

United States Patent Laws: An Integrated Picture

Peter A. Soukas, J.D.
NIH Office of Technology Transfer



Source of US Patent Law

- The United States Constitution grants to the Congress the power to grant patents; this power residing in the Congress is found in Article I, Section 8, Clause 8.
- The constitutional reward of a patent, together with the constitutional requirements of utility, novelty and non-obviousness, represent a delicate balance struck between the need to encourage innovation and the avoidance of exclusive rights that stifle competition without any advantage to society.

Codification of US Patent Law

- US patent law is codified in Title 35 of the United States Code (USC).
- The implementing regulations for the patent laws comprise Title 37 of the Code of Federal Regulations (CFR).
- The laws and regulations are further supplemented by Executive Orders and agency policies.

Patent Grant and Term

- A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.
- Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States or, from the date an earlier related application was filed.
- U.S. patent grants are effective only within the United States, U.S. territories, and U.S. possessions.
- Patent term extensions or adjustments may be available.

Patent Grant and Term

- The right conferred by the patent grant is, in the language of the statute and of the grant itself, "the right to exclude others from making, using, offering for sale, or selling" the invention in the United States or "importing" the invention into the United States.
- What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.
- Once a patent is issued, the patentee must enforce the patent without aid of the USPTO.

Federal Judicial Infrastructure

- Federal District Courts → Federal Circuit → US Supreme Court
- Patent law is exclusively Federal
- District courts are courts of original jurisdiction (i.e. they hear all initial appeals from the US PTO and infringement/declaratory judgment actions)
- Federal Circuit was created in the early 1980s to hear all appeals from district court cases, thereby creating one uniform patent arbiter
- United States Supreme Court is the ultimate arbiter of the law

Patentability Criteria

- Patentable Subject Matter - 35 U.S.C. 101: includes "anything under the sun that is made by man."
- Utility Requirement - 35 U.S.C. 101: invention is "useful" for some purpose.
- Novelty Requirement - 35 U.S.C. 102: applicant must demonstrate that every element of an invention is new. (Anticipation)

Patentability Criteria Cont.

- Nonobviousness Requirement - 35 U.S.C. 103
- (1) the differences between the prior art and challenged claims;
- (2) the level of ordinary skill in the field of the pertinent art at the time of plaintiff's invention;
- (3) what one possessing that level of skill would have deemed to be obvious from the prior art reference; and
- (4) objective evidence of obviousness or nonobviousness.

Patentability Criteria Cont.

- Adequate Description Requirement - 35 U.S.C. 112
- Enablement Requirement: describe invention allowing others to make invention
- Best Mode Requirement: Preferred way of carrying out invention.
- Written Description Requirement: Define invention with as much specificity as possible.

Patent Process

- Filing of non-provisional application (provisional applications not examined).
- Notice of Missing Parts/Restriction (i.e. non-substantive matters)
- Actual Examination: Office Action(s); examination on merits of patentability criteria
- Allowance/Appeal/RCE/Continuation/Continuation in Part (i.e. more "bites at the apple".)

Where does PHS file patent applications?

- Depends on licensing status, institute, indication, market, patentability.
- Generally: US, Europe, Canada, Australia, Japan.
- Increasingly: India, China, Brazil.
- Occasionally: South Africa, Mexico.

Publication of Patent Applications

- American Inventors Protection Act (1999)
- Publication occurs after the expiration of an 18-month period following the earliest effective filing date or priority date claimed by an application.
- Applicant may assert provisional rights. Damages for pre-patent grant infringement are available (under certain conditions.)
- Following publication, application is no longer held in confidence by the Office and the public may request access to the entire file history of the application.

Reissue/Reexamination/Interferences

- Reissue: When the patent is defective in certain respects.
- Following an examination in which the proposed changes correcting any defects in the original patent are evaluated
- Nature of the changes that can be made by means of the reissue are rather limited; new matter cannot be added.
- Reexamination: Any person may file a request for reexamination of a patent, along with the required fee, on the basis of prior art consisting of patents or printed publications.
- At the conclusion of the reexamination proceedings, a certificate setting forth the results of the reexamination proceeding is issued.
- Both very risky and possibly costly proceedings.

Interference Proceedings

- Patent can only be granted to one inventor.
- An "interference" is instituted by the Office to determine who is the first inventor and entitled to the patent.
- Interference proceedings may also be instituted between an application and a patent already issued, provided that the patent has not been issued, nor the application been published, for more than one year prior to the filing of the conflicting application, and provided also that the conflicting application is not barred from being patentable for some other reason.
- Expensive, long proceedings.

PHS Patent Policy

- In accordance with a longstanding tradition of scientific freedom, PHS research results are published freely.
- Publication of research is not to be significantly delayed for the purpose of either filing patent applications on patentable subject matter, or conducting further research to develop patentable subject matter.
- Once initiated, prosecution of patent applications and maintenance of issued patents will continue only as long as there exists a reasonable expectation of transferring the patent rights to a commercial partner through licensing.

PHS Patent Policy

- PHS will enforce and defend its patents, where appropriate, either through its own resources, by granting its licensees the right of enforcement and defense as provided by 35 U.S.C. 207 (a)(2).
- PHS may refer the matter directly to the Department of Justice.
- In any case, no litigation may be undertaken in the Federal Court system without approval of the Department of Justice.

Current PHS Patent Policy Issues

Research Exemptions

- *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (Jun. 13, 2005)
- "the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an [investigational new drug application] or [a new drug application]."

Current PHS Patent Policy Issues Nucleic Acid Patenting

- *In re Fisher*, 421 F.3d. 1365 (Fed. Cir., Sept. 7, 2005), relates to the patentability of certain expressed sequence tags (ESTs).
- Federal Circuit held that the claimed ESTs, which encode protein fragments in maize plants, lack specific and substantial utility, as required under 35 U.S.C. § 101, and that they are not enabled under 35 U.S.C. § 112.
- Federal Circuit held that the claimed ESTs were not supported by a specific and substantial utility "because Fisher does not identify the function for the underlying protein-encoding genes."