

Protective Orders - Are They Enough?

Pharmaceutical Law Update

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When faced with the prospect of defending parallel civil and criminal proceedings, companies and their attorneys must evaluate a number of important issues to develop an effective overarching defense strategy. The reach of a grand jury subpoena is one such issue that drug and medical device companies embroiled in civil litigation must consider carefully – particularly if the commencement of a criminal investigation is a reasonable possibility. Given the Food and Drug Administration's (FDA) recent pronouncements confirming its intent to increase the use of misdemeanor criminal prosecutions to hold company officials accountable for company activities, this issue presents an even greater challenge for drug and medical device companies as well as their employees.

Grand Jury Subpoenas vs Civil Protective Orders: The Tension Is Real

Pursuant to the Federal Rules of Civil Procedure, parties are entitled to "obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b). Federal courts, however, are empowered to issue protective orders for "good cause" "to protect any party or person from annoyance, embarrassment, oppression, or undue burden or expense" including: to limit the scope of disclosure or discovery to certain matters, to require that a deposition be sealed and opened only on court order, or to require that "a trade secret or other confidential research, development, or commercial information" not be revealed or only be revealed only in a specified way. Fed. R. Civ. P. 26(c). Civil protective orders play a very important role in the judicial process. Not only do they help mitigate the effects of liberal discovery rules, but they also help safeguard parties who are increasingly concerned with protecting their privacy and confidentiality, as well as reduce the risk of future litigation.

In the federal court context, grand juries are given broad power to investigate potential criminal matters. "The function of the grand jury is to investigate possible criminal violations of the federal laws and to return indictments against culpable corporations and individuals where there is probable cause to believe that a violation has occurred." Department of Justice, *Grand Jury Manual*, Ch. 1. To support that function, the grand jury is provided with a subpoena power that "is coextensive with its broad power to investigate." *Id.* at Ch. 3, Part I. That power allows a grand jury to "subpoena all witnesses, nonprivileged documents and other physical evidence relevant to its investigation, provided that the subpoenas are not unreasonably burdensome." *Id.*

The breadth of a grand jury's subpoena power, however, is oftentimes at odds with the safeguards that are meant to be created by the entrance of a valid and agreed-upon protective order. By way of example, a company may produce certain documents during the civil discovery process because they believe the documents will be safeguarded from further distribution through the execution of an appropriate protective order, including documents generally outside the reach of a grand jury's subpoena power such as foreign documents, or deposition testimony originating outside of the United States. Should a grand jury be able to obtain that discovery by serving a subpoena on the party who received the discovery during civil litigation, even though the grand jury would not ordinarily have access to some of those materials through the use of a direct subpoena to the producing party? As another example, a person who is hesitant to provide deposition testimony for the fear that he or she might potentially incriminate himself or herself criminally may provide that testimony under the safeguards of a protective order, rather than seek the protections of the Fifth Amendment's privilege against self-incrimination. Should a grand jury be able to obtain that deposition transcript through the use of a subpoena even though that deponent may have otherwise sought the protections of the Fifth Amendment privilege against self-incrimination during a criminal proceeding?

A Protective Order May Not Safeguard Discovery From a Grand Jury Subpoena

The question of whether a protective order supersedes a grand jury subpoena seeking the production of material covered by the scope of the order has divided the federal Courts of Appeal. The Fourth, Ninth, and Eleventh Circuits have adopted a per se rule under which "the existence of an otherwise valid protective order [is] not sufficient grounds to quash [a] subpoena duces tecum issued by [a] grand jury." In *re Grand Jury Subpoena (Roach)*, 138 F.3d 442, 444 (1st Cir. 1998), citing *In re Grand Jury Subpoena*, 836 F.2d 1468, 1478 (4th Cir. 1988); *In re Grand Jury Subpoena*, 62 F.3d 1222, 1224 (9th Cir. 1995); and *In re Grand Jury Proceedings*, 995 F.2d 1013, 1020 (11th Cir. 1993). The Second Circuit posits a presumption in favor of a protective order

when it clashes with a grand jury subpoena, finding that "absent a showing of improvidence in the grant of a protective order or some extraordinary circumstance or compelling need, a protective order is enforceable against any third party, including the government." *In re Grand Jury Subpoena Duces Tecum*, 945 F.2d 1221, 1224 (2d Cir. 1991) citing *Martindell v. International Tel. & Tel. Corp.*, 594 F.2d 291, 295 (2d Cir. 1979); see also, *In re Grand Jury Subpoena Dated April 19, 1991*, 945 F.2d 1221, 1223-224 (2d Cir. 1991). Finally, the First and Third Circuits follow a modified per se rule under which "[a] grand jury's subpoena trumps a Rule 26(c) protective order unless the person seeking to avoid the subpoena can demonstrate the existence of exceptional circumstances that clearly favor subordinating the subpoena to the protective order." *In re Grand Jury Subpoena (Roach)*, 138 F.3d at 445; *In re Grand Jury*, 286 F.3d 153, 157-58 (3d Cir. 2002).

This issue currently sits before the U.S. Supreme Court. Petitions for Certiorari have been filed in two matters, *White & Case LLP v. U.S.*, 627 F.3d 1143 (9th Cir. 2010) Docket No. 10-1147, and *Nossaman LLP v. U.S.*, 627 F.3d 1143 (9th Cir. 2010) Docket No. 10-1176, both of which address the central question of whether a grand jury subpoena trumps a civil protective order, allowing prosecutors to obtain discovery materials from a parallel civil action, regardless of any countervailing considerations. Should the Supreme Court accept these petitions, drug and medical device companies will obtain more guidance regarding the scope of protective orders, and can shape plans for ongoing litigation more effectively. In the interim, however, drug and medical device companies, when producing discovery in civil litigation, must consider, and account for the possibility, that the documents they produce could end up seeing the light of day, despite the steps taken to safeguard those records.

What's a Company to Do?

Though it would be great if this situation could be entirely avoided until the Supreme Court resolves the matter definitively, companies that currently find themselves embroiled in civil litigation do not have that luxury. Instead, they face the dueling considerations of defending themselves fully in a civil litigation at the risk of providing potentially incriminating discovery that might not otherwise be obtainable by a grand jury subpoena, versus the risk of receiving serious adverse consequences including monetary sanctions, adverse inferences or default for declining to produce that discovery during civil litigation. As a result, defense counsel should, at the outset, develop an overarching strategy for the production of discovery that will protect their clients to the greatest extent possible in all forums. That strategy should be guided by the following non-exhaustive list of considerations: (1) whether a related criminal investigation has already been commenced, or could be commenced; (2) the relevant laws of the applicable jurisdiction relating to the effect of a grand jury subpoena; (3) the type of litigation and whether the discovery sought in that type of litigation is generally broad or narrow; (4) whether any foreign discovery may be involved; and (5) whether any deposition testimony may result in the potential for self-incrimination.

Based on its evaluation of these factors, counsel should, first and foremost, consider seeking a stay of discovery in the civil litigation pending the completion of any criminal proceedings. Should a stay not be sought or granted, counsel should also consider proactively filing a motion pursuant to *Fed. R. Civ. P.* 26 to limit the scope of discovery based on relevancy, undue burden, undue cost, annoyance, embarrassment or oppression to avoid producing the discovery. If foreign documents are sought, and those documents may contain potentially incriminating information, counsel should weigh other production options including only making the documents available for review abroad, or limiting the production to the extent necessary to protect any applicable constitutional rights. With respect to providing potentially incriminating deposition testimony, counsel must weigh whether to provide the testimony, or risk receiving an adverse inference during trial due to the invocation of the Fifth Amendment's privilege against self-incrimination. While no one strategy will work in every circumstance, one thing is certain – drug and medical device companies facing the potential for parallel civil and criminal proceedings and their counsel must carefully evaluate the discovery being sought and develop a coordinated overarching defense strategy to best protect their interests.

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