Medical Device Considerations

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Preparing and prosecuting medical device patents can be unique and challenging. Patent owners and practitioners often must consider a wide range of converging technologies from the mechanical, electrical, chemical, and biotechnological arts. Here are a few best practices to keep in mind as part of your medical device prosecution toolkit:

Provide meaningful disclosure of the device as it relates to the underlying drug. Many products approved as drugs by the U.S. Food and Drug Administration (FDA) are delivered via a medical device. When drafting a patent application directed to the device, practitioners may include disclosure of structural details and functional parameters of the medical device that improve delivery of the specific drug involved. For example, a particular plunger force may be critical to the proper delivery of the drug. Also, practitioners should consider including claims of varying scope that recite the structural details and functional parameters of the device together with the drug to be administered. This can help support patentability, for example with pre-filled syringes and other devices, where at least some structural details of the device itself may be in the prior art but the use of such structure in the context of the underlying drug are not. Incorporation of the underlying drug into the patent claims may also improve the Orange Book eligibility of your medical device patent.

Generally include a robust disclosure of the structural elements of the device. Even outside the context of an underlying drug to be delivered, medical device applications should include as much detail as possible regarding the structure of the device. Practitioners may consider, for example, including dimensions of different structural elements, their relative positions, and how the elements are interconnected. Include detailed figures as necessary, including cross-sectional figures showing the internal design of the device. Consider these additional best practices for effectively disclosing and claiming a medical device:

- **Link functional language to structural elements in the disclosure.** For example, in a device configured to inject a drug, carefully describe what structural elements actually accomplish the injection (*e.g.,* needle, plunger, actuator, etc.). If possible, provide alternative structure to perform the desired function.
- **Discuss material selection.** Consider including multiple material options for important device elements, and discuss any advantages of choosing certain materials for a given element.
- **Consider linkages between the medical device and external networks and Internet of Things.** For some devices, a robust disclosure discussing any possible connection between the device and a digital network may be critical. Consider including the advantages gained in some embodiments by connecting the device to a network or the internet (*e.g.,* remote monitoring, improved maintenance, consumable reordering, etc.)
- **Include a method of using and/or method of manufacturing the device.** Include disclosure and claims discussing the method of using/manufacturing the device. The method of manufacturing the device may often be more relevant for infringement purposes, but the end user (*i.e.,* the method of using claims) may also be relevant. In general, these method sections are usually presented immediately following the structural description of the device.
- **Consider divided infringement when drafting the disclosure.** Where possible, ensure that the disclosure and claims provide opportunity to target infringement by a single desired entity, as well as by multiple entities. Depending on the nature of the device, it may be necessary to draft the disclosure and claims to address contributory infringement.

Keep other jurisdictions in mind. FDA approval in the United States and CE marking in Europe are often critical to medical device manufacturers. The patent rules in these jurisdictions are quite different and must be followed in the first filed priority application for your medical device invention. For example, for cases first filed in the United States, European patent practice must be considered when claiming and describing your medical device invention. For example, because the European Patent Office is very restrictive when it comes to amendments based on a combination of features from the general specification and the examples, the disclosure should specifically describe each relevant combination of features together. Also, because the EPO may not consider subject matter "incorporated by reference" to be part of your specification, the specification should include the most essential parts of the reference if you consider these to be important to the invention. Perhaps the most important strategy to implement is one that establishes effective

communication among your global prosecution team.

Consider design patent protection. In the United States, design patents protect the "look and feel" of a device or product. For medical device manufacturers, the non-functional appearance of the device may impart value that is not protected by a related utility application, and, thus, design protection can strengthen the medical device patent portfolio. In addition to mechanical features, design protection can protect the look of graphical user interface aspects of the medical device, and design of replacement components, for example. In the United States, design patents are often less expensive and quicker to obtain than utility patents.