UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAGE CHEMICAL, INC. AND TRUPHARMA, LLC, Plaintiffs, v. SUPERNUS PHARMACEUTICALS, INC., ET AL., Defendants.	Civil Action No. 1:22-cv-1302-CJB

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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Competition from cheaper generic versions of branded drugs saves consumers hundreds of billions of dollars per year. This is due in large part to laws and regulations that encourage the substitution of cheaper generic drugs for the brand version whenever they are available. The substantial savings generic competition provides consumers, however, come at a significant cost to brand pharmaceutical companies, which typically see their profits slashed upon the arrival of a generic competitor. This prospect can sometimes incentivize brand companies to take unlawful actions to delay or block generic competition. In this case, Plaintiffs Sage Chemical, Inc. and TruPharma, LLC allege that Defendants[1] engaged in numerous such strategies to block a generic version of their injectable apomorphine drug Apokyn. Many of these alleged strategies leverage Defendants' control over the Apokyn pen injector, a device that the FDA requires to be used to inject either brand or generic apomorphine cartridges, in order to prevent purchasers from accessing Plaintiffs' cheaper generic cartridges.

This case may have significant implications for patients who rely on apomorphine to treat debilitating symptoms of advanced Parkinson's Disease. Moreover, because the strategies alleged here are similar to strategies used by other branded pharmaceutical companies to block generic competition, there is a broader public interest in the legal issues this case presents. The FTC therefore respectfully submits this amicus brief to assist the Court's review of four important antitrust issues raised by Defendants' omnibus motion to dismiss (D.I. 59, Jan. 13, 2023):

[1] Named Defendants include: Supernus Pharmaceuticals, Inc., Britannia Pharmaceuticals Limited, US WorldMeds Partners, LLC, MDD US Enterprises, LLC (f/k/a USWM Enterprises, LLC), MDD US Operations, LLC (f/k/a US WorldMeds, LLC), USWM, LLC, Paul Breckinridge Jones, Herbert Lee Warren, Jr., Henry van den Berg, and Kristen L. Gullo. The FTC takes no position on the liability of each of the individual and corporate Defendants and refers to the actions taken by all or some of the Defendants collectively in this brief.

First, exclusion of a generic competitor harms not only that competitor, but also competition and consumers more generally.

Second, Plaintiffs' alleged development of a generic apomorphine cartridge to substitute as a refill for branded cartridges is not improper "free-riding" within the meaning of the antitrust laws. The governing legal and regulatory framework encourages the development of substitutable generic drug products, and the Supreme Court has long made clear that marketing a product that is designed to work with a different company's product is not improper free-riding.

Third, exclusive agreements can be unlawful when they substantially foreclose a competitor's access to a key input—even if that competitor can theoretically develop its own alternative version of the input.

Finally, defining a relevant antitrust market requires assessing which products are available for consumers to turn to if prices were raised above a competitive level, and there is no deficiency if this analysis results in a relevant market with one product.

INTEREST OF THE FTC

The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[2] It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry.[3] The FTC has substantial experience evaluating issues affecting competition for pharmaceuticals and has brought numerous enforcement actions challenging anticompetitive conduct in the pharmaceutical industry.

[2] 15 U.S.C. §§ 41–58.

[3] For a summary of the FTC's actions in the pharmaceutical industry, see *Overview of FTC Actions in Pharmaceutical Products and Distribution* (Jan. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

Most relevantly, the FTC has investigated numerous allegations that restraints imposed by brand drug companies—including exclusive dealing arrangements and distribution restrictions—have impeded generic drug competition and has filed several enforcement actions in this area. *See, e.g.*, *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022); *FTC v. Mylan Labs.*, *Inc*., 62 F. Supp. 2d 25 (D.D.C. 1999); *see also FTC v. Surescripts, LLC*, 424 F. Supp. 3d 92 (D.D.C. 2020) (challenging exclusive dealing in electronic health records industry). The allegations in this case involve a number of areas of law relevant to the FTC's competition mission and also implicate the interests of consumers.

BACKGROUND

Regulatory Background

Generic versions of branded drugs play a critical role in lowering prescription drug prices in the United States. This is due in large part to the Hatch-Waxman Act,[4] which Congress passed to "'speed the introduction of low-cost generic drugs to market' and promote competition." *FTC v. AbbVie Inc.*, 976 F.3d 327, 339 (3d Cir. 2020) (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013)). The first company to seek approval for a novel drug must file a New Drug Application (NDA) and go through the FDA's "full-length" application process, which requires extensive safety and efficacy data. *See AbbVie*, 976 F.3d at 338-39. The Act then allows subsequent companies to seek FDA approval for equivalent generic versions of the same drug with a streamlined Abbreviated New Drug Application (ANDA). *See id.* at 339. An ANDA applicant does not need to do its own safety or efficacy studies. Instead, it can rely on the brand company's data so long as it demonstrates to the FDA that its product is bioequivalent to the

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. § 355 and 31 U.S.C. § 271.

brand—meaning that it contains the same active ingredient and is absorbed into the body in the same way. *See* 21 U.S.C. § 355(j)(2)(A)(iv). This streamlined process allows generics to get to market faster and offer their competing products at a lower cost. The net result is significant health care savings for consumers.

The Hatch-Waxman Act works in tandem with public and private policies that encourage the use of cheaper generic drugs. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost A-rated[5] generic drugs for branded drugs.[6] When a pharmacist fills a prescription written for a branded drug, these laws allow the pharmacist to dispense an A-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.[7] Many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have also adopted policies to encourage the substitution of generic drugs for their branded counterparts. These laws and policies are important because "the pharmaceutical market is not a well-functioning market." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015). Unlike most markets, "the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect." *Id.* at 646. The Hatch-Waxman Act and state substitution laws work together to address this disconnect and facilitate generic competition, thereby lowering the cost of prescription drugs.

[5] An A rating is an FDA designation that the drug is therapeutically equivalent to the brand version and can be substituted and used interchangeably. *See Orange Book Preface*, FDA (2023), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

[6] *See* Nat'l Assoc. of Boards of Pharmacy, *2021 Survey of Pharmacy Law* (2020), pp. 97-101.

[7] *Id.*

Relevant Allegations[8]

Defendants market Apokyn, a branded injectable apomorphine hydrochloride product used to treat patients with advanced Parkinson's Disease. Parkinson's Disease is a progressive disorder that affects the body's central nervous system and often causes tremors or loss of motor function. Patients suffering from Parkinson's are primarily treated with levodopa, which controls dopamine levels in the brain and helps to mitigate problems with movement, but the quantity of levodopa a patient can take is limited. Patients with advanced Parkinson's Disease sometimes experience symptoms between dosages of levodopa, including sudden, debilitating difficulty moving, tremors, and intense, painful muscle cramping. These are known as "off episodes." Patients can use apomorphine hydrochloride injections to alleviate symptoms during these "off episodes."

Apokyn is approved by the FDA in the form of multi-dose cartridges for use with a reusable pen injector. Defendants contracted with Becton, Dickinson and Company ("BD"), a large medical technology and device company,[9] to supply the Apokyn pen injector. The pen injector is packaged separately from the apomorphine cartridges and can be reused for up to one year. Thus, the majority of Apokyn prescriptions are dispensed as refill cartridges. D.I. 19 at ¶ 175, Oct. 26, 2022.

In July 2018, Sage filed an ANDA for a generic apomorphine cartridge that was bioequivalent to the Apokyn cartridge and compatible for use with the Apokyn reusable pen

[8] This summary includes only the specific factual allegations relevant to the issues the FTC addresses in this brief. For the purposes of this brief, the FTC accepts the allegations in the complaint as true.

[9] BD bills itself as "one of the largest global medical technology companies in the world," BD, https://www.bd.com/en-us (last visited March 15, 2023), and reported $18.9 billion in revenue for the fiscal year ending September 30, 2022. Becton, Dickinson & Co., Annual Report (Form 10-K) at 5 (Sept. 30, 2022).

injector. Sage also engaged in discussions with BD about supplying the same model of reusable pen injector for use with its generic cartridge product. D.I. 19 at ¶ 118, Oct. 26, 2022. In September 2019, however, BD allegedly cut off discussions with Sage after signing an exclusive agreement with Defendants. Specifically, Defendants and BD converted their existing non-exclusive supply agreement into an exclusive agreement that prohibited BD from supplying compatible pens to anyone other than Defendants for use in administering apomorphine to treat symptoms of Parkinson's Disease.[10] The new agreement also allegedly required BD to terminate on-going discussions with Sage about such supply and to refrain from any future negotiations. D.I. 19 at ¶ 131, Oct. 26, 2022.

In February 2022, the FDA approved Sage's ANDA for an apomorphine hydrochloride injection cartridge "for use with a reusable pen injector (APOKYN Pen)."[11] The FDA also assigned an "A" rating to Sage's ANDA product, meaning it had determined the cartridges were bioequivalent to branded Apokyn cartridges. The FDA determined as part of its approval that Sage's generic apomorphine cartridge must be used with the Apokyn pen injector, and explained that "[p]atients should first obtain the prescribed Apokyn Pen through a specialty pharmacy" before utilizing the generic product.[12]

Defendants distribute Apokyn (including the pen injector and the apomorphine cartridges) through a network of three specialty pharmacies: Accredo Health Group, CVS

[10] D.I. 19 at ¶¶ 20, 121-22, Exhs. E & F, Oct. 26, 2022.

[11] Sage Chemical, Inc., ANDA 212025 (Feb. 23, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/212025Orig1s000ltr.pdf.

[12] Press Release, FDA, *Approved first generic for Apokyn injection cartridges requires separately packaged pen* (Feb. 24, 2022), https://www.fda.gov/drugs/drug-safety-and-availability/approved-first-generic-apokyn-injection-cartridges-requires-separately-packaged-pen.

Specialty Pharmacy, and Optum Rx Specialty. D.I. 19 at ¶ 161, Oct. 26, 2022. Upon FDA approval, TruPharma, Sage's marketing partner, entered into contracts with all three Apokyn specialty pharmacies for the purchase of generic apomorphine cartridges. D.I. 19 at ¶ 178, Oct. 26, 2022. The specialty pharmacies placed orders for the generic cartridges, and TruPharma shipped them. D.I. 19 at ¶ 179, Oct. 26, 2022. All three specialty pharmacies subsequently canceled orders, returned purchased generic product, and ceased future planned purchases of the generic cartridges. D.I. 19 at ¶ 183, Oct. 26, 2022. Defendants allegedly leveraged their position as the only provider of a compatible apomorphine pen injector to cause this change.

Although Apokyn has not had patent protection or regulatory exclusivity since 2011, it remains an extremely costly treatment for patients. In 2020, Medicare Part D alone spent an average of $23,612 per prescription and $97,787 per beneficiary on Apokyn.[13] A year after receiving FDA approval and an A rating, Sage's generic Apokyn product has made almost no sales. D.I. 19 at ¶ 223, Oct. 26, 2022. Meanwhile, the list price of branded Apokyn has allegedly risen by more than 30% over the past five years and continues to rise. D.I. 19 at ¶ 229, Oct. 26, 2022.

On October 3, 2022, Sage and TruPharma filed the instant action, alleging that consumers are paying supracompetitive prices for Apokyn because of Defendants' anticompetitive scheme, including, among other things, the agreements with BD and the specialty pharmacies described above. They allege that Defendants have monopoly power in two markets—the market for injectable apomorphine cartridges, and the market for compatible pen injectors—and have used a

[13] Medicare Part D Drug Spending and Utilization, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

variety of anticompetitive strategies to exclude Plaintiffs to maintain that power. Defendants have moved to dismiss the complaint in its entirety.

ARGUMENT

I. Exclusion of generic drugs harms consumers and competition

In the pharmaceutical industry, the exclusion of lower-cost generic drug competition typically causes significant harm to consumers and to competition. Defendants argue that their alleged efforts to block Sage's generic apomorphine cartridges from the market are lawful because, among other reasons, "the antitrust laws are enforced to protect competition and not individual competitors." D.I. 59 at 18, Jan. 13, 2023 (citing *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 342 (3d Cir. 2018)). As the Third Circuit has explained, however, "[w]hen a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, *i.e*. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 194 (3d Cir. 2005).

Generic drug competition—facilitated by the Hatch-Waxman Act and state substitution laws—has been tremendously successful in generating large savings for patients, health care plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the brand product.[14] Subsequent generic entry creates greater price competition, with discounts for some generic products reaching 85% or more off

[14] FTC, Authorized Generic Drugs: Short Term Effects and Long-Term Impact, at ii–iii (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

the price of the brand name drug.[15] Consumers benefit enormously from this price competition. For example, in 2021 the average copay for a generic drug was $6.16, while the average copay for a brand-name drug was $56.12—over nine times more expensive.[16] A recent report from the Association for Accessible Medicines found that in 2021 alone, generic and biosimilar[17] drugs saved the US health care system $373 billion.[18]

As a result of lower prices and payers' policies encouraging the use of generic products, many consumers routinely switch from a branded drug to an A-rated generic drug upon its introduction. A-rated generic drugs typically capture over 80% of a brand drug's sales within six months of market entry.[19] These substantial savings for consumers pose a corresponding threat to

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[15] FTC, Pay for Delay: How Drug Company Pay-offs Cost Consumers Billions, at 8 (2010) ("in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price"), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf; *see also* FDA, Facts About Generic Drugs, at 2 (2010), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

[16] Ass'n for Accessible Medicines, Report: 2022 U.S. Generic and Biosimilar Medicines Savings Report, at 7 (2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf; *see also* U.S. Congressional Budget Office, Effects of Using Generic Drugs on Medicare's Prescription Drug Spending, at 8 (2010) (retail price of a generic was 75% lower, on average, than the retail price of a brand-name drug), https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf. These figures apply to branded and generic drugs generally and are not being used to predict any specific discounting or copay difference that would apply to generic apomorphine products.

[17] Biosimilars are follow-on products that reference an existing FDA-approved biologic product.

[18] Ass'n for Accessible Medicines, Report: 2022 U.S. Generic and Biosimilar Medicines Savings Report, at 7 (2022), https://accessiblemeds.org/resources/reports/2022-savings-report; *see also* U.S. Gov't Accountability Office, Drug Pricing: Research on Savings from Generic Drug Use, Report No. GAO-12-371R, at 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf (generic drug use saves the health care system billions of dollars).

[19] FTC, Authorized Generic Drugs: Short Term Effects and Long-Term Impact, at 66-67 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-

(Continued…)

the brand's profits and can incentivize the brand company to develop new and innovative drugs that benefit consumers. This threat can also incentivize the brand company to engage in anticompetitive tactics to impede meaningful generic competition, forcing consumers to continue to pay supracompetitive prices.

The complaint alleges that Defendants' exclusionary conduct has prevented Apokyn consumers from obtaining a generic product that includes a pen or from obtaining refills with generic cartridges. If true, such conduct would cause significant harm to competition. The FDA has approved Sage's ANDA and issued it an A rating. As a generic drug, one would expect Sage's product to be priced at a significant discount, and Sage alleges that its cartridges are priced at "roughly half" the price of branded Apokyn. D.I. 19 at ¶ 228, Oct. 26, 2022. But Apokyn consumers have allegedly been deprived of the price competition and associated cost savings that ordinarily result from the entry of a cheaper A-rated generic substitute. These potential cost savings are substantial for patients who depend on apomorphine for treating debilitating symptoms of advanced Parkinson's Disease and for payers—including Medicare Part D, which spent close to $100,000 per beneficiary on Apokyn in 2020.[20]

II. A generic company's use of the regulatory and legal structures that promote generic competition is not "free-riding"

In the antitrust context, "[f]ree-riding is the diversion of value from a business rival's efforts without payment." *Chicago Pro. Sports Ltd. P'ship v. NBA,* 961 F.2d 667, 675 (7th Cir.

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effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[20] *See* Medicare Part D Drug Spending and Utilization, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug (Medicare Part D spent an average of $97,787 per beneficiary). This may not include manufacturers' rebates or other price concessions that the Center for Medicare & Medicaid Services is prohibited from publicly disclosing.

1992). Defendants accuse Plaintiffs of improperly "free riding on the brand-supplied Apokyn injector" by marketing a "cartridge-only generic" rather than developing and getting FDA approval for their own pen injector. D.I. 59 at 2, Jan. 13, 2023. Defendants further assert that their alleged steps to block Plaintiffs from the cartridge market are lawful because "[d]istribution restraints aimed at preventing free-riding are legitimate and competition enhancing." *Id.* at 21. But these arguments mischaracterize the concept of "free-riding" and ignore how generic competition works in the pharmaceutical industry.

The prospect of free-riding can deter companies from investing in a product or service, and practices designed to prevent free-riding can thus sometimes be procompetitive. *See*, *e.g.*, *N. American Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, 883 F.3d 32, 43 (2d Cir. 2018) ("Eliminating free riders can be a procompetitive advantage of alleged restraints on competition like vertical price agreements."). For example, courts have long recognized that resale price maintenance (in which a manufacturer sets a minimum price at which dealers must re-sell its products) can incentivize dealers to offer pre-sale services for the product (*e.g.*, instructions on use) without fear that another dealer that does not offer costly services to the consumer will "free-ride" on those services and sell the same product at a lower price. *See, e.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007). This "free-riding" defense is circumscribed, however. Courts have rejected free-riding justifications for restraints that purportedly had procompetitive benefits where such restraints were deemed not reasonable measures to stop the free-rider problem (*see, e.g., Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 592 (7th Cir. 1984)), and where there were less restrictive alternatives available. *See, e.g., Chicago Pro. Sports*, 961 F.2d at 674-76; *see also United States v. Dentsply Int'l, Inc*., 277 F. Supp. 2d 387, 441-48 (D. Del. 2003), *rev'd on other grounds and remanded*,

399 F.3d 181 (3d Cir. 2005) (holding that defendant's free-riding justification was pretextual and did not justify exclusionary conduct).

In this case, Plaintiffs' introduction of a generic cartridge for use with the Apokyn pen is not improper "free-riding" within the meaning of the antitrust laws. First, numerous courts have explained that "the Hatch-Waxman Act establishes and condones [free-riding], the 'piggybacking' of generics." *Teva Pharms. USA, Inc. v. Abbott Labs.*, No. CIV. 02-1512-SLR, 2008 WL 4809116, at *2 (D. Del. Nov. 5, 2008); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1051-52 (N.D. Ill. 2003), *vacated*, 403 F.3d 1331 (Fed. Cir. 2005) ("[T]hat kind of free riding the law permits, and indeed the Hatch-Waxman Act encourages."). Plaintiffs have availed themselves of the Hatch-Waxman Act's streamlined ANDA approval pathway to create an A-rated generic cartridge option that can be substituted interchangeably for the branded cartridge. The FDA explicitly approved Plaintiffs' generic apomorphine cartridge for use with the branded pen and instructed patients to "first obtain the prescribed Apokyn Pen . . . before being prescribed the generic apomorphine hydrochloride injection."[21] Plaintiffs' marketing of FDA-approved generic apomorphine cartridges that can be substituted as refills for the branded pen is thus "authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645-46 (2d Cir. 2015).

Second, it is not improper free-riding to market a product or service that is intended to be used in conjunction with a separate and distinct product sold by another company. The Supreme Court addressed a similar argument in *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S.

[21] Press Release, FDA, *Approved first generic for Apokyn injection cartridges requires separately packaged pen* (Feb. 24, 2022).

451 (1992). There, Kodak implemented a series of restrictions to prevent independent service organizations (ISOs) from marketing repair services to owners of Kodak micrographic equipment "at a price substantially lower than [Kodak's repair services]." *Id.* at 457. Just as Defendants here argue that Plaintiffs are free-riding because they do not sell cartridges without also selling their own pen injector, Kodak argued that the ISOs were "free-riding because they have failed to enter the equipment and parts markets." *Id.* at 485. The Supreme Court dismissed this "understanding of free-riding" as having "no support in our case law" because Kodak's underlying investment in micrographic equipment was in a different product market than the repair services. *Id.* at 485 & n.33.[22] The Court further noted, "one of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors by requiring them to enter two markets simultaneously." *Id.* at 485. Similarly, here, Plaintiffs have alleged that Apokyn's two components—cartridges and pen injectors—are distributed separately and are in two separate relevant markets. Even assuming Defendants made some underlying investment in the Apokyn pen (which they allegedly purchase from third-party BD rather than produce themselves), that investment would not justify conduct to prevent competition in a separate market for apomorphine refill cartridges.[23]

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[22] In a footnote, the Court distinguished cases where it had recognized a free-rider defense. It explained that a free-riding argument against the ISO's repair services could only apply if the ISOs were "relying on Kodak's investment in the service market" rather than the underlying equipment market. *Kodak,* 504 U.S. at 485 n.33.

[23] Defendants' free-rider defense would necessarily fail if pen injectors are capable of being priced and sold rather than given away for free. Areeda & Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2223 (CCH 5th ed. 2022) ("[F]ree rider defenses should be rejected when the firm that controls the input is able to sell, rather than give away, the good or service that is subject to the free ride."). Free-riding on input investments only poses a threat when a procompetitive investment in the input is otherwise unrecoverable. When the input can be sold, the investment is recoverable. *See id*. (If the product and the input can be priced separately, "then free riding would not be a problem"); *Chicago Pro. Sports*, 961 F.2d at 675 ("When payment is possible, free-riding is not a problem[.]).

III. Defendants mischaracterize and misinterpret the law on substantial foreclosure

A plaintiff bringing an exclusive dealing claim must allege that the exclusive agreements "foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012). Defendants claim that Plaintiffs "fail to allege substantial foreclosure" because Plaintiffs have "alternative means to reach the market"—i.e., developing and getting FDA approval for their own pen injector. D.I. 59 at 17-18, Jan. 13, 2023. But the law does not require Plaintiffs to plead that they had no alternative means to reach the market. The appropriate "test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. In the pharmaceutical context, "generics need not be barred from all means of distribution if they are barred from the cost-efficient ones." *Shkreli*, 581 F. Supp. 3d at 637 (S.D.N.Y. 2022) (citation omitted); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (claim that, despite restraints Microsoft implemented, a rival was "not completely blocked from distributing its product" did not shield Microsoft from liability "because, although Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones").

It is well established that barring a competitor's access to a key input in a market with high entry barriers can constitute substantial foreclosure even if the competitor could eventually develop its own alternative to that input. For example, in *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, the Second Circuit found sufficient evidence of foreclosure where a pharmaceutical company used an exclusive agreement to lock up its rival's source of a key ingredient, forcing the rival to spend a year developing an alternative supplier. 386 F.3d 485, 508 (2d Cir. 2004). In *FTC v. Shkreli*, the court held that a pharmaceutical company's exclusive agreements were unlawful where they "closed off access to the two most viable suppliers of [a key ingredient] for

years" and forced generic competitors to "undertake a time-consuming and costly journey to develop alternative [] manufacturers." 581 F. Supp. 3d at 634, 637 ("Generic drug companies need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market."). And in *Microbix Biosystems, Inc. v. Biowhittaker Inc.*, the court found sufficient evidence of foreclosure where a biotech company locked up the only FDA-approved supplier of a key input, noting that "the need to develop an alternative [] source presented a significant entry barrier to the [] market." 172 F. Supp. 2d 680, 692 (D. Md. 2000) ("If Plaintiff can establish these facts, the anti-competitive effects of the exclusive agreement would be obvious."); *cf. Medtronic Minimed Inc. v. Smiths Med. MD Inc.*, 371 F. Supp. 2d 578, 585-89 (D. Del. 2005) (rejecting tying and monopolization claims and finding the counterclaim plaintiff could have "produce[d] a compatible [medical device]" to sell to Medtronic's customers where other manufacturers had done the same). Thus, the possibility that Plaintiffs could have spent substantial time and money to develop their own injector and evade Defendants' anticompetitive restraints does not defeat their substantial foreclosure allegations.

IV. Single-brand or single-manufacturer markets are appropriate when there are no adequate substitutes

"Monopoly power is the ability to control prices and exclude competition." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). "If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power." *Id.* One way a plaintiff can establish monopoly or market power is to show "that a firm has a dominant share in a relevant market and that significant entry barriers protect that market." *Id.* (cleaned up).[24] Defendants challenge one of Plaintiffs' proposed product

[24] Alternatively, a plaintiff can prove monopoly or market power with "direct evidence of supracompetitive prices and restricted output." *Broadcom*, 501 F.3d at 307. In this case, (Continued…)

markets—a market for FDA-approved apomorphine-compatible pen injectors (*see* D.I. 19 at ¶ 235, Oct. 26, 2022)—as legally deficient. They contend that it is inappropriate that Plaintiffs' proposed market contains only the Apokyn pen injector, and suggest that single-brand or single-manufacturer markets are inherently deficient and subject to dismissal. That is not the law.

The Supreme Court has specifically rejected the argument that, "as a matter of law, a single brand of a product or service can never be a relevant market." *Kodak*, 504 U.S. at 481-82, 482 n.30. "The goal in defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *Geneva Pharms.*, 386 F.3d at 496. To do this, courts assess whether other products are substitutable by consumers and whether there is cross-elasticity of demand between them—i.e., would consumers switch from one product to another to avoid a small but significant price increase. *See, e.g., Mylan Pharms. Inc. v. Warner Chilcott plc*, 838 F.3d 421, 434 (3d Cir. 2016).[25] If this analysis yields a single-brand or single-product market, there is no legal deficiency.[26]

Plaintiffs have both alleged direct evidence and indirect evidence of monopoly power. Either approach would be sufficient on its own. *See id.* n.3 ("Because market share and barriers to entry are merely surrogates for determining the existence of monopoly power, direct proof of monopoly power does not require a definition of the relevant market." (citing 2A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 531a (2006)).

[25] In certain markets, such as those without prices, cross-elasticity may be assessed using other metrics, such as product quality. *See, e.g., Community Publ'rs, Inc. v. Donrey Corp.*, 892 F. Supp. 1146, 1153, 1158-59 (W.D. Ark. 1995) (where daily local newspapers competed for readers and advertisers, court assessed whether changes in quality constrained ability to exercise market power); 1 Am. Bar Ass'n, *Antitrust Law Developments* (2022), at § 6B-1-b n.46 (noting that cross-elasticity "may also be applied to a change in quality").

[26] As a technical matter, the alleged compatible injector market is not a single-brand or single-manufacturer market. Single-brand or single-manufacturer markets are defined by specific reference to a single unique product. *See*, *e.g.*, *Talley v. Christiana Care Health Sys.*, No. CV 17-926-CJB, 2018 WL 4938566, at *7-8 (D. Del. Oct. 11, 2018) (proposed single-brand market was (Continued…)

Indeed, in the pharmaceutical context, many courts have accepted a relevant market limited to a brand and generic version of a single drug, finding that the generic version was a uniquely close competitor to the brand.[27] Of course, if the facts show that other substitute products exist to sufficiently constrain pricing to competitive levels, then a single-brand market would be inappropriate. But the analysis for assessing a proposed single-brand market is the same as for any other market. *See*, *e.g.*, *Mylan*, 838 F.3d at 437 (rejecting single-brand market for the oral tetracycline drug Doryx "given the high degree of interchangeability and cross-elasticity demonstrated" between Doryx and other oral tetracycline products). Defendants' sole cited authority, *Talley*, 2018 WL 4938566, at *7-8 n.8, is not to the contrary; it rejected a proposed single-brand market where the complaint "contain[ed] very few facts that even nod at the concept of reasonable interchangeability of use or cross-elasticity of demand." *Id.* There is no special rule for assessing single-brand or single-product markets, and dismissal is inappropriate

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limited to the OBGYN practice at one specific Delaware hospital). Plaintiffs' proposed compatible injector market is defined as a category of products with certain features (namely FDA approval and compatibility for injecting apomorphine cartridges). To be sure, that category currently includes only one product, but that is true of any antitrust market in which one product has a 100% monopoly share.

[27] *See, e.g.*, *Shkreli*, 581 F. Supp. 3d at 630-32 (defining relevant market as FDA-approved brand and generic versions of pyrimethamine); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d. 1142, 1176 (N.D. Cal. 2017) (defining a market for Lidoderm and its generic equivalents); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 668 (D. Conn. 2016) (limiting discovery into other drug products and limiting case to assessment of plaintiffs' proposed market of Aggrenox and its generic equivalents); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (concluding that the relevant market consisted of the brand and generic alone); Petition for Review, *In re Impax Labs*., FTC Dkt. No. 9373 (June 7, 2019) at 26 (defining the relevant antitrust product market as branded and generic oxymorphone ER, noting "in most cases arising in the [pharmaceutical reverse payment] context, a brand and its generics will constitute the relevant market"); *Geneva Pharms.*, 386 F.3d at 485 (proposed market limited to only generic coumadin—and excluding branded coumadin—sufficient to survive summary judgment); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 82 (D.D.C. 2006) (relevant antitrust market was generic Lorazepam and Clorazepate tablets).

where the complaint plausibly alleges one. *See Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 723 (3d Cir. 1991) (noting that "under certain circumstances a relevant market could consist of one brand of a product").

CONCLUSION

The FTC respectfully requests that the Court consider the foregoing in resolving Defendants' omnibus motion to dismiss.

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Respectfully submitted,

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