



What Can the FTC Do about Orphan Drug Prices?

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More than thirty years ago,¹ Congress passed the Orphan Drug Act (ODA) of 1983 to facilitate the development of drugs that treat rare diseases, defined in the United States as those affecting fewer than 200,000 patients.² At the time, drug therapies for such diseases were rarely developed, and the ODA sought to change that by offering financial incentives to research and market orphan drugs. Recently, some orphan drugs have come under fire for their prices; commenters have argued that drug makers are using the ODA to their advantage to charge high prices.³ One of the agencies that is typically called upon to investigate high drug prices is the Federal Trade Commission (FTC). This article explores what the FTC looks for when investigating high pharmaceutical drug price claims.

¹ The views in this article are my own and do not necessarily reflect the views of Haug Partners LLP or the firm's clients.

² Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (21 U.S.C. §§ 360aa – 360ff-1).

³ Sarah Jane Tribble & Sydney Lupkin, *Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies*, Kaiser Health News (Jan. 17, 2017), [http://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies; Senator Chuck Grassley, Grassley Explores Possible Misuses of the Orphan Drug Program, News Release \(Feb. 10, 2017\), https://www.grassley.senate.gov/news/news-releases/grassley-explores-possible-misuses-orphan-drug-program](http://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies; Senator Chuck Grassley, Grassley Explores Possible Misuses of the Orphan Drug Program, News Release (Feb. 10, 2017), https://www.grassley.senate.gov/news/news-releases/grassley-explores-possible-misuses-orphan-drug-program) (“Based on the reporting from Kaiser Health News about how the orphan drug provisions appear to be stretched beyond their original intent, and the strong consumer concern about high drug prices, I’m interested in learning whether the unanticipated uses of the provisions are contributing to high prices for commonly used drugs.”).

Orphan Drug Act: A Brief Overview

Before the passage of the ODA, drug therapies for rare diseases were rarely developed.⁴ The thinking was that given the small patient population, the cost of developing and making the drug could not be recovered from sales of the drug.⁵ To cure this, Congress provided financial incentives to research and market orphan drugs. Those incentives include:

- Tax credits for the costs of clinical research;
- Annual grant funding to defray the costs of qualified clinical testing expenses (\$14 million total for 2008);
- Assistance in clinical research study design;
- Seven-year period of exclusive marketing after an orphan drug is approved;

⁴ Matthew Herder, *What is the Purpose of the Orphan Drug Act?*, PLoS Med. (Jan. 2017), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5207521/>.

⁵ FDA, *Congressional Findings for the Orphan Drug Act (1983)*, available at <https://www.fda.gov/forindustry/developingproductsforrareconditions/howtoapplyfororphanproductdesignation/ucm364750.htm> (“because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss”); Tribble & Lupkin, *supra* note 2 (“Research and development is ‘long, costly, risky,’ said Anne Pritchett, vice president, policy and research at industry lobbying group PhRMA. ‘When you look at cystic fibrosis, it was 25 years to the development of an effective therapy . . . I think we would be concerned about anything that would undermine the current [orphan drug] incentives.’”).



- Waiver of Prescription Drug User Fee Act filing fees (about \$1 million per application for fiscal year 2008).⁶

Since the ODA's passage, more than 600 drugs and biologic products for rare diseases have been developed and brought to market.⁷ However, more orphan drugs need to be developed and marketed.⁸ There are 7,000 rare diseases known to exist today, and only 5% of rare diseases have an approved treatment.⁹

FTC Pricing Investigations

One of the FTC's missions is to enforce the antitrust laws. These laws promote competition and protect consumers from anticompetitive mergers and business practices. While the antitrust laws can reach certain anticompetitive conduct such as agreements among competitors to fix prices or output or illegal exclusionary or predatory practices, the FTC has no

authority to regulate prices.¹⁰ As noted by now acting Chairman Maureen K. Ohlhausen:

Standing alone, a 'high' pharmaceutical price is not an antitrust violation if it simply reflects a legally obtained intellectual property right. Antitrust comes into play when a firm lifts a competitive constraint on its market power, such as by acquiring a competitor or engaging in a pay-for-delay agreement. Likewise, in some circumstances, an action by a monopolist to block a nascent threat to its monopoly can violate antitrust law.¹¹

When examining a price complaint, the FTC will first examine the circumstances surrounding the high price to determine if the price is a result of "normal market forces and thus [does] not present an antitrust issue."¹² For example, a common cause of price spikes has been supply problems, such as an ingredient shortage.¹³ If not, the FTC will continue its investigation to determine if the pharmaceutical company used unreasonable restraints of trade to facilitate or protect a price increase.¹⁴ Like all FTC

⁶ Rebecca Hyde & Diana Dobrovolsky, *Orphan Drug Pricing and Payer Management in the United States: Are We Approaching the Tipping Point?*, 3 *American Health & Drug Benefits* 15, 16 (2010).

⁷ FDA, *Developing Products for Rare Diseases & Conditions* (last updated June 29, 2017), <https://www.fda.gov/forindustry/developingproductsforrareconditions/ucm2005525.htm>.

⁸ NIH, *Rare Disease Day at NIH 2017*, National Center for Advancing Translational Sciences (Mar. 14, 2017), <https://ncats.nih.gov/rdd> ("According to Orphanet, there are 6,000 to 7,000 rare diseases. Only a few hundred have any treatment. Although each rare disease affects fewer than 200,000 Americans, in total these illnesses affect an estimated 25 million people in the United States. Less than 5 percent of rare diseases have a treatment. NCATS is all about getting more treatments to more patients more quickly.").

⁹ *Id.*; FDA, *Congressional Findings for the Orphan Drug Act* (1983), *supra* note 4 ("(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small numbers of individuals residing in the United States that the diseases and conditions are considered rare in the United States; (2) adequate drugs for many of such diseases and conditions have not been developed.").

¹⁰ FTC, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, Competition Matters Blog (May 18, 2015), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription> ("Although the FTC has no authority to regulate the price of any product, including prescription drugs, protecting American consumers from anticompetitive activity in the health care sector has long been one of our most important responsibilities. Congress has empowered the FTC to prevent unfair methods of competition, such as illegal anticompetitive agreements among competitors to increase prices or restrict supply, and illegal exclusionary or predatory practices.").

¹¹ FTC, *Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Mallinckrodt ARD Inc.*, (Jan. 18, 2017), <https://www.ftc.gov/public-statements/2017/01/concurring-statement-commissioner-maureen-k-ohlhausen-matter-mallinckrodt>.

¹² FTC, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, *supra* note 10.

¹³ *Id.*

¹⁴ See FTC, *Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Mallinckrodt ARD Inc.*, *supra* note 11; FTC, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, *supra* note 10.



investigations, staff will take account of the facts specific to the particular industry that they are investigating. For example for orphan drugs, staff will consider the facts inherent to the orphan drug industry, such as small markets with few players, limited distribution (i.e., orphan drugs are only sold to specialty pharmacies), and the regulatory overlay unique to the pharmaceutical industry. While keeping these considerations in mind, FTC staff will investigate to determine whether an unreasonable restraint of trade underlies the price increase. Staff may look for one or more of the following restraints of trade:

Collusion – Whether the pharmaceutical company entered into an agreement with a competitor or competitors on price or output.¹⁵

Acquisition – Did the company illegally acquire a competing drug? For this inquiry, staff will also look to see whether the company illegally acquired a potential competitor, such as a drug that has not yet received U.S. Food and Drug Administration’s (FDA) approval to market in the U.S.¹⁶

Denying Access to Customers – Whether the pharmaceutical company entered into exclusive supply arrangements with insurers, distributors, or

pharmacies to deny competitors’ access to customers.¹⁷

Denying Access to Inputs – Staff will review supply contracts to determine whether the pharmaceutical company entered into exclusionary agreements to deny competitors access to ingredients necessary to manufacture the drugs.¹⁸

Delayed Entry – Whether the pharmaceutical company’s actions delayed entry of a competitor. Specifically, staff will look to see whether the pharmaceutical company engaged in any of the following conduct to delay a competitor’s entry:

- 1) entered into a reverse payment settlement with any generic competitors - A patent settlement agreement where the branded company agrees to

¹⁵ Dep’t Justice, *Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies*, Justice News (Dec. 14, 2016), <https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer> (“Jeffrey Glazer, the former CEO of a generic pharmaceutical company, and Jason Malek, the former president of the same company, conspired to fix prices, rig bids and allocate customers for an antibiotic, doxycycline hyclate. Additionally, the Informations allege Glazer and Malek conspired to fix prices and allocate customers for glyburide, a medicine used to treat diabetes.”).

¹⁶ See FTC, *Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Mallinckrodt ARD Inc.*, *supra* note 10 (“I voted to accept the proposed consent in this matter because I have reason to believe that Mallinckrodt ARD Inc. . . . violated the antitrust laws by acquiring the rights to the drug Synacthen Depot in the United States to protect its H.P. Acthar Gel monopoly.”).

¹⁷ Senator Amy Klobuchar, *Klobuchar Calls for FTC Investigation of Mylan Pharmaceuticals for Possible Antitrust Violations in Light of Dramatic Price Increase of EpiPen Packs*, News Release (Aug. 22, 2016), <https://www.klobuchar.senate.gov/public/2016/8/klobuchar-calls-for-ftc-investigation-of-mylan-pharmaceuticals-for-possible-antitrust-violations-in-light-of-dramatic-price-increase-of-epipen-packs> (“Although the antitrust laws do not prohibit price gouging, regardless of how unseemly it may be, they do prohibit the use of unreasonable restraints of trade to facilitate or protect a price increase. The FTC should investigate whether Mylan Pharmaceuticals engaged in activity, such as using incentives or exclusionary contracts with insurers, distributors, or pharmacies, to deny an alternative product access to the market.”).

¹⁸ FTC, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, *supra* note 10 (“[S]everal years ago, the FTC and 32 state Attorneys General sued a drug manufacturer and the only suppliers of a key ingredient for signing illegal agreements that increased wholesale prices of two widely-prescribed anti-anxiety drugs by 2000-3000 percent. The FTC alleged that the drug maker, Mylan Laboratories, Inc., and three suppliers of a key ingredient entered into exclusive supply contracts to deny Mylan’s competitors access to ingredients necessary to manufacture the drugs. In exchange for their participation in the scheme, Mylan agreed to share its profits with the suppliers, and then raised the price of the drugs exponentially — in the case of one product, from \$7.30 for a 500-count bottle to \$190.”).



pay the generic company a large, unjustified payment in exchange for delayed entry.¹⁹

- 2) filed a sham citizen petition with FDA – A company files a objectively baseless citizen petition with FDA, which prevents FDA from approving a competing drug product until the agency rules on the petition.²⁰
- 3) filed sham litigation against a potential competitor – A company files an objectively baseless patent infringement lawsuit to delay FDA approval of a generic competitor.²¹
- 4) engaged in product hopping – A company “make[s] trivial and non-therapeutic changes to

existing drugs that make generic substitution laws inapplicable to a new formulation.”²²

- 5) refusals to deal – A branded orphan drug maker takes advantage of the limited distribution of orphan drugs—such as distribution only through specialty pharmacies—to deny generic competitors the drug samples they need to conduct necessary testing to meet the requirements for generic drug approval. A similar example of a refusal to deal could occur in the Risk Evaluation and Mitigation Strategy (REMS) context. FDA will require drug companies to propose and implement REMS for certain drugs whose risk-benefit profiles warrant safety measures beyond professional labeling. An example of refusal to deal in the REMS context is where a branded company uses REMS distribution restrictions to deny generic companies drug samples.²³

¹⁹ Pursuant to The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, FTC reviews all Hatch-Waxman litigation settlement agreements to determine if the settlement agreement contains a reverse payment. FTC, *Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, <https://www.ftc.gov/system/files/attachments/competition-policy-guidance/050210pharmrulesfaqsection.pdf>; FTC, *Overview of Agreements Filed in FY 2014: A Report by the Bureau of Competition*, (Jan. 13, 2016), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>. Thus, FTC may have already reviewed the agreements surrounding a potential reverse payment before it receives pricing complaints. For more information on reverse payments, please see FTC, *Quo Vadis Post-Actavis?*, Competition Matters Blog (Mar. 30, 2016), <https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/quo-vadis-post-actavis>.

²⁰ For more information on sham citizen petitions, please see FTC, *FTC Staff Comment Before the Food and Drug Administration Concerning Citizen Petitions*, Advocacy Filings (Mar. 2000), <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2000/03/ftc-staff-comment-food-and-drug-administration>; see also *FTC v. Shire ViroPharma Inc.*, No. 17-00131 (D. Del. filed Feb. 7, 2017) (sham citizen petition case).

²¹ For more information on sham litigations, please see 1-2 ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 2C (8th ed.) (2016); see also *FTC v. AbbVie Inc.*, No. 14-5151 (E.D. Pa. filed Sept. 8, 2014) (sham litigation case).

Examples of FTC Enforcement Actions Involving Orphan Drugs

Some of the FTC’s recent enforcement actions involved orphan drugs. While the unique nature of the orphan drug industry was likely relevant when investigating these matters, it is unclear how much of a role, if any, that uniqueness played in bringing the enforcement action. Indeed, the only complaint discussed below that indicated whether the drug had an orphan indication and/or exclusivity was the *Lundbeck* matter.

FTC v. Mallinckrodt ARD Inc., Civil Action No. 1:17-cv-00120 (D.D.C.)

On January 18, 2017, the FTC and the Attorneys General of Alaska, Maryland, New York, Texas, and Washington filed a complaint in federal district court

²² For more information on product hopping, please see Brief for FTC as Amici Curiae Supporting Plaintiff-Appellant, *Mylan Pharm., Inc. v. Warner-Chilcott PLC*, 838 F.3d 421 (3d. Cir. 2016), 2016 WL 6137296.

²³ For more information on REMS, please see Brief for FTC as Amici Curiae, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-05743 (D.N.J. filed Mar. 11, 2013), <https://www.ftc.gov/policy/advocacy/amicus-briefs/2013/03/actelion-pharmaceuticals-ltd-et-al-v-apotex-inc>.



for the District of Columbia seeking a permanent injunction and other equitable relief against Mallinckrodt ARD Inc. (Mallinckrodt), formerly known as Questcor Pharmaceuticals, Inc., and its parent company, Mallinckrodt plc for unfair methods of competition in violation of Section 5 of the FTC Act and monopolization in violation of Section 2 of the Sherman Act, as well as various state antitrust laws.²⁴ Specifically, the complaint alleged that Mallinckrodt illegally maintained its monopoly by acquiring rights to develop and market a potential competitor product, Synacthen Depot, to Mallinckrodt's H.P. Acthar Gel (repository corticotrophin) drug product.²⁵

The FDA approved H.P. Acthar Gel on April 29, 1952 for multiple indications.²⁶ The label was later expanded to include multiple sclerosis in 1972 and infantile spasms in pediatric patients in 2010.²⁷ H.P. Acthar Gel received orphan drug exclusivity for its infantile spasms indication, and that exclusivity expires on October 15, 2017.²⁸ Synacthen Depot is a synthetic ACTH alternative to Acthar, and is used in Europe, Canada, and other parts of the world, but it has not yet received approval from the FDA for sale in the U.S.²⁹

The FTC claimed that Mallinckrodt by acquiring Synacthen Depot "thwarted a nascent challenge to its Acthar monopoly and thereby harmed competition."³⁰ The complaint further alleged that the acquisition stifled competition by preventing any other company from using the Synacthen assets to

develop a synthetic ACTH drug, preserving Mallinckrodt's monopoly and allowing it to maintain extremely high prices for Acthar.³¹ The complaint stated that Mallinckrodt repeatedly raised the price of H.P. Acthar Gel from \$40 per vial in 2001 to more than \$34,000 per vial.³²

Mallinckrodt agreed to settle the case. Under a stipulated court order, Mallinckrodt must make a \$100 million monetary payment to FTC.³³ The states will receive \$10 million from the \$100 million judgement and an additional \$2 million as a payment for attorney's fees and costs.³⁴ Mallinckrodt must also grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.³⁵

FTC v. Endo Pharmaceuticals Inc., Civil Action No. 2:16-cv-01440-PD (E.D. Pa.)³⁶

On March 30, 2016, the FTC filed a complaint against Endo Pharmaceuticals Inc. (Endo) alleging that the company violated federal antitrust laws by illegally blocking lower-cost generic versions of the branded drugs Opana ER (oxymorphone hydrochloride) and Lidoderm Patch (lidocaine patch

³¹ *Id.* at 3, 12-13.

³² *Id.* at 2.

³³ FTC, *Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants*, *supra* note 24.

³⁴ *Id.*

³⁵ *Id.*

³⁶ FTC also brought reverse payment claims against Cephalon, Inc. for its drug, Provigil (modafinil). *See FTC v. Cephalon, Inc.*, No. 08-2141 (transferred to E.D. Pa. Apr. 28, 2008). FDA approved Provigil on December 24, 1998. Provigil received orphan drug exclusivity for the following indication: improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. FDA, Orphan Drug Product Designation for Provigil, <https://www.accessdata.fda.gov/scripts/opdlisting/opd/detailedIndex.cfm?cfgridkey=73793>. It's exclusivity ended on December 24, 2005. *Id.* Teva Pharmaceuticals Industries, Ltd., which acquired Cephalon in 2012, settled with FTC. FTC, *FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics*, Press Release (May 28, 2015), <https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill>.

²⁴ FTC, *Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants*, Press Release (Jan. 18, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it>.

²⁵ Complaint at 12, *FTC v. Mallinckrodt ARD Inc.*, No. 17-00120 (D.D.C. filed Jan. 18, 2017) (hereinafter "*Mallinckrodt Compl.*").

²⁶ FDA, NDA 022432 Approval Letter, at 3 (Oct. 15, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/022432s000ltr.pdf.

²⁷ *Id.*

²⁸ FDA, Orphan Drug Product Designation for H.P. Acthar Gel, <https://www.accessdata.fda.gov/scripts/opdlisting/opd/detailedIndex.cfm?cfgridkey=168103>.

²⁹ *Mallinckrodt Compl.* at 3, 8.

³⁰ *Id.* at 12.



5%).³⁷ Only the Lidoderm Patch has an orphan drug designation.³⁸ The FDA approved the Lidoderm Patch on March 19, 1999 for the treatment of pain in post-herpetic neuralgia.³⁹ The Lidoderm Patch received orphan drug exclusivity for the following indications: 1) relief of allodynia (painful hypersensitivity) and 2) chronic pain in post-herpetic neuralgia.⁴⁰ The exclusivity ended on March 19, 2006.⁴¹

In its complaint, the FTC alleges that Endo entered into reverse payment settlements between 2010 and 2012 on its two best-selling branded pharmaceuticals, Opana ER and the Lidoderm Patch, and used those settlements to maintain its monopoly on each drug.⁴² The complaint further alleges that, in each case, the generic company eligible for first-filer exclusivity agreed not to market its generic product for a period of time in exchange for a no-AG commitment and other compensation.⁴³ A no-AG commitment is where a branded pharmaceutical company agrees not to sell an authorized generic during the first six months of generic sales.

Other defendants named in the complaint were Impax Laboratories, Inc. (the first generic filer on most dosages of Opana ER), Watson Laboratories, Inc./Allergan plc (the first generic for the Lidoderm Patch), and Teikoku Pharma USA, Inc./Teikoku Seiyaku Co., Ltd. (Endo's partner for the Lidoderm Patch). The Teikoku entities settled with the FTC, and they agreed not to enter into similar reverse payments for a period of twenty years.⁴⁴ In October

2016, the Judge overseeing the complaint severed the Lidoderm Patch and Opana ER claims, and the FTC dismissed the action.⁴⁵ Subsequently, the FTC settled with Endo, and the company agreed not to enter into similar reverse payments for a period of ten years.⁴⁶ The FTC refiled a complaint against Watson/Allergan in the Northern District of California covering the Lidoderm claims (*FTC v. Allergan PLC*, Civil Action No. 17-cv-00312 (N.D. Cal.)), and an administrative complaint against Impax covering the Opana ER claims (*Impax Laboratories, Inc.*, D-9373).⁴⁷

FTC v. Lundbeck, Inc., Civil No. 0:08-cv-06379-JNE-JJG (D. Minn.)⁴⁸

In December 2008, the FTC brought a complaint against Ovation Pharmaceuticals (which was purchased in 2009 and renamed Lundbeck, Inc.)

⁴⁵ FTC, *Endo Pharmaceuticals Inc. Agrees to Abandon Anticompetitive Pay-for-Delay Agreements to Settle FTC Charges; FTC Refiles Suits Against Generic Defendants*, Press Release (Jan. 23, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/endo-pharmaceuticals-inc-agrees-abandon-anticompetitive-pay-delay>.

⁴⁶ Stipulated Order for Permanent Injunction at 21, *FTC v. Endo Pharm. Inc.*, No. 17-00312 (N.D. Cal. filed Feb. 2, 2017).

⁴⁷ FTC, *Endo Pharmaceuticals Inc. Agrees to Abandon Anticompetitive Pay-for-Delay Agreements to Settle FTC Charges; FTC Refiles Suits Against Generic Defendants*, *supra* note 45.

⁴⁸ FTC investigated whether Genzyme Corporation's acquisition of Novazyme Pharmaceuticals, Inc. (Novazyme) violated Section 7 of the Clayton Act. FTC, *FTC Closes its Investigation of Genzyme Corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc.*, Press Release (Jan. 13, 2004), <https://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001>. At the time of the acquisition, Novazyme was conducting pre-clinical studies relating to enzyme-replacement treatment ("ERT") for Pompe disease, and Genzyme also engaged in preclinical animal test of ERTs. *Id.* The Commission considered whether the transaction would impact "the pace and scope of research into the development of a treatment for Pompe disease." *Id.* This acquisition implicates the ODA because the Pompe disease is rare and the first Pompe therapy to gain FDA approval will have orphan drug exclusivity. *Id.* The Commission determined that no further action is warranted and closed its investigation January 13, 2004. *Id.*

³⁷ Complaint, *FTC v. Endo Pharm. Inc.*, No. 16-01440 (E.D. Pa. filed Mar. 30, 2016) (hereinafter "*Endo Compl.*").

³⁸ FDA, Orphan Drug Product Designation for Lidoderm Patch, <https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=92395>.

³⁹ FDA, NDA 20612 Approval Letter, at 1 (Mar. 19, 1999), https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/20612ltr.pdf.

⁴⁰ FDA, Orphan Drug Product Designation for Lidoderm Patch, <https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=92395>.

⁴¹ *Id.*

⁴² *Endo Compl.* at 12, 19-21, 26, 30, 34.

⁴³ *Endo Compl.* at 19-21, 30.

⁴⁴ Stipulated Order for Permanent Injunction at 12, *FTC v. Endo Pharm. Inc.*, No. 16-01440 (E.D. Pa. filed Apr. 7, 2016).



(Ovation) challenging its purchase of the U.S. rights to NeoProfen (ibuprofen lysine).⁴⁹ The FDA approved NeoProfen on April 13, 2016, and the drug received orphan drug exclusivity for the treatment of patent ductus arteriosus (“PDA”), a congenital heart defect usually found in severely underweight premature babies.⁵⁰ At the time of the purchase, Ovation already had rights to Indocin I.V. (indomethacin for injection), which also treated PDA.⁵¹

According to the FTC’s complaint, Ovation’s acquisition of NeoProfen eliminated its only competitor for the treatment of PDA.⁵² This allowed Ovation to preserve its monopoly and raise the price of Indocin IV nearly 1,300 percent from \$35 to nearly \$500 per vial.⁵³ When it launched NeoProfen in July 2006, Ovation set a similarly inflated price.⁵⁴ The complaint sought equitable relief, including divestiture and disgorgement of unlawfully obtained profits from Ovation’s sales of Indocin I.V. and NeoProfen.⁵⁵ The district court held that the FTC had not proven that NeoProfen and Indocin compete in the same product market, and therefore, that the FTC failed to show that the acquisition substantially lessened competition or maintained a monopoly.⁵⁶ The Eighth Circuit affirmed the district court’s opinion.⁵⁷

Conclusion

Orphan drug pricing will likely remain an area of concern. However, high pharmaceutical prices alone are not necessarily a concern of the FTC. From the

complaints discussed above, it is clear that FTC will continue to look for anticompetitive conduct regardless of type of drug at issue.

⁴⁹ Complaint, *FTC v. Ovation Pharm., Inc.*, No. 08-0637 (D. Minn. filed Dec. 16, 2008) (hereinafter “*Ovation Compl.*”).

⁵⁰ FDA, Orphan Drug Product Designation for NeoProfen, <https://www.accessdata.fda.gov/scripts/opdlisting/oopd/tailedIndex.cfm?cfgridkey=101496>. The exclusivity ended on April 13, 2013. *Id.*

⁵¹ *Ovation Compl.* at 1-2.

⁵² *Id.* at 2.

⁵³ *Id.* at 5.

⁵⁴ *Id.* at 6.

⁵⁵ *Id.* at 11.

⁵⁶ FTC, *Ovation Pharmaceuticals, Inc. d/b/a*, Cases and Proceedings (Oct. 3, 2011), <https://www.ftc.gov/enforcement/cases-proceedings/081-0156/ovation-pharmaceuticals-inc-dba>.

⁵⁷ *Id.*



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