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NON-TRADITIONAL TRADEMARK AND DESIGN PATENT STRATEGIES FOR MEDICAL DEVICES

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ABSTRACT

This paper discusses non-traditional trademarks and design patents as essential Intellectual Property assets for medical device companies. The paper presents a strategy for layering the time-limited protection offered by design patents with the perpetual protection afforded to trademarks as an effective strategy for permanent exclusivity of non-functional aspects of medical device products.

Keywords: medical devices, intellectual property, trademark, non-traditional trademark, patent, design patent, functionality, brand protection

1. INTRODUCTION

Medical device companies are increasingly recognizing the value of non-traditional trademarks, used in combination with design patents, to enhance brand identity, engage consumers, provide a multi-sensory experience, and differentiate products in crowded markets. However, securing and maintaining non-traditional trademarks requires foresight and sophistication beyond what is typically called for when building a traditional trademark portfolio. Maximizing the commercial value of non-traditional trademarks needs a proactive and forward-thinking strategy implemented across a company's engineering team, marketing team, sales team, regulatory team, and legal team. It is beneficial to develop a harmonized trademark and patent strategy early in a product's lifespan to help avoid potential pitfalls and to obtain perpetual protection of unique and non-functional aspects of the product.

2. TRADEMARKS: TRADITIONAL VS. NON-TRADITIONAL

The U.S. Trademark Act defines a trademark as ***any*** word, name, symbol, or ***design***, or any combination thereof, used in commerce to identify and distinguish the goods or services of one seller from those of another and to indicate the source or origin of those goods or services.[1] Thus, the Trademark Act allows for the registration of distinctive product names, logos, and slogans, i.e., "traditional" trademarks as well as trade dress, colors, texture, sounds, motions, scents/taste, and other attention-getting devices, i.e., "non-traditional" trademarks. Trade dress is divided into two categories: "product packaging" and "product design."

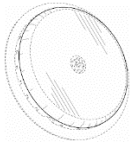
Product packaging is the overall combination and arrangement of the elements that make up the product's packaging, including graphics, layout, color, or color combinations. Product design, on the other hand, covers a product's shape or configuration and other design features. Where it is difficult to determine whether the trade dress at issue is product packaging or product design, courts are instructed to classify ambiguous trade dress as product design, thereby requiring acquired distinctiveness (discussed below), for exclusive rights and protection. Unlike patents and copyrights, trademark rights can last in perpetuity, provided the mark is not abandoned, does not become generic, or, in the case of trade dress, is not functional.

Although registration of trademarks with the United States Patent and Trademark Office ("USPTO") is not required, the owners of registered

marks benefit from a bundle of significant advantages over unregistered common law marks, including nationwide priority of use, evidence of validity and exclusive ownership with heightened protection after five years of continuous use, the right to use the symbol ® on goods or services listed in the registration, the right to sue in federal court and, in certain cases, obtain enhanced damages, and the ability to block the importation of infringing goods and counterfeits.[2] Obtaining the advantages of a registered trademark is often essential for efficiently protecting non-traditional trademarks.

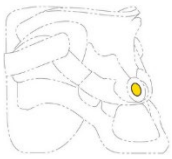
2.1 Non-traditional trademarks in the medical device industry

A search of the USPTO trademark database reveals a plethora of registered non-traditional trademarks for a variety of medical devices, including the following illustrative examples:

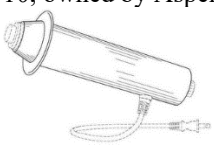


Registration No. 6,399,362 (three-dimensional configuration of an analyte sensor, comprised of a circular device housing) for "Electrochemical sensors for determination of analyte concentrations in fluids for medical purposes; sensors for medical use to gather analyte concentration data; medical device for monitoring and providing information related to analyte concentrations; medical diagnostic apparatus for determination of analyte concentrations; medical apparatus for monitoring analyte concentrations in interstitial fluid; wearable sensors used to measure and provide information related to analyte concentrations in interstitial fluid, all for medical purposes; patient monitoring sensors for monitoring analyte concentrations, all for medical purposes; patient monitoring sensors for determination of analyte concentrations in interstitial fluid, all for medical purposes" in Class 10, owned by Abbott Diabetes Care Inc.;

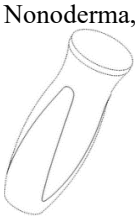
Registration No. 5,630,822 (blood glucose meter with a screen at the center) for "Blood glucose meter; Diabetic diagnostic medical devices; Devices for monitoring blood glucose for medical purposes" in Class 10, owned by Diabetic Supply of Suncoast, Inc.;



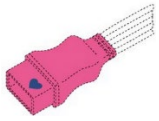
Registration No. 5,668,642 (three-dimensional configuration comprising an orthotic brace with a small yellow circle portion) for "Orthotics for spinal and neck immobilization devices" in Class 10, owned by Aspen Medical Products, LLC;



Registration No. 5,175,108 (three-dimensional configuration of the goods consisting of a cylindrical housing with an annular flange near a first end, the first end tapering to a truncated end) for "Radio frequency skin care device which generates ozone gas for the treatment of the skin; high-frequency skin care device which generates ozone gas for the treatment of the skin" in Class 10, owned by Nonoderma, LLC;



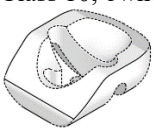
Registration No. 5,478,595 (a three-dimensional configuration comprising a wave-like pattern) for "Surgical instruments; manual surgical instruments; orthopedic instruments, namely, orthopedic instruments for diagnostic and therapeutic use; manual orthopedic surgical instruments; general orthopedic surgical instruments; surgical instruments, namely, bone awls; bone probes; surgical instruments, namely, tamps" in Class 10, owned by Gauthier Biomedical, Inc.;



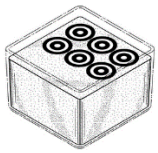
Registration No. 5,105,411 (three-dimensional configuration of ECG connectors in the color hot pink (Pantone PMS 806) with a small heart design in the color navy blue (Pantone PMS 281) at the end of the ECG connector) for "disposable medical devices and supplies, namely, ECG connectors" in Class 10, owned by KPR U.S., LLC;

Registration No. 4,839,588 (color yellow applied to the tube portion of feeding tubes) for

"Medical devices in the nature of feeding tubes, namely naso-gastric tubes, naso-intestinal tubes, gastrostomy tubes, jejunostomy tubes, oroenteric tubes, sump/decompression tubes, gastric pressure relief devices and NG/NI tube retention devices" in Class 10, owned by Avent, Inc.;

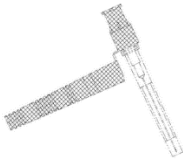


Registration No. 5,352,938 (three-dimensional configuration of a patient positioning medical device in the nature of a head cushion) for "medical and surgical supplies, namely, patient positioning medical devices in the nature of head cushions" in Class 10, owned by Dupaco, Inc.;



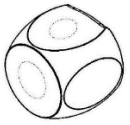
Registration No. 3,084,483 (configuration of a container for holding medical devices, namely, needles and other sharp objects, and a plurality of target designs printed on the upper surface of the container) for "Medical devices, namely, containers for holding needles and other sharps" in Class 10, owned by Merit Medical Systems, Inc.;

Registration No. 2,600,113 (configuration of the goods, namely a pressure regulator having a dodecagon cross-sectional body) for "gas pressure regulators and combination gas pressure regulators with flow metering devices for medical use" in Class 10, owned by Flotec, Inc.;



Registration No. 2,745,908 (color orange) for "medical needle protection devices, namely, protective sheaths for covering needles" in Class 10, owned by Smiths Medical ASD, Inc.;

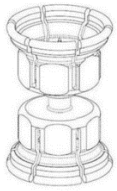
Registration No. 2,566,583 (configuration of the goods, namely a pressure regulator having a dodecagon cross-sectional body) for "gas pressure regulators and combination gas pressure regulators with flow metering devices for medical use" in Class 10, owned by Flotec, Inc.;



Registration No. 6,392,129 (three-dimensional configuration of a cuboid section of an endoscope or optical system for an endoscope having rounded and planar surfaces) for "surgical apparatus and instruments for use in endoscopic surgery; medical apparatus and instruments, namely, endoscopes and parts thereof, particularly the casing that houses the optics systems" in Class 10, owned by Karl Storz SE & Co. KG;

Registration No. 5,020,536 (configuration of the base portion of a resectoscope, in which the base portion features an eye piece at the remote end, an axially movable rod, 2 handles, and dual washing pipes, each at 90 degree angles to the shaft of the instrument. The ring at 1 remote end of the instrument is yellow. The casing around one portion of the sliding rod is white. The cylindrical extensions from the casing and smaller of the two handles are black. The remainder of the instrument is silver) for "medical instrument, namely, resectoscopes" in Class 10, owned by Karl Storz SE & Co. KG;

Registration No. 3,812,561 (round design, purple color, white color, and wave patterns of inhaler) for "pharmaceutical preparations and substances for the treatment and/or alleviation of respiratory disorders; inhalers filled with the pharmaceutical preparations for the treatment and/or alleviation of respiratory disorders" in Int'l Class 5, owned by Glaxo Group Limited;



Registration No. 5,860,032 (three-dimensional configuration of cylindrical shapes with curved edges) for "Medical devices, namely, disposable vial adapters for mixing between two substances in separate vials" in Int'l Class 10, owned by West Pharma;

These examples show the diversity of non-traditional trademarks in the medical device industry. Registrations include wearable medical tech, surgical

instruments, drug delivery systems, and single-color marks. In each case, these brand owners have obtained the USPTO's recognition of their medical device's unique aesthetic elements as source indicators that distinguish their devices from competitors.

2.2 Fundamental requirements: use in commerce and distinctiveness

Brand owners must establish that a mark meets two fundamental requirements for it to be eligible for registration with the USPTO. First, the brand owner must show that it uses the mark in commerce, or the brand owner must declare that it has a legitimate intention to use the mark in commerce when the application is filed.[3] The U.S. Trademark Act defines "use in commerce" as use in the ordinary course of trade. A mark will be deemed to be used in commerce when a brand owner has placed the mark on products, product packaging, labels, hang tags, or point-of-sale displays for its goods in the U.S. stream of commerce. In the context of medical devices, a brand owner may show use in commerce through use of its marks in clinical trials before a product is approved for use in the broader population. Alternatively, a brand owner may seek registration of a trademark on an intent-to-use basis by submitting an application declaring the brand owner has a good faith intention to use the mark in commerce in the future.

The second requirement is that the mark must be distinctive, i.e., capable of distinguishing the brand owner's goods from those of others. Selecting a candidate mark based on conceptual strength can increase the likelihood that the mark will make it through the examination process and will have broad rights against confusingly similar junior marks.

Trademark distinctiveness can be thought of as existing on a continuum.[4] Trademarks that are categorized as coined/fanciful (e.g., PEPSI®), arbitrary (e.g., APPLE®), or suggestive (e.g., POP TARTS®) are considered conceptually strong/inherently distinctive and thus immediately protectable and registrable on the Principal Register upon their first use in commerce. Trademarks that are categorized as descriptive (e.g., CALIFORNIA PIZZA KITCHEN®) are only registerable on the Principal Register if they have acquired distinctiveness through the brand owner's substantially exclusive and continuous use of the mark in commerce, typically for five years. Accordingly, inherent distinctiveness is a critical inquiry because it determines whether a mark can be immediately registered on the Principal Register, or if the brand owner must first show that the mark has acquired distinctiveness.

Product packaging, touch marks, sound marks, and motion marks, are types of non-traditional trademarks that may be inherently distinctive, in which case no proof of acquired distinctiveness is required for immediate registration on the Principal Register. Other non-traditional trademarks lack inherent distinctiveness and proof of acquired distinctiveness is always required for registration of these types of marks on the Principal Register. For example, single color marks, scent marks, flavor marks, certain sound marks, and product design are all deemed not to be inherently distinctive as a matter of law.

Marks that are not inherently distinctive but capable of eventually distinguishing goods, for example merely descriptive marks, ornamental marks, and product designs, may be initially registered on the Supplemental Register. The Supplemental Register is the secondary register of trademarks maintained by the USPTO. Benefits of the Supplemental Register include the ability to use the symbol ®, the ability to register the trademark outside the U.S. (subject to limitation), the right to sue for trademark infringement, and the opportunity to amend to the Principal Register once the mark has acquired distinctiveness.

Subjects that are generic (e.g., the word "email"), commonplace (e.g., the slogan "Have a Nice Day"), or functional (the color orange used for safety), can never receive trademark protection because they communicate the type of product, fail to distinguish one good from another, or only provide informational meaning. Importantly, if not properly maintained and enforced, a mark may become generic or so common that the brand owner can lose its exclusive right to prevent others from using the mark. This is called "genericide" and examples include ESCALATOR, once a brand name for a moving staircase, and ASPIRIN, once a brand name for acetylsalicylic acid.

2.3 Functionality: an absolute bar to trademark rights

The determination that a proposed mark is functional is an absolute bar to registration, even if the mark is conceptually strong or has acquired distinctiveness. In theory, the functionality doctrine encourages legitimate competition by maintaining a proper balance between the competing interests of trademark law and patent law, specifically utility patent protection. In practice, the functionality doctrine is a dangerous minefield that, if not carefully navigated, can obliterate non-traditional trademark rights at any point in the mark's life.

A feature is functional as a matter of law if it is either essential to the use of purpose of the product or if it affects the cost or quality of the product. Product design elements are presumed functional until proven otherwise by a brand owner. This burden may be

overcome if the design element is merely an ornamental, incidental, or arbitrary aspect of the device.

In examining applications for product designs, the USPTO considers four factors to determine whether a mark is functional.[5] The factors include:

1) the existence of a utility patent that discloses the utilitarian advantages of the design sought to be registered;

2) advertising by the applicant that touts the utilitarian advantages of the design;

3) facts pertaining to the availability of alternative designs; and

4) facts pertaining to whether the design results from a comparatively simple or inexpensive method of manufacture.

It is not necessary to consider all four factors in every case. Moreover, there is no requirement that all four factors weigh in favor of functionality to support a refusal to register.

Evidence that the proposed mark is the subject of a utility patent that discloses the utilitarian advantages of the configuration can be sufficient to support a functionality refusal. On the other hand, a design patent is a factor that weighs against a finding of functionality, because design patents, by definition, protect only ornamental and non-functional features. However, ownership of a design patent does not in itself establish that a product feature is non-functional and can be outweighed by other evidence supporting the functionality determination.

Advertising touting the utilitarian aspects of a product design or product packaging is strong evidence supporting a functionality refusal. Where functionality appears to be an issue, the USPTO must ask the brand owner to provide any available advertising, promotional, or explanatory materials concerning the goods/services and the features embodied in the proposed mark.

Similarly, evidence discussing utilitarian aspects of a mark is highly relevant where a third-party (often a business competitor) seeks to invalidate the mark on functionality grounds. For example, in a case before the USPTO, a German manufacturer of ceramics and ceramic components for medical prostheses used a chromium-based ceramic composite that imparts a pink color to its products. The company also owned a utility patent for the use of chromium-based materials in its products. Shortly before its patent expired, the company obtained a trademark registration for the color pink for its hip joint component on the Supplemental Register. The company then attempted to enforce its trademark against a Colorado-based manufacturer of pink ceramic components for medical prostheses. Striking back, the competitor petitioned to cancel the German company's registrations by claiming that pink is a byproduct of using chromium-based materials. As evidence, the competitor cited a series of articles published by researchers working for the German company, discussing the purported benefits associated with using chromium-based materials in ceramic hip implant components and its natural tendency to impart a pink color. The case is ongoing at the time of this writing.

Also relevant to the functionality inquiry is whether the claimed mark is used by competitors in the industry for functional purposes. The USPTO may review industry and trade publications to determine whether competitors offer similar designs and features or have written about the design and its functional features or characteristics. For example, in 2012, a California federal court ruled that a medical device company's use of the color orange for various markings and text on its medical syringe products was functional.[6] The decision was based on a finding that the color orange had a functional purpose in the medical industry, namely, to signify that a device is for oral/enteral use.

In light of the forgoing, medical device companies should avoid unnecessarily touting functional aspects of their non-traditional trademarks in promotional materials, advertisements, sales presentations, and customer communications. Instead, brand owners should highlight the non-functional, aesthetic aspects of their non-traditional marks with "look for" advertising and maintain records to establish a non-functional purpose, should a mark be challenged as functional. Failure to do so risks the erosion of a company's trademark portfolio and diminution of its goodwill. Careful planning and review of advertising materials and guidance from legal counsel can also help mitigate risks.

3. DESIGN PATENTS

Design patents provide a limited term of protection for the visual, non-functional characteristics of a product. Design patents can cover a shape, color, or pattern of an entire product or a portion of a product. Unlike utility patents, and as mentioned above, design patents weigh against a finding of trademark functionality. Accordingly, it is possible to dovetail the protection offered by design patents with perpetual trademark rights in medical device products. Layering these two complementary intellectual property regimes can confer significant economic benefit and marketplace advantage.

To obtain a design patent, the design must be an article of manufacture, ornamental, novel, and non-obvious over existing designs. Although the article can

serve a functional purpose, the portion of the design to be protected cannot be purely functional. If the design is the only way to maintain the functionality of the article, the design is not eligible for design patent protection. A design patent may not be available if an article embodying the design was publicly disclosed prior to filing the design patent application. Accordingly, it is often advantageous to file a design patent prior to sales or other disclosure of the product. If the product has been publicly disclosed for longer than an allotted grace period, only trade dress rights may be available. In 2015, the design patent term of protection changed from 14 years to 15 years. The longer term applies to any applications filed on or after May 13, 2015.

The remedies available for design patent infringement and trade dress infringement are similar, but not identical. Remedies for design patent infringement include injunctions, monetary damages, and in exceptional cases, attorneys' fees. While remedies include total profits as a possible damage award for both trade dress and design patent infringement, causation of injury from infringement is only required to be shown in trade dress infringement claims. Therefore, the damage award of total profits in design patent infringement cases can be easier to prove and can result in higher awards.

4. CONCLUSION

When appropriately employed, a comprehensive Intellectual Property strategy that accounts for non-traditional trademarks can produce significant economic and market advantages that enhance the value of the product and increase goodwill and public recognition of the brand and brand owner. And, from a risk management assessment, medical device companies are well-served by taking the non-traditional trademark rights of others into account during the due diligence process as a brand owner's new medical device is being developed. In the end, making sure that a medical device company's engineering team, marketing team, sales team, regulatory team, and legal team are all aligned on the best strategy for building and protecting valuable intellectual property assets is critical to maximizing corporate value and creating an advantageous separation from the competition.

REFERENCES

[1] 15 U.S.C. §§ 1051 et seq.
[2] Matal v. Tam, 137 S. Ct. 1744, 17653 (2017)/
[3] Wal-Mart Stores, Inc. v. Samara Brothers, Inc. 529 U.S. 205 (2000).
[4] Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9 (2d Cir. 1976).
[5] Traffix Devices, Inc. v. Marketing Displays, Inc. 535 U.S. 23 (2001).
[6] Acacia, Inc., v. NeoMed Inc., Case No. SACV 11-1329-JST (C.D Cal. July 23, 2012)