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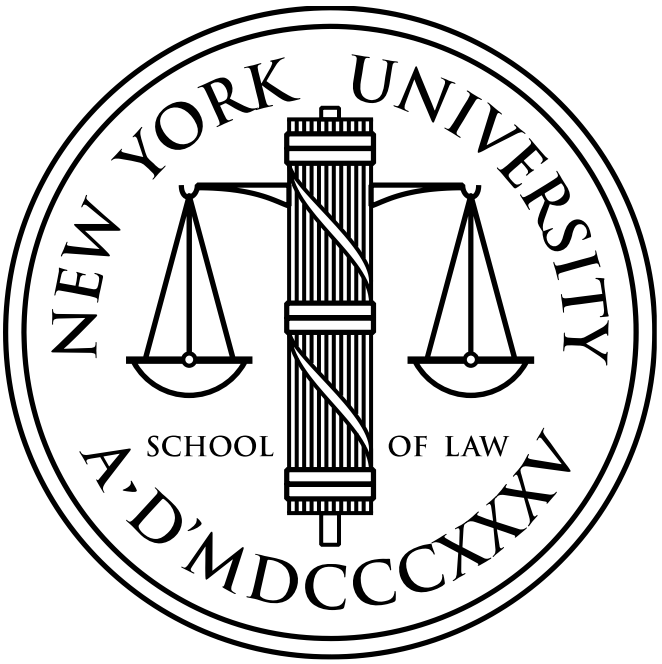

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TRADEMARKS, TRADE DRESS, AND THE PATIENT COSTS OF PHARMACEUTICAL BRANDING

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While the high cost of prescription drugs is often attributed to strong patent protections and special forms of market exclusivity granted to new small molecule drugs and biologics, there is another factor that explains high prices: the law of trademark and trade dress. Prescription drugs are not just introduced into the market after regulatory approval; they are released with special shapes, colors, packaging, logos, and comprehensive promotional campaigns. After their patent and exclusivity terms end, generic manufacturers, which may produce the medicines at 95% or less of the original retail price, may sell generic versions of the therapeutic compounds but may not sell them with the same appearance as the original medicines. The result is patient confusion, higher costs, and less adherence to drug regimens for the nearly two-thirds of U.S. adults who need prescription drugs. This Article analyzes the effect of trademark and trade dress law on prescription drug prices and recommends both regulatory and judicial approaches that may reduce the threat current law poses to individual and public health.

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INTRODUCTION

On July 9, 2021, U.S. President Joe Biden signed an executive order directing the U.S. Food and Drug Administration (FDA) to facilitate the approval for, and importation of, cheaper prescription drugs, but this order did not address one of the most important sources of high drug prices: appearance.[1] "More than 131 million people — 66 percent of all adults in the United States — use prescription drugs."[2] For millions of elderly individuals and those suffering from chronic conditions, they are an essential aspect of maintaining health. Access to those medications is affected by cost, and in that respect, conversations about prescription drugs frequently involve the role of patents as part of the reason prescription drug prices in the United States are so high.[3] This Article places the law of trademark and

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[1] Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 9, 2021), https://www.federalregister.gov/d/2021-15069 ("[T]o lower the prices of and improve access to prescription drugs and biologics, continue to promote generic drug and biosimilar competition, as contemplated by the Drug Competition Action Plan of 2017 and Biosimilar Action Plan of 2018 of the Food and Drug Administration . . . .").

[2] Emily Ihara, *Prescription Drugs*, GEO. HEALTH POL'Y INST., https://hpi.georgetown.edu/rxdrugs/ (last visited Jan. 20, 2022).

[3] *See, e.g.*, ERIN H. WARD, KEVIN J. HICKEY & KEVIN T. RICHARDS, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES (2021). *See generally* Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview*

trade dress on equal footing with patents and regulatory market exclusivities in the broader conversation on prescription drug prices so that policymakers, physicians, pharmacists, and other stakeholders will address the law of medicine appearance as well as other forms of market protection.[4] The recommendations contained below would stand even in the face of, or complementary to, other market exclusivity reforms.

Consider an elderly patient who is prescribed a drug regimen that begins with a bright green pill that is protected by patents, market exclusivity, as well as careful product design by its original manufacturer. After the patent and market exclusivity terms end, state law requires that the medicine be substituted by a cheaper generic version. The elderly patient, used to seeing the bright green pill, now sees a pill that is smaller and has a blue tinge. Believing that there is a mistake—perhaps the wrong medicine was put into the bottle—the patient stops taking the medication until she can speak with her doctor. After several weeks, the patient is convinced the change will not harm her health. Assume then, two weeks later, the pharmacy switches to a different generic supplier, whose pills again appear different. The medicine, dosage, strength, frequency, and all other relevant medical factors are unchanged, but the patient now believes, again, that there is a systematic error in the medical supply chain and stops taking the medicine again. All of this occurs because trademark and trade dress law prohibit the generic manufacturers from using the same pill appearance.

This scenario is routine, not exceptional. In one study, about half of patients (51%) reported receiving a prescription refill in which their pills' appearance changed in the last year and, of those patients, about half (53%) reported that it happened two or more times.[5] The relationship between patients and their medicines is deeply affected by how they appear (inside and outside packaging): their color, shape, hue, imprints, size, texture, and coating.[6] Patients taking generic versions of

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and Implications in Pharmaceutical Industry, 2 J. ADVANCED PHARM. TECH. RSCH. 88, 88-89 (2011).

[4] Indeed, as early as 1977, the Federal Trade Commission concluded that "the trademark, like the patent, might be given a limited life" due to the costs that trademarks impose on medicines. FED. TRADE COMM'N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 80 (Feb. 1977).

[5] Rachel E. Barenie, Aaron S. Kesselheim, Joshua J. Gagne, Zhigang Lu, Eric G. Campbell, Sarah K. Dutcher, Wenlei Jiang & Ameet Sarpatwari, *Preferences for and Experiences With Pill Appearance Changes: National Surveys of Patients and Pharmacists*, 26 AM. J. MANAGED CARE 340 (2020).

[6] Jeremy A. Greene & Aaron S. Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 N. ENG. J. MED. 83 (2011).

the same medication receive pills of different sizes, shapes, and colors routinely because of trade dress protections, and those changes, alterations, and adjustments, in turn, often adversely affect their adherence to their prescription schedules and trust in the medicines they need.[7]

The importance of drug products' appearance is well recognized in the industry: pharmaceutical firms invest as much or more in color, name, shape, and related branding and marketing features as they do in the development of the active pharmaceutical ingredients that actually treat disease and illness.[8] For the most part, those investments *are not* protected by patents. They are protected by the law of trademark and trade dress. And those laws, in turn, do more than just raise the cost of prescription drugs. They shape patient adherence to prescription drug regimens; cause or ameliorate the possibility of medication error; and play a complex role in the division of responsibility between licensing authorities, primarily the FDA and the U.S. Patent and Trademark Office (USPTO).[9]

Medicines may be protected by a patent as to the small molecule structure of the active compound, while the color, shape, and appearance of a capsule that contains the medicine may be protected by trademarks. Information accompanying the product may be protected by copyright.[10] Other aspects of production and

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[7] Jennifer L. Lenahan, Danielle M. McCarthy, Terry C. Davis, Laura M. Curtis, Marina Serper & Michael S. Wolf, *A Drug by Any Other Name: Patients' Ability to Identify Medication Regimens and Its Association with Adherence and Health Outcomes*, 18 J. HEALTH COMM. 31, 32 (Supp. 2013).

[8] Rebecca Farley, *Do Pharmaceutical Companies Spend More on Marketing than Research and Development?*, PHARMACYCHECKER, https://www.pharmacychecker.com/askpc/pharma-marketing-research-development/#! (last updated Apr. 28, 2021).

[9] *Compare* Ameet Sarpatwari, Joshua J. Gagne, Zhigang Lu, Eric G. Campbell, Wendy J. Carman, Cheryl L. Enger, Sarah K. Dutcher, Wenlei Jiang & Aaron S. Kesselheim, *A Survey of Patients' Perceptions of Pill Appearance and Responses to Changes in Appearance for Four Chronic Disease Medications*, 34 J. GEN. INTERNAL MED. 420 (2019) (examining patient adherence based on appearance), *with* Robert D. Litowitz & Lynn M. Jordan, *Procedures and Strategies for Pharmaceutical Brands: United States*, WORLD TRADEMARK REV. (Sept. 6, 2016), https://www.worldtrademarkreview.com/procedures-and-strategies-pharmaceutical-brands-united-states (discussing branding strategies that navigate the interplay between FDA and UPSTO requirements).

[10] Roseann B. Termini & Amy Miele, *Copyright and Trademark Issues in the Pharmaceutical Industry–Generic Compliance or Brand Drug Imitating–"Copycat or Compliance,"* PENN. BAR ASS'N Q., Jan. 2013, at 34; *see also* Thomas J. Daly & Alek Emery, *Branding Pharmaceuticals: Drug Naming and Non-Traditional Trademarks*, WORLD TRADEMARK REV. (July 17, 2019), https://www.worldtrademarkreview.com/brand-management/branding-pharmaceuticals-drug-naming-and-non-traditional-trademarks.

advertising may be protected by trade secrets.[11] All of these intellectual property protections affect cost most straightforwardly, but other aspects of patient welfare and provider knowledge as well.

This Article sheds light upon the substantial costs that trademark and trade dress impose on patients and emphasizes that, in the broader context of scrutinizing the relationship between intellectual property and high drug prices, patents and regulatory exclusivities are only a piece of a more complicated puzzle.[12] In highlighting trademark and trade dress, this Article endeavors to single out that form of intellectual property protection for special scrutiny by legislators, regulators, and judges.

Intellectual property, generally, is controversial.[13] On the one hand, each of the traditional forms of protection—copyrights, patents, and trademarks—involve giving an individual or a firm the right to exclude others and, in many cases, charge high prices for products.[14] Especially in the context of copyright and trademark, the intellectual property right burdens the use of words, information, and data that may be important for communication, learning, and expression.[15] On the other hand, those intellectual property rights provide incentives to create and invent.

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[11] Kristan Lansberry, *Protecting Trade Secrets in the Medical Product Approval Process*, FDLI (Apr. 2018), https://www.fdli.org/2018/04/update-protecting-trade-secrets-medical-product-approval-process/.

[12] *E.g.*, *id.*; Termini & Miele, *supra* note 10; WARD ET AL., *supra* note 3.

[13] *See generally* SAM F. HALABI, INTELLECTUAL PROPERTY AND THE NEW INTERNATIONAL ECONOMIC ORDER: OLIGOPOLY, REGULATION, AND WEALTH REDISTRIBUTION IN THE GLOBAL KNOWLEDGE ECONOMY (2018) (re-evaluating conventional wisdom of the distributive consequences of intellectual property rights).

[14] Shyamkrishna Balganesh, *Demystifying the Right to Exclude: Of Property, Inviolability, and Automatic Injunctions*, 31 HARV. J.L. & PUB. POL'Y 593, 628-29 (2008); Christine Greenhalgh & Mark Rogers, *The Value of Intellectual Property Rights to Firms and Society*, 23 OXFORD REV. ECON. POL'Y 541 (2007); Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1800 (2007) (observing how copyright law tends to place less reliance on exclusion than patent law and is thus less "property-like"); Fox Film Corp. v. Doyal, 286 U.S. 123, 127 (1932) ("The owner of the copyright, if he pleases, may refrain from vending or licensing and content himself with simply exercising the right to exclude others from using his property.").

[15] Annette Kur, *Fundamental Concerns in the Harmonization of (European) Trademark Law*, *in* TRADEMARK LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 151 (Graeme B. Dinwoodie & Mark D. Janis eds., 2008); TRADE MARKS AT THE LIMIT 163-64 (Jeremy Phillips ed., 2006).

These controversies play out vividly in the context of medicines[16] and remain the subject of heated debate.[17] Broadly speaking, disputes over the intellectual property protections afforded to pharmaceutical companies tend to focus on patents and market exclusivities given pursuant to the generation of data used to support regulatory approval.[18] These incentives, the companies argue, encourage continuous innovation.[19] Critics argue that the incentives do precisely the opposite: they encourage investment in incremental changes that just barely qualify for costly patent protection, keeping drug prices high and imposing significant barriers to entry for other manufacturers.[20]

Leaving to one side the acrimonious debate over the incentives that the regulatory state might extend to promote the optimal investment in the right number and variety of biomedical innovations, the reality is that trademark and trade dress

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[16] Levon Khachigian, *Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent*, 25 DRUG DISCOVERY TODAY 1135, 1146 (2020) ("This can be easily understood in the context of modern pharmaceutical innovation involving high development, testing and regulatory costs. An important part of any patent system is to ensure the public benefits from access to innovation. However, it is crucial to effectively facilitate public access to medicines that result from this innovation. As access to essential medicines is a core minimum obligation for states to realize the human right to health, this objective has great weight."); Aakash Shah, Jonathan Warsh & Aaron Kesselheim, *The Ethics of Intellectual Property Rights in an Era of Globalization*, 41 J.L. MED. & ETHICS 841 (2013); Frederick M. Abbott, *Falsified and Substandard Medicines: Current Challenges and Long Term Solutions: A Public Health Perspective*, IBSA (Oct. 15, 2010), http://www.law.nyu.edu/sites/default/files/ECM_PRO_074747.pdf ("The pharmaceutical industry, like most industries, is highly competitive. The actors with the power to do so fairly consistently demonstrate the willingness to use IPRs [intellectual property rights] to obtain commercial advantage beyond the 'legitimate scope' of their rights.").

[17] Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing than Research*, WASH. POST (Feb. 11, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/.

[18] Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive.

[19] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507 (2009).

[20] KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020) ("[P]atenting practices are used to keep drug prices high, without any benefit for consumers or innovation."); Sy Mukherjee, *Protect at All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-High*, FORTUNE (July 18, 2019, 6:30 AM), https://fortune.com/longform/abbvie-humira-drug-costs-innovation; Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE J.L. & TECH. 1 (2018).

are unique.[21] The product distinguishing rationale that purportedly justifies trademark and trade dress law arguably does precisely the opposite in the prescription drug context.[22]

This Article analyzes the protections that trademark and trade dress afford pharmaceutical companies outside of patents and regulatory exclusivities, which are generally placed at the center of pharmaceutical pricing and policy debates.[23] Quite apart from price, patients and their supporters use color, shape, logo, hue, size, and appearance—the classic areas of trademark and trade dress protection—to ensure that they are taking the correct medications, in the prescribed amounts, and at the right times to maintain their health, treat disease, and avoid adverse interactions between medications if they are taking more than one.[24] The Article identifies the specific individual and public health problems posed by trademark and trade dress protection and recommends changes in current law that may contribute toward the difficult question of balance that pervades all scholarship on the advantages and disadvantages of using intellectual property protection to promote innovation.[25] In the context of pharmaceutical trademarks and trade dress, this means understanding when allowing pharmaceutical firms to protect trademarks and trade dress is too costly relative to the value in having patients adhere to their prescribed medical

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[21] Megan Brewster & Pallab Singh, *Intellectual Property Protection for Biologics*, *in* ACAD. ENTREPRENEURSHIP FOR MED. & HEALTH SCIENTISTS (Nalaka Gooneratne, Rachel McGarrigle & Flaura Winston eds., 2019), https://repository.upenn.edu/ace/vol1/iss3/11; J.W. Kenagy & G.C. Stein, *Naming, Labeling, and Packaging of Pharmaceuticals*, 58 AM. J. HEALTH-SYST. PHARM. 2033, 2033 (2001).

[22] Kelley Clements Keller, *Free Riders at the Drugstore: Generics, Consumer Confusion, and the Public Good*, 12 CHI.-KENT J. INTELL. PROP. 184, 186 (2013) ("The difficulty lies in striking a balance between the competing interests of national brands to trademark protection for source identifiers on their products and the rights of generic labels to bring publicly accepted substitute drugs to market that earn the public's trust and confidence. Absent a stable and reliable body of law, both branded and generic manufacturers may be left with inadequate security or guidance for effective business planning with respect to advertising and branding schemes, a situation that will inevitably result in costly litigation and contribute to the rising cost of drugs.").

[23] Rebecca Tushnet, *Trademark Law as Commercial Speech Regulations*, 58 S.C. L. REV. 737-56 (2007).

[24] Barenie et al., *supra* note 5.

[25] Dan L. Burk & Brett McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575, 577 (2007) ("Thus, we posit a 'Goldilocks hypothesis' for intellectual property rights and the firm: like the size of a chair, the temperature of a porridge, or the firmness of a mattress, the provision of intellectual property rights should not vary too far to one extreme or another, but must be calibrated so that it is 'just right.'").

regimens, avoid medication error, and place trust in their providers and their medicines.

Part I situates trademark and trade dress protections for pharmaceuticals in the broader context of intellectual property protections, which (the Articles argues) overemphasize patents and regulatory exclusivities and underemphasize trademark and trade dress. Part II analyzes the specific costs that current trademark and trade dress law impose on patients as they attempt to adhere to their prescription drug regimens, as well as the costs imposed on physicians as they attempt to help their patients do so. Part III details the legislative, regulatory, and judicial possibilities for addressing the costs that trademark and trade dress impose on patient and physician populations. The Article then provides a brief conclusion.

I
PATENT, COPYRIGHT, AND TRADEMARK PROTECTION FOR PHARMACEUTICAL INNOVATIONS

From the manufacturer's perspective, planning the intellectual property protections for pharmaceuticals entails careful analysis of product features, the probability of inadvertent or uncontrollable disclosure, and the chemical or biochemical character. Although patents are generally regarded as the foundational and most important protection, they are of limited duration, may be costly to enforce, and are expensive to obtain *ex ante*.[26] Trademark protections, by contrast, are potentially indefinite and may guard significant aspects of a drug's value even after a patent term expires.

This Part describes the varying forms of intellectual property that explain the high costs of prescription drugs in the United States. It concludes with the specific kinds of protection that trademark and trade dress afford, and how those protections are indefinite so that even when other forms of intellectual property expire, trademark and trade dress still keep generic manufacturers from providing prescription drugs with all the precise attributes of the original medicine.

[26] Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658 (2017), http://dx.doi.org/10.1001/jamainternmed.2017.4329.

A. Patent and Regulatory Exclusivity

For small molecule drugs, patent protections cover a 20-year period, generally shortened by the time of disclosure to the time of regulatory approval.[27] By international treaty, the 20-year patent term is largely universal, but conditions for granting patents vary by country, and individual countries may allow non-patent forms of regulatory exclusivity.[28] For example, in the United States, regulatory exclusivities may generally offer 6-month, 3-, 5-, 7-, and (for biologics) 12-year protections, depending on approval channel and characterization.[29] These exclusivity periods allow pharmaceutical manufacturers to market drugs without competition.[30] At the expiration of the patent and regulatory exclusivity terms, generic drug manufacturers may enter the marketplace more efficiently and at a lower price by complying with formula and manufacturing specifications already approved by the FDA (or the equivalent national regulatory authority).[31] Under U.S. law, generic entrants are also encouraged with less stringent regulatory pathways and the possibility of 180 days of exclusivity if they are the first to the market.[32] In 2017, generic drugs constituted around 70% of total prescription drugs dispensed but only made up 16% of total drug spending.[33] Despite the development of an extensive regulatory framework, drug pricing still faces considerable scrutiny from Congress.[34]

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[27] Termini & Miele, *supra* note 10; Subhasis Saha, *Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceuticals*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 364, 366-67 (2009).

[28] *See* Roberto Romandini, *Flexibilities Under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law*, 15 J. MARSHALL REV. INTELL. PROP. L. 150, 183 (2016); Matthias Lamping et al., *Declaration on Patent Protection—Regulatory Sovereignty Under TRIPS*, 45 INT'L REV. INTELL. PROP. & COMPETITION L. 679, 681 (2014).

[29] Halabi, supra note 20, at 27.

[30] *Id.* at 20.

[31] *Id.* at 25; SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 26 (2d Cir. 2000).

[32] Ravi Gupta, Nilay D. Shah, & Joseph S. Ross, *Generic Drugs in the United States: Policies to Address Pricing and Competition*, 105 CLINICAL PHARM. & THERAPEUTICS 329, 330 (2019).

[33] Aaron S. Kesselheim, Alexander S. Misono, William H. Shrank, Jeremy A. Greene, Michael Doherty, Jerry Avorn & Niteesh K. Choudhry, *Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173 JAMA INTERNAL MED. 202, 202 (2013).

[34] *See, e.g.*, *Drug Pricing in America: A Prescription for Change, Part I: Hearing Before the S. Comm. on Finance*, 116th Cong. 116 (2019); *The Cost of Rising Prescription Drug Prices: Hearing Before the H. Ways and Means Comm.*, 116th Cong. (2019); *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight and Reform*, 116th Cong. (2019); Ryan Davis, *Breaking Down 3 New Senate Bills Targeting Drug Prices*, LAW360 (Apr. 18, 2019, 7:36 PM), https://www.law360.com/articles/1150045/breaking-down-3-new-senate-bills-targeting-drug-prices.

There are good reasons that patents and regulatory exclusivities are not the only intellectual property protection deployed as part of firms' strategies to maximize revenue. When challenged, small molecule drugs especially may fail tests for novelty and non-obviousness essential for patent validity.[35] Under U.S. federal law, generic manufacturers are encouraged to challenge the validity of patent claims before the technical expiry of the patent. By filing a so-called "paragraph IV" certification (named after its location in the Code of Federal Regulations), generic applicants, as part of their submissions, submit claims that one or more drug patents are "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the [generic] application is submitted."[36] In order to do so, the generic manufacturer must notify the patent holder of the patent challenge.[37] The patent holder must then file an infringement suit within 45 days to avoid immediate approval of the generic application.[38] If an infringement suit is filed within 45 days, then a 30-month stay is granted by the FDA to allow the parties to resolve the dispute.[39] If a generic manufacturer successfully challenges the validity

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[35] Roin, *supra* note 19, at 504-05 ("Amid this general optimism about the effectiveness of patents in promoting pharmaceutical innovation, scholars have overlooked a critical flaw in the system: socially valuable drugs often cannot be patented even though they are unlikely to be developed for public use without that protection. If the idea for a drug is not novel or is obvious—perhaps because it was disclosed in an earlier publication or made to look obvious by recent scientific advances—then it cannot be patented. Yet the mere idea for a drug alone is generally of little value to the public. Without clinical trials proving the drug's safety and efficacy—a prerequisite for approval by the Food and Drug Administration (FDA) and acceptance by the medical community—that drug is unlikely to benefit the public.").

[36] 21 C.F.R § 314.94(a)(12)(i)(A)(4) (2020); *Patent Certifications and Suitability Petitions*, FDA, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions (last updated Jan. 12, 2022).

[37] *In re* Lipitor Antitrust Litig., 868 F.3d 231 (3d Cir. 2017) ("On December 10, 2002, Teva obtained ANDA first-filer status for a generic version of Effexor XR. Teva's ANDA included paragraph IV certifications, asserting that Teva's sale, marketing, or use of generic Effexor would not infringe Wyeth's patents or that those patents were invalid or unenforceable . . . . Within the 45-day period prescribed by the Hatch-Waxman Act, Wyeth brought suit against Teva for patent infringement in the District of New Jersey."); Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373, 385 (2000).

[38] 35 U.S.C. § 271(e)(5).

[39] Liam Bendicksen, Jonathan J. Darrow & Aaron S. Kesselheim, *Challenging Patents to Promote Timely Generic Drug Entry: The Second Look Act and Other Options*, HEALTH AFF. BLOG (Aug. 31, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200827.532806/full/ ("A better option would be to continue to require that most patents be listed in the Orange Book, but reduce the 30-month stay to a shorter period, such as 18 months. Lawmakers could also limit the stay to a narrower set of patents or eliminate the stay entirely, though this could lead to delayed litigation (and thus delayed generic entry) by removing the incentive for brand-name

of a patent, then it is granted 180 days of generic market exclusivity upon approval.[40] If the patent is found to be invalid, the generic manufacturer still has to wait for the expiration of the exclusivity period granted by the FDA upon approval of the new drug product.[41]

After this process or expiration of the patent or regulatory exclusivity period, manufacturers rely upon alternative forms of intellectual property protection, some of which have stirred controversy.[42] Strategies including "evergreening," "authorized generics," "citizen petitions," and "pay for delay" allow firms to increase the length of market exclusivity and limit competition in ways related to, but technically outside of, the intellectual property sphere.[43] "Evergreening" means the patenting of peripheral features of drugs, like their coating or normal metabolites, that allow claims for longer exclusivity even though those patents do not relate to the active pharmaceutical ingredient.[44] "Evergreening" allows manufacturers to protect "new" drugs with patents following the expiration of the old patent.[45] These

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manufacturers to bring patent challenges within 45 days."); Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 198 (1999).

[40] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping*, 62 FLA. L. REV. 1009, 1014 (2010) ("[T]he Act provided 180 days of marketing exclusivity to the first generic firm to certify that the brand firm's patent was not valid or that the generic's drug did not infringe the patent. Such exclusivity was reserved for the first generic firm-known as a "Paragraph IV filer"-that sought to enter during the patent term. During the period, which begins after the first commercial marketing of the drug, the FDA cannot approve other ANDAs for the same product.").

[41] *See* 21 C.F.R. § 314.108 (2016); 21 C.F.R. § 316.31 (2013); 21 C.F.R. § 316.34 (2013).

[42] RICHARDS ET AL., *supra* note 20.

[43] *Id.*; *see also* Andrew Hitchings, Emma Baker & Teck Khong, *Making Medicines Evergreen*, 345 BMJ 1 (2012).

[44] James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI-KENT L. REV. 1519, 1542 (2007).

[45] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CMAJ E385, E385 (2013) ("As any would-be inventor knows, coming up with something the world has never seen before can be tough. Tweaking something old and calling it new, on the other hand, is considerably easier. In the pharmaceutical trade, when brand-name companies patent 'new inventions' that are really just slight modifications of old drugs, it's called 'evergreening.' And it's a practice that, according to some who have looked into it, isn't doing a whole lot to improve people's health. 'Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company's economic advantage,' says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. 'The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name

follow-on products are initially cheaper, which encourages prescribers to adopt their use, and by leveraging the trademark, trade dress, and brand of the follow-on product, drug manufacturers can maintain a significant share of the market.[46]

Under "pay for delay" agreements, brand-name pharmaceutical firms offer to pay generic manufacturers to delay the release of a generic drug.[47] These receive heavy criticism because they cost U.S. consumers more than $3.5 billion annually due to increased drug costs.[48] "Citizen petitions" also delay generic approval because firms may submit these to the FDA for priority review to have the FDA review the generic applications for possible changes.[49] Brand-name manufacturers can also release their own "authorized generics" as patent or exclusivity expiration nears.[50] If the "authorized generic" is the first generic on the market, it can obtain 180 days of generic exclusivity.[51] Lastly, brand-name manufacturers may limit generic manufacturers' ability to do bioequivalence testing by refusing or delaying access to the brand-name drug.[52]

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companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.'").

[46] *Id.* In one example, in Switzerland, a co-payment incentive program combined with an increase in generic drug competition contributed to the replacement of brand-name drugs and the reduced prices of brand-name drugs. However, this loss of profit from brand-name drugs was fully offset by successful marketing of follow-on drugs through evergreening strategies. Nathalie Vernaz, Guy Haller, Francois Girardin, Benedikt Huttner, Christophe Combeqcure, Pierre Dayer, Daniel Muscionico, Jean-Luc Salomon & Pascal Bonnabry, *Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis*, 10 PLOS MED. 1, 6 (2013).

[47] *See, e.g.*, Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 355 (2013).

[48] *Pay-for-Delay: When Drug Companies Agree Not to Compete*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay (last visited Jan. 20, 2022).

[49] *See In re* Flonase Antitrust Litig., 795 F. Supp. 2d 300, 309 (E.D. Pa. 2011) (denying summary judgment of whether defendant's conduct constituted "sham" petitioning); La. Wholesale Drug Co. v Sanofi-Aventis, No. 07 Civ. 7343 (HB) 1, 2 (S.D. N.Y. Aug. 28, 2009) (denying judgment as a matter of law following verdict that defendant's conduct did not constitute "sham" petitioning); *In re* DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 686 (2d Cir. 2009) (reversing dismissal for failure to state a claim of sham petitioning); *In re* Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 160 (E.D. Pa. 2009) (addressing standing for bringing complaint based on sham petitions).

[50] *See* Jay Hancock and Sydney Lupkin, *Drugmakers Master Rolling Out Their Own Generics to Stifle Competition*, KAISER HEALTH NEWS (Aug. 5. 2019), https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/.

[51] *Id.*

[52] *Id.*

Aside from these strategies, monetary and injunctive relief is available for brand-name manufacturers for claims related to copyright, trademark, trade dress, and trade secrets.[53]

B. Copyright

Copyright protects expressions of ideas, although not the ideas themselves.[54] As soon as an idea is expressed in a fixed, tangible medium, copyright protection generally attaches.[55] Copyrights can be held by individuals or corporations. For individuals, the copyright lifespan is for the life of the author plus an additional 70 years.[56] For firms (technically works for hire), the copyright lifespan is the first of 120 years from creation or 95 years after publication.[57]

Copyright protection for pharmaceutical manufacturers typically protects the packing material, the design and appearance of the package, and the labeling from being infringed, copied, or duplicated and from unauthorized use.[58] However, this does not protect medical literature; it only protects the "unique form of designing or explaining" the manufacturer's products.[59]

In the United States, copying a drug label is not generally copyright infringement if the FDA deems it necessary for approval of generic drugs, and if it does not interfere with existing principles of copyright law.[60] Because the U.S. Food, Drug, and Cosmetics Act requires compliance with the labeling guidelines to reassure bioequivalence of generic drugs, the FDA may require *verbatim* compliance

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[53] *Id.*; Abbott, *supra* note 16, at 1; Termini & Miele, *supra* note 10, at 35.

[54] Termini & Miele, *supra* note 10, at 35.

[55] 17 U.S.C. § 102(a); Christopher Buccafusco, *A Theory of Copyright Authorship*, 102 VA. L. REV. 1229, 1231-32 (2016) ("The Supreme Court has offered some guidance. In order to be copyrightable, a work must be original, at least minimally creative, and fixed in a tangible medium of expression. Original, in this sense, means that the work was not copied from another source. It is a binary distinction. Creativity is a scalar concept involving more or less novelty or cleverness. The Court has explained, however, that the threshold for creativity in copyright law is very low. And to constitute a fixed writing, a work must be made 'sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration.'").

[56] 17 U.S.C. § 302(a).

[57] 17 U.S.C. § 302(c).

[58] Javed Hasan, *Position of Design & Copyright Protection in Pharmaceutical Industry*, MEDICARE NEWS (June 30, 2018) https://medicarepharmabusiness.com/position-of-design-copyright-protection-in-pharmaceutical-industry/.

[59] Abbott, *supra* note 16, at 7.

[60] SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 23 (2d Cir. 2000).

with previously approved drug labeling.[61] Therefore, labeling may only be protected by copyright if the manufacturer adds creative parts to the labeling or adds labeling beyond the FDA's requirements.[62]

In some countries, copyright claims can arise in the pharmaceutical industry regarding product monographs.[63] A product monograph is a publicly available document containing information regarding the safety and efficacy of a particular drug.[64] In those cases, although the monographs are public scientific data, copyright infringement claims may be asserted if one or more competitors substantially reproduces a manufacturer's product monograph.[65]

While copyright may serve a relatively limited function in protecting drug-related information from legitimate competitors, it plays a special role in the context of counterfeit, falsified, and substandard drugs.[66] "Unfortunately, there are currently no accurate estimates of the global burden of falsified and substandard drugs precisely because activity occurs in global black and gray markets."[67] Evidence suggests, however, that the problem is most severe in low- and middle-income countries, so copyright plays a particularly important role in the customs context, where authorities examine imports for copyright infringement specifically.[68] Imitation drugs mimic other drugs or substances in appearance, whereas counterfeit drugs copy another drug's label, container, and/or identifying marks.[69] In that respect, copyright and trademark share important features with respect to

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[61] 21 U.S.C. § 355(j)(2)(A)(v).

[62] Termini & Miele, *supra* note 10, at 36. As with patents, copyright protections have achieved some uniformity through international treaty, but the conditions required for the assertion of copyright to protect drug information varies by the law in each country. Saha & Bhattacharya, *supra* note 3, at 89.

[63] Ryan Steeves, *"I Shouldn't Copy, Right?" Why Pharmaceutical Companies Should Care About Copyright*, MONDAQ (June 26, 2014), https://www.mondaq.com/canada/copyright/323120/i-shouldnt-copy-right-why-pharmaceutical-companies-should-care-about-copyright.

[64] *Id.*

[65] *Id.*

[66] Termini & Miele, *supra* note 10, at 38.

[67] Sam F. Halabi & Lawrence O. Gostin, *Falsified and Substandard Medicines in Globalized Pharmaceutical Supply Chains: Toward Actionable Solutions*, *in* FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZED MARKETS 51, 54 (Sam F. Halabi ed., 2015).

[68] *See* Sachiko Ozawa, Daniel R. Evans, Sophia Bessias, Deson G. Haynie, Tatenda T. Yemeke, Sarah K. Laing & James E. Herrington, *Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-Analysis*, JAMA NETWORK OPEN (Aug. 10, 2018), http://dx.doi.org/10.1001/jamanetworkopen.2018.1662.

[69] United States v. Articles of Drug, 601 F. Supp. 392, 395 (D. Neb. 1984).

pharmaceutical firms' intellectual property strategies. As with trademark protection, which will occupy the remainder of this Article, rights holders are often accused of over-enforcing their claims (for example, asserting copyright infringement at the border when the extent to which that protection applies may be in doubt).[70] Nevertheless, copyright, patent, and trademark play important roles in a comprehensive intellectual property strategy.[71]

C. Trademark and Trade Dress

While patents protect products and copyrights protect the expression of ideas fixed in a tangible medium, trademarks protect "any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified."[72] Trademark protection may also extend to sounds, scents, flavors, textures, and product appearance.[73] In the case of pharmaceuticals, other non-traditional marks (such as shape) can be protected as "trade dress" if the appearance of the drug has acquired distinctiveness.[74]

Within limits, trademark protection provides an incentive for firms to invest in the quality of goods and services and, relatedly, to reduce the costs to consumers of identifying products with desirable quality and price in the same class of products ("search costs").[75] Without laws prohibiting trademark infringement or misappropriation, imitators would be enabled to free ride on those investments and dupe consumers.[76] Where the product supplied is not only inferior but hazardous—medicines are an important example—the concern about quality is magnified.[77]

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[70] *See* Nokia Corp. v. Revenue & Customs Comm'rs, [2009] EWHC 1903 (Ch). (Eng.).

[71] Termini & Miele, *supra* note 10, at 35.

[72] Saha & Bhattacharya, *supra* note 3, at 89; *see also* 15 U.S.C. § 1127. *See generally* Sam F. Halabi, *Reconciling International Obligations to Protect Health and Trademarks: A Defense of Trademarks as Property*, *in* INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH 389, 389-406 (Daniel J. Gervais ed., Edward Elgar Publ'g Ltd. 2015).

[73] John T. Cross, *Trademark Issues Relating to Digitalized Flavor*, 19 YALE J.L & TECH. 339, 363 (2017) ("Trademark protection in the United States is not limited to words, logos, and other classic trade symbols. It also can extend to non-verbal, non-pictorial features of the product itself, including overall shape, color, decoration, sound, and even scent. At least in theory, the flavor of a product could also serve as a trademark for that product.") (footnotes omitted).

[74] Daly & Emery, *supra* note 10.

[75] William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON. 265, 275-80 (1987).

[76] Robert G. Bone, *Hunting Goodwill: A History of the Concept of Goodwill in Trademark Law*, 86 B.U. L. REV. 547, 555-56 (2006).

[77] Charles Clift, *Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?* (Nov. 2010) (Briefing Paper, Chatham House), The Royal Institute of International Affairs.

When well-functioning, trademark protection thus promises a mutual benefit to firms and consumers.[78]

1. Trademark

In the United States, the Lanham Act created a system of federal trademark registration and federal claims of relief for trademark infringement.[79] To be registered as a trademark, the mark must be distinctive.[80] In the context of trademark registration, the most distinctive marks have "inherent distinctiveness" if they are arbitrary, fanciful, or suggestive.[81]

Trademarks are one of the most important forms of intellectual property protection available to pharmaceutical firms.[82] The pharmaceutical industry invests at least $27 billion annually on marketing brand awareness to U.S. doctors and patients.[83] Like other forms of intellectual property protection, trademarks can provide a significant market advantage; however, the basis of that advantage differs. Patents and regulatory exclusivities prevent others from mimicking physical product features.[84] In that respect, trademarks appear less protective—other products with similar physical features may still be sold if their appearance is distinguished. But, unlike patent and regulatory exclusivity protection (or even copyright), trademark

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[78] Halabi, *supra* note 72, at 392-93.

[79] 15 U.S.C. 1051 *et seq*.

[80] Landes & Posner, *supra* note 75, at 287-88 ("Trademark protection is available only for a word or other signifier that identifies the underlying good (or service) and distinguishes it from that of other producers. Lack of distinctiveness would make the mark incapable of identifying the good . . . .").

[81] Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9 (2d Cir. 1976). *But see* Alexandra J. Roberts, *Trademark Failure to Function*, 104 IOWA L. REV. 1977, 2020 (2019) ("When it comes to trademark protectability . . . empirical data reveals that the current regime's over-emphasis on inherent distinctiveness and under-emphasis on use as a mark does not adequately predict or reflect the perceptions of real consumers."); Thomas R. Lee, Eric D. DeRosia & Glenn L. Christensen, *An Empirical and Consumer Psychology Analysis of Trademark Distinctiveness*, 41 ARIZ. ST. L.J. 1033, 1039-54 (2009) (finding that "context" corresponding to common indicators of trademark use had greater influence on consumer perception of distinctiveness than the *Abercrombie* taxonomy).

[82] KEVIN J. HICKEY, ERIN H. WARD & WEN S. SHEN, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 3 n.20 (2019), https://fas.org/sgp/crs/misc/R45666.pdf.

[83] *Persuading the Prescribers: Pharmaceutical Industry Marketing and Its Influence on Physicians and Patients*, PEW CHARITABLE TR. (Nov. 11, 2013), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients.

[84] Halabi, *supra* note 20.

protection is potentially perpetual when taking a few relatively inexpensive measures.[85]

More importantly, the drug's appearance may be, and frequently is, the most important market advantage: when trademarks protect brands with substantial value, the brand itself becomes a product characteristic that consumers value, even cherish, but competitors may not copy.[86] Moreover, because of what trademark is designed to achieve—trustworthiness in the view of the consumer—patients may refuse to switch to lower cost alternatives because doing so is costly—what is generally known as "search costs"—in that they must research the alternative's origin, price, and reputation.[87] There is substantial evidence that name brands of previously patent-protected medicines can maintain a premium price over newly available generic versions of the same medicines.[88] AstraZeneca's prescription drugs Prilosec

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[85] Deborah R. Gerhardt, *Beware the Trademark Echo Chamber: Why Federal Courts Should Not Defer to USPTO Decisions*, 33 BERKELEY TECH. L.J. 643, 645 (2018) ("[T]rademark rights can change dramatically over time. Most forms of intellectual property, like patents, copyrights, and rights of publicity, have set linear terms of protection and then move into the public domain. Trademarks are different. They can move in and out of protectable status as market uses and language evolve. A trademark, if carefully curated as a source identifying symbol, can last forever."); Jonathan Hyman, Charlene Azema & Loni Morrow, *If the IP Fits, Wear It: IP Protection for Footwear—A U.S. Perspective*, 108 TRADEMARK REP. 645, 661 (2018) ("There is no limit on the duration of trademark protection . . . . A federal trademark registration must be renewed every ten years and can be renewed indefinitely so long as the registrant attests to continued use of the registered mark in the United States with a supporting specimen as evidence of use."); *see also* Robert G. Bone, *Trademark Functionality Reexamined*, 7 J. LEGAL ANALYSIS 11 n.25 (2015) ("To be sure, some courts argued that granting a perpetual common law monopoly in features that were never patented or extending the patent monopoly beyond the patent term would conflict with the patent statute.").

[86] Sam Foster Halabi, *International Trademark Protection and Global Public Health: A Just-Compensation Regime for Expropriations and Regulatory Takings*, 61 CATH. U. L. REV. 325, 338 (2012) ("In some industry sectors, such as soda and tobacco, a trademark's value may comprise the majority of a company's worth precisely because of indivisibility of advertising, promotion, and marketing costs from consumer preference for the trademark. These investments yield even greater gains in states with high rates of illiteracy because symbols or diagrams are more important in product selection than written words.") (footnotes omitted); Shawn K. Baldwin, *"To Promote the Progress of Science and Useful Arts": A Role for Federal Regulation of Intellectual Property as Collateral*, 143 U. PA. L. REV. 1707, 1704 (1995) ("[T]rademarks may represent as much as eighty percent of a company's value.").

[87] *See generally* Mark P. McKenna, *A Consumer Decision-Making Theory of Trademark Law*, 98 VA. L. REV. 67 (2013) (discussing consumer search costs theory and its domination of the discussion of trademark law for the last several decades).

[88] Mark A. Hurwitz and Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 314 (1988).

and Nexium are both known in the marketplace as the "Purple Pill." Pfizer also succeeded in registering the blue diamond shape of its tablets as a trademark for its prescription drug Viagra. In short, in a world where information is costly, it is rational for patients to pay more for what they know rather than spend time researching potentially equivalent products.[89]

Brand names of drugs are protected by trademark, but this does not include the name of the drug itself.[90] Prozac, for example, is also called Erocap, Lorien, Lovan, and Zactin outside the United States, although the name of the compound is fluoxetine.[91] For a proprietary name to become a registered trademark, it must be reviewed by both the medicine's regulatory authority (in the United States, the FDA) as well as the trademark review authority (in the United States, the USPTO).[92]

The standards of review are different and reflect the mandates of those authorities. The FDA is primarily concerned with proposed trademark names that may induce medication error (for example, a name that may be confused when a physician writes the prescription, a pharmacy fills it, or a patient ingests it). Names

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[89] C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 682 (2011) ("Another common complaint is that manufacturers often use [direct-to-consumer pharmaceutical advertising] to promote expensive 'me-too' or 'copycat' drugs that might not offer any significant benefits over older and cheaper medications. For example, two heavily promoted diabetes treatments, rosiglitazone (Avandia, GlaxoSmithKline) and pioglitazone (Actos, Takeda), were found to be no more effective—or safe—than older drugs, even though they were much more expensive. In another study, older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as $600 per month less than olanzapine (Zyprexa, Eli Lilly), quetiapine (Seroquel, AstraZeneca), or risperidone (Risperdal, Janssen).") (footnotes omitted).

[90] Alfred B. Engelberg, *Have Prescription Drug Brand Names Become Generic?*, AM. J. MANAGED CARE (Nov. 18, 2014), https://www.ajmc.com/view/have-prescription-drug-brand-names-become-generic ("Bayer has maintained a large share of the aspirin market for decades by using the Bayer name to identify the original version of aspirin. The use of a corporate name in association with a generic name for a medicine would create a clear brand identity shared by the medicine and its original producer, which would permanently distinguish the original product from later generic versions. That would enable patients to choose between competing bioequivalent medicines, all of which have the same name and appearance, on price and real or perceived differences in quality just as they now do when purchasing over-the-counter medicines.").

[91] Ameet Sarpatwari & Aaron S. Kesselheim, *The Case for Reforming Drug Naming: Should Brand Name Trademark Protections Expire upon Generic Entry?*, PLOS MEDICINE (Feb. 9, 2016), https://doi.org/10.1371/journal.pmed.1001955.

[92] Katherine P. Califa, *Ready to Release a New Pharmaceutical? What to Think About When Selecting Your Drug Name*, NAT'L L. REV. (Nov. 8, 2017), https://www.natlawreview.com/article/ready-to-release-new-pharmaceutical-what-to-think-about-when-selecting-your-drug.

proposed for trademark protection are reviewed for visual and auditory similarities to other drugs.[93] To protect patients from misidentifying medications, drugs must avoid looking and sounding alike.[94] As Katherine P. Califa explains:

> The FDA considers spelling similarities such as whether two names share identical prefixes, suffixes, or infixes, and whether the names are a similar length. The FDA also considers the overall "shape" of the words. Do both names have similar looking letters in similar positions in the names – including "tall" letters ("l" "t" "f"), "round" letters ("o" "a" "c" "e" "u"), cross-stroke letters ("T" "Z" "F" "J" "I"), or down-stroke letters ("v" "r" "n" "u")? The FDA will balance these factors, along with an analysis of the phonetic similarities, to determine the overall similarity between two drug names.[95]

"The FDA views medication errors as preventable and has essentially adopted a zero-risk tolerance policy. [Overall], the FDA rejects proprietary names at a rate of 40% or more . . . ."[96]

The USPTO, on the other hand, reviews drug names to determine whether the new trademark is capable of registration, whether the new trademark conflicts with a prior trademark application or registration, and whether the trademark application complies with the USPTO's rules.[97] The USPTO's primary considerations when evaluating whether to grant registration include whether the mark is sufficiently distinctive and whether there is a likelihood of confusion with respect to other registered marks.[98] "The 'likelihood of confusion' test considers factors such as similarities in marks, the relatedness of goods and services, the relatedness of trade

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[93] *Id.*

[94] *See id.*; *see also Medication Errors Related to CDER-Regulated Drug Products*, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products (last updated Sept. 8, 2021).

[95] Califa, *supra* note 92.

[96] Nicholas de la Torre & Jennifer Theis, *United States*, *in* PHARMACEUTICAL TRADEMARKS 2013/2014: A GLOBAL GUIDE 82, 83 (4th ed. 2013), https://www.brinksgilson.com/files/pharma_2013_article.pdf.

[97] Califa, *supra* note 92; Termini & Miele, *supra* note 10, at 39; Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. & TECH. L. REV. 1, 6 (2015).

[98] 15 U.S.C. § 1052(d), (f).

channels, market conditions[,] and the number and nature of similar marks in use for similar goods."[99]

Trademark and trade dress protections are used to signal to consumers the source of a product; trademark generally addresses the name, logo, or symbol of a product whereas trade dress addresses the visual appearance of a product or its packaging. The standard for claiming trademark infringement has increased over the years as courts have shifted the burden to the party claiming trademark infringement to prove a "likelihood of irreparable harm" to obtain injunctive relief.[100] For many years, trademark infringement claims were granted a "presumption of irreparable harm," allowing for injunctive relief.[101] However, following the Supreme Court's rulings in *eBay v. MercExchange* and *Winter v. NRDC*, the standard changed from a "presumption of irreparable harm" to a burden upon the party claiming a "likelihood of irreparable harm."[102] Under current U.S. law, a plaintiff claiming trademark infringement must satisfy the elements in place for all types of injunctive relief. A plaintiff "must establish that [they are] likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest."[103]

2. Trade Dress

Within the protections legally offered by trademark, "trade dress" may apply to a product, giving additional claims against competitors.[104] Trade dress is generally

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[99] de la Torre & Theis, *supra* note 96, at 82; *see, e.g.*, Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492, 495 (2d Cir. 1961); AMF, Inc. v. Sleekcraft Boats, 599 F.2d 341, 348-49 (9th Cir. 1979).

[100] Anne Gilson LaLonde & Jerome Gilson, *Adios! To the Irreparable Harm Presumption in Trademark Law*, 107 TRADEMARK REP. 913, 924-26 (2017).

[101] *Id.* at 916, 918-19.

[102] *Id.* at 922-24; eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 394 (2006) ("Because we conclude that neither court below correctly applied the traditional four-factor framework that governs the award of injunctive relief, we vacate the judgment of the Court of Appeals, so that the District Court may apply that framework in the first instance.").

[103] Ferring Pharm., Inc. v. Watson Pharm., Inc., 765 F.3d 205, 210 (3d Cir. 2014) (quoting Winter v. NDRC, Inc., 555 U.S. 7, 20 (2008)).

[104] Indeed, scholars have challenged the close association between trademark law and trade dress protection. *See, e.g.*, Glynn S. Lunney, Jr., *The Trade Dress Emperor's New Clothes: Why Trade Dress Does Not Belong on the Principal Register*, 51 HASTINGS L.J. 1131, 1162-63 (2000) ("In addition to relying on perceived congressional intent, courts have also proffered superficial policy analyses as justifications for recognizing trade dress as principal register subject matter. In this vein, courts have typically asserted, first, that trade dress can act like a traditional trademark, helping consumers identify and distinguish products, and second, that so long as the functionality doctrine excludes protection for those features that represent 'the best or one of a few

a more fragile form of intellectual property protection than trademark, but in the context of medicines, it wields enormous influence in the control of entry by competing products.[105]

> To qualify as trade dress an attribute must meet three criteria: it must be nonfunctional, it must lead to confusion (or deception) if imitated, and it must have a secondary association with the product for the consumer. A product's functional attributes are essential to the use or purpose of the product or must affect the cost or quality of the product. Functionality is key in pharmaceutical-related trade dress, because if a company with a brand-name drug owned exclusive rights over a functional attribute of that drug, a competitor could not offer a truly equivalent generic version.[106]

Under U.S. law, trade dress is generally divided into two types: product design and product packaging.[107] If the identifying dress serves a function, trade dress protection is unavailable.[108] Typical functional attributes of drugs are safety and efficacy, although courts have found features like chocolate flavoring or a "pleasing" pink color to serve a functional purpose.[109] To claim trade dress infringement, firms

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superior designs available,' trade dress protection will generate no anticompetitive consequences. However, this analysis fails to justify recognition of trade dress as principal register subject matter for two reasons. First, the Court has repeatedly warned against 'simplistically . . . assuming that *whatever* furthers the statute's primary objective must be the law.' Second, the policy analysis that courts have offered both overstates the benefits that such recognition achieves and understates its true cost. A more careful analysis of the policies implicated by trademark protection fully justifies distinguishing between the protection of words and symbols as trademarks and the protection of trade dress under principles of unfair competition.") (footnotes omitted).

[105] Greene & Kesselheim, *supra* note 6. On trade dress fragility, see Homeland Housewares, LLC v. Euro-Pro Operating LLC, No. CV 14-03954 DDP (MANx), 2014 U.S. Dist. LEXIS 156675 at *7-9 (C.D. Cal. Nov. 5, 2014); Mike Vaughn Custom Sports, Inc. v. Piku, 15 F. Supp. 3d 735, 744-49 (E.D. Mich. 2014).

[106] Green & Kesselheim, *supra* note 6, at 83.

[107] Sabrina Rodrigues, *Say "Yes" to the [Trade] Dress: A Comment on Trade Dress Protection for the "Look and Feel" of Lifestyle Blogs*, 53 WAKE FOREST L. REV. 1005, 1021 (2018).

[108] *Id.* at 1024; *see, e.g.*, Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003); Ives Labs., Inc. v. Darby Drug Co., 601 F.2d 631 (2d Cir. 1979).

[109] William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924); Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 572 (2d Cir. 1959); *see also In re* Ferris Corp., 59 U.S.P.Q.2d (BL) 1587 (T.T.A.B. 2000) (finding that the applied-for color "pink" is functional for wound dressings).

endeavor to avoid disclosing or advertising utilitarian advantages of features that may serve as the basis of trade dress protection.[110]

Section 43(a) of the Lanham Act, which codifies the federal unfair competition act, includes trade dress protection from infringement if the criteria above are satisfied.[111] Courts' interpretations of the criteria for trade dress protection under the Lanham Act are consistent for the first two elements. However, the third element (secondary association) has divided authorities. Some courts require trade dress to have "acquired secondary meaning" while other courts require a showing of either "secondary meaning" or that the product is "inherently distinctive."[112]

In the pharmaceutical context, "secondary meaning" suggests that the protected mark leads a patient or consumer to associate that dress or mark with the drug.[113] "Secondary meaning" is the traditional rule that results from consumer

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[110] Daly & Emery, *supra* note 10; *In re* Change Wind Corp., 123 U.S.P.Q.2d (BL) 1453 (T.T.A.B. 2017); John L. Welch, *Precedential No. 19: TTAB Affirms Section 2(e)(5) Functionality Refusal of Wind Turbine Configuration*, TTABLOG (July 24, 2017), http://thettablog.blogspot.com/2017/07/precedential-no-19-ttab-affirms-2e5.html ("The TTAB affirmed a Section 2(e)(5) refusal to register the product configuration shown below, for 'Wind turbines; Windpowered electricity generators,' finding the design to be functional because 'it is essential to the use or purpose of the product.' [Applicant] Change Wind's own utility patent took the wind out of its sails.").

[111] William F. Gaske, *Trade Dress Protection: Inherent Distinctiveness as an Alternative to Secondary Meaning*, 57 FORDHAM L. REV. 1123, 1125-26 (1989) ("Section 43(a) of the Lanham Act codifies the federal unfair competition law, which includes the protection of trade dress from infringement. A successful claim for trade dress infringement under section 43(a) requires proof of three elements. First, the trade dress must be nonfunctional. Second, the trade dress of the competitor's product must be so similar to the trade dress of plaintiff's product that confusion as to the product's source is likely. Courts agree on these first two elements but are split on the third requirement. A number of courts require that the trade dress have acquired 'secondary meaning,' while other courts require that the trade dress either have 'secondary meaning' or be 'inherently distinctive.'") (footnotes omitted).

[112] *Id.*

[113] *Ives Labs.*, 601 F.2d at 643 ("One would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the Warner case . . . the blue and blue-and-red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well. The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants. The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes, essential to effective competition. At this stage of the case we need not go beyond saying that the judge was warranted in considering this to be fairly arguable. With respect to secondary meaning we cannot say that Ives would necessarily be unable to establish that consumers had come

association of a product with a single source or manufacturer rather than the product generally.[114] "Inherent distinctiveness" requires a product to have distinguishing characteristics that are an indication of the source or manufacturer.[115] "Secondary meaning" is acquired over time, while "inherent distinctiveness" is immediate.[116] To meet the "inherent distinctiveness" standard, a product will likely have to be considered "arbitrary," "fanciful," or "suggestive" as a trademark.[117]

In the pharmaceutical context, manufacturers have asserted trademark rights regarding the shape and color of drug capsules.[118] In *In re American Home Products Corp.*, the drug manufacturer attempted to register a "tri-colored three dimension circular shaped design."[119] There, the Patent and Trademark Office determined that the drug met the qualifications for trademark registration.[120] The tri-coloration and shape were not considered "inherently distinctive."[121] However, the extensive marketing for more than 20 years that was directed at identifying the drug based on its coloring scheme was "clearly and unambiguously" used to promote trademark recognition and "secondary meaning."[122]

Generic manufacturers have generally asserted that brand-name manufacturers may not legitimately assert trade dress protection because the aesthetics of drugs are "functional."[123] A mark is "functional" if a manufacturer's competitors would need the mark to communicate information about their products to consumers.[124] The issue has divided courts interpreting and applying trade dress

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to associate the blue and blue-and-red colors with the trademark Cyclospasmol.") (citations omitted); Daly & Emery, *supra* note 10.

[114] Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205, 211 (2000).

[115] Michele A. Shpetner, *Determining a Proper Test for Inherent Distinctiveness in Trade Dress*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 947, 973-74 (1998).

[116] *Id.* at 972-74.

[117] *Id.* at 959-61.

[118] Lenahan et al., *supra* note 7, at 32.

[119] *In re* Am. Home Prods. Corp., 226 U.S.P.Q. (BL) 327, 328 (T.T.A.B. 1985).

[120] *Id.* at 330-31.

[121] *Id.* at 329.

[122] *Id.* at 330.

[123] *See, e.g.*, Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125 (S.D.N.Y. 2008); Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003); Ives Labs., Inc. v. Darby Drug Co., 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom.* Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844 (1982), *aff'd*, 697 F.2d 291 (2d Cir. 1982).

[124] *Johnson & Johnson*, 87 U.S.P.Q.2d (BL) at 1128.

law.[125] Two cases demonstrating differing applications of trade dress law to aesthetic properties of drug products are relevant for the recommendation made in Part III.

In general, the functionality doctrine allows for the protection of color, for example, if the color is not "essential to the use or purpose of the article" and does not "affect[] the cost or quality of the article."[126] Courts have upheld functionality arguments barring trade dress in some pharmaceutical contexts when patients associate product features with therapeutic care.[127] In *Ives Lab., Inc. v. Darby Drug Co.*, Ives sued generic manufacturers for utilizing a similar color scheme for varying doses of cyclandelate, a medicine taken mostly by elderly patients with vascular diseases, which Ives sold under the trademark Cyclospasmol.[128] A functionality defense was successful after first being reversed, and then subsequently upheld after multiple appeals.[129]

Ives manufactured cyclandelate, marketing it as Cyclospasmol in 200mg doses contained in pale blue capsules imprinted with "Ives 4124," and 400mg doses in red and blue capsules imprinted with "Ives 4148." The generic manufacturers purchased bulk cyclandelate powder and colored capsules to assemble their products in the same color-coded dosage scheme. The court held that the capsule colors were functional and that "secondary meaning" of the colors as a means of identifying source, rather than chemical ingredient, function, or dose, was not shown.[130]

> The court finds that the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly but are caused considerable anxiety and confusion by the change. When

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[125] J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 7:69, Westlaw (coverage through Dec. 2021).

[126] TRADEMARK MANUAL OF EXAMINING PROCEDURE §1202.02(a) (July 2021).

[127] *See, e.g.*, *Shire*, 329 F.3d at 350 ("Shire's product literature, promotional materials, and mailings, which its sales staff distributed to physicians, feature color pictures of the Adderall tablets and sometimes direct patients to examine the tablets to ensure that they have received exactly the drug prescribed. Shire does not advertise its products in general consumer publications, but pictures of Adderall tablets appear in the Physician's Desk Reference and in certain consumer books.").

[128] *Ives*, 488 F. Supp. at 396.

[129] Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844, 844 (1982).

[130] *Ives*, 488 F. Supp. at 398.

> patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. Thus color is an important ingredient in the commercial success of the product.
>
> Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepares a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times.[131]

Subsequent cases have recognized that "competitors might be free to copy the color of a medical pill where the color serves to identify the kind of medicine . . . ."[132] Therefore, under some circumstances, the color and shape of drugs carry utilitarian functions and thus are ineligible for trade dress protection.

However, the extent of the freedom to copy colors for identification purposes may be limited. In *Johnson & Johnson v. Actavis Group*, the U.S. District Court for the Southern District of New York concluded that even if a yellow-gold color was generally associated with over-the-counter antibiotic ointments, the particular use of that color on packaging of Johnson & Johnson's Neosporin, an antibiotic ointment, was not essential to its use by consumers and awarded summary judgment against a functionality defense.[133]

Neosporin is packaged in a tube that Johnson & Johnson (J&J) argued was distinguished by a yellow-gold background, a green color and particular typeface for the brand name, and a curving arrow in the gold/yellow color. Actavis, the generic manufacturer, sold the antibiotic ointment in a tube with the same yellow-gold feature, but none of the other features asserted to have trademark and trade dress protection.[134]

J&J sued Actavis for violation of its trademark and trade dress. Actavis argued that the yellow-gold color was functional, allowing consumers to identify that the product contained an antibiotic. Actavis provided evidence of consumer association

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[131] *Id.* at 398-99.
[132] *Shire*, 329 F.3d at 358 (quoting *Inwood*, 456 U.S. at 853).
[133] Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125, 1128-29 (S.D.N.Y. 2008).
[134] *Id.* at 1126-27.

between shades of yellow and antibiotics, and it pointed out that the gold-colored drop on packaging for J&J's Band-Aids signified the presence of an antibiotic ointment (that itself was manufactured by Actavis for inclusion in J&J's Band-Aids). However, J&J provided evidence that other antibiotic ointments were sold in other colors of packaging.[135]

Although the separate issue of "secondary meaning" was held to be a disputed issue of fact, the court granted summary judgment for J&J on the issue of functionality, holding that protecting the color would not significantly hinder competition.[136] Thus, while evidence of an association with therapeutic effect that was "not universal" in *Ives* was sufficient to demonstrate functionality, similar evidence of an association between yellow-gold and antibiotic function was not enough to allow a functionality defense to reach a jury in *Johnson & Johnson*, demonstrating that the functionality of aesthetic properties of drugs is fact-specific and subject to significant uncertainty.[137]

To summarize, in litigation, trademark and trade dress protections are handled similarly, with some additional burdens placed upon the latter class of plaintiffs.[138] Trademark protections involve a mark placed on the product or its packaging, whereas trade dress protections involve the aesthetic of the product or its packaging.[139] Because trade dress is a subset of trademark protection, claims must conform to the same standards as trademark protections.[140] However, courts seem uncertain as to whether a "secondary meaning" standard or an "inherent distinctiveness" standard is optimal for determining if a manufacturer should be granted trade dress protections.[141] Finally, in the pharmaceutical context specifically, a product's appearance (like its color or shape) may have functionality (allowing patient identification of therapeutic effect) and be barred from trade dress

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[135] *Id.* at 1127-28.

[136] *Id.*

[137] *Compare* Ives Labs., Inc. v. Darby Drug Co., 488 F. Supp. 394, 398-99 (E.D.N.Y. 1980) ("One doctor testified that he prepares a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times."), *with Johnson & Johnson*, 87 U.S.P.Q.2d (BL) at 1128 ("The fact that one brand of bandages uses a color to depict a drop of ointment that is similar to the Gold Mark used as a background color on the NEOSPORIN(r) packaging is insufficient for a jury to conclude that the Gold Mark is functional when used to sell antibiotic ointment.").

[138] Ann Bartow, *Counterfeits, Copying and Class*, 48 HOUS. L. REV. 707, 710-11 (2011).

[139] Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 170 (1995).

[140] Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 770 (1992).

[141] Gaske, *supra* note 111, at 1126.

protection.[142] However, significant uncertainty arises due to the fact-intensive inquiry involved in a functionality defense.[143]

As will be more fully discussed below, in the context of prescription drugs, trade dress protections (or at least the uncertainty and expense of overcoming purported protections) have large impacts on patient health outcomes. Patients are often unable to recognize medications after generic substitution of functionally equivalent (but aesthetically different) medications. The changes reduce patient adherence or the successful continuation of treatment regimens. This causes a negative perception of generic medications because patients associate a loss of safety and efficacy with the change in appearance.[144]

II
THE UNIQUE COSTS TRADEMARK AND TRADE DRESS IMPOSE UPON PATIENTS

Whatever the effect of trademark and trade dress protections elsewhere in the economy, their effect on patients deserves special scrutiny. More than 131 million people—66% of all adults in the United States—use prescription drugs. Utilization is particularly high for older people and those with chronic conditions.[145] Women are generally more likely than men to use prescription drugs; approximately 40% of men and 66% of women age 18 to 34 use prescription drugs, although those populations converge as they reach 80.[146]

This Part explains why trademark and trade dress law cause medication adherence problems, raise barriers to efforts to lower prescription drug costs, and increase the risk of medication error. Trademark and trade dress law force generic manufacturers to adapt the color, appearance, and shape of the medicines they sell, and there is not uniformity as to how generic firms approach drug appearance—only that they not infringe on the appearance of trademark and trade dress protected features. Because pharmacies switch generic supplier firms with some regularity, this means that patients may receive different looking medications more than once or twice per year. Thus, trademark and trade dress law keep prices high, cause patient confusion, and result in medication error and patient nonadherence.

Patient adherence to prescription drug regimens is essential for maintaining health and avoiding severe illness and premature death. Patients are considered

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[142] *E.g.*, *Qualitex*, 514 U.S. at 170.

[143] *Cf.* Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125, 1128-29 (S.D.N.Y. 2008).

[144] *See infra* Part II.

[145] Ihara, *supra* note 2.

[146] *Id.*

adherent to medications when they take prescribed agents at doses and times recommended by a healthcare provider and agreed to by the patient.[147] Patient adherence to prescription drug regimens is affected by many factors of unequal weight, but a substantial body of evidence suggests that, in aggregate, cost and potential confusion are important factors. In a survey of 14,464 Medicare beneficiaries, patients who did not fill at least one prescription reported the following reasons: "thought it would cost too much" (55.5%), "medicine not covered by insurance" (20.2%), "didn't think medicine was necessary for the condition" (18.0%), and "was afraid of medicine reactions/contraindications" (11.8%).[148]

The relationship between adherence and cost is more emphasized among the socioeconomically marginalized, including racial and ethnic minorities. Specific factors that have been identified as barriers to medication adherence among inner-city patients with low socioeconomic status include high medication costs, lack of transportation, poor understanding of medication instructions, and long wait times at the pharmacy.[149] "Patient *nonadherence* to prescribed medications is associated with poor therapeutic outcomes, progression of disease, and an estimated burden of billions per year in avoidable direct health care costs."[150]

Over 90% of prescription drugs dispensed are generic drugs, both because they are less expensive and because state mandatory substitution laws require that pharmacies in most states fill prescriptions with generic versions where available.[151] For approval by the FDA, generic drugs must be the bioequivalent of the brand-name version, meaning it must have the same "dosage form, safety, strength, route

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[147] Lars Osterberg & Terrence Blaschke, *Adherence to Medication*, 353 NEW ENG. J. MED. 487, 487 (2005) ("Adherence to (or compliance with) a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers. The word 'adherence' is preferred by many health care providers, because 'compliance' suggests that the patient is passively following the doctor's orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician.").

[148] Jae Kennedy, Iulia Tuleu & Katherine Mackay, *Unfilled Prescriptions of Medicare Beneficiaries: Prevalence, Reasons, and Types of Medicines Prescribed*, 14 J. MANAGED CARE PHARMACY 553, 553 (2008).

[149] Sunil Kripalani, Laura E. Henderson, Terry A. Jacobson & Viola Vaccarino, *Medication Use Among Inner-City Patients After Hospital Discharge: Patient-Reported Barriers and Solutions*, 83 MAYO CLINIC PROC. 529 (2008).

[150] Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MGMT. & HEALTHCARE POL'Y 35, 35 (2014) (emphasis added).

[151] ASS'N FOR ACCESSIBLE MEDS., 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 16 (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf; *see also* Kesselheim et al., *supra* note 26.

of administration, quality, performance characteristics and intended use."[152] Unlike drug names, the FDA does not regulate the physical appearance of drugs, although it has issued guidance with respect to size and shape of tablets and capsules as well as some aspects of packaging.[153] Because of this, pharmaceutical companies may protect the physical attributes of their drugs through trademark and trade dress.[154]

The essential question with respect to trademark and trade dress protection in the pharmaceutical context, then, is: does the benefit to patients from identification of brand-name prescription medications (the trademark rationale) outweigh the cost to patients in the form of reduced adherence attributable to more expensive medicines *and* the cost imposed when trade dress confuses rather than clarifies (the "IP cost" and the "confusion cost")? This Article argues that the answer is "no" and makes specific recommendations to incorporate that answer into law.

A. Trade Dress and Demand-Side Measures to Increase Drug Affordability

Physicians and public authorities (who often pay for treatment for some or all of their populations) have emphasized supply-side measures to ensure access to medicines at an affordable cost—to individuals when they are required to pay and by the public treasury for populations covered by universal health insurance systems.[155] Supply-side measures include investment in generic manufacturing capability; regulatory and intellectual property incentives for generic manufacturers to enter markets; and state substitution laws that allow or require that pharmacies fill prescriptions with lower cost generic drugs that are therapeutically equivalent.[156] For example, streamlining the generic drug approval process in the United States by prioritizing applications from manufacturers who introduce a generic drug with limited competition would decrease prices and similarly limit the number of

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[152] Abdulrazaq S. Al-Jazairi, Sakra Blhareth, Iyad S. Eqtefan, & Saleh A. Al-Suwayeh, *Brand and Generic Medications: Are They Interchangeable?*, 28 ANNALS SAUDI MED. 33, 33 (2008).

[153] Kesselheim et al., *supra* note 33, at 202-03.

[154] *Id.*

[155] Fritz von der Schulenburg, Sotiris Vandoros & Panos Kanavos, *The Effects of Drug Market Regulation on Pharmaceutical Prices in Europe: Overview and Evidence from the Market of ACE Inhibitors*, 1 HEALTH ECON. REV. 18, 18 (2011) ("We find that although some measures are effective in reducing originator prices, others appear to have an insignificant effect. Results suggest that supply side measures such as mandatory generic substitution, regressive pharmacy mark-ups and claw-backs are effective in reducing pharmaceuticals prices.").

[156] Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. PHARMACIST 30 (2008).

competing products with disparate visual schemes.[157] Supply- and demand-side policies help to encourage the use of generic drugs over brand-name drugs.[158]

Demand-side policies are necessary to improve prescribing physicians' and patients' perceptions of generic drugs to encourage more prescriptions.[159] Demand-side policy proposals include charging fees to increase resources for more efficient reviewal processes; addressing anticompetitive strategies; and providing financial incentives to physicians and pharmacists.[160] Some European countries have implemented financial incentives to physicians and pharmacists to encourage the use of generic drugs, and similar measures could be taken by states with respect to disease categories where patient confusion is widespread or severe.[161] State substitution laws already use the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) as the measure for substitutability, so at the very least, it would be possible to incorporate a notice system for pharmacies to use when substituting therapeutically equivalent drugs.[162]

Generic drugs are relatively inexpensive when compared to brand-name drugs because of the less strict regulatory pathway to obtaining approval and the already-existing competitive market for the drug.[163] To maintain competitive and sustainable pricing, drug manufacturers must be ensured that a high volume of generic drugs will enter the market and be used through supply- and demand-side policies.[164] Regulations have generally addressed supply-side policies and decreased the average cost of generic drugs by 10-80% of the cost of brand-name drugs while

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[157] *See* Olivier J. Wouters, Panos G. Kanavos & Martin McKee, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending*, 95 MILBANK Q. 554, 570 (2017).

[158] Pieter Dylst, Arnold Vulto & Steven Simoens, *Demand-Side Policies to Encourage the Use of Generic Medicines: An Overview*, 13 EXPERT REV. PHARMACOECONOMICS OUTCOMES RSCH. 59 (2013).

[159] *Id.*

[160] *Id.* at 61-65.

[161] *Id.* at 64.

[162] *Id.*

[163] Wouters et al., *supra* note 157, at 556.

[164] OECD, ROUNDTABLE ON GENERIC PHARMACEUTICALS 22 (2010), https://www.oecd.org/competition/abuse/46138891.pdf ("These policy developments in France, and particularly the agreement with physicians, were an important part of the sudden growth in the use of generics: rates of generic substitution increased from 18% of drugs for which there were generic versions in 2000 to 48.2% by 2002. However, by 2006, generics accounted for only 17% by volume of all reimbursed medicines, compared with 65% in the UK. These numbers in France increased following the implementation of a reference price scheme covering off-patent drugs in 2003.") (citations omitted).

improving access to the market.[165] However, demand-side policies are needed to incentivize prescriptions of generic medications by physicians and substitutions to generic drugs by pharmacists, and to improve patients' perceptions of the safety and efficacy of generic drugs.[166]

Demand-side measures should include laws, regulations, and judicial interpretations that acknowledge the special costs that trademark and trade dress impose in the prescription drug context.[167] Although sometimes it may be necessary to prescribe brand-name medications (for example, if a patient has an allergy to the generic alternative), the majority of the time, generic drugs are avoided due to misconceptions or habits by physicians.[168] Several successful policies exist addressing generic drug misconceptions in European countries and the United States.[169] Studies have shown that low health literacy action plans can also encourage adherence to generic drugs because the physician and/or pharmacist will be more involved with counseling patients regarding therapy, which may include discussing the visual differences between brand and generic forms of the prescription drug.[170]

B. Trade Dress and Nonadherence

As analyzed above, trade dress allows pharmaceutical firms to apply identifiable physical attributes to their products if they do not change the functional attributes of the medications—indeed, functionality would render those features ineligible for trade dress protection.[171] Health scholars have long criticized the protections given to medications under trade dress doctrine for at least two reasons. As a purely legal matter, patient adherence can be shown to depend upon drug appearance, rendering all aspects of drug appearance "functional."[172] For example,

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[165] Dylst, *supra* note 158, at 59.

[166] *Id.*

[167] Wouters et al., *supra* note 157, at 573.

[168] *Id.*

[169] *Id.* at 555.

[170] H. Shonna Yin, Ruchi S. Gupta, Suzy Tomopoulos, Alan L. Mendelsohn, Maureen Egan, Linda van Schaick, Michael S. Wolf, Dayana C. Sanchez, Christopher Warren, Karen Encalada & Bernard P. Dreyer, *A Low-Literacy Asthma Action Plan to Improve Provider Asthma Counseling: A Randomized Study*, 137 PEDIATRICS 1, 8 (2016).

[171] Aaron S. Kesselheim, Katsiaryna Bykov, Jerry Avorn, Angela Tong, Michael Doherty & Niteesh K. Choudhry, *Burden of Changes in Pill Appearance for Patients Receiving Generic Cardiovascular Medications After Myocardial Infarction*, 161 ANNALS INTERNAL MED. 96, 101 (2014).

[172] *But see* Marc P. Misthal, *Looks Can be Deceiving—Protectable Elements of a Pill's Appearance*, GOTTLEIB, RACKMAN & REISMAN, P.C., https://grr.com/publications/looks-can-deceiving-protectable-elements-pills-appearance/ (last visited Jan. 20, 2022) (discussing the

patients who take multiple medications are often 80 years of age or older with higher rates of visual or other impairment, increasing the risk of errors.[173] As a result, the legal framework introduces deadweight loss by incentivizing pharmaceutical firms to make design decisions for the purpose of preserving monopoly power rather than patient benefit.

Studies have shown an increase in patient harm because of nonadherence due to reliance on the physical appearance of drugs.[174] Patients receiving generic versions of the same medication receive pills of different sizes, shapes, and colors routinely because of trade dress protections.[175] In a study testing medication nonadherence for those with uncontrolled blood pressure, the ability of a patient to identify their medication based on its appearance was directly correlated to a diagnosis of uncontrolled blood pressure and an increase in hospital visits over the course of a year.[176] Patients who relied solely on the appearance of medication were 1.26 times more likely to report uncontrolled hypertension and 1.35 times more likely to report hospitalization in the past year.[177] These patients self-reported an increased nonadherence to generic medications.[178]

Similar outcomes have been reported in other studies. For example, in a study of 11,472 patients who had failed to fill a prescription for anti-epileptic drugs (in 4

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implications of Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003), on protections for the appearance of Pfizer's Viagra).

[173] Juan Cardenas-Valladolid, Carmen Martin-Madrazo, Miguel A. Salinero-Fort, Enrique Carrillo de-Santa Pau, Juan C. Abanades-Herranz & Carmen de Burgos-Lunar, *Prevalence of Adherence to Treatment in Homebound Elderly People in Primary Health Care: A Descriptive, Cross-Sectional, Multicentre Study*, 27 DRUGS & AGING 641 (2010); Brian R. Levinthal, Daniel G. Morrow, Wanzhu Tu, Jingwei Wu & Michael D. Murray, *Cognition and Health Literacy in Patients with Hypertension*, 23 J. GEN. INTERNAL MED. 1172 (2008).

[174] Lenahan et al., *supra* note 7, at 32 (finding that patients who were unable to identify their hypertension medications either by name or by appearance were more likely to miss taking a medication in the past week compared with those who were able to identify by name or appearance); Kesselheim et al., *supra* note 171, at 101 ("The odds of nonpersistence in case patients increased by 34% after a change in pill color."); Anton J.M. de Craen, Pieter J. Roos, A. Leonard de Vries & Jos Kleijnen, *Effect of Colour of Drugs: Systematic Review of Perceived Effect of Drugs and of Their Effectiveness*, 313 BRITISH MED. J. 1624, 1625 (1996) ("Most colours have universal meanings in a wide variety of cultures, red generally being considered strong and active, and blue and green to be associated with good. The colour of drug formulations might cause different expectations in patients, and could therefore produce different therapeutic effects.") (footnotes omitted).

[175] *See* Lenahan et al., *supra* note 7, at 32.

[176] *Id.* at 35.

[177] *Id.*

[178] *Id.*

shapes and 37 colors) within 5 days of the elapsed days were approximately 30% more likely to have had the color of their pill changed before that failure relative to a control group of 50,050 patients who did not so fail.[179] Gaps in filling medication were 27% greater following a color discordance in anti-epileptic drugs when compared to a control.[180] For patients suffering from a seizure disorder, there was a 53% increase in prescription filling gaps when a color discordance occurred prior to filling.[181] Color appeared to be more relevant than shape.[182] Likewise, with prescription drugs dispensed to patients following myocardial infarctions, a 30% increase in nonadherence was observed in patients who received a medication with a different shape or color.[183]

An international study tested members of the United States, China, and Colombia to determine the psychological effects of different colors and shapes of medication.[184] The study revealed that patients associate certain characteristics with different shapes and colors.[185] For example, a pink-colored drug may be viewed as sweet compared to a white-colored drug that may be perceived as salty, or a round-shaped drug may be perceived as more easily swallowed compared to a drug with edges.[186] This study suggests that people around the world may have similar perceptions regarding the physical appearance of drugs, and that these perceptions may have adverse effects on a patient's adherence to a treatment plan.[187]

The evidence linking objective measures of prescription drug appearance is even more important given that health literacy plays such an influential role in a patient's independent ability to adhere to prescription drug regimens.[188] Health literacy is correlated to nonadherence to medication or to nonadherence to a dependent's treatment plan with medication.[189] In the aforementioned study for uncontrolled blood pressure, patients who were unable to identify their medication by name or appearance were more likely to miss taking a medication compared to

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[179] *See* Kesselheim et al., *supra* note 33, at 203-04.
[180] *Id.* at 204-05.
[181] *Id.*
[182] *See id.* at 205.
[183] *See* Kesselheim et al., *supra* note 171, at 100-01.
[184] Xiaoang Wan et al., *Assessing the Expectations Associated with Pharmaceutical Pill Colour and Shape*, 45 FOOD QUALITY & PREFERENCE 171, 171 (2015).
[185] *Id.* at 179.
[186] *Id.*
[187] *Id.* at 180.
[188] Lenahan et al., *supra* note 7, at 35.
[189] *Id.*; *see also* Yin et al., *supra* note 170, at 2.

those who could identify all of their medications by name or appearance.[190] However, this difference was not significant when compared to those who relied solely on identifying medication based on its physical appearance.[191]

Moreover, there is some evidence that the need to closely align prescription drug appearance with adherence will disproportionately affect children. "Low health literacy . . . is likely to contribute to poor management of child asthma."[192] Physicians who have utilized low literacy written asthma action plans (WAAP) with parents or guardians have seen greater medication adherence by child patients.[193] The low-literacy WAAP involved clear communication that included a presentation of medication instructions and inhaler colors, spacer use, a statement including the need for everyday use and the importance of the "yellow zone" on Flovent and Singulair, and explicit words used to present symptoms of exacerbation.[194] The low-literacy WAAP showed self-reported increased adherence to treatment and an increased understanding of the medication, as well as an increased satisfaction amongst the physicians utilizing the plan.[195]

Thus, substituting generics with differing look-and-feel subject to trade dress protections implicates poorer health outcomes. Nonadherence to medication is shown to be related to a patient's ability to identify the medication based on the color of the pill and health literacy.[196] Due to the number of generic medications on the market and the prevalence of generic substitutions by physicians and pharmacists, patients are exposed to medications of bioequivalence that differ in physical appearance.[197] The difference in appearance casts doubt on a patient's perception of efficacy, which contributes to nonadherence and potential adverse outcomes.[198]

These studies suggest that modifying the current FDA regulations to prohibit or limit drug manufacturers from claiming trade dress protection on the appearance of drugs could lead to more consistent adherence to drug therapies by improving patient confidence in the safety and efficacy of prescription drugs.

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[190] Lenahan et al., *supra* note 7, at 35.
[191] *Id.*
[192] Yin et al., *supra* note 170, at 2.
[193] *Id.*
[194] *Id.* at 3.
[195] *Id.* at 7.
[196] Leslie R. Martin, Summer L. Williams, Kelly B. Haskard & M. Robin Dimatteo, *The Challenge of Patient Adherence*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 189 (2005); Kesselheim et al., *supra* note 171, at 96.
[197] Kesselheim et al., *supra* note 171, at 96.
[198] Kesselheim et al., *supra* note 26, at 206.

C. Trade Dress and Medication Error

Regulatory authorities, including the FDA, have long known that aspects of prescription drugs (including pill shape and packaging) potentially impact rates of medication error, defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."[199] In guidance released in 2013, the FDA acknowledged that packaging trade dress could make it difficult for healthcare professionals, caregivers, and/or patients to readily locate and understand critical safety information.[200] The guidance encouraged pharmaceutical firms to avoid or minimize the use of corporate trade dress that could make it difficult for end users to distinguish between different medications or different strengths of the same medication.[201]

> For example, the FDA recommends that the container label size should not be too small and should feature text sizes that are easy to read. The Guidance goes so far as to almost dictate a 12-point sans serif font size (such as Arial) to improve readability of pharmaceutical labels. In addition, the FDA seeks to define an acceptable color contrast between the text and the container label background color to afford adequate legibility of the text. Most importantly, the FDA intends to actively discourage the use of logos, bars, stripes, watermark graphics, lines, and symbols on container labels and / or carton labeling because they can distract the reader from important information and add to label clutter. Instead, the Guidance recommends placement of images of tablets and / or capsules on the packaging so patients or caregivers can verify the contents of the container and supposedly reduce medication errors.[202]

Similarly, in 2015, the FDA released guidance on the size, shape, and other physical attributes of tablets and capsules, acknowledging that "differences in

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[199] *Working to Reduce Medication Errors*, FDA, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/working-reduce-medication-errors (last updated Aug. 23, 2019).

[200] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SAFETY CONSIDERATIONS FOR CONTAINER LABELS AND CARTON LABELING DESIGN TO MINIMIZE MEDICATION ERRORS: DRAFT GUIDANCE (2013), https://www.fda.gov/media/85879/download.

[201] *Id.*

[202] Hanna Blake, *The FDA's Guidance on Labels and Cartons: Yet Another Attack on Pharmaceutical Trade Dress?*, PHARMAPHORUM (Nov. 11, 2013), https://pharmaphorum.com/views-and-analysis/the-fda-s-guidance-on-labels-and-cartons-yet-another-attack-on-pharmaceutical-trade-dress/.

physical characteristics (e.g., size and shape of the tablet or capsule) may affect patient compliance and acceptability of medication regimens or could lead to medication errors."[203] In both its 2013 and 2015 guidance, the FDA was explicit that the findings were non-binding and have had a correspondingly minimal effect on firm behavior.[204] In other words, the FDA has expressed clear awareness that the size, shape, and color of medications matter (or are arguably "functional") for purposes of patient understanding and avoidance of medication error. That awareness should serve as a basis for judicial interpretations of the law when adjudicating trademark and trade dress claims in the prescription drug context.

III
LEGISLATIVE, REGULATORY, AND JUDICIAL SOLUTIONS TO TRADEMARK AND TRADE DRESS COSTS

This Part addresses legislative, regulatory, and judicial measures that may be taken with respect to trademark and trade dress barriers to producing generic medicines that appear as original drugs, cause less patient confusion, result in less medication error, and allow generics to occupy a larger share of the market, thereby lowering costs. While legislative solutions are always more burdensome, some of the measures below may require changes in the federal Food, Drug & Cosmetics Act. But others may be implemented through existing FDA authorities and the adoption by federal courts of reasoning applied in the Third Circuit's *Shire* decision.

The legislative and regulatory solutions to many of the problems outlined above are available through existing FDA findings and guidance, statutory text, and judicial opinions that address the reach and limits of trademark and trade dress. Legislatively, Jeremy Greene and Aaron Kesselheim have argued that the FDA

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[203] U.S. FOOD & DRUG ADMIN., SIZE, SHAPE, AND OTHER PHYSICAL ATTRIBUTES OF GENERIC TABLETS AND CAPSULES: GUIDANCE FOR INDUSTRY 1 (2015), https://www.fda.gov/media/87344/download.

[204] Katharyn Grant, *FDA Releases Final Guidance for Size, Shape and Other Physical Attributes of Generic Drugs*, NORTON ROSE FULBRIGHT (July 8, 2015), https://www.thebrandprotectionblog.com/fda-releases-final-guidance-for-size-shape-and-other-physical-attributes-of-generic-drugs/ ("Although the FDA had announced in October 2014 that it was concerned that differences in color between brand and generic products could cause patient confusion and decrease drug regimen adherence, the newly released guidance includes no recommendation that generic tablets or capsules should be the same color as the RLD [reference listed (brand) drug]. The FDA's guidance is not binding, and by its own terms, it applies only to new generic drug products submitted to the Office of Generic Drugs via an abbreviated new drug application (ANDA) . . . . [G]eneric drug companies should be careful that their efforts to adhere to FDA guidance do not expose them to trade dress infringement claims.").

could address problems caused by trademark and trade dress by using their existing authority over drug names and applying it to other aspects of drug appearance:

> A first step toward reform would be to include FDA certification of pharmaceutical size, shape, and color in the drug-approval process. For example, a pill's attributes could be proposed by the manufacturer during the original New Drug Application. Currently, such a process occurs for the brand name of the medication; extending it to pill appearance should not require additional legislation. This would create a clear path for generic manufacturers to declare during the ANDA process that their products have similar appearances. Where these drugs do differ (e.g., as in dyes, fillers, or excipients), physicians or pharmacists could still locate manufacturer data from unique identifier codes embossed on pills. Further public health benefits could emerge if the reduction in trade dress helps to combat the physician's persistent use of, and the patient's preference for, costly brands when generic equivalents are available.[205]

For products already on the market, legislation could address the highest priority drug classes where confusion results in nonadherence and impose a color-based scheme, as has already been piloted for inhalers and ophthalmologic products in the United Kingdom and the United States respectively.[206]

Judicially, reform is even more straightforward. There is already federal appellate precedent for acknowledging that the color, size, and shape of drugs affect adherence.[207] Indeed, in *Ives*, analyzed above, the U.S. Supreme Court granted review of the case and, while reaching its conclusion on a different basis, acknowledged that the generic producer had offered a legitimate basis for its imitation of pill appearance.[208] Acknowledging that these aspects of drugs are functional and clarifying the evidentiary burden to reduce uncertainty would disqualify them from trademark and trade dress protection while not obviously rendering them susceptible of other intellectual property protections like patents that would cause higher prices.

These proposals, of course, address only a specific aspect of the nonadherence problem. Legislation at the state and federal levels could do more to address health illiteracy, which has generally accompanied studies of prescription drugs' visual

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[205] Greene & Kesselheim, *supra* note 6, at 87.
[206] *Id.*
[207] Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348, 355-59 (3d Cir. 2003).
[208] Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844, 857-58 (1982).

effect.[209] Greater communication from healthcare providers to patients using health literacy action plans has shown to improve nonadherence to generic medications. Demand-side policies should be enacted by governments to improve physicians' and patients' perceptions of generic drugs, including discussing the color schemes and appearance of alternatives.

CONCLUSION

Trademark and trade dress impose more costs on patients than the benefit they impart through their purported function of helping patients distinguish different kinds of drugs. This Article has analyzed how current use of trademark and trade dress fuel patient nonadherence to prescription drug regimens, cause medication error, and raises prices. Partial and even complete solutions to some of these problems may be found in existing legal authorities. The FDA has already explicitly acknowledged the confusion that may arise through drug names otherwise protected by trademark and has aggressively used its authority to reject 40% or more of names that may result in nonadherence, patient confusion, and medication errors by both providers and patients. It has further implicitly acknowledged in guidance related problems that pill shape, color, and size may raise with respect to the same patients.

What is more, it appears that the new generation of blockbuster drugs—biologic drugs that treat numerous autoimmune conditions—may be similarly affected by trademark and trade dress. As Michael S. Sinha has carefully analyzed, companies are pairing these injectable and inhalable medicines with devices and delivery systems over which they are also patenting functional and non-functional features.[210] If the law is not clarified, then these next generation drugs may be just as costly as the last generation of small molecule drugs.

To address these problems, the FDA may expand the reach of its authority with respect to manufacturing to certify pharmaceutical size, shape, and color. Federal judges, who almost exclusively review the issues raised by allegedly trademark infringing drugs, could apply persuasive appellate and U.S. Supreme Court authority to find that most features of drugs are functional.

These measures, of course, are limited to the effects of trademark and trade dress protection on patients. In this context, as in many others, there is a great need

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[209] *See, e.g.*, Sandra Vamos, Orkan Okan, Tetine Sentell & Irving Rootman, *Making a Case for "Education for Health Literacy": An International Perspective*, 17 INT'L J. ENV'T RSCH. PUB. HEALTH 1436 (2020), https://doi.org/10.3390/ijerph17041436.

[210] Michael S. Sinha, *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*, 23 MINN. J.L. SCI. & TECH. (forthcoming).

for publicly supported programs that expand health literacy, especially in contexts for which there is already a great deal of evidence as to sources of confusion and nonadherence. But the role of trademark and trade dress protection is relatively straightforward and should be addressed in ways more consistent with better individual and public health outcomes.