POLSINELLI

Publications

February 19, 2025 • Updates

Personal Jurisdiction Considerations for International Biosimilars Companies

The Federal Circuit recently issued decisions in a pair of appeals that provide guidance about when international filers of abbreviated Biologics License Applications (aBLAs) are subject to jurisdiction in the United States. Specifically, the Federal Circuit held that international biosimilars companies are subject to jurisdiction in the United States when they have submitted an aBLA with the intent to market the finished product in the forum state.

1. Regeneron's Patent Infringement Lawsuits

The plaintiff in each case is Regeneron Pharmaceuticals, Inc., which holds Biologics License Application (BLA) No. 125387 for EYELEA®, which is approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with angiogenic eye diseases —Wet Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)—via injection into the body of the eye.

Regeneron sued several companies, including Samsung Bioepis Co., Ltd. (SB) and Formycon AG (Formycon), that had filed aBLAs with the FDA seeking approval under the Biologics Price Competition and Innovation Act (BPCIA) to market EYLEA® biosimilars. The cases were consolidated in the U.S. District for the Northern District of West Virginia and the district issued preliminary injunctions against SB and Formycon, barring them from offering for sale or selling the products described in their aBLAs, which have been approved by the FDA. SB appealed the preliminary injunction on several grounds, including that they were not subject to personal jurisdiction, which is the focus of this article.

2. SB's Connections to the United States

SB is a biosimilar-products company headquartered in Incheon, South Korea. SB argued it has no facilities or employees in the United States; is not registered to do business and has no registered agent in West Virginia; and does not do business with entities in West Virginia. SB also argued that although it would sell its finished product to Biogen MA Inc. (a U.S. company) in a state other than West Virginia, it would not distribute, market or

Related People

- Mark T. Deming

Related Capabilities

- Hatch-Waxman & Biologics
- Intellectual Property Litigation
- Life Sciences

otherwise sell the product in the United States.

3. Formycon's Connections to the United States

Formycon is a biopharmaceutical company based in Bavaria, Germany. Formycon argued that it has no "direct" ties to West Virginia; is not registered to do business and has no registered agent there; has no assets or employees there; and that it had contracted with manufacturers and packaging partners who would produce the finished product and related materials in other states. Formycon further argued that having developed the product pursuant to an agreement with another German company, it had no plans or rights to itself commercialize the product in the United States. Instead, the product would be sold to another company for marketing and distribution, and Formycon would have no control over the selection of that company or its decisions regarding commercialization.

4. The Federal Circuit's Jurisdiction Analysis

When evaluating if a defendant is subject to personal jurisdiction in the forum of a particular state, the court looks to (1) whether the state's long-arm statute permits service of process and (2) whether the assertion of jurisdiction would be inconsistent with due process under the U.S. Constitution. In many states, including West Virginia, the long-arm statutes are "coextensive with the full reach of due process," so the questions collapse into one constitutional inquiry.

Under the U.S. Constitution, a court in a state may exercise jurisdiction over a defendant that has sufficient "minimum contacts" with the state that it would not "offend traditional notions of fair play and substantial justice." This standard requires that the defendant's suit-related conduct create a "substantial connection" with the forum state. The application of the standard in these cases is not necessarily straightforward because patent infringement cases based on an aBLA filing are not easily analogized to other types of actions or even traditional patent infringement cases.

The Federal Circuit, therefore, relied on its precedent in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), which considered the jurisdictional question in the context of a suit arising out of the filing of an Abbreviated New Drug Application (ANDA). In *Acorda*, the court had held that "minimum contacts" were satisfied by planned future interactions with the state. The submission of an ANDA with the intent to distribute the generic product in a state was held sufficient to support exercising jurisdiction.

Extending *Acorda* to aBLA cases, the Federal Circuit found similar evidence of conduct sufficient to exercise jurisdiction. Specifically as to SB, the court observed that SB had filed an aBLA; had served Regeneron with a Notice of Commercial Marketing, which communicates an intent to market upon FDA approval; had engaged various partners within the United States; and had entered into a nationwide distribution agreement with a U.S. company, through which SB retained "significant involvement" in commercialization activities.

Notwithstanding the apparent differences in involvement in commercialization activities, the Federal Circuit also found that Formycon intended to market the finished product in West Virginia and other states. As with SB, the court relied on Formycon's filing of the aBLA, service of Notice of Commercial Marketing, and partnering with U.S. companies to manufacture, package and label its product. Although it had not yet entered into an agreement with a marketing partner, the court found Formycon intended to ultimately distribute the finished product nationwide.

Thus, filing an aBLA, providing Notice of Commercial Marketing, and having more than

speculative plans to market the finished product throughout the United States appears sufficient to subject an international biosimilar company to jurisdiction in any state having a long-arm statute coextensive with the U.S. Constitution. The stronger the relationship to commercialization plans, the stronger the argument will be for jurisdiction, although these factors appear to primarily support a finding of jurisdiction as opposed to playing a significant role in the analysis in the first instance.

5. Guidance for International Biosimilars Companies

International biosimilars companies that file aBLAs in the United States with plans to market the finished product should expect a high likelihood of being subject to jurisdiction for related patent infringement cases. Some steps may mitigate the risk, however, and increase the likelihood of avoiding jurisdiction:

- Reduce contact with the United States as much as possible. For example, perform all development, sourcing, manufacturing, packaging and labeling outside the United States.
- Introduce layers between the aBLA filer and the ultimate marketer. For example, the aBLA filer may contract with other international companies that, in turn, independently contract with a marketing partner in the United States. If the agreement between the aBLA filer and the second international company is not limited to marketing rights in the United States, that may further help.
- Carve out particular states. If there are states in which the international biosimilar company does not want to be subject to jurisdiction, expressly exclude those states from commercialization agreements.

These and other factors can significantly affect whether a company is ultimately subject to jurisdiction in the United States, and similar considerations may affect other partners in the international supply chain. At Polsinelli, our Hatch-Waxman and Biologics attorneys can provide litigation and pre-litigation counsel about all aspects of BPCIA-related matters, including assessing the risk of being subject to suit in the United States and strategies for mitigating against the same.