

# Trademarks & Brand Protection for Pharma and Medical Devices

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MIND + MUSCLE



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# Agenda

1. Why Trademarks are Critical in Pharma
2. Pharma Trademarks are Different – Clearance Considerations
3. Think Outside the Name
4. Trademark and Anti-Counterfeiting Enforcement
5. Strategic Approach

## Why Trademarks Matter

- Shorthand for everything great about company/product
- Creates credibility
- Product differentiation, including in commoditized market
- Distinguishes products and prevents confusion
- Helps maintain consumer loyalty after patents expire – can remain in force indefinitely
- Trademark registrations critical for enforcement
- Strong brand recognition influences prescribing decisions

# Clearing Pharma Marks

**Pharmaceutical trademark owners must surmount two hurdles before they can use and register their trademarks in the US.**

- **Trademark Registration** -- Brand owners must obtain approval of the U.S. Patent and Trademark Office (USPTO) to obtain federal trademark registration.
- **FDA Approval to Use** -- Brand owners must obtain approval from the Food and Drug Administration (FDA) to use the pharmaceutical name.

## Clearing Pharma Marks

- USPTO and the FDA both purport to accept only names that will not cause confusion between drug names.
- But, both agencies compare different universes of data in making these determinations, and apply somewhat different standards.



## Clearing Pharma Marks

- USPTO will consider whether the proposed brand name is confusingly similar to marks that are already applied for and registered as trademarks.
- Often, pharmaceutical companies apply for several alternative brands for a single product launch, and the USPTO's search may therefore result in a refusal to register a mark based on a trademark that will never appear in the FDA database.

## Clearing Pharma Marks

- FDA looks at nonproprietary pharmaceutical names, established USP-NF monographs, generic names, and trademarks approved for use by the FDA but not yet applied for or registered.
- Approval from both agencies is ultimately necessary before a brand can be considered available for use as a new pharmaceutical trademark.

# Think Outside the Name

## Brands encompass more than just product names

- Slogans and logos
- Appearance of product and packaging can be just as important to distinguish products from competitors
  - Trade dress (overall commercial image of product):
    - Product configuration or shape
    - Inner and outer packaging (e.g., cartons, IV bags, vials, etc.)
    - Color(s)
  - Copyright
  - Design patent





## Enforcement - Counterfeiting

- Counterfeiting is a global concern – impacts all industries, all countries; can't underestimate damage– reputation, health
- In some countries, 70% of all drugs in the supply chain are counterfeit
- India – huge fake drug industry; 15,000 factories account for 75% of the world supply of counterfeit drugs
- As many as 200,000 malaria deaths in Africa are thought to have resulted from the use of sub-potent anti-malarials
- 97% of all counterfeit pharmaceuticals seized at U.S. border in 2015 were shipped from China, Hong Kong, India, and Singapore

## Enforcement

### Be proactive – assemble the tools you need to enforce:

- Trademark registrations – international, growing economies, defensive registrations
- Protect trade dress, design elements
- Register with Customs
- Register copyrights in design marks
- Monitoring services – trademarks, domain names, online marketplaces

## Enforcement Plan

- Assess impact of infringement/counterfeiting – in sales, reputation, liability
- Not all infringements are the same – prioritize
- Make a plan – counterfeiting should be viewed as any other competitive challenge, organizational involvement
- Targeted approach – impact, geographic, or product-based approach
- Litigation – direct and John Doe
- Measure success

## Creative Enforcement Solutions

- Strong brand and trade dress identity
- Set up distribution channels to deter counterfeiters
- Carefully consider geographic expansion and outsourcing manufacturing
- Consumer education
- Certification marks
- Authentication

## Think Strategically

- 1. Plan branding strategy early** — Allow adequate time to search and clear a mark before using it in clinical trials, promoting it within the industry, or submitting it to the FDA.
- 2. Conduct a proper clearance** — Invest upfront in a trademark/FDA clearance search conducted by an attorney experienced with pharmaceutical marks.
- 3. Be creative**— Avoid words that look or sound similar to existing brands, do not borrow from an existing brand or generic name, and do not use pharmaceutical stems as a prominent part of your drug name, choose unique trade dress.

## Think Strategically

4. **Proactively Register**
5. **File for alternatives** — The USPTO recognizes the challenges of obtaining FDA drug name approval and, for that reason, considers the filing of alternative drug names to be a bona fide Intent to use a mark in commerce as required to support an application.
6. **Collaboration between marketing and legal** — A successful branding program requires buy-in from the entire business.
7. **Coordinated approach to enforcement**

# Thank you!



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