# A Surgeon's Simplified Guide to US Patents

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A hallmark of a good surgeon is the ability to problem solve through skill and innovation. This Viewpoint provides a step-by-step guide to US patenting for surgeons, serving as a primer, alongside legal expertise, to protect their innovations.

In its simplest form, a patent grants its owner legal protection, preventing others from making, selling, or using an invention without permission.<sup>1</sup> They are granted by governmental or semi-governmental bodies such as the US Patent and Trademark Office (USPTO).

# **Types of Patents**

There are 3 types of patents: utility, design, and plant.<sup>2</sup> Utility patents, valid for 20 years, apply to new or improved products, processes, or machines. In the US, surgical procedures can also be patented, but the Medical Procedure Exemption to Patent Infringement allows other surgeons to perform them. The exemption followed a legal dispute, Pallin vs Singer, where a physician sought royalties for the patented single-stitch cataract surgery. Although some countries have similar exemptions, others allow the collection of royalties. Therefore, we recommend checking local patent laws regarding surgical procedures.

Design patents, valid for 15 years, protect an item's visual appearance rather than function. Finally, plant patents, granted for 20 years, cover newly created or discovered plants.

## **Patenting Criteria**

Three criteria must be considered before applying for a patent<sup>3</sup>:

- 1. Novelty. An invention must be novel or substantially different from what is publicly known. Public knowledge is established if a patent has previously been granted.
- Usefulness. It must be functional with a clear purpose or utility. In the In re Swartz case, cold fusion—a method purported to generate energy at room temperature—was not patentable as it lacked evidence demonstrating functionality.<sup>4</sup>
- 3. Nonobvious. Defined as *invention not found obvious by a person having ordinary skill in the art* by the USPTO. Even if novel, it must not be a simple and predictable improvement of an existing invention. One way patent examiners check this criterion is by assessing whether an average-skilled person finds the invention obvious. In the Ethicon Endo-Surgery Inc vs Covidien LP case, a surgical stapler with a lockout safety feature to prevent misfiring was unpatentable as it was merely a combination of 2 patents.

## Patent Search

A key step before filing is patent search. It also allows one to identify similar inventions and assess if one's idea is sufficiently different. Below is a step-by-step algorithm (Figure contains details and tips).

1. Identify all terms that could be used to describe your invention.

- 2. Conduct a keyword search using the Patent Public Search database, accessed through the USPTO website.<sup>5</sup>
- 3. Review all the tagged entries.
- 4. Review the invention's specifications.
- Expand the search with relevant Cooperative Patent Classification set by patent reviewers to categorize patents based on their characteristics.

# **Development Process**

Before filing, proactive protective steps must be taken. This includes keeping detailed documentation of the development process, such as sketches, notes, and prototypes.<sup>6</sup> Additionally, nondisclosure agreements should be used when sharing ideas with potential collaborators or investors.<sup>6</sup>

Tip: Consider filing a provisional patent application, which is cheaper and not reviewed by the USTPO, before presenting or sharing your idea. It grants you 12 months to refine the concept, seek funding, and secure a priority date against competing filings.

## **Filling the Patent**

We highly recommend consulting with a patent attorney with expertise in your invention to assist in filing, as the laws for surgically related areas have become intricate. Before consulting them, describe the type of invention, its purpose, novelty, materials required, mechanism of action and a sketch of its design to ensure the right expert is involved.

Tip: Financial terms are not included in the patent application. Consider involving attorneys in drafting an agreement outlining royalties distribution.

Pitfall: Patent claims may leave your innovation susceptible to infringement if they do not include all its aspects. Claims, which establish an inventor's rights, are legal descriptions of the invention, including specific features that make the invention unique. In the Nautilus Inc vs Biosig Instruments case, a dispute involving heart rate monitors, the Supreme Court ruled against Biosig Instruments, finding their patent ambiguous and indefinite. The patent was invalidated because it used "spaced out" to refer to their electrodes' positioning rather than specifying the exact distance. This highlights the need to use precise language, giving clear notice to the public, preventing overbroad and ambiguous claims.

# Cost and Timeline

High cost and lengthy process (average of approximately 3 years) may deter some surgeons from filing patents. However, as stated previously, one can apply for a provisional patent before a formal patent is issued. This may protect inventors in legal disputes.<sup>7</sup>

Patents can be expensive, ranging from \$10 000 to \$100 000. Although there are no precise data on how many patents recuperate

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#### **Opinion Viewpoint**

#### Figure. Step-by-Step Algorithm to Perform a Patent Search in the US Before Filing



The Patent Public Search database,<sup>5</sup> accessed through the US Patent and Trademark Office (USPTO), offers basic and advance search options. CPC indicates Cooperative Patent Classification.

<sup>a</sup>Boolean operators include AND to combine terms, OR to include either term, and NOT to exclude terms.

<sup>b</sup>Listed without ranking significance, inventors' names include people involved in the patent's development, not just its execution. <sup>c</sup>Found at the end of the document, patent claims are critical to review because they legally define what is covered.

their costs, estimates indicate that most do not.<sup>8</sup> However, this should not derail surgeons because medical patents have one of the highest financial returns compared with others.<sup>9</sup> Moreover, medical products often require millions of dollars in research and development; protecting them is important to recuperate their financial returns.<sup>10</sup>

Tip: If affiliated with an academic institution, consider consulting technology transfer offices or incubators to determine a product's commercial value and marketability. These specialized offices can provide mentorship, cover patenting fees, seek funding opportunities, and offer guidance to tailor the product for the market. Additionally, legal clinics run by law students can help offset filing costs.

Tip: Consult an attorney to review your employment contract for intellectual property provisions. Some institutions mandate inventors to use the employer's resources for ownership or revenue share in exchange (which may vary from one institution to another).

Patents are usually nonrenewable. Once expired, the invention can be freely used, produced, or sold. However, rare extensions can be granted for delays caused by the USPTO or regulatory bodies. For example, Pfizer extended amlodipine's patent by 4 years due to US Food and Drug Administration delays.

#### Conclusions

As surgeons continue innovating, we hope that this guide can motivate them to protect their ideas. This often-perceived cumbersome process can be tackled with a basic framework and appropriate knowledge.

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## REFERENCES

1. Mehta H, Tidwell L, Liotta LA. Inventions and patents: a practical tutorial. *Methods Mol Biol*. 2017; 1606:379-397. doi:10.1007/978-1-4939-6990-6\_25

2. Mayfield DL. Medical patents and how new instruments or medications might be patented. *Mo Med.* 2016;113(6):456-462.

**3**. Simonton DK. Taking the US patent office criteria seriously: a quantitative 3-criterion creativity definition and its implications. *Creat Res J.* 2012;24 (2-3):97-106. doi:10.1080/10400419.2012.676974

4. Owens SK. Cold fusion: incredible claim or energy of the future. *T M Cooley J Pract Clin Law*. 2006;9:37.

 US Patent and Trademark Office. Patent public search. Accessed March 4, 2025. https://ppubs. uspto.gov/pubwebapp/static/pages/landing.html

**6**. Manzini R, Lazzarotti V. Intellectual property protection mechanisms in collaborative new

product development. *R&D Manage*. 2016;46(S2): 579-595. doi:10.1111/radm.12126

7. Migliorini RA. Twelve years later: provisional patent application filing revisited. *J Pat Trademark Off Soc.* 2007;89(6):437-455.

8. Key S. In today's market, do patents even matter? Accessed February 8, 2025. https://www. forbes.com/sites/stephenkey/2017/11/13/intodays-market-do-patents-even-matter/?utm\_ source=chatgpt.com

**9**. Cockburn I, Long G. The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals. *Expert Opin Ther Pat*. 2015;25(7):739-742. doi:10.1517/13543776.2015. 1040762

**10**. DiMasi JA, Grabowski HG. The cost of biopharmaceutical R&D: is biotech different? *Manage Decis Econ*. 2007;28(4-5):469-479. doi:10.1002/mde.1360

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