

The Metropolitan Corporate Counsel

www.metrocorpcounsel.com

Volume 18, No. 3

© 2010 The Metropolitan Corporate Counsel, Inc.

March 2010

An Overview Of Initial Considerations For Products Liability Litigation Involving “Live” Products

Andrew W. Schwartz

SILLS CUMMIS & GROSS P.C.

In the early days of mass torts, litigation was often commenced after the FDA had already taken regulatory action to remove the product from the market. More recently, however, many of the products involved in mass tort litigation are not the subject of regulatory action. They remain beneficial products that continue to be marketed during the litigation. The continued sales and development of products during litigation results in new challenges in defending the actions, particularly with regard to discovery.

In cases where the product is no longer on the market during the litigation, such as occurred with Vioxx and PPA, discovery typically involves a finite set of documents. However, when dealing with “live” products – those which remain on the market during products liability litigation – discovery is complicated by the ongoing development of the product. The business of the product, including its science, regulation, marketing, and research and development, continues alongside discovery and trial preparation. Counsel is con-

Andrew W. Schwartz is Of Counsel to Sills Cummis & Gross P.C.’s Product Liability Practice Group and Health and Hospital Law Practice Group. The views and opinions expressed in this article are those of the author and do not necessarily reflect those of Sills Cummis & Gross P.C.



Andrew W. Schwartz

fronted with the need to both identify relevant discovery and develop a litigation strategy while the universe of information related to the product remains in flux.

Counsel should consider at the outset of the litigation changes that may arise in the midst of discovery, especially with regard to the product’s safety and efficacy. Three issues in particular should be addressed in the early stages of the litigation. First, a company must take measures to ensure that its electronic documents – including those created after the commencement of litigation – are preserved. Second, a company should establish a process to identify documents created during the litigation which will need to be included in supplemental discovery responses. Third, counsel must develop a litigation strategy that anticipates and accounts

for potential developments with the product.

All Electronic Documents Created During The Litigation Must Be Preserved

One of the most challenging aspects of modern litigation is discovery of electronic documents. In litigation involving live products, the challenge is enhanced because the set of electronic documents to be produced may continue to grow. The Honorable Shira A. Scheindlin, in the Southern District of New York, recently imparted the following caution regarding discovery of electronic documents: “Courts cannot and do not expect that any party can meet a standard of perfection. Nonetheless, the courts have a right to expect that litigants and counsel will take the necessary steps to ensure that relevant records are preserved when litigation is reasonably anticipated, and that such records are collected, reviewed, and produced to the opposing party.” *Pension Comm. of the Univ. of Montreal, Pension Plan. v. Banc of America Secur., LLC., 2010 U.S. Dist. LEXIS 1839*, at *1-2. Judge Scheindlin did not specifically address documents created during litigation, but her rationale applies. Counsel must make provisions to ensure that electronic documents created after the commencement of the litigation are captured for production.

In-house counsel should review the company’s document retention policy to determine whether it is consistent with the company’s obligation to preserve electronic documents on a going-forward basis. Many companies, in response to the expense of electronic

Please email the author at aschwartz@sillscummis.com with questions about this article.

discovery, particularly those without regulatory requirements to preserve documents, have instituted policies that limit the retention of electronic documents. Under such policies, emails may be automatically deleted from employee inboxes in as few as 30 days and from online storage folders annually (or sooner). These policies usually provide an opportunity for the employee to designate certain documents as “business critical” in order to avoid deletion. However, unless a document is so designated, it will be deleted in accordance with the policy and may no longer be accessible when litigation is commenced.

With regard to live products, this type of document retention policy may be inconsistent with a company’s obligation to preserve relevant documents created after the commencement of litigation. Even if employees actively designate “business critical” documents, these designations may not include all documents that are relevant in discovery. As such, at the outset of litigation, in-house counsel should develop a plan with the company’s IT department to protect all relevant documents created after the start of the case from automatic deletion. In formulating an effective preservation plan, counsel, together with the appropriate product managers, should identify all employees who may generate relevant electronic documents during the litigation (the list should be updated as necessary to add new members of the product team). As to these employees, a plan should be devised to identify and store all documents they create which are related to the product on an ongoing basis. Then, during discovery, these documents may be culled to identify and produce those documents that are relevant to the case. By actively identifying and storing documents related to the product at the start of litigation, a company will be prepared to demonstrate that it has acted in good faith to produce electronic documents.

The Duty To Supplement Discovery

After a company has secured its electronic documents, it should next establish a plan to supplement its discovery during the litigation with newly created documents. The obligation to supplement discovery is well settled in both

federal and state court rules. Federal Rule of Civil Procedure 26(e), for example, provides that a party “*must* supplement or correct its disclosure ... in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect....” When dealing with live products, the duty to supplement includes all relevant documents created after the commencement of the litigation. The consequence of failing to supplement discovery includes possible sanctions (*e.g.*, fines, exclusion of witnesses, and preclusion of evidence).

At the start of litigation, a company should circulate a litigation hold memo to all employees who may possess documents related to the product, whether or not the product at issue is still on the market. When dealing with a live product, the litigation hold memo should also expressly advise employees that the obligation to preserve documents is ongoing and includes documents they create on a going-forward basis. Counsel may choose to include in the litigation hold memo a schedule for employees to provide them with documents generated after the start of the litigation. Counsel should also consider circulating additional litigation hold memos, particularly as time passes during litigation, to remind employees of their continuing obligation to preserve newly created documents related to the product.

In addition, in-house counsel should be alerted when new employees are added to projects involving the product (including both new hires and current employees who had not previously worked with the product). Each new employee should be advised of the litigation and their obligation to preserve all documents related to the product. They should also be added to the circulation list of litigation hold memos and to the protocol for capturing electronic documents.

Counsel Should Anticipate Future Product Developments

Another critical concern for counsel when litigating with a live product is the possibility, and in some cases, the likelihood, that there may be developments regarding the safety and efficacy of the product while the litigation is pending. To the extent possible, potential future

developments with the product should be anticipated at the outset of litigation and included in litigation strategy. Advance consideration of potential changes with the product will enable counsel to more readily adapt their litigation strategy if developments do occur during the litigation.

It is recommended that counsel (both in-house and outside) meet with the key product team members as early in the litigation as feasible to discuss the product’s history and its projected future. At this meeting, all historic, ongoing and proposed projects should be considered for their relevance to and potential impact on the litigation. Areas of potential change that should be considered include scientific studies, modifications to the product, marketing campaigns, label changes, the company’s public filings, and any other public statements by the company or its employees regarding the product (including press releases, journal articles and presentations at conventions). Litigation strategy should be crafted with an eye toward potential future developments. Ideally, a partnership should be established between counsel and the product team. Product managers should be encouraged to seek legal advice from counsel with regard to prospective product developments and to keep counsel apprised of all developments regarding the product on a current and ongoing basis. This will enable counsel to revise their strategy to account for any new information regarding the product.

Conclusion

Cases involving live products present different challenges from those involving products that are no longer on the market. With a live product, a company must take steps to ensure that all relevant documents created after the start of the litigation are preserved so that it may satisfy its obligation to produce electronic documents and to supplement discovery. Further, significant developments with a “live” product may occur during the litigation. In order to minimize their impact in the litigation, a company and its counsel should actively assess all ongoing and future projects, anticipate potential developments and factor them into their litigation strategy.