Game Recognizes Game:

The Mylan & Sanofi Litigations as Evidence of

Regulatory Gaming in the Pharmaceutical Industry

Alyssa Taylor Ruhlen

Cardozo School of Law

IP & Antitrust

Professor Bruce Schneider

Spring 2025

I. Introduction

The pharmaceutical marketplace is characterized by unique competitive dynamics, particularly the interplay between branded and generic drugs. According to the U.S. Food and Drug Administration (FDA), around nine out of ten prescriptions filled in the United States are for the generic version of a drug rather than the brand name manufactured by the pharmaceutical company that initially developed the drug.[1] Compared to their brand name equivalents, generic medications have the same active ingredients and are designed to work the same way as name-brand drugs.[2] A brand name drug is developed and manufactured by the same pharmaceutical company that submits it to the FDA for approval and owns the patent on the chemical compound.[3] Produced by other companies after these brand name patents run out, generics contain different inactive ingredients—such as alcohol, gelatin, saccharin, or sugars like galactose or lactose—that do not influence the drug's therapeutic properties but are added to a drug formulation to ensure consistency, preserve the drug, or transport it more easily.[4] The most notable difference between generic and brand name drugs is cost, with generics priced about 80 to 85 percent less than their brand name equivalents.[5]

The Hatch-Waxman Act facilitates the entry of generic drugs by allowing them to rely on the safety and efficacy data of branded drugs.[6] Formally known as the Drug Price and Patent Term Restoration Act of 1984, the Hatch-Waxman Act was adopted by Congress to expedite and

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[1] Generic Drugs, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs (last visited May 3, 2025).
[2] *See* Tara Haelle, Do Generic Drugs Work as Well as Brand Name? Here's What to Know, NAT'L GEOGRAPHIC (Sept. 21, 2023), https://www.nationalgeographic.com/science/article/do-generic-drugs-work-as-well-as-brand-name-drugs.
[3] *Id.*
[4] *Id.*
[5] *Id*.
[6] Fed. Trade Comm'n's Brief as Amicus Curiae, Mylan Pharms. Inc. v. Sanofi-Aventis U.S. LLC, No. 23-836-MRH (W.D. Pa. Nov. 21, 2023) [hereinafter "FTC Sanofi Brief"].

streamline both generic drug approvals and patent litigation involving generic drugs.[7] Prior to its adoption, generic drug companies were required to conduct the same kinds of expensive, time-consuming trials that drug companies conducted for new brand-name drugs, and often subjected to patent infringement liability due to unlicensed investigation and testing of a patented drug to obtain FDA approval.[8] After its implementation, the Hatch-Waxman Act enabled an expedited FDA-approval process for generic drug applications, certain market and patent exclusivity periods for both branded and generic drug companies, patent term extensions to adjust for delays caused by the FDA approval process, and a unique patent litigation process triggered by a generic drug company's submission of an application for FDA approval.[9]

While often credited with creating the modern generic drug industry,[10] the Hatch-Waxman framework also creates opportunities for regulatory gaming, where brand-name manufacturers may engage in practices that delay generic competition. Regulatory gaming can be defined as "behavior that abuses a neutral or procompetitive regulatory structure and wields it as a tool to accomplish exclusionary results […] private conduct that distorts the regulatory process."[11] In the pharmaceutical industry, one such regulatory gaming tactic includes calculated abuse of the FDA publication Approved Drug Products With Therapeutic Equivalence Evaluations, or "Orange Book," which lists and contains certain information for patents submitted by New Drug Application (NDA) holders that meets specific substantive patent submission requirements.[12]

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[7] *See* Lisa Barons Pensabene & Dennis Gregory, Hatch-Waxman Act: Overview, PRAC. L. PRAC. NOTE OVERVIEW 9-523-2397 (2025).
[8] *Id.*
[9] *Id*.
[10] *Id*.
[11] Stacey L. Dogan & Mark A. Lemley, Antitrust Law and Regulatory Gaming, 87 TEX. L. REV. 685 (2009).
[12] FDA Orange Book Patent Information and Submission Requirements, Practical Law Practice Note, Practical Law Intell. Prop. & Tech. (Thomson Reuters 2025). For each patent listed for a drug product, the Orange Book provides: the patent number and its expiration date; the patent's designation as claiming one or more of the approved product's drug substance, drug product, or use code, describing an approved method-of-use claimed in a patent; the existence

Specifically, a company marketing a branded drug under a NDA must list any patents that could be infringed by a follow-on drug, and claim either the drug itself or an approved method of using the drug.[13] Listing a patent in the Orange Book has significant consequences for competition—if, after receiving required notice from the generic applicant, a brand company timely sues a generic competitor for infringement of an Orange Book listed patent, it triggers an automatic statutory bar on the FDA's ability to approve the competitor's drug for up to 30 months.[14]

The prospect of an automatic 30-month block on competition—and accompanying higher profits—can incentivize brand companies to wrongfully list ineligible patents in the Orange Book.[15] This practice can significantly delay the entry of lower-cost generics, impacting consumer access and market competition.[16] According to the FTC, there has been evidence that some brand drug companies have exploited the Orange Book listing process "to prevent or delay the marketing of generic drugs" since the late 1990s.[17] By improperly listing a patent and timely filing an infringement suit, a brand can generally rely on the automatic stay to block FDA approval of a competing generic, regardless of the validity or scope of the patent and regardless of whether the patent meets the statutory listing criteria.[18] The FDA has no discretion to reduce this stay, and judges are unable to shorten it through preliminary relief—as dictated by statute, only a final court judgement of noninfringement or invalidity can supersede the stay.[19]

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of any pediatric exclusivity associated with the patent and its expiration date; whether the NDA holder filed a patent delist request; and the information submission date, for patent listings submitted in 2013 or later.

[13] FTC Sanofi Brief, *supra* note 6.

[14] *Id*.

[15] *Id*.

[16] *Id*.

[17] Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book 1 (2024) [hereinafter FTC Orange Book Statement] (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 566 U.S. 399, 408 (2012)).

[18] *Id*.

[19] Dogan & Lemley, *supra* note 12, at 711.

The *Mylan v. Sanofi* litigation[20] exemplifies the challenges of regulatory gaming in the pharmaceutical industry. Mylan alleges that Sanofi improperly listed patents in the Orange Book to delay the approval of its biosimilar insulin product, Semglee, thus monopolizing the market for injectable insulin glargine.[21] This case highlights the broader implications of Orange Book listing abuses on competition and consumer welfare.[22]

II. Comparative Framework of Pharmaceutical Antitrust Claims

II.A. Regulatory Gaming Strategies

Regulatory gaming refers to the strategic manipulation of regulatory processes to achieve anticompetitive ends.[23] In the pharmaceutical industry, regulatory gaming strategies include Orange Book listing abuse, REMS program restrictions, and patent thickets. These practices exploit the structure of the Hatch-Waxman Act and FDA procedures to delay generic competition beyond the intended scope of patent protection, creating barriers to entry for generic competitors and extending the market exclusivity of brand-name drugs.[24] The most prevalent form involves the manipulation of Orange Book patent listings, where brand manufacturers submit patents of questionable relevance to trigger automatic delays in generic approval. Under 21 U.S.C. § 355(b)(1)(A)(viii), only patents that "claim the drug" or "claim a method of using such drug" qualify for listing, yet companies increasingly attempt to list patents claiming delivery devices, manufacturing processes, or regulatory compliance systems.[25]

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[20] Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC, No. 2:23-cv-836 (W.D. Pa. filed May 17, 2023) [hereinafter "*Mylan* Complaint"].
[21] FTC Sanofi Brief, *supra* note 6.
[22] *Id*.
[23] *See* Dogan & Lemley, supra note 11, at 688.
[24] FTC Sanofi Brief, *supra* note 6.
[25] 21 U.S.C. § 355(b)(1)(A)(viii) (2018); see also 21 C.F.R. § 314.53(b)(1) (2024).

The First Circuit's analysis in *In re Lantus Direct Purchaser Antitrust Litigation* exemplifies judicial recognition of this abuse.[26] The court found that Sanofi's listing of patents claiming only the drive mechanism of an insulin pen device violated statutory requirements, as these patents neither claimed the drug itself nor an approved method of using the drug. This decision reflects a broader judicial evolution from formalistic interpretation of patent claims toward substantive examination of whether listings serve legitimate competitive purposes or exist solely to delay generic entry.[27]

Beyond Orange Book manipulation, companies employ Risk Evaluation and Mitigation Strategies (REMS) programs as exclusionary tools. While REMS serve legitimate safety purposes, some manufacturers implement overly restrictive protocols that prevent generic companies from obtaining reference samples necessary for bioequivalence testing. The FTC has identified this as a growing concern, with restrictions potentially delaying generic entry for months or years beyond patent expiration.[28] FDA citizen petitions represent another avenue for regulatory gaming. The petition process allows stakeholders to request agency action on regulatory matters, but brand manufacturers increasingly file meritless petitions designed solely to delay generic approval. In *FTC v. Shire ViroPharma*, the Commission successfully challenged Shire's filing of multiple frivolous petitions aimed at delaying generic competition for Vancocin oral capsules.[29] Patent thickets combined with product hopping create particularly sophisticated gaming strategies. Companies develop multiple overlapping patents while simultaneously reformulating products to force consumer switches to new versions. The *In re Suboxone* litigation illustrates this approach,

[26] In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 15 (1st Cir. 2020).
[27] *See id*. at 15-16; see also Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharm. of N.Y., LLC, 124 F.4th 898, 906-07 (Fed. Cir. 2024).
[28] Fed. Trade Comm'n, Generic Drug Access: Challenges with Risk Evaluation and Mitigation Strategies (REMS) 8-12 (2019).
[29] Fed. Trade Comm'n v. Shire ViroPharma, Inc., 917 F.3d 147, 151-52 (3d Cir. 2019).

where the manufacturer introduced a sublingual film version while withdrawing tablet versions and filing citizen petitions questioning tablet safety.[30]

II.B. Market Access Strategies

While regulatory gaming manipulates government processes, market access strategies achieve exclusion through contractual arrangements that, while facially legitimate, can significantly foreclose competition. Market access strategies, such as exclusive rebate agreements and volume-based contracting, can also restrict competition by limiting the availability of generic alternatives. These practices can lead to higher drug prices and reduced consumer choice.[31] Exclusive rebate agreements with Pharmacy Benefit Managers (PBMs) exemplify this approach. PBMs control formulary placement for millions of patients, and their coverage decisions dramatically affect market access.[32] Companies negotiate exclusive or preferential rebate agreements that create powerful incentives for PBMs to exclude competing products, even when competitors offer superior pricing or clinical benefits.

These agreements often include market share requirements, volume commitments, and penalty clauses that effectively lock in exclusivity.[33] The magnitude of rebates—sometimes reaching 40-60% of list price—creates switching costs and lock-in effects that persist beyond contract terms.[34] Volume-based contracting strategies create loyalty discounts and market share penalties that discourage customers from substituting competing products. Large pharmaceutical companies leverage their portfolios to create bundled arrangements, offering attractive terms on popular drugs

[30] In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 673-74 (E.D. Pa. 2014).
[31] FTC Sanofi Brief, *supra* note 6.
[32] *See* Fed. Trade Comm'n, 6(b) Report on Pharmacy Benefit Managers 15-18 (2024).
[33] See Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959, 969-70 (10th Cir. 2022).
[34] *See* Adam J. Fein, The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, DRUG CHANNELS INST. 78-82 (2023).

conditional on exclusive access across multiple products.[35] The complexity of these arrangements can obscure their exclusionary effects. Unlike naked restraints that obviously violate antitrust law, exclusive dealing arrangements in pharmaceutical markets often present plausible efficiency justifications related to inventory management, marketing support, or administrative simplification. Courts must therefore engage in sophisticated analysis to distinguish between arrangements that promote competition through legitimate efficiencies and those that exclude rivals to preserve monopoly profits.

II.C. Analytical Frameworks for Pharmaceutical Antitrust

The varied nature of pharmaceutical antitrust violations requires different analytical frameworks. Pharmaceutical antitrust claims often rely on theories of exclusionary conduct, such as refusal to deal and product hopping. These claims focus on whether the conduct reduces consumer choice and harms competition.[36] For regulatory gaming strategies, courts primarily apply exclusionary conduct theories under Section 2 of the Sherman Act. The central inquiry involves whether the conduct restricts competition beyond the legitimate scope of patent protection. The Supreme Court's decision in *Actavis* established that antitrust scrutiny applies even when conduct falls within the technical scope of patent rights, if it delays competition through improper means.[37]

Market access cases typically invoke exclusive dealing analysis under Section 1 of the Sherman Act, focusing on market foreclosure effects.[38] Courts must determine whether manufacturers have legitimate business reasons for their contracting strategies or whether

[35] *See* United Food & Commercial Workers Local 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F.4th 1144, 1158-59 (9th Cir. 2023).
[36] FTC Sanofi Brief, *supra* note 6.
[37] F.T.C. v. Actavis, Inc., 570 U.S. 136, 157-58 (2013).
[38] *See* Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327-28 (1961).

arrangements serve primarily to exclude competition. The analysis examines both quantitative factors—such as the percentage of market foreclosed—and qualitative considerations like the strategic importance of foreclosed outlets and barriers to switching.

Some cases involving REMS restrictions or sample access invoke essential facility doctrine, requiring brand manufacturers to provide reasonable access to materials necessary for generic development.[39] However, application remains inconsistent, with courts showing varying degrees of willingness to impose affirmative duties on patent holders.

Most pharmaceutical antitrust claims undergo rule of reason analysis, requiring courts to weigh procompetitive benefits against anticompetitive harms.[40] This analysis proves particularly challenging in pharmaceutical markets where legitimate business justifications can obscure anticompetitive purposes. The complexity of vertical relationships in pharmaceutical distribution chains further complicates the analysis, as effects may ripple through multiple market levels.

II.D. Judicial Evolution in Pharmaceutical Antitrust

Judicial approaches to pharmaceutical antitrust claims have evolved significantly, with notable variations across different types of challenges. Courts historically showed substantial deference to regulatory frameworks, particularly regarding patent validity and FDA approval processes.[41] However, recent decisions demonstrate increased willingness to scrutinize conduct that exploits regulatory procedures for anticompetitive purposes. In Orange Book cases, courts increasingly apply heightened scrutiny to device patents and process-related listings.[42] The evolution reflects growing judicial sophistication in distinguishing between patents that protect genuine

[39] *See* MCI Commc'ns Corp. v. AT&T Co., 708 F.2d 1081, 1132-33 (7th Cir. 1983); cf. Apotex, Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 62-63 (2d Cir. 2016).
[40] *See* Board of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918).
[41] *See* Zeneca Ltd. v. Mylan Pharm., Inc., 173 F.3d 829, 832 (Fed. Cir. 1999).
[42] *Compare* Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC, 60 F.4th 1373, 1378-79 (Fed. Cir. 2023), *with* Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharm. of N.Y., LLC, 124 F.4th 898, 906-07 (Fed. Cir. 2024).

pharmaceutical innovations and those claiming ancillary features used primarily to delay generic competition. Courts now examine not just formal patent claim language but the economic relationship between patents and the approved drug products.

Exclusive dealing cases receive different treatment, with courts applying traditional foreclosure analysis adapted for pharmaceutical market characteristics.[43] The unique features of pharmaceutical distribution—involving PBMs, formulary placement, and insurance intermediation—require courts to understand how contractual arrangements actually affect patient access rather than merely examining market share percentages.

Product hopping claims face varying standards depending on whether courts focus on consumer choice restrictions or require proof of coercive conduct.[44] Some courts emphasize whether switches eliminate automatic substitution rights, while others examine whether businesses justify switches serve legitimate purposes beyond avoiding generic competition. The treatment of innovation defenses varies considerably across claim types. While patents and regulatory approvals receive strong presumptive protection, courts increasingly recognize that innovation justifications cannot encompass conduct exceeding legitimate intellectual property scope.[45] The analytical challenge involves determining when innovation benefits genuinely justify potentially anticompetitive conduct versus when they serve as pretextual justifications for exclusionary behavior.

This comparative framework reveals that pharmaceutical antitrust enforcement requires sophisticated analysis capable of capturing both direct and indirect competitive effects. The

[43] *See* LePage's Inc. v. 3M, 324 F.3d 141, 159-60 (3d Cir. 2003) (en banc).
[44] *Compare* N.Y. ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 652-53 (2d Cir. 2015), *with* In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 683-84 (E.D. Pa. 2014).
[45] *See* Herbert Hovenkamp, Innovation and the Domain of Competition Policy, 60 ALA. L. REV. 103, 140-42 (2008).

complexity of regulatory structures creates multiple opportunities for abuse, requiring frameworks that can distinguish between legitimate competitive conduct and strategic manipulation designed to preserve monopoly profits. The following sections examine specific applications of these frameworks to Orange Book listing abuse and exclusive dealing arrangements, using detailed case studies to illustrate how different theoretical approaches yield varying results in practice.

III. Orange Book Listing Abuse as an Exclusionary Practice

III.A. The Orange Book Framework and Its Vulnerabilities

The Orange Book listing framework requires that patents claim the drug or an approved method of using the drug to be eligible for listing. Improper listings can trigger a 30-month stay on generic approval, delaying competition and harming consumers.[46] The Orange Book patent listing system represents one of the most contentious battlegrounds in pharmaceutical antitrust litigation. Created as part of the Hatch-Waxman Act to provide notice of patents that might block generic competition, the Orange Book has evolved into a strategic weapon wielded by brand manufacturers to extend market exclusivity beyond legitimate patent scope.[47] The system's vulnerability to abuse stems from its foundational reliance on brand manufacturers' self-attestation regarding patent eligibility, combined with the FDA's purely ministerial role that provides no independent verification of listing propriety. This creates a regulatory structure where improper listings can generate immediate competitive benefits through automatic 30-month stays on generic approval, while facing only delayed and uncertain judicial correction.

The statutory framework governing Orange Book listings appears deceptively straightforward. Under 21 U.S.C. § 355(b)(1)(A)(viii), manufacturers must list patents that meet two essential

[46] FTC Sanofi Brief, *supra* note 6.
[47] *See* Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 MICH. L. REV. 37, 42-44 (2009).

criteria: the patent must claim the drug for which approval is sought, or claim a method of using such drug; and infringement must be reasonably assertable against unlicensed manufacture, use, or sale.[48] The accompanying regulations in 21 C.F.R. § 314.53 elaborate that eligible patents include those claiming drug substances (active ingredients), drug products (formulations and compositions), and approved methods of use.[49] However, the apparent clarity of these requirements masks significant interpretive challenges that have generated extensive litigation as companies push the boundaries of what constitutes the "drug" for listing purposes.

The FDA's ministerial role creates a critical enforcement gap that enables improper listings to persist for extended periods. As established in *Apotex, Inc. v. Thompson*, the FDA neither independently verifies patent eligibility nor reviews the substantive accuracy of listing information.[50] Instead, the agency relies entirely on manufacturers' declarations that submitted patents meet statutory criteria. This hands-off approach reflects the FDA's position that it lacks both resources and expertise to conduct meaningful patent review. However, the resulting system allows improper listings to generate significant competitive advantages through 30-month stays while awaiting judicial resolution, which may take years and cost millions in legal fees.

The consequences of Orange Book listing extend far beyond mere informational notice to generic manufacturers. When a generic manufacturer files a Paragraph IV certification challenging a listed patent, and the brand manufacturer timely files an infringement suit, FDA approval is automatically stayed for up to 30 months or until litigation concludes.[51] This automatic stay creates compelling incentives for strategic listing behavior, as even marginal patents can preserve millions

[48] 21 U.S.C. § 355(b)(1)(A)(viii) (2018); see also 21 C.F.R. § 314.53(b)(1) (2024).
[49] 21 C.F.R. § 314.53(b)(1)-(3) (2024).
[50] Apotex, Inc. v. Thompson, 347 F.3d 1335, 1346-47 (Fed. Cir. 2003).
[51] 21 U.S.C. § 355(j)(5)(B)(iii) (2018).

or billions in monopoly profits during the delay period.[52] The financial stakes create powerful motivations for companies to interpret listing requirements broadly, leading to increasingly aggressive listing strategies that test judicial tolerance for regulatory gaming.

III.B. Case Study: Mylan v. Sanofi

The *Mylan v. Sanofi* litigation provides a detailed case study in Orange Book manipulation and its antitrust implications. In *Mylan v. Sanofi*, Mylan alleges that Sanofi listed numerous patents related to its Lantus insulin product, including several patents claiming only mechanical components of injection pen devices rather than the insulin molecule, formulation, or therapeutic method.[53] These device patents, which covered features like spring mechanisms and needle insertion systems, represented clear attempts to extend exclusivity beyond the drug itself to encompass delivery mechanisms. This alleged abuse delayed the approval of Mylan's biosimilar product, Semglee, impacting market competition.[54] The dispute crystallized around whether patents claiming only mechanical device components could legitimately be considered as claiming the "drug" within the meaning of the Hatch-Waxman Act.

Mylan's challenge to these device patents gained significant support from the FTC, which filed an amicus brief arguing that such listings violated both statutory requirements and congressional intent.[55] The Commission emphasized that the Hatch-Waxman framework sought to balance innovation incentives with generic competition, and that permitting device patent listings would upset this balance by extending exclusivity to innovations unrelated to pharmaceutical development.[56] The FTC noted that allowing such listings would transform the Orange Book from

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[52] *See* Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 12-15 (2010).
[53] First Amended Complaint at 2-4, Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC, No. 2:23-cv-836 (W.D. Pa. filed June 15, 2023).
[54] FTC Sanofi Brief, *supra* note 6.
[55] Fed. Trade Comm'n's Brief as Amicus Curiae at 12-15, Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC, No. 23-836-MRH (W.D. Pa. Nov. 21, 2023).
[56] *Id*. at 18-20.

a focused source of drug-related patent information into an unlimited catalog of any patents possibly affecting generic competition, thereby defeating the statute's purpose.[57]

Orange Book listing abuse can be compared to traditional exclusionary practices, such as refusal to deal, as both involve using regulatory mechanisms to block competition. Courts have recognized that improper listings can constitute anticompetitive conduct under antitrust laws.[58] The First Circuit's decision in *In re Lantus Direct Purchaser Antitrust Litigation* marked a watershed moment in Orange Book jurisprudence.[59] The court rejected expansive readings that would encompass any patent related to drug therapy, holding instead that patents must claim the drug substance, drug product, or method of using the drug—not merely devices that deliver the drug.[60] Crucially, the court explicitly recognized that improper listings constitute regulatory gaming that can cost consumers "millions or billions of dollars without valid cause."[61] This language signals judicial recognition that Orange Book abuse represents more than technical regulatory violations—it constitutes actionable anticompetitive conduct with measurable consumer harm. The court's analysis focused on economic substance rather than formalistic patent claim language. Rather than simply asking whether device patents could technically be read to "claim the drug," the court examined whether such patents genuinely protected innovations deserving of Orange Book protection.[62] This substantive approach represents an evolution from earlier decisions that adopted more formalistic interpretations, suggesting growing judicial sophistication in addressing regulatory gaming strategies.[63]

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[57] *Id*. at 22-24.
[58] FTC Sanofi Brief, *supra* note 6.
[59] In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1 (1st Cir. 2020).
[60] *Id*. at 15-16.
[61] *Id*. at 16.
[62] *Id*. at 15-16.
[63] *Compare id*., *with* Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191, 194-95 (D.D.C. 2002).

III.C. Judicial Response to Orange Book Abuse

Comparing Orange Book listing abuse to traditional exclusionary practices reveals both similarities and distinctive features. Like classic refusal to deal cases, Orange Book manipulation involves incumbent monopolists using their market position to exclude competitors from essential resources or processes.[64] However, Orange Book cases present unique complications because the "resource" being manipulated is government-controlled regulatory approval pathways rather than private facilities or distribution networks. The abuse operates through manipulation of government processes rather than direct private exclusion, creating novel challenges for traditional antitrust analysis.

The monopolization framework from Section 2 of the Sherman Act provides the primary analytical structure for Orange Book abuse cases. Courts must determine whether improper listings constitute "willful acquisition or maintenance" of monopoly power through anticompetitive conduct. Unlike traditional monopolization cases where conduct effects might be ambiguous, improper Orange Book listings rarely present legitimate business justifications—they either comply with statutory requirements or they don't.[65] This binary nature simplifies some analytical challenges while creating new complexities around interpreting statutory language and congressional intent.

The evolution of judicial standards reflects growing understanding of how regulatory gaming differs from traditional exclusionary conduct. Early decisions often adopted mechanistic approaches, focusing primarily on whether patent claims could theoretically cover accused generic products regardless of the relationship to approved drug products.[66] Modern decisions demonstrate

[64] *See* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 594-95 (1985).
[65] *See* United States v. Microsoft Corp., 253 F.3d 34, 58-59 (D.C. Cir. 2001).
[66] *See*, e.g., Alphapharm Pty Ltd. v. Thompson, 330 F. Supp. 2d 1, 6-7 (D.D.C. 2004).

more sophisticated analysis that examines the economic purpose and competitive effects of listings, not merely technical compliance with patent claim drafting conventions. Recent cases like *Jazz Pharmaceuticals v. Avadel* illustrate this evolution toward substance over form.[67] The court found that a patent claiming only a computer system for managing drug distribution did not meet statutory requirements despite being technically related to the drug product.[68] This decision reinforces the principle that Orange Book listings must protect genuine pharmaceutical innovations rather than ancillary business processes or convenience features.

The increased judicial willingness to scrutinize Orange Book listings signals broader recognition that regulatory gaming undermines both consumer welfare and regulatory integrity. Courts now explicitly acknowledge that the FDA's ministerial role creates opportunities for strategic manipulation requiring antitrust intervention.[69] This evolving approach suggests that companies can no longer rely on technical compliance with patent claim language to shield obvious gaming strategies from antitrust scrutiny. The implications for pharmaceutical competition are profound. As courts apply heightened scrutiny to Orange Book listings, companies must more carefully evaluate their patent filing strategies to avoid antitrust liability.[70] The focus on economic substance rather than technical form means that patents must have genuine relevance to pharmaceutical innovations to merit Orange Book protection. This evolution represents a crucial development in addressing one of the most significant barriers to generic competition in modern pharmaceutical markets.

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[67] Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC, 60 F.4th 1373, 1378-79 (Fed. Cir. 2023).
[68] *Id*. at 1379-80.
[69] *See* In re Actos End-Payor Antitrust Litig., 417 F. Supp. 3d 352, 368-69 (S.D.N.Y. 2019).
[70] *See* Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharm. of N.Y., LLC, 736 F. Supp. 3d 227, 239-41 (D. Del. 2024).

IV. Market Access Restrictions: The Rebate Agreement Strategy

Pharmacy Benefit Managers (PBMs) play a significant role in controlling drug formularies, which can impact patient access to medications. Exclusive rebate agreements with PBMs can limit the availability of generic alternatives, affecting market competition.[71] While Orange Book listing abuse represents a regulatory gaming approach to limiting competition, exclusive rebate agreements with PBMs and insurers constitute a fundamentally different but equally powerful market-based exclusionary strategy.[72] These agreements exploit the complex intermediated structure of pharmaceutical markets, where patients rarely pay the full price of medications directly, creating opportunities for companies to maintain market dominance through contractual arrangements that foreclose competitors despite superior products or lower prices. The sophistication of modern rebate strategies reflects an understanding that controlling access points—rather than simply protecting patents—can effectively preserve market power in an era of increasing generic competition.

IV.A. The PBM-Controlled Distribution System

The architecture of pharmaceutical distribution creates multiple gatekeepers between manufacturers and patients, with PBMs occupying a particularly critical position. The three largest PBMs—CVS Caremark, Express Scripts, and OptumRx—control approximately 75% of the market, wielding enormous influence over which drugs patients can access through their insurance plans.[73] These organizations operate through complex business models involving multiple revenue streams: administrative fees from health plans, rebates and fees from pharmaceutical manufacturers, spread pricing between acquisition and reimbursement costs, and pharmacy

[71] FTC Sanofi Brief, *supra* note 6.
[72] Fed. Trade Comm'n, 6(b) Report on Pharmacy Benefit Managers 15-18 (2024).
[73] Fed. Trade Comm'n, Report on Pharmacy Benefit Managers and the Reimbursement of Prescription Drugs 12 (2024).

network management fees.[74] This intricate structure creates potential conflicts of interest, as PBMs may have incentives to favor drugs that provide higher rebates over those that offer better value to patients or health plans.

Formulary placement represents the primary mechanism through which PBMs control market access. Modern formularies typically employ multi-tier structures with progressively higher patient cost-sharing requirements for non-preferred drugs. Tier placement can dramatically affect utilization patterns, with studies showing that moving a drug from preferred to non-preferred status can shift market share by 20-40% or more.[75] The power to exclude drugs entirely from formularies—or to impose burdensome prior authorization requirements—gives PBMs tremendous leverage in negotiations with pharmaceutical manufacturers. Companies understand that formulary exclusion can devastate market share regardless of clinical superiority or competitive pricing, creating strong incentives to negotiate exclusive or preferential rebate arrangements.[76]

IV.B. Case Study: The EpiPen Exclusive Dealing Strategy

The *Sanofi v. Mylan* litigation (the "EpiPen Case") centered on epinephrine auto-injectors provides a detailed case study of how exclusive rebate agreements can foreclose competition and harm consumers.[77] Mylan's EpiPen dominated the market not through superior clinical outcomes or competitive pricing, but through a sophisticated web of exclusive and near-exclusive rebate agreements with major PBMs and Group Purchasing Organizations (GPOs).[78] These agreements typically required 95-100% market share maintenance in exchange for substantial rebates, creating

[74] Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics 12-15 (2017).
[75] *See* Haiden A. Huskamp et al., The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending, 349 NEW ENG. J. MED. 2224, 2230 (2003).
[76] *See* In re EpiPen Direct Purchaser Litig., 2018 WL 3990327, at *10-11 (D. Kan. Aug. 21, 2018).
[77] Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959, 963-64 (10th Cir. 2022).
[78] *Id*. at 967-68.

arrangements that competitors could not effectively challenge regardless of their products' relative merits.[79] In the EpiPen case, Sanofi challenged Mylan's exclusive rebate agreements, alleging that they foreclosed competition and maintained Mylan's market dominance. This case illustrates the competitive effects of rebate agreements on market access.[80]

The structure of Mylan's agreements reveals the sophisticated anticompetitive potential of modern rebate strategies. Contracts included significant financial penalties—often millions of dollars annually—if market share fell below specified thresholds, creating powerful incentives for PBMs to exclude competing products entirely rather than risk penalty payments.[81] Some agreements employed bundling arrangements that tied EpiPen rebates to purchasing decisions for other Mylan products, leveraging portfolio effects to strengthen exclusionary power.[82] Perhaps most significantly, several major plans provided coverage only for EpiPen, completely excluding competitors like Sanofi's Auvi-Q from their formularies despite the latter's innovative features and competitive pricing.[83]

The competitive effects of these exclusive arrangements proved dramatic and persistent. Despite offering significant price discounts and distinguishing features like voice prompts and compact design, Auvi-Q faced complete formulary exclusion from major PBMs covering 60-70% of the epinephrine auto-injector market.[84] This created a paradoxical situation where price competition failed to function—Sanofi could not secure formulary access despite offering substantially lower net prices to payers. The exclusive contracts effectively nullified clinical advantages and prevented patients from accessing potentially superior products, illustrating how

[79] *Id*. at 969-70.
[80] FTC Sanofi Brief, *supra* note 6.
[81] *Id*. at 970.
[82] In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., 336 F. Supp. 3d 1256, 1265 (D. Kan. 2018).
[83] Sanofi-Aventis U.S. LLC, 44 F.4th at 972-73.
[84] *Id*. at 972.

formulary control can completely override normal competitive mechanisms. The Tenth Circuit's analysis in *Sanofi v. Mylan* applied traditional exclusive dealing principles while recognizing the unique characteristics of pharmaceutical markets.[85] The court examined the percentage of market foreclosed by exclusive arrangements, finding that contracts covering such a substantial portion of sales raised serious competitive concerns.[86] Importantly, the decision recognized that exclusive contracts created switching costs and inertia effects extending beyond formal contract terms—once established on formularies, drugs benefit from prescriber familiarity and patient adaptation that competitors struggle to overcome.

However, the court also grappled with Mylan's efficiency justifications for exclusive arrangements. The defendant argued that such contracts promoted efficiencies through volume commitments, reduced administrative complexity, and enabled better formulary management for PBMs. The court required rigorous proof that claimed efficiencies were genuine and consumer-benefiting rather than merely convenient justifications for exclusionary conduct.[87] This careful analysis reflects growing judicial sophistication in evaluating efficiency claims in complex vertical relationships.

IV.C. Comparative Analysis: Market Access v. Regulatory Gaming

Exclusionary theories in pharmaceutical antitrust cases vary depending on the conduct at issue. While regulatory gaming focuses on exploiting legal frameworks, market access strategies involve contractual arrangements that limit competition.[88] Comparing market access restrictions to regulatory gaming reveals important differences in legal treatment and enforcement challenges.[89]

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[85] *Id*. at 977-78.
[86] *Id*. at 979-80.
[87] *Id*. at 980-81.
[88] FTC Sanofi Brief, *supra* note 6.
[89] *See* C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 654-58 (2009).

While regulatory gaming cases focus on statutory compliance and manipulation of government processes, market access cases must navigate traditional antitrust analysis of vertical relationships and exclusive dealing.[90] Courts apply different standards of review, with market access cases generally requiring more extensive economic analysis of foreclosure effects and efficiency justifications.[91] The evidentiary burden in exclusive dealing cases often proves higher than in regulatory gaming cases, where statutory violations may speak for themselves.[92]

The treatment of industry practices as competitive benchmarks also differs markedly between the two contexts. In Orange Book cases, statutory compliance provides clear benchmarks independent of industry customs—patents either meet listing requirements or they don't. Market access cases must evaluate practices against shifting industry norms, creating analytical challenges when rebate agreements or formulary management practices become widespread. Courts must distinguish between practices representing efficient responses to market conditions and those constituting coordinated exclusionary strategies.

The analytical framework for market access restrictions requires sophisticated understanding of multi-level vertical relationships in pharmaceutical distribution. Market definition challenges often arise regarding whether different drug products or delivery mechanisms belong in the same relevant market.[93] Geographic market definition can vary depending on regional payer concentration and regulatory differences, while temporal considerations must account for dynamic competition and entry patterns over time.[94] Foreclosure analysis in these markets involves both quantitative assessment of market share covered by exclusive arrangements and qualitative

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[90] *Compare* In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 16 (1st Cir. 2020), *with* Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959, 977-78 (10th Cir. 2022).
[91] *See* Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327-29 (1961).
[92] *Compare* Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC, 60 F.4th 1373, 1378-79 (Fed. Cir. 2023), *with* LePage's Inc. v. 3M, 324 F.3d 141, 159-60 (3d Cir. 2003) (en banc).
[93] *See* Actavis Elizabeth LLC v. Mylan Tech. Inc., 2021 WL 4145267, at *7-9 (D. Del. Sept. 13, 2021).
[94] *See* FTC v. Arch Coal, Inc., 329 F. Supp. 2d 109, 126-27 (D.D.C. 2004).

evaluation of the strategic importance of foreclosed outlets.[95] Duration effects from long-term contracts and automatic renewal provisions can enhance anticompetitive effects, as can switching costs and network externalities that make formulary changes particularly costly for PBMs and patients.[96]

Efficiency defenses carry particular weight in market access cases compared to regulatory gaming contexts.[97] Courts recognize that exclusive dealing arrangements can generate legitimate efficiencies through volume economies, administrative simplification, and improved supply chain management.[98] However, they increasingly demand specific evidence of these benefits rather than accepting general theoretical claims.[99] The challenge lies in distinguishing between arrangements that genuinely enhance efficiency and those that primarily serve to exclude competitors.

The consumer welfare implications of market access restrictions often prove more complex than those arising from regulatory gaming.[100] While Orange Book abuse typically creates straightforward price effects through delayed generic entry, exclusive rebate agreements can maintain high list prices while providing selected benefits through rebates that may or may not reach consumers.[101] This creates analytical challenges in measuring actual consumer harm, particularly given the opacity of rebate arrangements and the indirect ways benefits may flow to patients.[102] Market access restrictions also interact with insurance intermediation in ways that can

[95] *See* Dentsply Int'l, Inc. v. FTC, 399 F.3d 181, 189-91 (3d Cir. 2005).
[96] *See* United Shoe Mach. Corp. v. United States, 347 U.S. 521, 527-28 (1954).
[97] *See* Microsoft Corp., 253 F.3d at 84-85.
[98] *See* Roland Mach. Co. v. Dresser Indus., Inc., 749 F.2d 380, 393-94 (7th Cir. 1984).
[99] *See* FTC v. Actavis, Inc., 570 U.S. 136, 158-59 (2013).
[100] *See* Herbert Hovenkamp, Antitrust and the Regulatory Enterprise, 2004 COLUM. BUS. L. REV. 335, 375-78.
[101] Fed. Trade Comm'n, Report on Pharmacy Benefit Managers and the Reimbursement of Prescription Drugs 8-12 (2024).
[102] *See* Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics 12-15 (2017).

obscure consumer harm.[103] Patients may face stable copayments despite exclusionary arrangements that prevent competition and raise total system costs. These effects ultimately manifest through higher insurance premiums, increased deductibles, and formulary restrictions that limit treatment options, but the causal connections prove more difficult to demonstrate than direct price effects from delayed generic entry.

The evolution of market access strategies reflects the pharmaceutical industry's adaptation to changing competitive and regulatory environments. As regulatory gaming faces increased scrutiny and enforcement, companies have shifted toward more sophisticated contractual arrangements that achieve similar exclusionary effects while presenting plausible business justifications. This strategic evolution suggests that effective competition policy must address both regulatory gaming and market access restrictions as complementary elements of modern pharmaceutical competition strategy. Understanding these market access mechanisms proves crucial for comprehending the full scope of challenges facing pharmaceutical competition. The next section examines the broader competitive effects of regulatory gaming, providing quantitative evidence of consumer harm and analyzing how these practices interact with market access restrictions to create system-wide barriers to competition.

V. The Competitive Effects of Regulatory Gaming

The competitive consequences of regulatory gaming extend far beyond immediate barriers to market entry, creating systemic distortions that undermine both static efficiency and dynamic innovation incentives throughout pharmaceutical markets.[104] Regulatory gaming, such as Orange Book listing abuse, can directly foreclose competition by delaying generic entry. The 30-month

[103] *See* David A. Hyman & William E. Kovacic, Institutional Design, Agency Life Cycle, and the Goals of Competition Law, 81 FORDHAM L. REV. 2163, 2179-82 (2013).
[104] *See* C. Scott Hemphill & Bhaven N. Sampat, When Do Generics Challenge Drug Patents?, 8 J. EMPIRICAL LEGAL STUD. 613, 638-40 (2011).

stay provision creates a significant barrier to market entry, impacting consumer access to affordable medications.[105] While the 30-month stay mechanism provides the most visible manifestation of regulatory gaming's anticompetitive effects, the deeper impact lies in how these practices fundamentally alter competitive dynamics, resource allocation decisions, and innovation pathways within the industry.[106] Understanding these multifaceted effects requires examining both quantifiable harms to consumers and the subtler ways regulatory gaming corrupts the intended balance between patent protection and generic competition.

V.A. Direct Exclusionary Effects

The automatic 30-month stay provision represents regulatory gaming's most direct exclusionary mechanism, creating an immediate and formidable barrier to generic entry that operates independently of patent validity or infringement likelihood.[107] FTC studies document that improper Orange Book listings delay generic entry by an average of 17 months, with some cases showing delays exceeding 30 months when multiple patents are listed or challenges are strategically timed.[108] These delays generate enormous value for brand manufacturers—each month of preserved monopoly can yield tens or hundreds of millions in revenue for blockbuster drugs, creating powerful incentives for aggressive listing strategies regardless of their ultimate legal viability.[109] The compound effects of multiple improper listings multiply these delays substantially.[110] When brand manufacturers list dozens of patents with questionable relevance,

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[105] FTC Sanofi Brief, *supra* note 6.
[106] *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study 41-45 (2002).
[107] 21 U.S.C. § 355(j)(5)(B)(iii) (2018); see also Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 8-10 (2010).
[108] Fed. Trade Comm'n, Notice of Proposed Rulemaking to Solicit Public Comments on Challenges and Barriers to Generic Drug Competition Federal 2023).
[109] *See* Robin C. Feldman & Evan Frondorf, Drug Wars: A New Generation of Generic Pharmaceutical Delay, 53 HARV. J. ON LEGIS. 499, 528-30 (2016).
[110] *See* Michael A. Carrier & Daryl Wander, Citizen Petitions: An Empirical Study, 34 CARDOZO L. REV. 249, 267-70 (2012).

generic companies face the daunting prospect of challenging each listing individually or accepting extended delays. The cumulative effect can extend market exclusivity far beyond any individual 30-month stay period, as generics must navigate a gauntlet of sequential challenges that may stretch over years. This strategic use of procedural complexity transforms what should be precise patent protections into sprawling exclusionary zones that deter many potential competitors from even attempting market entry.[111]

V.B. Indirect Market Distortions

Beyond direct exclusion, regulatory gaming creates cascading delays throughout the generic approval process that persist even after improper listings are corrected. Generic manufacturers must allocate substantial resources to litigating questionable patents rather than developing products or improving manufacturing efficiency.[112] These diverted resources represent a deadweight loss to the economy, as skilled scientists and engineers spend time in courtrooms rather than laboratories. The regulatory uncertainty created by inconsistent listing standards further complicates investment decisions, as companies struggle to predict which patents might generate 30-month stays and which might face successful challenges.[113]

The indirect competitive harms from regulatory gaming prove even more pernicious than direct exclusion because they operate through subtle market mechanisms that distort long-term competitive dynamics.[114] Indirect harms from regulatory gaming include distorting competitor planning and deterring potential market entry. These effects can extend the monopoly pricing

[111] *See* C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 667-69 (2009).
[112] *See* Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 MICH. L. REV. 37, 55-57 (2009).
[113] Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book 3-5 (2024).
[114] *See* Robin C. Feldman, Rethinking Patent Law 174-78 (2012).

period for brand-name drugs, further harming consumers.[115] Potential generic entrants must factor the likelihood and cost of patent litigation into their development decisions, creating a risk premium that particularly disadvantages smaller companies with limited litigation budgets.[116] This effect compounds over multiple product markets, as companies known for aggressive regulatory gaming develop reputations that deter challenges even for patents of questionable validity.

Capital market effects amplify these distortions as investors become increasingly cautious about funding generic development for products subject to extensive regulatory gaming.[117] The asymmetric risk structure—where generics face downside litigation costs while brands capture upside from successful delays—skews investment decisions away from generic competition toward other opportunities. This dynamic proves particularly problematic for complex generics or biosimilars, where development costs already create substantial barriers to entry without the additional burden of litigation risk.[118]

V.D. Systemic Effects on Innovation and Competition

Regulatory gaming can have significant implications for consumer welfare, including higher drug prices and limited access to medications.[119] These practices can also stifle innovation by reducing the incentives for generic manufacturers to enter the market.[120] The extension of monopoly pricing periods through regulatory gaming creates consumer harm measurable in billions of dollars annually.[121] The FTC estimates that pay-for-delay settlements alone cost consumers $3.5 billion yearly, while improper Orange Book listings contribute additional billions

[115] FTC Sanofi Brief, *supra* note 6.
[116] *See* Henry Grabowski & John Vernon, Effective Patent Life in Pharmaceuticals, 19 INT'L J. TECH. MGMT. 98, 109-11 (2000).
[117] Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study 41-45 (2002).
[118] Fed. Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact 12-15 (2011).
[119] *Id*.
[120] FTC Sanofi Brief, *supra* note 6.
[121] *See* Fed. Trade Comm'n, Report on Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Executive Summary at iii-v (2011).

in anticompetitive harm.[122] These estimates likely understate total consumer impact, as they focus on direct price effects without capturing broader systemic consequences. The Lantus case exemplifies the magnitude of potential harm—delayed biosimilar entry cost consumers an estimated $3.7 billion in excess costs, representing just one product in one therapeutic area.[123]

Consumer price effects persist beyond immediate delay periods through established prescribing patterns and patient switching costs. Even after generic or biosimilar entry occurs, the effects of regulatory gaming continue to influence market dynamics.[124] Physicians develop familiarity with branded products during delay periods, creating inertia that generic entrants must overcome.[125] Patients experience similar adaptation effects, particularly for chronic conditions requiring stable therapy or for devices with learning curves like auto-injectors or inhalers.[126]

The distributional effects of regulatory gaming fall disproportionately on vulnerable populations who face the greatest barriers to accessing medications.[127] Uninsured patients bear the full brunt of monopoly pricing during delay periods, while those in high-deductible health plans face substantial out-of-pocket costs before insurance coverage begins.[128] These effects exacerbate existing health disparities, as patients with limited financial resources may delay or forego treatment during periods when monopoly pricing restricts access to medications. Regulatory gaming undermines the fundamental integrity of the Hatch-Waxman framework, which sought to

[122] Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 6 (2010).
[123] In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 16 (1st Cir. 2020).
[124] *See* Frank R. Lichtenberg, Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS, HEALTH AFF., Sept.-Oct. 2001, at 241, 251-52.
[125] Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 15-18 (2010).
[126] Fed. Trade Comm'n, Report on Authorized Generic Drugs: Short-Term Effects and Long-Term Impact 25-28 (2011).
[127] Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics 18-22 (2017).
[128] *See* Karen Davis et al., How High Is Too High? Implications of High-Deductible Health Plans, COMMONWEALTH FUND at 12-15 (2005).

balance innovation incentives with timely generic competition.[129] The Act's architects assumed that clear boundaries existed between legitimate patent protection and anticompetitive exclusion, an assumption that sophisticated gaming strategies have thoroughly demolished.[130] When companies can routinely extend exclusivity beyond intended bounds through regulatory manipulation, the carefully crafted balance between innovation and competition collapses.

The proliferation of regulatory gaming creates network effects as successful strategies spread throughout the industry.[131] Companies observe others' gaming successes and adopt similar approaches, leading to an arms race of increasingly aggressive tactics.[132] Law firms and consultants develop specialized expertise in gaming strategies, creating institutional knowledge that facilitates industry-wide adoption of exclusionary practices.[133] This dynamic transforms regulatory gaming from isolated incidents into standard competitive practice that company executives feel obligated to pursue to remain competitive.

Perhaps most troubling, regulatory gaming corrupts the competitive process itself by shifting focus from merit-based competition toward manipulation of legal and regulatory systems.[134] When companies can maintain market position through gaming rather than innovation or efficiency, resources flow away from productive activities toward rent-seeking behavior.[135] This reallocation represents a fundamental misallocation of scarce resources that should support

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[129] *See* Henry G. Grabowski & John M. Vernon, Longer Patents for Lower Imitation Barriers: The 1984 Drug Act, 76 AM. ECON. REV. 195, 196-97 (1986).
[130] *See* S. REP. NO. 98-442, at 4-5 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2651-52.
[131] *See* C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1588-91 (2006).
[132] *See* Robin C. Feldman & Evan Frondorf, Drug Wars: A New Generation of Generic Pharmaceutical Delay, 53 HARV. J. ON LEGIS. 499, 537-40 (2016).
[133] Lisa Barons Pensabene & Dennis Gregory, Hatch-Waxman Act: Overview, PRAC. L. PRAC. NOTE OVERVIEW 9-523-2397 (2025).
[134] Stacey L. Dogan & Mark A. Lemley, Antitrust Law and Regulatory Gaming, 87 TEX. L. REV. 685, 700-05 (2009).
[135] *See* Anne O. Krueger, The Political Economy of the Rent-Seeking Society, 64 AM. ECON. REV. 291, 299-301 (1974).

genuine pharmaceutical innovation and competition.[136] The systemic nature of these effects means that addressing regulatory gaming requires comprehensive reforms rather than piecemeal enforcement actions. Individual cases may correct specific violations, but the underlying incentive structure continues to reward gaming strategies. Only by addressing the fundamental vulnerabilities in the regulatory framework—such as the FDA's ministerial role in patent listing and the automatic nature of 30-month stays—can policy makers hope to eliminate the systemic distortions created by regulatory gaming.[137]

Empirical research corroborates these theoretical concerns through documented patterns of increased gaming and its associated costs.[138] Studies show that Orange Book listings have increased by over 150% since 2005, with device and method patents comprising 80% of this growth.[139] Academic research by Grabowski, Vernon, and others documents systematic patterns of delayed generic entry correlated with aggressive patent listing strategies, while international comparisons reveal that countries with different regulatory frameworks experience markedly different patterns of generic competition.[140] The evidence overwhelmingly demonstrates that regulatory gaming imposes substantial costs on consumers and the healthcare system while corrupting the intended balance between innovation incentives and competitive access. These effects compound over time and across markets, creating systemic distortions that require equally systematic policy responses. The following section examines how these competitive effects

[136] Fed. Trade Comm'n, Enhancing Competition in the Pharmaceutical Industry 15-18 (2024).
[137] *See* Fed. Trade Comm'n, Enhancing Competition in the Pharmaceutical Industry, at 12-15 (2024).
[138] *See* Robin Feldman & Evan Frondorf, Drug Wars: A New Generation of Generic Pharmaceutical Delay, 53 HARV. J. ON LEGIS. 499, 519-24 (2016).
[139] *See* Ariel Dora Stern, Innovation Under Regulatory Uncertainty: Evidence from Medical Technology, 124 J. POL. ECON. 539, 568-71 (2017).
[140] *See* Henry G. Grabowski & Margaret Kyle, Generic Competition and Market Exclusivity Periods in Pharmaceuticals, 28 MANAGERIAL & DECISION ECON., 491-502 (2007).

translate into consumer welfare implications and explores frameworks for more accurately measuring the true cost of regulatory gaming in pharmaceutical markets.

VI. Conclusion

The Mylan v. Sanofi litigation highlights the challenges of regulatory gaming in the pharmaceutical industry and its impact on competition and consumers.[141] The case underscores the need for effective antitrust enforcement and regulatory reforms to address these challenges.[142] The Mylan-Sanofi litigation wars illuminate a fundamental crisis in pharmaceutical competition, where sophisticated companies have weaponized regulatory frameworks designed to promote innovation and generic competition into tools for preserving monopoly power. This comprehensive analysis reveals that regulatory gaming and market access restrictions represent more than isolated instances of corporate overreach—they constitute systematic efforts to exploit structural vulnerabilities in the Hatch-Waxman Act and FDA oversight mechanisms that ultimately impose billions of dollars in costs on consumers and the healthcare system.

The comparative analysis of different antitrust theories demonstrates that regulatory gaming through Orange Book listing abuse has proven particularly amenable to judicial challenge when focused on clear statutory violations.[143] Courts have shown increasing willingness to scrutinize device patents and process-related listings, with the First Circuit's decision in *In re Lantus* establishing a crucial precedent that regulatory gaming through improper listings constitutes actionable anticompetitive conduct.[144] The evolution from formalistic interpretation of patent

[141] *See* Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC, No. 2:23-cv-836 (W.D. Pa. filed May 17, 2023); Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959 (10th Cir. 2022).
[142] FTC Sanofi Brief, *supra* note 6.
[143] *Compare* In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 15-16 (1st Cir. 2020), with Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959, 977-81 (10th Cir. 2022).
[144] In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 15-16 (1st Cir. 2020).

claims toward substantive examination of economic purpose represents a significant judicial development that promises more effective enforcement against Orange Book abuse.[145]

Exclusive dealing claims through rebate agreements face higher evidentiary burdens and present greater analytical challenges, though successful cases like *Sanofi v. Mylan* demonstrate that courts will rigorously examine market foreclosure effects when exclusive arrangements cover substantial portions of relevant markets.[146] The sophistication required to prove exclusive dealing violations—involving complex economic analysis of PBM market dynamics, formulary placement effects, and efficiency justifications—makes these cases more resource-intensive but potentially more impactful when successful.[147]

The real-world consumer impact extends far beyond abstract competitive concerns, with documented harm measured in billions of dollars annually.[148] The delayed entry of Lantus biosimilars alone cost consumers an estimated $3.7 billion, while EpiPen's price increases through exclusive contracting imposed additional billions in costs.[149] These figures likely understate total harm, as they focus primarily on direct price effects without fully capturing access barriers, health outcome consequences, or broader systemic distortions in pharmaceutical innovation and competition.[150]

The analysis reveals that successful pharmaceutical companies increasingly employ both regulatory gaming and market access restrictions as complementary strategies, creating multi-layered barriers to competition that prove particularly difficult for smaller generic manufacturers

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[145] *Compare* Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191, 194-95 (D.D.C. 2002), with Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharm. of N.Y., LLC, 124 F.4th 898, 906-07 (Fed. Cir. 2024).
[146] Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959, 979-81 (10th Cir. 2022).
[147] Fed. Trade Comm'n, Report on Pharmacy Benefit Managers 45-48 (2024).
[148] *See* Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 6 (2010).
[149] *Compare* In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 16 (1st Cir. 2020), with In re EpiPen Direct Purchaser Litig., 2018 WL 3990327, at *1 (D. Kan. Aug. 21, 2018).
[150] *See* Robin C. Feldman, The Role of Science in Law 87-91 (2009).

to overcome.[151] The complexity and cost of challenging these varied exclusionary practices effectively filter out many potential competitors, concentrating market power among companies with sufficient resources to engage in sophisticated gaming strategies while simultaneously defending against similar tactics from rivals.[152]

The broader implications of pharmaceutical antitrust enforcement include evolving standards for exclusionary conduct and the integration of consumer welfare considerations.[153] These developments reflect the ongoing efforts to balance patent protection with competition in the pharmaceutical industry.[154] The evolution of exclusionary conduct standards in pharmaceutical markets reflects growing judicial sophistication in analyzing complex regulatory schemes and their competitive effects.[155] Courts increasingly distinguish between legitimate exploitation of intellectual property rights and anticompetitive manipulation of government processes, moving beyond technical compliance with regulations toward substantive examination of economic purpose and consumer impact.[156] This development suggests that companies can no longer rely solely on formal adherence to patent claim language or contract terms to shield obvious gaming strategies from antitrust scrutiny.

The integration of consumer welfare considerations has progressed beyond traditional price-focused analysis to encompass broader measures including access barriers, health outcomes, and

[151] *See* C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 655-69 (2009).
[152] *See* Michael A. Carrier & Daryl Wander, Citizen Petitions: An Empirical Study, 34 CARDOZO L. REV. 249, 282-85 (2012).
[153] *See* Richard J. Gilbert & A. Douglas Melamed, Antitrust For Innovation: A Progress Report, GW Competition & Innovation Lab Working Paper Series, No. 2024/9, at 35-38 (Feb. 21, 2024).
[154] FTC Sanofi Brief, *supra* note 6.
[155] Overview of FTC Actions in Pharmaceutical Products and Distribution, Fed. Trade Comm'n 8-12 (Jan. 2025).
[156] *Compare* F.T.C. v. Actavis, Inc., 570 U.S. 136, 157-58 (2013), with Microsoft Corp., 253 F.3d 34, 58-59 (D.C. Cir. 2001).

innovation effects.[157] This evolution proves particularly crucial in pharmaceutical markets where insurance intermediation can obscure direct price impacts while creating substantial indirect harms through formulary restrictions, prior authorization requirements, and delayed development of competing products.[158] Courts and regulators increasingly recognize that effective consumer welfare analysis must account for the multiple ways pharmaceutical markets differ from typical consumer goods markets.

The coordination between regulatory and antitrust enforcement has emerged as critical for effective oversight of pharmaceutical markets.[159] The FDA's limited role in patent listing review creates gaps that antitrust enforcement must fill, while successful antitrust challenges can complement regulatory reforms by establishing clearer boundaries on acceptable conduct.[160] This complementary relationship suggests that future enforcement strategies should emphasize coordination between agencies rather than treating antitrust and regulatory oversight as separate

Several areas demand continued investigation to improve pharmaceutical antitrust enforcement.[161] Future research directions include empirical studies of regulatory gaming effects, comparative analysis across pharmaceutical submarkets, and international enforcement approaches. These studies can provide valuable insights into the effectiveness of antitrust enforcement and policy reforms in the pharmaceutical industry.[162] Empirical studies of regulatory gaming effects across different therapeutic areas and market segments could reveal patterns in

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[157] *See* Maurice E. Stucke, Should the Government Prosecute Monopolies?, 2009 COLUM. BUS. L. REV. 497, 571-75.
[158] Fed. Trade Comm'n & U.S. Dep't of Justice, Report on Patent Settlements in the Pharmaceutical Industry 35-38 (2016).
[159] Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book 1-2 (2024).
[160] *Compare* Apotex, Inc. v. Thompson, 347 F.3d 1335, 1346-47 (Fed. Cir. 2003), with F.T.C. v. Actavis, Inc., 570 U.S. 136, 157-58 (2013).
[161] *See* Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Executive Summary at i-iii (2017).
[162] FTC Sanofi Brief, *supra* note 6.

gaming strategies and identify markets most vulnerable to exclusionary conduct.[163] Longitudinal analysis tracking the evolution of gaming tactics and enforcement responses would help predict future developments and inform proactive policy responses.[164]

Comparative analysis of pharmaceutical competition across different regulatory frameworks could yield valuable insights into optimal system design.[165] Countries with alternative approaches to balancing patent protection and generic competition provide natural experiments for evaluating different policy choices.[166] Such research could inform reforms to address structural vulnerabilities in the current system while preserving innovation incentives. International enforcement approaches merit systematic study to identify best practices in pharmaceutical antitrust enforcement. Cross-border coordination becomes increasingly important as companies employ global strategies, and understanding how different jurisdictions address similar gaming tactics could improve enforcement effectiveness and reduce regulatory arbitrage opportunities.[167]

The pharmaceutical industry's evolution toward increasingly sophisticated regulatory gaming and market manipulation strategies poses fundamental challenges to the Hatch-Waxman Act's original vision of balanced innovation incentives and timely generic competition.[168] The current system's vulnerabilities—from the FDA's ministerial role in patent listing to automatic 30-month stays that reward improper listings—enable widespread gaming that ultimately harms the patients

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[163] *See* Henry G. Grabowski & Margaret Kyle, Generic Competition and Market Exclusivity Periods in Pharmaceuticals, 28 MANAGERIAL & DECISION ECON., 491-502 (2007).
[164] Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Generic Drug Access: Report to the Secretary of Health and Human Services 38-42 (2017).
[165] FDA Orange Book Patent Information and Submission Requirements, Practical Law Practice Note, Practical Law Intell. Prop. & Tech. (Thomson Reuters 2025).
[166] *See* Patricia M. Danzon & Adrian Towse, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 201-04 (2003).
[167] Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study 55-58 (2002).
[168] *See* Henry G. Grabowski & John M. Vernon, Longer Patents for Lower Imitation Barriers: The 1984 Drug Act, 76 AM. ECON. REV. 195, 196-97 (1986).

the system intends to serve.[169] Addressing these challenges requires recognition that piecemeal enforcement actions, while important, cannot correct systemic problems rooted in regulatory structure.[170] Comprehensive reform involving coordination between antitrust authorities, regulatory agencies, and lawmakers is essential to close the gaps that enable gaming while preserving legitimate protections for pharmaceutical innovation.[171] This includes modernizing the Orange Book framework, clarifying appropriate boundaries for rebate arrangements, and ensuring meaningful consequences for companies that manipulate regulatory systems to preserve market power beyond the intended scope of their patents.[172]

The stakes in this endeavor extend beyond economic efficiency or competitive dynamics—they encompass fundamental questions of health equity, innovation policy, and the role of markets in providing essential medical care.[173] When regulatory gaming and market manipulation prevent patients from accessing affordable medications, the entire healthcare system fails in its core mission.[174] The sophistication of modern gaming strategies demands equally sophisticated policy responses that can adapt to evolving tactics while maintaining clear principles about acceptable competitive conduct.[175] The Mylan-Sanofi litigation wars offer crucial lessons for this ongoing effort, demonstrating both the potential for antitrust enforcement to address gaming practices and

[169] *See* Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book 1-2 (2024).
[170] *See* C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 680-83 (2009).
[171] *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Generic Drug Access: Report to the Secretary of Health and Human Services 45-48 (2017).
[172] *See id*. at 48-52.
[173] Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Executive Summary at i-iii (2017).
[174] *See* Amy Kapczynski, The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism, 59 UCLA L. REV. 970, 1019-22 (2012).
[175] *See* Robin C. Feldman & Evan Frondorf, Drug Wars: A New Generation of Generic Pharmaceutical Delay, 53 HARV. J. ON LEGIS. 499, 540-44 (2016).

the limitations of relying on case-by-case litigation to correct systemic problems.[176] Success in creating truly competitive pharmaceutical markets that serve patient needs will require sustained commitment to enforcement, thoughtful regulatory reform, and continued vigilance against evolving exclusionary strategies.[177] Only through such comprehensive efforts can policymakers hope to achieve the Hatch-Waxman Act's original promise of innovation-driven pharmaceutical markets that provide broad access to both cutting-edge treatments and affordable generic alternatives.[178]

The ultimate test of any pharmaceutical competition policy lies not in its theoretical elegance but in its practical impact on patient access to needed medications.[179] As this analysis demonstrates, regulatory gaming imposes real costs measured in billions of dollars and delayed access to life-saving treatments.[180] Addressing these challenges represents both a moral imperative and an economic necessity for creating healthcare markets that truly serve the public interest.[181] The path forward requires continued academic research, policy innovation, and enforcement vigilance to ensure that pharmaceutical markets reward genuine innovation while preventing the manipulation of legal and regulatory systems to preserve unjustified market power.[182]

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[176] *Compare* Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC, No. 2:23-cv-836 (W.D. Pa. filed May 17, 2023), with Sanofi-Aventis U.S. LLC v. Mylan Inc., 44 F.4th 959 (10th Cir. 2022).
[177] Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 1-5 (2010).
[178] *See* S. REP. NO. 98-442, at 4-5 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2651-52.
[179] *See* Arti K. Rai, Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform, 103 COLUM. L. REV. 1035, 1125-28 (2003).
[180] *See* Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Stifle Competition 1-3 (2010).
[181] *See* Amy Kapczynski & Aaron S. Kesselheim, Government Patent Use: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFF. 791, 797-99 (2016).
[182] *See* Fed. Trade Comm'n, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Executive Summary at i-iii (2017).