



Global Medical  
Technology Alliance  
*Innovating for a Healthier World*

## Patents for Medical Devices and Pharmaceuticals – Summary of Key Differences

**Introduction:** Members of the Global Medical Technology Alliance (GMTA)<sup>i</sup> are often asked how patents are applied to medical devices, and the differences between their use in the medical device and pharmaceutical domains. Although not exhaustive, this paper is intended to outline the key differences for the general reader. It does not cover trademarks, copyright, domain names, or technical knowhow and trade secrets, nor does it cover differences in patent regimes in different countries.

### Summary of Key Differences

- **Nature of product:** There is a much greater number and diversity of medical devices than pharmaceuticals. Medical devices are typically based on mechanical, electrical, information technology and systems engineering, and stem from ideas typically generated in a clinician's practice. Pharmaceuticals are based on chemistry, biotechnology and genetics, coming from an R&D laboratory.
- **Patent coverage:** Many more fields of art contribute to the development of a medical device as compared to a pharmaceutical. Medical device patents are typically directed to the structure, function, and methods of using the device. As a result, many more patents are used to cover a medical device than a pharmaceutical.
- **Patent types:** Patents for medical devices cover many different structures, processes, methods and components (configured to operate in a certain way), including alternative embodiments. This typically leads to many patents covering a medical device, compared to 1-2 patents covering a pharmaceutical.
- **Alternate designs:** "Design-arounds" are common for medical devices, but not for pharmaceuticals. The prevalence of alternate medical device designs typically precludes an exclusive position in the marketplace.
- **Improvements and product life-cycle:** The commercial life of a given type-model of medical device is normally short (~24 months), much less than the duration of the patent (20 years from filing). Pharmaceuticals typically remain on the market during the entire life of the patent and beyond.

## Medical Devices

- Nature of product: A single medical device may comprise a variety of technologies from many different fields of art such as materials science, electrical engineering, mechanical engineering, semiconductors, computer software, wireless communications and so forth. They are constructed to deliver one or more capabilities relating to diagnosis, therapy delivery and/or surgical navigation. The underlying ideas often originate in a clinician's medical practice. The arts from each field must be applied together to produce a functioning device for an intended purpose.
- Patent coverage: Due to the wide variety of structures and technologies embodied, many different patents typically cover a single medical device. For example, a pacemaker will typically have separate patents covering the housing, battery, capacitor, electrical circuit, communication system, software programs for therapy delivery, sensing and detection, lead structure, and electrical system (electrodes and sensors) on the lead. Subsequent generations of similar devices will typically use the material disclosed but not claimed in some of the same patents, and procure a patent on the additional structures and technologies, reflecting advances in the state of the art.
- Patent types: The ultimate effectiveness and benefit of a medical device is dependent in part on the skill of the clinician using or implanting the device. In this regard, medical device patents may cover method of implant, installation, surgical navigation, placement, adjustment, calibration, and adaptation to particular patients. Specifically, medical device patents also may have method claims such as method of manufacturing, method of implanting, method of operating, method of initiating etc. While method claims are not generally allowed in most foreign jurisdictions, they are broadly asserted in the United States.

## Pharmaceuticals

- Nature of product: Pharmaceutical products are based on the fields of chemistry, biotechnology, and genetics. The function of a pharmaceutical product is typically fulfilled by a limited number of molecules within a structural class of molecules. To be effective, the chemical composition must be maintained within narrow boundaries and does not permit many alternatives or variations.
- Patent coverage: There are normally very few patents for most pharmaceutical products. Since there are a finite number of molecules that may be used to elicit a desired biological response and clinical outcome, competitors may be effectively excluded from making the pharmaceutical product by a single patent covering the class of molecules that comprise the pharmaceutical product. Once the patent expires, or is no longer applicable, it is possible for competitors to produce "generic" copies.
- Patent types: Most pharmaceutical products are either ingested or introduced into the body directly and therefore constitute therapies themselves-- not diagnostics or therapy delivery systems. Pharmaceuticals utilize the body as a natural delivery system. Accordingly, with very few exceptions, pharmaceutical patents do not have method claims regarding delivery mechanisms. Further, pharmaceutical product patents are usually directed to the structure of the molecules themselves or methods of making or purifying that compound.

- Alternate designs: A medical device will typically have many structural and functional variations, different components and/or materials. Other devices that deliver the same or similar functionality can often be designed and built in countless ways. As a result, there is no such thing as a “generic” medical device. Competitor companies are typically able to design around patented structure and functional features to create a product with similar operational/functional characteristics. While patents for medical devices may be directed to many different embodiments, it is very difficult in practice to predict all conceivable ways in which competitor companies could work around a design. A successful redesign often cuts short the effective life of a patent by rendering it unenforceable against the new design. Thus, over time, it may be possible to incorporate features and designs from patents that have expired or are no longer enforceable in new devices. This allows producers to develop competitive devices. While there may be litigation over overlapping patent claims, this typically occurs only in the United States, Europe and a few other developed markets.
- Improvements and product life-cycles: As new technologies continue to develop, each field of art may implement these new technologies, which make iterative product improvements possible on a frequent basis. As a result, medical devices have a short commercial life-cycle, typically on the order of 18-24 months. Each new component or improvement (with the new technology implemented in the product) may be individually patentable. Accordingly, a single medical device may be covered by hundreds of patents.
- Alternate designs: Pharmaceutical products generally do not lend themselves to “design around” efforts and do not require several patents covering variations or alternative designs. Once a key pharmaceutical patent is expired, it will be possible for other manufacturers to make “generic” versions of the same pharmaceutical.
- Improvements and product life-cycle: Pharmaceuticals typically have a long commercial life-cycle (10-20+ years), during which they do not undergo significant changes.

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<sup>i</sup> For more information, refer to <http://www.globalmedicaltechnologyalliance.org/>