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**HEART PILLS ARE RED, VIAGRA IS BLUE . . .
WHEN DOES PILL COLOR BECOME
FUNCTIONAL? AN ANALYSIS OF UTILITARIAN
AND AESTHETIC FUNCTIONALITY AND THEIR
UNINTENDED SIDE EFFECTS IN THE
PHARMACEUTICAL INDUSTRY**

Signe H. Naeve†

Abstract

As consumers, we often associate pill color and shape with particular medications. Should that trade dress be protected beyond the expiration of the patent? Legal scholars have recognized some of the tensions and inconsistencies in court opinions when it comes to trade dress protection for pill shape and color. This article focuses on the specific tensions between requiring secondary meaning and non-functionality, as well as the potential of “genericide” when generic pharmaceuticals enter the market. Ultimately this article makes some novel recommendations to assess functionality at the time of FDA approval for the pharmaceutical and to have the FDA responsible for determining when a shape and color should be an industry standard, creating an exception to trade dress protection. Some exceptions for allowing protection for pill shape and color could be for flavor and colors that indicate flavor, for medications that indicate dosage, or for medications that are associated with a particular patient compliance or psychosomatic effect.

INTRODUCTION

Imagine a world without the little blue pill or the purple pill. For pharmaceuticals, colors and shapes not only signify the type of medication to a consumer, they can also represent the source of each

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medication. Most consumers would identify a shiny, round, brown pill not just as an anti-inflammatory medication or even as Ibuprofen, but as Advil. “The purple pill” is Nexium and the light blue angular pill, Viagra. Relying on trade dress to protect the pill color and shape after the patent term has expired enables the manufacturer to extend its market power via another form of intellectual property protection. Like most medications, however, trade dress protection can have unintended side effects.

To obtain trade dress protection for shape and color, the design cannot be functional and the owner must demonstrate that it has acquired secondary meaning in the minds of consumers. A problem arises because, as the brand owner develops secondary meaning in the trade dress, the color and shape can begin to cross the line into functionality, which would then exclude it from protection. “The purple pill” not only signifies the brand Nexium, but it also identifies the pill for acid reflux. In other cases, a shape or color may become associated with a particular dosage, efficacy, result or soothing effect. Sometimes an element of the medication that was not “functional” in its original design begins to serve a purpose over time and the manufacturer is now potentially a victim of its own success. Additionally, a form of trade dress “genericide” has the potential of occurring to allow generic drugs to enter the market.

This article will first briefly explain the history of trademark and trade dress protection for color and shape. Second, it will introduce the functionality limitations that have arisen in relation to pill shape and color and introduce the concept of aesthetic functionality. Third, it will consider public interest considerations that justify allowing or disallowing protection. Fourth, it will examine more deeply the protection that has been afforded pill shape and color and assess whether trade dress protection is being preempted in the pharmaceutical context due to functionality, aesthetic functionality, and genericness concerns.

Ultimately, this article will argue that color and shape should not become functional or be subject to genericide as a result of creating secondary meaning; that substitution for generic drugs should not be a reason to find that a color and/or shape are functional or generic; that functionality could be determined when the color and/or shape are adopted, not at the time of assessing secondary meaning; that using color and/or shape to indicate a general type of medication should not be considered functional, unless they are industry-regulated by the FDA; that using industry-accepted color and/or shape to indicate dosage is an acceptable functionality limitation, but it too should be

regulated by the FDA; and finally that flavor and colors that indicate flavors should be considered functional due to scarcity concerns.

I. TRADEMARK AND TRADE DRESS PROTECTION FOR COLOR AND SHAPE

A. Trademark Protection for Color

Under United States trademark law, it is possible for non-traditional source indicators, such as color,¹ taste,² sound,³ and smell⁴ to qualify for trademark protection.⁵ Prior to 1995, there was a circuit split regarding the protection available for colors as trademarks.⁶ This split was resolved with the landmark case, *Qualitex v. Jacobson Products*.⁷ In *Qualitex*, the Supreme Court held that there was no special rule preventing color from serving a trademark function, and hence color was not per se prohibited from protection.⁸ Accordingly, the greenish-gold color of the dry cleaning press pads at issue in the case could be registered for trademark protection.⁹ *Qualitex* thus resolved an earlier debate and opened the door for trademark protection for colors.

Two of the main arguments addressed by the Court in *Qualitex* were the fear of shade confusion and color depletion.¹⁰ Jacobson argued that if color were a permissible trademark, there would be uncertainty as to permissible shades and courts would constantly be forced to resolve disputes about lawful and unlawful uses of color.¹¹ How can we tell the difference between sky blue and light blue? The Court rejected the shade confusion argument reasoning that color disputes were no different from any of the other likelihood of

1. See generally *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159 (1995) (holding green-gold color for dry cleaning press pads registerable; no per se exclusion to registration of color).

2. See *In re N.V. Organon*, 79 U.S.P.Q.2d 1639 (T.T.A.B. 2006) (rejecting orange flavor for medication as trademark, placing flavor with color and product design as non-inherently distinctive).

3. See *In re Gen. Elec. Broad. Co., Inc.*, 199 U.S.P.Q. 560 (T.T.A.B. 1978) (“Ship’s Bell Clock” registerable if could show acquired distinctiveness).

4. See *In re Clarke*, 17 U.S.P.Q.2d 1238 (T.T.A.B. 1990) (plumeria flower fragrance on sewing thread and embroidery yarn registerable).

5. This article will not address trademark protection for sound or smell.

6. See *Qualitex*, 514 U.S. at 161.

7. See *id.*

8. See *id.* at 164.

9. See *id.* at 174.

10. See *id.* at 167-68.

11. See *id.* at 167.

confusion analyses that courts undergo on a regular basis.¹² Jacobson also argued that colors are in limited supply and competitors would be placed at a disadvantage if suitable colors were unavailable.¹³ The Court also rejected this argument reasoning that the rare circumstance where color scarcity might be a concern did not warrant a blanket prohibition against allowing trademark protection for color.¹⁴ These arguments continue to have relevance as color has been applied in the pharmaceutical context.

B. Trademark and Trade Dress Protection for Shape

Protection for shape is more appropriately addressed under trade dress protection, a recognized subset of trademark protection for product packaging and design. Trade dress includes the product's packaging and its independent appearance.¹⁵ Famous examples of trade dress include the distinctive Robin's egg blue bags and boxes with the white satin ribbons used by Tiffany and Co.¹⁶ and the yellow arches and red and yellow décor of McDonald's restaurants.¹⁷ Courts have actually separated trade dress into at least two different categories—product packaging and product design—and have created a legal distinction between the two.

1. Product Packaging

In *Two Pesos v. Taco Cabana*,¹⁸ the Supreme Court considered the protectability of a Mexican restaurant's brightly colored décor. The Court addressed whether trade dress for décor would fall on the traditional *Abercrombie*¹⁹ spectrum of distinctiveness. Along the *Abercrombie* spectrum, trademarks that are generic will receive no protection, trademarks that are descriptive can receive protection only if secondary meaning is shown, and trademarks that are suggestive, arbitrary or fanciful can receive protection without a showing of

12. *See id.*

13. *See id.* at 168.

14. *See id.*

15. *See* William T. Fryer, *Trademark Product Appearance Features, United States and Foreign Protection Evolution: A Need for Clarification and Harmonization*, 34 J. MARSHALL L. REV. 947, 948 (2001) (discussing functionality and trade dress protection).

16. *See* U.S. Registration No. 2416794 (claiming date of first use of 1939).

17. *See, e.g., Our History, McDonalds*, http://www.mcdonalds.com/us/en/our_story/our_history.html (last visited Oct. 14, 2010).

18. *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992).

19. *Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4 (2d Cir. 1976).

secondary meaning.²⁰ Suggestive, arbitrary, and fanciful marks are considered to be “inherently distinctive,” hence requiring no additional proof of distinctiveness²¹ whereas trademarks that are descriptive require extra proof before they will be awarded protection.²² The *Two Pesos* Court held that the restaurant’s décor was possible of being inherently distinctive and hence no showing of secondary meaning would be required before protection could be awarded.²³

2. Product Design

In *Wal-Mart v. Samara Brothers*,²⁴ however, the Court addressed distinctiveness for product appearance and held that “product design” was not inherently distinctive.²⁵ The Court drew this reasoning from some dicta in *Qualitex*, which stated that color could never be inherently distinctive.²⁶ The *Wal-Mart* case involved seer-sucker patterned children’s clothing rather than restaurant décor. The Court accordingly drew a distinction between product packaging, like the restaurant décor in *Two Pesos*, and product design, like the children’s clothing in *Wal-Mart*.²⁷ The Court said that product packaging could be inherently distinctive whereas product design could not.²⁸ As a result, product packaging does not require a showing of secondary meaning whereas product design does. If in doubt, the Court advised to favor a finding of product design, requiring a showing of secondary meaning.²⁹ Pill shape and color are considered product design, so, like the clothing in *Wal-Mart*, secondary meaning is required.³⁰

20. See *id.* at 9.

21. See *id.* at 9-10.

22. See *id.*

23. See *Two Pesos*, 505 U.S. at 776.

24. *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205 (2000).

25. *Id.* at 215.

26. *Id.* at 211-12 (citing *Qualitex*, 514 U.S. at 162-63). See also Fryer, *supra* note 15, at 955 (discussing trade dress cases).

27. See David E. Shipley, *What do Flexible Road Signs, Children’s Clothing and the Allied Campaign in Europe during WWII have in Common? The Public Domain and the Supreme Court’s Intellectual Property Jurisprudence*, 13 U. BALT. INTELL. PROP. L.J. 57, 71 (2005) (noting that the *Wal-Mart* decision was justified to protect competition and consumer interests).

28. See *Wal-Mart*, 529 U.S. at 212-13.

29. See *id.* at 215.

30. See, e.g., *Inwood Lab., Inc. v. Ives Lab., Inc.*, 456 U.S. 844, 857 (1982).

II. SECONDARY MEANING AND FUNCTIONALITY LIMITATIONS FOR SHAPE AND COLOR

A. *Secondary Meaning*

To obtain trademark protection for non-traditional source indicators, such as color, shape, and trade dress product design, therefore, it is necessary to show secondary meaning.³¹ These features are considered not to be inherently distinctive and must acquire an association in the minds of the consumer to obtain protection.³² In order to surpass the secondary meaning threshold and to acquire distinctiveness, the mark holder must contribute a significant investment in marketing to create the association between the products and its source in the minds of consumers.³³ Evidence to support secondary meaning can include surveys, affidavits, extensive advertising, focused advertising, success of sales, copying by competitors, and long exclusivity of use.³⁴ For the purple pill, this meant \$41.9 million in marketing efforts in 1997.³⁵ This number had grown to \$107.9 million by 2000.³⁶

B. *Utilitarian Functionality*

In addition to secondary meaning, the color and shape must be non-functional.³⁷ The USPTO defines functionality as an element that is “essential to the use or purpose of the article or if it affects the cost or quality”³⁸ Competitive need is also a significant consideration, although it is not determinative.³⁹ Traditional

31. See 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, § 7:44 (4th ed. 2006).

32. See U.S. PAT. & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, TRADEMARK MANUAL OF EXAMINING PROCEDURE §§ 1202.05, 1212 (7th ed., 2010) [hereinafter TMEP].

33. See RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 13 (1995).

34. See generally David E. Rigney, Annotation, *Application of secondary meaning test in action for trade dress infringement under § 43(a) of Lanham Act (15 U.S.C.A. § 1125(a))*, 87 A.L.R. FED. 15 (1988).

35. David M. Fritch, *Should “The Purple Pill” by Any Other Drug Company Still be as Purple? The Changing Face of Trade Dress Protection for Pharmaceutical Manufacturers*, 47 IDEA 171, 188 (2006) (citing RICHARD FRANK ET AL., KAISER FAMILY FOUNDATION, TRENDS IN DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS Exhibit 6 (2002), available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commons/spot/security/getfile.cfm&PageID=14881>).

36. *Id.*

37. See TMEP, *supra* note 32, § 1202.02(a)(III)(A).

38. *Id.* § 1202.02(a) (citing *TraFFix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 33, 58 U.S.P.Q.2d 1001, 1006 (2001)).

39. *Id.* § 1202.02(a)(v)(C) (citing *Valu Engineering, Inc. v. Rexnord Corp.*, 278 F.3d

utilitarian functional features are ones that “insure ‘practical operation of the article,’ or [] promote efficiency for the purpose to which it is devoted, or [] secure[s] the excellence or functional perfection of the product; and/or is for the sake of economy, e.g. to reduce the cost of manufacture.”⁴⁰ According to the Chicago school of economics, a feature is functional if it would be costly to design around or it would be found in most brands, even when deception is not a goal.⁴¹

To determine functionality normally requires an assessment of the *Morton-Norwich*⁴² factors: “(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.”⁴³ These factors are not individually determinative,⁴⁴ but they generally point to the useful aspects of the feature: was it useful enough that it was awarded a patent? Is this an essential feature, and was it emphasized in product advertising? Could a competitor have adopted a different design or would a design-around be cost prohibitive and anti-competitive?

These factors allude to the traditional line that functionality draws between trade dress protection and patent protection.⁴⁵ Thus, in *TrafFix Devices v. Marketing Displays*,⁴⁶ road signs with a dual spring design, which previously had been covered by a utility patent, were not eligible for trade dress protection.⁴⁷ Another example involving traffic signs is the functional advantage to using yellow or orange for safety signs.⁴⁸ Because colors serve a functional purpose, to aid with safety, one company cannot monopolize them.

1268, 1277 (Fed. Cir. 2002)).

40. 3 LOUIS ALTMAN & MALLA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 19:8 (4th ed. 2010) [hereinafter CALLMANN] (discussing functionality for utilitarian features).

41. *See id.*

42. *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 1340 (C.C.P.A. 1982).

43. TMEP, *supra* note 32, § 1202.02(a)(v) (citing *Morton-Norwich*, 671 F.2d at 1340-41).

44. *See id.* § 1202.02(a)(v).

45. *See Shipley, supra* note 27, at 58.

46. *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23 (2001).

47. *See id.* at 35.

48. *See TMEP, supra* note 32, § 1202.05(b) (citing *Saint-Gobain Corp. v. 3M Co.*, 90 U.S.P.Q.2d 1425, 1447 (T.T.A.B. 2007) (finding deep purple shade for coated abrasives functional)).

Accordingly, functionality separates the scope of intellectual property protection and is a dividing line for whether trade dress protection is available.⁴⁹

C. *Aesthetic Functionality*

The *TrafFix* case actually articulates two tests for functionality. In addition to the traditional test, whether the feature is essential to the use or purpose or affects the cost or quality, the case also identified a second test, whether a feature's exclusive use would put competitors at a significant, non-reputation-related, disadvantage.⁵⁰ This second test is often referred to as "aesthetic functionality."⁵¹ Thus, independent from utilitarian functionality, a feature may be functional if competitors need it to compete for reasons other than building upon a competitor's goodwill. In the context of color, aesthetic functionality is a companion to utilitarian functionality, "where the evidence indicates that the color at issue provides specific competitive advantages that, while not necessarily categorized as purely 'utilitarian' in nature, nevertheless dictate that the color remains in the public domain."⁵² A feature that is aesthetically functional thus makes the product more pleasing or attractive in some regard.⁵³

D. *Color and Functionality*

Courts have recognized an interesting relationship between color and functionality, including aesthetic functionality. Prior to the *Qualitex* decision, the Federal Circuit addressed trademark protection for color and color scarcity, and awarded protection for the color pink in fibrous insulation.⁵⁴ Essentially the Federal Circuit collapsed the color scarcity and functionality arguments into one consideration.⁵⁵ In a two-to-one decision, the Federal Circuit ruled in favor of Owen-

49. See Fryer, *supra* note 15, at 957. Note that a similar line is drawn in copyright with useful articles and the idea/expression dichotomy.

50. See CALLMANN, *supra* note 40, § 19:8 (citing *TrafFix*, 532 U.S. at 33).

51. See *TrafFix*, 532 U.S. at 33 (citing *Qualitex*, 514 U.S. at 170).

52. TMEP, *supra* note 32, § 1202.05(b) (citing *Brunswick Corp. v. British Seagull Ltd.*, 35 F.3d 1527, 1533 (Fed. Cir. 1994, *cert. denied*, 514 U.S. 1050 (1995))).

53. See Fryer, *supra* note 15, at 964; *Qualitex*, 514 U.S. at 166 (For example, it was argued that the press pad color may make the product more attractive because it would conceal stains). See also *Deere & Co. v. MTD Holdings Inc.*, 70 U.S.P.Q.2d 1009 (S.D.N.Y. 2004) (stating farm equipment could be in green and yellow for aesthetic functionality reasons, although Deere could protect its specific green and yellow combination).

54. See *In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116 (Fed. Cir. 1985).

55. See 1 MCCARTHY, *supra* note 31, § 7:42.

Corning and its Pink Panther insulation campaign, determining that the color pink was not precluded from registration.⁵⁶ Significantly, the court said that “pink has no utilitarian purpose and does not deprive competitors of any reasonable right or competitive need.”⁵⁷ Owens-Corning had devoted extensive resources in its Pink Panther advertising campaign in an effort to get consumers to make the connection with its product and purchase the pink insulation.⁵⁸

Pink was an arbitrary selection; it was not necessary for the functioning of the insulation. Any other color would have worked equally well and insulation is rarely seen by anyone other than the person installing it. Furthermore, there was no competitive need for another company to use pink, unless others were trying to free-ride on the goodwill that had been created by Owens-Corning. This is particularly true of a product like insulation that is identifiable when purchasing it, but does not need to match with other insulation.

Qualitex took the “Pink Panther” case one step further and recognized functionality as a limitation that could help to resolve the color scarcity debate.⁵⁹ Color scarcity had previously been viewed by several circuits as a reason for a per se limitation against allowing trademark protection for color.⁶⁰ *Qualitex* recognized that policy reasons did not justify a per se limitation on color, but in reaching this conclusion the Court seemed to find some solace in the outer bounds of functionality. The Court reasoned that if a color depletion or color scarcity problem were to arise, that “the trade mark doctrine of ‘functionality’ normally would seem available to prevent the anticompetitive consequences”⁶¹ For example, the *Qualitex* Court recognized previous determinations involving some limitations relating to color, such as the color green and yellow for farm equipment because purchasers might want their equipment to match; the color black for outboard motors because it made the motors appear smaller and ensured compatibility; and the color blue for fertilizer because the scientific community recognized blue to signify nitrogen.⁶² Thus, functionality could step in where color scarcity leaves off.

56. *Id.*

57. *Id.* (quoting *Owens-Corning*, 774 F.2d at 1122).

58. *See Owens-Corning*, 774 F.2d at 1126-27.

59. *See* 1 MCCARTHY, *supra* note 31, § 7:44.

60. *See, e.g., NutraSweet Co. v. Stadt Corp.*, 917 F.2d 1024, 1028 (7th Cir. 1990) (holding absolute prohibition for protection of color).

61. *Qualitex*, 514 U.S. at 169.

62. *See id.* *See also* 1 MCCARTHY, *supra* note 31, § 7:44.50.

E. Genericide, Functionality, and Trade Dress

The role that functionality plays in trade dress protection in some aspects parallels the role of generic trademarks. Under traditional trademark jurisprudence, a term would be considered generic, and hence not inherently distinctive and not entitled to legal protection, if it represented the genus rather than the species of a good.⁶³ For example, the word “table” on its own could never serve as the trademark for a table. Moreover, a term that originally had a distinct meaning, but over time becomes commonly accepted as the genus rather than the species of a good, can suffer a fate known as genericide. One example is the “Murphy bed case.”⁶⁴ The genus was a bed that folds down from the wall. The species was the “Murphy bed.” Unfortunately for the original manufacturers of the “Murphy bed,” it became the commonly accepted term for a bed that folds down from the wall, so they could no longer monopolize “Murphy bed” as a trademark.

Genericness for trade dress is similar in concept, but slightly different in scope from generic trademarks like the “table” example. As one court has summarized, there are three basic categories of generic trade dress: (1) a design that is an overbroad or generalized theme or style of doing business; (2) a design that has such a basic or necessary format that no one should have a monopoly; and (3) a design that is so common in an industry that it is incapable of identifying any particular source.⁶⁵ For example, “packaging lime-flavored soda in green twelve-ounce cans is so common in the soft drink industry that such packaging probably is not inherently distinctive, although without the industry practice green cans would be either suggestive or arbitrary and therefore inherently distinctive.”⁶⁶ Likewise, one court determined that a rectangular shortbread cookie diagonally dipped in chocolate is a generic cookie

63. See *A.J. Canfield Co. v. Honickman*, 808 F.2d 291, 305-06 (3d Cir. 1986).

64. *Murphy Door Bed. Co. v. Interior Sleep Sys., Inc.*, 874 F.2d 95,101 (2d Cir. 1989).

65. See *Big Island Candies, Inc. v. The Cookie Corner*, 269 F. Supp.2d 1236, 1243-44 (D. Hawaii 2003).

66. *The Paddington Corp. v. Attiki Imps. & Distribs., Inc.*, 996 F.2d 577, 583-84 (2d Cir. 1993) (comparing product packaging for Ouzo bottles and upholding distinctiveness under *Two Pesos*). See also Deborah F. Buckman, Annotation, *When is trade dress “inherently distinctive” for purposes of trade dress infringement actions under § 43(a) of Lanham Act (15 U.S.C.A. § 1125(a))* — *Cases after Two Pesos*, 161 A.L.R. FED. 327, 342 (2000); *Fun-Damental Too, Ltd. v. Gemmy Indus. Corp.*, 111 F.3d 993 (2d Cir. 1997) (holding district court did not err in finding that collective features of packaging for toy bank shaped like toilet was inherently distinctive, even if individually elements were not).

design and would be unprotectable.⁶⁷ Although these examples fall under the generic category, the reasoning for forbidding generic designs⁶⁸ in trade dress echoes some of the previously discussed functionality concerns, in particular the ability to compete and aesthetic functionality.

Similarly, when a patent expires and that patent determines the shape and manufacture of the good, then that shape and manufacture may fall into the public domain. In a 1938 case before the Supreme Court, the Kellogg Company sought to protect a trademark for “Shredded Wheat” as well as trade dress protection for the square pillow shape of its shredded wheat cereal.⁶⁹ The Court upheld the conclusion that “shredded wheat” was descriptive of the product.⁷⁰ For this and other reasons the Court would not allow Kellogg to maintain a monopoly over the term.⁷¹ Regarding the cereal shape, the Court was influenced by the fact that the patented device that created the cereal had expired and hence the technology had fallen into the public domain.⁷² The technology covered by the patent dictated the form of the cereal and hence the form, like the patent, had also fallen into the public domain.⁷³ If the Court reached a different conclusion, the public would not be able to practice the expired patent, so the Court denied trade dress protection.

III. PUBLIC INTEREST CONCERNS

While pharmaceutical companies may have valid reasons for wanting trade dress protection for pill shape and color, public interest concerns in some instances weigh in favor of that protection and in some instances weigh against protection. This section will highlight some of those public interest concerns.

67. See *Big Island Candies*, 269 F. Supp.2d at 1247-48.

68. Note that these cases were actually packaging, not design cases. The courts were not assessing secondary meaning, but rather were seeking to determine whether the design of the packaging was inherently distinctive after *Two Pesos*. Although both the *Paddington* and the *Fun-Damental* cases upheld the lower courts’ findings that the packaging was distinctive, in both instances the Second Circuit noted that packaging that was industry standard would not be protected.

69. See *Kellogg Co. v. Nat’l Biscuit Co.*, 305 U.S. 111 (1938).

70. See *id.* at 116.

71. See *id.* at 116-17.

72. See *id.* at 119-20.

73. *Id.* at 120.

A. Ability to Identify Medication

Pills potentially have several different “consumers.” Each of these consumers has their own concerns with regard to identifying the medication. The first consumer, a doctor, nurse, or pharmacist, will want to ensure that he is prescribing and/or dispensing the proper medication to the patient.⁷⁴ Once the packaging is removed, the pill color and shape may be the last line of defense as it still serves the purpose of identifying the medication and potentially minimizing errors.⁷⁵ Allowing protection for a unique trade dress would further these goals. If the doctor or pharmacist supports the substitution of generic medications, however, then allowing the same trade dress for both the pioneer as well as the generic drugs would further that goal.

The second consumer is the patient. The patient may want the generic substitution for cost reasons,⁷⁶ but would like the psychological reassurance that the new medication is the same as the original.⁷⁷ Allowing the same color and shape combinations may increase patient compliance in this regard.⁷⁸ Furthermore, the patient may become familiar with a certain color or shape representing a certain type of medication or they mix medications in the same container and then rely upon visual cues to identify the medication.⁷⁹ In contrast, the patient may want assurance that the pill is the same that she has taken successfully in the past, and that it has not been substituted by a generic version. Permitting trade dress protection for the original would assure this clarity. Allowing only one true provider for a drug with a distinct trade dress may also assist with countering

74. See, e.g., James A. Thomas, *The Errors of Error Testing: Potential Liability Issues for Medication Error Testing of Pharmaceutical Trademarks under U.S. Law*, 59 FOOD DRUG L.J. 325, 327 (2004) (describing error testing for medications and mistakes that can occur because of trademarks that are close in name).

75. See Kevin J. McGough, *Reassessing the Protectibility of Prescription and OTC Drug Trade Dress*, 81 TRADEMARK REP. 255, 255-56 (1991); Darrel C. Karl, “Look-alike” Capsules, *Generic Drug Substitution, and the Lanham Act: The Elusive Contributory Infringement Standard of Inwood Lab., Inc. v. Ives Lab., Inc.*, 32 CATH. U.L. REV. 345, 347 (1982) (noting that similar drug colors can facilitate illegal substitution).

76. See Karl, 32 CATH. U. L. REV. at 345 (noting that generic substitution laws favor competitive pricing); see also Melissa K. Davis, Comment, *Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357, 365 (1995).

77. Daniel R. Bereskin, *Brand Name and “Look-Alike” Drugs in Canada after Ciba-Geigy v. Apotex: A Proposal for Relief from Slavish Imitation*, 94 TRADEMARK REP. 1086, 1087 (2004) (citing to arguments presented by generic companies); see also *infra* Part IV.C (discussing psychosomatic effect and patient compliance).

78. *Id.*

79. *Id.*

counterfeits.⁸⁰

The third potential consumer is the hospital or emergency responder. Consistency in pill shape and color for medications and/or dosages could assist emergency personnel when responding to an emergency situation, especially if the patient is unconscious or otherwise unable to communicate. This argument would support consistency in pill shape and color and not support trade dress protection.

B. Bioequivalence

Similarly, the issue of bioequivalence contains public interest concerns that can cut both ways. There is debate about whether two different formulas can ever really be bioequivalent because some patients react differently to filler ingredients, even when the active ingredients are consistent.⁸¹ The only way to make sure that a patient is taking the exact same medication is to not allow substitution. Because similar trade dress can assist or accidentally lead to substitution, requiring different trade dress can alleviate concerns regarding bioequivalence. In contrast, if a drug truly is bioequivalent,⁸² some would argue that substitution should be allowed and that using the same shape and color would assist with substitution and patient compliance.

C. Generic Substitution

One of the public interest arguments in favor of allowing the same pill shape and color for pioneers as well as generics is to support patient compliance with generic substitutions.⁸³ The Hatch-Waxman Act⁸⁴ is a strong policy statement in favor of generics experiencing a smooth entry into the marketplace. It allows development and clinical

80. See generally Merri C. Moken, Comment, *Fake Pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices*, 29 AM. J.L. & MED. 525 (2003) (describing the easy substitution of counterfeit drugs both for original pharmaceuticals as well as generics).

81. See Fritch, *supra* note 35, at 199 (citing COUNCIL ON SCIENTIFIC AFFAIRS AND PUBLIC HEALTH, AMERICAN MEDICAL ASSOCIATION, FEATURED REPORT: GENERIC DRUGS, June 2002, available at <http://www.ama-assn.org/ama/no-index/about-ama/15279.shtml>).

82. See generally CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY BIOEQUIVALENCE RECOMMENDATIONS FOR SPECIFIC PRODUCTS (2010), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072872.pdf>.

83. See *infra* Part IV.C. But see McGough, *supra* note 75, at 261.

84. 35 U.S.C. § 156 (1988).

trials to begin sooner than in the past and for generics to be off and running when the patent for the pioneer drug expires.⁸⁵ Consistent with these public policy goals, allowing the same color and shape would assist generics in competing against the pioneer drug companies. Rejecting this argument, at least one court has recognized that a simple doctor's explanation could alleviate any confusion or anxiety regarding generic substitution, and that when doctors or pharmacists explain that the generic drug is the same as the original, patients generally accept it.⁸⁶

As an argument against allowing generic drugs to use the same shape and color, pioneer drug companies might contend that Hatch-Waxman and other factors already assist generic drug companies' ability to compete in the marketplace.⁸⁷ Additionally, the pioneer drug company was the one who invested in the research and development for the pharmaceutical,⁸⁸ much of which usually does not lead to a marketable drug. To support the progress of science and useful arts,⁸⁹ some compromise should be reached to continue some protection through the identifying function of pill shape and color. The generic drug company may counter that the pioneer drug company already received this protection through its patent. Indeed, one potential downside of extending trade dress protection beyond the life of the patent is that doing so could upset the balance between the limited monopoly of owning a patent and the potentially perpetual protection of trademark.

85. See H.R. REP. NO. 98-857, pt. 2, at 5 (1984).

86. See *Ives Labs., Inc. v. Darby Drug Co.*, 638 F.2d 538, 544-45 (2d Cir. 1981) (judgment reversed by *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982)).

87. Prior to 1984, when Hatch-Waxman passed, generics were less than four percent of total prescriptions in the United States. As of 2006, that number exceeded fifty-three percent. See Fritch, *supra* note 35, at 172 (citing *Examining the Administration's Proposed Health Security Act, To Establish Comprehensive Health Care for Every American: Hearings Before the S. Comm. on Labor and Human Resources*, 103d Cong. 181 (1993) (statement of Lodewijk de Vink, President and CEO, Warner-Lambert Co.)); *Increasing Generic Drug Utilization: Saving Money for Patients: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 109th Cong. 10 (2005) (statement of Kathleen Jaeger, President and CEO, Generic Pharmaceutical Association), available at <http://energy-commerce.house.gov/108/Hearings/05182005hearing1526/Jaeger.pdf>.

88. See *id.* at 173 (citing PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) PHARMACEUTICAL INDUSTRY PROFILE 2006, 2, 45 (2006), available at <http://phrma.org/files/2006IndustryProfile.pdf>).

89. U.S. CONST. art. I., § 8, cl. 8.

IV. APPLICATION OF FUNCTIONALITY TO PILL COLOR AND SHAPE

Taking the general trademark principles and public interest considerations previously discussed and applying them in an analysis of the leading pharmaceutical cases, this next section will separate the cases not by whether color and shape were protectable, but rather by what aspect of the medication was at issue. What precisely made the pharmaceutical functional (or not)? This section will separate federal court and Trademark Trial and Appeal Board (TTAB) decisions into categories relating to flavor, psychosomatic effect, dosage/patient compliance, utilitarian function, arbitrary color/shape selection, generic substitution, and genericide. Ultimately, this section will conclude that color/shape related to psychosomatic effect, dosage, utilitarian function or generic substitution generally have not been protected by trade dress while color/shape arbitrarily selected generally, but not always, have been protected.

A. Flavor and Colors that Indicate Flavor

In one of the first cases examining trademark protection for a pharmaceutical product, the Supreme Court separated the use of chocolate as an ingredient from the unfair trade practices of a competitor. The Court held that the use of chocolate flavor was permissible; whereas the competitor's trade practices of inducing product substitution by druggists was not.⁹⁰ The case, *Warner v. Eli Lilly*, involved the products "Coco-Quinine" and "Quin-Coco." Eli-Lilly produced Coco-Quinine and Warner and Co. produced Quin-Coco. Eli-Lilly added chocolate as an ingredient to impart a distinctive color, but also because it made the preparation more palatable and it served as an effective suspension medium.⁹¹ For these reasons, the Court determined that the color and flavor did more than identify the preparation and could not be monopolized.⁹² Nonetheless, Warner was enjoined because it had been attempting to expand its market by showing druggists that it would be in their best interest to substitute Warner's similar and lower-priced Quin-Coco for Eli-Lilly's Coco-Quinine.⁹³

Similarly, in *In Re N.V. Organon*, the TTAB affirmed the trademark examiner's denial of registration for an orange flavor in an

90. See *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924).

91. See *id.* at 531.

92. See *id.* at 531-32.

93. See *id.* at 529-31.

anti-depressant medication.⁹⁴ The examiner concluded that “the orange flavor gives an orally administered pharmaceutical product a competitive advantage, and that giving applicant exclusive rights to the flavor would place competitors at a substantial competitive disadvantage.”⁹⁵ The applicant argued that the orange flavor did not make the product more effective or impact its cost or quality.⁹⁶ It asserted that the orange flavor was added for a distinctive quality, “to distinguish its product rather than for its flavor.”⁹⁷ Articles submitted in the record suggested that flavor was important for compliance and showed the prevalence of orange flavor in medications.⁹⁸ The Board applied the *Morton-Norwich* factors and gave particular weight to the fact that the applicant’s promotional materials highlighted the utilitarian advantages of the orange flavor, and ultimately determined that the flavor was functional and, hence, could not be protected by trade dress.⁹⁹

B. Psychosomatic Effect

In a decision issued between *Eli-Lilly* and *In re Organon*, the Second Circuit extended functionality considerations and refused to allow trade dress protection for the color pink of Pepto-Bismol because it said that pink had a “psychosomatic effect.” In *Norwich Pharmaceutical Co. v. Sterling Drug*,¹⁰⁰ the Second Circuit denied Pepto-Bismol protection for its bright pink color. The Court determined that the color was functional because it was “soothing” to patients.¹⁰¹ Despite this functionality determination, there was evidence that Sterling Drug selected bright pink for its product, Pepsamar, to mimic Pepto-Bismol.¹⁰² Nonetheless, the court reasoned that there was a “difference between a deliberate attempt to deceive

94. *In re N.V. Organon*, 79 U.S.P.Q.2d 1639 1650 (T.T.A.B. 2006).

95. *Id.* at 1641.

96. *See id.*

97. *Id.*

98. The record cited an article stating that kids like strange flavors, such as “blue raspberry,” whereas adults prefer citrus flavors like lemon, orange, and honey. *Id.* at 1642.

99. *Id.* at 1645.

100. *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959).

101. *Id.* at 573.

102. The color was intentionally selected to build upon the goodwill that had been established by Norwich Pharmacal’s Pepto-Bismol product. If pink is the only color with a soothing effect, then the functionality argument makes sense. However, Sterling Drug could have selected a different color with a similar soothing effect that would not have relied upon the market power of Pepto-Bismol. *Id.*

and a deliberate attempt to compete.”¹⁰³ In this case, according to the Second Circuit, Sterling Drug was trying to compete.¹⁰⁴

An extension of this argument, not yet posed in any cases, is that color possesses a certain inherent quality, and hence one company should not be permitted to monopolize that color because it would limit the competitiveness of other companies. This argument is based more upon aesthetic functionality than traditional utilitarian functionality. For example, studies have shown that blue is thought to be a masculine color, hence the blue color for Viagra.¹⁰⁵ The market acceptance would be much different for a pill for erectile dysfunction that was bright pink. Similarly, studies have shown that purple is thought to be a regal and dignified color, potentially a good choice for an acid reflux drug.¹⁰⁶

C. Patient Compliance; Color/Shape Indicates Dosage

The selections of palatable flavors and colors that have a psychosomatic effect have been linked to another reason where courts have found functionality: patient compliance. In the flavor cases, patients, especially children, were more likely to take their medication if it tasted good.¹⁰⁷ In the Coco-Quinine/Quin-Coco case, the chocolate flavor and color was chosen in part because it was believed that patients would take a medicine that tasted like chocolate.¹⁰⁸ In the Pepto-Bismol case, if pink were perceived as soothing, then it made the color more desirable and consumers would use the medication.¹⁰⁹

Sometimes the kind of ailment seems to have influenced courts when they are assessing functionality in support of patient compliance. For example, the orange-flavored medication in *In re Organon* was an anti-depressant.¹¹⁰ The Board may have been influenced by the general unwillingness of depressed patients to be compliant with taking their medications and this seemed relevant to its functionality determination.¹¹¹

103. *Norwich*, 271 F.2d at 572.

104. *Id.*

105. See Fritch, *supra* note 35, at 182 (citing Charles W. Schmidt, *Have I Got a Drug for You!*, MODERN DRUG DISCOVERY, Dec. 2001, at 41, available at <http://pubs.acs.org/subscribe/journals/mdd/v04/i12/html/12money.html>).

106. *Id.* at 182.

107. *In re N.V. Organon*, 79 U.S.P.Q.2d 1639, 1641-42(T.T.A.B. 2006).

108. *Warner*, 265 U.S. at 529, 531.

109. *Norwich* 271 F.2d at 526.

110. *In re N.V. Organon*, 79 U.S.P.Q.2d at 1640.

111. See generally *In re N.V. Organon*, 79 U.S.P.Q.2d. 1639

Patient compliance also seemed to influence the Third Circuit in *Shire v. Barr Laboratories*,¹¹² where the patients had attention deficit hyperactivity disorder (ADHD). In *Shire*, the court admitted testimony as to why the color coding was important to ADHD patients:

[B]ecause ADHD patients overuse visual cues, (1) when therapeutically equivalent ADHD products have similar visual recognition properties, adult ADHD patients will experience less confusion in correctly identifying the agent and/or its dosage strength; (2) given that almost all patients required some initial dosage titration and a subsequent substantial majority required intermittent dosage adjustment, the color coding of a particular preparation of mixed amphetamine salts tablets confers a substantial degree of clinical functionality for the patient in the titration/adjustment process; (3) many adult patients may take multiple daily dosages of different strength amphetamine salts tablets, also inferring the usefulness of similar color-coding.¹¹³

The patient compliance in *Shire* was also linked to the fact that the medication, Adderall, came in two different dosages with colors and shapes to indicate the strength. Originally the pills came in two dosages and two colors: 10 mg. (blue/round) and 20 mg. (orange/round).¹¹⁴ At the time of the dispute there were seven variations, all indicated by size and color: 5 mg. (blue/round); 7.5 mg. (blue/oval); 10 mg. (blue/round); 12.5 mg. orange/peach, round); 15 mg. (orange/peach, oval); 20 mg. (orange/peach, round); and 30 mg. (orange/peach, round).¹¹⁵ The tablets were scored and had “AD” stamped on one side and the dosage stamped on the other.¹¹⁶ Although the colors and shapes may have been arbitrarily selected, their color and shape were indicative of a particular dosage, with up to seven variations for the ADHD patients, thus making the color in combination with the size and shape of the pills functional according to the court.¹¹⁷

D. Color/Shape Serve a Utilitarian Function

These cases compare to more traditional utilitarian functions, such as the pills in *Smith Kline & French Laboratories v. Clark &*

112. *Shire U.S., Inc. v. Barr Labs., Inc.*, 329 F.3d 348 (3d Cir. 2003).

113. *Id.* at 354.

114. *Id.* at 350.

115. *Id.*

116. *Id.*

117. *See id.* at 352.

Clark.¹¹⁸ In *Clark*, the Third Circuit agreed that the pills were functional, although the court ultimately supported its determinations under unfair trade practices.¹¹⁹ The functional features of the pills recognized by the court included the scoring and shape of the edges and the color.¹²⁰ The scored design allowed for easier breaking of the pills and the edges kept the pills from crumbling.¹²¹ The pills' color, white, was the natural color of the compound.¹²² To change the color would require an additional manufacturing step. It is easy to see how these features serve utilitarian functional purposes and that the manufacturer should not be permitted to monopolize these characteristics.

E. Arbitrary Combination of Color and Shape

When color and shape have been arbitrarily selected and marketed, however, courts have generally upheld the selection and permitted trade dress protection.¹²³ In *Ross-Whitney v. Smith Kline & French Laboratories*,¹²⁴ one of the earlier pill color cases, the Ninth Circuit upheld protection for heart-shaped pills in orange and pink. Smith, Kline & French (SKF) had patents on benzyl methyl carbinimine, which it marketed under the trademark "Benzedrine," and dextro-amphetamine sulfate, which it marketed under the trademark "Dexedrine."¹²⁵ Initially SKF sold Benzedrine in a round, white tablet, with beveled edges and a concave bottom.¹²⁶ It sold Dexedrine in a similar shape in yellow.¹²⁷ A few months prior to expiration of the patents,¹²⁸ SKF changed the colors of the pills to pinkish-brown for Benzedrine and orange for Dexedrine.¹²⁹ It also changed the shape to resemble a Valentine's heart.¹³⁰ From 1949 to

118. *Smith, Kline & French Labs. v. Clark & Clark*, 157 F.2d 725 (3d Cir. 1946).

119. *See id.* at 730-31.

120. *Id.* at 730.

121. *Id.*

122. *Id.*

123. *See Bereskin, supra* note 77, at 1087.

124. *Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190 (9th Cir. 1953).

125. *Id.* at 191-92.

126. *Id.* at 192.

127. *See id.*

128. Compare this patent in the compound to the patent for manufacturing the alleged trade dress in the shredded wheat case. The patent in the compound enables the manufacturer to copy the active ingredients. This does not necessarily lead to copying the trade dress as it did in *Kellogg*.

129. *Ross-Whitney*, 207 F.2d at 192.

130. *Id.*

1951, SKF spent in excess of \$1.2 million to advertise the new shape and color.¹³¹ In 1951, Ross-Whitney, doing business as the Heart Pharmaceutical Co. of California, produced a dextro-amphetamine sulfate pill, in the same shape and color as Dexedrine, and advertised it as "Heart Brand Dexedrine."¹³²

The district court determined that Dexedrine was marketed "in a unique, distinctive, non-functional, well-advertised color and shape combination which ha[d] acquired a secondary meaning."¹³³ The court also found copying, palming off by some pharmacists, which was possible because of the counterfeit tablets, that Dexedrine was not a generic name, and that some of the generic pills were not of the same potency as the original. The court concluded that "neither the trademark Dexedrine nor the shape-color combination of SKF's tablets [was] in the public domain"¹³⁴ and held that there had been unfair competition. The Ninth Circuit upheld the district court's determinations, reasoning that there was clear evidence that the shape and color were intended to identify SKF's Dexedrine.¹³⁵ According to the Ninth Circuit, "[t]he wrong was in designedly enabling the dealers to palm off the preparation as that of (SKF)."¹³⁶ Hence, SKF's unique shape and color were protected.

Similarly in *Boehringer Ingelheim G.m.b.H v. Pharmadyne Laboratories*,¹³⁷ a district court upheld trade dress protection when the color and shape were arbitrarily selected and not related to the therapeutic effect of the medication.¹³⁸ Boehringer marketed its pill, Dipridamole, in small orange biconvex tablets for more than 15 years.¹³⁹ Boehringer had not selected the shape to be easier to break or the color to represent a particular flavor or dosage.¹⁴⁰ The only differences between the competitor's pills were small logos imprinted on the pills.¹⁴¹ Because Boehringer's trade dress was not functional and the company proved secondary meaning, the court forbade

131. *See id.*

132. *Id.*

133. *Id.* at 192.

134. *Id.* at 193.

135. *See id.* at 196. The court did not determine, "[w]hether or not the heart shape is functional in that it prevents the tablet from rolling away when dropped." *Id.*

136. *Id.* at 197 (citing *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 530 (1924)).

137. *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*, 532 F. Supp. 1040 (D.N.J. 1980).

138. *See id.* at 1057.

139. *See id.* at 1056.

140. *See id.* at 1057.

141. *See id.* at 1045.

Pharmadyne from copying the unique trade dress.¹⁴² Other examples of successful arbitrary combinations of color and shape include the little blue pill, Viagra,¹⁴³ and the purple pill with yellow stripes, Nexium.¹⁴⁴

F. Generic Substitution/Genericide

Courts have not always upheld trade dress protection of an arbitrary selection of pill shape and color. In *Marion Laboratories v. Michigan Pharmacal*,¹⁴⁵ for example, a district court denied protection for a clear and brown gelatin capsule. The drug at issue was a vasodilator that originally was available only by tablet or injection, which had to be administered every two hours.¹⁴⁶ The drug fell into disuse until Marion decided to produce the drug in a sustained-release form, requiring administration only every eight to twelve hours.¹⁴⁷ The capsule itself was purchased from Eli Lilly and Co.¹⁴⁸ Eli Lilly produced a color wheel demonstrating 12,000 possible color combinations. Marion selected clear and brown for its capsule and expended \$2.5 million between 1970 and 1971 to advertise its trademarked product, Pavabid.¹⁴⁹

The defendant, Michigan Pharmacal, copied both the time-release formula and the brown and clear capsule.¹⁵⁰ Michigan Pharmacal was not alone, as 30 to 40 other companies also began distributing the vasodilator in brown and clear capsules.¹⁵¹ Thus, out of the 12,000 color combinations possible, Marion's competitors, including Michigan Pharmacal, all selected brown and clear capsules.¹⁵² Marion lost its case in part because it failed to prove secondary meaning.¹⁵³ Although the court did not equate its determinations to genericide, essentially that is what happened. Eli

142. See *id.* at 1067.

143. See, e.g., *Meeting the Pharma Challenge*, WORLD TRADEMARK REV. 52 (Nov./Dec. 2006), available at <http://www.worldtrademarkreview.com> (discussing international protection for light blue and unique geometric shaped pharmaceuticals).

144. See generally Fritch, *supra* note 35 (noting that purple pill also has yellow stripes).

145. *Marion Labs., Inc. v. Mich. Pharmacal Corp.*, 338 F. Supp. 762 (1972).

146. See *id.* at 768.

147. See *id.*

148. See *id.*

149. See *id.* at 764, 768.

150. See *id.* at 768.

151. See *id.*

152. See *id.*

153. See *id.* at 769.

Lilly had spent \$2.5 million dollars in one year on marketing,¹⁵⁴ and normally this would support a finding of secondary meaning.¹⁵⁵ The only reason that brown and clear was used by at least thirty others was to copy and usurp the goodwill established by Marion. Marion's efforts thus led to genericide of its brown and clear capsule as that became the industry standard allowing others to trade off of Marion's expenditures and goodwill.

Contrast the *Marion* case with the famous *Smith, Kline, & French v. Premo Pharmaceutical Laboratories*¹⁵⁶ case, where competitors selected a variety of different color combinations. In *Premo*, the plaintiff's maroon and white color combination also was arbitrarily selected, yet its competitors chose other color combinations. Premo, the producer of the generic form of the drug, selected the same trade dress as SKF and entered testimony that copying the color combination was desirable in the pharmaceutical industry for identification of medications, to ensure proper dispensing, and for rapid identification in emergency situations.¹⁵⁷ Other leading pharmaceutical manufacturers, however, sold different drugs also in a maroon/white or dark red/white combination, thus undercutting the argument for standardization.¹⁵⁸ In addition, the court reasoned that the color was not functional because the identical drug combination as SKF's was successfully marketed in an orange tablet.¹⁵⁹ Therefore, the color combination was found not to be functional, because it was arbitrarily selected, there were other successful products with different colors in the same market, and there were similar colors for pills for different medications.¹⁶⁰

In one of the seminal drug cases, *Inwood Laboratories v. Ives Laboratories*,¹⁶¹ the Supreme Court considered whether the manufacturer of a generic drug, which copied the appearance of a competitor's drug, could be held vicariously liable for pharmacists who mislabeled the generic drugs with the competitor's registered trademark. Ives had a patent on the drug cyclandelate, a vasodilator

154. See *id.* at 764.

155. See e.g., Deborah F. Buckman, Annot., *When is trade dress "inherently distinctive" for purposes of trade dress infringement actions under § 43(a) of Lanham Act (15 U.S.C.A. § 1125(a)) — Cases after Two Pesos*, 161 A.L.R. FED. 327 (2000) (collecting cases).

156. *SK&F v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055 (3rd Cir. 1980).

157. See *id.* at 1060.

158. See *id.*

159. See *id.* at 1064.

160. See *id.* at 1063.

161. *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982).

intended for vascular diseases. It sold the drug in blue capsules with “Ives 4124” imprinted for the 200 mg. dosage and blue/red capsules imprinted with “Ives 4148” for the 400 mg. dosage.¹⁶² When the patent expired, several generic drug manufacturers began marketing the generic version of Ives’ “Cyclospasmol” in the same color combinations.¹⁶³ Some pharmacists mislabeled and dispensed the generic drugs as Cyclospasmol.¹⁶⁴

Ives argued that the colors were not functional and that they had acquired secondary meaning.¹⁶⁵ More importantly, they argued “that pharmacists would continue to mislabel generic drugs as CYCLOSPASMOL so long as imitative products were available.”¹⁶⁶ Denying Ives’ claims and its request for injunctive relief, the Court determined that the court of appeals erred when it rejected some of the district court’s findings, which were not clearly erroneous.¹⁶⁷ Among these were the district court’s conclusions that the blue and blue/red colors were functional because:

many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. . . . In addition, because Ives had failed to show that the colors indicated the drug’s origin, the court found that the colors had not acquired a secondary meaning.¹⁶⁸

In addition to the policy considerations, the plaintiff had failed to prove secondary meaning.¹⁶⁹ Although the Court did not mention it explicitly, part of their reasoning for pill identification may have been influenced by the fact that the pills were blue or a combination of red and blue, which could have aided in identifying a heart medication. This is also a situation where different colors represented different dosages.

In another generic substitution case, *American Home Products v.*

162. *Id.* at 846-47.

163. *Id.* at 847.

164. *See id.*, n.4.

165. *Id.* at 850-51.

166. *Id.* at 851.

167. *See id.* at 855-58.

168. *Id.* at 853.

169. *Id.*

Barr Laboratories,¹⁷⁰ a district court found that there was no likelihood of confusion between plaintiff's trademarked Advil product and defendant's generic ibuprofen. The court compared the two pills and although they were similar in color, the defendants argued that they differed in shape, surface finish, and labeling."¹⁷¹ The court noted that the color, shape, sheen, and label of Advil, presented an overall "'high style' 'high design,' perhaps even 'high tech,' look"¹⁷² The generic ibuprofen, in contrast, was more of a flat brown.¹⁷³ It was thick like traditional aspirin, rather than convex like Advil.¹⁷⁴ It was not shiny like Advil and its mark was stamped, rather than printed on the pill.¹⁷⁵ The court concluded that the consumer would not likely be confused given these differences in appearance.¹⁷⁶ Unlike in the prescription cases where sometimes the only distinguishing feature is the color and/or shape of the pharmaceutical, this over-the-counter drug also had distinguishing boxes, bottles, labels and promotional materials.¹⁷⁷

V. PROPOSED SOLUTIONS/REGULATORY OPTIONS

Taking these various court decisions and public interest concerns into account, following are a list of suggestions for regulating pill shape and color.

A. *Color/Shape Should Not Become Functional by Genericide as a Result of Creating Secondary Meaning*

In the non-trade dress context, genericide will occur when the trademark comes to be associated with the genus, rather than the species, of a product.¹⁷⁸ However, for color, shape and product design, the owner must extensively advertise and promote its product to create the secondary meaning.¹⁷⁹ It seems that the more successful the product, then, the more likely that it will become "generic" in the

170. *American Home Prods. Corp. v. Barr Labs., Inc.*, 656 F. Supp. 1058 (D.N.J. 1987).

171. *Id.* at 1064.

172. *Id.* at 1063.

173. *See id.* at 1064.

174. *See id.*

175. *See id.*

176. *See id.* at 1068.

177. *See id.* at 1068-69.

178. *See A.J. Canfield Co. v. Honickman*, 808 F.2d 291, 298 (3d Cir. 1986).

179. *See generally* David E. Rigney, Annotation, *Application of secondary meaning test in action for trade dress infringement under § 43(a) of Lanham Act (15 U.S.C.A. § 1125(a))*, 87 A.L.R. FED. 15 (1988).

mind of consumers, as it did in the *Ives* case.¹⁸⁰ It has been argued that this popularity should be a reason to award the particular protection for the shape or color because it can support secondary meaning, rather than allow it to be a means for genericide.¹⁸¹ Furthermore, it has been argued that when a color and/or shape are arbitrarily selected to indicate the source, there should be no finding of functionality.¹⁸² This article supports these arguments.

Although not directly addressed in case law, the reality is that when owners are investing enough resources in the marketing of their product to create an association in the minds' of the public, then the color/shape begins to assume a meaning other than just identifying the source of the good. This sort of genericide potentially leads to a finding of functionality by some courts and an exclusion of protection of otherwise acceptable trade dress. As argued below, if the color and or shape were to become functional or generic because it is accepted as the industry standard, then the FDA should set this standard, not generics that enter the market with the same design as the pioneer.

The *Marion* and *Ives* cases represent the scenario where a pharmaceutical color and/or shape become functional after the period of use necessary to create secondary meaning.¹⁸³ In *Marion*, several competitors free-rode on Marion's goodwill and adopted the same color scheme.¹⁸⁴ In the *Ives* case, patients had come to associate the drug color and shape with its therapeutic effects and *Ives* was unable to establish secondary meaning.¹⁸⁵ The consumers recognized it as a heart medication, rather than as the particular pharmaceutical or as being associated with a particular manufacturer. As the plaintiff argued in *Ives*, it is the similarity of the medications that make illegal substitution and unfair competition practices even possible.¹⁸⁶ "It was the manufacturers' use of capsules identical in size, shape, and color

180. See 3 CALLMANN, *supra* note 40, § 19:8.

181. See McGough, *supra* note 75, at 256-57. "[W]ith a few possible exceptions, the protectibility of prescription trade dress should not be analyzed in terms of functionality." *Id.* Instead, McGough contends, the analysis should focus on whether the trade dress actually is generic. See *id.*

182. See Karl, *supra* note 75, at 367 (arguing that functionality should not act as a shield when people intentionally pass off their goods). See also Bereskin, *supra* note 77, at 1087 ("In the case of pharmaceutical get-ups, usually there is no utilitarian, cost or quality reason sufficient to justify making a generic product look like the brand name product").

183. See *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982); see *Marion Labs., Inc. v. Mich. Pharmacal Corp.*, 338 F. Supp. 762 (E.D. Mich., S.D. 1972).

184. *Marion*, 338 F. Supp. 762.

185. *Inwood*, 456 U.S. 844.

186. See Karl, *supra* note 75, at 346.

to ‘Cyclospasmol,’ together with the catalogs comparing the appearances and prices of the two drugs, that amounted to ‘suggestion by implication.’”¹⁸⁷ Without the color and shape similarities, one would question whether the unfair trade practices resulting with illegal substitution would be as likely to occur.

To draw some contrasts with the *Marion* case, it seems illogical that one company (Marion) should be penalized for its success and the fact that its arbitrarily selected color combination was copied, while another company (SKF) should be rewarded because there were some competitors who did not copy its color combination. Defendant Premo¹⁸⁸ was in the same position as defendant Michigan¹⁸⁹—both copied the color combinations and attempted to ride on someone else’s goodwill and marketing efforts. Yet, in *Marion*,¹⁹⁰ a form of genericide took place, while in *Premo*¹⁹¹ it did not.

Even in *Shire*, there was some blurring between secondary meaning and functionality. As David Fritch notes in his article, “Should ‘The Purple Pill’ by any other Drug Company still be as Purple? The Changing Face of Trade Dress Protection for Pharmaceutical Manufacturers:”

The very elements of Shire’s trade dress that the Shire court found to give the color scheme functionality, however, are the source of the scheme’s secondary meaning and trademark protection. . . . In the case of generic drugs, any therapeutic benefit derived from the familiarity of a pill’s color is because the brand name manufacturer created secondary meaning in their pill’s color scheme.

When a patient takes a generic drug that looks identical to its brand-name counterpart, the purported ‘therapeutic benefit’ from the identical color scheme is derived from the patient’s strong association between the pill’s color and its perceived source.¹⁹²

Hence, the function of the pill actually resulted from the patients’ perception that they were taking the prescription drug Adderall, rather than the active ingredient shared with the generic drug.¹⁹³ This functionality is then linked to the purpose of requiring development of secondary meaning, and usually afforded benefit for

187. *Id.* at 365 (quoting *Ives*, 638 F.2d at 542).

188. *SK&F v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055 (3rd Cir. 1980).

189. *Marion*, 338 F. Supp. 762.

190. *Id.*

191. *SK&F*, 625 F.2d 1055.

192. Fritch, *supra* note 35, at 195.

193. *See id.*

this success. “The Shire Court, however, found the elements of secondary meaning to be a functional characteristic and grounds for denying protection for Shire’s trade dress.”¹⁹⁴

Furthermore, as Daniel Bereskin argues in his article on look-alike drugs, “it surely must also be the case that patients, who have relied upon a medication for many months or years, including patients who associate the [trade dress] with a particular medicine, believe that the medicine comes from a particular source and they have learned to trust that source.”¹⁹⁵ The patients make an association that is a result of the effort expending to acquire secondary meaning or from long-time use of a particular drug. They associate the drug with the source that they have come to expect, even if the trade dress also signifies a particular kind of drug to them. The fact that the trade dress indicates a single source should be enough to afford protection.¹⁹⁶

B. Generic Substitution Should Not Be a Reason for Color/Shape to Be Functional

Nonetheless, the argument could be made that generic substitution and patient acceptance of generics should be a reason to allow substitution of confusingly similar color and shape. After all, it furthers the goals of the Hatch-Waxman Act.¹⁹⁷ However, intentional confusion runs counter to the Lanham Act.¹⁹⁸ If we are to provide trade dress protection at all, then we should require differences in appearance. Consumers have the right to know that a generic drug is actually provided by a different manufacturer and allow them to choose the lower-priced option, rather than forcing compliance by presenting them with confusing trade dress.¹⁹⁹ This is particularly important in prescription drugs where packaging and other features that might eliminate confusion are no longer present.

For example, part of the problem in *Ives* was that the district court had determined that there was no secondary meaning because *Ives* had failed to show that the colors indicated the drug’s origin.²⁰⁰

194. *See id.*

195. Bereskin, *supra* note 77, at 1092.

196. *See* Aaron M. Pile, *What’s in Your Bottle? Shire US Inc. v. Barr Laboratories Inc. and its Effect on Prescription Drug Trade Dress Protection in the Third Circuit*, 5 U. PITT. J. TECH. L. POL’Y 1, 2 (2005).

197. *See* 35 U.S.C. § 156 (2006).

198. *See* 15 U.S.C. § 1125(a) (2006).

199. *See* Bereskin, *supra* note 77, at 1087 (arguing that trade dress is an important aspect of a patient’s right to choose the source of his medicine).

200. *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 853 (1982).

The same issue arose in *Shire*.²⁰¹ One reason that a drug may not be associated with its source might very well be because generic drugs are allowed to enter the market with the same color scheme. Consumers would not expect a particular color scheme, even one that is arbitrarily selected and not affiliated with dosage, to be associated with a particular manufacturer if anyone can enter the market with the same trade dress. If the feature is a generic one, like the chocolate dipped cookies, or if the patent had dictated the shape and color, like the shredded wheat, had expired, then the situation would be different.

In pharmaceuticals, however, there is a self-fulfilling prophecy that drug color is associated with the genus of medication, not the species or the source. For example, a company expends money to gain market share and identifiable trademarks and trade dress. As soon as competitors can enter the market, they intentionally adopt the same trade dress and confuse consumers. Consumers thus begin to associate the trade dress with the kind of medication (the genus), not the source (the species).²⁰² No secondary meaning is found despite the fact that the only reason that there is an association is due to the investment by the pioneer company to create the association in the minds of the consumers.

Furthermore, the secondary meaning and functionality are now blurred (not to mention genericide) and the trade dress is “functional” because it now represents a type of medication. The effort that was required to gain protection now negates that same protection. If this is a desired result, then the shape and color of a drug should be regulated by the FDA along with the generic approval process, rather than by applying circular reasoning for secondary meaning and functionality and blurring these with the parallel purpose of genericide.

C. Functionality Should Be Determined When Adopted

At a minimum, functionality should be clearly removed from secondary meaning and could be determined at the time that it is adopted.²⁰³ A manufacturer can thus still use the traditional methods to prove that it has acquired secondary meaning in the marketplace. If

201. *Shire U.S., Inc. v. Barr Labs., Inc.* 329 F.3d 348, 358 (3d Cir. 2003).

202. *See Bereskin, supra* note 78, at 1087 (arguing that allowing generic imitation actually leads to consumer confusion).

203. *See Pile, supra* note 196, at 8 (arguing that functionality should play less significant role in determination of trade dress infringement and also lessening role of distinctiveness).

the functionality determination were made at the time that the trade dress were adopted, then it would not get confused with this analysis—the color would not become “functional” over time. This is the inverse of Callmann’s statement in his treatise’s section on functionality: “In the case of functional features . . . they do not lose their functional character despite the acquisition of secondary meaning, or even despite any inherent distinctiveness. Competitors still have the same legitimate need to employ [the feature] for their functional advantages.”²⁰⁴ Likewise, a feature should not acquire functionality because it has acquired distinctiveness.

At the time that a color, shape, or flavor is adopted it either serves a functional purpose or it does not. The orange and chocolate flavors were functional when they were adopted because they made the medication more palatable. The seven different color/shape schemes for the ADHD medication were functional when they were adopted because they indicated the relative dosage, not just the manufacturer. The brown and clear capsules, the blue capsules, the blue and red capsules, the maroon and white capsules, all served no functional purpose when they were adopted. It would be the manufacturer’s separate burden in those cases to show that they had acquired secondary meaning, but at least that determination would not be blurred with an assessment of functionality and generic substitution.

Similarly aesthetic functionality should be determined at the time that an appearance is chosen. A color and shape that is arbitrarily selected does not add to the aesthetic of the product. The consuming public does not purchase a pharmaceutical necessarily because they like the color or shape of the product, but rather because they recognize it. After extensive advertising campaigns, consumers recognize “the purple pill” or the “little blue pill.” These features do not necessarily make the product more desirable or attractive to the consumer; they merely make the product more memorable in the minds of consumers. This is not a non-reputational need; it is a reputation-related need. As the Ninth Circuit has stated the distinction: “A feature which gives the consumer a substantial reason for purchasing the product, as opposed to merely to distinguishing it from other products, is functional. By contrast, if a feature serves primarily to identify a product and does not contribute substantially to the product’s value, as determined by consumers, it is non-functional

204. 3 CALLMANN, *supra* note 40, at § 19:7.

and may not be copied.”²⁰⁵ The generic company or other competitor wants to build upon the reputation of the pioneer company to be able to compete; this is not the same thing as aesthetic functionality.

D. Industry Standards and Generic Use of Color/Shape Should Be Regulated by the FDA, Not Courts or the USPTO

Ultimately, courts and the USPTO are not the proper venues to determine the functionality of colors and shapes for pharmaceuticals.²⁰⁶ The authority more properly rests with the FDA.²⁰⁷ In error medication testing, for example, the FDA’s focus is “not on commercial rights, but on the risk of medication-dispensing errors.”²⁰⁸ This focus would be appropriate to make objective determinations regarding color and shape. These objective determinations would then lead to commercial implications, but not necessarily be made because of them.

In fact, the FDA already has a procedure in place for approval of trademarks on pharmaceuticals.²⁰⁹ This procedure could be extended to include an assessment of trade dress color and shape. When the color and shape are adopted, the FDA could determine whether they are functional and make the parallel determination whether they should become the industry standard due to the psychosomatic effect of the particular color, the need to distinguish between a variety of dosages, or the suggestion that the color represents a particular kind of medication. If the color, color combination and/or shape are arbitrarily selected, however, the FDA will likely not determine that it should be the industry standard and the pioneer company then still would have the burden to develop and prove secondary meaning. If the pioneer company knows from the beginning that the color or combination will become the industry standard, then it might decide to invest fewer resources in marketing those features.

In the FDA, the Center for Drug Evaluation and Research

205. *Famolare, Inc. v. Melville Corp.*, 472 F. Supp. 738, 743 (D. Haw. 1979).

206. *See Karl, supra note 75*, at 366 (stating, “It is difficult to conclude that color can be a functional attribute of a drug capsule or tablet in the absence of a universal color identification standard.”)

207. *See, e.g., Bereskin, supra note 77*, at 1102. Footnote 14 in Bereskin’s article, *id.* at 1089, notes that there was an initiative launched prior to 1984 in the United States for the FDA, but it was rejected because appearance was not closely enough related to safety or effectiveness. If this is the case, then should compliance and patient safety be arguments for functionality? If there are no safety or effectiveness concern for FDA to regulate, then shouldn’t this be a basis for supporting functionality and substitution?

208. *Thomas, supra note 74*, at 326.

209. *See 3 McCarthy, supra note 31*, at § 19:149

(CDER) has transferred the authority for reviewing proposed pharmaceutical trademarks to the Division of Medication Errors and Technical Support (DMETS) of the Office of Drug Safety (ODS).²¹⁰ “DMETS’s purpose is to minimize medication errors resulting from trademarks for pharmaceuticals that look or sound like currently marketed drug names, other medicinal products, or commonly used medical abbreviations, medical procedures, and/or lab tests.”²¹¹

During Phase II of clinical trials, companies submit proposed package insert labeling, a visual representation of the proposed label, including two possible trademarks.²¹² The trademark is then reviewed for name suitability (i.e. does it imply a clinical process unsupported by clinical data or is it too similar to the generic drug name).²¹³ When reviewing the proposed trademark, the DMETS attempts to simulate the prescription process to predict confusion.²¹⁴ It uses input from doctors, pharmacists, nurses, and other health care practitioners.²¹⁵ The name is tested for both the written and verbal prescription process.²¹⁶ The trademark undergoes a second review ninety days prior to the formal approval of the drug to compare it to any subsequently approved trademarks.²¹⁷ Even though the drugs may be prescriptions, “the rule regarding a lesser degree of likelihood of confusion for medicinal products should control over the suggested ‘sophistication’ of physicians and pharmacists.”²¹⁸ Furthermore, if a prescription and a non-prescription drug have similar names, people who self-diagnose may be misled into believing that they are equivalent.²¹⁹

Admittedly, the FDA evaluation of the trademark and a USPTO evaluation serve different purposes: the DMETS considers whether the trademark would be confused by health practitioners or pharmaceuticals whereas the USPTO assesses confusion by anyone, including consumers.²²⁰ Accordingly, the FDA’s standard of proof to

210. *See id.*

211. *Id.*

212. *See id.*

213. *See id.*

214. *See id.*

215. *See id.*

216. *See id.*

217. *See id.*

218. *See* 4 MCCARTHY, *supra* note 31, § 23:32 (citing *Glenwood Labs., Inc. v. Am. Home Prods. Corp.*, 455 F.2d 1384 (C.C.P.A. 1972)).

219. *See id.* (citing *Eli Lilly & Co. v. Natural Answers, Inc. Inc.*, 233 F.3d 456, 56 U.S.P.Q.2d 1942 (7th Cir. 2000)).

220. *See* 3 MCCARTHY, *supra* note 31, § 19:150.

show a likelihood of confusion with drug and pharmaceutical names is different than that of the USPTO: the Lanham Act covers confusion as to source as well as confusion between products.²²¹

Despite the different concerns, it seems that if the confusion is addressed at the source, when the drugs are approved by the FDA, that this would limit the permissibility of pharmaceuticals with confusingly similar trade dress to enter the market. This is particularly true with regard to generic drugs, despite the expedited process that is accorded generic drugs to enter the market more quickly after Hatch-Waxman.²²² The USPTO and courts could then serve as a backstop for broader consumer likelihood of confusion and secondary meaning concerns. The DMETS is already in place to assess the likelihood of confusion between pharmaceuticals for verbal and written confusion. It would be a logical step to add sight for trade dress to this assessment. Thus, if the color is not the industry standard, then the pioneer would still need to invest enough to develop secondary meaning. This would eliminate genericide, unless after the term of the patent for the pioneer drug, the pioneer is unable to establish secondary meaning. It would also eliminate the stretching of functionality to extend beyond utilitarian and aesthetic functionality.

Accordingly, the FDA could determine when it would be industry-accepted practice for color or shape to signify a particular dosage or that the color has a unique psychosomatic effect. Whereas examiners and judges have been influenced by the kind of ailment at issue, the FDA would be in the best place to assess whether the particular visual cues are necessary for compliance or whether the shape and color that indicate a particular dosage should be accepted as an industry standard.

E. No Trade Dress Protection for Flavor

Finally, colors that represent flavors or flavors themselves are the one category where there are legitimate scarcity and utilitarian functionality arguments and because trade dress protection should not be available, no regulation is necessary.²²³ This standard would be consistent with non-pharmaceutical cases, such as *Dippin Dots v. Frosty Bites Distribution*, where the Eleventh Circuit held that the colors used in ice cream were functional because they suggested

221. See *id.* (citing *KOS Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700 (3rd Cir. 2004)); see also Thomas, *supra* note 74, at 326.

222. 35 U.S.C. § 156 (1984).

223. See 3 CALLMANN, *supra* note 40, § 19:8.

particular flavors.²²⁴

For medicinal preparations and pills that dissolve, there are only a few flavors that are competitive (i.e. palatable). A quick tour of the over-the-counter section of the pharmacy reveals the popularity of lemon, orange, grape, cherry, honey, and mint. As the Board recognized in *In Re Organon*, certain flavors are more palatable to consumers, such as citrus flavors for adults and berry flavors for children. To allow manufacturers to corner a monopoly on these flavors would have anti-competitive effects, such as the TTAB determined in the *Organon*²²⁵ proceeding. If there is a flavor associated with a particular medication, the functionality limitation would naturally relate to the use of color to represent that particular flavor, for example orange color to represent orange flavor.

CONCLUSION

“Unlike in other industries, several courts have denied protection where it can be demonstrated that the product design serves any useful purpose to the doctor or patient—including the ability to distinguish the product from others in the marketplace.”²²⁶ This useful purpose is being called a functional feature, even when it does not fit the traditional notions of utilitarian or aesthetic functionality.

My proposed solution is to clearly separate secondary meaning and genericide from functionality so that they serve complementary rather than opposing purposes. Accordingly, one possible solution is to assess functionality at the time when the color/shape is adopted, not at the time of assessing secondary meaning. In addition, if generic drug companies or other competitors are allowed to use the same trade dress as the pioneer company, then this determination should be made by the FDA, not the courts or the USPTO. The FDA could also determine industry standards for a particular medication rather than a determination of genericide by the courts. In addition, the FDA could make decisions regarding industry standards regarding acceptable trade dress for dosage specifications.

Ultimately, a pill’s shape or color should be determined to be functional because it meets traditional definitions of utilitarian and aesthetic functionality, not because a court determines that it is

224. *Dippin’ Dots Inc. v. Frosty Bites Distribution, LLC*, 369 F.3d 1197, 1203-4 (11th Cir. 2004).

225. See 3 CALLMANN, *supra* note 40, § 19:8.

226. Julia Anne Matheson & Michael R. Justus, *Eye Candy*, MM&M, Apr. 2009, at 56, available at http://media.haymarketmedia.com/documents/2/eye%20candy_1542.pdf.

functional as a result of the effort expended to create secondary meaning or that there is an "industry standard" because the second comers have intentionally copied the pioneer.