Life Sciences Companies May Face More Scrutiny in Using FDA Documents to Dismiss Securities Cases

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If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

James R. Carroll
Partner / Boston
617.573.4801
james.carroll@skadden.com

Michael S. Hines
Partner / Boston
617.573.4863
michael.hines@skadden.com

Alisha Q. Nanda
Partner / Boston
617.573.4804
alisha.nanda@skadden.com

Rene H. DuBois
Associate / Boston
617.573.4869
rene.dubois@skadden.com

Four Times Square
New York, NY 10036
212.735.3000

500 Boylston St.
Boston, MA 02116
617.573.4800

Following a recent decision from the U.S. Court of Appeals for the Ninth Circuit in *Khoja v. Orexigen Therapeutics, Inc.*, plaintiffs alleging securities fraud against companies in the pharmaceutical and life sciences sector are increasingly opposing the introduction of extrinsic documents by defendants in motions to dismiss under the Private Securities Litigation Reform Act (PSLRA). Because companies in this industry frequently are targets of opportunistic strike suits (usually due to potentially large stock price movements following public disclosures regarding products or drug candidates under development), they need to be particularly aware of this trend and its potential implications on their litigation strategies.

Consider a common example: A plaintiff will allege that a company's positive statements about a drug candidate's safety were rendered false or misleading when the company failed to disclose the full extent of adverse events data. Such complaints often allege that the purported "truth emerged" following a negative public announcement, such as a Food and Drug Administration (FDA) decision not to approve a drug. Rarely, however, do those complaints attach or reference the publicly available FDA documents upon which they rely. In many cases, those omitted materials provide important context about the nature and occurrence of adverse events data and may contain information that directly undermines allegations that a company acted with an intent to defraud investors. Because courts must construe as true all well-pled allegations in a complaint when considering a motion to dismiss, they are reluctant to wade into factual complexities at the pleading stage. Nonetheless, life sciences companies have been successful in obtaining dismissal of securities lawsuits by pointing courts to documents that are integral to, yet strategically omitted from, the complaint.

For example, in *Hirtenstein v. Cempra, Inc*. in the U.S. District Court for the Middle District of North Carolina, the plaintiffs alleged that a biopharmaceutical company misled investors by concealing the impact of certain adverse events observed during clinical trials for its infectious diseases drug. The plaintiffs' allegations relied on FDA advisory committee materials describing the adverse events, but the plaintiffs did not attach the documents to their complaint. In addition to those materials specifically referenced in the complaint, the company also submitted, in connection with its motion to dismiss, the company's publicly available FDA briefing document to show that it had reasonably interpreted the adverse event data differently than the FDA. The court rejected the plaintiffs' argument that the FDA briefing should not be considered because it was neither specifically cited in their complaint nor integral to their case. Instead, the court held that the plaintiffs themselves alleged that their complaint was based, in part, on their review of unidentified FDA advisory committee materials, and that the FDA briefing document was "highly relevant" to the issue of intent. The court dismissed the complaint, finding that a "comparison of the extensive briefing materials prepared by the FDA staff and [the company] reveals that each side had its own interpretation of the data" and thus any "failure to disclose the adverse events in the [clinical] trials did not result from any dishonest or reckless behavior."

Khoja Sets Guidelines for Consideration of Extrinsic Documents

Plaintiffs have attempted to rely on the recent *Khoja* decision to challenge the defense strategy successfully used in cases like *Cempra*. In *Khoja*, a biotechnology company asked a court to consider 21 extrinsic documents in order to dismiss a case alleging that the company had misled investors about the interim results in a post-approval clinical trial. In holding that the lower court abused its discretion in considering many of those documents when dismissing the case, the Ninth Circuit noted a "concerning

pattern in securities cases" where defendants attempt to assert "their version of the facts" in an effort "improperly to defeat what would otherwise constitute adequately stated claims at the pleading stage."

Khoja sets forth several guidelines for when a court can consider extrinsic documents at the pleading stage. First, a court cannot consider a fact in a publicly available government report if it is subject to dispute or varying interpretations. *Khoja* found that a European Medicines Agency (EMA) report was improperly considered because the report did not conclusively establish which company entity reported the interim results to that agency. Second, a court can consider documents that are referenced "extensively" in the complaint or that form the basis for a claim. *Khoja* found that an FDA report was properly considered because the complaint referenced it extensively, even though the claims did not rely on the report itself. In contrast, *Khoja* found that an EMA press release was improperly considered because it was not specifically referenced or identified in the complaint, even though the facts alleged were contained in that same press release. In that regard, the court questioned whether a document can ever form the basis of a claim if the complaint does not reference the document at all, because submitting such documents to create a defense is little more than another way of disputing otherwise well-pled factual allegations.

Observations and Trends Since *Khoja*

In the months since the Ninth Circuit's decision, dozens of plaintiffs already have relied on *Khoja* to oppose the use of extrinsic documents in securities cases. Approximately half of those challenges were made in cases outside the Ninth Circuit, demonstrating plaintiffs' attempts to persuade courts not bound by *Khoja* to follow the ruling. Early observations and trends from those cases include:

- Courts are now more carefully scrutinizing requests to consider extrinsic documents that in years past might otherwise have been considered without dispute.
- Plaintiffs have seen mixed results within the Ninth Circuit. Numerous courts have adhered firmly to *Khoja*, resulting in either fewer documents being considered at the motion to dismiss stage or documents being considered for a limited purpose. But other courts either have distinguished *Khoja* or found that *Khoja* nevertheless supported consideration of the extrinsic documents.
- Outside the Ninth Circuit, relatively few courts have discussed or mentioned *Khoja*, though at least one (the U.S. District Court for the District of Maryland in *In re Under Armour Sec. Litig.*) relied on Khoja to reason that a court must specify the particular facts within a document being judicially noticed.

It remains to be seen how *Khoja* will continue to affect cases that challenge disclosures made by life sciences companies and, in particular, if plaintiffs can defeat a motion to dismiss by strategically omitting references to documents they necessarily relied upon in making their allegations. In the meantime, life sciences companies should expect more vigorous opposition to attempts to introduce FDA or other contextual documents as part of their strategy to dismiss cases brought under the federal securities laws. Companies also should expect courts to place increased attention on the threshold issue of what documents they may consider at the pleading stage before analyzing the sufficiency of the complaint under the heightened pleading standards mandated by the PSLRA.