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.



INVENTION

A patent starts with an idea that can be described in a patent application, which is thoroughly reviewed at the USPTO*. Typically, in the biopharmaceutical industry, the filing of a patent application is preceded by a long period of research and experimentation.



APPLICATION FILED

The patenting process starts with filing a patent application with the USPTO. The patent application must describe the invention clearly enough for someone knowledgeable in the field to understand, make and use it. A patent application **breaks an invention down into discrete claims** which become the legal description that limits the enforceable scope of the invention.



EXAMINATION



The patent application is evaluated by a patent examiner, who is a skilled scientist or engineer often with an advanced degree. The examiner thoroughly reviews the patentability of applications with the aid of the USPTO's vast library of references. Frequently, the examiner rejects patent claims that fail to meet statutory requirements that include being **novel, useful and nonobvious** as well as being adequately described. 18 months after filing, the vast majority of applications will be published and made publicly available. **The process from patent application to issuance takes about two years on average.**



REJECTION



More than 85% of patent applications are rejected at least once by the examiner.



APPEAL/AMEND

The applicant may amend the application to address the examiner's concerns, may appeal the examiner's decision, or try to address the examiner's concerns in an on-the-record discussion. Only if the examiner is satisfied, the patent will be allowed.





PATENT ISSUANCE

Once issued, a patent gives the inventor the right to prevent others from making, using, or selling the patented invention described in the claims for a period of **20 years from the application date**. In the case of prescription medicines, a patent does not on its own constitute FDA authorization to sell a product made with the invention. **Issued patents can also be challenged.**



If a patent applicant does not believe that the examiner's objections can be addressed and overcome, the application may be abandoned and the patent will not be issued.

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.



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.