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Pharmaceutical Antitrust Complexity

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I. INTRODUCTION

The pharmaceutical industry is unique in its complexity. Markets are nuanced. Multiple regulatory regimes apply. Generic entry is an event with dramatic consequences. These characteristics have encouraged brand-name drug firms to engage in an array of conduct that exploits this complexity to delay generic entry. This essay discusses these issues, focusing on two activities: (1) “product hopping” from one version of a drug to another and (2) settlements by which brands pay generics to delay entry.²

II. MARKETS

Pharmaceutical markets are complex. Unlike other markets, “the consumer who pays does not choose, and the physician who chooses does not pay.”³ This disconnect has created a gap that can be exploited. Brand firms can convince doctors to prescribe expensive drugs even if equally effective cheaper drugs are available. And brands have done so through an array of activity that includes samples, mailings, detailing (sales calls to doctor’s offices), sponsored continuing medical education programs, and advertising in media and medical journals.⁴

This range of activity entails significant expenditures, with brands often spending more on marketing than on research and development (“R&D”).⁵ And it has been effective. Just to give one example, nearly half the doctors in one study considered information provided by sales representatives important and almost one-third changed their prescribing behavior as a result.⁶

¹ Distinguished Professor, Rutgers Law School. Copyright © 2014 Michael A. Carrier.

² Brand firms have engaged in other activities that rely on complexity to block generic entry and that lie outside the scope of this article. *See, e.g.*, *Caraco Pharm. Labs v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (overbroad listing codes in Orange Book); *Actelion Pharms. v. Apotex Inc.*, Case 1:12-cv-05743-NLH-AMD (D.N.J. Oct. 21, 2013) (use of Risk Evaluation & Mitigation Strategy (REMS) to deny generic samples needed for bioequivalence testing); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 *CARDOZO L. REV.* 249 (2012) (use of citizen petitions to delay generic entry).

³ *DRUG PRODUCT SELECTION*, STAFF REPORT TO THE FTC 2-3 (Jan. 1979).

⁴ STUART O. SCHWEITZER, *PHARMACEUTICAL ECONOMICS AND POLICY* 87-93 (2d ed. 2007).

⁵ *Id.* at 82 (“While the R&D expenses varied between 11% and 15% of annual sales for [Johnson & Johnson, Pfizer, and Eli Lilly], marketing and promotional expenses ranged from 21% to 40% of annual sales.”); Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, XXXI *J. L. & ECON.* 299, 302 (1988) (“For many research-based firms the promotion budget can be twice to four times as large as the budget for research and development.”).

⁶ SCHWEITZER, at 85.

At the same time, drug firms have increased direct-to-consumer advertising, which has resulted in doctors acceding to patients' wishes and writing more prescriptions.⁷

III. REGULATORY REGIME

In addition to complex markets, the pharmaceutical industry is characterized by a complicated regulatory regime consisting of patent law, the Hatch-Waxman Act, and state drug product selection laws.

First is the patent system. The pharmaceutical industry has famously trumpeted the costs of bringing a drug to market and its need for patents.⁸ In product-hopping cases, brands highlight the benefits of their (often patented) reformulated drugs. And in settlement cases, brands seek to highlight the strength of their patents.⁹

The second aspect of the regulatory regime is the Hatch-Waxman Act, Congress's calibration of the patent and antitrust laws in the pharmaceutical industry.¹⁰ The Act fostered brand innovation through patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of generic approval.¹¹ And the Act increased generic competition by allowing experimentation on a drug during the patent term, letting generics rely on brands' safety and effectiveness studies, and providing 180 days of marketing exclusivity to the first generic (known as a "Paragraph IV filer") to challenge a brand's patent.¹²

Third are state drug product selection laws, which are in effect in all 50 states and are designed to lower prices to consumers. Absent a doctor's contrary instructions, these laws allow (and in some cases require) pharmacists to substitute generic versions of brand drugs. The laws address the disconnect between prescribing doctors who are not responsive to price and paying insurers and consumers who do not select the drug.¹³ In particular, they carve out a role for pharmacies, which vigorously compete on price with other pharmacies and which enjoy higher margins on generic drugs.¹⁴

IV. GENERIC ENTRY

The complexity of the pharmaceutical industry is accompanied by an event with dramatic consequences in the lifecycle of a drug: generic entry. The Federal Trade Commission ("FTC")

⁷ *Id.* at 98-99. See also National Institute for Health Care Management Foundation, *Prescription Drugs and Mass Media Advertising*, Sept. 2000, at 7, <http://www.nihcm.org/pdf/DTCbrief.pdf> ("doctors strive to please their patients").

⁸ PhRMA, *Intellectual Property Protections Are Vital to Continuing Innovation in the Biopharmaceutical Industry*, <http://www.phrma.org/innovation/intellectual-property> (last visited Oct. 15, 2014) (claiming \$1.2 billion cost to bring compound to market).

⁹ *E.g.*, *Time Ins. Co. v. AstraZeneca*, 2014 WL 4933025 (E.D. Pa. Oct. 1, 2014); *FTC v. Cephalon*, 2014 WL 3731753 (E.D. Pa. July 29, 2014).

¹⁰ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

¹¹ See generally Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 43-45 (2009).

¹² 21 U.S.C. § 355(j)(5)(B)(iv).

¹³ DRUG PRODUCT SELECTION, STAFF REPORT TO THE FTC 2-3 (Jan. 1979).

¹⁴ Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 46 (2009).

has concluded that, on average, a generic market matures one year after the first generic enters.¹⁵ At that time, the generic penetration rate is roughly 90 percent, with prices roughly 85 percent lower than the brand price before generic entry.¹⁶ Just to give one example (and using approximate figures), a 100-pill (oral 500-mg) bottle of the antibiotic ciprofloxacin that cost \$322 fell after generic entry to \$14, a 95 percent difference in price.¹⁷

The combination of complex markets, multiple regulatory regimes, and the dramatic event of generic entry sets the stage for an array of potentially anticompetitive behavior in the pharmaceutical industry. To be clear, not all the conduct discussed in this article is anticompetitive. Nonetheless, the complexity of these issues ensures that there at least is the potential for conduct that has serious anticompetitive effects.

V. PRODUCT HOPPING

A. Background

Product hopping (sometimes referred to as “evergreening” or “line extension”) refers to a brand firm’s reformulation of its product. Certain reformulations could provide benefits to patients. But others present concern, especially when the reformulations are exceedingly modest and occur on the eve of generic entry.

In an empirical survey of product hopping between 1995 and 2009, Steve Shadowen, Keith Leffler, & Joseph Lukens found that the product changes most likely to be part of a strategy to impair generic competition (81 of 425 total changes) occurred when reformulation occurred in the period from three years before U.S. Food and Drug Administration (“FDA”) approval of the reformulated product to one year after approval.¹⁸ And the authors concluded that the greatest antitrust concern was presented by the changes with “lowest therapeutic value,” such as from “a capsule to another pill form (i.e., a tablet, [orally dissolving] tablet, or chewable tablet)” or from “a tablet to another pill form (i.e., a capsule, [orally dissolving] tablet, or chewable tablet).”¹⁹ The authors also found concern with reformulations to extended-release capsules or tablets as part of a strategy of multiple product changes.²⁰

Reformulation interferes with the operation of state drug product selection (“DPS”) laws. These laws play a crucial role in lowering price by allowing pharmacists to substitute generic versions of brand drugs. Such substitution is possible, however, only if the generics are “AB-rated” by the FDA. To receive an AB rating, a generic drug must be pharmaceutically equivalent (having the same active ingredient, form, dosage, strength, safety, and efficacy) and bioequivalent (absorbed in the body at roughly the same rate).²¹

¹⁵ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (Jan. 2010).

¹⁶ *Id.*

¹⁷ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005).

¹⁸ Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, at 25, 27.

¹⁹ *Id.*

²⁰ *Id.* at 31.

²¹ Center For Drug Evaluation and Research, FDA, U.S. Department of Health and Human Services, *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations* (34th ed. 2014), <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm>.

The concern when a brand reformulates its drug is that the generic version of the original product is not bioequivalent or pharmaceutically equivalent to the reformulated product. And while the generic may eventually demonstrate equivalence, such a showing likely will not occur for years as the generic reformulates its product, seeks FDA approval, and awaits the expiration of the brand's 30-month stay of FDA approval.

Compounding this problem, and as discussed below (in the setting of the *Provigil* case), the brand typically will switch its promotional efforts to the reformulated drug, highlighting its advantages. At the same time, no other party has the incentive and ability to promote the original product, which leads to doctors receiving “an entirely one-sided presentation” of the relative merits of the products.²²

Product hopping is most successful when brands can not only avoid state DPS laws but also orchestrate effective timing. If brands can switch the market before generic entry, patients would not experience the benefits of lower prices and would be unlikely to make a second switch to the generic.²³ For example, in the *TriCor* case discussed below, the brand estimated that it would sell more than ten times as many tablets if it switched the market before generic entry.²⁴ And the European Commission has received similar comments from brands, such as: “Each patient that is not switched quickly enough” to the reformulated product is “forever lost to the generics.”²⁵

B. Case Law

Courts in the United States have considered antitrust issues presented by product hopping. In the two leading cases, they have focused on whether the brand removed the original product from the market.²⁶ In the first case, *Abbott Labs. v. Teva*, Abbott made a series of changes to its billion-dollar cholesterol and triglycerides drug TriCor.²⁷ It marginally lowered the drug's strength, switched from a capsule to a tablet, stopped selling capsules, bought back existing supplies of capsules from pharmacies, and changed the code for capsules in the national drug database to obsolete.²⁸ Even after the generics developed equivalents for the reformulated tablets, Abbott again transitioned to a new (marginally lower strength) tablet, stopped selling the original tablets, and changed the database code to obsolete.²⁹

The district court found that Abbott's “allegedly manipulative and unjustifiable formulation changes” prevented generics from offering “cost-efficient means of competing” in

²² Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, at 46.

²³ *Id.* at 55.

²⁴ *Id.* at 52.

²⁵ EUROPEAN COMMISSION, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT ¶ 1028 (2009).

²⁶ For important product-hopping cases in Europe, see General Court of the European Union, Press Release No 67/10 (AstraZeneca abused dominant position by delaying generic version of ulcer medication Losec through the provision of misleading information to patent offices and the deregistering of capsule marketing authorizations); Decision of the OFT, Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc OFT Decision CA98/02/2011 (2011) (Reckitt Benckiser abused dominant position by withdrawing Gaviscon, a medicine treating heartburn and acid reflux, to block generic competition).

²⁷ 432 F. Supp. 2d 408 (D. Del. 2006).

²⁸ *Id.* at 415-16.

²⁹ *Id.* at 418.

the market.³⁰ And it found that Abbott “allegedly prevented [consumer] choice by removing the original formulations from the market while introducing new formulations.”³¹ The court therefore denied Abbott’s motion to dismiss.

The second case involved AstraZeneca’s conversion from heartburn drug Prilosec to Nexium.³² The plaintiffs alleged that there was “almost no difference” between the drugs and that AstraZeneca was able to switch the market (to a drug receiving patent protection for an additional 13 years) only through “distortion and misdirection in marketing, promoting, and detailing Nexium.”³³

The court nonetheless granted AstraZeneca’s motion to dismiss, concluding that “there is no allegation that AstraZeneca eliminated any consumer choices,” but that, to the contrary, the company “added choices.”³⁴ Even if the court’s conclusion does not sufficiently wrestle with the complexity of pharmaceutical markets, the factual scenario differed from that in the *Teva* case, in which Abbott removed its original version from the market.

In fleshing out this framework, two recent cases bear watching. In the first, the plaintiffs are alleging that Warner Chilcott removed the original version of Doryx—a treatment for acne and bacterial infections—from the market, asked customers to return inventory, and made three product reformulations that “provided little or no benefit other than to exclude generic competition” and that were conceded to be “merely [] an anti-generic strategy.”³⁵

In the second case, the New York Attorney General has sued manufacturers of Alzheimer’s drug Namenda, alleging that they withdrew the original version and forced patients to switch to the reformulated version (which could be taken once, rather than twice, a day), with the switch allowing the defendants to reap “several more years” of patent protection and prevent generic substitution.³⁶

Product-hopping activity is complex. The typical “hard switch” case, in which the brand firm pulls the original drug off the market, often makes sense only if the purpose is to thwart the operation of state DPS laws and block generic entry. More nuance is presented by the “soft switch” case, in which the brand keeps the original drug on the market. But the conclusion that “two products are better than one” does not sufficiently grapple with the complexities of pharmaceutical markets, in which the buyer is not the decider and brands engage in a vast array of promotion activity to ensure that patients switch to the reformulated version.

VI. SETTLEMENTS

A. Court Decisions

A second category of behavior presenting complexity involves settlements by which brands pay generics to delay entering the market. The harms from this conduct resemble the

³⁰ *Id.* at 423.

³¹ *Id.* at 422.

³² *Walgreen Co. v. AstraZeneca Pharmaceuticals LP*, 534 F. Supp. 2d 146 (D.D.C. 2008).

³³ *Id.* at 148-49.

³⁴ *Id.* at 151.

³⁵ Complaint, *Mylan v. Warner Chilcott*, Case 2:12-cv-03824-PD, ¶¶ 3-5, 53, 55, 67 (E.D. Pa. Nov. 21, 2012).

³⁶ Complaint, *New York v. Actavis*, 14-CV-7473, ¶ 4 (S.D.N.Y., Sept. 15, 2014).

dangers of *per se* market division.³⁷ But instead of allocating geographic space, in which the parties reserve territories for themselves, they allocate time.³⁸ The brand and generic, in other words, agree that the brand will not be subject to competition for a period of time, thus dividing the market.

From 2005 to 2012, the settling parties justified their settlements by offering defenses—which courts adopted—based on the “scope of the patent,” pro-settlement policy, and presumption of patent validity.³⁹ But in 2013, in *FTC v. Actavis*, the Supreme Court rejected these defenses.⁴⁰

Regarding the scope-of-the-patent test, the Court found it “incongruous” to “determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”⁴¹ The Court found that reverse-payment settlements have the “potential for genuine adverse effects on competition” since “payment in return for staying out of the market . . . keeps prices at patentee-set levels.”⁴² And in fact, the size of the payment could serve as “a strong indicator of [market] power” and “provide a workable surrogate for a patent’s weakness.”⁴³

The Court also rejected defenses based on risk, stating that even strong patents are not immune from the concern with payments, as an unexplained payment on a “particularly valuable patent . . . likely seeks to prevent the risk of competition,” with this consequence “constitut[ing] the relevant anticompetitive harm.”⁴⁴ Finally, the Court found that the policy in favor of settlement did not immunize the agreements because of five arguments that centered on the (1) anticompetitive effects, (2) lack of justification, and (3) market power revealed by reverse payments, along with (4) the feasibility of judicial analysis, and (5) parties’ ability to settle without payment.⁴⁵

Despite these assertions, however, some lower courts have already sown ambiguity by ignoring the Court’s opinion. For example, the New Jersey district court in *In re Lamictal Direct Purchaser Antitrust Litigation* allowed defendants to justify their settlement on the grounds that it eliminated patent risk.⁴⁶ The Rhode Island district court in *In re Loestrin 24 FE Antitrust Litigation* somehow found in *Actavis* a deference to settlements that warranted antitrust scrutiny for cash, but not non-cash, settlements.⁴⁷ And that court, as well as the *Lamictal* court, ignored

³⁷ See *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (per curiam) (cited in *FTC v. Actavis*, 133 S. Ct. 2223, 2227 (2014)).

³⁸ *In re Schering-Plough Corp.*, 136 F.T.C. 956, 971 (2003), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

³⁹ *In re Ciprofloxacin*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). See generally Carrier, *Unsettling Drug Patent Settlements*, at 60-66.

⁴⁰ 133 S. Ct. 2223 (2013).

⁴¹ *Id.* at 2231.

⁴² *Id.* at 2235.

⁴³ *Id.* at 2236-37.

⁴⁴ *Id.* at 2236.

⁴⁵ *Id.* at 2234-37.

⁴⁶ 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

⁴⁷ 2014 WL 4368924, at *11 (D.R.I. Sept. 4, 2014).

Actavis' instruction that the risk of antitrust liability from payment "does not prevent litigating parties from settling their lawsuit"⁴⁸ in worrying that applying antitrust scrutiny to non-cash settlements would reduce patent litigants' ability to settle.⁴⁹

The *Lamictal* and *Loestrin* courts also inappropriately shifted several burdens to the plaintiffs. The *Lamictal* court provided an irrebuttable presumption that the settlement at issue was procompetitive based on its mere assertions that the agreement did not "have the potential for genuine adverse effects on competition," that the payment was justified, and that "the sweep of the settlement does not suggest that it is intended to maintain supracompetitive prices and serve as a 'workable surrogate for a patent's weakness.'"⁵⁰ And the *Loestrin* court raised the burdens to extremely high levels, requiring plaintiffs to show a payment's "true value" and asserting that the failure to make such a precise calculation would prevent them from showing each of the "factors" it expected plaintiffs to prove: anticompetitive effect, unjustified payment, market power, patent weakness, and the reasons for settlement.⁵¹

In short, antitrust analysis of settlements has become more complex because of court decisions that ignore or misconstrue crucial *Actavis* holdings. Analysis also is complex in the array of behavior that has recently been incorporated into settlements.

B. Complex Settlements and Product Hopping

One example of this complexity is presented by the use of settlements to effectuate a product-hopping strategy. Settlements that prevent patent challenges for a period of time can give the brand space in which it can comfortably switch the market to the new product.

Absent settlement, generics could challenge brand patents and demonstrate invalidity or non-infringement, opening the floodgates to generic entry and allowing pharmacists to substitute generics before the brand can switch the market to the reformulated product. In contrast, when a first-filing generic agrees not to challenge a patent, brands can guarantee that their patents will not be subject to challenge.⁵²

Just as important as certainty for the brand is the timing of this maneuver, which keeps generics off the market until the brand switches patients to the reformulated product. Once the brand shifts the market, after having raised the price of the original product and promoted the reformulated product, generic competition will not play a meaningful role. Settlements allow brands to ensure the effectiveness of a product-hopping strategy that otherwise would face the "risks" of generic competition and lower prices.

⁴⁸ *Actavis*, 133 S. Ct. at 2237.

⁴⁹ *Lamictal*, 2014 WL 282755, at *10; *Loestrin*, 2014 WL 4368924, at *11.

⁵⁰ *Lamictal*, 2014 WL 282755, at *10.

⁵¹ *Loestrin*, 2014 WL 4368924, at *9.

⁵² See Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1014-15 (2010) (discussing difficulties of non-sued generics obtaining declaratory judgment); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1586 (2006) (discussing later-filing generics' reduced incentives to pursue patent challenges).

One example of the use of settlements to promote product hopping is presented by Cephalon, which sought to switch the market from its sleep-disorder drug Provigil to modestly reformulated Nuvigil (which could be taken once, as opposed to twice, a day). Because the FDA had not yet approved Nuvigil before generic versions of Provigil were expected on the market, Cephalon paid the four first-filing generics \$200 million to delay entry for six years.⁵³ During this period, it stopped promoting Provigil (and raised the price 74 percent) while heavily promoting Nuvigil.⁵⁴ As the CEO conceded, the maneuver provided “six more years of patent protection,” which was “\$4 billion in sales that no one expected.”⁵⁵

C. Complex Settlements and Authorized Generics

Another form of conduct that has recently been incorporated into settlements is a brand’s promise that it will not launch an “authorized generic” (approved by the FDA as a brand but marketed as a generic⁵⁶) that would compete with the first-filing generic during the valuable 180-day exclusivity period reserved for first filers.⁵⁷ In its most recent survey, the FTC found that 19 of 40 potential reverse-payment settlements involved no-authorized-generic provisions.⁵⁸

The introduction of an authorized generic substantially lowers the first-filing generic’s sales and profits. The first-filing generic loses 25 percent of its market share when it competes with an authorized generic during the exclusivity period.⁵⁹ And the first-filer’s revenues are approximately twice as high during the period (with effects continuing afterwards⁶⁰) when it does not face competition from an authorized generic.⁶¹ At the same time, brands that promise not to introduce authorized generics cede revenue, as launches of these drugs during the 180-day period increase brands’ profits by 6 to 21 percent.⁶²

Even though the Supreme Court recognized that this period “can prove valuable” and could be worth “several hundred million dollars,”⁶³ two courts have concluded that such promises do not count as a “payment.” The *Lamictal* court found that “nothing in *Actavis*” indicated that “a no-[authorized-generic] agreement is a ‘payment.’”⁶⁴ The court found “[t]hat [the settling generic] was allowed early entry, that there was no payment of money, and that the duration of the No-[authorized-generic] Agreement was relatively brief,” which led it to

⁵³ Complaint for Injunctive Relief ¶¶ 3, 52, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008) (No. 08-0244), 2008 WL 446785.

⁵⁴ Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL ST. J., Nov. 17, 2008, at B1; Cephalon, Inc., Q4 2008 Earnings Call Transcript, SEEKINGALPHA.COM (Feb. 13, 2009).

⁵⁵ Cephalon Complaint ¶ 4.

⁵⁶ FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT i (2011).

⁵⁷ 21 U.S.C. § 355(j)(5)(b)(IV).

⁵⁸ FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2012 1 (2013).

⁵⁹ FTC, AUTHORIZED GENERIC REPORT, at 57.

⁶⁰ *Id.* at iii (revenues of the first-filing generic are 53 to 62% lower in the 30 months following exclusivity).

⁶¹ *Id.* at 58-59.

⁶² *Id.* at 62.

⁶³ 133 S. Ct. at 2229 (citation omitted).

⁶⁴ 2014 WL 282755, at *7 (D.N.J. Jan. 24, 2014).

conclude that “the settlement was reasonable and not of the sort that requires *Actavis* scrutiny.”⁶⁵ In fact, the court remarkably found that the brand’s promise—which, again, could be worth hundreds of millions of dollars according to the Supreme Court—did not even have the “potential for genuine adverse effects on competition.”⁶⁶

In the second case, the *Loestrin* court found that the plaintiffs were not able to show the existence of an anticompetitive effect because they did not calculate the “true value” of the no-authorized-generic clause (as well as other payments).⁶⁷ And the court manufactured requirements that plaintiffs must compare the brand’s expected monopoly profits to the size of the payment.⁶⁸ Having created these astronomical hurdles, the court then lamented that they undercut the Supreme Court’s decision in *Bell Atlantic Corp. v. Twombly*⁶⁹ (as plaintiffs filed “two robust complaints”) and provided an “obvious cue” to drug companies to “structure their settlements in ways that avoid cash payments” so as to “evade Sherman Act scrutiny.”⁷⁰

There should not be much nuance about whether there is a payment when a brand makes a promise worth millions of dollars to a generic. And in fact, most courts that have addressed the issue have more justifiably concluded that payments can include more than just cash.⁷¹ Nonetheless, the *Lamictal* and *Loestrin* courts’ misguided conclusions on this issue make it easy for the settling parties to introduce unneeded complexity and evade scrutiny.

D. Complex Settlements and Poison Pills

A third example of complexity in settlements is presented by “poison pill” or acceleration clauses. These promises ensure that a generic that has settled with a brand on terms providing for entry in the future can accelerate its entry if another generic enters the market earlier. These provisions frequently appear in settlements, with one observer noting that they are “a standard component of every settlement today.”⁷²

Poison pills increase complexity while reducing incentives for later-filing generics to file patent challenges. Absent such a clause, the settling generic is bound to the date, presumably years in the future, on which it agreed to enter. Even accounting for the running of the 180-day period reserved for the settling first-filer, the later generic winning a court decision finding the patent invalid or not infringed can enter the market before the settling generic.⁷³

⁶⁵ *Id.* at *9.

⁶⁶ *Id.* at *10.

⁶⁷ *In re Loestrin* 24 FE Antitrust Litigation, 2014 WL 4368924, at *9 (D.R.I. Sept. 4, 2014).

⁶⁸ *Id.*

⁶⁹ 550 U.S. 544 (2007).

⁷⁰ *Loestrin*, 2014 WL 4368924, at *11-12.

⁷¹ *In re Effexor XR* Antitrust Litigation, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca*, 2014 WL 4933025, at *3 (E.D. Pa. Oct. 1, 2014); *In re Lipitor* Antitrust Litigation, No. 3-12-cv-02389(PGS), at 30-31 (D.N.J. Sept. 12, 2014); *In re Niaspan* Antitrust Litigation, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014); *In re Nexium* (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

⁷² Hearing on H.R. 1706 before Subcomm. on Commerce, Trade, & Consumer Protection of H. Energy & Commerce Comm., 111th Cong., at 11 (2009) (testimony of Dr. Bernard C. Sherman).

⁷³ Under the Medicare Amendments of 2003, a later-filing generic is able to enter the market upon the later of (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding the patent invalid or not infringed. 21 U.S.C. §355(j)(5)(D)(i).

Settling generics are able to avoid this scenario through a poison-pill clause, which allows it to have the best of both worlds, drafting the later-filing, litigating generic as its risk-free surrogate ensuring its exclusivity. If the surrogate *loses* the patent case, the settling generic still can exploit its 180-day period, which is delayed under the settlement. And if the surrogate *wins*, the settling generic can show up on the scene after the hard work has been done, claiming the valuable 180-day period that the Hatch-Waxman Act reserves for first filers and that is triggered by the success of the litigating generic.⁷⁴

Complex poison-pill provisions have not yet been interpreted by courts. But when they are, they will present challenges. Courts need to be aware that the agreements provide significant value to generics and that they offer generics certainty that could not have been obtained through patent litigation.⁷⁵

E. Complex Settlements and Multiple Litigation

The final example of complexity in settlements is provided by agreements resolving multiple lawsuits. For example, in *In re Lipitor Antitrust Litigation*, the plaintiffs alleged that brand Pfizer paid generic Ranbaxy through a “sweetheart’ agreement to dismiss damages claims likely worth hundreds of millions of dollars in [unrelated] litigation in exchange for a token ‘pretextual’ payment of \$1 million” and “the right to market generic Lipitor in at least eleven foreign markets outside the United States.”⁷⁶

The *Lipitor* court required a non-cash payment to be “converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.”⁷⁷ But plaintiffs would not be able to make such a showing on a motion to dismiss, and *Actavis* made clear that it was defendants that had the burden of justifying payments for services.⁷⁸

In addition, the court added unneeded layers of complexity. It required plaintiffs to prove a patentee’s lost profits through showings of: “(1) demand for the product; (2) absence of noninfringing substitutes; (3) manufacturing and marketing capability; and (4) the amount of profit.”⁷⁹ Even more, some of these elements had subparts. For example, the amount of profit consisted of components including “the number of sales the patentee would have made, the price change for those sales, and the cost to produce and market same.”⁸⁰

At the same time, the court refused to consider relevant evidence. Pfizer’s CEO told company shareholders that “[Pfizer] had very, very substantial damages in the way of lost profits that we intend to recover from Ranbaxy” in the unrelated case.⁸¹ And in other litigation, a Pfizer

⁷⁴ 21 U.S.C. § 355(j)(5)(B)(iv)(I).

⁷⁵ See Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. ___ (forthcoming 2014), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2418685.

⁷⁶ No. 3-12-cv-02389(PGS), at 29.

⁷⁷ *Id.* at 32.

⁷⁸ *Actavis*, 133 S. Ct. at 2236.

⁷⁹ *Lipitor*, at 35.

⁸⁰ *Id.* at 35.

⁸¹ *Id.* at 40.

attorney asserted, “Pfizer will be claiming hundreds of millions of dollars in damages for the infringing sales.”⁸²

While forgiveness of damages arising from the patent at issue in the settlement could be consistent with potential outcomes of litigation, the additional layer of complexity from a second set of patents and potential damages calls for caution. Heightened scrutiny is particularly appropriate when a brand forgives a significant amount of damages in unrelated litigation. For in such a case, the conduct could—hidden under the cloak of complexity—mask a payment to the generic for delayed entry.

VII. CONCLUSION

The combination of complex markets, multiple regulatory regimes, and numerous types of conduct poses challenges for those seeking to unravel the knot of potentially anticompetitive behavior in the pharmaceutical industry. With layer piled upon layer, and defenses based on patents, innovation, and settlement that cannot easily be dismissed, brands are using complexity to their advantage. Whether it is to the advantage of consumers is far less clear and will bear the close watching of antitrust enforcers and plaintiffs. Even more important, it will require a careful and nuanced analysis by courts.

⁸² *Id.* at 40-41 (citation omitted).