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Three Problems with the FTC's Section 2 Theory on Patent-Applications in *CareFirst of MD v. Amgen*

by Jay DeSanto

The Federal Trade Commission recently filed an amicus brief in *CareFirst of Maryland, Inc. v. Amgen Inc.*, No. 26-1473 (4th Cir.), asking that the Fourth Circuit recognize a new form of unlawful conduct under Section 2 of the Sherman Act: the acquisition of patent applications. The FTC argues that a firm's acquisition of a patent application may violate Section 2 even if the application is acquired before it issues into a patent. The FTC's theory is novel and difficult to reconcile with Section 2 doctrine. If accepted, it risks chilling future mergers and acquisitions, spelling trouble for innovation in the pharmaceutical industry and beyond.

So what's the case about? In 1998, drug company Immunex licensed patents from another drug company, Roche, to commercialize "Enbrel"—generically known as "etanercept"—a drug used to treat arthritis. Years later, Amgen acquired Immunex, and in 2004, exclusively licensed the same etanercept patent rights from Roche, including two etanercept patent applications. The applications issued as patents in 2011 and 2012. Then, in 2016, Amgen asserted those patents against drug-maker Sandoz, who sought to market a biosimilar version of etanercept. Amgen prevailed in that patent-infringement suit. But in 2024, CareFirst sued Amgen under Section 2, asserting that Amgen had unlawfully acquired and extended market power in the sale of etanercept by acquiring exclusive rights to the patent applications.

Although the FTC nominally supports neither party, its brief urges adoption of a legal theory that would preserve CareFirst's claims. Its argument—that acquisition of patent applications can constitute exclusionary conduct under Section 2—is problematic for at least three reasons.

Patent applications are not exclusionary rights, and the FTC's theory lacks support in Section 2 precedent.

The FTC's argument falters from the start. A monopolization claim under Section 2 requires conduct intended to "*exclude rivals* on some basis other than efficiency." *2311 Racing LLC v. NASCAR*, 139 F.4th 404, 410 (4th Cir. 2025) (emphasis added). But a patent application is not a vested property right and carries with it no enforceable right to exclude. *See Gover v. United States*, 73 F. App'x 401, 405 (Fed. Cir. 2003) ("[S]ubmission of a patent application is the inception of an uncertain process that might possibly result in vested rights at some later time."). The "right to exclude does not inure until the patent issues." *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1581 (Fed. Cir. 1997).

Unsurprisingly, then, the FTC doesn't cite any case that holds acquisition of a patent application constitutes Section 2 exclusionary conduct. Instead, it relies on *United States v. Singer Mfg. Co.*, 374 U.S. 174, 189 (1963), but that reliance is misplaced. FTC Br. 8. *Singer* doesn't hold that acquisition of a patent application can constitute exclusionary conduct under Section 2. *Singer* is a Section 1 conspiracy case in

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which overwhelming evidence showed that sewing-machine manufacturer Singer and its counterparts conspired through their patent dealings to drive Japanese competitors from the market. The Supreme Court expressly acknowledged that the case was not about whether "it is illegal for one merely to acquire a patent"—much less a pending application. *Singer*, 374 U.S. at 189. *Singer* provides no basis for the FTC's theory.

The absence of case law supporting the FTC's position reveals the novelty of its argument. If acquisition of patent applications has long constituted exclusionary conduct under Section 2, one would expect case law saying so. But there is none, and that's because an application itself is not exclusionary.

The FTC's theory can't be squared with Section 2's intent requirement.

Without case law supporting its argument, the FTC sets up a two-step move. It cites *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981) to argue that acquisition of *issued* patents may constitute anticompetitive conduct under Section 2. And from there, it posits that because acquiring a patent application may "lead to *more* anticompetitive harm than acquiring an issued patent," acquisition of an application can necessarily constitute anticompetitive conduct as well. FTC Br. 9 (emphasis in original). This maneuver faces serious problems under Section 2's intent standard, which the FTC fails to address.

As WLF recently argued in the case *CareFirst v. Johnson & Johnson*, No. 26-1248 (4th Cir.), Section 2 is not a strict-liability statute. The Supreme Court and Fourth Circuit have consistently distinguished between the willful acquisition of monopoly power and market power obtained through happenstance. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004); *2311 Racing LLC*, 139 F.4th at 410. Only the former is actionable. At a minimum, Section 2 requires that a defendant know the facts giving its conduct exclusionary significance at the time it performed the alleged unlawful act.

Section 2's intent requirement would be especially difficult to satisfy where the alleged unlawful act is acquisition of a patent application. A plaintiff would need to show that the acquirer knew the facts needed to understand the competitive significance of the application "at the time of acquisition." *SCM*, 645 F.2d at 1207-08. But the FTC never attempts to identify any facts that an acquirer must know when it purchases an application. Its non-attempt underscores the theory's incompatibility with Section 2's requirement of "willful" monopolization. *Trinko*, 540 U.S. at 407.

Patent applications are uncertain instruments that can be amended, narrowed, or expanded, making it difficult to prove a defendant's knowledge of their competitive effects at the time the applications are acquired. Look no further than the two patent applications in the underlying case. The Roche applications took seven years to issue following Amgen's exclusive license, and during that time, the applications were amended multiple times based on feedback from the patent examiner.

Rather than dispute these points, the FTC embraces them, resting its argument on the contention that pending applications are valuable precisely because their scope is uncertain. FTC Br. 10. But in doing so, it unwittingly kills its argument at the feet of Section 2's intent requirement.

Liability can't rest on happenstance followed by hindsight. The FTC's theory invites courts to infer exclusionary intent from later developments in patent prosecution that may not have been known when the application changed hands. That position risks transforming Section 2 from a prohibition on willful monopolization into an offense of retrospective strict liability. No court has ever endorsed that view.

Acceptance of the FTC's theory will chill innovation by discouraging early-stage IP transactions.

Under the FTC's theory, a transaction that appears lawful when consummated could become the basis for a Section 2 lawsuit years later after patent prosecution unfolds and market conditions evolve. If accepted, this theory could have disastrous consequences for innovation in the pharmaceutical industry and beyond.

Patent applications are routinely bought, sold, or licensed as part of mergers and acquisitions. These transactions are particularly important in the pharmaceutical and biotech sectors, where smaller firms typically drive early-stage innovation but lack the capital, regulatory expertise, and infrastructure to bring new drugs to market. Larger firms often provide these capabilities through M&A activity, which helps enable new products to advance through late-stage trials and a complex regulatory morass to reach markets and patients. M&A activity is the lifeblood of the research ecosystem. It incentivizes future breakthroughs by rewarding early-stage innovators. *See, e.g.,* Roerich Bansal et al., *What's behind the pharmaceutical sector's M&A push*, McKinsey on Finance, No. 68 at 3-4 (Oct. 2018).

But the FTC's theory introduces uncertainty into this well-known process. Treating the acquisition of patent applications as actionable monopolization would make investment in early-stage IP legally perilous. It would demand that firms speculate about whether a valid patent would issue, whether the issued patent would materially differ from the application, and whether the resulting patent might someday intersect with a competitor's product or process.

That's not ordinary diligence. It's hindsight-driven clairvoyance. It will slow transactions, chill investment in companies selling their IP, and undermine the Supreme Court's instruction to "safeguard incentives to innovate." *Trinko*, 540 U.S. at 407. Firms will become reluctant to acquire early-stage IP, transactions will become more costly, and some won't occur at all. The losers will be smaller innovators, who need help bringing their product to market, and the American consumer, who otherwise benefits from new and effective drugs.

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Before this case, no court has held that acquisition of a patent application constitutes exclusionary conduct under Section 2. The FTC asks the Fourth Circuit to become the first, but the court should decline that invitation. Patent applications are uncertain, non-exclusionary assets. Their competitive significance can't be reasonably known when acquired. And treating their acquisition as unlawful monopolization risks discouraging the very innovation that both patent and antitrust law are meant to protect.

