**COPYRIGHT** - Manuals describing the medical device, videos illustrating proper use, and any software contained within the medical device are all examples of protectable intellectual property known as copyright. Although there is no international copyright, most countries have agreed to protect creative works through various international agreements. Notably, protection for these creative works is automatic and includes prohibiting the reproduction and distribution of the work.

## **RESOURCES**

- Learn more about the following topics by visiting www.STOPfakes.gov
  - Madrid Protocol
  - Patent Cooperation Treaty
  - Hague The International Design System
  - Trade Secrets
- The Foreign Commercial Service can help you find a local attorney knowledgeable about IP issues in your export market.
  - Visit: http://www.trade.gov/cs/
- Exporters can find additional resources online. Visit: www.export.gov
- Learn about leading export markets.
  Visit: www.trade.gov/topmarkets/
- Find the electronic version of this brochure at: www.STOPfakes.gov



If you found this information useful please let us know!

Comments can be sent to ITA's Office of Intellectual Property Rights at IndustryIP@trade.gov





International markets supported more than \$50 billion in exports for the U.S. medical device sector

in 2016. While export markets offer U.S. companies tremendous opportunities, these same markets pose potential challenges to the protection and enforcement of valuable intellectual property (IP). Intellectual property is a key foundation of the highly innovative U.S. medical devices export base, yet establishing IP protection in the United States does not trigger automatic global protection.



## THE INTERNATIONAL TRADE ADMINISTRATION

helps U.S. medical device exporters identify their IP assets and proactively take steps to protect them. U.S. medical device exporters enjoy competitive advantages through innovative products, state-of-the-art manufacturing techniques, and brand recognition. The very core of these advantages is built around intangible assets known as intellectual property; in this sector primarily patents, trade secrets, trademarks, and designs.

PATENTS - Continuous innovation is at the heart of global competitiveness for U.S. medical device manufacturers, from game-changing new devices and breakthrough manufacturing techniques, to continuous improvement of existing products. As nations seek to meet the health care needs of their citizens, the need for innovative medical devices is expanding. For many small companies, patent protection prevents competitors from simply copying their innovations and aids in attracting investor capital needed to grow, to build market share, and to create jobs.

For U.S. small businesses trying to compete in global markets, securing patent protection overseas

can be a critical precondition to successfully internationalizing and developing into the productivity powerhouses of tomorrow. The Patent Cooperation Treaty (PCT) allows U.S. businesses to file for a patent in 151 countries with one international patent application.

**TRADE SECRETS** - Proprietary information with commercial value can help U.S. companies win sales in highly competitive global markets. Trade secrets are valuable intangible assets for U.S. medical device manufacturers. These secrets might underpin technologies in the manufacturing process, or support customer retention, advertising, or sales channel development strategies.

Protection for trade secrets varies by country, but most countries have some form of protection (e.g., breach of contract, unfair competition, violation of fiduciary duty, criminal code). Where there is protection, three things are generally required of the owner. The information must be secret, have commercial value, and reasonable steps must be taken to protect it.

**TRADEMARKS** - U.S. medical device companies are recognized global leaders in quality, reliability, and innovation.

The power of a U.S. company's brand provides a significant edge, allowing it to seize buyers' attention in highly competitive international markets. Protection for this asset through trademark registration should be a priority for all companies – particularly those who export. Trademarks must be registered in every country where the company wishes to have protection.



## TAKE AWAYS

- A U.S. patent or trademark does not provide protection outside of the United States.
- Companies wishing to protect their patents in foreign markets should consider applying for patents using the Patent Cooperation Treaty.
- Companies wishing to protect their trade secret should take reasonable steps to protect it.
- Companies wishing to protect their trademarks in foreign markets should consider registering their trademarks utilizing the Madrid Protocol.
- Companies wishing to protect their designs in foreign markets should consider registering their designs using the Hague System for the International Registration of Industrial Designs.

The Madrid Protocol provides a mechanism for trademark owners to file one application with The United States Patent and Trademark Office (USPTO) and designate other countries where they wish to register their mark. A major benefit of using the Madrid System is that once registered in the designated countries, the trademark owner can maintain all those registrations via a central filing mechanism at the World Intellectual Property Organization (WIPO).

PRODUCT DESIGNS - Medical device designs support the diversity of high quality, innovative, and practical products that are the hallmark of U.S. medical device companies. Protecting a product's design requires registration in the country where protection is sought.

The Hague System for the International Registration of Industrial Designs provides a practical business solution for registering up to 100 designs in over 65 territories through filing one single international application.