HHS Public Access

Author manuscript

Methods Mol Biol. Author manuscript; available in PMC 2017 November 08.

Published in final edited form as:

Methods Mol Biol. 2012 ; 823: 391–408. doi:10.1007/978-1-60327-216-2_26.

Inventions and Patents: A practical tutorial

J. Lille Tidwell[1] and **Lance A. Liotta**[1,*]

[1]George Mason University, Manassas, VA 20110

Abstract

Patents are designed to protect and encourage creativity and innovation. Patenting a biomedical discovery can be a requirement before a pharma or biotech entity will invest in the lengthy and costly clinical testing necessary to achieve patient benefit. Although scientists and clinicians are well versed in research publication requirements, patent descriptions and claims are formatted in a manner quite different from a research paper. Patents require a) a series of logical statements clearly delineating the boundaries of the novel aspects of the invention and b) sufficient disclosure of the invention so that it can be reproduced by others. Patents are granted only for inventions that meet three conditions: novelty, non-obviousness and usefulness. This chapter provides basic guidelines and definitions for inventions, inventorship, and patent filing which are summarized using a question and answer format.

Keywords

disclosure; discovery; invention; non-disclosure agreement; patent; technology transfer

1. Introduction

Patenting biomedical discoveries is an important requirement for commercialization. A pharmaceutical company, a diagnostic company, or a biotechnology firm will not spend the considerable resources to develop a new product that can benefit patients suffering from disease, if the product is not covered by an issued or pending patent (Jones 2005 reference).

*Corresponding author: Lance A. Liotta, MD, PhD, George Mason University, Center for Applied Proteomics and Molecular Medicine, 10900 University Blvd, MS 4E3, Manassas, VA 20110, Phone: 703-993-9444, Fax: 703-993-8606, lliotta@gmu.edu.

[2]Question: What are the requirements for a patent figure or table.

The figure must be on A4 paper, with one inch margins, 32mm text (14 point font) and must be in black and white. The resolution must be adequate for reproduction (300 dpi). A listing of a nucleic acid sequence must comply with the following patent rules: 1.821, 1.822, 1.823, 1.824, and 1.825, and may be in paper or electronic form (See: 35 United States Code 271; http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf.) (5)

[5]Common pitfalls encountered by inventors are listed below in Notes 6–9. Failure to record the invention process. You should keep detailed records of the concepts, data, and other information related to making an invention in a logbook. Start a logbook entry series from the very first moment you think of an idea. Proper record keeping can be used as proof of the conception date of an invention. The best way to prove that an idea is yours is by maintaining an inventor's journal or logbook, recording the experiments and discussions including with whom you discussed the invention, and having a witness who can testify that you made the invention (3, 8).

[7]Pursuing an invention that has no commercial market. Before using your children's college funds to heavily invest in your invention, assess the true value in the market compared to the existing state of the art. Does your invention offer true advantages in performance or economy? Know when it's time to move on to your next great idea (11).

[8]Revealing your invention prematurely. In the US, a one-year countdown begins the instant you reveal your invention to the public or anybody that has not signed a confidentiality agreement with you (see definition of novelty above). You only have one year to patent your invention in the US. For other countries, if you reveal the invention, this is no one-year grace period and you lose the rights.

Even experienced academic scientists may not understand that inventorship, an invention, and a patent are quite different from a scientific publication. In many ways, obtaining a granted patent can be much harder and longer than publishing a research study in a peer reviewed journal. This is because of the requirement for absolute novelty and utility, as judged by the lengthy examining process by the US Patent and Trademark Office (USPTO, www.uspto.gov) (Jones 2005; Gholz 2007 reference). Patent claims must be written in a form of an independent clause or multiple dependent clauses that logically delineate the novel features claimed under the invention. Licensing and assignment of intellectual property rights (inventions) provide employers/inventors with a means to effectively sell or "rent" the invention under specific conditions. (Merges 1999 reference).

Molecular profiling and individualized therapy are providing new insights into disease treatment while at the same time providing new technologies and therapies. Although the concept of genomic and proteomic analysis is not new, the wealth of patentable information gleaned from these molecular insights is constantly challenging current health and patent laws (Kelton; Jones, Shi reference). It is our intent in this chapter to explain basic guidelines applicable to biomedical inventions and patents, including a tutorial for writing a patent application (based on the Patent Cooperative Treaty and United States Patent and Trademark Office requirements).

2. Types of Patents

Question: What constitutes an invention that can be patented?

Answer: Inventions can be patented if they are novel, non-obvious, and useful **(Jones 2005; Shi 2005 reference)**.

Meaning of Novel, Non-obvious, and Useful in Patent Terms: New and Novel: For a United States patent the invention must never have been disclosed in public in any way, anywhere in the world, more than one year before the date on which the patent application is filed. In other countries, the inventor does not have a one year grace period.

Original and Non-obvious: An invention involves a creative, inventive step. When compared with what is already known, it would not be obvious to someone experienced in the subject matter, or would be unexpected or contrary to established theories or findings. Useful: This means that the invention must take the practical form of a machine, apparatus, device, diagnostic kit, pharmaceutical compound, it has to accomplish something of practical value to society.

A **utility invention** can fulfill any of the following definitions: a Kit for accomplishing a useful goal, a Method or Process of synthesis or production, a Machine, an Article of Manufacture, a Composition of Matter (such as a chemical compound), or an improvement of any of the above categories.

Design patents are for the new ornamental design of an article of manufacture.

Plant patents provide patent protection for any asexually reproduced distinct and new variety of plant.

2.1. Issued Patents

Question: What is an issued patent and what protection does it afford to the inventor?

Answer: The term “patent” is derived from “letters of patents patent”; an open letter by which a sovereign entity conferred a special privilege or right on subject. The first recorded patent was granted to Filippo Brunelleschi in 1421 in Florence, Italy for an industrial invention. Since then countries have set their own rules to grant patents, including the duration, types of patents and filing rules.

An invention is a property right (an owned article of property that comes into existence the instant it is invented) for an invention granted by a government to the inventor. A United States patent gives inventors the right “to exclude others from making, using, offering for sale, or selling their invention throughout the United States or importing their invention into the United States” for a limited time.

Utility and plant patents are granted for a term that begins with the date of the grant and usually ends 20 years from the date the applications were filed. You must make the timely payment of the appropriate maintenance fees.

Design patents last 14 years from the date you are granted the patent. No maintenance fees are required for design patents.

The patent is a personal property: so it can be sold, assigned or transferred as determined by the owner. As such there can be disputes, in which case the authority or jurisdiction concerned has to mediate and investigate infringement. If infringement is found then a determination must be made to grant penalties to the violator and award damages to the rightful owner.

In the 1990’s the establishment of World Trade Organization set forth a common minimum set of rights that should be granted to all patent owners by governments, as well as a period of 20 years (from the date the application filed) as the term of the patent.

Table 1 lists links to patent offices/organizations/procedural guideline sources for selected countries, world bodies and interest groups.

2.1.2. Non-patentable articles—Question: What cannot be patented?

Answer: Unmodified pre-existing articles of nature cannot be patented. You cannot patent an unmodified natural chemical, gene, protein, or animal, or plant species (Jones 2005; Shi 2005 reference). However, you can patent a modified form of an article of nature if the modification serves a useful purpose. You can patent the use of existing articles of nature in devices, compounds, or diagnostic kits that are useful.

A 2010 court case ruling highlights the controversy concerning the patenting of genes and proteins (1, 2). A US district court ruled in March 2010 that the claims were not valid in seven patents covering genetic testing using breast cancer susceptibility genes. The ruling followed a lawsuit against the company Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the *BRCA1* and *BRCA2* breast cancer susceptibility genes (1). A woman who tests positive has on average an 82% risk of developing breast cancer in her lifetime and a 44% risk of developing ovarian cancer, according to Myriad. The plaintiffs who brought the lawsuit were the Association for Molecular Pathology and the American College of Medical Genetics and they were represented by the American Civil Liberties Union (ACLU) and the New York–based Public Patent Foundation. Judge Robert Sweet of the US District Court for the Southern District of New York ruled that both Myriads' composition and method claims are invalid under the law, because a product of nature, in this case a gene, even if isolated, can not be patented as an invention (1). While this case is being appealed, many experts worry that the ruling will have a chilling impact on the biotechnology industry. Nevertheless, if the ruling is upheld it does not prevent the patenting of diagnostic tests using genes or proteins to predict disease or guide therapy. The take home message is to craft patent claims around the non-obvious practical use of a gene or protein, or its modified form, instead of trying to patent the gene or protein itself as a composition of matter.

You cannot patent: laws of nature, physical phenomena, abstract ideas, literary, dramatic, musical, and artistic works. These can be copy write protected. You cannot patent inventions that are considered not useful or physically impossible by the USPTO (for example perpetual motion machines) or considered offensive to public morality.

2.2. Persons qualifying as inventors or co-inventors

Question: If two people or groups make the same invention around the same time, who gets the patent?

Answer: First to Invent Rule: The United States grants a patent to the first inventor who conceives and reduces the invention to practice, e.g. a working prototype or well-written description. Other countries use the **first to file rule** granting a patent and all rights to the first person who files a patent application for an invention (3, 4).

Clause 101 of US Code 35 states:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, . . ."

This has further been defined by the following case law:

> "He who first perfected a thing is the inventor although others might have experimented with the idea." Agawam Co. v Jordan (1869) 74 US583, 19 L Ed 177, and "Crude and imperfect experiments are not sufficient to confer right to patent; until invention is perfected and adapted to use it is not patentable and he

> who first perfects it and adapts it to use is first inventor in sense of patent law and entitled to patent." Seymour v Osborne (1871) 78 US516, 20 L Ed 33.

With effect from 1st January, 1996, clause 104 of US Code 35 was changed with the effect that residents of World Trade Organization member countries can now rely on the law of "first to invent" in establishing invention priority in the USA (5).

> "In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country . . ." (http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf reference)(6).

2.2.1. Co-inventors—Question: Who qualifies to be a co-inventor?

Answer: Each co-inventor must have made an independent creative contribution to at least one of the claims specified in the patent. This definition is quite different from co-authorship on a scientific publication. Thus, those who creatively and directly generated the invention, qualifying to be co-inventors, may be only a small subset of co-authors listed on a research publication relevant to the subject invention (7).

2.3. Provisional Patent Application

Question: When should I file a Provisional application?

Answer: You may be in a hurry to get a patent because you see immediate commercial application or you want to beat a competitor. In the US, you can take the option of filing a Provisional Application for Patent. The Provisional application discloses detailed information about the invention, but not to the depth required in the regular application. You must file a regular patent application on the invention of your Provisional application within one year.

The Provisional application establishes a registration date for your invention that is much earlier in time than the ultimate date of patent issue after filing the regular application. The Provisional in no way resembles a regular utility patent, as it expires in a year's time, cannot be searched, and "it does not start a 20 year patent term running".

Provisional applications are usually filed for reasons of urgency to establish priority. However, sometimes there are many good reasons not to file a Provisional application, such as higher overall costs and extra time delay before the patent is granted (prosecution will begin only on the utility application). US patent laws have been amended to allow upgrading of the Provisional application into a Utility patent application.

An alterative means of proving that you were the first to think of the idea is a Disclosure Document. A Disclosure Document is an "evidence of conception" of an idea or an invention. In no way does it substitute for a Provisional application or a regular utility patent application. For a fee of $10, it enables the applicant a to have a recorded proof of date of

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.