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Trade Dress Disputes Continue To Be a Bitter Pill in Pharma

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A recent federal court decision highlights the delicate balance between U.S. Food and Drug Administration (FDA) guidance and trade dress protections for drugs administered in a tablet or capsule form. Last month, a district court issued a preliminary injunction against a competing generic to the cardiovascular drug Entresto, after finding that the generic pill's size, shape, and color were likely to violate Entrestro's trade dress.

FDA guidance recommends similarities in size, shape, and other traits between generics and their branded counterparts to promote patient safety, compliance with drug regimens, and other considerations. But these recommendations are at odds with trade dress laws, leaving generic manufacturers walking a regulatory tight rope and branded drug manufacturers seeking to protect their established goodwill in the market.

Here are some considerations for generic and branded manufacturers in light of this latest ruling.

Functionality

While the overall look and feel of a pill are potentially eligible for trade dress protection, this protection is only available for the pill's nonfunctional features. This requirement is designed to reduce the possibility of a single manufacturer monopolizing a useful pill feature to gain an unfair competitive advantage. Functional features excluded from trade dress protection are those that are essential to the use or purpose of the drug or impact its cost or quality.

However, the functionality inquiry is a flexible one, and features such as size, shape, color, coating, and taste could either be nonfunctional or functional depending on the facts and circumstances of each particular case.

To the extent manufacturers wish to pursue trade dress protections for a drug, they should consider incorporating multiple nonfunctional features into their dosage designs. These features could include a combination of unique traits, such as shape and color.

Patient recognition of generic's dosage form that is similar to the branded equivalent could improve patient drug regimen compliance and reduce medication errors. However, generic manufacturers should not assume that patient recognition always indicates functionality, or that it is necessary for a generic dosage to emulate the overall look and feel of a branded tablet or capsule. Whether patient recognition is functional could potentially depend on a multitude of factors, such as whether the target patient is more vulnerable to pill errors (*e.g.*, children, elderly) or

if there is a need to distinguish doses (*e.g.*, a typical regimen requires the patient to take multiple pills of varying doses each day).

From a risk mitigation perspective, both branded and generic manufacturers should document and evaluate the functionality or nonfunctionality of all tablet or capsule features before they are incorporated into the applicable dosage form.

Secondary Meaning

In order for a brand drug manufacturer to claim trade dress protection, the pill's trade dress must also have "secondary meaning." This means the public must associate the tablet or capsule's design, packaging, or overall appearance with a particular source or brand.

Size, shape, and color can contribute to secondary meaning, but are not always enough on their own. Additional factors that may contribute to the secondary meaning analysis, include:

- *Market Exclusivity.* Courts will often consider the length of use and exclusivity of trade dress when determining whether secondary meaning has been established. Branded pharmaceutical drugs from large companies may have an advantage in establishing this factor due to the length of regulatory exclusivity their products often have in the market**.**

- *Consumer Surveys***.** Customer surveys and testimony supporting recognition of the drug can potentially provide direct evidence of secondary meaning. However, it's important to consider that for purposes of secondary meaning, the ultimate "consumer" is generally a prescriber or pharmacy, not the patient.

- *Promotional Efforts***.** Drug manufacturers' use of a pill's trade dress in their promotional efforts with prescribers is another factor that may be considered when evaluating whether the pill's features have secondary meaning.

Likelihood of Confusion

Even if the tablet or capsule features at issue are nonfunctional and secondary meaning of the trade dress is established, there is no trade dress infringement unless it is determined there is a likelihood that a prescriber will confuse the generic with its branded counterpart. This is often evaluated by courts with a multifactor test.

It's important to note that many of the factors used in the functionality and secondary meaning analysis can contribute to a court's evaluation of likelihood of confusion. For example, a generic could argue that the similar traits are a function of FDA regulatory considerations, but if functionality is not ultimately established, a court could potentially attribute the generic's intention to develop a similar dosage form appearance to an intent to copy — a factor considered in the likelihood of confusion analysis.

Conclusion

Navigating the complex interplay between FDA regulations and trade dress protections requires careful consideration and strategic planning. Generic manufacturers must balance the need to comply with regulatory guidelines while avoiding potential trade dress infringement claims. On the other hand, branded drug manufacturers must remain vigilant in protecting their market position and the goodwill they have developed in

their products, including from any distinctive trade dress embodied in tablet or capsule design.

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