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The Broad Impact of Edwards v. Meril on the Safe Harbor Provision

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The Federal Circuit's decision in *Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd.*, has garnered significant attention, especially concerning the application of the "safe harbor" provision under 35 U.S.C. § 271(e)(1). The Federal Circuit's ruling, and the subsequent denial of Edwards's petition for rehearing *en banc*, underscores the breadth of the safe harbor, putting to bed the question of whether "solely" means "only" in the context of the safe harbor.

The Safe Harbor Provision: A Brief Overview

The safe harbor provision under 35 U.S.C. § 271(e)(1) was introduced as part of the Hatch-Waxman Act to facilitate the development of generic drugs and medical devices. This provision exempts certain activities from patent infringement liability if they are "solely for uses reasonably related" to obtaining U.S. Food and Drug Administration (FDA) approval to market the product. The purpose of the provision is to allow companies to conduct necessary testing and development without the risk of patent infringement litigation, as long as these activities are directed toward securing regulatory approval.

***Edwards v. Meril*: A Closer Look**

In E*dwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd.*, Edwards brought a patent infringement suit against Meril, alleging that Meril's activities related to heart valve technology infringed Edwards's patents. Meril countered by invoking the safe harbor defense, arguing that its activities were protected because they were aimed at obtaining regulatory approval, including submissions to foreign regulatory bodies.

The Role of the Term "Solely"

The Federal Circuit's decision turned on the scope of the term "solely" within the context of the safe harbor provision and what activities can be shielded from patent infringement under this provision. In *Edwards v. Meril*, the court closely examined whether Meril's activities were indeed "solely" for the purpose of regulatory submission. Meril imported its preapproval heart valve device to the U.S. for a conference, but did not sell or physically disclose the system, and kept it in a hotel closet and storage room. The Federal Circuit found that Meril's activities, which included conducting clinical trials and gathering data for submission to foreign regulatory bodies, fell within the safe harbor provision, as they were reasonably related to obtaining regulatory approval in the U.S. as well. This continues the court's trend of not focusing on alternative uses or consequences of activities. The court's interpretation suggested that even if the activities were conducted with multiple objectives, as long as one of those objectives was to secure FDA approval, the safe harbor could apply.

The Federal Circuit's Denial of Rehearing *En Banc*

Edwards petitioned for an *en banc* rehearing, challenging the panel's interpretation, particularly the application of the term "solely." The Federal Circuit, however, denied the petition, upholding the original decision. This denial has significant implications, as it solidifies the broader interpretation of the safe harbor provision, potentially allowing more tangentially related activities to be shielded under the safe harbor.

Will Edwards Petition the Supreme Court for Certiorari?

Given the importance of the term "solely" in the application of the safe harbor provision, and the Federal Circuit's broad interpretation in this case, it is likely that Edwards will consider petitioning the Supreme Court for certiorari. Several factors suggest this possibility:

1. The Importance of the Issue: The interpretation of "solely" in the safe harbor provision has far-reaching implications for patent holders, particularly in the pharmaceutical and biotechnology industries. The continued broad interpretation by the Federal Circuit could impact the enforcement of U.S. patents in cases where companies conduct activities abroad and import products into the U.S.

2. Potential for Supreme Court Review: The Supreme Court has historically shown interest in cases that involve important interpretations of patent law, particularly those that affect the balance between innovation and competition. Given the potential impact of this decision on patent rights and the regulatory landscape, the case may attract the Court's attention.

3. Desire for Clarity: Patent holders may seek greater clarity and consistency in how the safe harbor provision is applied. A Supreme Court review would likely draw significant interest from amicus across the spectrum of life sciences companies.

Conclusion: Navigating the Post-*Edwards v. Meril* Landscape

The *Edwards v. Meril* case represents a pivotal moment in the interpretation of the safe harbor provision, particularly concerning the term "solely." The Federal Circuit's ruling, reinforced by the denial of an *en banc* rehearing, maintains the broad scope of activities that can be shielded from patent infringement under the safe harbor. For companies in the medical device, biotechnology and pharmaceutical sectors, this decision underscores the importance of carefully navigating the complex interplay between patent law and regulatory compliance.

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