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Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and a Prescription for Reform

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Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and a Prescription for Reform

Dana M. Herberholz*

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INTRODUCTION

ZANTAC^{®1} and XANAX^{®2} are not cities in China or galaxies explored by Captain Kirk. Nor do LAMISIL^{®3} and LAMICTAL^{®4} refer to sick farm animals. In fact, these peculiar terms, which share both a similar handwritten appearance and similar sound, are actually the unique brand names of four popular prescription drugs. As with any brand name or trademark, using these drug names in a manner likely to confuse consumers jeopardizes the goodwill of the trademark owner and threatens fair competition. For this reason, like any other good or service, drug trademarks must remain subject to regulation to ensure fair, robust competition.

There is a much more compelling reason to minimize confusion among prescription drug names, however. That reason is protecting lives. According to the Food and Drug Administration (FDA), such confusion among look-alike and sound-alike drugs accounts for approximately ten percent of all reported medication errors⁵ and injures approximately 1.3 million people every year.⁶ One example involved an eight-year-old boy who was to be treated for Attention Deficit Disorder with the drug methylphenidate but died after being prescribed and ingesting methadone, the opiate-based drug used to treat heroin withdrawal.⁷ In addition, a fifty-year-old

1. ZANTAC Home Page, <http://zantac.com> (last visited Jan. 20, 2007) (stating that ZANTAC helps fight Gastroesophageal Reflux Disease).

2. XANAX Home Page, <http://www.anxietyinfo.com> (last visited Jan. 20, 2007) (stating that XANAX helps fight anxiety disorders).

3. LAMISIL Home Page, <http://www.lamisil.com> (last visited Jan. 20, 2007) (stating that LAMISIL helps fight nail fungus).

4. LAMICTAL Home Page, <http://www.lamictal.com> (last visited Jan. 20, 2007) (stating that LAMICTAL is a maintenance medication for bipolar disorder).

5. Carol Rados, *Drug Name Confusion: Preventing Medication Errors*, FDA CONSUMER MAG., July-Aug. 2005, at 35.

6. *Medication Errors*, FDA CDER HANDBOOK, available at <http://www.fda.gov/cder/handbook/mederror.htm>.

7. Rados, *supra* note 5, at 35.

woman was hospitalized after allegedly ingesting the prostate drug FLOMAX[®] rather than the drug with a similar sounding name, VOLMAX[®], which is used to treat bronchospasms.⁸

The health risks associated with confusingly similar drug names have raised the eyebrows of the FDA.⁹ In response, the FDA's Associate Director for Medication Error, Jerry Phillips, announced that the FDA's Office of Post-Marketing Drug Risk Assessment (now the Center for Drug Evaluation and Research) would begin conducting independent reviews and testing of drug trademarks.¹⁰ Although preventing medication errors and protecting patient safety is of utmost importance, the FDA's assumed authority to evaluate pharmaceutical trademarks has placed the FDA and the United States Patent and Trademark Office (PTO) (the federal agency entrusted with regulating trademarks) in a peculiar jurisdictional overlap.

This article argues that the current system under which the FDA and the PTO evaluate proposed drug trademarks, although necessary, lacks efficiency and specificity and also fails to provide drug manufacturers with clear and predictable guidelines for obtaining drug trademark approval. Although maintaining public safety must remain the primary concern regardless of how the FDA and the PTO review drug names, this end can be achieved more appropriately and more efficiently by requiring both agencies to develop and implement clear, integrated, and workable guidelines for reviewing proposed pharmaceutical trademarks.

Part I of this paper will provide a general overview of trademark law, the Food and Drug Administration, and the processes by which both the FDA and the PTO evaluate proposed drug names. Part II will briefly examine alternatives to joint agency review and will discuss why the FDA and the PTO are indispensable to the drug name approval process, particularly in light of the growing trend of direct-to-consumer (DTC) advertising. Part III will highlight the complications and inefficiencies associated with the current system of joint review and will propose: (1) a modification of the PTO's intent-to-use provisions for purposes of pharmaceutical drug trademarks, and (2) a requirement for the FDA to complete its proposed drug

8. *Id.*

9. *Cf.* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(a) (2000) (stating that a drug shall be deemed misbranded if it is false or misleading).

10. See Marc J. Scheineson, *FDA Limits on Dual Trademarks Tread on Patient Safety and Law*, LEGAL BACKGROUNDER, Apr. 25, 2003, at 1.

name review during a specific and predictable timeframe. Part IV will explore specific FDA shortcomings and will argue for a codified, statistically reliable procedure for evaluating proposed drug names.

PART I - OVERVIEW

A. TRADEMARK LAW

1. The Functions of Trademark Law and the Likelihood of Confusion Analysis

A trademark is “any word, name, symbol, or device, or any combination thereof...used by a person... to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown.”¹¹ The protections of trademark law enable the supermarket customer to choose to purchase COCA-COLA® to the exclusion of other colas, knowing that the famous red label showcasing white letters refers to a particular and familiar brand of cola. Trademarks carry economic utility in that purchasers confronted with an array of similar products made by different producers are able to reject potentially or actually non-satisfactory products in favor of those that were satisfactory in the past.¹² Succinctly described, “[t]rademarks fix responsibility. Without [trade]marks, a seller’s mistakes or low quality products would be untraceable to their source.”¹³

Broadly speaking, trademark law is an arm of the law of unfair competition.¹⁴ The overarching purpose of trademark law is to foster a competitive fair market, free from the burdens of unfair competition, while providing consumer protection.¹⁵ In achieving this end, trademarks have, throughout history, served to indicate the producer or source of the particular goods or services offered.¹⁶

11. Lanham Trademark Act, 15 U.S.C. § 1127 (2000).

12. J.THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 2:3 (4th ed., vol. 1 2006).

13. *Id.* at § 2:4.

14. *Moseley v. V. Secret Catalogue, Inc.*, 537 U.S. 418, 428 (2003).

15. See MCCARTHY, *supra* note 12, at § 2:2.

16. See generally Benjamin G. Paster, *Trademarks — Their Early History*,

To safeguard the economic value of a trademark, trademark law aims to protect owners from the parasitic attempts of competitors who might attempt to capture the trademark owner's goodwill.¹⁷ Goodwill is "a business value that reflects the basic human propensity to continue doing business with a seller who has offered goods and services that the customer likes and has found adequate to fulfill his needs."¹⁸ As Justice Frankfurter explained, trademark law "promotes honesty and comports with experience to assume that the wrongdoer who makes profits from the sales of goods bearing a mark belonging to another was enabled to do so because he was drawing upon the good will generated by that mark."¹⁹ The forbidden practice of "poaching" another's goodwill, known as "infringement,"²⁰ has the potential to deceive consumers, rob profits, and destroy the trademark owner's goodwill.²¹ Federal law known as the "Lanham Trademark Act" (Lanham Act),²² among its many provisions, provides several remedies for trademark owners aggrieved by the effects of infringement.²³

2. The PTO's Role in Evaluating Trademarks

Like any other good or service, pharmaceutical trademarks

59 TRADEMARK REP. 551, 551-72 (1969) (giving an in-depth analysis of trademark history).

17. See *Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 207 (1942).

18. See MCCARTHY, *supra* note 12, at § 2:17.

19. *Id.* (stating that purchasers may be induced to buy because they believe they are buying another's product).

20. See 15 U.S.C. § 1114(1)(a) (2000). Infringement occurs when any person shall,

without the consent of the registrant, use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion or cause mistake or to deceive.

Id.

21. See *Mishawaka*, 316 U.S. at 206-07.

22. Lanham Trademark Act, 15 U.S.C. § 1051-1127 (2000).

23. See 15 U.S.C. §§ 1114, 1116 (2000). The primary remedy for trademark infringement is injunctive relief. *Id.* However, where a trademark owner is a victim of willful infringement, the mark owner may be entitled to "(1) the defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action." 15 U.S.C. § 1117(a) (2000). In exceptional cases, treble damages and reasonable attorney's fees are available." 15 U.S.C. § 1117(b) (2000). Finally, a court may also order that the infringer destroy all infringing articles. 15 U.S.C. § 1118 (2000).

are eligible for trademark registration with the PTO.²⁴ Applications for pharmaceutical trademarks are reviewed in much the same way as applications for other trademarks.²⁵

The initial step in protecting a trademark is using it in commerce.²⁶ The next step in protecting a trademark, particularly a mark used nationwide in interstate commerce, is obtaining federal registration through the PTO.²⁷ Although registration of a trademark is not necessary to acquire trademark rights,²⁸ registration provides greater economic protection to the trademark owner²⁹ and is the key to use of the trademark to the exclusion of others.³⁰

As an early alternative to using the trademark in commerce, an applicant for federal registration may take advantage of the Lanham Act's intent-to-use provisions.³¹ Applicants who file intent-to-use applications with the PTO

24. U.S. DEP'T OF COMMERCE, PATENT AND TRADEMARK OFFICE, TRADEMARK MANUAL OF EXAMINING PROCEDURE (TMEP) § 1401.02(b) (2d ed. 1997) (listing pharmaceuticals as a class 5 good).

25. See Mary Anthony Merchant, *Getting and Keeping RX Trademarks*, TECHNOLOGY, INTELLECTUAL PROPERTY & THE LAW, Spring 2004, at 6, 8 (describing the PTO process for reviewing pharmaceutical trademarks). *But see*, Suzanne Skolnick, *Overlap in Mark Registration Authority Between the PTO and the FDA*, 12 J. CONTEMP. LEGAL ISSUES 100, 100 (2001) (because of the significant public health risks of medication errors due to confusing drug names, the PTO has adopted a "doctrine of greater care" in resolving opposition proceedings) (citing Martha M. Rumore, *the Role of Pharmacists in the Pharmaceutical Trademark Evaluation Process*, 6 J. PHARMACY & L. 83, 85 (1997)). As compared to a non-pharmaceutical trademark application, this elevated standard requires the applicant to overcome a more stringent quantum of proof that the proposed trademark is not likely to cause confusion. Skolnick, *supra*, at 100–01. What that quantum of proof is, however, is unclear, because the doctrine of greater care has not been enacted into law.

26. See MCCARTHY, *supra* note 12, at §§ 19:1-5.

27. See MCCARTHY, *supra* note 12, at § 19:3.

28. One may obtain common law rights to a trademark simply by using the trademark in commerce. See MCCARTHY, *supra* note 12, at § 19:3.

29. First, the registrant is armed with a presumption that the trademark is valid and "incontestable" once the mark has been registered for a period of five years. 15 U.S.C. § 1065 (2000). Second, registration provides competitors with *constructive notice* of trademark use. 15 U.S.C. § 1072 (2000). Third, the registrant has automatic access to the federal courts by virtue of registration and without the need of an independent basis for federal jurisdiction such as diversity of citizenship, subject matter jurisdiction, or supplemental jurisdiction. 15 U.S.C. §§ 1070–71 (2000).

30. See 15 U.S.C. §§ 1051–52, 1057 (2000) for the specific requirements and methods of trademark registration.

31. 15 U.S.C. §§ 1051(b)–(d) (2000).

need not immediately use the trademark in commerce as a prerequisite to registration.³² Rather, the applicant's trademark will be published on the principal register, and he or she may delay use for up to six months after the PTO issues a "notice of allowance."³³ If the applicant is unable to use the trademark within six months after the notice of allowance issues, the applicant may obtain extensions in six-month increments, with total extension time not to exceed thirty months.³⁴ On average, obtaining trademark registration through the PTO's intent-to-use provisions takes approximately twenty months.³⁵

Whether filing a use-based application or an intent-to-use application, obtaining federal registration under the Lanham Act requires that the proposed trademark be sufficiently distinct from existing trademarks such that use of the proposed trademark will not cause confusion.³⁶ In determining whether a proposed trademark is likely to cause confusion among the purchasing public, a PTO trademark examiner considers several factors (referred to as *DuPont* factors).³⁷ Among them are the following:

- (1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.
- (2) The relatedness of the goods or services as described in an application or registration or in connection with which a prior mark is in use.
- (3) The similarity or dissimilarity of established, likely-to-continue trade channels.
- (4) The conditions under which and buyers to whom

32. See 15 U.S.C. § 1051(d)(1) (2000).

33. *Id.*

34. 15 U.S.C. § 1051(d)(2) (2000) (the thirty month extension period is in addition to the original six month period).

35. MCCARTHY, *supra* note 12, at § 19:125 (reporting that in 2004, the average time to obtain registration under the PTO's intent-to-use provision was 19.5 months).

36. 15 U.S.C. § 1052(d). Specifically, registration of a trademark will be refused if the mark

[c]onsists of or comprises a mark which so resembles a mark registered in the Patent and Trademark Office, or a mark or trade name previously used in the United States by another and not abandoned, as to be *likely*, when used on or in connection with the goods of the applicant, *to cause confusion, or to cause mistake, or to deceive* *Id.* (emphasis added).

37. See *In re E. I. DuPont de Nemours & Co.*, 476 F.2d 1357 (C.C.P.A. 1973).

- sales are made, i.e. “impulse” vs. careful, sophisticated purchasing.
- (5) The number and nature of similar marks in use on similar goods.
 - (6) A valid consent agreement between the applicant and the owner of the previously registered mark.³⁸

3. Confusion Analysis in the Courts

Like PTO trademark examiners evaluating a proposed trademark, courts presiding over suits alleging trademark infringement analyze whether the alleged infringing party is using the plaintiff’s trademark in a manner that is likely to confuse.³⁹ In evaluating the likelihood of confusion between goods or services, courts generally consider some variant of the eight “*Polaroid* factors.”⁴⁰ A judicial emphasis on *consumer* confusion, which stems from adoption of the *Polaroid* factors, appears in every federal appellate circuit.⁴¹ Among its other forms, “confusion,” in the trademark sense, may refer to product

38. TMEP, *supra* note 24, at § 1207.01; *see also In re E.I. DuPont de Nemours*, 476 F.2d at 1361.

39. MCCARTHY, *supra* note 12, at § 23:1.

40. *Polaroid Co. v. Polarad Electronics Co.*, 287 F.2d 492 (2d Cir. 1961), *cert. denied*, 368 U.S. 820 (1961). These factors include (1) the strength of the plaintiff’s trademark; (2) the degree of similarity between the plaintiff’s and defendant’s trademarks; (3) the proximity of the products or services; (4) the likelihood that the plaintiff will “bridge the gap;” (5) evidence of actual confusion; (6) whether the defendant acted in good faith in adopting the trademark; (7) the quality of the defendant’s product or service; and (8) the level of sophistication with which buyers purchase the product or service. *Id.* at 495.

41. *See, e.g., Star Industries, Inc. v. Bacardi & Co., Ltd.*, 412 F.3d 373, 383 (2d Cir. 2005) (“numerous, ordinary, prudent purchasers”) (citations omitted); *Kemp v. Bumble Bee Seafoods, Inc.*, 398 F.3d 1049, 1058 (8th Cir. 2005); *Bosley Medical Institute, Inc. v. Kremer*, 403 F.3d 672, 676-77 (9th Cir. 2005); *KOS Pharmaceuticals, Inc. v. Andrx Corp.*, 369 F.3d 700, 713 (3d Cir. 2004) (“ordinary consumers”); *Scott Fetzer Co. v. House of Vacuums Inc.*, 381 F.3d 477, 484-85 (5th Cir. 2004) (the “digits of confusion” test requires analysis of the likelihood of consumer confusion); *International Bancorp, LLC v. Societe des Bains de Mer et du Cercle Des Etrangers a Monaco*, 329 F.3d 359, 382 (4th Cir. 2003); *Gray v. Meijer, Inc.*, 295 F.3d 641, 645 (6th Cir. 2002) (“prospective purchasers”); *Davidoff & CIE, S.A., v. PLD Intern. Corp.*, 263 F.3d 1297, 1303 (11th Cir. 2001); *Eli Lilly & Co. v. Natural Answers, Inc.*, 233 F.3d 456, 461 (7th Cir. 2000); *I.P. Lund Trading ApS v. Kohler Co.*, 163 F.3d 27, 43 (1st Cir. 1998); *Big O Tires, Inc. v. Bigfoot 4x4, Inc.*, 167 F.Supp.2d 1216, 1222 (D. Colo. 2001) (“likely to cause confusion in the market place”) (citation omitted).

confusion or source confusion.⁴² An example of source confusion, the most common form of trademark confusion, is the confusion caused by the names SLICKCRAFT and SLEEKCRAFT in reference to two different brands of boats.⁴³ In cases of source confusion, the confused consumer mistakenly believes the senior user, that is, the user entitled to priority use of the trademark, is the manufacturer of the infringing product.⁴⁴ On the other hand, product confusion does not involve confusion regarding the source or origin of the goods, but may arise merely by the “identity of the product itself.”⁴⁵ One example of product confusion is the confusion between the cholesterol drug ADVICOR[®] and the drug formerly marketed as ALTOCOR.⁴⁶

B. FDA

1. Agency Overview

The FDA is responsible for regulating select “food products, . . . human and animal drugs, therapeutic agents of biological origin, medical devices, [and] radiation emitting products for consumer, medical and occupational use, cosmetics, and animal feed.”⁴⁷ Initially named the “United States Bureau of Chemistry,” the agency did not obtain its present name until 1930.⁴⁸ Nevertheless, while empowering the Bureau of Chemistry, Congress paved the path for modern day drug laws with the passage of the Federal Food and Drugs Act of 1906 (1906 Act).⁴⁹ The 1906 Act, ultimately inspired by journalistic exposure of the abhorrent, “nauseating” conditions of the

42. MCCARTHY, *supra* note 12, at § 23:5.

43. See *AMF Inc. v. Sleekcraft Boats*, 599 F.2d 341, 346 (9th Cir. 1979).

44. See MCCARTHY, *supra* note 12, at § 23:5.

45. *Id.*

46. *Id.* Because ALTOCOR was held to be confusingly similar to ADVICOR, ALTOCOR is no longer a trademark. See *KOS Pharmaceuticals Inc. v. Andrx Corp.*, 369 F.3d 700, 70 U.S.P.Q.2d. 1874 (3d Cir. 2004).

47. John P. Swann, *History of the FDA*, U.S. Food and Drug Administration, <http://www.fda.gov/oc/history/historyoffda/fulltext.html> (last visited Sept. 25, 2006). One hundred and five patients died, many of whom were children, as a result of the drug, a chemical analogue of antifreeze, being placed on the market without testing. Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS OF INTERNAL MED. 456 (March 15, 1995), available at <http://www.annals.org/cgi/content/full/122/6/456>.

48. Swann, *supra* note 47.

49. *Id.* See Food and Drugs Act of June 30, 1906, ch. 3915, 34 Stat. 768.

meatpacking industry, affected not only butchers, cattlemen, and plant workers, but also individuals involved in the manufacture and/or marketing of drugs.⁵⁰ While regulation of the food industry was a priority under the 1906 Act, the Act also empowered the Bureau of Chemistry to seize any food or drug featuring labels that were either false or misleading.⁵¹

Although the 1906 Act was a step in the right direction, the Bureau of Chemistry did little under the Act to prevent deceptive advertising for drugs, medical devices, and cosmetics.⁵² For example, the FDA was unable to stop commercial sales of drugs such as *Banbar*, which failed to cure diabetes as promised, and *Lash-Lure* mascara, which caused blindness.⁵³ Despite the deceptiveness with which *Banbar* and *Lash-Lure* were marketed, overwhelming support for the passage of more stringent drug regulations did not arise until 1937 when over one hundred people died from Tennessee Drug Company's newly marketed pediatric "wonder drug" *elixir sulfanilamide*.⁵⁴ As a result, President Roosevelt signed the Food Drug and Cosmetic Act of 1938 (FDCA) into law.⁵⁵ With its primary aim of consumer safety, the FDCA (1) required drug labels to incorporate directions for safe use prior to being made available on the market, (2) prohibited the marketing of drugs with false therapeutic claims, and (3) required FDA laboratory analysis of all new drugs to ensure their safety for the marketplace.⁵⁶ Today, although the FDA is charged with protecting the public health, the agency has evolved from its days of monitoring meatpacking plants and mascara. Currently, the FDA employs over 9,000 individuals⁵⁷ and operates with an annual budget of approximately 1.4 billion dollars.⁵⁸

50. Swann, *supra* note 47.

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. FDA OFFICE OF EQUAL EMPLOYMENT OPPORTUNITY AND DIVERSITY MANAGEMENT, STRATEGIC ACTION PLAN FY 2004 AND BEYOND..., available at <http://www.fda.gov/oc/eo/strategicplan04.html> (last visited Sept. 25, 2006).

58. FDA Office of Financial Management, Budget Frequently Asked Questions, <http://www.fda.gov/oc/oms/ofm/budget/budgetfaqs.htm> (last visited Sept. 25, 2006).

2. The FDA Drug Approval Process

“It takes twelve years on average for an experimental drug to travel from lab to medicine chest.”⁵⁹ Before the FDA gets involved, the drug applicant has typically completed approximately three and one half years of pre-clinical testing.⁶⁰ The pre-clinical phase analyzes laboratory and animal studies for the purpose of making a preliminary safety determination.⁶¹ FDA involvement begins when the drug applicant files an Investigational New Drug Application with the FDA.⁶² Shortly thereafter, the drug is tested on humans during three phases of clinical trials.⁶³ Only 1 in 1000 drugs studied in pre-clinical testing continues on to clinical trials.⁶⁴

During the Phase I clinical trial, which typically lasts one year, the drug applicant administers the drug to approximately twenty to eighty healthy volunteers to determine the drug’s safety and dosage, and to analyze how the drug is metabolized.⁶⁵ During Phase II, the drug applicant administers the drug to up to 300 patient volunteers with a disease or sickness to evaluate the drug’s efficacy and potential side effects over the course of approximately two years.⁶⁶ During Phase III, which typically lasts three years, the volunteer sample size increases approximately ten-fold to verify the drug’s efficacy and to monitor any adverse reactions from long term-use.⁶⁷

Only after completing all three stages of clinical trials does the drug applicant file a New Drug Application (NDA) with the FDA.⁶⁸ During this phase, the FDA reviews all phases of clinical trials and makes a decision whether to approve or reject the drug, a process requiring approximately two and a half years.⁶⁹ In the end, only about one of every five drugs that enter

59. DALE E. WIERENGA & C. ROBERT EATON, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, PHASES OF PRODUCT DEVELOPMENT, http://www.allp.com/drug_dev.htm (last visited Sept. 25, 2006).

60. *Id.*

61. *Id.*

62. Michelle Meadows, *The FDA’s Drug Review Process: Ensuring Drugs are Safe and Effective*, 36 FDA CONSUMER MAGAZINE 4, (July-August 2002), available at http://www.fda.gov/fdac/features/2002/402_drug.html.

63. *Id.*

64. See WIERENGA & EATON, *supra* note 59.

65. *Id.*

66. *Id.*

67. *Id.*

68. Meadows, *supra* note 62.

69. See, e.g., *id.*; WIERENGA & EATON, *supra* note 59.

clinical trials is approved by the FDA for commercial use.⁷⁰

TABLE 1: STAGES OF DRUG TESTING AND APPROVAL⁷¹

	Preclinical Testing		Phase I	Phase II	Phase III		FDA Review	Phase IV
Average Years/Stage	3.5		1	2	3		2.5	
Test Population	Laboratory and animal studies	File IND at FDA	20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers	File NDA at FDA	Review process / Approval	Additional Post marketing testing required by FDA
Purpose	Assess safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness, monitor adverse reactions from long-term use			
New Drug Candidates	5,000 compounds evaluated		5 enter trials				1 approved	

A. THE FDA AND DRUG NAMES

1. Components of a Drug Name

An FDA-approved drug has not one, but three official names. Each drug has a chemical name, a generic (non-proprietary) name, and a brand (proprietary) name.⁷² Except for chemists, few people are likely to recognize even the names of famous drugs such as N-(4-hydroxyphenyl) acetamide. One does not have to be a chemist, however, to recognize the generic name “acetaminophen.” In fact, these are the chemical and

⁷⁰ WIERENGA & EATON, *supra* note 59.

⁷¹ *Id.*

⁷² Rados, *supra* note 5, at 36.

generic names of the drug known and marketed as “TYLENOL®.”⁷³

a. Chemical Names

A drug’s chemical name indicates its chemical makeup and is generally not used in practice among physicians and pharmacists.⁷⁴ When the FDA approves a drug, the United States Adopted Names Council (USAN Council) creates its generic or “official” name.⁷⁵ The Council is a private organization composed of three sponsoring organizations: the American Medical Association, United States Pharmacopeia, and the American Pharmaceutical Association.⁷⁶ The FDA is also represented on the USAN Council⁷⁷ and has reserved the authority to designate a drug name if “necessary or desirable in the interest of usefulness and simplicity.”⁷⁸ The decisions of the USAN Council do not bind the FDA. The FDA, however, defers to the Council in “recogniz[ing] the skill and experience of [the USAN Council] in deriving names for drugs.”⁷⁹ After both the USAN Council and the World Health Organization approve a generic name, the USAN Council then publishes the name in the “Trademark Bulletin of the Pharmaceutical Research and Manufacturers of America,” and in the “Pharmacopeial Forum.”⁸⁰

b. Generic Names

A drug’s generic name is designed to direct physicians and pharmacists to a particular drug class and is typically composed of a medically significant stem and a chemically significant root.⁸¹ For example, the prefix “dopa” refers to the class of drugs known as “dopa receptor agonists,” and the suffix

73. THE MERCK MANUAL OF MEDICAL INFORMATION – SECOND HOME EDITION 88-89 (Mark H. Beers ed., Pocket Books 2003), available at <http://www.merck.com/mmhe/sec02/ch017/ch017a.html>.

74. Rados, *supra* note 5, at 37.

75. The Merck Manual, *supra* note 73, at 88-89.

76. 21 C.F.R. § 299.4(c) (2006). See also Linda Gundersen, *The Complex Process of Naming Drugs*, 129 ANNALS OF INTERNAL MED. 677, 677-78 (1998), available at <http://www.annals.org/cgi/content/full/129/8/677>.

77. 21 C.F.R. § 299.4(d) (2006).

78. 21 U.S.C. § 358(a) (2001).

79. See 21 C.F.R. § 299.4(c).

80. Gundersen, *supra* note 76.

81. Rados, *supra* note 5, at 37.

“mab” refers to “monoclonal antibodies.”⁸² Generic names are continuously in the public domain.⁸³ Therefore, unlike a proprietary name, the manufacturer does not have an exclusive right to the generic name.⁸⁴ Drugs with generic prefixes and suffixes may look and sound confusingly similar to drugs with a similar name, but a substantially different use.⁸⁵ This can result in patients being prescribed the wrong drugs.⁸⁶

c. Proprietary Names

Finally, a new drug will receive a proprietary name. The FDA defines the term “proprietary name” as “the name the applicant or other entity will use for the commercial distribution of the product,” which is a drug’s trademark or brand name.⁸⁷ The proprietary name is intended to solicit brand recognition and generate sales. This name is the central focus of a drug company’s overall advertising campaign for the drug.⁸⁸ The drug manufacturer may acquire trademark rights in the brand name through use and, almost invariably, federal registration.⁸⁹ Unlike a drug’s generic name, which is intended to describe its function or structure,⁹⁰ a proprietary name is typically coined by consulting firms with expertise in prescription drug “naming.”⁹¹ As one author succinctly summarized, “creating a generic name is a science; creating a

82. *Id.*

83. Gunderson, *supra* note 76.

84. *Id.*

85. One such example is confusion about the common prefix “meth,” which has caused confusion between the substantially different drugs methadone and methylphenidate. *See* Rados, *supra* note 5, at 35 and accompanying text.

86. *See id.* Although prescription errors due to confusingly similar generic names is an important topic, the issues presented by such generic name confusion and how they should be resolved are beyond the scope of this article.

87. *See* Regulatory SOPP 8001.4 Review of CBER Regulated Product Proprietary Names (August 15, 2002), <http://www.fda.gov/cber/regsopp/80014.htm>.

88. *See* Merchant, *supra* note 25, at 8-9.

89. *See* MCCARTHY, *supra* note 12, at §§ 19:1-5.

90. *See* The Merck Manual, *supra* note 73.

91. Rados, *supra* note 5, at 35. Brand Institute Inc. and Medical Error Recognition are examples of these firms. *See* Brand Institute Inc., http://www.brandinstitute.com/consumer_index.asp (last visited Oct. 17, 2006); Med-E.R.R.S.[®], <http://www.med-errs.com/services.asp> (last visited Oct. 17, 2006).

brand name is more of an art.”⁹²

2. FDA Review of Proprietary Names

FDA authority for reviewing proprietary names is rooted in the agency’s authority to regulate misleading drug labeling.⁹³ A drug name may mislead if its proprietary name, “because of similarity in spelling or pronunciation, may be confused with the proprietary name or the [generic] name of a different drug or ingredient.”⁹⁴ The FDA requires a drug applicant to submit two proposed names in order of preference for review,⁹⁵ and the FDA must review all proposed pharmaceutical and over-the-counter drug trademarks prior to their use in commerce.⁹⁶ In rather bureaucratic fashion, the FDA’s Center for Drug Evaluation and Research (Center) assigns the majority of such trademark reviews to the Office of Drug Safety’s (ODS) “Division of Medication Errors and Technical Support” (Division of Medication Errors).⁹⁷ The Division of Medication Error’s fundamental purpose is to minimize medication errors that may arise from drug trademarks that look or sound like the trademarks of other drugs.⁹⁸ Typically, the FDA reviews the proposed drug name as early as the end of Phase II clinical trials and again within ninety days of the drug’s expected date of approval.⁹⁹ Thus, on average, over five years lapse between the FDA’s first review of the proposed name and the FDA’s final review on the eve of the drug’s market approval.¹⁰⁰

Although both the FDA and the PTO seek to preclude confusion, their reviews serve independent and “fundamentally different purposes.”¹⁰¹ The PTO does not guard public safety, but rather attempts to ensure that “consumers are able to distinguish and identify the source of the drug product bearing

92. Gundersen, *supra* note 76.

93. Stephen C. Clifford, *The Name Game: Creating a Trademark for a New Drug Product*, DRUG DELIVERY TECH., Sept. 2002, available at <http://www.drugdeliverytech.com/cgi-bin/articles.cgi?idArticle=67>. See also 21 U.S.C. § 352(a); 21 C.F.R. §§ 201.10-201.323.

94. 21 C.F.R. § 201.10(c)(5).

95. MCCARTHY, *supra* note 12, at § 19:149.

96. See Gundersen, *supra* note 76.

97. MCCARTHY, *supra* note 12, at § 19:149.

98. *Id.*

99. Clifford, *supra* note 93.

100. See WIERENGA & EATON, *supra* note 59.

101. MCCARTHY, *supra* note 12, at § 19:150.

the trademark.”¹⁰² The FDA’s review seeks to guard against confusing and misleading drug names and labels that might result in errors in prescription, dispensing, and consumption.¹⁰³ The FDA’s interest in proposed drug trade names extends, in part, to barring drug names that are inherently misleading, that make false promises, or suggest their function and purpose (efficacy).¹⁰⁴ Such authority stems from the FDA’s mandate to regulate false or misleading drug labels.¹⁰⁵ For example, Upjohn, the manufacturer of the drug known today as ROGAINE®, originally attempted to use the name REGAIN for its hair growth drug.¹⁰⁶ The FDA denied such use, reasoning that use of the name REGAIN would send a message to consumers of guaranteeing, or at least suggesting, hair growth.¹⁰⁷

In addition to regulating misleading drug names, the FDA is also concerned with eliminating “look-alike sound-alike” confusion among phonetically or visually similar drug names.¹⁰⁸ In evaluating whether a proposed drug name looks or sounds like another drug, the FDA’s Division of Medication Errors first employs an expert panel to exchange opinions regarding any risks associated with potential look-alike or sound-alike drug trademarks.¹⁰⁹ The panel is comprised of “medication error prevention staff and representatives from the Division of Drug Marketing and Advertising Communications.”¹¹⁰ These experts discuss whether a proposed proprietary name might be confused with an existing name.¹¹¹ If there is a possibility of confusion,

102. Clifford, *supra* note 93.

103. *Id.*

104. Susan Ipaktchian, *The Name Game*, STAN. MED. MAG., Summer 2005, available at <http://mednews.stanford.edu/stanmed/2005summer/name-game.html>.

105. See 21 U.S.C. § 352(a).

106. See Danielle A. Gentin, *You Say Zantac, I Say Xanax: A Critique of Drug Trademark Approval and Proposals for Reform*, 55 FOOD & DRUG L.J. 255, 260 (2000) (citations omitted).

107. See *id.*

108. See MCCARTHY, *supra* note 12, at § 19:150.

109. Carol Holquist & Jerry Phillips, *How FDA Reviews Drug Names*, FDA Safety Page, Apr. 2, 2001, <http://www.fda.gov/CDER/drug/MedErrors/reviewDrugNames.pdf>.

110. *Id.*

111. Public Meeting Transcript, FDA Institute for Safe Medication Practices, Evaluating Drug Names for Similarities: Methods and Approaches (June 26, 2003), available at

the panel compiles a list of proprietary names that are similar to the proposed name.¹¹² This list will be one factor in the overall consideration of whether a proposed proprietary name is found to be likely to confuse.¹¹³

In addition to the expert panel review, the Division of Medication Errors also conducts handwriting and verbal analyses to determine whether the proposed trademark is confusingly similar to another drug name.¹¹⁴ During this phase, nurses, pharmacists, and physicians are asked to participate in a mock simulation of the prescription ordering process.¹¹⁵ Because prescription drugs may be accessed by methods other than in writing, the Division of Medication Errors also employs a similar evaluation for verbal prescription orders.¹¹⁶

Following the handwriting and verbal analyses, the proposed trademark is entered into an FDA computer database designed to alert the operator of any potential look-alike sound-alike confusion associated with use of the trademark.¹¹⁷ Finally, the Division of Medication Errors forwards the results to the Center's Office of New Drugs, which makes the final decision as to whether the proposed name will be approved or rejected.¹¹⁸ During this phase, the Office of New Drugs considers the results from the expert panel review, the clinical analysis, and the computer-assisted analysis to evaluate whether the proposed drug name might be confusing in light of the following factors: (1) the dosage forms or routes of administration (injection, oral, etc.); (2) the marketing status (whether the

<http://www.fda.gov/cder/meeting/drugnametranscript.doc>.

112. *Id.*

113. *Id.* All participants must be FDA employees; non-FDA employees are excluded from participation. *Id.*; see Part IV(b) *infra*.

114. Holquist & Phillips, *supra* note 109.

115. *See id.* One such test involves presenting the participant with a series of handwritten drug names (some of which are on the market and some of which are not) shown one at a time. The participant is then asked a series of questions relating to the handwritten drug names, including what the name of the drug was, whether the participant had seen the name before, and if so, what condition it is used to treat. *Id.*

116. 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). One method of testing the likelihood that the proposed name will confuse when used verbally is the FDA's process of leaving telephone messages with the proposed name and questioning the recipient of the message. *See* Public Meeting Transcript, *supra* note 111, at 55, 82.

117. *See* Holquist & Phillips, *supra* note 109.

118. Public Meeting, *supra* note 111, at 34.

drug is available by prescription or over-the-counter at the time of application); (3) the indications and directions for use; (4) the storage configuration; (5) the clinical setting for dispensation or use; (6) the packaging and labeling; and (6) the strength of the drug.¹¹⁹

After the above processes have been completed, the Division of Medication Errors then forwards a detailed written report to the Office of New Drugs, which makes the final determination whether to approve or reject the proposed trademark.¹²⁰

PART II – THE NECESSARY EVIL OF DUAL AGENCY REVIEW

A. EXPERTISE AND AUTHORITY

Although the FDA and the PTO are concerned with eliminating the likelihood of confusion, each agency is concerned with a unique type of confusion, and approval or rejection of the proposed trademark by one agency is independent from the other.¹²¹ The FDA's Division of Medication Errors is concerned only with the clinical context in which the proposed trademark will operate, namely whether approval of the mark will result in confusion during the prescription process.¹²² On the other hand, the PTO is concerned mainly with the commercial context, namely whether approval of the mark will result in confusion about the source of the drug.¹²³ Therefore, a drug manufacturer may obtain FDA approval for a proposed drug name, yet may be unable to secure registration with the PTO. Similarly, a drug manufacturer may fulfill the PTO's intent-to-use requirements but may be unable to acquire FDA approval for the drug name.

At first blush, calling on two independent agencies to regulate something as benign as catchy names and colorful packaging appears wasteful and superfluous and poses obvious questions: Is it necessary to strain the resources of both the FDA and the PTO? If not, is it feasible to lodge this

119. *Id.*

120. *See* MCCARTHY, *supra* note 12, at § 19:149.

121. *See* MCCARTHY, *supra* note 12, at § 19:150.

122. *See id.*

123. *See id.*

responsibility in one agency to avoid such duplicative efforts?

Although entirely removing one agency from the process has the obvious advantage of efficiency, such a solution is impractical for several reasons. First, no matter how adept at determining a likelihood of source confusion, the PTO lacks the expertise and scientific resources to conduct a full examination of a proposed drug name, particularly the resources necessary to determine whether a proposed trademark is intended to describe or suggest efficacy.¹²⁴ Consider again the hair loss drug ROGAINE®. Its original proposed name, REGAIN, falls into the descriptive¹²⁵ category of trademarks and cannot be registered as a trademark absent a showing of secondary meaning.¹²⁶ Confronted with a decision to approve registration of the proposed mark, the PTO examiner lacks the expertise and the resources necessary to determine whether the drug actually does what it promises—that is, whether it actually helps consumers “regain” their hair. The necessary scientific and experimental resources and expertise to make such determinations lie instead with the FDA.¹²⁷ Of course, the PTO lacks the expertise to determine whether other non-pharmaceutical products do what they promise. However, the fact that confusion among drug names may be fatal demands that the PTO seek the guidance and input of the administration designed to protect the public health.

Second, so long as drugs have generic names, the FDA is the only agency suitable to participate in the USAN Council and in the process of approving generic drug names. Therefore, entirely removing the FDA from the drug name review process

124. Gentin, *supra* note 106, at 262.

125. “A descriptive term is one that directly and immediately conveys some knowledge of the characteristics of a product or service.” MCCARTHY, *supra* note 12, at § 11:16.

126. 15 U.S.C. §§ 1052(e)(1), (f) (2000) (proof of secondary meaning requires five years of “substantially exclusive and continuous use”).

127. Despite the FDA’s expertise,

There are a number of instances where the USPTO has found pharmaceutical trademarks to be confusingly similar. Examples of such include Nicostatin for hyperlipidemia and Mycostatin for an antibiotic preparation; Paxetol for cancer treatment and Paxil for an antidepressant; Premarin for menopausal conditions and Presamine for an antidepressant; and Nalex and Nolex, both used as nasal decongestants.

Haseeb R. Jabbar, *Pharmaceutical Trademarks: Likelihood of Confusion vs. Likelihood of Harm*, PATENT ORLANDO.COM NEWSLETTER, July 2003, <http://www.patentorlando.com/july03.html>.

is not a feasible option. With its longstanding expertise in medicine and public health, the FDA is the only agency with sufficient knowledge to approve names of generic drugs given a generic name's characteristic of conveying descriptive medical information.¹²⁸ In contrast, the PTO does not have the knowledge, expertise, or the resources¹²⁹ to regulate a drug's generic name,¹³⁰ nor does the Lanham Act provide protection for generic names.¹³¹ Since there is no need to register generic names with the PTO, the agency need not concern itself with generic name review.¹³²

Third, while the FDA is equipped to analyze drug efficacy, it plays no role in federal registration of trademarks.¹³³ Instead, the PTO, not the FDA, is backed by a statutory mandate and has agency proficiency to examine whether consumers are likely to confuse the *source* of a proposed trademark with the source of a similar, existing mark.¹³⁴ Of course, federal registration is not required to obtain a trademark.¹³⁵ Nevertheless, the nationwide and global distribution of prescription drugs absolutely requires trademark registration and PTO involvement. For these reasons, both the PTO and the FDA must be involved in the pharmaceutical trademark approval process.

B. DIRECT- TO- CONSUMER ADVERTISING AND THE GROWING IMPORTANCE OF THE PTO

America has witnessed a staggering increase in pharmaceutical drug expenditures over the last decade. In 2001 alone, annual U.S. spending on prescription drugs reached \$2.38 billion— a 200-fold increase over the amount spent in 1989.¹³⁶ This increase may be attributable to the United States

128. See Gentin, *supra* note 106, at 262.

129. Skolnick, *supra* note 25, at 101.

130. For example a trademark examiner, if charged with reviewing the generic name "rofecoxib" can not be expected to understand that the term 'cox' used in a generic name refers to the family of drugs known as Cox inhibitors, let alone have any idea what a cox inhibitor is. This is a task best left to those so trained by the FDA.

131. Skolnick, *supra* note 25, at 101 (citing *Park N' Fly, Inc. v. Dollar Park and Fly, Inc.* 469 U.S. 189, 194 (1985)).

132. Skolnick, *supra* note 25, at 101.

133. Gentin, *supra* note 106, at 258.

134. 15 U.S.C. § 1052(d) (2000).

135. 74 AM. JUR. 2D *Trademarks and Tradenames* § 8 (2005).

136. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-*

Supreme Court's decision in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*¹³⁷ and, in large part, to the FDA's 1997 guidelines for using television and radio broadcasts in DTC advertising.¹³⁸ Regardless of its roots, DTC advertising has been highly profitable and very efficient. One study concluded that of the 30% of respondents who spoke to their physician about a specific drug, 44% were given a prescription for that drug.¹³⁹ Another survey conducted by the FDA revealed that during doctor visits, 25% of patients requested a particular drug from their physician, and of those individuals, 69% of them received that prescription.¹⁴⁰ Furthermore, in 2001, every dollar spent on DTC advertising resulted in an additional \$4.20 in sales.¹⁴¹ DTC advertising is

Consumer Prescription Drug Advertising Regulation, 57 FOOD & DRUG L.J. 423, 424 (2002).

137. 425 U.S. 748 (1976). In *Virginia Pharmacy* the Court held that a Virginia law prohibiting pharmacists from advertising the price of prescription drugs unconstitutional on First Amendment commercial speech grounds. *Id.* at 773. To no avail, the State of Virginia defended the law on several grounds, including the argument that permitting such advertisements would commercialize the job of the pharmacist and reduce his status as an expert in prescribing drugs to that of "a mere retailer." *Id.* at 768. In his dissent, Justice Rehnquist feared that opening the door to price advertisements would inevitably lead to non-physician commercial advertisement of the drug itself: "In the case of 'our' hypothetical pharmacist, he may now presumably advertise not only the prices of prescription drugs, but may attempt to energetically promote their sale so long as he does so truthfully." *Id.* at 788. Justice Rehnquist's prediction has become a reality as pharmaceutical companies now directly advertise to the public without physician involvement.

138. See Tamar Nordenberg, *Direct to You: TV Drug Ads that Make Sense*, FDA CONSUMER MAGAZINE, Jan.-Feb. 1998, available at http://www.fda.gov/fdac/features/1998/198_ads.html. Prior to the 1997 guidelines, pharmaceutical companies did not utilize television or broadcast media due to a 1983 FDA moratorium on such forms of DTC advertising. See Patrick A. Moore & Michael A. Newton, *Prescription Drug Advertising on the Internet: A Proposal for Regulation*, 2 W.VA. J. L. & TECH. 1 (1998), available at <http://www.wvu.edu/~law/wvjolt/Arch/Moore/Moore.htm>. For more on the history of the FDA's regulation of DTC advertising, see generally *id.*

139. Wendy Macias & Liza Stavchansky Lewis, *A Content Analysis of Direct-To-Consumer (DTC) Prescription Drug Websites*, J. OF ADVERTISING, Winter 2003/2004, available at http://www.findarticles.com/p/articles/mi_qa3694/is_200301/ai_n9321002.

Justice Rehnquist also predicted this effect, explaining that permitting pharmacists to advertise the costs of prescription drugs would "generat[e] patient pressure upon physicians to prescribe [advertised drugs]." *Virginia Pharmaceutical*, 425 U.S. at 788-89 (Rehnquist, J., dissenting).

140. Macias & Lewis, *supra* note 139.

141. KAISER FAMILY FOUNDATION, *IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING* 2 (2003) available at

expected to become even more pervasive as drug companies further their use of the Internet, which has proven to be the most cost-efficient and profitable method of DTC advertising.¹⁴²

The responsibility and workload of the PTO will continue to increase as drug companies continue this onslaught of DTC advertising. As new drugs make their way to the market, more advertisements will undoubtedly follow. More advertisements for more drugs, by more drug manufacturers, will have the logical effect of increasing the amount of confusion among those targeted by the advertisements. This increase in DTC advertising will require use of the PTO's expertise¹⁴³ in minimizing source confusion. Although the FDA has the expertise and resources to approve or reject a drug name if it is likely to be confused in clinical settings or if it otherwise violates the agency's labeling requirements, it does not have the expertise or the statutory authority to determine whether it is likely to cause *consumer* confusion about the drug's *commercial* source.¹⁴⁴ Such a task is uniquely within the skill set of the PTO.¹⁴⁵

PART III – AGENCY INTEGRATION

Since both the FDA and the PTO play indispensable and increasingly significant roles in the drug name approval process, improving the system under which proposed drug names are reviewed necessarily requires cooperation between both agencies. In its current state, however, the system of dual agency review is unduly cumbersome and inefficient and fails to provide drug applicants with clear and adequate guidelines for evaluating proposed drug names. Further, the differing timetables of the two agencies hinder the efforts of potential drug applicants to protect their trademark interests.

<http://www.kff.org/rxdrugs/upload/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf>

142. Christopher Saunders, *Web Heating Up for DTC Pharma Promotions*, CLICK Z NEWS, Sept. 25, 2002, <http://www.clickz.com/news/article.php/1470351>. See also Moore and Newton, *supra* note 138.

143. As described in Part I(a)(2), *supra*, the PTO's expertise in minimizing source confusion is rooted, in part, in its ability and exclusive authority to scrutinize trademarks proposed for registration by application of the *DuPont* factors.

144. See 21 U.S.C. § 352; 21 C.F.R. § 201.10 (2006).

145. See TMEP, *supra* note 4, at § 1207.01.

Currently, obtaining trademark registration through the PTO's intent-to-use provisions takes an average of 19.5 months.¹⁴⁶ The FDA's proprietary name review typically begins at an unspecified point, but can occur as early as the later stages of Phase II clinical trials.¹⁴⁷ In addition, an average of more than five years will lapse between the time the drug applicant completes clinical trials and the time the FDA ultimately approves the drug for commercial use.¹⁴⁸ Commercial use, of course, is required to satisfy the Lanham Act's intent-to-use provision.¹⁴⁹ The problem is that a drug manufacturer cannot reserve trademark rights for five years under the intent-to-use provisions.¹⁵⁰ If the drug manufacturer waits too long to file with the PTO, the manufacturer runs the risk that a competitor will register the trademark first, thereby surrendering commercial priority to the competitor.¹⁵¹ Conversely, if the drug manufacturer prematurely files an intent-to-use application with the PTO, it runs the risk that the intent-to-use timeframe will expire before the FDA approves the proposed name and before it can be used in commerce to the satisfaction of the PTO. Consequently, since the mark is published on the principal register after the notice of allowance issues,¹⁵² another user can "steal" the mark from the principal register if the applicant is unable to use it in commerce within the thirty month maximum timeframe of the PTO.¹⁵³

Drug manufacturers' efforts to avoid this predicament have spawned abuse of the Lanham Act's intent-to-use provisions.¹⁵⁴

146. MCCARTHY, *supra* note 12, at § 19:125.

147. Merchant, *supra* note 25, at 8.

148. See *supra* Part I(b)(2) ("Drug Approval Process").

149. 15 U.S.C. § 1051(d)(1).

150. *Id.* After filing an intent-to-use application with the PTO, the applicant must use the trademark in commerce and file a statement of use within six months after the PTO issues a notice of allowance. *Id.* The applicant may obtain extensions to the six-month statement of use requirement in six-month increments for a maximum of thirty months. 15 U.S.C. § 1051(d)(2) (2000).

151. Although the FDA does not publish the proposed names it receives so that competitors could "steal" from such a publication, the possibility always exists that a competitor will apply for and ultimately secure the same mark before the person who initially developed the mark.

152. 15 U.S.C. § 1051(b)(1) (2000).

153. Such a "user" may be a competitor or may be another company involved in a similar, yet distinct industry such as nutritional supplements, for example.

154. See Melvin A. Silver, *Pharmaceutical Trademarks – A Prescription for Care*, PATTISHALL, MCAULIFFE NEWSLETTER (Pattishall, McAuliffe, Chicago,

In the current process of name review, drug manufacturers routinely file multiple intent-to-use applications with the PTO as a shroud to prevent competitors from determining which names are actually submitted to the FDA pursuant to FDA requirements.¹⁵⁵ Such a practice undermines the Lanham Act's requirement that any mark applied for be the subject of a bona fide intent-to-use rather than registered merely to reserve rights.¹⁵⁶ Not only do such frivolous filings with the PTO lockup otherwise usable trademarks, they also undermine the Lanham Act's requirement that intent-to-use applications be filed in good faith.¹⁵⁷ The conflicting timetables of FDA and PTO reviews of proposed drug names encourage applicants to evade the PTO's good faith requirement and, in the end, waste valuable PTO resources and undermine the agency's efficiency.

First, to reduce such abuse and minimize gamesmanship, the PTO should place limits on the number of intent-to-use applications a drug manufacturer may submit for any one drug. Unlike the FDA, which limits its name review to two proposed names, the PTO places no restrictions on the number of intent-to-use applications that may be filed for a drug.¹⁵⁸ Not only will limiting the number of intent-to-use applications prevent applicants from locking up marks they never intend to use, it will also better serve the good faith requirement of the Lanham Act's intent-to-use provision.

Second, to reduce the temporal hurdles associated with complying with the PTO's intent-to-use provisions, the PTO should not accept intent-to-use applications until the FDA approves the proposed name at a specific point during Phase III, rather than Phase II, clinical trials.¹⁵⁹ Requiring the FDA

Ill.), Winter 2002, at 1, available at http://www.pattishall.com/pdfs/winter_2002.pdf.

155. *Id.*

156. See 15 U.S.C. § 1051(d) (2000) (explaining that the intent-to-use application must include a statement that the mark is "used in commerce"). "The term 'use in commerce' means the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark." 15 U.S.C. § 1127 (2000) (emphasis added).

157. 15 U.S.C. § 1051(d)(1) (2000).

158. Merchant, *supra* note 25, at 8. Arguably, the PTO's bona fide intent-to-use requirement is, by itself, a restriction on the number of intent-to-use applications that may be filed. Nonetheless, the PTO should develop and enforce a specific limit to the number of intent-to-use applications that may be filed.

159. This change can be implemented most effectively by a specific

to complete its review of the drug brand name no earlier than 1.5 years into Phase III clinical trials will help ensure that the PTO's intent-to-use provisions are not ultimately exhausted. Similarly, delaying FDA review will ensure that drug manufacturers are able to use the approved name in commerce within the timeframe of the current intent-to-use provisions.¹⁶⁰

These proposed solutions, however, are not without downsides. Placing a restriction on the number of intent-to-use applications that a drug trademark applicant may file singles out the pharmaceutical industry while permitting other industries to continue the practice of filing multiple applications. Nonetheless, the complexity surrounding pharmaceutical trademarks calls for a unique set of regulations to manage that complexity; put simply, desperate times call for desperate measures. Even if the pharmaceutical industry is unfairly targeted by such a restriction, the result will only ensure compliance with the congressional requirement that applicants manifest a bona fide intent-to-use the mark in commerce; a requirement that other industries should already be following.

Another concern is whether the Lanham Act forbids the FDA from acting as a gatekeeper for the PTO in filtering out the pool of proposed trademarks to be reviewed by the PTO. What business does the FDA have telling the PTO which drug names are and are not deserving of federal registration? After all, the PTO has the sole authority to register trademarks and administer proceedings associated therewith.¹⁶¹ Although valid, such a concern exalts form over function. Because a pharmaceutical drug trademark cannot realistically be used in

amendment to the Lanham Act's intent-to-use provisions directed toward pharmaceutical trademarks. The following language could be used in such an amendment: "In the case of class 5 goods, the applicant shall not submit its application under this section without a verified statement of approval from the Food and Drug Administration."

160. Another conceivable solution is to simply extend the PTO's intent-to-use provisions for class 5 trademarks (pharmaceuticals). Although such an exception would permit applicant's to reserve rights in the proposed mark, it would contribute to the overall inefficiency of the drug name approval process. Such a process would continue to encourage drug applicants to file multiple intent-to-use applications, thereby drawing on the PTO's already limited resources. The better solution is to require definitive timelines and attempt to operate within the already generous intent-to-use timeframe.

161. See 15 U.S.C. § 1123 (2000) ("The Director shall make rules and regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office under this chapter.").

commerce unless approved by both the FDA and the PTO, it makes no difference whether the FDA rejects a drug name before the PTO can review it. On the other hand, predicating PTO review on FDA approval will increase efficiency because the PTO will not be required to review multiple intent-to-use applications for names that will later be rejected by the FDA.

PART IV – SHORTCOMINGS OF THE CURRENT FDA CONFUSION ANALYSIS & PROPOSED SOLUTIONS

A more predictable and efficient system of pharmaceutical brand name review may be accomplished by integrating the procedures by which the PTO and the FDA analyze likelihood of confusion and by substantively improving the manner in which the FDA conducts its confusion analysis. The current process by which the FDA evaluates look-alike, sound-alike confusion among proposed proprietary names is flawed. Studies designed to simulate the prescription of a proposed proprietary name lack the statistical precision and accuracy necessary to provide pharmaceutical companies with a predictable and evenhanded appraisal of their proposed names. Furthermore, the FDA provides no definite and objective criteria by which proposed proprietary names will be evaluated, imposing significant financial burdens on pharmaceutical companies.

A. THE LACK OF SPECIFIC FDA GUIDELINES AND CRITERIA FOR REVIEWING PROPOSED DRUG NAMES IMPOSES AN UNDUE BURDEN ON DRUG MANUFACTURERS.

As explained by one pharmaceutical trademark consulting firm, “[t]he proprietary name is an unsleeping salesman that ceaselessly promotes the product and, therefore, should pack as much recognition and recall value as possible.”¹⁶² As this quote suggests, naming a pharmaceutical drug can be an expensive process. In fact, many pharmaceutical companies spend more money on drug marketing than on research and development.¹⁶³

162. James L. Dettore & Patricia K. Staub, *Legal and Regulatory Considerations in the Selection of a Pharmaceutical Proprietary Name*, Sept. 28, 2001, http://www2.brandinst.com/NEWS/FOCUS_12_01.HTM.

163. See Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 45 (2002) (reporting that “brand name [drug] companies” allocate twelve percent of their budgets to research and development and thirty percent toward marketing). In 2000, the most

For every drug, it is estimated that pharmaceutical companies spend anywhere from \$250,000 to \$2.5 million on developing a name that will have a favorable impact on the public.¹⁶⁴ The naming process is a calculated and deliberate attempt to conjure up a favorable image in the minds of consumers. This process usually involves the help of pharmaceutical marketing firms.¹⁶⁵

Drug naming is not only expensive; it is also highly technical and subliminal. “Relational asemantics”¹⁶⁶ or “phonologics” for example, are terms drug-branding experts have used to describe the unconscious reaction one may have to hearing a drug name.¹⁶⁷ “Fricative” letters such as X, F, S, and Z are frequently used to imply speed.¹⁶⁸ Examples include XANAX[®], ZYRTEC[®], and ZOVIRAX[®]. “Plosive” letters such as P, T, and D, are also used frequently in a drug name to convey a subliminal indication of power.¹⁶⁹ Examples include TORADOL[®], DOLOBID[®], and TESTODERM[®]. In addition to developing names that convey speed or power, pharmaceutical companies may also invest in developing suggestive trademarks. Examples include the drug CELEBREX[®], which is intended to convey celebration,¹⁷⁰ and CLARITIN[®], intended to convey clarity.¹⁷¹ Some names are even more imaginative. The well known drug VIAGRA[®], with its use of the prefix “vi,” is said to indicate vitality and “conjur[e] images of power and fury of Niagara Falls.”¹⁷²

With the FDA’s current role in the drug name approval process, pharmaceutical companies are left without any

profitable pharmaceutical companies spent three times more on drug marketing than on research and development. *Id.*

164. See Julie Kirkwood, *What’s in a Name?* EAGLE TRIBUNE (North Andover, Mass.), Sept. 1, 2003, available at <http://www.igorinternational.com/press/eagletrib-drug-names.php>. See also Ipaktchian, *supra* note 104.

165. Some of these firms include Brand Institute Inc. (<http://www2.brandinst.com>) and Med-E.R.R.S., Inc. (<http://www.med-errs.com>).

166. See Rados, *supra* note 5.

167. Donald G. McNeil Jr., *The Science of Naming Drugs (Sorry, the Z is Already Taken)*, NY TIMES, Dec. 27, 2003, § 4, at 10.

168. Ipaktchian, *supra* note 104.

169. *Id.*

170. *Id.*

171. *Id.*

172. Kirkwood, *supra* note 164.

regulations or indication as to what criteria and standards the FDA uses in reviewing a proposed name. Unlike the PTO, which follows the Trademark Manual of Examination Procedures (TMEP), which provides some objective explanation as to how a proposed mark will be reviewed, the FDA has no regulations or clear protocols for drug manufacturers to follow. Applicants are left only with those provisions detailing the FDA's administrative authority to regulate misleading drug labels¹⁷³ and a general knowledge that the drug name will undergo surveys that will be limited to FDA employees. How and when these surveys will be conducted, the method used to select the survey participants, and the time and manner in which these events will occur are unknown and are evidently left to the discretion of the FDA.

These procedures need to be codified or adopted in the Code of Federal Regulations just as the TMEP describes how a trademark will be reviewed. Doing so will provide drug applicants with an objective and predictable framework under which they can develop their brand names.¹⁷⁴ So long as the current system persists in its ambiguity and discretion, pharmaceutical companies will continue to face the risk of wasting millions of dollars on blind development of proposed drug names that the FDA may ultimately reject using subjective criteria not rooted in any specific rule of law.

B. CURRENT FDA REVIEW OF LOOK-ALIKE SOUND-ALIKE CONFUSION LACKS PRECISION AND ACCURACY

In a public meeting discussing look-alike sound-alike confusion of drug names, Tom Hassall, director and regulatory liaison of Merck pharmaceuticals, concluded, "prescription analysis studies don't really test the name for the risk of medication error."¹⁷⁵ Partially to blame is the FDA's failure to employ sound statistical principles that account for the lack of reliability in the prescription analysis studies. Although the FDA cannot be expected to create a statistically flawless method of evaluating a concept as subjective as look-alike sound-alike confusion, the agency should review proposed drug names with elementary statistical principals in mind.

173. 21 U.S.C. § 352(a) (2000). *See also*, 21 C.F.R. §§ 201.10- 201.323 (2006).

174. *See* Public Meeting Transcript, *supra* note 111, at 52.

175. *Id.* at 58.

A reliable survey must incorporate an adequate pool of participants free from selection bias.¹⁷⁶ Selection bias, in particular, is “a systematic tendency on the part of the sampling procedure to exclude one kind of person or another from the sample.”¹⁷⁷ Bias in the selection procedure can destroy the accuracy of the study even when the overall sample size is sufficient.¹⁷⁸

In the United States, there are over 500,000 physicians¹⁷⁹ and approximately 230,000 pharmacists.¹⁸⁰ Rather than utilize this qualified and diverse base of physicians and pharmacists, the FDA samples approximately 130 persons, all of whom are FDA employees, for its handwriting and verbal analysis testing.¹⁸¹ Thus, the vast majority of physicians and pharmacists who are not FDA employees are excluded from the sample. Biasing the sample in this manner fails to test confusion possibilities in the broad array of clinical settings in which physicians and pharmacists work. The clinical circumstances surrounding a prescription ordered in a busy emergency room, for example, may be very different than the circumstances surrounding a prescription that is written by a family physician.

The FDA’s sample may be further biased if the same participants are routinely being used to participate in the clinical evaluations. If a particular doctor is asked to participate in a proprietary name evaluation and has already done so with four different prescription drugs, he may have a tendency to compare the relative degree of look-alike sound-alike confusion that one proposed name has to existing drugs to the degree of look-alike sound-alike confusion another drug had with other drug names.

For these reasons, in its surveys, the FDA should utilize a randomized sample of physician-prescribers and pharmacists employed in a wide variety of settings and should not limit its survey participants to FDA employees.

176. See DAVID FREEDMAN, ROBERT PISANI & ROGER PURVES, STATISTICS 335 (3d ed. 1998).

177. *Id.*

178. *Id.*

179. See BUREAU OF LABOR STATISTICS, U.S. DEPARTMENT OF LABOR, OCCUPATIONAL OUTLOOK HANDBOOK (2006-07 ed.), available at <http://www.bls.gov/oco/pdf/ocos074.pdf> (reporting that physicians and surgeons accounted for 567,000 jobs in 2004).

180. *Id.*

181. Public Meeting Transcript, *supra* note 111, at 55.

One major hurdle to implementing more reliable surveys is the FDA's confidentiality requirements.¹⁸² Currently, the character and proposed name of a drug pending FDA approval is confidential.¹⁸³ To the extent these confidentiality requirements ultimately protect patent rights and the medical records of those participating in clinical trials, such confidentiality is necessary. However, there is little use in keeping proposed drug names confidential. To eliminate selection bias and ultimately increase accuracy, the FDA should relax its confidentiality requirements, so that it may utilize participants from outside of the FDA to participate in its confusion testing.

CONCLUSION

In summary, the complexities surrounding the approval of proposed pharmaceutical drug names require the expertise and resources of both the FDA and the PTO. Although both agencies play a role in the current process of reviewing, approving, and regulating pharmaceutical trademarks, the current method is legally unsound, inefficient, and fails to provide pharmaceutical manufacturers with deliberate and reliable guidelines for developing drug names. Until the FDA can provide an impartial, statistically accurate method of reviewing the degree of confusion that a proposed drug name elicits, and until the PTO and the FDA can coordinate their timetables to permit pharmaceutical companies to comply in good faith with the Lanham Act's intent-to-use provisions, millions of dollars spent on developing drug names will continue to be in jeopardy.

182. See 21 C.F.R. § 314.430 (2006); 21 C.F.R. § 601.50; 21 C.F.R. § 601.51. (2006).

183. See 21 C.F.R. § 314.430(b) (2006) ("FDA will not publicly disclose the existence of an application [which includes the proposed drug names] . . . before an approvable letter is sent to the applicant.").