The Case for Standardizing the Appearance of Bioequivalent Medications

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It is common knowledge that patients rely on the color, size, and shape of medication for reassurance that they are taking the right pill.1,2 Yet, not only do most bioequivalent generic drugs not look like the brand-name medicine, they don't even look like each other. As a result, patients can receive a drug that looks different when they refill a prescription leading to confusion, failure to take medications as prescribed, and the waste of valuable time of physicians and pharmacists in counseling patients to reduce their anxiety. The problem is particularly troublesome for elderly patients who often take several medications concurrently and are more susceptible to confusion. The U.S. Food and Drug Administration (FDA) has recently decided that the current system of providing medical information to consumers about drugs is inadequate and is developing more patient-friendly information to accompany prescriptions.3,4 Standardization of appearance for bioequivalent medicines should be at the top of the FDA's list of concerns as it seeks to improve patient medication information.

More than 30 years ago, prior to the enactment of the Federal Hatch-Waxman Act promoting the use of generic drugs and state laws mandating the substitution of lower-cost bioequivalent generic drugs for brand name drugs, a number of court decisions held that the appearance features of a medication were entitled to protection against copying on the theory that these features constituted protectable “trade dress,”5 (i.e., they functioned like trademarks to identify the product's manufacturer).6 Given these precedents, it may be reasonable for the FDA to assume that it lacks the authority to regulate the appearance of a medication in a manner that might undermine the proprietary rights of brand name manufacturers. That assumption is no longer true—if it ever was. Judicial precedent has significantly restricted the circumstances under which a valid claim to trademark rights in the appearance of any product can exist, and industry practices in the sale and dispensing of medications in an era of mandated substitution have evolved in a manner that makes it highly unlikely that valid trademark rights can ever be established for the appearance of a medicine.7,8 The appearance of a product may well be commercially important where a consumer actually sees the product before it is purchased, but a patient rarely, if ever, sees a medicine before it is dispensed. Moreover, state laws mandating the substitution of lower-cost, FDA-approved generic drugs have eliminated any basis for asserting that substitution of a look-alike medicine by the pharmacist is an act of unfair competition, “passing off” or counterfeiting—a pivotal issue in the early precedents that protected the appearance of drugs as a proprietary right. The United States Supreme Court has stated that an appearance feature of a product, such as its color, cannot be protected under trademark principles unless it can be proven that the primary significance of that appearance in the minds of consumers is to identify the source of a product and not the product itself.7 In addition, no valid trademark rights can ever be acquired in the appearance of a product if that appearance serves a functional purpose. In the words of the Supreme Court: “The functionality doctrine … forbids the use of a product's feature as a trademark where doing so will put a competitor at a significant disadvantage because the feature is ‘essential to the use or purpose of the article’ or ‘affects [its] cost or quality.’ … For example, this Court has written that competitors might be free to copy the color of a medical pill where that color serves to identify the kind of medication (e.g., a type of blood medicine) in addition to its source.”9

Relying on the Supreme Court's functionality doctrine, the Third Circuit Court of Appeals has held that “by being physically similar to Adderall, Barr's generic amphetamine salts tablets materially benefitted the patient population” because “similarity in tablet appearance enhances patient safety by promoting psychological acceptance.” (emphasis added)9 The Court also credited expert testimony from an executive of Rite-Aid that generic drugs which looked like the branded drug had a competitive advantage because such products enhance patient safety and compliance. The dispositive facts establishing functionality in the Adderall case are applicable to all drugs. Publications promoting medication safety from such trusted sources as the FDA,10 Consumers Union,11 the Institute of Safe Medication Practices,12 and Pfizer13 all encourage patients to rely on the appearance of their medication for reassurance that they are taking the right medicine at the right time and to refrain from taking any medication that looks different without getting professional reassurance. The American Medical Association has concluded that differences in the appearance of bioequivalent brand and generic medicines as well as between bioequivalent generic products produced by different manufacturers were the cause of significant confusion and anxiety for patients and has formally recommended that (a) pharmacists avoid refilling prescriptions with a different looking generic drug manufactured by a different source, when possible; (b) patients be individually counseled about appearance changes when they do occur; and (c) refill prescriptions carry an additional label indicating that: “This medication contains the same...
active ingredient you have been getting. Color, size, or shape may appear different."14 These recommendations have been implemented by many pharmacists.

Brand-name drug manufacturers also routinely rely on the appearance of a medication to gain a competitive advantage in the sale of generic drugs to pharmacies. During the last decade, hundreds of brand-name medicines have been launched as “authorized generics.” An “authorized generic” is a drug manufactured under the originally approved New Drug Application (NDA) and is identical to the branded product except that the brand name and the original manufacturer’s name are removed from both the product and its packaging and are replaced by the drug’s generic name and the name of a different distributor. Prasco, an independent distributor of authorized generics, relies on the fact that its authorized generics look exactly like the branded product to gain a competitive advantage by marketing with a message that “with authorized generics you can avoid lengthy explanations about product characteristics” during the generic conversion process.15 And Patriot Pharmaceuticals, a subsidiary of Johnson & Johnson (J&J) created to distribute generic versions of J&J products, proclaims that “store level patient counseling may be streamlined due to the fact that authorized generic pharmaceutical products have the same taste, color, mouth feel, size and shape as the innovator product.”16 The claim that look-alike generic products enjoy a commercial advantage because their appearance has functional value for patients forecloses any claim to trade dress rights5 under the principles of law enunciated by the Supreme Court. Moreover, removal of the brand name and the manufacturer’s name from the authorized generic blinds consumers to the fact that the authorized generic is made by the same manufacturer as the brand drug. That deliberate separation of the manufacturer’s identity from the appearance of a product is also totally inconsistent with the efforts normally made by manufacturers to connect a product’s appearance to a single manufacturing source.

Generic manufacturers individually and arbitrarily select an appearance for each product simply to avoid expensive litigation with brand-name manufacturers wrongfully claiming trademark rights in the appearance of a medicine. The generic manufacturers make no effort to associate the appearance of their products with a particular source and have never asserted any trade dress claims of their own. Absent leadership from the FDA, generic manufacturers are unlikely to set industry standards regarding uniformity of appearance because of antitrust concerns that arise whenever competitors take joint action. Formal recognition by the FDA of the important functional role that product appearance plays in reducing patient anxiety and enhancing medication safety would bring an end to most trade dress claims because it is ultimately up to the FDA, and not the courts, to determine which attributes of a medicine play an important role in making drugs safe and efficacious.

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DISCLOSURES

The author is an intellectual property attorney who formerly represented generic drug manufacturers and was a principal participant in the negotiations that led to the enactment of the Hatch-Waxman Act. The author has not actively practiced law on behalf of clients since 1995. He has no financial interest in or current relationship with any generic drug company. The Engelberg Foundation supported creation of the Engelberg Center for Health Care Reform at the Brookings Institution.

REFERENCES

6. See cases cited in Shire U.S. v. Barr Laboratories, Inc., No. 02-3647, 329 F.3d 348 (3rd Circuit, 2003) at p 355 Available at: http://scholar.google.com/scholar_case?case=3749449146391160258&hl=en&as_sdt=2&as_vis=1&oi=scholarr. Accessed April 2, 2011. At the time these cases were decided, substitution of a look-alike product was generally believed to be an act of unfair competition (i.e., an attempt to “pass off” the copy as if it was the original product—a behavior similar to counterfeiting).
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