Akin®

District Court: Factual Disputes Preclude Application of Safe Harbor to Gene Editing Technology at the Pleading Stage

January 17, 2025

Reading Time : **2 min**

By: Megan R. Mahoney, Matthew George Hartman, Rachel J. Elsby

The District of Delaware recently denied a motion to dismiss a patent infringement complaint involving gene editing technology that sought relief under the Safe Harbor Provision of the Hatch-Waxman Act. Specifically, the court found the patentee's complaint sufficiently alleged at least some uses of the claimed technology that, when taken as true, were not solely uses of a "patented invention" that were "reasonably related" to an FDA submission.

The patents in this case claimed gene editing tools known as bi-directional insertion templates (BDITs) and methods of their use. The patentee accused the defendant of using its patented BDITs for the research, identification and optimization of therapeutic candidates. As an example, the complaint alleged that defendant uses the BDITs as a platform technology to collaborate with other entities to develop therapeutic candidates. The defendant moved to dismiss the complaint, arguing that its accused research activities were reasonably related to obtaining FDA approval, and thus immunized by the Safe Harbor provision of the Hatch-Waxman Act. The defendant argued that it developed its BDIT platform before the asserted patents issued, and its current activity was limited to late-stage development of therapies for FDA approval where the BDITs were incorporated into the therapeutic candidate.

In denying the motion, the court found it could not resolve on a motion to dismiss whether the accused uses of the BDITs were solely for uses reasonably related to obtaining FDA approval. The court noted that the Supreme Court construed "patented inventions" as used in the Hatch-Waxman Act to mean instrumentalities that are subject to premarket approval.

Here, the patentee alleged that defendant's BDITs were used as a tool to generate and identify therapeutic candidates, but the BDITs would not themselves be subject to FDA approval. Thus, at least at the pleading stage, patentee's allegations were sufficient to preclude application of the Safe Harbor. The court further determined that patent owner's allegations regarding defendant's collaborations with other entities to develop therapeutics and defendant's experimentation to identify potential candidates, when taken as true, reflected commercial activity not reasonably related to obtaining FDA approval. And for this additional reason, the allegations were sufficient to survive a motion to dismiss.

Despite this result, the court acknowledged that BDITs present a "tricky fact pattern" because they are tools that have the potential to be incorporated into the final therapeutic candidate. But here again, the court found that it could not distinguish between early stage development and uses that actually do become part of the therapeutic.

Practice Tip: While the Safe Harbor Provision affords some protection from claims of patent infringement, those protections are not absolute. As this case demonstrates, it is important to distinguish between technology that will be the subject of FDA review and technology that is used as a tool in development. While the former is likely protected under the Safe Harbor, the latter may fall outside its protections.

BlueAllele Corp. v. Intellia Therapeutics, Inc., 1-24-cv-00791, D.I. 35 (D. Del. Dec. 9, 2024)

Categories

Patent Litigation | Patent Law | Litigation

Food and Drug Administration (FDA)

such. Prior results do not guarantee a similar outcome. Akin is the practicing name of Akin Gump LLP, a New York limited liability partnership authorized and regulated by the Solicitors Regulation Authority under number 267321. A list of the partners is available for inspection at Eighth Floor, Ten Bishops Square, London E1 6EG. For more information about Akin Gump LLP, Akin Gump Strauss Hauer & Feld LLP and other associated entities under which the Akin Gump network operates worldwide, please see our Legal Notices page.