
	Continued back and forth
2/23/18	Notice of Allowance