Freedom to Operate



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FTO – Legal, Regulatory, & Financial

Legal Intellectual Property

Regulatory FDA, etc.

Financial Reimbursement

Types of Intellectual Property

- * Patents
- * Trade secrets
- * Trademarks
- * Copyright

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Trade Secret

- * A trade secret is essentially any type of information as long as it:
 - * has commercial value from not being known or readily ascertainable (e.g., formulas, processes, customer lists, etc.); and
 - * is the subject of reasonable efforts to keep the information secret
- * Trade secret vs. patent considerations
 - * Is it even patentable subject matter
 - * Can it be reverse engineered easily or independently invented
 - * Enforceability: TS enforceable only if misappropriated by improper means
 - * Duration or term of protection: TS unlimited; patent is 20 years from filing

Why Patent?

- * A patent owner has the right to <u>exclude</u> others from making, using, selling, offering for sale, or importing the patented invention into the United States for the term of the patent
- * A patent does not give the owner an affirmative right to practice their invention.

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Types of Patents

* UTILITY PATENTS

- Directed to <u>structure and functionality</u> of invention
- Only granted to inventions that are novel, non-obvious and useful
- Term of protection 20 years from filing

* DESIGN PATENTS

- Directed to <u>ornamental appearance</u> of an item
- Only granted to designs that are novel, non-obvious and ornamental
- Term of protection 14 years from date of issue

What Does it Cost - US

- Obtaining a U.S. Patent
 - Drawings \$300-\$1,000+
 - Government filing fees \$1,125 (\$655 small entity) without excess claim fees
 - Application preparation fees \$6-\$10k
 - Prosecution fees \$3k-\$6k+ (highly variable)
 - Government issue and publication fees \$2k (\$1,170)
 - Total \$10,000-\$20,000+
- Maintaining a U.S. Patent
 - 3.5 year maintenance fee \$1,130 (\$565)
 - 7.5 year maintenance fee \$2,850 (\$1,425)
 - 11.5 year maintenance fee \$4,730 (\$2,365)
 - Total \$8,710 (\$4,355)

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Patentability Requirements

- * Inventors Ownership
- * Statutory subject matter
- * Novelty
- * Non-obviousness (inventiveness)
- * Disclosure requirements

Novelty - New

- Loss of novelty occurs when each and every element of the claimed invention is disclosed in a single piece of "prior art" before the effective filing date of the application
- * In the United States, there is currently a one year grace period
- * In many other jurisdictions, there is an "absolute novelty" requirement no grace period
- * Pursuant to the America Invents Act, on March 16, 2013, the United States will adopt a "modified" absolute novelty requirement
 - * One year grace period will only apply to disclosures made by (i) an inventor; (ii) someone who obtained the disclosed subject matter from an inventor; or (iii) someone associated with an inventor via a joint research agreement

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Novelty - continued

- * <u>Prior art</u> is any publicly known information that has a date earlier than the effective filing date of the invention under consideration
 - * Prior art can be other patents or patent applications, abstracts from conferences, products, advertisements, etc.
 - * Other disclosures that qualify as prior art include public use of the invention, sale or offer for sale of the invention, displaying or promoting the invention

Disclosure Requirements

- * Written description
 - * Adequately describe what is claimed
- * Enablement
 - * Describe the invention so another can carry it out as claimed without undue experimentation
- * Best mode
- * Clear claims