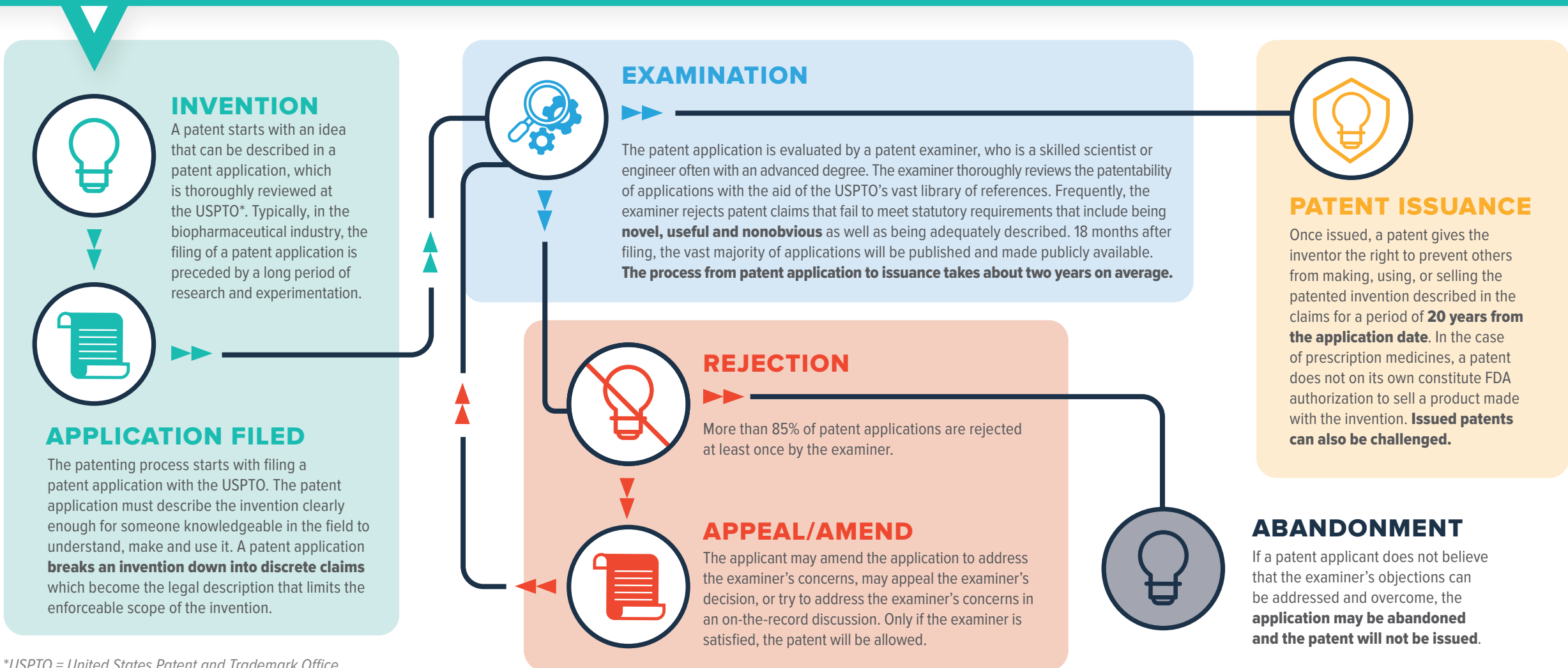


# Obtaining a Patent Requires Passing Through a Robust and Thorough Process

Patents are a form of IP protection referenced in the U.S. Constitution that grant inventors the exclusive right to make, use, or sell their inventions for a set period of time. Patents are an essential incentive to innovation and are particularly important to the biopharmaceutical industry. The process for obtaining a patent requires extensive review by patent examiners and substantive responses by the patent applicant, often taking several years.



\*USPTO = United States Patent and Trademark Office

# Even After A Patent Has Been Granted It Remains Subject To Legal Challenges



## PATENT IS CHALLENGED

Even after a patent is issued, the entire patent or one or more of its claims can be challenged and potentially invalidated or held unpatentable.

A patent challenge may be heard in Federal Court, by a panel of 3 administrative judges at the USPTO's\* Patent Trial and Appeal Board (PTAB), and in some cases by the USPTO's Central Reexamination Unit.

Patent challenges in the courts and at the PTAB may run concurrently.



## FEDERAL COURT

In challenges heard in court cases, **challengers can raise any ground, and patent owners are subject to due process protections.** District court rulings can be appealed to a federal appeals court. Parties may also settle prior to a ruling.



## PTAB

### PGR

**Within the first 9 months after the patent issues,** a third party may petition for a post-grant review (PGR), which is a procedure to challenge a patent at the PTAB **on nearly any ground.**

### IPR

**From 9 months after the patent issues through expiration,** a third party may file an inter partes review (IPR). An IPR is a procedure that allows patents to be challenged at the PTAB **on the basis of novelty and obviousness.** This is the most common challenge to an issued patent at the USPTO.

### Ex Parte Reexamination

Ex parte reexamination allows patents to be challenged before a specialized group of patent examiners if **“a substantial new question of patentability”** is presented. If the patent is found unpatentable, the decision can be appealed to the PTAB.



## FEDERAL APPEALS COURT

The Federal appeals court decide a challenge in one of three ways

### Patent Upheld

If the Federal appeals court finds that a patent is not invalid, then the patent has been upheld and **can be enforced in the courts.**

### Patent Upheld In Part

If the Federal appeals court finds some claims to be valid but others invalid, those **claims are removed from the patent and may not be enforced in the courts.**

### Patent Invalidated

If the Federal appeals court invalidates all of a patent's claims in their entirety, then that **patent cannot be enforced in the courts.**

\*USPTO = United States Patent and Trademark Office