The District of Delaware Adopts the Federal Circuit's Factors in Rejecting Regulatory Bar in a Protective Order

Aug 30, 2023

Categories:

Gibbons
Pharmaceuticals

Authors:

Charles H. Chevalier
Michael V. Caracappa

In *Amicus Therapeutics US, LLC v. Teva Pharmaceuticals USA, Inc.*, United States Magistrate Judge Christopher J. Burke rejected the defendants-generic drug manufacturers' demand that a so-called regulatory bar be included in the parties' proposed protective order. In denying the request, Judge Burke adopted the Federal Circuit's approach as set forth in cases like *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373 (Fed. Cir. 2010). Despite denying the defendants' request, and while noting the rarity of courts ordering the inclusion of similar provisions in protective orders, Judge Burke explicitly left the door open to the possibility, emphasizing the highly fact-sensitive nature of these disputes.

The defendants sought the inclusion of a regulatory bar that would preclude anyone who was granted access to information marked "Confidential" or "Highly Confidential" under the proposed protective order from participating in any FDA proceedings concerning migalastat (the drug at issue in the case), including by filing a citizen petition.

In deciding under what factors to analyze this discovery dispute, Judge Burke identified two possibilities: (a) the Third Circuit's *Pansy* factors, or (b) the Federal Circuit's *Deutsche Bank* factors. The court and the parties agreed the latter should be applied because the Third Circuit's *Pansy* factors generally concern whether information should be protected from *intentional disclosure* from the public, whereas the Federal Circuit's factors concern the risk of *inadvertent disclosures*. The court further noted "a number of the *Pansy* factors are just not that likely to be particularly relevant to the regulatory bar/protective order calculus."

The Federal Circuit's approach proceeds in two parts: First, a court considers the risk of inadvertent disclosure or competitive use. Then, if a court is satisfied that such a risk exists, it balances the risk against the potential harm to the opposing party from restrictions

2026 FBT Gibbons LLP. All rights reserved. ADVERTISING MATERIAL.

imposed on its right to have the benefit of counsel of its choice.

In the instant case, the defendants failed to convince the court there was anything more than a generalized or speculative risk that the plaintiffs-brand manufacturers' counsel would actually participate in future FDA proceedings involving migalastat, much less a risk of inadvertent disclosure. Specifically, the defendants argued the plaintiffs retained an attorney who only had regulatory experience, intimating that his participation was a ploy to allow him to access confidential information that he could later use against the defendants in regulatory proceedings. The plaintiffs proved otherwise, neutralizing the first factor by demonstrating the attorney had significant litigation experience. Judge Burke noted that, had the defendants been correct, he might have supported their request.

Turning to the second factor, the court stated it lacked any helpful information on the indispensability of the plaintiffs' counsel. Consequently, the court found the factor was also neutral. The defendants, having failed to show the need for a protective order, had their request denied by the court.

The import of Judge Burke's opinion is twofold. First, it further supports the use of the Federal Circuit's *Deutsche Bank* factors in similar disputes in the Third Circuit. The District of New Jersey already uses the *Deutsche Bank* factors in regulatory bar disputes. For example, in a short letter order in *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-3632, Judge Cathy L. Waldor denied ordering the inclusion of a regulatory bar in the parties' discovery confidentiality order because she found the opponent failed to raise more than a speculative risk of inadvertent disclosure. Even before the *Deutsche Bank* factors, the District of New Jersey would generally deny a regulatory bar if the proposed discovery confidentiality order restricted the use of confidential information. Second, it also reminds proponents and opponents that disputes over provisions like these in protective orders/discovery confidentiality orders are often fact-intensive disputes that require careful attention; boilerplate or speculative contentions will not protect a party's interests.

© 2026 FBT Gibbons LLP. May be considered attorney advertising in some jurisdictions.

2026 FBT Gibbons LLP. All rights reserved. ADVERTISING MATERIAL.