United States Court of Appeals for the Federal Circuit

GENENTECH, INC.,
Plaintiff-Appellant

CITY OF HOPE,
Plaintiff

v.

IMMUNEX RHODE ISLAND CORPORATION, AMGEN INC.,
Defendants-Appellees

2019-2155

Appeal from the United States District Court for the District of Delaware in No. 1:19-cv-00602-CFC, Judge Colm F. Connolly.

Decided: July 6, 2020

CHARLES L. MCCLOUD, Williams & Connolly LLP, Washington, DC, argued for plaintiff-appellant. Also represented by PAUL B. GAFFNEY, DAVID I. BERL, THOMAS S. FLETCHER, KATHRYN SCHLECKSER KAYALI.

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, argued for defendants-appellees. Also represented by

MICHAEL GREGORY PATTILLO, JR., LUCAS M. WALKER; SIEGMUND Y. GUTMAN, SARAH CORK, AMIR A. NAINI, Proskauer Rose, Los Angeles, CA; STEVEN M. BAUER, JOHN E. ROBERTS, Boston, MA; MELANIE K. SHARP, Young, Conaway, Stargatt & Taylor LLP, Wilmington, DE; DREW DIAMOND, NANCY GETTEL, WENDY A. WHITEFORD, Amgen Inc., Thousand Oaks, CA.

Before MOORE, O'MALLEY, and HUGHES, *Circuit Judges.*

MOORE*, Circuit Judge.*

Genentech, Inc. and City of Hope (collectively, Genentech) filed an emergency motion and a motion for a temporary restraining order based on Immunex Rhode Island Corporation's and Amgen Inc.'s (collectively, Amgen) alleged failure to comply with the notice requirement of 42 U.S.C. § 262(*l*)(8)(A). Genentech appeals the United States District Court for the District of Delaware's denial of the motions. *Genentech, Inc. v. Immunex Rhode Island Corp.*, 395 F. Supp. 3d 357, 366 (D. Del. 2019). For the reasons stated below, we affirm.

BACKGROUND

Genentech manufactures and sells bevacizumab, a biological product used to treat certain types of cancer, under the name Avastin. Amgen filed a biologics license application with the Food and Drug Administration (FDA) pursuant to 42 U.S.C. § 262(k) to market a biosimilar version of Avastin—Mvasi. Mvasi received FDA approval effective September 14, 2017. On October 6, 2017, Amgen sent a letter pursuant to 42 U.S.C. § 262(*l*)(8)(A) notifying Genentech of its intent to commercially market Mvasi starting no earlier than 180 days from the date of the letter. In August 2018, after two prior supplements, Amgen filed a third supplement to its Mvasi application to add a manufacturing facility and a fourth supplement to change its drug label.

By July 8, 2019, Amgen decided it would commercially launch Mvasi, intending to market it immediately.

Genentech filed two motions in the District of Delaware seeking to preclude Amgen from commercially marketing Mvasi "until such time as Amgen . . . provides notice of its intent to commercially market such product[] pursuant to [42] U.S.C. § 262(*l*)(8) and 180 days have elapsed." J.A. 3. It argued that Amgen's third and fourth supplements resulted in new and distinct applications that require new notices under Section 262(*l*)(8)(A). The district court denied both motions, reasoning that Amgen's October 2017 commercial marketing notice for Mvasi satisfied Section 262(*l*)(8)(A)'s notice requirements. Genentech appeals. We have jurisdiction under 28 U.S.C. §§ 1292(a)(1) and (c)(1).

DISCUSSION

The parties' dispute centers on the district court's interpretation of Section 262(*l*)(8)(A)'s notice requirements. "Statutory interpretation is a question of law that we review de novo." *Forest Grp., Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1301 (Fed. Cir. 2009). "In statutory interpretation disputes, a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law itself. Where, as here, that examination yields a clear answer, judges must stop." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019) (citations omitted).

Section 262(*l*)(8)(A) recites:

> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)

The statute makes clear that the biosimilar applicant must provide notice to the reference product sponsor prior to commercially marketing *the biological product*. The

Biologics Price Competition and Innovation Act defines "biological product" as used in Section 262 as:

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. § 262(i)(1).

Amgen notified Genentech of its intent to commercially market its biological product, Mvasi, on October 6, 2017. Despite its later supplements to its applications adding a manufacturing facility and changing its drug product label, Amgen's biological product, Mvasi, did not change. Genentech, therefore, had notice of Amgen's intent to commercially market Mvasi as required under Section 262(*l*)(8)(A) as early as October 6, 2017.

Genentech argues that the phrase "licensed under subsection (k)" in Section 262(*l*)(8)(A) is defined "by particular manufacturing facilities and labeling." Appellant Op. Br. at 15. It argues that Amgen's third supplement adding a manufacturing facility for Mvasi and fourth supplement amending Mvasi's label created distinct "biological product(s) licensed under subsection (k)" triggering new notice obligations under Section 262(*l*)(8)(A). *Id.* at 17–18. We do not agree. Section 262(k), not Section 262(*l*)(8)(A), details the contents and requirements for biosimilar licensure, including manufacturing and labeling. Section 262(k) relates to disclosure for licensure. Section 262(*l*)(8)(A) expressly requires prior notice regarding commercial marketing of the "biological product," the definition of which makes no reference to Section 262(k). Section 262(*l*)(8)(A) relates to timing.

Our interpretation is consistent with the Supreme Court's decision in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (*Sandoz II*). In *Sandoz II*, the Supreme Court explained that the term "licensed" in Section 262(*l*)(8)(A) simply means that the product must be licensed on the date of the first commercial marketing, *id.* at 1677, not that each supplemental application results in a new license requiring the biosimilar applicant provide further notice. In fact, *Sandoz II* recognized that "nothing in § 262(*l*)(8)(A) turns on the precise status or characteristics of the biosimilar application." *Id.* at 1678. Section 262(*l*)(8)(A)'s notice requirement is separate from Section 262(k)'s licensure requirements. *Sandoz II* also explained that "Section 262(*l*)(8)(A) contains a single timing requirement: The applicant must provide notice at least 180 days prior to marketing its biosimilar." *Id.* at 1677. Thus, Genentech's interpretation, which would impose several timing requirements where each supplement necessarily triggers another notice requirement, is inconsistent with the statute and with *Sandoz II*. A biosimilar applicant that has already provided Section 262(*l*)(8)(A) notice regarding its biological product need not provide another notice for each supplemental application concerning the same biological product.

Accordingly, we conclude that Amgen's October 6, 2017, letter, which notified Genentech of Amgen's intent to commercially market Mvasi at least 180 days before its July 2019 launch, satisfied Section 262(*l*)(8)(A).

CONCLUSION

We have considered the parties' remaining arguments and do not find them persuasive. Because the district court correctly determined that Amgen provided the required notice under Section 262(*l*)(8)(A) and therefore properly denied Genentech's motions for failure to establish likely success on the merits, we affirm.

AFFIRMED