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Medical Devices: obtaining Patent Protection in Brazil

Roberto Rodrigues Pinho, Rhuan Quintanilha, Rodrigo Mourao (RNA Law) · Wednesday, May 14th, 2025

ANVISA (the Brazilian regulatory authority) is considering updating rules addressing medical devices in a clear indication that this market is growing and requires more attention.

Medical devices play a vital role in healthcare, having evolved from simple tools like thermometers and bandages to sophisticated technologies such as robotic surgical systems, implantable neurostimulators, and AI-powered diagnostics.

Recent innovations, driven by progress in electronics, materials science, biotechnology, and information technology, have led to a new generation of devices that integrate hardware, software, data analytics, and connectivity. These include wearable monitors with ECG capabilities, mobile health applications, implantable devices, and software-based diagnostics. The rise of Software as a Medical Device (SaMD) and the Internet of Medical Things (IoMT) has further expanded the definition of medical devices, enabling real-time monitoring, remote diagnostics, and personalized treatment.

As this interdisciplinary field continues to evolve, securing patent protection becomes a strategic necessity to ensure market exclusivity and to attract investment.

Patentability of Medical Devices in Brazil

Article 10 of the Brazilian Industrial Property Statute (Law No. 9,279/96) outlines what isn't considered patent-eligible subject matter, with item VIII excluding diagnostic, therapeutic, and surgical methods practiced on the human or animal body, and item V excluding software *per se*.

Despite these restrictions, medical devices are frequently eligible for patent protection when claims emphasize their technical features. Devices with well-defined physical structures, integrated hardware-software systems, and novel configurations that produce a technical effect are generally considered patentable. Even inventions involving diagnostic or therapeutic use may be protected if claims are directed to the device or a technical process rather than the medical act itself. For example, a diagnostic system that processes imaging data may be patentable if claims focus on the image processing functionality rather than the diagnostic step.

Enablement and Written Description Requirements

To meet the enablement requirement, patent applications must provide sufficient technical details

to allow a person skilled in the art to reproduce the invention. For medical devices, this includes, for instance, descriptions of structural components such as sensors, processors, and actuators, as well as diagrams illustrating the device's operation. For inventions involving software, particularly AI or machine learning models, the application should explain how the software interacts with the hardware, how the system processes inputs, and what outputs it generates. For AI-powered systems, disclosing information about training datasets and inference models may be necessary to demonstrate technical contribution and sufficiency of disclosure.

The Brazilian PTO places significant emphasis on claim clarity. Vague or purely functional language, such as "configured to" or "adapted for," must be supported by concrete examples and detailed descriptions in the specification. This ensures that the invention is both clearly understood and enforceable.

Examples of BRPTO's Examination of Medical Device Applications

Several cases decided by the BRPTO demonstrate how medical device patent applications can overcome objections and secure protection:

- **UFMG (PI0902539-1)**: This application claimed a device and method for identifying cardiac arrhythmias and electrolyte abnormalities via ECG signal analysis. It was initially rejected under Article 10(VIII) of the Brazilian IP Statute for being a diagnostic method applied to the human body. However, on appeal, the applicant clarified that the signals are received, saved and processed offline, meaning the signal processing to detect arrhythmias and measure heart rate variability occurred independently of direct application to a patient. The second-instance examiners then reversed the rejection decision, citing Rule #411/16, which allows diagnostic methods that are not applied directly to the body to be considered inventions, even when implemented via computer.

Another example of acceptable subject matter provided by the rule is electrocardiographic signal processing methods used to generate parameters that assist a physician in diagnosing pathologies.

- **INTERMED (PI0705091-7)**: This application is related to a hospital-grade ventilator system intended to monitor and mechanically control pulmonary ventilation. The system includes physical components such as valves, tubes, connectors, sensors, solenoids, microprocessors, and control units. Initially rejected under Article 10(VIII), but, on appeal, the second-instance examiners recognized that the invention is a medical apparatus comprising several components which together perform a technical method, and not a method practiced on the human body.

This case demonstrates how well-defined physical structures, and clear technical contributions can overcome objections under Article 10.

- **SUN PHARMACEUTICAL INDUSTRIES (BR112018016287-6)**: The application relates to a perfusion system comprising a plurality of containers pre-filled with aqueous solutions of antineoplastic drugs at predefined concentrations. The system included instructions for combining these containers to prepare a patient-specific dose within an acceptable deviation margin, without manipulating the drug solutions.

The BRPTO initially rejected this application as being a therapeutic method. On appeal, the patent office concluded that the claims defined a product, not a therapeutic act. The case was then returned to the first instance for further examination of patentability requirements.

This case is noteworthy for illustrating how product-focused claims—especially those involving drug delivery systems—can avoid exclusion under Article 10 (VIII) if they are carefully drafted to emphasize structure and functionality over therapeutic purpose.

- **IMPLANTICA PATENT (BR122019021070-5)**: This divisional application, derived from PI0906747-7, claimed an implantable device for treating obesity, featuring adjustable expansion mechanisms, surface textures to prevent fibrosis, fluid volume control systems, and optional patient monitoring sensors. The application was initially rejected on the grounds of double patenting, as well as lack of clarity and enablement. On appeal, the BRPTO determined that the specification met formal requirements and that there was no overlap with the original application. The second-instance examiner concluded that, although both applications shared a common inventive concept, they were based on distinct technical features: the original application covered a device positioned externally in the stomach via a non-invasive approach, while the divisional claimed a device intended for internal attachment within the stomach.
- **Synthes GMBH (PI 0815225-0)**: The application is related to a system for attaching a bone plate to bone tissue, and a method for forming holes in the plate. The claims were initially rejected for lack of novelty. However, the second-instance examiners identified meaningful distinctions from the prior art and proceeded directly to a new substantive examination, ultimately granting the patent.

Conclusion and Strategic Recommendations

Obtaining patent protection for medical devices in Brazil requires familiarity with local legal provisions and BRPTO examination practices. Applications should:

- Avoid claiming subject matter excluded under Article 10 by emphasizing the technical characteristics of the invention.
- Ensure software- and diagnostics-related inventions are tied to physical components or to steps of the methods/processes that clearly demonstrate a technical effect.
- Provide detailed, reproducible descriptions to satisfy enablement and clarity requirements.
- Anticipate possible objections and proactively address them during the drafting process.

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