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Regeneron v Novartis and Vetter: Walker Process Client Update

In an appeal that attracted a dozen amici, including the Department of Justice, the Federal Trade Commission, five states, and the District of Columbia, the Second Circuit gave the *Walker Process* antitrust doctrine a shot in the arm in a patent dispute related to pre-filled syringes ("PFSs") used for injection of anti-VEGF biologic medicines into patients' eyeballs (i.e., intravitreal injections).[1] Under *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965), patentees who obtain patents through fraudulent behavior or inequitable conduct can be liable under the Sherman Antitrust Act. In a complaint filed in the Northern District of New York, Regeneron alleged Novartis and Vetter committed a *Walker Process* violation by obtaining and asserting patents for PFSs. The Second Circuit held that the district court made a mistake by dismissing Regeneron's suit because it focused on the functional similarities in the markets for anti-VEGF medicines in PFSs and vials. In reversing, the Second Circuit held that the correct approach must focus on an economic market analysis rather than a functional market analysis, and that Regeneron's complaint plausibly alleged that anti-VEGF PFSs constituted their own economic product market. As the amicus interest signals, the decision may have significant implications, both for the blockbuster market for anti-VEGF medicines and, more broadly, for defining the markets for different pharmaceutical methods of administration.

In its complaint, Regeneron alleges that in 2005, it had contracted with Vetter, a company providing pharmaceutical filling services, to collaborate on a PFS for its blockbuster anti-VEGF product, EYLEA.[2] It alleges that its agreement with Vetter granted Regeneron ownership in any patent related to EYLEA PFSs. *Id.* Notwithstanding its agreement with Regeneron, Vetter later entered into a confidential agreement with Novartis to develop a PFS for anti-VEGF biologics, which are used to treat macular degeneration and other retinal conditions. *Id.* Indeed, both parties agree on the benefits of PFSs for patients and providers of anti-VEGF medicines—ease in administration, improved safety, and greater efficiency—compared to vials, which must be used to fill a separate syringe.[3] Novartis has an anti-VEGF biologic, LUCENTIS, which Genentech markets in the United States.

Regeneron alleges that Vetter contributed to Novartis's invention of U.S. Patent No. 9,220,631 (the "'631 Patent") and that Novartis concealed Vetter's contribution to inventorship from the PTO to avoid alerting Regeneron to its contractual violations. *Id.* Concealing inventorship from the PTO can constitute inequitable conduct and form the basis for a *Walker Process* claim. (Regeneron also alleges Novartis improperly withheld key prior art references from the PTO

during prosecution.) Novartis's resulting '631 Patent specifically claims EYLEA's active ingredient as a treatment for use in Novartis's patented syringe.[4] Regeneron contends that the defendants' pattern of conduct delayed its entry into the PFS market, resulting in significant damages.[5] Regeneron also alleges that, after the '631 Patent issued, Vetter leaned on it in contract negotiations to enter a long-term deal and to agree not to challenge the validity of the '631 Patent.[6] Novartis sued Regeneron on the '631 Patent in the ITC and the Northern District of New York in 2020, and there is a pending Federal Circuit appeal regarding the validity of the patent.[7]

The Second Circuit held that "the district court improperly concluded that Regeneron failed to plead adequately the existence of a distinct anti-VEGF PFS market because it… placed improper weight on the functional, rather than economic, similarities between anti-VEGF PFSs and vials."[8] Rather than look to the *functional* similarities in the markets for PFSs and vials (i.e., same drug, same medical condition), the Second Circuit held that the proper analysis was *economic*. That is, whether products are "reasonably interchangeable by consumers for the same purposes," as assessed by examining "sufficient cross-elasticity of demand."[9] Regeneron's complaint alleges that physicians transferred 80% of patients from vials to PFSs when they were offered for LUCENTIS. The Second Circuit found Regeneron's allegation adequately pled a hypothetical monopoly market by pleading that the physicians' switching behavior showed that a "small, but significant, price increase in the PFS version would not cause physicians to substitute the vial version for PFS."[10]

Second, the Second Circuit held that the district court was wrong to decide that an antitrust market cannot be coextensive with a patent's scope. Instead, "once an antitrust plaintiff has demonstrated that [1] a patent was obtained through fraud, it must [2] separately explain how the fraudulently obtained patent enabled the defendants to achieve market power within the relevant market."[11] Regeneron's allegations regarding inventorship and improperly withheld prior art satisfied the "fraudulently obtained" prong of the test.[12] Next, the Second Circuit found that Regeneron's complaint adequately pled the "market power" prong, crediting Regenoron's allegation that Novartis and Vetter attempted to use the '631 patent to coerce Regeneron into a long-term exclusive PFS filling relationship and demanding other modifications to Regeneron and Vetter's 2005 agreement.[13]

Why the Decision Matters

The Second Circuit's decision stands out for two reasons. First, anti-VEGF biologics are a big business for innovator companies, biosimilar makers, and government payers. EYLEA's total revenue for 2023 was nearly $5.9 billion.[14] Roche, which through its subsidiary Genentech commercializes LUCENTIS in the US, reported $460 million CHF in 2023 revenue, down from approximately $1 billion CHF in 2022 after entry from two biosimilars, with more pending.[15] Biosimilars referencing EYLEA are also pending FDA approval or in clinical trials.[16] Government payers are naturally interested in age-related macular degeneration (AMD) medications: among Americans over 65, the CDC estimates that approximately 1.3 million have vision-threatening AMD, with another 10.9 million having milder AMD.[17] Indeed, the state amici's brief supporting Regeneron noted the states' interest in the markets for AMD drugs.[18]

Second, and more broadly, a product's presentation or method of administration—pill vs. liquid; standard vs. extended release; IV vs. subcutaneous injection—has major implications for patients, providers, and product lifecycle. Different methods of administration may expand a product's commercial reach and, as this case shows, provide additional patent protection (and possibly market exclusivity). Antitrust scrutiny directed to narrowly defined markets for methods of administration—here PFSs—is noteworthy. The amicus brief from the DoJ and FTC makes

clear that it is supporting neither side and "take[s] no position as to whether the complaint adequately pleads a relevant antitrust market or states an antitrust claim."[19] However, the Federal government's amicus brief also stated that the district court erred in its decision, and the brief's analysis of the proper market definition parallels the reasoning ultimately adopted by the Second Circuit.[20]

This decision relates to a motion to dismiss under Rule 12(b)(6), where the court only looks for a plausible, well-pled complaint. Novartis will have its day in court at the summary judgment and trial stages, where Regeneron will owe a higher burden of proof. However, antitrust claims are powerful tools because they carry the monetary risk of treble damages as well as the possibility of scrutiny from regulators. These risks must be weighed, not just by outside counsel and CLOs, but by CEOs and boards of directors.

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[1] *See Regeneron Pharm., Inc. v. Novartis Pharma AG et al.*, No. 22-427, slip op. at 1 (March 18, 2024). As the Second Circuit explains, "[t]he products in question are prescription medications used to treat the overproduction of vascular endothelial growth factor ('VEGF'), a naturally occurring protein that, if overproduced, can lead to various eye disorders and, in some cases, to permanent blindness."

[2] Slip op. at 9

[3] *Id.* at 8-9

[4] *See* '631 Patent at Claim 12

[5] *See* slip op. at 10-11.

[6] *Id.* at 13-14.

[7] *Id.* at 15-16.

[8] *Id.* at 19.

[9] *Id.* at 20-21 (citing *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962) and *United States v. Am. Express. Co.*, 838 F.3d 179 (2d Cir. 2016)).

[10] Slip op. at 26; *see, e.g., Am. Express*, 838 F.3d at 199 (small but significant non-transitory increase in price ("SSNIP") may demonstrate that the proposed market is relevant market).

[11] Slip op. at 30 (citing *Walker Process*, 382 U.S. at 177).

[12] *Id.* at 30-31.

[13] *Id.* at 31-32. In addition to reversing the district court's decision on the antitrust claim, the Second Circuit reversed the court's dismissal of Regeneron's claim for tortious interference with contract as time barred, crediting Regeneron's equitable estoppel arguments.

[14] "Regeneron Reports Fourth Quarter and Full Year 2023 Financial and Operating Results," Feb. 2, 2024, **https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2023-financial** (last visited March 20, 2024).

[15] "Roche Finance Report 2023," at 16, **https://assets.roche.com/f/176343/x/3b1fb647e2/fb23e.pdf** (last visited March 20, 2024).

[16] *See, e.g.*, "New and Upcoming biosimilar launches," at 6 **https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-biosimilar-launches.pdf** (last visited March 20, 2024).

[17] *See* “Prevalence of Age-Related Macular Degeneration (AMD), at Table 1, **https://www.cdc.gov/visionhealth/vehss/estimates/amd-prevalence.html** (last visited March 20, 2024).

[18] *See Brief of Amici Curiae Nevada, District of Columbia, Illinois, Louisiana, Minnesota, and New Mexico as Amicus Curiae in Support of Plaintiff-Appellant, Regeneron Pharmaceuticals, Inc.*, Case 22-427, Dkt. 106 at 2.

[19] *See Brief for the United States and the Federal Trade Commission as Amici Curiae in Support of Neither Party*, Case 22-427, Dkt. 90 at 1.

[20] *Id.* at 12.