

NOTE: This order is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

IN RE IMPAX LABORATORIES, INC.,
Petitioner.

Miscellaneous Docket No. 131

On Petition for Writ of Mandamus to the United
States District Court for the District of Delaware in case
no. 11-CV-1152, Judge Sue L. Robinson.

ON PETITION

Before LINN, DYK, and WALLACH, *Circuit Judges.*
DYK, *Circuit Judge.*

O R D E R

Impax Laboratories, Inc. petitions for a writ of mandamus to direct the United States District Court for the District of Delaware to vacate its order declining to enter a protective order with a Food and Drug Administration (FDA) bar. Cephalon and CIMA LABS, Inc. (Cephalon) oppose. Impax replies.

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This petition arises from a Hatch-Waxman suit brought by Cephalon, Inc. to prevent Impax from bringing to market a generic version of Fentora, which are fentanyl buccal tablets. Impax argues that Cephalon, simultaneously with its patent enforcement proceedings, has launched a campaign with the FDA to oppose the approval of generic fentanyl buccal tablets. Because of the overlap of the matters and the attorneys involved, Impax urged the district court to adopt an FDA bar in the protective order, which would generally prohibit any recipient of designated material in the litigation from participating in FDA correspondence relating to generic fentanyl buccal tablets for one year after final termination of the action.

The district court held a hearing and allowed both sides to present arguments relating to an FDA bar, but it declined to adopt such a provision. It held that there is no support for Impax's argument that the risk of inadvertent disclosure of confidential material to the FDA warrants the substantial burden that such a bar would impose. The district court also held that the other provisions in the existing protective order already govern the use of litigation-generated information.

Mandamus requires the petitioner to establish: (1) there are no alternative means of obtaining the relief desired, *Mallard v. U.S. District Court*, 490 U.S. 296, 309 (1989), and (2) the right to the relief sought is "clear and undisputable," *Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33, 35 (1980). Mandamus is an "extraordinary remedy," justifiable only in "exceptional circumstances, amounting to a judicial usurpation of power . . ." *Id.*

Impax's petition fails to meet this high standard. The district court found Impax's concerns about the lack of an FDA bar to be unpersuasive given the other provisions protecting sensitive material. Namely, the court noted

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that these other provisions would require both Cephalon and its attorneys to ask for and receive permission from the district court before disclosing any litigation-generated information.

The court also acknowledged that it had not yet received “an explanation of what circumstances would allow [Cephalon’s] counsel to be interfacing with the FDA about a competitor’s ANDA, resulting in a risk of an inadvertent disclosure of confidential, litigation-generated information. Until such time, if ever, that I am so informed, I decline to put a FDA bar in place.” The district court thus left open the possibility that Impax could present specific circumstances to the district court for reconsideration.

Accordingly,

IT IS ORDERED THAT:

The petition for a writ of mandamus is denied.

FOR THE COURT

OCT 17 2012

Date

/s/ Jan Horbaly

Jan Horbaly
Clerk

cc: Roger J. Chin, Esq.
Jonathan Elliot Singer, Esq.

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