

UNDER SCRUTINY:

SHB's Government Enforcement & Compliance Update

GOVERNMENT ENFORCEMENT & COMPLIANCE

Our clients face unprecedented enforcement scrutiny and novel legal theories. Today, government enforcement actions can include civil as well as criminal investigations and litigation. They can involve a host of independent actors including federal and state prosecutors, regulators, whistleblowers and their counsel, and class-action attorneys. These cases must be defended under the watchful eye of investors and the public.

Our Government Enforcement & Compliance Practice consists of former prosecutors – including a former U.S. Attorney, former Justice Department officials and even former corporate executives – who counsel and defend companies, their executives and employees in the full range of criminal, civil and regulatory government enforcement actions at the state and federal level. We counsel clients on how to avoid enforcement scrutiny. When investigations do arise, however, we work with our clients to resolve them as efficiently, cost-effectively and quietly as possible.



EXPIRED PATENTS LISTED ON PRODUCTS CARRY BILLIONS IN POTENTIAL EXPOSURE

An emerging and troubling trend is developing related to patents listed on product labels, including products regulated by the Food & Drug Administration (FDA), potentially creating billions in potential litigation exposure for product manufacturers.

Recently, more than 100 *qui tam* actions have been filed against a variety of companies alleging “false patent marking” in violation of 35 U.S.C. §292, which prohibits intentionally marking an item with a patent number that has expired or that does not protect the item. Companies throughout the pharmaceutical, medical device and cosmetic industries, as well as consumer product companies, have been targeted in these cases, in part because their labels or products often contain patent information and also because of the high volume of units being sold.

The statute provides for fines for false marking conduct that is intended to deceive the public. Importantly, anyone can file these *qui tam* suits, and several rulings appear not to require actual injury for standing to sue under §292 (although the standing issue is coming before the Federal Circuit in the *Stauffer* case discussed below). The statute provides “[a]ny person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States.”

While false marking claims are not new, a recent Federal Circuit ruling has clarified what constitutes an “offense” for the calculation of damages, and this clarification made these cases far more attractive to potential plaintiffs.

In *Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295 (Fed. Cir. 2009), the Federal Circuit determined that the **\$500** maximum penalty applies to **each individual item** that is falsely marked as opposed to each decision or event of false marking. This distinction is significant where, as is the case with pharmaceutical and consumer products, a single decision leads to the marking of millions of product items.

The *Forest* court pointed out that \$500 is the maximum penalty and that courts have discretion to impose lesser penalties under this section: “[b]y allowing a range of penalties, the statute provides district courts the discretion to strike a

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balance between encouraging enforcement of an important public policy and imposing disproportionately large penalties for small, inexpensive items produced in large quantities.”

Even at the smallest per item penalty, however, the monetary damages could be astronomical for products that are sold in large quantities. For example, in the pending appeal involving alleged false marking of 21 billion Solo Cup lids, the potential damages could be anywhere between \$21 million (at a tenth of a penny per item fine as discussed in *Forest*) and more than \$10 trillion dollars (at the \$500 per item maximum fine).

While these cases involve trolling by the plaintiffs' bar on behalf of uninjured plaintiffs, the *Forest* court was undisturbed by this fact (despite evidence that individuals are setting up holding companies as investments to file these *qui tam* suits). The court stated that “the clear language of the statute allows” the court to “interpret[] the fine of \$292 to apply on a per article basis [which] would encourage ‘a new cottage industry’ of false marking litigation by plaintiffs who have not suffered any direct harm.” The court found that the interpretation of penalties on a per item basis as opposed to a per decision basis is consistent with the *qui tam* provisions of \$292 allowing individual plaintiffs to help control false marking.

Because the plaintiff would be entitled to half of any damage recovery with the federal government taking the other half, these cases are attractive investments for the plaintiffs' bar, and we anticipate that they will continue to pour in. Given the current economy, it would not be surprising for the federal government to look at this type of case as an opportunity as well. And, in fact, the government sought to intervene in *Stauffer v. Brooks Brothers*, 2009 WL 1675397 (S.D.N.Y. 2009), to aggressively argue in support of *qui tam* false marking lawsuits. On the other hand, however, the Senate is considering an amendment to the Patent Reform Act of 2010 to limit these suits to only those plaintiffs who have suffered an actual competitive injury, thus reducing the trolling.

We anticipate that this area of law will continue to evolve rapidly. The Federal Circuit's resolution of pending appeals in *Stauffer* (addressing standing requirements for \$292 suits) and the *Solo Cup* case should significantly affect the attractiveness of these cases to *qui tam* plaintiffs. Companies would be wise to review their product labels and products for expired patent information and to make certain that the listed patents apply to the product. ■

For further information or to ask questions, please contact SHB Partner [Adam Moore](#) at (816) 559-2304.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.