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U.S. District Court Adopts Expansive Definition of aBLA "Submitter"

Charlotte Jacobsen (Gibson, Dunn & Crutcher LLP) and Filko Prugo, Monica Ortel (Ropes & Gray LLP) · Monday, September 20th, 2021

Submission of an abbreviated Biologics License Application ("aBLA"), under the Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA"), for a biosimilar version of an already-approved biologic drug constitutes an "artificial act of infringement" for which the biologic's patent owner may file suit.[1] In the recent *AbbVie Inc. v. Alvotech hf.*[2] decision, the district court adopted an expansive definition of what it means to "submit" an application, and allowed infringement claims to be brought against the foreign parent company of the applicant listed in the aBLA. This decision has important implications for cases where the biosimilar manufacturer is based outside of the United States.

Background

In *Alvotech*, Iceland-based defendant Alvotech hf. developed, and in 2018, began clinical trials for a biosimilar version of AbbVie's product Humira®, which is used to treat autoimmune conditions including rheumatoid arthritis, psoriasis, and Crohn's disease.[3] In 2019, Alvotech hf. formed a wholly-owned U.S. subsidiary, Alvotech USA. In fall of 2020, the U.S. subsidiary Alvotech USA submitted an aBLA seeking approval for the biosimilar. As envisioned by the BPCIA, Alvotech USA notified AbbVie of its application.[4] AbbVie then filed a suit for patent infringement in the Northern District of Illinois based on the aBLA submission.

In the lawsuit, AbbVie named Iceland-based Alvotech hf. as the defendant—not U.S.-based Alvotech USA.[5] AbbVie argued in its complaint that Alvotech hf. created and prepared the aBLA information; it further argued that, if approved, Alvotech hf. would engage in the manufacture, commercialization, and sale of the biosimilar.[6] Alvotech hf. moved to dismiss the complaint.[7]

The District Court's Interpretation of "Submit"

Under U.S. patent law, it is an act of infringement to ***submit*** an ANDA or an aBLA "if the purpose

of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."[8] Alvotech hf. argued that the suit should be dismissed because it did not "submit" the aBLA; only Alvotech USA was listed as the applicant.

The district court denied Alvotech hf.'s motion, and in doing so, pointed to Hatch-Waxman case law adopting an expansive meaning of the "submitter" for ANDA products.[9] In particular, *Rosuvastatin* where the Federal Circuit interpreted the word "submit" within the statutory "act of artificial infringement," holding that an entity "submits" an ANDA if it "intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution and/or sale of the generic drug."[10]

In *Alvotech*, the court held that the term "submit" in 35 U.S.C. § 271(e)(2) applies equally to the Hatch-Waxman Act and BPCIA subsections of the statute, so *Rosuvastatin*'s interpretation of "submitter" applied even though *Rosuvastatin* involved an ANDA submission.[11] The *Alvotech* district court rejected Alvotech hf.'s argument that direct participation in the "patent dance" procedures of the BPCIA was a prerequisite for being sued, finding that § 271(e)(2)—not the BPCIA-specific provisions—provided the statutory authority for the claim for patent infringement.[12]

Applying the standard from ANDA case law, the court found that AbbVie sufficiently alleged that Alvotech hf. was a "submitter" of the aBLA through its creation and preparation of the information in it.[13] Indeed, at least one clinical trial was performed before Alvotech USA came into existence and Alvotech hf. communicated with the FDA before beginning the trial. AbbVie also alleged that Alvotech hf. would engage in the manufacture, supply, development, and registration of the Humira® biosimilar.[14] The court found these allegations sufficient at the motion to dismiss stage to deny Alvotech hf.'s motion.[15]

Implications for Biosimilars Litigation

The Hatch-Waxman Act was passed in 1984, twenty-five years earlier than the BPCIA. Based on this significant gap, there is far more case law in the ANDA than the aBLA context. It is thus possible that other courts will borrow other principles from Hatch-Waxman litigation as further cases are adjudicated under the BPCIA.

Critically, those developing biosimilars should be aware that non-U.S. parties may be named as defendants consistent with the *Alvotech* court's expanded definition of "submitter." Entities that created or prepared the information in the aBLA, or entities that will participate in manufacture, distribution, marketing, or importation of a biosimilar may be subject to a suit for patent infringement, even if they are not named in the aBLA. For BLA holders, this decision may allow

suit to be brought in a more favorable venue. Additionally, for foreign corporations at arms-length from the U.S. entity named in the aBLA, it will be important to factor into any contracts or licensing arrangements the associated potential liabilities and costs, as well as control of the litigation and its settlement.

[1] 35 U.S.C. § 271(e)(2)(C).

[2] *AbbVie Inc. v. Alvotech hf.*, No. 1:21-cv-02258, Doc. 51 (N.D. Ill. Aug. 23, 2021) ("*Alvotech*"),

[3] *Alvotech* at *5–6.

[4] *See* 42 U.S.C. § 262(k).

[5] *Alvotech* at *6–7.

[6] *Id.*

[7] *Id.* at *11–12.

[8] 35 U.S.C. § 271(e)(2).

[9] *Id.* at *14, 17–19.

[10] *Alvotech* at *18–19 (citing *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 528 (Fed. Cir. 2012); *Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, No. CV-18-73-LPS, 2019 WL 581618, at *4 (D. Del. Feb. 13, 2019)).

[11] *Alvotech* at *15, 18.

[12] *Id.* at *15–18.

[13] *Id.* at *19.

[14] *Id.*.

[15] *Id.* at *19–20.

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This entry was posted on Monday, September 20th, 2021 at 10:23 am and is filed under Biologics, Case Law, Infringement, United States of America
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