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Design Protection can be a Game-Changer for Indiaâ??s Med-Tech Boom

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Synergy between design innovation and legal protection will be instrumental in shaping a healthier future



India's medical technology (med-tech) device sector, crucial to its healthcare system, offers a wide range of products like catheters, needles, syringes, cardiac stents, and orthopaedic implants. Valued over Rs 90,000 crore ($11 billion) in 2022, it is projected to grow at a CAGR of 16.4%, reaching $50 billion by 2030. This positions India as Asia's fourth-largest medical devices market (behind Japan, China, and South Korea) and among the top 20 globally, propelled by growing medical

demand and higher public health spending.

To promote the med-tech sector's growth, the Indian government has enacted policies like the National Health Policy 2017, permitting 100% foreign direct investment, and the National Medical Devices Policy, 2023, aiming to enhance access, affordability, and innovation. Additionally, initiatives like the establishment of an export promotion council, and schemes such as the Production Linked Incentive (PLI) and Promotion of Medical Devices Parks are in place to boost the sector's growth and establish India as a global hub for medical device manufacturing and innovation.

Importance of Intellectual Property for protecting Med-tech devices

In the med-tech devices sector, Intellectual Property (IP) rights, encompassing patents, trademarks, copyrights, trade secrets, and design registrations, are crucial for protecting innovations, maintaining competitiveness, and attracting investment. Design protection specifically protects a device's aesthetics such as shape and configuration which appeal to and are judged solely by the eye. Med-tech devices, blending hardware, software, and biotech under strict regulations, represent a significant financial commitment in healthcare due to the substantial investment involved. Therefore, protecting all possible aspects of the devices is very crucial. Design registration offers protection for their external appearance, providing an additional layer of protection on the features of the product. To qualify for design registration, a device must typically meet the following criteria in most jurisdictions:

1. Be novel or original, i.e., should not be something that's already known or used in the public domain.
2. Relate to a visual feature of the product.
3. Should not contain scandalous or obscene content.
4. Be visible on the device during use

Advantages of Securing Design Rights

Design registration in the med-tech devices is crucial for several reasons:

1. **Faster and Easier to Obtain**: Design registrations are faster and simpler to obtain. While a patent can take several years, design registrations may be completed in months, ensuring a layer of IP protection.
2. **Cost-Effectiveness:** Design registrations are affordable which is beneficial for startups and small to medium enterprises (SMEs), with budget constraints.
3. **Strategic Importance of Design Registrations:** A well-rounded IP portfolio, enables companies, especially startups seeking funding, to gain a market competitive edge and provides investors a basis to assess the technology's potential success pre-commercialization.
4. **Impact on Product Identity and Innovation:** Design rights help in shaping product identity and influencing consumer choices through aesthetics and preference alignment, while also guarding against infringement and preserving uniqueness and potential sales profits. Design registration also protects unique designs of individual components. For instance, securing design registration for elements like the inhaler body and its cartridges can create barriers for competitors trying to create similar designs. This not only enhances the product's profitability but also helps in safeguarding against infringements that could compromise patient safety.
5. **Protect Evolving Products and Components**: Med-tech companies frequently redesign existing products. While patenting the product is not possible since the underlying technology is the same, design registration can protect these new aesthetic design components. For each new version of the same equipment, a new design application can be filed for each unique version.

Growing Scope of Design Protection in Med-tech Device Sector in India

Design registrations in India for med-tech devices, particularly under Locarno Classification's Class 24 (covering medical and laboratory equipment), have significantly increased from 441 in 2018 to 927 in 2022, a growth of 110.20%. This indicates a strong commitment to protecting intellectual property in this sector.

Challenges in Design Registration

Interfaces: The integration of advanced user interfaces (UIs) and software in med-tech devices presents unique challenges in design registration, particularly for Graphical User Interfaces (GUIs). These challenges stem from the evolving legal interpretations under the Indian Designs Act, 2000, and the Designs Rules, 2001, which have significant implications for protecting innovative designs in the med-tech sector.

Functional Designs: Another key issue in registering device design is the functionality of the device, which refers to how a device works. The Indian Design law does not allow registration of such designs. This is especially relevant for medical devices since they are made to either detect or cure a disease. Here, it becomes important to understand that only devices that are purely designed to perform a particular function are not registerable. However, there are no restrictions to protect the aesthetically appealing design, yet performs its intended function.

Strategic Importance of Design Registration

As India aims to become a global hub for medical device innovation, prioritising design protection is not only a defensive or an add-on strategy; it is key to fostering creativity and excellence. Design registration enhances the industry's competitiveness and paves the way for future healthcare innovations. This, in turn, promises to enhance patient care, drive industry growth, and position India at the forefront of medical technology innovation.

As the industry continues to advance, the synergy between design innovation and legal protection will be instrumental in shaping a healthier, more technologically adept future.

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