

# Patent Protection 101

**Patent protection is an aspect of business that concerns many, but truly understood by few. It is a critical piece of any new technology development venture and as such, engineers must be aware of the steps they need to take to safeguard an invention against competitors or counterfeiters. This article provides an overview of several key elements that stakeholders should be mindful of when designing a new technology.**

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Congratulations. Your team is responsible for the development of pioneering cardiac-assist technology that will help save countless numbers of people waiting for a compatible donor heart to become available for transplant. Before you complete your development work and launch the product into the marketplace, you had better make sure that your intellectual property game plan is in place. Otherwise, you could be making a costly mistake.

Patent protection is the key to exploiting the new technology. Patents provide the owner with the right to exclude others from practicing the patented invention for a limited period of time (generally, 20 years from filing). This limited monopoly over the use of the invention enables the innovator to receive a return on the investment that led to the discovery while public dissemination of information about the patented invention stimulates additional innovation by others. Absent patent protection, a competitor may be able to copy the technology and undersell the innovator because they incur very little expense in copying the technology.

With patent protection, the innovator can use litigation to enforce its rights against those who infringe—recouping damages adequate to compensate for the infringement. The patent holder can also obtain an injunction against future infringement. These are powerful tools that enable the patent holder to keep competition out of the market (and, therefore, maintain pricing).

Patent rights can also be bought, sold, or licensed like any other property. Thus, patent rights may be useful in raising capital, in generating licensing revenue, and in reaching markets that the patent holder might not otherwise be able to reach through agreements with third-party manufacturers, distributors and sales organizations. For these reasons, it is critical to consider patent issues and implement good patent practices during the earliest stages of product design and development.

### **Invention Disclosure Forms**

One helpful patent practice is to require the company's engineers and scientists to identify new inventions utilizing an "invention disclosure form." The idea behind this practice is to encourage personnel to document and disclose new ideas that may be of value to the company, including ideas that are tangential to on-going research and development work.

There is no standard format for an invention disclosure form—many different forms are available online. However, a comprehensive form will help facilitate evaluation of the invention by management. At a minimum, the form should request the following information:

• A title for the invention

• A list of all persons who contributed to the conception of the invention

• A description of the circumstances under which the invention was conceived, and the date that it was conceived

• A detailed explanation of the invention, how it works, and how it is constructed

• An explanation of how the invention differs from existing technology and why the identified differences are important (identify technical and economic benefits)

• Drawings, photos, and flow charts that explain the invention

• Results of any testing showing the advantages or benefits of the invention

• The circumstances (including dates) of any disclosure of the invention outside the company (e.g., trade shows, seminars, publications)

The invention disclosure form should be signed and dated by the author, the inventor(s), and a witness who is capable of understanding its contents, such as a supervisor. Also, the information should be legible (typed or handwritten neatly in ink). Because invention disclosure forms may be relied upon in litigation, completed forms should be retained in a central, secure location, so that they can be located many years subsequent to their creation, if needed.

There should also be clear procedures in place for submission and review of invention disclosure forms. While many companies rely upon their legal department for review of these submissions, others employ review committees made up of managers, engineers, and persons with patent experience. Regardless, the submission needs to be reviewed by persons with experience in evaluating new

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ideas, and the authority to decide what should be done with the submission (e.g., patentability searching, patent protection, continue research, commercialize, scrap). The outcome of the review, and the persons involved, should also be recorded.

As an incentive for completing and submitting these forms, some companies offer their employees rewards for submission of the form, including possible bonus payments for patents that result from the disclosed ideas.

### **Lab Notebooks**

Most countries in the world have first-to-file patent systems, meaning that patent rights are awarded to the first entity that submits a patent application. However, the United States has a first-to-invent patent system, meaning that in a battle of competing patent applications, a U.S. patent will be awarded to the entity that was first to conceive the invention (so long as they were thereafter diligent in developing it into a complete invention). For purposes of winning such a battle, the company should encourage its personnel to keep detailed records regarding research and development work. This often is accomplished by using handwritten lab notebooks, which are bound books prepared and maintained by the company's engineers and scientists. To be effective as evidence, notebook entries should be reviewed, countersigned, and dated by a witness—a person capable of reviewing the entries and understanding them.

Software for generating electronic lab notebook records (known as ELNs) is now gaining in popularity. While these programs help to reduce the burden of preparing and maintaining written lab notebooks, the usefulness of electronic notebook records has not yet been fully tested in patent litigation. In any event, the important point here is that the company must be able to prove what it has done, and when the conception and follow-up work occurred.

### **Pre-Patent Filing Disclosure of Innovation**

Certain activities can result in forfeiture of patent rights if they occur before a patent application is filed. These activities include public uses, offers to sell, and published disclosures of the invention. While the United States provides a one-year grace period before forfeiture occurs, many other countries do not allow any such activity before patent filing. On the other hand, the filing of a U.S. patent application before these activities preserves the company's rights, and permits it to later file in the other countries without loss of rights.

To ensure that the company is able to secure patent protection, the company should educate its personnel to refrain from disclosing new technology outside the company until the company determines whether it will seek patent protection for that technology. Scientists and other company personnel should refrain from speaking at conferences and publishing articles about their inventions without discussing the risks of such disclosure with legal advisors and management. If any

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non-confidential disclosure has already occurred, for any reason, it should be brought to the attention of the company's legal advisors as soon as possible so that an evaluation can be made and the company's rights preserved, if that is still possible.

### **Developing a Patent Game Plan**

The type and scope of patent protection is also important, and depends on many factors, including:

For example, a new device for robotic transplant surgery is likely to be a high cost, low volume device with a long lifecycle. The device might be sold or leased, and royalties might be charged on a per procedure basis. Additional royalty streams might flow from equipment for enhanced or specialized procedures, from training services, from maintenance and spare parts, and from updates to firmware and software. While the new device and methodology will be a core focus of any patent procurement strategy, if available and appropriate, protection for the other potential sources of revenue should be considered, including separate coverage for future, specialized, add-on equipment.

In comparison, the patent strategy for an improvement to an existing cardiac-assist device (e.g., an improved impeller design) would be more limited, since the market is already well-defined and the improvement will likely have a more limited life than an invention creating a new product category. Also, third party patents might present obstacles to marketing of a new design, so the company may also need to consider cross-licensing opportunities.

If the invention comprises a new portable battery pack for a cardiac-assist device (one that makes it easier to change packs), the patent strategy would seem to be very narrow. However, the opportunity to customize the technology design for other goods might present alternative opportunities for patent protection and additional sources for revenue (through direct sale of such products or licensing of the technology to others).

### **Conclusion**

Determining the patent strategy for a given product, and building an effective patent portfolio on a cost-effective basis requires extensive consultation with management, marketing personnel, and legal advisors. The legal team can conduct patentability searches to determine whether technology is new and advise the company on the forms of protection that may be available. As the invention is refined, the attorneys can pursue protection for the technology that is consistent with the business objectives, and can conduct freedom-to-operate searches to guide the innovator around third-party patents that might interfere with the manufacture and sale of the products and services under consideration. Ultimately, the key to building an effective patent portfolio and having a successful product launch is communication. Therefore, it makes sense to start as early as possible; it pays to

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implement patent-oriented policies and to consult with legal advisors when promising technology is first discovered.

### Online

For additional information on the topics discussed in this article, see *MDT* online at [www.mdtmag.com](http://www.mdtmag.com) [2] or Cohen Pontani Lieberman & Pavane LLP at [www.cplplaw.com](http://www.cplplaw.com) [3].

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