PATENT SEARCHING IN PHARMACY

New dosage form designs must be *invented*. Think of new drug products as innovative new technologies. The best resource to find a highly detailed description of a new technology is its patent. This level of detail is generally not available anywhere else.

A patent is an intellectual property contract between the inventor and the government in which the inventor publicly provides a complete description of the new technology in return for the government excluding others from making, using, or selling that technology. To qualify for a patent, a technology must meet criteria proving it is new, useful, and inventive.

Relevant patents and other literature are referenced in each patent. Because so much research is done by an inventor and patent examiner prior to patenting, patents are an excellent gateway to literature on a specific technology or invention.

READING A U.S. PATENT:

**Patent Number:** A patent’s unique identifier. Patents are numbered in the order they are issued. Note the country code in the patent you are referencing (e.g., US8501759, CN102659609). Google Patents retrieves patents internationally. In PHM 388M Pharmaceutics, however, you will only be discussing FDA-approved drug products, so you should only cite US patents.

**Kind Code:** Letter or number that follows a patent number used to distinguish the type of patent document (e.g., design, plant, utility) and its level of publication.

**Issue Date:** The date that a patent application becomes a U.S. patent and patent rights can be exercised. Patents expire 20 years after the filing date, not the issue date. Fun fact: U.S. patents are always issued on Tuesdays.

**Title, Inventors, and Assignee:** U.S. patent law requires that the applicant in a patent application must be the inventor(s). An assignee is listed if the patent is owned by a company or an individual other than the inventor(s). In the past, it was the practice to give vague and general titles to patents, but now titles are more specific in their description of the new technology.

**Abstract and Body:** The abstract is a concise summary of the patent and typically includes the inventor’s primary claim to originality. Within the body, Background and Summary of the Invention contain a detailed description of the new technology, while Claims defines the invention and what aspects are legally enforceable.

**References Cited:** Also known as “prior art.” References include patents and other literature (e.g., articles, product catalogs) that the inventor(s) considers similar but not identical to the new technology. Citations that are flagged with an asterisk (*) are those that the patent examiner felt were particularly relevant to the patentability of the new technology.
Classification: U.S. patents are organized by a system using a 3-digit class and a 3-digit subclass to describe every similar grouping of patent art. For example, patent US6037353 A for Allegra® is classified under 514/317.

- 514: Drug, Bio-Affecting, and Body-Treating Compositions
- 317: Subject matter which contains an additional ring

A single invention may be described by multiple classification codes. *Classification codes are a good place to start when searching for related patents.*

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RETRIEVING A U.S. PATENT USING A PATENT NUMBER:

1. Access the Orange Book online through either the PHM 388M Pharmaceutics Portal or the FDA website. Patent information in the Orange Book is updated daily. The Orange Book is for approved human drug products. The Green Book is for approved animal drug products.

2. Search for your desired drug product by either active ingredient or proprietary name.

3. Click on the application number for the appropriate drug product(s). For example, Kaletra® has three different application numbers corresponding to the capsule, solution, and tablet formulations, respectively.

4. After clicking on the application number, you will see that drug product’s application information. Click “Patent and Exclusivity Info for this product: View.”

5. Search for the resulting patent number(s) in either Google Patents or the U.S. Patent and Trademark Office database (both are accessible from the portal). Note that a single product may have multiple patents. For example, Kaletra® oral solution has eight patents, each detailing a different aspect of the technology required for this dosage form design.

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RETRIEVING A U.S. PATENT USING A KEYWORD SEARCH:

1. If you are using a keyword search rather than searching by patent number, start your search with Google Patents. Google Patents has a higher relevance ranking than the U.S. Patent and Trademark Office (USPTO) database.

2. Type in words that describe your research or invention (use about three words and enclose phrases in quotes).

3. Note the U.S. classifications of the patents you have retrieved (located at the bottom of the patent on Google Patents). Click on the hyperlinked classification (e.g., 514/317) to go to its page on the USPTO database.

4. Click on the red “P" to examine other patents issued under those classifications.