



# Look-Alikes

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## A NEW COURT RULING MAY OPEN THE DOOR TO GENERIC DRUGS THAT LOOK NEARLY THE SAME AS THEIR BRAND COMPETITORS.

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**G**enerics companies walk a fine line between making their pills look somewhat like the brand-name product and violating “trade-dress” laws. But a recent federal appellate decision in *Shire US v. Barr Laboratories, Inc.*, may give generics manufacturers a green light to make their drugs look more similar to brand names than they have in the past.

The initial ruling came from a federal trial court in Newark, New Jersey. Judge Joel Pisano decided in August 2002 that it is not necessarily a violation of US trademark law for Barr Laboratories to market its generic version of Shire’s Adderall (amphetamine) with a color and shape that is similar in appearance to the original. The

United States Court of Appeals for the Third Circuit upheld his decision on May 23, 2003.

Shire manufactures Adderall tablets in two colors and two shapes, depending on the dosage. Tablets with strength of less than 12.5 mg are blue, and those with a dosage strength of 12.5 mg or greater are peach. Shire embosses its tablets with the letters “AD” on one side and the dosage strength on the other. Barr also makes its generic equivalent in blue and peach colors that are similar to Shire’s and uses a shape that is similar to Adderall’s. Barr’s tablets are embossed with the dosage strength on one side and a stylized “B” or the word Barr on the other.

### Similar But Not Identical

In reaching his decision, Pisano found that the two products are similar but not identical and that they do not contain similar source-identifying features. The Barr product has a different shape and contains a house mark. In addition, he relied on the testimony of several expert witnesses who explained that the function of color coding pharmaceuticals is to lessen patient confusion in correctly identifying the drug and its dosage strength. Minimizing confusion, the witnesses noted, enhances patient safety, compliance, and acceptance of the drug.

In affirming Pisano's decision, the Court of Appeals agreed that Barr's use of similar colors is permissible because it enhances patient safety by promoting patient acceptance. The court thoroughly discussed several older judicial decisions that refused to let generics makers use colors, shapes, and sizes that were very similar to the appearance of an established brand-name drug. In distinguishing Shire's case, the Court of Appeals noted that all of the earlier rulings involved illegal activity such as pharmacists passing off a generic product as a brand name or illegally substituting one for the other, practices that predate the 1984 Hatch-Waxman Act.

Taking a fresh look at the issue, the Third Circuit recognized that, although in the 1980s some courts rejected the same "color function" arguments that Pisano accepted, other courts agreed with Pisano's approach. For example, in the 1982 case of *Ives Laboratories*, a New York federal court found that capsule colors were functional because patients often relied on color to identify their drugs, particularly when they mingled them in a single container. In addition, the *Ives* court found that drug color could be useful for identifying overdoses in emergency situations. Thus, the Third Circuit accepted Barr's evidence that similarity of tablet appearance enhances patient safety by promoting psychological acceptance. The Third Circuit also drew heavily on more recent decisions from the US Supreme

Court that have limited the scope of trade-dress protection, especially when the product's "dress" consists of functional features.

### Opening the Door

Although the Shire decision is narrow and may be confined to the specific facts of its case, it holds open the possibility for a future reassessment of whether trade-dress protection should apply at all to the shape, color, and size of prescription drugs. Two factors were at play in the Shire case that may affect its impact on other lawsuits: (1) Adderall is a Schedule II controlled drug, available only by prescription and (2) the product is used to treat attention deficit hyperactivity disorder (ADHD).

That the drugs are sold only by prescription is significant because the test for trade-dress infringement rests on the possibility of confusion between the established drug and the newcomer. The basis for that test, in turn, rests on the underlying realities of the drug purchasing decision, although the courts have yet to thoroughly examine those factors in detail.

In the retail over-the-counter drug market, the individual consumer makes the purchasing decision, and the product's appearance and packaging—its trade dress—may alter that decision. The prescription drug market is totally different. In that market, the consumer/patient has very little choice in the purchase decision. In some cases, the prescribing physician may require that the prescription be filled with the brand-name product, which precludes generic substitution. In many other cases the patient's health insurance carrier will, in effect, insist on the generic because it will not pay for the brand-name drug. Thus, the choice is rarely the patient's to make.

Adderall's use as a treatment for ADHD is equally significant in this case. Barr was able to rely on expert evidence that this patient population is particularly dependent on visual clues; thus, color and appearance are especially functional.



**Barr makes its generic equivalent in blue and peach colors that are similar to Shire's.**

### Legal Shift?

The combination of those two factors undercuts the application of trademark law's traditional legal analysis to the prescription drug market. When doctors and insurance companies control product choice, it makes little sense to ask whether the appearance of the tablet confuses patients in their purchasing decision.

Even in cases in which patients make the purchasing decision, that choice likely occurs without any consideration of the product's appearance. Patients will choose the brand name or the generic based on price or on subjective preferences such as a capsule versus a tablet, not on appearance, particularly if they have never seen the drug before.

The Shire decisions do not discuss the fundamental difference between the "consumer choice" market theory and the Rx drugs marketplace. Thus the determination of whether the Shire ruling portends a significantly increased ability for generics makers to copy the appearance of brand-name drugs remains to be decided by a future court.

But for now, the decisions seem to give increased freedom to generics companies to make their drug similar in appearance to branded products, at least in cases like this one, in which the brand-name manufacturer has not used the product's appearance in marketing or promotion. When a company has used appearance to market its products—such as Nexium's purple pill—then traditional principles of trademark law and avoidance of consumer confusion may continue to apply. ■

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