COMMENTS

THE GAME OF THE NAME: SHORTCOMINGS IN THE DUAL-AGENCY REVIEW OF DRUG TRADEMARKS AND A REMEDIAL CURE

TY HALASZ*

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* J.D. Candidate, 2013; B.A., Texas Christian University (go Frogs), 2006. This Comment would have been either awful or impossible without some great people: Jonathan Stroud for the crushable inspiration; Andrew Kim for the perennial generosity with his time; Shannon Cain and David Van Fleet Bloys for being the best people to write for—two years running; Professor Lewis Grossman for his limitless expertise and guidance; and the Team for general support. Predictably saving the best for last, thanks to Twink Halasz, my mother, who told me at a young age that I could do anything I set my mind to. I believed her.

INTRODUCTION: THE STAKES AND MISTAKES OF PHARMACEUTICAL TRADEMARKS

What do *Viagra*, *Silagra*, *Eviva*, and *Erecto* have in common? They are not characters from a far-flung Hollywood fantasy or even a comic book; they are all trade names for the same drug.[1] These names are not merely random—they are sophisticated and expensive identifiers for which the stakes of creation are incredibly high. The pharmaceutical industry as a whole spends $19 billion each year marketing its portfolio of drugs to the American public,[2] which is almost twice as much as it spends on research and development.[3] The industry is estimated to spend anywhere from $802 million to $1.7 billion developing each new drug from conception to approval.[4] Every year, 1.3 million people suffer injuries from medication

1. *See* Donald G. McNeil, Jr., *The Science of Naming Drugs (Sorry, 'Z' Is Already Taken)*, N.Y. TIMES, Dec. 27, 2003, http://www.nytimes.com/2003/12/27/business/28mcne.html. What we know as *Viagra* in the United States is called *Silagra* in India (derived from its generic name, sildenafil citrate), *Eviva* in Latin America, and *Erecto* in the Middle East. *Id.*

2. *See* Ray Moynihan, *Who Pays for the Pizza? Redefining the Relationships Between Doctors and Drug Companies. 1: Entanglement*, 326 BRIT. MED. J. 1189, 1191 (2003) (explaining that in-person sales representative visits account for a large part of the pharmaceutical industry's $19 billion annual promotional budget in the United States).

3. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 32 (2008), *available at* http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001 (follow the "PDF" hyperlink) (finding that, based on data collected in 2004, the pharmaceutical industry spent 24.4% of sales dollars on promotion as opposed to 13.4% on research and development); *see also Big Pharma Spends More on Advertising Than Research and Development, Study Finds*, SCI. DAILY, Jan. 7, 2008, http://www.sciencedaily.com/releases/2008/01/080105140107.htm (distilling the 2004 data into layman's terms).

4. *See, e.g.*, Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (contending that $802 million is the magic number); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 476 (2007) (updating a previous estimate to $1.3 billion); Jim Gilbert et al., *Rebuilding Big Pharma's Business Model*, IN VIVO BUS. & MED. REP., Nov. 2003 (putting the number at $1.7 billion in a Bain & Co. study). *But see* Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 1, 13 (2011) (taking issue with inflated industry-sponsored estimates and placing the true cost around $43.4 million). The Bain & Co. study also found that the cost of drug development is rising largely as a result of an increasing failure rate for prospective drugs in clinical trials—the total cost of development increasing 55% from 1998 to 2003. Gilbert et. al., *supra*.

errors,[5] ten percent of which are caused by physician, pharmacist, or consumer confusion among drugs.[6] Approximately 7,000 of those medication errors result in deaths.[7] With so much money and so many lives in the balance, the differentiation between drugs like *Zantac* and *Zyrtec* has seldom been more critical.[8]

Of the substantial sums expended to move a drug through the approval process, a portion goes to developing a compelling, yet arbitrary, name for the drug, and then to gaining approval for the drug's proprietary name (its trademark).[9] Approval for new drugs is governed by the United States Food and Drug Administration (FDA),[10] but approval for their trademarks is governed by two agencies, each independently evaluating different aspects of the mark—yet both with virtually binding authority. The United States Patent and Trademark Office (PTO) fulfills its statutory duty by ensuring that drug trademarks are adequately distinct from existing trademarks and do not cause consumer confusion.[11] The FDA also

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5. *See Medication Error Reports*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm080629.htm (last updated Apr. 30, 2009). The United States Food and Drug Administration (FDA) has been given reports of medication errors by the U.S. Pharmacopeia since 1992. *Id*.

6. Carol Rados, *Drug Name Confusion: Preventing Medication Errors*, FDA CONSUMER, July–Aug. 2005, at 35, 35, *available at* http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2005/405_confusion.html.

7. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 27 (Linda T. Kohn et al. eds., 2000); *see also* Susan Ipaktchian, *The Name Game: Take Two Whatchamcallits and Call Me in the Morning*, STAN. MED. MAG., Summer 2005, http://stanmed.stanford.edu/2005summer/name-game.html (recounting studies that estimate "anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion").

8. *See, e.g.*, *Medication Errors Associated with Zantac and Zyrtec*, U.S. FOOD & DRUG ADMIN. (Sept. 20, 2000), http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm080702.htm (describing a growing problem where *Zyrtec* syrup was dispensed for *Zantac* prescriptions, causing adverse reactions in the pediatric population, such as diarrhea, vomiting, and other illnesses).

9. McNeil, *supra* note 1 ("Drug companies . . . spend $500,000 on a name and packaging. But after clinical trials costing tens or hundreds of millions of dollars, 'even a couple of million dollars spent on a name [is] chump change.'" (quoting Bill Trombetta, professor of pharmaceutical marketing at Saint Joseph's University in Philadelphia)).

10. *See generally* Michelle Meadows, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA CONSUMER, July–Aug. 2002, at 19, *available at* http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2002/402_drug.html (outlining the steps for the FDA's drug review from formative and investigational stages to formalized clinical testing and approval).

11. *See* J. THOMAS MCCARTHY, 1 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 2:2 (4th ed. 2011); *see also* 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/ME2/Default.asp (noting that the U.S. Patent and

evaluates for confusion, but from a safety-oriented perspective; misleading drug names or labels could lead to physician errors in prescribing drugs, pharmacist errors in distributing drugs, or consumer errors in taking drugs.[12]

While such a redundancy is nothing new in the modern regulatory state, the trouble for drug trademarks arises from the potential for divergent decisions following PTO and FDA reviews.[13] It is entirely possible for either agency to approve a trademark only to have the other agency reject that mark, resetting the process. What is perhaps more concerning is the FDA's effective takeover of the PTO's authority over the usage of trademarks; while the PTO remains sovereign over federal registration of marks, the FDA, in practice, holds the real ability to accept or reject a drug trademark.[14] Neither agency consults with the other, and the FDA goes so far as to accord no weight to any previous PTO approval when evaluating a trademark.[15] This structure not only creates administrative inefficiencies and unreliable results with both consumer safety and substantial amounts of money at stake, it also leaves the PTO with little facility to perform its important responsibility.

This Comment surveys the unique jurisdictional overlap between the PTO and the FDA in the review and approval of drug trademarks. In particular, this Comment assesses the practicality and efficiency of the independent dual-agency review and offers recommendations to streamline the process for both agencies and new drug sponsors. Part I provides an overview of trademark law and the process of trademark review. Parts II and III detail the previous structures by which the PTO and FDA reviewed marks, and also explains the current processes used by the agencies to reach

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Trademark Office's (PTO's) central focus is to ensure that, through the trademark, consumers are able to identify and differentiate the source of the pharmaceutical product).

12. Clifford, *supra* note 11 (contrasting the PTO's focus with the FDA's, which is to "prevent errors in prescription, dispensing, and consumption that might result from confusing and misleading drug names and drug labels").

13. *See, e.g.*, Gabrielle A. Holley, *Practice Guidelines for Prescription Drug Trademarks*, UPDATE MAG., July–Aug. 2002, *available at* http://library.findlaw.com/2002/Sep/20/132457.html ("It is unfortunate when a company obtains a federal registration of a trademark only to discover that the FDA will not approve the same mark for use with the company's product.").

14. *See* Suzanne Skolnick, *Overlap in Mark Registration Authority Between the PTO and the FDA*, 12 J. CONTEMP. LEGAL ISSUES 100, 103 (2001) (pondering whether the FDA's trademark review could be an overextension of authority into an area exclusively granted to the PTO).

15. *Pharmaceutical Trademark Law: Some Tips & Considerations to Keep in Mind*, LOMBARD & GELIEBTER, LLP, THE BLOG (July 8, 2010, 4:16 PM), http://www.blogtrademark.com/archives/815 (asserting that the FDA accords no deference to the PTO's assessment of trademark "registrability").

their decisions. Part IV evaluates the strengths and weaknesses of those current processes, and Part V recommends a significant overhaul to streamline and modernize drug trademark review. Finally, this Comment concludes that a joint committee comprised of both PTO and FDA personnel vested with binding authority on both agencies would be the most efficient and effective structure for the review of drug trademarks.

I. A BRIEF OVERVIEW OF THE GOALS AND TENETS OF TRADEMARK LAW

Trademarks, such as the pervasive "golden arches" of McDonald's, are indicators of the familiar and reliable, allowing the consuming public to consistently choose a Big Mac over a Whopper upon seeing the renowned arches. The regulation of trademarks serves two goals: "to protect . . . consumers from deception and confusion over trade symbols" and to protect the goodwill inherent to trademarks and their owners.[16] A trademark is legally defined as "any word, name, symbol, or device . . . used by a person . . . to identify and distinguish his or her goods . . . from those manufactured or sold by others and to indicate the source of the goods."[17] Economically speaking, trademarks are symbols that allow consumers to identify goods or services they have previously found to be satisfactory and reject those that have yielded dissatisfaction.[18] Trademarks fix responsibility and create an incentive to maintain a predictable quality of goods or services offered[19] and have done so for thousands of years.[20]

In general, trademark law is a "part of the broader law of unfair competition," where the central purpose is to prevent one person from passing off his goods as those of another.[21] "All trade-mark cases are cases

16. *See* 1 MCCARTHY, *supra* note 11, § 2:2; *see also* Mark P. McKenna, *The Normative Foundations of Trademark Law*, 82 NOTRE DAME L. REV. 1839, 1840–41 (2007) (stating that "trademark law was not traditionally intended to protect consumers. Instead, trademark law, like all unfair competition law, sought to protect producers from illegitimate diversions of their trade by competitors").

17. Federal Trademark Act of 1946 (Lanham Act), 15 U.S.C. § 1127 (2006); *see also* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 733 (5th ed. 2010) (defining trademarks as "devices that help to reduce information and transaction costs by allowing customers to estimate the nature and quality of goods before purchase").

18. 1 MCCARTHY, *supra* note 11, § 2:3.

19. *Id.* at § 2:4 (suggesting that, without trademarks, a seller's blunders or inferior goods or services are untraceable to the source).

20. MERGES, *supra* note 17, at 733 (tracing the history of trademarks back 4,000 years through discoveries in China, India, Persia, Egypt, Rome, Greece, and elsewhere (citing WILLIAM H. BROWNE, A TREATISE ON THE LAW OF TRADEMARKS 1–14 (2d ed. 1885))).

21. *See* Am. Steel Foundries v. Robertson, 269 U.S. 372, 380 (1926).

of unfair competition and involve the same legal wrong."[22] Regardless of what avenue litigants take—trademark or unfair competition—the operative infringement test is whether the defendant's acts are likely to cause confusion in the minds of consumers.[23] Trademark infringement protects the mark's goodwill against opportunistic attempts by competitors to associate themselves with the mark's owner for personal gain.[24] Goodwill itself is somewhat difficult to define, but has come to mean the expectancy of continued patronage.[25]

A trademark should "identify a single source; be capable of distinguishing one product from another; and be protectable under the laws of the country (or countries) in which the product will be marketed."[26] Trademarks fall into four categories based on their distinctiveness: "fanciful/arbitrary,"[27] "suggestive,"[28] "merely descriptive,"[29] and "generic."[30] While fanciful/arbitrary and suggestive marks receive a high level of legal protection, generic marks receive no protection, and merely descriptive marks only receive protection when they have acquired a secondary meaning.[31]

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22. S. REP. NO. 79-1333, at 4 (1946), *reprinted in* 1946 U.S.C.C.A.N. 1274, 1275 ("There is no essential difference between trade-mark infringement and what is loosely called unfair competition."); *accord* 1 MCCARTHY, *supra* note 11, § 2:7.

23. *See* 1 MCCARTHY, *supra* note 11, § 2:8.

24. *See* Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co., 316 U.S. 203, 207 (1942) (noting that it "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").

25. Newark Morning Ledger Co. v. United States, 507 U.S. 546, 556 (1993) (basing the definition of goodwill on the notion that the value of intangible assets is, to a degree, related to the continued expectation of customer patronage).

26. Dana R. Kaplan & Michael J. Freno, *Intricacies of Choosing a Pharmaceutical Trademark*, INTELL. ASSET MGMT. (Apr. 2, 2008), http://www.iam-magazine.com/reports/Detail.aspx?g=a484cebb-f78e-437f-9cc0-fd614e0dcade ("Although these concepts must be considered each time a mark is chosen, there is a greater level of analysis involved in developing and branding a new chemical compound.").

27. *Id.* Arbitrary or fanciful marks are the most abstract, such as *Kodak*, *Exxon*, and *Xerox*. They have almost no relationship to the goods or services, which typically creates the need for an extensive advertising campaign to introduce such marks. *See id.*

28. *Id.* Suggestive marks require some measure of imagination to associate with the goods or services, such as *Coppertone*, *Tums*, and *Whirlpool*.

29. *Id.* Merely descriptive marks are those indicative of what the goods or services are, such as *Rollerblade*, *Weight Watchers*, and *American Airlines*.

30. *Id.* Generic marks, such as *Aspirin*, *Corn Flakes*, and *Escalator*, are those that are most general and that have become so common in the marketplace that it is impossible to identify a single source of the goods or services.

31. *Id.* (noting that secondary meanings are typically acquired as a result of advertising).

II. THE PATENT AND TRADEMARK OFFICE

A. History and Regulatory Basis

The PTO's origins lie in the Patent Act of 1793, which tasked the clerks in the Department of State with patent examination pursuant to the Patent and Copyright Clause of the Constitution.[32] When the Secretary of State gave sole authority over patent review and issuance to the clerk of the Department of State in 1802, the Patent Office was born.[33] Trademarks only enjoyed common law protection until Congress enacted its first trademark legislation in 1870, which assigned mark registration to the Patent Office.[34] The Supreme Court invalidated this statute for grounding its regulatory authority in the Patent and Copyright Clause (a trademark is neither a patent nor copyright),[35] but Congress enacted a second trademark statute in 1881[36] with authority under the Commerce Clause.[37] Today, more than 232,000 trademark applications are received each year[38] by approximately 400 examining attorneys[39] pursuant to the Federal Trademark Act of 1946 (also called the Lanham Act).[40] Trademarks are organized into forty-five classifications depending on the type of good or service the mark represents.[41]

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32. U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."); *see History*, U.S. PATENT & TRADEMARK OFFICE, http://usptocareers.gov/Pages/WhyWork/About.aspx (last visited Feb. 7, 2012). Before the Patent Act of 1793, both the President (George Washington) and Secretary of State (Thomas Jefferson) had to sign off on patents, resulting in three being approved in 1790, thirty-three in 1791, eleven in 1792, and twenty in 1793. *See id.*; *Patents*, THOMAS JEFFERSON'S MONTICELLO, http://www.monticello.org/site/research-and-collections/patents (last visited Feb. 7, 2012).

33. *See History*, *supra* note 32.

34. *See* MERGES, *supra* note 17, at 734.

35. *See* The Trade-Mark Cases, 100 U.S. 82, 99 (1879) (striking down as unconstitutional the Trademark Act of 1870, ch. 280, 16 Stat. 198).

36. Trademark Act of 1881, ch. 138, 21 Stat. 502.

37. U.S. CONST. art. I, § 8, cl. 3 ("To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.").

38. *History*, *supra* note 32.

39. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE & ACCOUNTABILITY REPORT: FISCAL YEAR 2009, at 140 (2009) (listing trademark examining attorneys at a mere 388 in 2009, as opposed to 6,242 patent examiners).

40. 15 U.S.C. §§ 1051–1127 (2006).

41. T.M.R.P. § 6.1 (2010), 37 C.F.R. § 6.1 (2010). Pharmaceutical trademarks are included in Class 5. *Id.*

B. Trademark Review Process

There are four ways to obtain federal registration of a trademark: a use-based application,[42] an intent-to-use (ITU) application,[43] a foreign firm application,[44] and a Madrid Protocol application.[45] Because the latter two provide a structure for international firms to receive protection for their marks in the United States, this Comment focuses on the former two, especially ITU applications. Federal registration, whether use-based or ITU, does not create the trademark; rather, the mark is established by use in the marketplace.[46] There are two ways that the PTO publishes trademarks: the principal and the supplemental registers.[47] Publication on the principal register entitles the trademark owner to all the privileges of federal registration,[48] whereas publication on the supplemental register merely records designations "that have not yet acquired a trademark significance but are capable of doing so."[49]

Though other jurisdictions allow the registration of trademarks before actual use of the mark, the United States requires (in most cases) that the

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42. 3 MCCARTHY, *supra* note 11, § 19:1; *see also* 15 U.S.C. § 1051(a). These applications are based on "prior actual use of the mark in interstate or foreign commerce." 3 MCCARTHY, *supra* note 11, § 19:1. After the advent of intent-to-use applications, use-based applications decreased and now comprise only 20% of all applications. *Id.*

43. 3 MCCARTHY, *supra* note 11, § 19:1; *see also* 15 U.S.C. § 1051(b). These applications are filed by those who have a "bona fide" intention to use the mark, and registration will not be granted until the applicant files a verified statement (with proof) that the mark has been used. 3 MCCARTHY, *supra* note 11, § 19:1. In 2004, 75% of all applications were intent-to-use (ITU) based. *Id.*

44. 3 MCCARTHY, *supra* note 11, § 19:1; *see also* 15 U.S.C. § 1126(a). These applications are filed by foreign firms with a foreign application or registration. 3 MCCARTHY, *supra* note 11, § 19:1. Applicants must state their intention to use the mark in the United States. but are not required to prove actual use. *Id.*

45. 3 MCCARTHY, *supra* note 11, § 19:1; *see also* 15 U.S.C. § 1141a(a). These applications are for foreign entities to extend trademark registration from their home nation to the United States under the Madrid Protocol. 3 MCCARTHY, *supra* note 11, § 19:1.

46. Miller v. Glenn Miller Prods., 454 F.3d 975, 979 (9th Cir. 2006) (citing Cal. Cooler, Inc. v. Loretto Winery, Ltd., 774 F.2d 1451, 1454 (9th Cir. 1985)).

47. *See generally* 15 U.S.C. §§ 1051–1072 (providing the primary mechanism for federal registration on the principal register); 15 U.S.C. §§ 1091–1096 (allowing for marks that are not eligible for the principal register to appear on the supplemental register).

48. Such advantages include a legal presumption of ownership and the registrant's right to exclude other uses, 15 U.S.C. §§ 1057(b), 1115(a); the ability to bring an action in federal court, *see* 15 U.S.C. § 1121; and the ability to enlist Immigration and Customs Enforcement to prevent the importation of infringing goods, *see* 15 U.S.C. § 1124.

49. 3 MCCARTHY, *supra* note 11, § 19:32. Accordingly, the supplemental register affords the registrant less protection than the principal register. *See* 15 U.S.C. § 1094 (excluding certain advantages offered by the Lanham Act).

mark be used in the marketplace before registration is issued.[50] Whereas patent seekers race to the PTO to file their patent applications before any of their competitors,[51] trademark seekers "race to the marketplace" because the first entity to use a mark in commerce is considered the senior owner of that mark.[52] Requiring use prior to registration is economically efficient[53] and ensures that registration reflects the marketplace.[54]

Despite the United States' persistence in a use-based trademark structure, the ITU option was introduced in 1989 and is now the most popular avenue to registration.[55] ITU functions the same as a use-based application but is broken into two stages. The first is the familiar examination, but instead of issuing registration upon the completion of a successful review, the PTO issues a Notice of Allowance that requires the applicant to prove use of the mark within a maximum of thirty-six months.[56] PTO processing of ITU applications took an average of 13.5 months in 2010.[57] The second stage is an additional examination after the applicant files a Statement of Use (SOU).[58] Following the issuance of a Notice of Allowance, applicants have six months to file an SOU, and, upon request, receive an extension of an additional six months for a fee.[59] After that, applicants can request up to four extensions in six-month increments, but only if they show good cause.[60] In filing an SOU, an applicant must provide a verified statement that the applicant believes it is the mark owner, that the applicant has used the mark, the dates of first use in commerce,

50. 3 MCCARTHY, *supra* note 11, § 19:1.25.

51. The America Invents Act of 2011 changed the PTO's existing "first to invent" rule to a "first inventor to file" rule: the first applicant to file for a particular patent is considered the senior applicant, allowing him or her to bar subsequent applications for the same patent. Pub. L. No. 112-29, § 3, 125 Stat. 284, 285–93 (2011) (to be codified at 35 U.S.C. § 100).

52. *See* 3 MCCARTHY, *supra* note 11, § 19:1.25.

53. *See* William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON. 265, 282 (1987) ("If the good is not available for sale, the trademark confers no benefit. Thus, conditioning trademark rights on use is a way of limiting the use of scarce enforcement resources to situations in which the rights in question are likely to yield net social benefits.").

54. *See* 3 MCCARTHY, *supra* note 11, § 19:2.

55. *Id.* § 19:1.

56. *Id.* § 19:13.

57. *See* 3 MCCARTHY, *supra* note 11, § 19:125.

58. *Id.* at § 19:13.

59. *Id.* The request for extension must also be accompanied by a verified statement of a continued bona fide intention to use. *Id.*

60. *Id.*; *see also* T.M.R.P. § 2.89(d) (2010), 37 C.F.R. § 2.89(d) (2010) (detailing good cause to be proof of "ongoing efforts to make use of the mark in commerce," such as "research or development, market research, manufacturing activities, promotional activities . . . or other similar activities").

and a specimen of use.[61]

Much like trademark infringement analysis in courts, the trademark review process includes a confusion analysis to determine whether a mark is "likely to cause confusion with a previously used or registered mark."[62] The test for infringement is slightly different in each of the circuit courts of appeals, but most courts use about eight factors to weigh potential confusion.[63] For example, the United States Court of Appeals for the Ninth Circuit weighs the following factors as they relate to competing marks:

1. strength of the mark;
2. proximity of the goods;
3. similarity of the marks;
4. evidence of actual confusion;
5. marketing channels used;
6. type of goods and the degree of care likely to be exercised by the purchaser;
7. defendant's intent in selecting the mark; and
8. the likelihood of expansion of the product lines.[64]

C. Nature of Pharmaceutical Trademark Review

The PTO's review process for pharmaceutical trademarks has been relatively consistent, in contrast to the FDA's approach, which has frequently been in flux. Pharmaceutical trademarks are in Class 5,[65] which sees around 1,000 applications every month.[66] Though the PTO has no specified channel that drug trademark applications travel through—they are treated just like any other application—pharmaceutical companies have a specific process for the PTO. Pharmaceutical companies typically submit a cluster of ITU applications for PTO review, each with a new drug name

61. 3 MCCARTHY, *supra* note 11, § 19:23; *see also* T.M.R.P. § 2.56(b)(1) (2010), 37 C.F.R. § 2.56(b)(1) (2010) (defining a trademark specimen as "a label, tag, or container for the goods or a display associated with the goods").

62. 4 MCCARTHY, *supra* note 11, § 23:1.

63. *Id.*

64. AMF Inc. v. Sleekcraft Boats, 599 F.2d 341, 348–49 (9th Cir. 1979).

65. T.M.R.P. § 6.1 (2010), 37 C.F.R. § 6.1 (2010) ("Pharmaceutical and veterinary preparations; sanitary preparations for medical purposes; dietetic substances adapted for medical use, food for babies; plasters, materials for dressings; material for stopping teeth, dental wax; disinfectants; preparations for destroying vermin; fungicides, herbicides."). In total, there are thirty-four trademark classifications for goods and eleven for services. *Id.*

66. R. John Fidelino, *IP for Business: The Fall and Rise of Pharma Brand Names*, WIPO MAG., June 2008, at 12, http://www.wipo.int/wipo_magazine/en/pdf/2008/wipo_pub_121_2008_03.pdf).

that may or may not be assigned to an actual new drug;[67] different pharmaceutical companies employ this strategy for different reasons.[68] Drugmakers have little choice but to choose the ITU route to registration because filing a use-based application would require companies to obtain FDA approval of the drug first, thus delaying federal trademark registration another year or more after the drug enters the marketplace.[69] Although the PTO treats all trademark applications equally, in administrative adjudicative proceedings involving pharmaceutical marks a "doctrine of greater care" is employed.[70] In these cases, the trademark applicant must meet a more rigorous standard of confusion because of the potential harm associated with drug names.[71]

III. THE FOOD AND DRUG ADMINISTRATION

A. History and Regulatory Basis

The FDA originated with a single chemist in the Department of Agriculture, starting off as the Division of Chemistry and taking its present form in 1927.[72] Its central regulatory functions came with the passage of

67. *See* Dana M. Herberholz, *Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and a Prescription for Reform*, 8 MINN. J. L. SCI. & TECH. 97, 118 (2007).

68. *Compare id.* (explaining that multiple ITU applications are filed with the PTO "as a shroud to prevent competitors from determining which names are actually submitted" for FDA approval), *with* JEROEN LALLEMAND, THOMSON COMPUMARK, PHARMACEUTICAL TRADEMARKS: HOW TO SURVIVE THE NAME GAME, NEW CHALLENGES AND OPPORTUNITIES FOR PHARMACEUTICAL COMPANIES 7 (2011), *available at* http://trademarks.thomsonreuters.com/resource-request?cid=98&nid=330 (fill out information and select "Send Request," follow "Download" hyperlink) (last visited Feb. 8, 2012) (showing that drug companies reduce to a list of five to ten the names that will be filed with the PTO as a safeguard in case the FDA or its European counterpart approves disparate names).

69. *See* discussion *infra* Part IV (exploring the problems with drug companies' use of the ITU option).

70. Schering Corp. v. Alza Corp., 207 U.S.P.Q. (BNA) 504, 509 (T.T.A.B. 1980) ("If there is *any* possibility of . . . confusion in the case of medicines, public policy requires that the use of the confusingly similar name be enjoined." (emphasis added) (quoting Morgenstern Chem. Co. v. G.D. Searle & Co., 253 F.2d 390, 394 (3d Cir. 1958))).

71. Skolnick, *supra* note 14, at 100–01 ("The doctrine of greater care rests on the assumption the PTO functions as a guardian of the public interest and . . . will increase the obstacles to the registration of potentially confusing marks.").

72. John P. Swann, *Food and Drug Administration*, *in* A HISTORICAL GUIDE TO THE U.S. GOVERNMENT 248–49 (George Thomas Kurian ed., 1998) (recounting the FDA's transformation from the Division of Chemistry to the Bureau of Chemistry in 1901, the Food, Drug and Insecticide Administration in 1927, the Food and Drug Administration in 1930, and eventually moving from the Department of Agriculture to the Department of

the Pure Food and Drug Act of 1906[73] and the Federal Food, Drug, and Cosmetic Act of 1938,[74] the latter providing the basis for the FDA to regulate drug trademarks and names.[75] The FDA's new drug and trademark reviews take place in its Center for Drug Evaluation and Research (CDER),[76] where the FDA reviews roughly four hundred new drug names a year and rejects a third of them.[77]

B. New Drug Application Review

Today, it can take up to fifteen years for new drugs to travel from the laboratory to the medicine cabinet[78] and can cost hundreds of millions of dollars.[79] Pharmaceutical companies begin by preclinical (animal) testing, after which an investigational new drug (IND) application is filed with the FDA outlining what the drug sponsor proposes for clinical trials involving humans.[80] Clinical trials then occur in three phases—the first involving twenty to eighty people, the second involving a few dozen to three hundred people, and the final phase involving several hundred to three thousand

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Health and Human Services in 1980).

73. Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906).

74. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399 (2006)). Today, the FDA regulates items accounting for a substantial twenty-five cents of every dollar spent by consumers. Swann, *supra* note 72, at 248.

75. *See* 21 U.S.C. § 352(a) (stipulating that a drug is misbranded—and thus unlawful—if its labeling is false or misleading in any particular way); *see also* James L. Dettore & Patricia Kuker Staub, *Legal and Regulatory Considerations in the Selection of a Pharmaceutical Proprietary Name*, BRAND INST. (Sept, 28, 2011), http://www.brandinstitute.com/news/focus_12_01.htm ("The labeling of a drug may be misleading if it includes a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name . . . of a different drug or ingredient." (citing 21 C.F.R. § 201.10(c)(5) (2001))).

76. 3 MCCARTHY, *supra* note 11, § 19:149.

77. *FDA 101: Medication Errors*, FDA CONSUMER HEALTH INFO., Feb. 20, 2009, at 2, http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143038.pdf.

78. *Drug Discovery and Development*, PHRMA, http://www.phrma.org/research/drug-discovery-development (last visited Feb. 7, 2012); *see also Development Process: The Drug Development and Approval Process*, AVANIR PHARMACEUTICALS, http://www.avanir.com/product/development.php (last visited Feb. 7, 2011) ("Only five in 5,000 compounds that enter preclinical testing advance to human testing, and only one of these five is eventually approved.").

79. *See* DiMasi et. al., *supra* note 4, at 166.

80. Michelle Meadows, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA CONSUMER, July–Aug. 2002, at 19, *available at* http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2002/402_drug.html. The investigational new drug (IND) application is reviewed by both the FDA and a local institutional review board, which is "a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research." *Id.*

people.[81] Following successful clinical trials, the sponsor will file a new drug application (NDA); if the FDA accepts the NDA as complete, the agency will assign a review team "to evaluate the sponsor's research on the drug's safety and effectiveness."[82] After inspecting the manufacturing facilities and reviewing label information, the NDA will be approved, be found "approvable," or be found "not approvable."[83]

Throughout the new drug review process, a drug will acquire three separate names: a chemical name, a generic (nonproprietary) name, and a trade (proprietary) name used by the drug sponsor for a seventeen-year period.[84] A drug's chemical name is assigned at the earliest stage when the compound is developed.[85] The pharmaceutical company applies for a chemical name from the Chemical Abstracts Service, which assigns the compound a registry number. That number serves as a unique identifier to distinguish a compound from millions of other compounds that also have chemical names.[86]

Before the sponsor begins preclinical testing on animals, it submits three generic names to the United States Adopted Names Council,[87] which is responsible for assigning generic drug names.[88] The five-member council assigns the drug a U.S. adopted name (USAN) that is generic per se and can be used by anyone, including competitors.[89] The FDA is not bound by the council's decision, but it cooperates with and is represented on the council, and it recognizes the council's skill and experience.[90] Obtaining a

81. *Id.* At the end of Phase 2, the FDA and sponsor discuss how large-scale Phase 3 studies should be conducted and attempt to come to a consensus. *Id.* at 22.

82. *Id.* at 19, 21. The review team will analyze study results and looks for possible issues or weaknesses in the application. Reviewers then submit their conclusions, which are evaluated by FDA brass. *See id.* at 22.

83. *See id.* at 24.

84. *See* Ipaktchian, *supra* note 7. Pharmaceutical companies have exclusive rights to make and sell an approved drug for seventeen years. *Id.*

85. *See* Kaplan & Freno, *supra* note 26 (noting that the first step taken after developing a new drug is to apply for a generic chemical name).

86. *Id.*

87. The Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the American Pharmaceutical Association, and has assigned drug names since 1964. 21 C.F.R. § 299.4(c) (2010).

88. Ipaktchian, *supra* note 7. When the Council receives a completed U.S. adopted name (USAN) application, it examines the drug name using certain criteria, such as: its usefulness to healthcare providers, how safe it is for patients, its conformity to nomenclature rules, and how easy it is to pronounce. *See* Kaplan & Freno, *supra* note 26.

89. *See* Ipaktchian, *supra* note 7; Kaplan & Freno, *supra* note 26. Once a U.S. adopted name (USAN) is assigned, it goes to the World Health Organization, which assigns the drug an international nonproprietary name. *See* Ipaktchian, *supra* note 7.

90. *See* 21 C.F.R. § 299.4(c)–(e).

USAN is recommended before filing an IND or NDA with the FDA.[91]

Proprietary names are the names that accompany a drug in its marketing to physicians and consumers, and the names this Comment will discuss at length. In 2004, there were more than 33,000 trademarked drug names in the United States—overshadowing the mere 9,000 generic names.[92] To develop a trade name, pharmaceutical companies often engage branding consultants or agencies, which in turn often employ focus groups of relevant parties to gauge public response to drug names.[93] The ideal name typically makes proficient use of the letters X, Z, C, and D, which some say subliminally indicate power.[94] The FDA prohibits trade names associated with the drug's intended use and avoids names that imply effectiveness, which is why the resulting names sound so foreign—they are intended to vaguely connote positive thoughts to consumers through meaningless words.[95]

C. Drug Name Review Background and Process

The FDA has consistently reevaluated and restructured its trademark review apparatuses and processes within CDER. In the late 1990s, the FDA reviewed only those drug trademarks that its reviewing divisions forwarded to the Labeling and Nomenclature Committee (LNC).[96] The LNC was made up of a cross section of FDA staff and had no binding authority, merely providing a recommendation of the mark's adequacy to the reviewing division, which retained the authority to approve or deny the mark.[97] In 1998, the FDA assigned its trademark review to the Office of

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91. *Id.* § 299.4(d) (encouraging all applicants and sponsors to contact the USAN Council for assistance in selecting a "simple and useful name" for new chemical entities).

92. Rados, *supra* note 6, at 37.

93. *See* Julie Kirkwood, *What's in a Name?*, EAGLE-TRIB. (N.H.), Sept. 1, 2003, http://www.igorinternational.com/press/eagletrib-drug-names.php (recounting a focus group made up of 200 doctors and pharmacists nationwide who participated in the marketing research for *Levitra*, which was at one point tentatively called *Nuviva*).

94. *See* McNeil, *supra* note 1 ("The harder the tonality of the name, the more efficacious the product in the mind of the physician and the end user." (quoting James L. Dettore, President, Brand Inst., Inc.).

95. *See* Ipaktchian, *supra* note 7 (contending that the ideal trade name should be "memorable without promising efficacy," pointing to *Celebrex* (which conveys celebration) and *Claritin* (which implies clarity)).

96. *See* Daniel Boring & Chris Doninger, *The Need for Balancing the Regulation of Pharmaceutical Trademarks Between the Food and Drug Administration and the Patent and Trademark Office*, 52 FOOD & DRUG L.J. 109, 111 (1997). Labeling and Nomenclature Committee (LNC) members would discuss the submitted names at a monthly meeting. *See id.*

97. *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, 259 (2000).

Post-Marketing Drug Risk Assessment (OPDRA),[98] where the mark was subject to a more stringent "safety risk assessment," from which the OPDRA developed recommendations.[99] In 2002, the FDA reorganized its risk management function under the Office of Drug Safety, where trademark review was transferred to the Division of Medication Errors and Technical Support (DMETS).[100] The FDA later renamed DMETS as the Division of Medication Error Prevention and Analysis (DMEPA), which is now the current incarnation of the FDA trademark review apparatus.[101] Though DMEPA was originally like the previous incarnations—providing a recommendation on drug names to the reviewing division that retained authority—the FDA delegated all trademark review authority to DMEPA on April 29, 2009.[102]

DMEPA's trademark review is set in motion as early as Phase 2 of the NDA process.[103] The sponsor submits its first and second choices for a proprietary name, which is forwarded to DMEPA to evaluate the trademark.[104] This could be before, during, or after the PTO conducts its review, but as previously noted, the timeframe is irrelevant because the FDA accords no weight to the PTO's decision.[105] The DMEPA review includes the following elements: (1) an analysis of similar names and marks; (2) a review by the FDA's Division of Drug Marketing and Advertising

98. *See* Clifford, *supra* note 11.

99. *See* Marc J. Scheineson, *FDA Limits on Dual Trademarks Tread on Patient Safety and Law*, LEGAL BACKGROUNDER (Wash. Legal Found.), Apr. 25, 2003, at 2, *available at* http://www.wlf.org/upload/042503LBScheineson.pdf (noting that approval authority still rested with the reviewing division or the director of the Office of Drug Evaluation, and that the focus would be on reducing the potential for errors associated with "look-alike or sound-alike" names).

100. *See* Clifford, *supra* note 11.

101. *See DSI Participates in FDA Meeting on Naming, Labeling and Packaging*, BRANDNEWS (Drug Safety Inst.), July 2010, at 1. *See generally* OFFICE OF NEW DRUGS & OFFICE OF SURVEILLANCE & EPIDEMIOLOGY, CTR. FOR DRUG EVALUATION & RESEARCH, MANUAL OF POLCIES AND PROCEDURES 6720.2, PROCEDURES FOR HANDLING REQUESTS FOR PROPRIETARY NAME REVIEW 2 (2009) [hereinafter MAPP 6720.2] (listing Division of Medication Error Prevention and Analysis (DMEPA) procedures for handling proprietary name requests); Maury M. Tepper, *Preparing for the Future Pharmaceutical Trademark Regime*, WORLD TRADEMARK REV., Apr.–May 2010, at 33, 34, *available at* http://www.worldtrademarkreview.com/Issues/Article.ashx?g=397eb2ec-ccbe-4938-b06b-a77edb5a3567 (describing DMEPA's final responsibility for decisions on pharmaceutical trademarks).

102. Tepper, *supra* note 101, at 34 (noting also that any appeals of DMEPA decisions are now communicated directly between the sponsor and DMEPA).

103. *See id.*

104. *See id.* at 35; MAPP 6720.2, *supra* note 101, at 8.

105. *See* Holley, *supra* note 13, at 20 (showing that the review criteria and concerns are different for FDA and PTO).

Compliance to determine whether the name implies an unsubstantiated claim or is misleading; (3) a simulation to find situations where the name would be incorrectly identified when written or spoken;[106] and (4) a comprehensive analysis to determine potential errors the name may cause.[107] If the trademark is approved, such approval is merely tentative, and the mark must be reevaluated by DMEPA ninety days before the drug itself is approved to ensure that no confusion has surfaced in the time lapsed since the initial approval.[108]

D. The Pilot Program

The DMEPA review process, however, is currently subject to change. The 2007 reauthorization and expansion[109] of the Prescription Drug User Fee Act (PDUFA)[110] significantly broadened and strengthened the FDA's drug safety program.[111] In conjunction with the PDUFA reauthorization, the FDA agreed to implement a pilot program enabling participant drugmakers to evaluate proposed names and submit the data to the FDA for review, thus shifting the FDA's role from testing to evaluating data.[112] In the program, the FDA asks participants to offer two submissions for each potential trademark—one with the original materials and another with more comprehensive data.[113] DMEPA then conducts two separate reviews, the first in the usual manner and the second with the new data; both review teams meet to compare conclusions.[114] The comprehensive data within

106. Tepper, *supra* note 101, at 34; *see* Clifford, *supra* note 11 ("Verbal analysis is . . . conducted in simulated clinical environments to assess potential communication errors with other sound-alike drugs.").

107. CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., HOW FDA REVIEWS PROPOSED DRUG NAMES 2–4 (2010), http://www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/ucm080867.pdf.

108. *See* Tepper, *supra* note 101, at 34; Clifford, *supra* note 11.

109. Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

110. Pub. L. No. 102-571, 106 Stat. 4491 (1992) (codified as amended in scattered sections of 21 U.S.C.).

111. U.S. FOOD & DRUG ADMIN., PDUFA PILOT PROJECT: PROPRIETARY NAME REVIEW CONCEPT PAPER 1 (2008) [hereinafter PROGRAM PROPOSAL], http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf.

112. *Id. See generally* Pilot Program to Evaluate Proposed Name Submissions; Concept Paper; Public Meeting, 73 Fed. Reg. 27,001, 27,001–02 (May 12, 2008) (publicizing a meeting to discuss logistics of the pilot program); Pilot Program to Evaluate Proposed Proprietary Name Submissions; Procedures To Register for Participation and Submit Data, 74 Fed. Reg. 50,806 (Oct. 1, 2009) (soliciting participants for the pilot program).

113. PROGRAM PROPOSAL, *supra* note 111, at 8.

114. *Id.* (indicating the first review evaluates an applicant's proprietary name according

such submissions are comprised of a new, systematic approach to evaluating the safety of a trademark, including the following seven aspects: preliminary screening,[115] a USAN stem search,[116] review for similarities,[117] computational methods,[118] medication error data,[119] name simulation studies,[120] and a failure mode and effects analysis.[121] The outcome of the pilot program, which was slated to close in 2011, is still uncertain, but it has succeeded in providing pharmaceutical companies a transparent rubric with which they can evaluate trademarks.[122]

IV. STRENGTHS AND WEAKNESSES OF INDEPENDENT DUAL-AGENCY REVIEW

The dual-agency review structure presents a number of obstacles to the efficiency of new drug approval, though the situation is not devoid of promise. The FDA's pilot program has been a remarkable step forward.[123]

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to the new methods and the second review analyses the proposed proprietary name using the FDA's traditional approach). "At the end of the review process . . . the two reviewers, along with other FDA experts in proprietary name review, will meet to discuss the data and their conclusions." *Id.*

115. *Id.* at 11–12; *see also* LALLEMAND, *supra* note 68, at 11 (explaining that preliminary screening merely indicates a first-step review to ensure that the mark does not use any medical abbreviations or dosing instructions).

116. PROGRAM PROPOSAL, *supra* note 111, at 13. The USAN stem cannot be used as a part of the trade name for a drug.

117. *Id.* at 13–14. This review is for orthographic and phonetic similarities and involves a comprehensive search to eliminate potential similarities to existing marks.

118. *Id.* at 15–16. "Some analysis must be applied to determine which of those names may bear a degree of similarity sufficient to contribute to a potential medication error;" however, the FDA did not articulate a rubric for making this determination, instead merely listing recommended data to include. Tepper, *supra* note 101, at 36. Pilot program participants, therefore, have tremendous influence as to what this step means. *Id.* (arguing that this may be the vaguest step in the pilot program).

119. PROGRAM PROPOSAL, *supra* note 111, at 16 (referring to medication errors involving the active ingredient in the United States or abroad). Most new drugs, however, would not have any such data. *See* Tepper, *supra* note 101, at 36.

120. PROGRAM PROPOSAL, *supra* note 111, at 17–19 (denoting a simulation with focus groups in at least twenty scenarios to ascertain diverse handwriting samples and spoken orders among at least seventy active, practicing volunteers).

121. *Id.* at 21–24 (explaining a conditional, two-prong test to determine if any similarities to current drugs would realistically cause errors in a usual practice setting).

122. *Cf. id.* at 7 (stating that the FDA expects that program enrollment will last two years).

123. *See* LALLEMAND, *supra* note 68, at 11 (contending that the steps outlined in the Pilot Program provide a relatively detailed rubric for drug sponsors to use during premarketing development); Tepper, *supra* note 101, at 36 (predicting the pilot program can increase efficiency and reduce uncertainty).

The agency has been criticized for its murky approach to trademark review, where pharmaceutical companies and their counsel are largely uncertain of the FDA's review criteria and its impact of producing unpredictable decisions.[124] With the advent of the pilot program, drugmakers have been empowered with a systematic approach to trademark review that, even if the program is scrapped, informs the decisionmaking process when three hundred names are being winnowed to a select few,[125] thus increasing the likelihood of mark approval as pharmaceutical companies go forward. As the program's processes become second nature to the major stakeholders in the drug-naming world, it will create a "more synchronous [research], marketing and regulatory relationship."[126]

On the PTO side of the equation, the use of a "doctrine of greater care" in administrative adjudicative proceedings is a positive step in the right direction because it confirms that the PTO, at least to a certain extent, understands and appreciates the peculiar nature of pharmaceutical marks.[127] Any strength in this PTO doctrine is tenuous because the doctrine of greater care is without structure and is not enacted into law at the congressional or administrative level.[128]

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124. *See* Boring & Doninger, *supra* note 96, at 114 (noting criticism of the FDA for shrouding its trademark review in secrecy and suggesting publication of guiding principles and general criteria); Herberholz, *supra* note 67, at 123 ("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."). *But see* CTR. FOR DRUG EVALUATION & RESEARCH AND CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: CONTENTS OF A COMPLETE SUBMISSION FOR THE EVALUATION OF PROPRIETARY NAMES (2010) [hereinafter 2010 GUIDANCE], http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf (elucidating for the first time what the FDA considers when it evaluates drug trademarks in guidance for pharmaceutical companies); Guidance for Industry on the Contents of a Complete Submission for the Evaluation of Proprietary Names; Availability, 75 Fed. Reg. 6210 (Feb. 8, 2010) (publicizing the release of the drug name review guidance).

125. *See* LALLEMAND, *supra* note 68, at 7.

126. *Id.* at 11 (quoting Martin Burke, Managing Director, Thomson CompuMark).

127. *Compare* Alfacell Corp. v. Anticancer Inc., 71 U.S.P.Q.2d (BNA) 1301, 1306 (T.T.A.B. 2004) (supporting a finding of likelihood of confusion with the doctrine of greater care), *with* Baseball Am. Inc. v. Powerplay Sports Ltd., 71 U.S.P.Q.2d (BNA) 1844, 1848 (T.T.A.B. 2004) (citing *In re* E.I. du Pont de Nemours & Co., 476 F.2d 1357, 1361 (C.C.P.A. 1973) (conducting the traditional trademark confusion analysis with the *du Pont* factors for Class 16 paper and printed goods).

128. *See* Herberholz, *supra* note 67, at 101 n.25 (explaining that the doctrine of greater care requires a more stringent quantum of proof and noting that such quantum of proof is unclear because it has not been made law).

Despite these advancements, there is a litany of problems with the dual-agency structure. Most notably, this approach leaves the PTO reviewing trademarks with no discernible meaning because the marks are simply names—they could be legitimate, they could be decoys, or they could be safety submissions, but no matter what, the PTO is in the dark.[129] The PTO's approval then becomes a simple rubber-stamp process, thereby according the FDA its true authority to meaningfully assess the trademark. This practice eviscerates the PTO's ability to fulfill its legislative duty of regulating trademarks and presents an administrative quandary as to whether the FDA has the authority to overtake the PTO in practice.[130]

In addition, the ITU provision conditions approval on the trademark owner using the mark in commerce within a maximum of three years following a notice of allowance. This requirement presents problems for pharmaceutical companies because they are subject to the FDA's separate review of both the drug and its mark, a review that could stretch well past the expiration of the PTO's conditional approval.[131] The resulting uncertainty creates a gamble wherein drugmakers must strategically aim to file at the appropriate time with the PTO while approximating the estimated completion of the NDA process.[132] Pharmaceutical companies are then forced to abuse the ITU option by filing their cluster of names[133] with full knowledge that some will not be used in commerce, which prevents others from using perfectly good trademarks in the marketplace.[134] Additionally, since the ITU trademarks are published on the principal register, another company can effectively appropriate a mark for itself if the applicant does not receive FDA approval in time to satisfy the PTO.[135] In

129. Companies may submit numerous names to the PTO to prevent competitors from knowing the real drug or to have an arsenal at the ready in case of rejection by the FDA. *See* Herberholz, *supra* note 67, at 118–19; LALLEMAND, *supra* note 68, at 7.

130. *But see* Herberholz, *supra* note 67, at 120 (reasoning that such a concern exalts form over function because drug trademarks cannot be used in commerce unless approved by both agencies, so it makes no difference which order the decisions come in).

131. *See id.* at 119 (noting that completion of the FDA review "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").

132. *See id.* (stating there are "temporal hurdles associated with complying with the PTO's intent-to-use provisions").

133. Thomson CompuMark, a division of Thomson Reuters, even counsels its potential pharmaceutical clients to "file early, file often." LALLEMAND, *supra* note 68, at 12.

134. *See* Herberholz, *supra* note 67, at 119 (explaining that because the PTO does not place restrictions on the number of intent-to-use applications that may be filed for a drug, applicants lock up marks they never intend to use).

135. *Id.* at 118. Competitor poaching of trademarks is a significant weakness in the trademark regulatory system because it allows the opposite of what trademarks exist to prevent—the appropriation of a given mark in commerce by another party. *See* 1

the end, the disparate timelines of the dual-agency review wastes PTO resources and makes the agency less efficient.[136]

The resources wasted by the PTO reviewing unnecessary trademarks is dwarfed by the amount of money wasted by pharmaceutical companies paying top dollar to branding consultants and trademark lawyers to devise a list of winning names and then get them registered.[137] Hundreds of thousands of dollars, perhaps even millions, are spent on consultants to create the perfect name,[138] and more is spent on the lawyers. With drugmakers spending so much, and particularly now that the burden of obtaining data appears to be shifting to the private sector under the pilot program,[139] a new system free from redundancy and abuse is necessary. Global filings for pharmaceutical trademarks have risen over 300% in the last thirty years to 238,010 in 2010.[140] Even if the pilot program results in a structured system for drug trademarks on the FDA side, the other side of the dual-agency review must be addressed and remedied in kind.

V. RECOMMENDATIONS FOR A BETTER APPROACH

A. What Others Have Proposed

Any proposals should be in light of what has previously been proffered as a possible solution. Because the FDA has reorganized its trademark review function on such a frequent basis, some commentators' recommendations address a review structure that is no longer applicable,[141] but their recommendations still merit discussion.

As far back as 1997, Daniel Boring (then-chair of the LNC) and Chris

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MCCARTHY, *supra* note 11, § 2:2 (stating one of the goals of trademark law is to "protect the plaintiff's infringed trademark as property").

136. Herberholz, *supra* note 67, at 119.

137. *See* McNeil, *supra* note 1 (calling $2 million spent creating an unused drug name "chump change" (quoting Bill Trombetta, Professor of Pharmaceutical Marketing, St. Joseph's Univ.)).

138. *See id.* Though the article is silent on the matter, it is likely that legal costs are not included in the *Times*' estimate.

139. *See* Tepper, *supra* note 101, at 35 ("At the conclusion of the two-year pilot scheme, the FDA will . . . determine whether it is feasible to accept data from sponsors in lieu of engaging in its own data generation exercise").

140. LALLEMAND, *supra* note 68, at 3 (referencing a graph (Figure 1) that shows a sharp rise in filings around 2002).

141. *See, e.g.*, Boring & Doninger, *supra* note 96, at 114 (addressing the shortcomings of the now-defunct LNC); Gentin, *supra* note 97, at 265 (proposing changes to the LNC as well); Herberholz, *supra* note 67, at 124 (offering suggestions before the pilot program brought FDA processes to light).

Doninger (an examining attorney in Class 5 at the PTO)[142] offered three central recommendations to increase efficiency in pharmaceutical trademark review on both sides of the dual-agency divide.[143] They first proposed the publication of LNC trademark review factors, which at the time were largely unspoken, specifically pointing to a document that purported to crystallize the LNC's review process.[144] The two asserted that publication of this document would apprise the industry of the committee's approach and allow it to self-correct.[145] Boring and Doninger then suggested adding PTO personnel to the LNC as a means of preventing the FDA from acting independently from the PTO.[146] The authors concluded by proposing the PTO alter its approach to pharmaceutical applications by refusing to review those trademarks that have yet to be reviewed by the FDA, effectively granting the PTO final say over registration.[147]

Not long after Boring and Doninger, in 2000, Danielle Gentin proposed empowering the LNC within the FDA and increasing dialogue between the two agencies[148] after dismissing options such as assigning full authority to either the PTO or FDA.[149] She contended that bestowing upon the LNC the authority to bind the rest of the FDA in its trademark decisions would be efficient and effective in creating a systematic process.[150] Gentin reasoned that the LNC's recommendation (or lack thereof) for a trademark to the PTO would inform the PTO's ability to make an appropriate

142. Recall that the LNC was the central apparatus of FDA trademark review and that Class 5 is the PTO classification for pharmaceutical marks. In other words, these two were essentially the definitive voices on the issue from both agencies at the time.

143. Boring & Doninger, *supra* note 96, at 114–16.

144. *Id*. at 114. This document was entitled *Guidance for Industry on Proprietary and Established Drug Names*, *id.*, which seems substantially similar to the guidance published in 2010. *See generally* 2010 GUIDANCE, *supra* note 124.

145. *See* Boring & Doninger, *supra* note 96, at 114 (advocating the publication of the document, among other reasons, to provide the industry an opportunity to comment and supply constructive criticism).

146. *Id.* at 115 (contending that the inclusion of PTO personnel would contribute to the LNC's compositional balance and increase industry confidence).

147. *Id.* at 115–16 (insisting this proposal would accord deference to the FDA's safety inquiry and allow confidentiality to be maintained in the process).

148. Gentin, *supra* note 97, at 264–66 (observing that an FDA regulation empowering the LNC "would send a powerful message to pharmaceutical companies, encouraging more careful selection of potential marks").

149. *Id*. at 263 (arguing that vesting all authority in either the PTO or the FDA is ill-conceived because of the different goals of each agency).

150. *See id.* at 264. Gentin also proposed requiring all drug names to receive LNC review, *id.*, as opposed to the voluntary basis on which the reviewing FDA divisions sought LNC review.

decision regarding federal registration.[151]

Years later in 2007, long after the LNC's existence, Dana Herberholz proposed recommendations for both agencies.[152] First, he argued, the PTO should limit the number of ITU applications that drugmakers can file and refuse to accept any pharmaceutical trademark applications until the FDA completes its review at a certain point during Phase 3 trials, instead of during Phase 2 of the NDA process.[153] Second, Herberholz advocated for the FDA's trademark review guidelines and criteria to be codified, like the PTO's, because their absence imposes an undue burden on pharmaceutical companies.[154] Finally, he criticized the FDA's orthographic and phonetic confusion analysis as too limited,[155] proposing instead to broaden the sample size.[156]

Recently, Deirdre A. Clarke, a student at Loyola New Orleans, addressed the dual-agency review directly, coming to a conclusion similar to this Comment's.[157] Clarke first proposed the creation of a joint commission to review drug names, wherein the review functions of each agency would be melded to focus on all aspects of the likelihood of confusion analysis.[158] Clarke recommended that, in the alternative to a joint commission, the agencies could establish a joint federal advisory committee to review the regulatory framework of each agency and make recommendations toward collaboration and efficiency.[159] Finally, Clarke

151. *See id.* at 265 (reasoning that while "the PTO, and not the LNC, should retain the authority to deny trademark registration," the LNC should review trademarks in those areas where the PTO lacks expertise and make recommendations to the PTO about confusing claims).

152. Herberholz, *supra* note 67, at 120–25.

153. *Id.* at 120.

154. *Id.* at 122–24 (explaining that the lack of clear guidelines and criteria is expensive and wasteful).

155. Before the pilot program, the DMETS's verbal and handwriting confusion analysis samples were comprised only of FDA employees. *See id*. at 125 (citing Transcript of Public Meeting, FDA Institute for Safe Medication Practices, Evaluating Drug Names for Similarities: Methods and Approaches (June 26, 2003)) (expressing dismay that the FDA samples around 130 of its employees rather than utilizing the "qualified and diverse" base of physicians and pharmacists across the United States).

156. *Id.* at 124–25 (recommending the FDA include a randomized sample of physicians and pharmacists).

157. Deirdre A. Clarke, Comment, *Proprietary Drug Name Approval: Taking the Duel Out of the Dual Agency Process*, 12 LOY. J. PUB. INT. L. 433, 455–60 (2011) (arguing for more collaboration and a joint venture between the FDA and the PTO).

158. *Id.* at 455 (recommending, somewhat paradoxically, that a joint commission would "*respect the differences*" in the confusion analysis "by honing the expertise of both agencies to *focus on all aspects*" of the analysis (emphases added)).

159. *Id.* at 458–59 (comparing the prospect of a federal advisory committee to another such committee created between the Securities and Exchange Commission and the

concluded, as Herberholz did, with a recommendation to codify the FDA's trademark review criteria and process.[160]

B. Solutions Going Forward

With the advent of the pilot program and its potential progeny, the FDA's trademark standards and criteria would seem to be a known quantity, negating the need for their publication and making calls for transparency somewhat of a nonissue.[161] However, the pharmaceutical industry still believes that, no matter who is gathering the data, the confusion analysis itself is vague and requires clarity.[162] The industry has criticized the FDA for reviewing trademarks without any validated measures or processes to define or determine when two names are confusingly similar.[163] As such, the FDA should take the initiative to codify its criteria as the PTO has,[164] which will promote transparency and benefit both the pharmaceutical companies that sponsor drugs and the FDA personnel who review drug names.

Beyond that persistent concern, the pilot program, barring a dramatic meltdown, is a sound program that empowers pharmaceutical companies, shifting the onus from the government to the private sector. Its approach to review is echoed by the Executive Branch's efforts to reduce unnecessary regulation.[165] If the pharmaceutical industry can collect the requisite

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Commodity Futures Trading Commission, which has "taken an active role in considering and developing solutions to emerging . . . issues of common interest"). This Comment counsels against federal advisory committees because of their temporary mandate, transparency requirements, and nonbinding recommendations. *See infra* notes 178–179 and accompanying text.

160. Clarke, *supra* note 157, at 460; Herberholz, *supra* note 67, at 122–24.

161. *See also* 2010 GUIDANCE, *supra* note 124, at 5–6 (shedding even more light on the FDA's review process). *But see* Comments of PhRMa, Periodic Review of Existing Regulations; Retrospective Review Under Exec. Order 13,563, (Docketing FDA-2011-N-0259) (June 27, 2011), [hereinafter PhRMA Comments], http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0259-0045 (follow the "PDF" hyperlink) (detailing comments submitted to the FDA by the Pharmaceutical Research and Manufacturers of America, the drug industry's trade organization, in response to the following notice: Periodic Review of Existing Regulations; Retrospective Review Under Exec. Order 13,563, 76 Fed. Reg. 23,520 (Apr. 27, 2011)).

162. PhRMA Comments, *supra* note 161, at 8.

163. *Id.*

164. *See generally* 37 C.F.R. §§ 2.1–11.61 (2010) (codifying the Trademark Rules of Practice (TMRP)).

165. *See, e.g.*, Exec. Order No. 13,563, 76 Fed. Reg. 3821–23 (Jan. 21, 2011) (requiring executive agencies to, among other things, conduct cost–benefit analyses before enacting significant regulation and making agencies look retroactively for regulations they can reduce or eliminate).

trademark data, then it makes sense to relieve the government of such responsibilities and transition it into a purely analytical role. The program should be extended and streamlined with comment and feedback from the participants.

Most importantly, the PTO and the FDA should combine forces in a real and comprehensive way as their statutory duties relate to pharmaceutical trademarks. The effective solution is a joint committee comprised of PTO and FDA personnel that acts as a one-stop shop for regulatory approval of drug names, producing a single decision, binding on both agencies and sponsors, and maintaining the valuable confidentiality that DMEPA currently affords sponsors. In practice, the committee would be similar to the LNC,[166] only without the LNC's shortcomings, since the joint committee would include all of the productive strides that DMEPA has made.[167] It would not need to have a set member balance—half PTO, half FDA, for example—because the agencies are not in competition to review trademarks. Rather, if the committee had, hypothetically speaking, seven FDA members (one for each pilot program step), two or three PTO attorney examiners would be sufficient to evaluate proposed marks and perform legal confusion analysis. The PTO would then perform its inquiry in tandem with the FDA and return one decision to the sponsor; a rejection from either agency on the committee would result in an overall rejection. Likewise, approval from both sides would result in overall approval. The sponsor's submission to the PTO would still be under the PTO's statutory authority for ITU applications, and the ITU provisions would still apply to the trademark's approval.[168] While the FDA's inquiry would remain mandatory, drug sponsors would not be forced to obtain federal registration for their trademarks, though it is difficult to imagine a scenario where a sponsor would forego the opportunity to register its mark.

Centralizing each agency's efforts would synchronize the timeline that is hampering drugmakers, thus eliminating the need for pharmaceutical companies to play the guessing game of when to file trademark applications. But there is much more to be gained through a joint

166. The concept of a joint committee finds its roots in Boring and Doninger's suggestion of the addition of PTO personnel to the LNC. *See* Boring & Doninger, *supra* note 96, at 115 ("Because FDA seeks to have LNC comprised of a range of experts in the many . . . disciplines that affect the use of trademarks on drugs, it would make sense to add personnel from PTO . . . .").

167. Such as reviewing every drug trademark, having the last word on those reviews, and enacting the pilot program. *See supra* notes 96–108 and accompanying text.

168. Approval from the committee would require the drug sponsor to use the trademark in commerce and submit a Statement of Use (SOU) within a maximum of thirty-six months of the decision. *See supra* notes 55–62 and accompanying text.

committee.

An empowered joint committee would enable drugmakers to assign a preferred name to a drug early in its development just like "normal" commercial products, as there would be no need to maintain an arsenal of registered trademarks in the event that the FDA rejects a name. Since the PTO would be with the FDA on the committee reviewing marks in a synchronous timeline, the PTO would review a sponsor's backup name (or even third choice) at the same time the FDA does rather than forcing sponsors to reset their PTO clocks with new registration applications.[169] In addition to being much more efficient, the newfound lack of divergent timelines and "wargaming" over such timelines would conserve sponsor resources and thus replenish the treasuries at pharmaceutical companies, perhaps allowing them to spend more on research and development.[170]

A joint committee structure would also reduce the need for pharmaceutical companies to abuse the ITU application option. As mentioned above,[171] applicants either aim to shield their true trademarks from competitors or they warehouse trademarks in case the FDA rejects any. Regardless of which option is chosen, neither is a bona fide intent to use the mark in commerce. With the confidentiality of the committee providing a safe haven from opportunistic competitors and the need for a trademark warehouse taken away, abuse of the ITU applications should disappear quickly.[172] With less ITU abuse and more names that are associated with a drug (as opposed to names existing nebulously, unassigned to actual drugs), the PTO can conduct a more meaningful review. A joint committee would not, however, be able to prevent all ITU application abuse without statutory change at the PTO; concerned companies could still file a collection of applications at the PTO independent of the joint FDA review to shield their prospective marks from competitors.[173]

The clearest advantage to a joint committee approach is the seat it offers

169. Recall that without other registered trademarks at the ready, pharmaceutical companies would have to restart the PTO application process with a new drug name if the FDA rejected its PTO-approved submissions. *See supra* Part IV.

170. *See* Gagnon & Lexchin, *supra* note 3, at 32 (noting drugmakers spend almost twice as much on marketing as they do on product development).

171. *See supra* notes 67–68 and accompanying text.

172. It is important to note that *complete* confidentiality for trademark review cannot be obtained. At the heart of the PTO's review process is the public listing of marks, allowing for opposition. To allow pharmaceutical companies the ability to avoid a public disclosure would be to undermine competitors' abilities to rightfully challenge an illegitimate mark.

173. Only a statutory change mandating drug trademarks be evaluated in the joint committee would prevent such abuse, though it stands to reason that this is a general weakness of the ITU option not exclusive to pharmaceutical marks, as any company can avail itself of this strategy.

the PTO at the drug trademark table. As mentioned above,[174] the PTO lacks a meaningful review under the current system, where it exists as a clearinghouse for whatever names pharmaceutical companies would prefer to have lying in wait.[175] The PTO will not likely attain the importance that the FDA carries in drug trademark evaluation because the FDA's purpose is to protect consumer health, as opposed to the PTO's protection of intellectual property. Be that as it may, the PTO should function as the equally important coordinate agency in the federal government that it is, and a joint committee would allow it to do so.

C. How the Committee Forms

The obvious remaining issue is how this committee could be established. Congress certainly has the authority to mandate its creation by statute,[176] as Congress frequently sets the course for agency action, but moving anything through both the House of Representatives and Senate is a lengthy and cumbersome order.[177] Either the PTO or FDA (or the Executive) has the option to create a federal advisory committee.[178] Unsurprisingly, however,

174. *See supra* notes 129–130 and accompanying text (noting how the PTO's approval becomes a simple rubber–stamp).

175. *See* LALLEMAND, *supra* note 68, at 7 fig.8 (reporting that it is typical for pharmaceutical companies to submit five to ten trademarks to the PTO for registration as opposed to a mere two names to the FDA).

176. Congress could easily base its power to mandate a joint committee in the Commerce Clause, where it already bases its authority to regulate trademarks and drugs. *See generally* The Trade-Mark Cases, 100 U.S. 82 (1879) (invalidating the Trademark Act of 1870 for basing congressional authority to regulate trademarks in the Patent and Copyright Clause); Trademark Act of 1881, ch. 138, 21 Stat. 502 (rooting Congressional authority to regulate trademarks in the Commerce Clause); United States v. 7 Jugs of Dr. Salsbury's Rakos, 53 F. Supp. 746, 752 (D. Minn. 1944) (calling the Federal Food, Drug & Cosmetic Act of 1938 one of the most important Commerce Clause enactments and stating that drug legislation should be given a liberal construction).

177. *See* PEW RESEARCH CTR. FOR THE PEOPLE & THE PRESS, MARCH 2010 POLITICAL SURVEY 3 (2010), http://people-press.org/files/legacy-questionnaires/598.pdf (finding that a plurality of survey respondents chose *dysfunctional* as the one word that best describes Congress); JON STEWART ET AL., AMERICA (THE BOOK): A CITIZEN'S GUIDE TO DEMOCRACY INACTION 57 (Jon Stewart et al. eds., 2004) (equating the "convoluted" legislative process in Congress, or "quagmire," to movement through the gastrointestinal tract—satirically of course).

178. *See* Federal Advisory Committee Act of 1972, 5 U.S.C. app. 2 §§ 1–16 (2006). Federal advisory committees are created by Congress through statute, by the Executive through executive order, or by directive from an agency head. Whether called commissions, committees, councils, or task forces, they exist to hash out policy opinions and recommendations on topics ranging from organ transplant practices to Department of Homeland Security operations. WENDY R. GINSBERG, CONG. RESEARCH SERV., R40520, FEDERAL ADVISORY COMMITTEES: AN OVERVIEW 1, 8 (2009), http://www.fas.gov/

advisory committees exist to advise agencies and do not have the ability to make binding decisions on an agency's behalf, rendering such an option less than ideal to address the dual-agency review issues.[179]

The FDA's latitude to regulate drug trademarks is considerably wide,[180] and the PTO's ability to structure its offices is also quite expansive.[181] While the FDA could not conscript PTO personnel to participate on the committee, nor could PTO examiners invade the FDA's process, there is nothing preventing the FDA from politely inviting the PTO to participate and the PTO from accepting the invitation. Interagency collaboration is nothing new,[182] and that is really what this committee would be—FDA and PTO personnel would collaborate in a way that gives depth to each side's review, yet still focus on what they know best.[183] This committee would not reduce the substance or character of either agency's trademark review; rather, the committee would synchronize the review process.[184] As long as that is the case, the creation of a joint committee at the agency level would

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sgp/crs/misc/R40520.pdf.

179. 5 U.S.C. app. 2 § 2(b)(6). An advisory committee would also run into other problems as a framework for the joint committee: committees are required by the Federal Advisory Committee Act to be temporary (two years unless an enabling statute specifies otherwise) and accessible to the public (confidentiality of new drug applications would be shot). *See* GINSBERG, *supra* note 178, at 10–11. Such a committee would, in practice, be similar to the original LNC.

180. *See* 21 U.S.C. § 352(a)–(n) (2006) (giving the FDA authority to regulate a drug's label, package form, information on the label, names, directions, warnings, containers, colors, and advertisements). The FDA's expansive authority on the subject is echoed by its ability to constantly refigure its trademark review apparatus within the Center for Drug Evaluation and Research (CDER), each incarnation garnering more exclusivity over the process. *See* Gentin, *supra* note 97, at 259 (explaining how the LNC's role expanded since its inception); Scheineson, *supra* note 99, at 2 (noting how the FDA evaluated proposed drug trade names through the Office of Post-Marketing Drug Risk Assessment, which was a part of CDER); Tepper, *supra* note 101, at 34 (observing CDER now has final responsibility for decisions on pharmaceutical trademarks); Clifford, *supra* note 11 (stating the evaluation of proposed drug names expanded when it was undertaken by CDER).

181. *See Patent Technology Centers Management*, U.S. PATENT & TRADEMARK OFFFICE, http://www.uspto.gov/web/patents/contacts/tcmgrs.htm (last visited Feb. 7, 2012) (listing over fifty-five patent review sections, organized into nine "technology centers" that are segregated by patent application type, thus showing the PTO's tremendous flexibility).

182. *See, e.g.*, Office of the Vice President, *Improving Regulatory Systems*, 34 JURIMETRICS J. 331, 338 n.7 (1994) (outlining numerous interagency collaborations between the National Institute of Standards and Technology and the Nuclear Regulatory Commission, Environmental Protection Agency, and FDA itself).

183. It is important to be clear: neither agency would be telling the other what to do under this proposal. The goal should never be for the PTO's review to become more like the FDA's or vice-versa—they each perform an important and valuable function as it is.

184. *See supra* notes 131–136 and accompanying text (elaborating on the uncertainty caused by disparate timelines in the dual-agency review process).

be within the agency's administrative purview.

Since the FDA pursues the weightier mission (saving lives versus the PTO's saving of dollars) and conducts a more labor-intensive analysis in the dueling reviews of drug trademarks, it is unlikely that the PTO could initiate the creation of a joint committee. If the pilot program is permanently adopted, the FDA's process would be less laborious, but at least until that happens, the FDA would be in the appropriate position to invite the PTO's participation. It seems likely that the FDA could, rather painlessly, create a new review committee and vest in it the authoritative power it currently assigns to DMEPA with the inclusion of PTO personnel.[185]

The simplest method of including PTO personnel on a joint committee would be publishing a Memorandum of Understanding (MOU) in the *Federal Register*.[186] In 1987, the FDA published an MOU giving notice that it had collaborated with the PTO to develop procedures where the FDA assists the PTO in determining a product's eligibility for patent term restoration.[187] This particular MOU exhibits the agencies' ability to freely work together and even create a set of rules by which either can expect the other to operate. If the FDA and PTO could do it once, the simple notion is that they can do it again by "exchanging information" on pharmaceutical trademarks and establishing "review period determinations,"[188] which are, after all, the crux of the synchronization that this Comment proposes.

CONCLUSION

There is too much money and safety at stake for independent dual-agency review of pharmaceutical trademarks to continue in its current form. Both agencies have the legal authority to review trademarks under federal law. Both agencies therefore play a crucial role in the regulation of drugs. The administrative structure should enable them to provide their most meaningful, comprehensive evaluation and simultaneously provide an unencumbered and efficient process for industry stakeholders. The pilot

185. *Cf.* Boring & Doninger, *supra* note 96, at 115 (recommending, as chair of the LNC, that PTO personnel should be added to the LNC); Tepper, *supra* note 101, at 34 (chronicling the FDA's delegation of trademark review authority to DMEPA in 2009).

186. *E.g.*, Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, 52 Fed. Reg. 17,830, 17,830 (May 12, 1987) ("The MOU establishes procedures whereby FDA assists PTO in determining a product's eligibility for patent term restoration . . . .").

187. *Id.* The Memorandum of Understanding also established procedures for exchanging information between the agencies regarding regulatory review period determinations, due diligence petitions, and informal FDA hearings. *Id.*

188. *Id.*

program should be standardized to empower pharmaceutical companies and involve them in the trademark regulation process. The FDA should also codify its trademark review standards and processes like the PTO has to increase transparency and clarity for both drug sponsors and mark reviewers. A joint committee of PTO and FDA personnel established to review all drug trademarks and provide a single, binding decision would pay substantial dividends for both agencies and pharmaceutical companies. As the FDA has shown through its constant reinvention, there are a number of different ways to move toward an efficient system, but a joint committee could be the bold move that can empower both agencies in their review efforts and keep the consumer safe. With the relative ease that accompanies an MOU, there is little reason to delay a remedy to the glaring issues caused by independent dual-agency review.