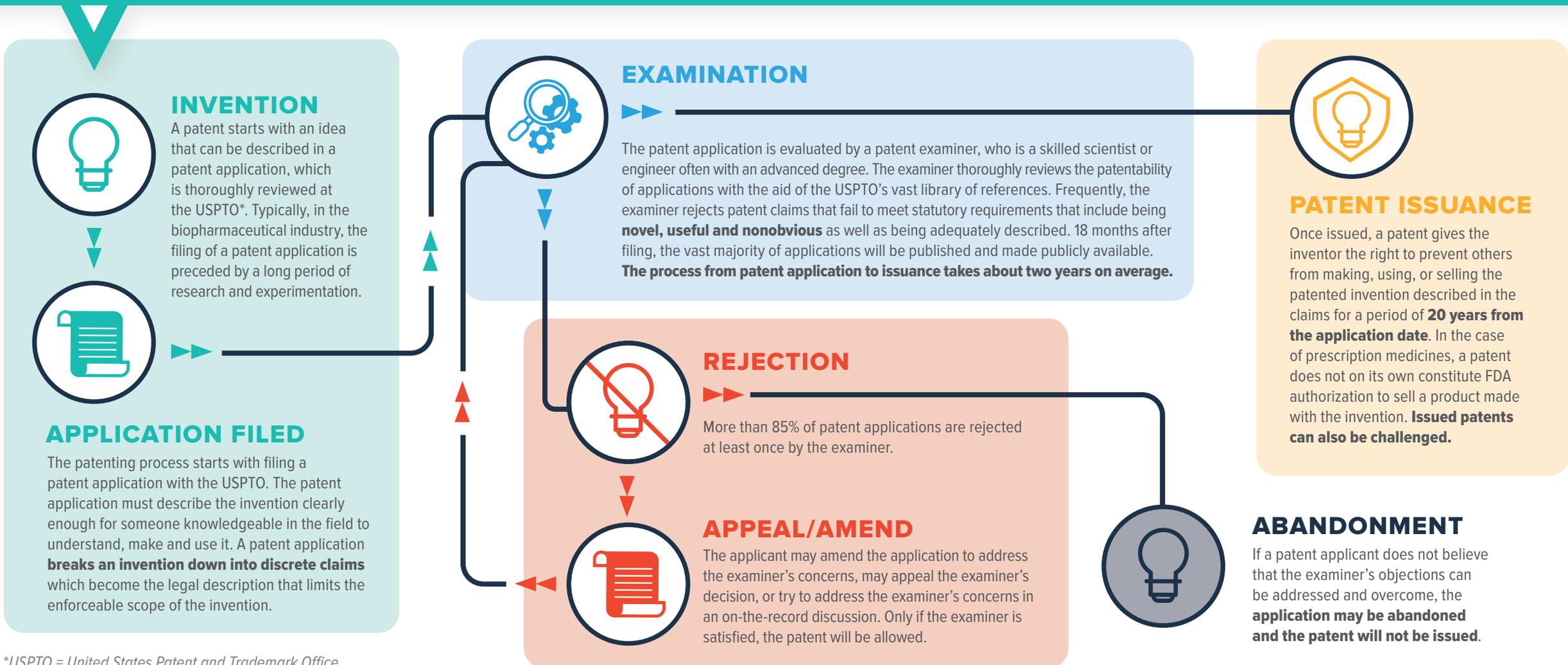


Obtaining a Patent Requires Passing Through a Robust and Thorough Process

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