

Review Article

Trade Dress in Pharmaceuticals

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Abstract

The aim is to provide the basic information & understanding of pharmaceutical trade dress in current pharmaceutical environment along with the example. The trade dress is a kind of property of Pharmaceutical industry which is protected under different IP laws so that to stand in the market with unique identity of a particular product, pharmaceutical companies exploring creative ways of protecting their intellectual property (IP) to provide themselves with a competitive market advantage. Companies relying solely on the standard means of IP protection, for example patents, copyrights and traditional trade marks (such as word marks), may find themselves at a competitive disadvantage. One area of IP protection that many companies would be well advised to explore is the possibility of using the trade mark laws to protect the overall look and feel i.e. trade dress of their product designs. The current review provides a discussion of trade dress with pharmaceutical view this covers the historic background, legal system & areas, trade dress infringement cases & remedies available.

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Keywords: Trade dress, formulation appearance, Pharmaceuticals, packaging, Intellectual property

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Introduction

The sweeping competition injected into the industry by generic-drug manufacturers has increased the need for brand-name drug makers to boost consumer recognition of, and desire for, their branded products. To combat market erosion, many drug makers have turned to DTC advertising to encourage patients to recognize and request a particular drug by name. To augment this effort, pharmaceutical companies have also focused on the design of the drugs themselves, adding unique source-identifying features such as color, shape, size, taste, or aroma to differentiate their products in the marketplace² In the pharmaceuticals the drug products origin of prescription as well as the OTC are having a big earnings for the pharmaceutical sector where the industries invests an average and average of 12 years and

Trade dress is a legal term of art that generally refers to characteristics of the visual appearance of a product or its packaging that signify the source of the product to consumers. Trade dress usually refers to the total image or overall appearance of all elements in which a product or service is presented. It includes the product, its packaging, and its advertising. It must function as a trademark. If it does not, it cannot be protected as trade dress. Trade dress is a one of the form of intellectual property rights & it is legally protected under the Lanham act³

Pharmaceutical Trade Dress

To qualify as trade dress it should meet the following criteria it must be non functional, it must leads to deception if imitated and should have the secondary association with the product for the consumer. The legal protection for pharmaceutical trade dress is raised in the middle of 20th century which increasing concerns about counterfeit drugs, this copied the appearance, packaging, and name of a brand name drug^{4,16}. This concept of trade dress underlies labeling and packaging issues for the pharmaceutical industry. Trade dress refers to how the drug package actually looks. The imperatives of trade dress are an important part of the culture of each company. The dominant message is, "Don't change anything that works." The more successful the company, the more resistant it is to changing trade dress^{5,17}, this concept mainly concern with marketing and image of the product which is to be good looking, neat, clean and tidy which should reciprocate the quality image. This image should intentionally be distinguishable in pharmacy shelves compare with marketed competitors product. Trade dress" is the concept that highlights labeling and packaging issues for the pharmaceutical industry. Trade dress indicates how the drug package actually looks. The imperatives of trade dress are an important part of the pattern of each company. The dominant message is, "Don't change anything that works." The more successful the company, the more resistant it is to changing trade dress⁷

The past five years have seen a significant increase in complaints that include trade dress counts Trade dress litigation has strong appeal over utility patent litigation due to lower overall cost to trial

Pro: No claim construction hearing; no infringement or invalidity contention proceedings; no significant technical issues requiring expert testimony.

Con: Need to show confusion, secondary meaning, nonfunctionality.

Basic Needs for Legal protection (Requirements for registration of trade dress)⁸⁻¹²

It can be difficult to obtain protection for trade dress, as applicants must prove that the design has secondary meaning to consumers

Functionality

To opt registration in the Principal Register or common law protection under the Lanham Act, a trade dress must not be "functional." That is, the configuration of shapes, designs, colors, or materials that make up the trade dress in question must not serve a utility or function outside of creating recognition in the consumer's mind. For example, even though consumers associated a distinct spring design for wind resistant road signs with a particular company, the spring design was not protectable for trade dress purposes because the springs served the function of withstanding heavy wind conditions.

What is considered "functional" depends upon the specific product or thing sought to be protected. For example, the color red in a line of clothing may not be functional (and thus part of protectable trade dress) whereas the same color on a stop sign would be functional because the color red serves the function of putting drivers on alert (and thus would not be part of a protectable trade dress).

Distinctiveness

To gain registration in the Principal Register or common law protection under the Lanham Act, a trade dress must be "distinctive." This means that consumers perceive a particular trade dress as identifying a source of a product.

Claimed trade dress in the product design -- as opposed to product packaging -- context can no longer be "inherently distinctive"; it must acquire distinctiveness through "secondary meaning." Distinctiveness through secondary meaning means that although a trade dress is not distinctive on its face, the use of the trade dress in the market (the "good will" of the trade dress) has created an association between that trade dress and a source in the mind of the consumer.

Although the law is evolving, as it stands now, product packaging (including packaging in very general terms, such as a building's décor) may be inherently distinctive. However, product design, that is the design or shape of the product itself, may not be inherently distinctive, and must acquire secondary meaning to be protected.

an application to register trade dress with the United States Patent and Trademark Office (USPTO) must include all of the same content as any other trademark application, including a description of the trade dress, identification of the product or service to be covered and payment of the appropriate fee. Substantively, the trade dress must be both distinctive (i.e., recognizable to consumers as identifying the source of the product or service) and nonfunctional (i.e., not be essential to the use or purpose of, and not affect the cost or quality of, the product or service). Functional trade dress is not registrable even if it is distinctive.

The requirements for registering trade dress vary widely from country to country. Generally speaking, an application for trade dress must meet the standard requirements for any trademark application. The trade dress must either be inherently distinctive or have acquired distinctiveness. It cannot be functional.

Trade Dress Example

For basic understanding here are few example of trade dress described below

1) Prozac trade dress

Two generic companies marketed generic versions of Prozac having the same colour, shape and size as Eli-Lilly's version, Eli Lilly was unsuccessful in an action for passing-off. The Court did not find Eli-Lilly had established distinctiveness or likelihood of confusion. The Trade-Marks Opposition Board found that Eli Lilly had not met the test for distinctiveness for the trade-dress to be registered as a trade-mark. The Trade-Marks Opposition Board allowed the appeal and rejected the trade-mark application.

In the Federal Court, Eli Lilly present that the test for distinctiveness should be met by:

(a) Establishing that the trade-mark is distinctive in relation to one group: physicians, pharmacists OR patients – not all 3

(b) Establishing distinctiveness in relation to a product category (i.e. antidepressants and not pharmaceutical industry generally).

The Federal Court disagreed and found the trade-mark to lack distinctiveness in view of:

(a) Several other similar pharmaceutical products on the market prescribed for conditions other than depression.

(b) Evidence of patients was not convincing and physicians and pharmacists rely on markings on the capsule, not only appearance, to identify the product^{4,5}.



Fig.1: Prozac capsule

2) Viagra Trade dress:

Pfizer has filed the 3 trade mark application related to appearance of Viagra tablet (25, 50 & 100 mg doses) this application is accepted for publication but Novopharm & Teva opposed the application Trade-mark claimed: The colour blue applied to the whole of the

Visible surface of the table (Fig 2)



Fig.2: Viagra tablet of Pfizer

The Trade-Marks Opposition Board refused the applications because the written description of the trade-mark does not allow a determination of the 3-dimensional limits of the tablets: "...it is unclear whether the Marks consist of the colour blue alone or the colour blue applied to the diamond-shaped tablets"^{5,17}.

3. Advair Diskus:

Advair Diskus is a register trade mark of the GSK. Apotex filed against the appearance of the trademark Glaxo's trade-mark registration was struck from the Register. Trade-mark claimed: the colours dark purple and light purple applied to the visible surface of portions of the particular object



Fig. 3: Image of Advair Diskus GSK

GSK attempted to support the distinctiveness of its trade-mark with evidence of:

(a) millions of dollars promoting its inhaler in advertising

(b) appearance being one-of-a-kind

(c) affidavit evidence from patients, physicians and pharmacists regarding use of appearance to distinguish GSK inhaler from others

The Court did not accept this evidence as establishing distinctiveness.

- (1) Anecdotal evidence of 2 consumers not sufficient
- (2) No notice given of the Trade-Dress on the product package or on the inhaler
- (3) Trade-name Advair is the dominant mark
- (4) No prudent physician or pharmacist would rely on colour or shape of inhaler to exercise a professional judgment about the product
- (5) Advertising does not depict Trade-Dress as self-standing mark^{5, 6, 17}.

Trade Dress Infringement Examples

AstraZeneca & Dr. Reddys

US-based pharma AstraZeneca had, not so long ago, filed a suit before a Delaware court against the purple colour of the generic version of AstraZeneca's antacid pill, Nexium, being sold by Dr. Reddy's Laboratories in the US. This, it claims, is a significant breach of a settlement arrived at between the two companies that would discharge Dr. Reddy's from any liability in connection with the generic Nexium's sale. AstraZeneca alleged that the shade of purple used was similar to the shade of the original pills, effectively infringing on their trademark for their purple pills. The Court granted a temporary injunction in favour of AstraZeneca, imposing a temporary ban on the sale of Dr. Reddy's generic pills. In a recent development, it appears that Dr. Reddy's has countersued AstraZeneca in a New Jersey Court claiming that its actions were perfectly in line with the terms of an earlier settlement in 2011, where the former's intention to use the colour purple had allegedly been made fully known.¹⁴



Glaxo & Sunlifesciences

Delhi High Court granted ad interim stay in favour of Glaxo Group Ltd & Anr (Plaintiff), thereby refraining Sunlife Sciences Pvt Ltd (Defendants) from manufacturing, selling and trading pharmaceutical preparations under the mark in question and also from using deceptively similar trade dress to that of Glaxo's during the pendency of the suit. Glaxo Group is a well-known pharmaceutical company which has been selling pharmaceutical formulations under the marks BETNOVATE and BETNOVATE-C, CROCIN and

ZINETAC/ZANTAC. They alleged that Sunlife Sciences were using the brand names B-NATE-C, COR-SUN and ZEETAK which were deceptively similar to the marks used by Glaxo, not only in terms of the color scheme, get up and layout but also phonetically, to the extent of not only violating Glaxo's statutory rights but also causing confusion in the minds of the public by selling deceptively similar products.

In their written statement Sunlife Sciences raised doubts firstly, about the maintainability of the suit stating that it had not been instituted properly and was therefore liable to be rejected and as such the question of granting an ad interim stay in favour of Glaxo did not arise. Secondly, it was contended that Sunlife's office was based in Bangalore and their pharmaceutical products were not circulated in Northern India much less in Delhi and thus the Court did not have the jurisdiction to adjudicate upon the present suit.¹⁵

Remedies in case of Infringement

If a trade dress is a registered trademark, a claim for trade dress infringement may be asserted under Section 32(1) of The Lanham Act (15 U.S.C. Section 1114(1)). When the trade dress is not registered, a trade dress infringement claim may be asserted under Section 43(a) of The Lanham Act (15 U.S.C. Section 1125(a)). The action may be brought in a United States District Court where personal jurisdiction and venue are proper.

The remedies for trade dress infringement are the same as those for trademark infringement, i.e., injunctions (15 U.S.C. Section 1116), recovery of damages in the form of the defendant's profits or the plaintiff's actual damages (trebled in the court's discretion), and/or attorney's fees in "exceptional" cases. (15 U.S.C. Sections 1114-1119).¹³

Conclusion

In conclusion, trade dress is a today's essential need and fascinating legal area in the world. There are many issues which are not usually present in word trademark cases, such as functionality. There is minimum requirement of uniqueness (Distinctiveness) and it should be either indicative or identified of particular functionality using these one who can sought the legal protection. Trade dress provides confidence to enter in the market with high vision of commercial benefits. As trade dress law continues to evolve and be refined by the courts the area should remain of great interest to trademark practitioners. To capture the market with proper identity every industry trying to get some brands highlighted with trade dress legal protection. It's very important while entering in the market to avoid any kind of infringement so that there will be no complex or legal fight. Pharmaceutical industries are one of the largest industries after FMCG which are in the area of delivering quality goods with subject to health of consumers, along with huge expense in the manufacturing R&D & marketing industry requires uniqueness, this distinctiveness will be its kind of source in the market which provides ease picking of

the product from the market followed by highest revenue generation.

Conflicts of Interest

All authors declares no conflict of interest, the images, trademark & logo shown in the paper are of their respective owners there is no any kind of marketing intentions

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