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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]

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[1] Distinguished Professor, Rutgers Law School.

[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")

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[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]

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[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

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[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.

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[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 generic[56]) 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 afterwards[60]) 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]

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[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).

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"Product Hopping" on Both Sides of the Pond: A Survey of U.S. and EU Cases

Ingrid Vandenborre, Julia K. York, & Michael J. Frese

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"Product Hopping" on Both Sides of the Pond: A Survey of U.S. and EU Case Law

Ingrid Vandenborre, Julia K. York, & Michael J. Frese[1]

I. INTRODUCTION

In recent years, courts in both the United States and the European Union have increasingly been asked to consider under what circumstances the introduction of a new pharmaceutical drug product harms, rather than benefits, competition in contravention of the antitrust and competition laws. In the European Union, antitrust regulators have been active in challenging so-called "evergreening" where a brand-name company seeks to ensure continued revenues based on an "extended life" for a branded drug on the basis of a new formulation, with the switch to the new formulation being accomplished through conduct that affirmatively harms potential generic challengers. These practices have been challenged in the European Union as both single-firm and collusive conduct.

In the United States, three courts have substantively considered the same question, evaluating so-called "product hopping" conduct under single-firm monopolization precedent. In addition, the U.S. Federal Trade Commission ("FTC") has also weighed in with a proposed legal standard for evaluating "product hopping," but has not yet brought a case under that standard. Given that several "product hopping" cases are currently pending on both sides of the Atlantic, additional decisions will be forthcoming soon.

II. PRODUCT HOPPING IN THE UNITED STATES

The U.S. antitrust laws operate under the assumption that, ordinarily, the "introduc[tion of] new products is[] generally considered procompetitive."[2] Several U.S. federal courts in recent years have confronted the question of whether, in light of the U.S. regulatory framework applicable to pharmaceutical products, the introduction of new brand-name pharmaceutical products can violate the antitrust laws when the effect of that introduction may be to shrink the market for generic equivalents of older versions of those brand-name products.

A. Case Law Developments

To date, three U.S. federal courts have substantively addressed the conditions under which the introduction of a new pharmaceutical drug product may potentially violate Section 2. Each decision has focused on consumer choice: where consumers have the freedom to choose between a new brand name product and generic equivalents of the older version, and prefer the

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[2] *AstraZeneca AB v. Mylan Labs., Inc.*, MDL Dkt. No. 1291, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010).

newer brand product, the introduction of the new product will not implicate antitrust harm; conversely, where the branded firm has taken affirmative steps forcibly to "switch" customers from the older branded product to the new one and prevent the consumer from making the choice, the antitrust laws may come into play.

In *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* ("*TriCor*"),[3] the court denied the branded firm's motion to dismiss product-hopping claims. The branded firm, Abbott, had—on two separate occasions—introduced new formulations of TriCor, allegedly to stay ahead of FDA approval of applications for generic versions of the original branded product. Abbott had also allegedly taken affirmative steps to interfere with the generic firms' ability to compete by (i) "delisting" the original brand-name product codes from a database used by pharmacies for automatic substitution purposes, and (ii) affirmatively repurchasing inventory of the original strength branded product.

The court ruled that the plaintiffs had stated an antitrust claim for a Section 2 violation. Acknowledging that "innovation inflicts a natural and lawful harm on competitors,"[4] the court noted that where "consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and 'antitrust should not intervene when an invention pleases consumers.'"[5] However, the TriCor plaintiffs had alleged that the generic firms' opportunity to compete had "been prevented entirely" by the defendants' conduct,[6] thereby thwarting choice; the court concluded that if the plaintiffs could show anticompetitive harm arising from the formulation changes, that harm would be weighed against any benefits presented by the defendants.[7]

A few years later, in *Walgreen Co. v. AstraZeneca Pharmaceuticals, L.P.* and *AstraZeneca AB v. Mylan Laboratories, Inc.*, two district courts addressed allegations that AstraZeneca had deliberately switched the market from its prescription heartburn drug Prilosec to its new prescription product Nexium and to its new over-the-counter version of Prilosec.[8] Both courts dismissed the complaints, finding that the allegations were insufficient to support a reasonable inference that AstraZeneca's conduct was exclusionary for purposes of Section 2.[9] Because antitrust injuries "'include only those injuries that result from interference with the freedom to compete,'" the facts alleged as to AstraZeneca's conduct in *Walgreen* were easily distinguishable from those alleged in *TriCor*, where the elimination of choice had been a "critical factor in the court's decision to deny Abbott's motion to dismiss the complaint."[10] In contrast, AstraZeneca was not alleged to have eliminated consumer choice—indeed, the allegations demonstrated that AstraZeneca had *added* choices.[11]

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[3] 432 F. Supp. 2d 408 (D. Del. 2006).

[4] *Id.* at 420-421.

[5] *Id.* at 421 (quoting IIIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 776d (2d ed. 2002)).

[6] *Id.* at 423.

[7] *Id.*

[8] *AstraZeneca AB v. Mylan Labs., Inc.*, MDL Dkt. No. 1291, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010); *Walgreen Co. v. AstraZeneca Pharms., L.P.*, 534 F. Supp. 2d 146, 152 (D.D.C. 2008).

[9] *Walgreen Co.*, 534 F. Supp. 2d at 148; *AstraZeneca AB*, 2010 WL 2079722 at *6.

[10] *Id.* at 150.

[11] *Id.* at 151, 152.

In addition, the relative merits of the innovation were irrelevant, for "[c]ourts and juries are not tasked with determining which product among several is superior," given that new products "are not capable of affecting competitors' market share unless consumers prefer the new product[.]"[12] Two years later, the *Mylan* court agreed with the *Walgreen* analysis, and further declared that:

> [the plaintiff's] allegation that Astra[Zeneca] aggressively pressured physicians and persuaded consumers to convert sales of Prilosec to Nexium fails to 'identif[y] any antitrust law that prohibits market switching through sales persuasion short of false representations or fraud, or any court that has identified such conduct as exclusionary for purposes of §2 of the Sherman Act.'[13]

In late 2012, the FTC weighed in with an *amicus curiae* brief in a case involving product-hopping allegations, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company* ("*Doryx*").[14] The FTC proposed that antitrust scrutiny for new drug product introductions is warranted where (i) the branded manufacturer "makes minor non-therapeutic changes to the brand product, such as a dosage or form change," and then (ii) "prior to generic entry," (iii) the branded firm "removes the original product from the marketplace, or accomplishes this indirectly, such as by recalling supply of the original product or raising the price of the initial product by a meaningful amount above the reformulated one."[15]

According to the FTC, not only direct actions (such as in *TriCor*) can "force[] the switch"; a potentially anticompetitive switch can also be accomplished by "indirect" actions, such as "raising the price of the original product by a meaningful amount or by creating supply shortages of the original product prior to facing generic competition."[16] While the *Doryx* court allowed the brief, the judge later characterized the plaintiffs' product-hopping theory as "'novel' at best," expressing "skeptic[ism] that the 'product hopping' alleged . . . constitutes anticompetitive conduct under the Sherman Act[.]"[17]

At least three additional antitrust cases implicating product switches are currently pending in U.S. courts.[18] Most recently, the New York State Attorney General ("NYAG") sued Actavis plc and Forest Laboratories, alleging an imminent unlawful product hop in connection with the drug Namenda.[19] The complaint contends that the defendants intend to "switch" the

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[12] *Id*.

[13] *AstraZeneca AB*, 2010 WL 2079722 at *6 (quoting *Walgreen Co*., 534 F. Supp. 2d at 152).

[14] Federal Trade Commission Brief as *Amicus Curiae*, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co*., Case No. 2:12-cv-03824-PD (E.D. Pa. filed Nov. 21, 2012) (Dkt No. 116) ("FTC *Doryx* Brief").

[15] *Id*. at 8.

[16] *Id*. at 13.

[17] Order at 3-4, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co*., Case No. 2:12-cv-03824-PD (E.D. Pa. filed June 12, 2013) (Dkt No. 280). The judge denied the defendants' motion to dismiss, however, as it required consideration of facts beyond the complaint in contravention of Rule 12 of the Federal Rules of Civil Procedure.

[18] *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litig*., Case No. 2:13-md-02445-MSG (E.D. Pa.); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*., Case No. 14-md-02503-DJC (D. Mass.); *State of New York v. Actavis plc et al.*, Case No. 14-cv-7473 (S.D.N.Y.). Oral argument was recently held on the defendant's motion to dismiss in *Suboxone*.

[19] Complaint, *State of New York v. Actavis plc et al.*, Case No. 14-cv-7473 (S.D.N.Y. filed Sept. 15, 2014) (Dkt. No. 1).

market from an immediate-release version of Namenda to an extended-release version in violation of federal and state antitrust laws, and seeks an order enjoining the defendants "from discontinuing Namenda [Immediate Release] until generic memantine is available in the market and for a reasonable period thereafter," among other relief.[20] The NYAG moved for a preliminary injunction,[21] asserting a likelihood of success on the exclusionary conduct element because—adopting the *TriCor* standard—the defendants' planned "forced switch" away from Namenda IR to Namenda XR allegedly "significantly harms competition" and "lacks a legitimate business justification".[22]

In opposing the NYAG's allegations, the defendants have argued that the NYAG is asking the court "for the first time" to interpret the antitrust laws "to impose a mandatory, affirmative duty on an innovator to continue selling an older product, solely for the benefit of its generic competitors" and "order unprecedented remedies to force Forest to continue selling its old Namenda IR tablets … solely to help Forest's generic rivals compete and take sales away."[23] Because "'[a]ny firm, even a monopolist, may generally bring its products to market whenever and however it chooses,'"[24] the defendants argue that the court "should not require [defendants] to slow the pace of innovation for competitors."[25] Defendants also emphasized the lack of coercion of patients to purchase only Namenda XR.[26] Briefing on the motion to dismiss appears slated to resume after the court hears the motion for the preliminary injunction in mid-November 2014.

B. Implications of Recent Product-Hopping Case Law and Enforcement Activity

These decisions and pending cases do not completely answer what it means to prevent choice and forcibly "switch" customers, particularly where none of the decisions has been reviewed by any appellate court. On the basis of the issued decisions in *TriCor*, *Walgreen Co.*, and *AstraZeneca AB*, antitrust scrutiny of "product-hopping" appears warranted only where the brand-name drug company has taken direct, affirmative steps to interfere with generic substitution mechanisms and thereby reduced choices available to consumers. Under existing case law, absent such affirmative steps, the introduction of a new product and aggressive marketing alone cannot satisfy the "exclusionary conduct" requirement of Section 2.

Although the FTC has advocated that "indirect" actions should also satisfy Section 2's "exclusionary conduct" requirement, this untested position presents courts with a difficult

[20] *Id.* at p. 38 (demand for judgment ¶ d).

[21] Pl's. Mem. of Law in Support of its Mot. for Prelim. Inj. (Public Version) at 1, *State of New York v. Actavis plc et al.*, Case No. 14-cv-7473 (S.D.N.Y. filed Oct. 30, 2014) (Dkt. No. 51). The court held evidentiary hearings on Plaintiff's motion for a preliminary injunction in mid-November 2014..

[22] *Id.* at 2-3.

[23] Defs.' Mem of Law in Support of Defs' Mot. to Dismiss (Public Version) at 1, *State of New York v. Actavis plc et al.*, Case No. 14-cv-7473 (S.D.N.Y. filed Oct. 15, 2014) (Dkt. No. 35).

[24] *Id.* at 5 (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979)); *see also id.* at 8. Defendants also argued that the New York AG failed to allege that Forest possessed an *illegal* monopoly, since Forest holds valid patent and regulatory exclusivities covering Namenda IR and XR.

[25] *Id.* at 2.

[26] *Id.* at 13-14, 21-22.

challenge in having to separate conduct that harms the competitive process from conduct that is lawful, vigorous competition. Under this "indirect action" approach, a branded manufacturer's unilateral pricing, marketing, and manufacturing decisions would be placed under the antitrust lens and potentially be subject to treble-damage liability where they had an impact on the size of the market for the original product.

The NYAG's suit most starkly illustrates the difficulties courts would face if left with an overly ambiguous threshold for an unlawful product hop. Courts would be required to decide the appropriate level of manufacture, marketing, and price for older versions of individual branded drug products.[27] Ambiguous rules that fail clearly to define anticompetitive conduct, and which require intensive court supervision, appear to be at odds with the U.S. Supreme Court's "repeated[] emphasi[s on] the importance of clear rules in antitrust law," and its observation that "[c]ourts are ill suited 'to act as central planners, identifying the proper price, quantity, and other terms of dealing.'"[28] This ambiguity only underscores the importance of legitimate business justifications, which under the *TriCor* approach may be presented by a defendant in response to a plaintiff's showing of anticompetitive harm flowing from the "product hop."

III. PRODUCT HOPPING IN THE EUROPEAN UNION

In the European Union, "product hopping" could also run counter to antitrust rules. Product hopping (in the European Union better known as "evergreening") was identified in the EU Commission's 2009 Pharmaceutical Sector Inquiry.[29] In the context of this sector inquiry, the Commission investigated a number of practices in the pharmaceutical industry, including lifecycle strategies for second-generation products. The Commission recognized the importance of incremental research, but noted that "the launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product."[30]

Although the sector inquiry was not intended to provide guidance as to the compatibility of certain practices with EU competition law,[31] the Commission did point out that in order to optimize the switch between first- and second-generation products, originator companies can flank the launch of second-generation products with "bridging strategies" aimed at adapting the prescribing behavior.[32] Recent decisions at both the EU and Member State levels indicate that some of these strategies could run counter to Articles 101 and 102 of the Treaty on the Functioning of the European Union ("TFEU").

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[27] *See* Defs' Mem. in Opp'n to Pl's. Mot. for Prelim. Inj. (Public Version) at 2, *State of New York v. Actavis plc et al.*, Case No. 14-cv-7473 (S.D.N.Y. filed Oct. 30, 2014) (Dkt. No. 52) (relief sought by plaintiff would "impose an unprecedented duty to sell" and require the court "to act as a monitor to ensure that [Forest] sells the older version of Namenda at certain levels and through certain distribution channels").

[28] *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 452 (2009) (*quoting Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)).

[29] *Available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[30] Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 14.

[32]Commission Staff Working Document (Technical annex to the Commission Communication), Part 1, ¶ 1029.

A. EU and Member State Decisions

In the European Union, evergreening practices have been mainly investigated as alleged abuses of a dominant position with respect to the pharmaceutical(s) concerned.

The Commission's 2005 *AstraZeneca* decision was the first product hopping case in the European Union.[33] In that decision, the Commission imposed a fine on AstraZeneca for abusing its dominant position by misleading regulatory authorities and by withdrawing its marketing authorization for a first-generation product in a number of jurisdictions while launching a second-generation product. On appeal, the General Court concluded that the deregistration, without objective justification, of the marketing authorizations for Losec capsules in Denmark, Sweden, and Norway qualified as an infringement of Article 102 TFEU.[34]

The Court considered that Article 102 TFEU imposes on undertakings in a dominant position the special responsibility not to impair competition through methods other than competition on the merits.[35] Accordingly, a dominant undertaking cannot use regulatory procedures in such a way as to prevent, or make more difficult, the entry of competitors on the market, except when this is needed to defend legitimate interests or when there are other objective justifications.[36] The Court observed that a dominant company's strategy to minimize the erosion of its sales and to enable it to deal with competition from generic products is considered part of the normal competitive process and therefore legitimate, provided that the conduct "does not depart from practices coming within the scope of competition on the merits."[37] It then held that:

> the withdrawal from the market of Losec capsules and the introduction on the market of Losec MUPS, was not capable, in itself, of producing the anticompetitive effects alleged by the Commission in the present case, namely the creation of regulatory obstacles to the market entry of generic omeprazole and to parallel imports of Losec capsules.[38]

The General Court's findings were all upheld by the Court of Justice.[39]

Following *AstraZeneca*, the U.K. Office of Fair Trading ("OFT") (now the Competition and Markets Authority ("CMA")) issued the 2011 *Reckitt Benckiser (Gaviscon)* decision.[40] Reckitt Benckiser ("RB") had withdrawn and delisted its Gaviscon Original Liquid ("GL") product from the NHS prescription channel after the product's patent had expired but before publication of the product's generic name, with the result that more prescriptions would be written for the company's patent-protected product, Gaviscon Advance Liquid ("GA"), a strategy that was expressed in company internal documents. The OFT found that without a generic name, GPs could only write prescriptions that refer to brand names. These so-called "closed scripts," in turn, obliged pharmacies to dispense the branded product.

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[33] Case COMP/A.37.507/F3 – *AstraZeneca*.
[34] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805.
[35] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805, ¶ 671.
[36] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805, ¶ 672.
[37] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805, ¶ 804.
[38] Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805, ¶ 808.
[39] Case C-457/10 P *AstraZeneca v Commission*, nyr.
[40] Case CE/8931/08, OFT 1368.

The OFT concluded that this amounted to an abuse of a dominant position, contrary to Article 102 TFEU and the equivalent domestic legal provision. Key for the OFT's finding was that the withdrawal "would have been commercially irrational were it not for the anticipated benefits to RB of hindering the development of full generic competition."[41] The OFT further concluded—in line with *AstraZeneca*—that while an intention to convert sales of GL to GA may be consistent with a "normal lifecycle management strategy," achieving that strategy by the withdrawal is not.[42] Moreover, it was a key element of the OFT's finding that the company's internal documents arguably reflected a strategy to minimize generic conversion. The *Reckitt Benckiser* decision was based on a settlement with the OFT and has not been appealed.

More recently, the Italian Competition Authority ("AGCM") issued a decision against Novartis and Roche on the basis that the companies had engaged in artificial product differentiation in the area of ophthalmic drugs with the object and effect to increase sales of the higher-priced product.[43] Rather than identifying an abuse of dominance, the AGCM concluded that Novartis and Roche had infringed Article 101 TFEU by taking part in an anticompetitive agreement.

The products in question concerned Avastin and Lucentis. Avastin has been developed by Genentech, whereas Lucentis has been jointly developed by Genentech and Novartis. Genentech is a subsidiary of Roche whereas Roche is 33.33 percent owned by Novartis. In the United States, Genentech markets these products on its own. In the European Union, Avastin and Lucentis are marketed by Roche and Novartis, respectively, on the basis of licenses granted by Genentech. Although Avastin was approved for the treatment of cancer, some doctors also prescribed it as an ophthalmic drug. Lucentis, which arrived on the market two years later, was approved for some of the eyesight conditions for which Avastin was used. After the introduction of Lucentis, doctors continued to prescribe Avastin. While these products were to some extent substitutable, there was a significant price difference: the price of an injection of Lucentis was EUR 900 (initially even EUR 1700), whereas an Avastin injection was sold at maximum price of EUR 81.

The AGCM found that Roche and Novartis aimed at excluding the ophthalmic use of Roche's Avastin in order to safeguard the sales of Novartis' Lucentis. In particular, the two companies were found to have colluded to create an artificial product differentiation by claiming that Avastin was more dangerous than Lucentis with the aim to influence doctors and patients. The claims were made against the backdrop of a growing number of international scientific studies supporting the equivalence of the two drugs in ophthalmic uses. This case is currently under appeal. While not strictly a "product hopping" or "evergreening" case, it is informative of some EU Member State competition authorities' assessments of the boundaries of product positioning and lifecycle management more generally.

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[41]Case CE/8931/08, OFT 1368, ¶ 6.1.

[42]Case CE/8931/08, OFT 1368, ¶ 6.57.

[43]I/760, *Roche-Novartis/farmaci Avastin e Lucentis* (27 February 2014). The description of this case is based on: ECN Brief 2/2014; Gabriele Accardo, *The Italian Competition Authority establishes an anticompetitive agreement in the market for ophthalmic drugs used to treat vascular eyesight diseases (Roche/Novartis),* E-COMPETITIONS, No 66857 (February 2014); Luca Arnaudo, *The Strange Case of Dr. Lucentis and Mr. Avastin: The Italian Competition Authority Fines Roche and Novartis for Collusion,* 35(7) EUR. COMPETITION L. REV., 347-351 (2014).

B. Implications of Recent Product-Hopping Case Law and Enforcement Activity

Based on these EU and Member State decisions, it is clear that, like in the United States, the launch of a second-generation product in and of itself is not likely to be deemed contrary to EU antitrust rules. However, "bridging strategies" that support the launch of a second-generation product may potentially contravene Article 101 or 102 TFEU if they have the object or effect to hinder generic entry, and no legitimate interests or other objective justifications can be demonstrated. Although the above three cases do not provide an exhaustive list of potentially problematic bridging strategies, it is clear that deregistration, delisting, and artificial product differentiation may result in antitrust infringements in the absence of a justification. It remains unclear whether, and to what extent, the effects of a bridging strategy on generic competition in the first-generation market can be offset by proof that the strategy is necessary for an effective launch of an improved, second-generation product, and what types of bridging strategies may be viewed as legitimate.

In September of this year, the EU Court of Justice clarified the application of the "by object" threshold as requiring that the practices concerned in themselves reveal a sufficient degree of harm to competition,[44] which likely will make it a difficult standard to effectively apply to "evergreening" practices.

IV. CONCLUSION

The approaches in the United States and the European Union with respect to "product hops" appear to be similar in that direct, affirmative steps that prevent generic competition could give rise to antitrust scrutiny. In view of the pending cases, it remains to be seen whether further decisions will confirm the existing trend, or instead expand the scope of conduct that could potentially raise the specter of antitrust liability.

[44]Case C-67/13 *Groupement des cartes bancaires (CB)*, nyr.

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"Good Luck" Post-*Actavis*: Current State of Play on "Pay-for-Delay" Settlements

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Wilson Sonsini Goodrich & Rosati

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I. INTRODUCTION

Chief Justice Roberts' statement "good luck to the district courts" in his dissent in *FTC v. Actavis* was certainly prophetic.[2] Since the Court's issuance of that decision in June 2013, the district courts have been dragged into numerous additional cases—more than a dozen cases are currently pending—and more than a half dozen decisions have come down with rulings providing a broad spectrum of interpretations as to what the Court meant by a "large and unexplained" payment.

The U.S. Federal Trade Commission ("FTC"), which brought the *Actavis* case, has added further layers of complexity to pharmaceutical companies trying to understand the post-*Actavis* landscape. On September 8, 2014, the FTC brought its first "pay-for-delay" case since it filed the *Actavis* case back in January 2009—a case against AbbVie that also includes sham litigation claims—and has launched at least three significant investigations during 2014. The FTC also, changing tack after more than a decade, is now pursuing disgorgement in "pay-for-delay" cases, although the dissenting votes of the two Republican Commissioners in the *AbbVie* case may indicate a lack of uniformity on this issue, and perhaps indicate some break in the lock-step bipartisan support "pay-for-delay" cases have enjoyed at the FTC since the late 1990's.

This article examines the current quagmire in the courts, the FTC's recent activities, and finally explores growing interest outside the United States in getting into the "pay-for-delay" fray.

II. WHAT IS A "LARGE" AND "UNEXPLAINED" PAYMENT AND HOW DOES ONE PLEAD IT?

This fall, Judge Peter Sheridan in the District of New Jersey issued two significant opinions in the "pay-for-delay" arena.[3] Up until this point, district courts had split on whether *Actavis* applies only to reverse payments of cash.[4] Judge Sheridan offered a third approach to the

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[2] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, at 2245 (U.S. 2013) (Roberts, J., Dissenting).

[3] *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877 (D.N.J. 2014); *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. 2014).

[4] *Compare In re Nexium Esomeprazole Antitrust Litig.*, 2014 U.S. Dist. LEXIS 126954, at *75 (D. Mass. Sept. 4, 2014) ("unlawful reverse payments are not limited to monetary payments") *with In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 U.S. Dist. LEXIS 9257, at *22 (D.N.J. Jan. 24, 2014) ("the Supreme Court considered a reverse payment to involve an exchange of money").

binary framework set forth in previous decisions. Specifically, he concluded that while non-monetary payments could constitute reverse payments under *Actavis*, a complaint must demonstrate a "reliable cash value of the non-monetary payment"[5] and dismissed the *Lipitor* and *Effexor* complaints for failing to do so. These decisions and their implications are discussed in more detail below.

A. Lipitor

In *Lipitor*, direct purchaser plaintiffs filed suit against Pfizer and Ranbaxy for allegedly entering into a "pay-for-delay" settlement with respect to Pfizer's blockbuster cholesterol drug, Lipitor (atorvastatin).[6] According to plaintiffs, Ranbaxy agreed to take a later entry date under the settlement in exchange for the following payments from Pfizer to Ranbaxy: (1) a "sweetheart" agreement to dismiss Pfizer's damages claims against Ranbaxy (likely worth hundreds of millions of dollars) in unrelated patent litigation (the Accupril II litigation) for a token payment of $1 million; and (2) foreign patent litigation settlements permitting Ranbaxy to launch generic Lipitor in at least 11 non-U.S. markets prior to patent expiration.

On September 12, 2014, Judge Sheridan dismissed direct purchasers' complaint with prejudice. The court found that Actavis was not restricted to cash payments, but that any non-monetary payment alleged "must 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."[7]

For the payment alleged through Pfizer's agreement to dismiss damages in the *Accupril II* litigation, plaintiffs generally argued that the non-monetary payment could be the same amount as the bond posted in the patent litigation ($200 million) or it could be the difference in the brand's gross sales ($525 million to $70 million) with and without a generic competitor. However, the court found that these estimates were insufficient, as plaintiffs never attempted to value this non-monetary payment to a reliable measure of damages through a risk-adjusted lost profits analysis. Similarly, for foreign market licenses, the court determined that the complaint "lack[ed] any foundation to estimate the cash value of the alleged licenses granted in other countries."[8] Because the complaint failed to provide a reliable foundation showing a cash value of the non-monetary payment, its reverse payment allegations were implausible.

The court also noted that plaintiffs failed to consider, or even address, the fact that the payments (even if clearly pled) could have constituted "saved litigation costs." According to the court, the agreement settled three U.S. patent infringement litigations and 23 foreign legal actions, so the saved litigation costs could have been in the hundreds of millions of dollars. Plaintiffs' failure to attempt to properly value the alleged reverse payments, including the subtraction of any saved litigation costs, made any analysis of whether such payments were "large" impossible.

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[5] *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877, at *65.

[6] Indirect purchaser plaintiffs also filed suit and, in a separate, later-issued opinion, Judge Sheridan dispatched their claims for similar reasons.

[7] *Id.* at 64.

[8] *Id.* at 72.

In response to Judge Sheridan's decision, direct purchaser plaintiffs filed a motion to amend the judgment to permit them leave to file an amended complaint.[9]

B. Effexor

In *Effexor*, direct purchaser plaintiffs filed suit against Wyeth and Teva for allegedly entering into a "pay-for-delay" settlement with respect to Effexor XR (venlafaxine hydrochloride), an anti-depressant drug. According to plaintiffs, Teva agreed to accept a later generic entry date under the settlement in exchange for Wyeth's promise to refrain from marketing an authorized generic product during Teva's first 180-days on the market (a "no-AG agreement").

On October 7, 2014, similar to his *Lipitor* decision, Judge Sheridan dismissed plaintiffs' "pay-for-delay" allegations with prejudice.[10] While Judge Sheridan found that the no-AG agreement alleged in *Effexor* did have value, plaintiffs did not convert it to a specific value using a reliable method. Specifically, plaintiffs asserted that the no-AG payment was worth over $500 million by: (1) claiming that "Teva would realize about double the volume of generic sales at significantly higher, supra-competitive prices,"[11] and (2) that, for Paxil (a similarly sized drug), another generic firm told the FDA that the presence of an authorized generic cost the company approximately $400 million during its 180-day exclusivity period. The court, however, found that plaintiffs' $500 million calculation based on these facts to be "vague and amorphous."[12]

In addition, the court noted that the question of whether there is a "reverse payment" involved more than just an analysis of the no-AG agreement. To analyze a payment, one must: (1) value any consideration flowing from the patentee to the claimed infringer, which may take forms other than cash; (2) deduct from that payment the patent holder's avoided litigation costs; and (3) deduct from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions). The resulting net payment is "otherwise unexplained" and hence an unlawful reverse payment.

Here, in addition to failing to reliably calculate the value of the no-AG promise, plaintiffs failed to set forth a reliable foundation for valuing Wyeth's saved litigation costs or the royalty payments paid by Teva to Wyeth. Because plaintiffs did not reliably value the "payment" under the court's three-step analysis, the court could not determine whether it was reverse (i.e., whether the resulting net payment flowed from alleged infringer to patent holder), whether it was "large," or whether it was "unexplained."

On October 21, 2014, direct purchasers filed a motion asking Judge Sheridan to reconsider his decision to dismiss plaintiffs' complaint in *Effexor*, and allow them to re-plead.[13] The crux of plaintiffs' motion for reconsideration is that it was a clear error of law for Judge Sheridan to dismiss plaintiffs' complaint—under a "novel" pleading standard that the judge

[9] Motion to Amend Judgment, *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877 (D.N.J. 2014).
[10] Judge Sheridan, however, allowed plaintiffs' *Walker-Process* claim to proceed.
[11] *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *67.
[12] *Id.* at *69.
[13] Motion to Reconsider, *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. 2014).

announced after the complaint was filed—with prejudice. Plaintiffs asserted that they could set forth specific allegations valuing the no-AG agreement even under the court's heightened pleading standard, and claimed to do so in their proposed amended complaint, which was attached to their motion for reconsideration.

C. Implications

As a result of Judge Sheridan's decisions in *Lipitor* and *Effexor*, we expect that plaintiffs, in the future, will include significant detail in their complaints regarding the method by which they are calculating the cash value of any non-monetary payment. For example, in their motion for reconsideration in *Effexor*, plaintiffs spent over 20 paragraphs in their proposed amended complaint on valuing the alleged non-monetary reverse payment—the no-AG clause—in an attempt to calculate the cash value of the non-monetary payment using an industry-reliable method.[14] In particular, if other district courts adopt Judge Sheridan's pleading standard, plaintiffs may even be inclined to engage economists or other experts in preparing their complaints to help bolster key valuation allegations on alleged payments through non-monetary settlement provisions.

Moreover, given that on November 19, 2014 the Third Circuit heard the oral argument on the *Lamictal* appeal—concerning whether a no-AG agreement can be a reverse payment under *Actavis*—it will also be interesting to see whether the panel will rule on Judge Sheridan's proposed pleading standard in its forthcoming opinion. While the issue is not directly before the Third Circuit, it could opine more broadly on what is required to properly allege a payment under *Actavis*, as it will be the first Circuit court to issue a decision on this issue. Clients and practitioners alike should stay apprised on continued developments in the direct purchaser plaintiffs' motions for leave to re-plead in *Lipitor* and *Effexor* as well as the Third Circuit's forthcoming decision in *Lamictal*.

III. FTC HAS BEEN INVIGORATED POST-*ACTAVIS*

After years of waiting for the Supreme Court to weigh in on the "pay-for-delay" debate, the Court's decision in *FTC v. Actavis* has invigorated the FTC's enforcement efforts. The *Actavis* ruling certainly did not give the FTC everything it wanted, as the Court rejected the FTC's preferred "presumption of illegality" standard that had been set forth by the Third Circuit in *K-Dur*.[15] However, the Court's rejection of the "scope of the patent" test favored by several circuits, and expression of concern about patent settlements that contained "large and unexplained" payments, certainly left the FTC feeling emboldened post-*Actavis* to investigate and challenge settlements.

The FTC's foray back into the federal courts in the *AbbVie* suit reflects the FTC's continued skepticism regarding "side-deal" arrangements. The FTC filed its September 8, 2014 complaint against AbbVie, Abbott, Unimed, Besins, and Teva in the Eastern District of

[14] *Id*. at ¶ 284-305.

[15] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, at 218 (3d Cir. 2012) ("the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade").

Pennsylvania. The decision to file the complaint was a 3-2 decision, with Commissioners Wright and Ohlhausen dissenting. The case involves the same drug (Androgel) as in the *Actavis* case.

The complaint alleges that, as trial approached in the AbbVie/Teva Androgel patent litigation, AbbVie entered into a "pay-for-delay" settlement with Teva to prevent Teva from winning the patent litigation and opening up the generic market. While the complaint's "pay-for-delay" allegations are heavily redacted, it appears that the compensation was in the form of a side deal—namely a "product supply" agreement for Teva to serve as the authorized generic for AbbVie's TriCor product.[16] The complaint alleges that the authorized generic agreement enabled Teva to compete "before independent generic entry is expected,"[17] and suggests that Teva got a far higher split of profits than is typical in these sorts of deals.

The complaint is also novel in that it alleges that AbbVie pursued sham litigation against Teva and Perrigo, asserting infringement of its '894 patent even though Teva and Perrigo's formulations were clearly outside of the literal scope of the '894 patent and did not infringe. Nearly 14 pages of the total 40 pages in the complaint focus on sham litigation—which indicates that the sham claims are of significant importance to the FTC. This case marks the first ever FTC challenge to Hatch-Waxman litigation on sham grounds, although this is an area that the FTC has previously probed.

Focusing back on the "pay-for-delay" allegations, the agreement at issue does not raise any particularly novel issues. The FTC—and private plaintiffs—have challenged numerous "side-deal" arrangements over the past decade and a half. What is of note in *AbbVie* is a new standard set forth by the FTC that is novel, and not reflected in the Court's *Actavis* decision. The new standard is as follows: If the generic receives anything from the brand that it could not obtain as a result of winning the patent litigation, it is a reverse payment under *Actavis*.[18] While this standard has appeared in other private suits and some academic works, the Court in *Actavis* certainly did not set forth a standard along these lines and no district court since then has endorsed or offered an opinion on whether this standard is consistent with *Actavis*.

It is also quite noteworthy that the Commission vote in the *AbbVie* suit was 3-2 with Republican Commissioners Ohlhausen and Wright voting against filing the complaint. All prior FTC "pay-for-delay" consents and suits since the late 1990s were brought on a bi-partisan basis, and Ohlhausen and Wright have supported various recent FTC amicus briefs stating that no-AG agreements constitute compensation. It is unclear why they dissented in this instance as they did not issue dissenting statements when the complaint issued. One potential area of divergence, which could be at least part of the rationale for the dissenting votes, is that the *AbbVie* complaint seeks disgorgement. Prior FTC "pay-for-delay" complaints did not seek disgorgement,[19] and

[16] Complaint at ¶120, *FTC v. AbbVie, Inc.*, 2:14-cv-05151, (E.D. Pa. 2014).

[17] *Id*. at ¶126.

[18] *See Id.* at ¶124 ("The TriCor authorized generic deal was something Teva could not have obtained had it won the AndroGel patent infringement litigation. Even if Teva had prevailed in the AndroGel litigation, it would not have secured a right to sell an authorized generic version of TriCor.").

[19] The FTC complaint in its Cephalon litigation did not seek disgorgement, although the FTC did later amend its position in that case. Complaint, *FTC v. Cephalon, Inc.,* 551 F. Supp. 2d 21 (D.D.C. 2008).

Commissioners Ohlhausen and Wright have expressed concern over the use of this tool except in a few narrow circumstances.[20]

As far as the pipeline for new FTC challenges following the *AbbVie* suit, the Commission appears to be dedicating significant resources to investigating settlements. Following the *Actavis* decision, Chairwoman Ramirez testified before the Senate Judiciary Committee in July 2013 stating: "The Supreme Court's decision in *Actavis* confirms that [reverse payment] settlements harm consumers and competition, and the Commission will continue to aggressively prosecute these anticompetitive settlements."[21] Additional statements from FTC officials at the time further indicated that the FTC would be reviewing prior patent settlement filings to find appropriate cases for challenge.

In the wake of these statements, there are a number of publicly disclosed FTC investigations that have emerged over the last year.[22] As part of these investigations, the FTC has issued broad subpoenas, sought investigational hearings of numerous party witnesses, and taken an aggressive position on subpoena compliance in particular with regard to privilege claims.

It remains to be seen whether any of these investigations will ripen into litigation. The FTC is busy with three ongoing federal court litigations. In addition to the *AbbVie* case, the FTC is back in discovery in the *Actavis* case following remand to the district court in Georgia, and the ongoing *Cephalon* case in federal court in Philadelphia could end up in trial following the court's oral argument on summary judgment that took place on November 6, 2014.

Thus, while the FTC waited for years for a Circuit split to emerge, which ultimately resulted in the *Actavis* decision, it now is proceeding post-*Actavis* with a significant number of litigations and investigations. Companies thus need to remain cognizant about whether their settlements could lead them into an investigation and the courts, while at the same time keeping their eye on private plaintiffs, as discussed above, who likewise remain very active in challenging patent settlements.

IV. PATENT SETTLEMENT INVESTIGATIONS GO GLOBAL

While the focus on "pay-for-delay" settlements began in the United States, interest in such agreements has gone global in recent years as international antitrust enforcers have increasingly focused on pharmaceutical patent settlements—a trend that undoubtedly will

[20] *See* Statement of Commissioner Maureen K. Ohlhausen – Dissenting from the Commission's Decision to Withdraw its Policy Statement on Monetary Equitable Relief in Competition Cases, FTC File No. P859910 (July 31, 2012) *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/statement-commissioner-maureen-k.ohlhausen/120731ohlhausenstatement.pdf; Joshua D. Wright, "The Federal Trade Commission and Monetary Remedies," Remarks at the 18th Annual Competition Law and Policy Workshop, (July 19, 2013) *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/federal-trade-commission-monetary-remedies/130719monetaryremedies.pdf.

[21] *Pay-for-Delay Deals: Limiting Competition and Costing Consumers Before the S. Judiciary Comm*, 113th Cong. 1 (July 23, 2013) (statement of Edith Ramirez) *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/statement-chairwoman-edith-ramirez-pay-delay-settlements/130923pfdopeningstatement_0.pdf.

[22] Press reports have noted certain of these investigations. *See, e.g.*, David McLaughlin, *U.S. Steps Up Probes of Deals to Block Generic Drugs*, BLOOMBERG (June 23, 2014) *available at* http://www.bloomberg.com/news/2014-06-23/u-s-steps-up-probes-of-deals-to-block-generic-drugs.html.

continue. Global pharmaceutical companies need to be mindful of antitrust risk, both in and outside the United States, as they negotiate and enter into these agreements.

A. European Commission

Since 2009, the European Commission ("EC") has closely monitored pharmaceutical patent settlements. In July 2014, the EC handed down its largest penalty related to a "pay-for-delay" settlement when it imposed a U.S $449 million fine on Servier for "abusing its dominance" by entering into settlements that the EC believed kept generic versions of Perindopril, a blood pressure medication, off the market.[23] The EC also imposed U.S. $120.2 million worth of fines on the five generic firms involved in the agreements.

The *Servier* case is not the first time the EC has investigated patent settlements. In 2013 it fined Lundbeck and various generic firms $195.5 million[24] and Johnson & Johnson and Novartis $22.4 million[25] because of "pay-for-delay" agreements; however, the *Perindopril* case was the EC's most aggressive case yet. Not only did the EC impose its largest "pay-for-delay" fine to date, *Servier* was also the first time the EC investigated a pharmaceutical patent settlement under a dominance standard. The *Johnson & Johnson* and *Lundbeck* cases, on the other hand, were brought under the EC's authority to regulate restrictive agreements. By using both the restrictive agreement and dominance standards, which is akin to bringing a claim under both Sections 1 and 2 of the Sherman Act, the EC has signaled that it will continue to challenge pharmaceutical patent settlements.

B. Canada

Until recently, Canada was not viewed as a country that was playing a role in investigating or challenging pharmaceutical patent settlements. However, at a recent conference on global pharmaceutical antitrust issues, John Pecman, Canada's Commissioner of Competition, indicated that Canada will pursue criminal cases predicated on "reverse-payment settlements" in certain circumstances.[26] No other country to date has indicated that they view such settlements as raising criminal antitrust implications.

Pecman explained that the Competition Bureau, Canada's antitrust enforcers, "would be more inclined to commence an inquiry under [Canada's] criminal provision" in three circumstances: (1) patent settlements that include "conduct with respect to markets or products that are not the focus of the patent litigation," (2) patent settlements that include conduct "beyond the scope of the patent," or (3) patent settlements where there is "direct or circumstantial evidence that indicates that the settlement is a vehicle for a 'naked restraint' on competition."

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[23] Melissa Lipman, *3 Key Facts from the EU's Latest Pay-For-Delay Case*, LAW360, (July 15, 2014) *available at* http://www.law360.com/articles/557308/3-key-facts-from-the-eu-s-latest-pay-for-delay-case.

[24] Kathryn Brenzel, *EU Fines Lundbeck $125.6M in Pay-For-Delay Probe*, LAW360, (June 19, 2013) *available at* http://www.law360.com/articles/451345.

[25] Stewart Bishop, *J&J, Novartis Fined $22.4M over Pay-For-Delay Deal*, LAW360, (Dec. 10, 2013) *available at* http://www.law360.com/articles/494572.

[26] John Pecman, Canadian Commissioner of Competition, Remarks at the Global Antitrust Institute Conference: Global Antitrust Challenges for the Pharmaceutical Industry, (Sept. 23, 2104) *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03817.html.

He further explained that settlements where "a generic agreed to enter beyond the expected expiry date of the patent in exchange for a payment" or where "the evidence suggest[s] that [the] payment was strictly to delay or prevent entry" would likely lead to criminal investigations.

Pecman also indicated that the Bureau would encourage regulatory changes designed to make it easier to monitor, and ultimately challenge, pharmaceutical patent settlements. He stated that the Bureau would like Canada to adopt a settlement notification system similar to the one in the United States, saying that it would "would furnish the Bureau with substantive information about settlement agreements and enhance [its] ability to address potentially anti-competitive agreements."

C. India

This summer India's competition authority, the Competition Commission of India ("CCI"), began investigating two sets of patent settlements between brand and generic firms.[27] The CCI's analysis of these and other pharmaceutical patent settlements will likely mirror that of the FTC.

In 2012, the CCI entered into a Memorandum of Understanding with the FTC and U.S. Department of Justice ("DOJ") that promised to increase coordination and communication between the agencies; additionally, FTC staff has served as advisors to help the CCI develop its antitrust policy.[28] Considering the FTC's experience with patent settlements, and their history of working closely with the CCI, it is likely that India will apply similar standards as the FTC when investigating patent settlement agreements.

D. Other Countries Likely to Follow Suit

As so-called "pay-for-delay" issues continue to attract more attention, additional countries will invariably begin opening their own investigations. In fact, several countries have already taken actions on agreements that, in antitrust enforcers' minds, were designed to delay generic entry.

Both the Administrative Council for Economic Defense ("CADE")—Brazil's competition authority—and the French Competition Authority ("FCA") have recently issued fines against pharmaceutical companies that offered pharmacies and distributors discounts that allegedly were designed to hinder generic adoption.[29] Additionally, in February 2014, the Australian Competition and Consumer Commission filed an antitrust suit against Pfizer for similar

[27] *India Enters "Pay-for-Delay" Fray: CCI Investigating Pharmaceutical Patent Settlements*, WSGR, (Aug. 12, 2014) *available at* http://www.wsgr.com/WSGR/Display.aspx?SectionName=publications/PDFSearch/wsgralert-CCI.htm; *CCI to Scan Drug Patent Settlements*, LiveMint, (Aug. 3, 2014) *available at* http://www.livemint.com/Companies/RVVDhRh7oTfpqlIphkb6jM/CCI-to-scan-drug-patent-settlements.html.

[28] *FTC and DOJ Sign Memorandum of Understanding With Indian Competition Authorities*, Federal Trade Commission (September 27, 2012) *available at* http://www.ftc.gov/news-events/press-releases/2012/09/ftc-doj-sign-memorandum-understanding-indian-competition.

[29] *Global Convergance on 'Pay-for-Delay' settlements*, BRISTOWS, (Oct. 16, 2014) *available at* http://www.bristows.com/articles/global-convergence-on-pay-for-delay-settlements.

conduct.[30] While the facts of these cases are not analogous to a traditional "pay-for-delay" case, the alleged anticompetitive effect, delayed generic entry, is identical. Companies should expect that France, Brazil, Australia, and many other countries may soon open their own pharmaceutical patent settlement investigations.

[30] Dan Prochilo, *Australia Hits Pfizer with Antitrust Suit Over Lipitor*, LAW360, (Feb. 13, 2014) *available at* http://www.law360.com/articles/509768/australia-hits-pfizer-with-antitrust-suit-over-lipitor.

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Competition Issues in the Canadian Pharmaceutical Industry

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Alan Gunderson[1]

I. INTRODUCTION

Health care is a very important sector within the Canadian economy. A recent report estimates total health care spending at CDN $211.2 billion in 2013 which represents 11.2 percent of the Canadian economy or approximately CDN $5,988 per capita.[2] Pharmaceuticals comprise the second largest component of total health care spending, estimated to be 16.3 percent of such spending in 2013 (CDN $34.5 billion).[3] A significant percentage of pharmaceutical spending is for prescription drugs (84.6 percent in 2011) and, unlike spending on hospitals and physicians, most pharmaceutical spending is from the private sector.[4] Private sector spending includes spending by both private health insurance plans, estimated at 59.6 percent in 2011, and households who pay out-of-pocket, estimated at 40.4 percent.[5]

Among Canadian prescription drugs in 2013, generics were estimated to have a 66 percent share of retail prescriptions but only 23.5 percent of total prescription drug expenditures.[6] These figures reflect the dramatic savings that consumers who pay out-of-pocket and drug plan providers experience from the availability of generic prescription drugs.

Given the importance of pharmaceuticals to Canada's health care sector and the role that generic drugs have played in limiting pharmaceutical spending, the Canadian Competition Bureau ("Bureau") has focused its advocacy and enforcement efforts in this sector on continuing to ensure that competition from generic drugs is not delayed or foreclosed through anticompetitive conduct. This article discusses two topics related to this effort. First, it discusses a recent Bureau enforcement investigation relating to a product life-cycle management strategy

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[2] Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2013*, at xiii. *Available at* https://secure.cihi.ca/free_products/NHEXTrendsReport_EN.pdf.

[3] Hospitals are the largest component and are estimated at CDN $62.6 billion in 2013 (29.6 percent of total health care spending). Spending on physicians is the third largest component at CDN $31.4 billion (14.8 percent). *Ibid.,* at xiii.

[4] In 2011, 57 percent of total expenditure on prescribed drugs was from the private sector while 43 percent was from the public sector. *Id*., at 29.

[5] *Id*., at 31.

[6] Canadian Generic Pharmaceutical Association, *available at* http://www.canadiangenerics.ca/en/advocacy/docs/CanadianMarketShare2013.pdf.

commonly known in competition circles as "product hopping" or "product switching." Second, this article provides some preliminary thoughts as to how Canadian competition law could apply to patent litigation settlements ("Settlements") in the pharmaceutical industry. To set the stage for what follows, a brief overview of Canada's competition statute is provided in the following section.

II. CANADIAN COMPETITION LEGISLATION

Canada's legislation to prohibit anticompetitive practices is the federal *Competition Act* ("Act").[7] Its principal provisions include those governing: (i) criminal conspiracies, (ii) civil collaborations or agreements among competitors, (iii) abuses of dominance, (iv) mergers, and (v) deceptive marketing practices.

The criminal conspiracy provision of the Act (section 45) prohibits agreements or arrangements between competitors to fix prices, allocate markets or customers, or limit production or supply.[8] Conspiracies are a criminal offense that may involve both fines and prison terms imposed by the courts.

Part VIII of the Act deals with conduct that is not anticompetitive in all circumstances, and, as such, constitutes reviewable matters by the Competition Tribunal ("Tribunal") under civil law. It includes the abuse of dominance provision (section 79) and the civil competitor collaborations provision (section 90.1). The abuse of dominance provision seeks to prevent dominant firms from engaging in anticompetitive acts that cause a substantial prevention or lessening of competition ("SPLC"). The civil competitor collaborations provision prohibits agreements or arrangements between competitors that do not merit treatment as criminal conspiracies, but which nonetheless substantially prevent or lessen competition in a market.

More information on sections 45, 79, and 90.1 will be provided below in the context of discussing the potential application of the Act to Settlements.

III. LIFE CYCLE MANAGEMENT STRATEGIES: "PRODUCT SWITCHING"

Life-cycle management strategies in the pharmaceutical industry are not inherently anticompetitive. In pro-competitive circumstances, such strategies may bring significant advancements in health care for the benefit of consumers, as well as drug companies. However, life-cycle management strategies that are designed to impede competition from generic drug companies, such as product switching strategies, may cause significant harm to competition.

In November 2012, the Bureau initiated an inquiry to examine whether Alcon Canada Inc. ("Alcon"), a branded pharmaceutical firm, was dominant in a relevant market and, if so, whether it had, among other things, intentionally disrupted the supply of its prescription ocular anti-allergy drug, Patanol, as part of a strategy to switch patients to a second generation formulation of the drug and hinder meaningful competition from generic companies. This

[7] R.S.C. 1985, c. C-34.

[8] To provide guidance concerning which agreements between competitors are likely to be enforced on a criminal standard, the Bureau has issued *Competitor Collaboration Guidelines* (2009), *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf/$FILE/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf.

strategy is widely known as "product switching" or "product hopping" in the antitrust literature.[9] The Bureau's inquiry sought to determine whether Alcon's conduct excluded generic drug companies from the relevant market, contrary to the abuse of dominance provision of the Act.

By way of background, Alcon began supplying Patanol in Canada in February 1998. Alcon's patent for the medicinal ingredient of Patanol, olopatadine hydrochloride, expired on November 21, 2012. Alcon also had a formulation patent with respect to Patanol that would expire on May 3, 2016.

In February 2010, Apotex Inc., Canada's largest generic pharmaceutical company, had sought Health Canada's approval to market a generic version of Patanol. Pursuant to Canada's regulations governing generic entry prior to patent expiry, Apotex provided Alcon with notice that it was challenging Alcon's formulation patent but that it would wait until the expiry of Alcon's patent on the medicinal ingredient olopatadine hydrochloride before entering the market. Alcon responded by triggering an automatic 24-month stay that prevented Health Canada from providing regulatory approval to Apotex until Apotex's patent challenge could be resolved by the Federal Court. Ultimately, the Federal Court litigation involving Apotex's challenge was discontinued by Alcon in April 2012. Meanwhile, in April 2011, Alcon had begun selling Pataday in Canada. Pataday is an olopatadine formulation for once-a-day dosing and is under patent protection until 2022.[10]

While Patanol and Pataday were simultaneously on the market, Pataday sales were increasing but remained low compared to those of Patanol. In July 2012, Alcon suspended the supply of Patanol in Canada and advised the market that Patanol would be on "back order" for the foreseeable future. With that supply disruption, physicians no longer had the option of prescribing Patanol and many began prescribing Pataday. Sales of Pataday replaced the vast majority of sales of Patanol.

Following commencement of the Bureau's inquiry in November 2012, Alcon resumed supply of Patanol to the Canadian market in January 2013. By May 2013, Patanol sales were comparable with sales prior to the supply disruption. Subsequently, competitors entered the market with generic versions of Patanol and the Bureau's inquiry was discontinued.[11]

IV. PATENT LITIGATION SETTLEMENTS: A CANADIAN APPROACH

Given the importance of pharmaceuticals to Canada's health care sector, the Bureau has an interest in preventing Settlements between brand name and generic pharmaceutical manufacturers that delay generic entry. The Bureau's general approach to assessing collaborations among competitors, which includes Settlements that may delay generic entry, is reflected in the Bureau's *Competitor Collaborations Guidelines*.[12] Where the Bureau has determined that a Settlement could raise issues under either criminal or civil provisions of the

[9] *See* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry,* 108 COLUMBIA L. REV. (2008) and Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLORIDA L. REV. (2010).

[10] Patanol requires twice-a-day dosing.

[11] The Bureau published a position statement on the case that is *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html.

[12] *Supra* note 8.

Act, it will then determine whether the criminal conspiracy provision in section 45, the civil competitor collaboration provision in section 90.1, or the abuse of dominance provision in section 79 is applicable. The decision to pursue a matter under either the criminal or civil provisions will depend on the facts and evidence of each case. Accordingly, in the event an inquiry is commenced under section 10 of the Act, the Bureau may pursue a dual-track inquiry under criminal and civil provisions (i.e., sections 45, 90.1, and 79) until a decision is made on the appropriate section to be applied.[13]

If a Settlement is between competitors and includes conduct with respect to markets or products that are not the focus of the patent litigation, or the conduct is beyond the scope of the patent—such as fixing a generic entry date beyond the term of the patent—the Bureau would likely pursue the Settlement under the section 45 criminal provision if the conduct is of a type prohibited under section 45. Similarly, if the Bureau finds direct or circumstantial evidence that indicates that a Settlement is a vehicle for a "naked restraint" on competition that is not implemented in furtherance of a legitimate collaboration, or was motivated by factors beyond the issues associated with the litigation, the Bureau would also likely pursue the Settlement under section 45.

For Settlements where neither of these two conditions is met, the Bureau will use its enforcement discretion to decide whether to pursue the matter under section 45 or one of the relevant civil provisions under Part VIII of the Act. Considerations that may inform the Bureau in the exercise of its enforcement discretion include, in general terms: the type and value of consideration flowing from the brand to the generic for an agreed upon generic entry date, the amount of time until generic entry, and any other available evidence.

A. Section 45 of the Competition Act

Where business conduct satisfies the constituent elements of the criminal section 45, it may be investigated under section 45. In the Bureau's view, section 45 of the Act could apply to Settlements that have terms where there is compensation (i.e., a "payment") from the brand to the generic and the generic agrees not to enter the market before a certain date. This payment could take a variety of forms (e.g., cash, a promise not to launch an authorized generic, or provision of services, to name a few).

Where the constituent elements of an offense under section 45 are satisfied, the Bureau will consider whether the ancillary restraints defense under subsection 45(4), or another defense set out in section 45, may apply.[14]

Where the Bureau determines that there is sufficient evidence to establish that an agreement satisfies the ancillary restraints defense, it will not refer the matter to the Director of Public Prosecutions (the "DPP") with a recommendation to commence a prosecution under

[13] The Bureau's bulletin on *Communication during Inquiries* summarizes more generally when and how the Bureau generally communicates with parties whose conduct is being inquired into pursuant to section 10 of the Act. *Available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03747.html.

[14] As described more generally in the Bureau's *Competitor Collaboration Guidelines*, agreements that are directly related to, and reasonably necessary for giving effect to, a broader agreement may be subject to an ancillary restraints defense.

section 45, but it may instead seek a remedy from the Competition Tribunal in respect of the agreement under section 90.1 where the Settlement is likely to prevent or lessen competition substantially.

As is the case in general, parties may approach the Bureau at any time to resolve a criminal matter prior to referral to the DPP for prosecution. The Bureau's Immunity and Leniency Programs provide a clear framework for cooperation and the provision of information by cooperating parties during investigations related to the criminal provisions of the Act.[15] However, the DPP has the sole authority to engage in plea and sentencing discussions with counsel for an accused.

While the Bureau may, where appropriate, initially elect to evaluate a Settlement under the criminal section 45, it may subsequently decide that circumstances warrant pursuing a remedy from the Competition Tribunal under the civil provisions of the Act at any time prior to referral of the matter to the DPP for prosecution. In cases where the matter is referred, but the DPP elects not to pursue prosecution, the Bureau may choose to re-evaluate whether the Settlement should be subject to a remedy under the civil provisions of the Act. At no time, however, will the Bureau use the threat of criminal prosecution to induce a Settlement in cases proceeding by way of the civil track.

B. Part VIII of the Competition Act: Civil Reviewable Practices

Where the Bureau, in exercising its enforcement discretion, elects to pursue a matter under Part VIII of the Act, it is most likely to examine a Settlement agreement under section 90.1, but may also consider an examination under section 79 under certain circumstances.[16] In general, agreements between competitors that may be examined under section 79 include, but are not limited to situations where (i) the parties are dominant, or jointly dominant, and (ii) the agreement results in or facilitates conduct that has a negative effect on a competitor that is exclusionary, predatory, or disciplinary, such that it has had, is having, or is likely to have the effect of preventing or lessening competition substantially in a market.[17] Both sections 79 and 90.1 require the Bureau to establish that the agreement at issue has, or is likely to have, the effect of causing an SPLC.

The Tribunal has adopted a "but for" test to assess whether an SPLC was caused by a given anticompetitive practice.[18] If, but for the Settlement, the parties would have been likely to compete, thereby disciplining the exercise of market power to lead to lower cost alternatives for consumers, the Settlement may be found to be causing an SPLC. This analysis may include an examination of the expected date of generic entry but for the Settlement and the agreed entry

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[15] For more information, please consult the Bureau's bulletins *Immunity Program under the Competition Act* (*available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03248.html) and the *Leniency Program* (*available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03288.html), as well as their respective FAQs.

[16] There are limits to initiating more than one proceeding arising from the same or substantially the same facts. *See* section 79(7) and section 90.1(10) of the Act.

[17] *Supra* note 8, at 2.

[18] This test was first accepted by the Federal Court of Appeal in *Canada (Commissioner of Competition) v. Canada Pipe Co. 2006 FCA 233.*

date, and the difference between the prices that would have been expected to prevail in each case. Importantly, the alternative "but for" the Settlement is not necessarily the fully litigated outcome. It is possible that the parties may have reached an alternative Settlement with less restrictive terms.

One approach to help determine whether a Settlement has created an SPLC is to consider whether the value transfer to the generic is in excess of what the patentee could have been expected to pay in the event it had lost the litigation. The rationale behind this approach is that any payment exceeding this amount would likely be for the purposes of delaying generic entry. In Canada, this threshold could include the patentee's expected litigation costs and, perhaps, the patentee's potential liability for damages under Canada's regulatory regime governing generic entry before patent expiry.[19] All else being equal, the greater the value transfer from the brand to the generic, the greater the likelihood of an SPLC.

Where the constituent elements of sections 79 or 90.1 are met, the Bureau will then consider possible business justifications (under section 79) or economic efficiencies (under section 90.1). When assessing business justifications or efficiencies, the Bureau will consider a number of factors, including (i) the credibility of the claims, (ii) the link to the Settlement, (iii) the likelihood of the benefits being achieved, and (iv) whether the benefits would or could not be obtained but for the Settlement.

Where the business justifications or economic efficiencies provided by the parties are not valid, or do not offset any negative effects on competition, the Bureau may seek a remedy from the Tribunal to prohibit the Settlement or the anticompetitive terms of the Settlement. The Bureau may also seek an administrative monetary penalty from the parties to the Settlement.[20] In addition, the Tribunal is also empowered to make an order directing any or all persons against whom an order is sought to take such actions as are reasonable to overcome the effects of the practice of anticompetitive acts in that market.

Under section 90.1, the Tribunal may make an order prohibiting any person from doing anything under the Settlement, or requiring any person (with the consent of that person and the Bureau) to take any other action.

V. CONCLUSION

Given the importance of pharmaceuticals to Canada's health care sector, and the role that generic entry plays in fostering the benefits of competition, one of the Bureau's enforcement concerns is to prevent anticompetitive conduct in the pharmaceutical industry. In this regard, the Bureau has taken a fervent interest in life-cycle management strategies, such as "product-hopping," as well as Settlements between brand and generic drug manufacturers that may delay generic entry.

[19] Canada's *Patented Medicine Notice of Compliance Regulations* governs generics that seek to sell their product before patent expiry. Under section 8 of these regulations, the brand is liable for the generic's losses from being kept off the market until issues such as patent validity and infringement can be addressed by the Courts.

[20] Subsection 79(3.1) of the Act specifies that if the Tribunal makes an order against a person under section 79, it may also order them to pay an administrative monetary penalty in an amount not exceeding CDN$10 million and, for each subsequent order, an amount not exceeding CDN$15 million.

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The Rising Tide: Competition Law Enforcement in the Indian Pharmaceutical Sector

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I. INTRODUCTION

Given the sensitivity and direct impact on consumers, it is of little surprise that the pharmaceutical industry—if not an absolute—ranks as one of the most controversial and actively pursued sectors by antitrust authorities across the world. India is no exception to this rule.

On September 4, 2014, the Competition Commission of India ("CCI") issued a notice seeking public comments subsequent to initiating its first Phase II investigation in the *Sun/Ranbaxy* merger case.[2] Not only is this case a watershed development in merger enforcement, it is also a strong indication towards increasing competition law enforcement in the Indian pharmaceutical sector. This article highlights the recent developments and future trends in this industry in India.

II. INDIAN PHARMACEUTICAL INDUSTRY

In order to fully comprehend the specific importance of this sector, it's imperative to first understand some peculiarities of the Indian pharmaceutical industry.

In India, unlike most countries, the burden of healthcare expenditure is primarily borne by private individuals. In such a scenario, price becomes one of the most pertinent issues in relation to pharmaceutical products. This is evident from the fact that, in India, there are numerous policies and regulations controlling the prices of various pharmaceutical products.[3] This is perhaps one of the primary explanations for the proliferation of generic manufacturers in India.

Predictably, government authorities in India have been even more attuned to the burden on consumers in this sector. The first compulsory license granted by the Indian Patents Office, for the manufacture and sale of Bayer's patented drug Nexavar,[4] is an excellent manifestation of this. In such a situation, it is only natural to expect rigorous competition law enforcement in this sector.

III. CURRENT ENFORCEMENT IN THE PHARMA SECTOR

To date, enforcement in this sector has been limited to cases related to anticompetitive agreements and mergers.

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[2] C-2014/05/170, *available at* http://cci.gov.in/May2011/PressRelease/C-2014-05-170-Press-Release.pdf.

[3] For instance, *see* Drug Policy 1986 *available at* http://www.nppaindia.nic.in/index1.html.

[4] *Natco Pharma Limited v. Bayer Corporation,* Compulsory License Application No 1/2011.

A. Anticompetitive Agreements—The Muddled Distribution Chain

Competition law across the world is replete with cases relating to the pharmaceutical sector. Typically these cases pertain to concerted practices between pharmaceutical manufacturers—recent transatlantic proliferation of pay-for-delay agreements has made this industry rather infamous.

Surprisingly, the CCI has taken a somewhat unconventional approach in cases relating to anticompetitive agreements. Notably, in India, it is the distribution chain that has been in the limelight for anticompetitive practices. The CCI, in as many as eight cases,[5] has penalized various trade associations of chemists and druggists for imposing certain conditions on their members to be in contravention of Section 3(3) of the Competition Act, 2002 (Competition Act). Section 3(3) of the Competition Act is the equivalent of the colloquial *per se* anticompetitive agreements; it provides for certain types of conducts that are deemed *per se* anticompetitive.[6] The CCI, in these eight cases, held the imposition of such conditions by the associations to directly or indirectly result in controlling the prices and supply of drugs through concerted and restrictive practices, thereby violating Section 3(3).

The novelty of these cases however, is not so much in the substantive assessment of the conduct but the unprecedented enforcement by the CCI. The CCI in all these cases imposed a fine of 10 percent of the aggregate turnover of these associations—the maximum penalty leviable for anticompetitive practices.[7] Not only did the CCI impose maximum penalties in these cases, some of them happened to be the few where the CCI has also prosecuted individual officers for infringement under Section 48 of the Competition Act.[8] Further, the CCI—again for the first time—also issued a notice in public interest, specifically highlighting the anticompetitive practices of the trade associations.[9]

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[5] *Varca Druggist & Chemist & Ors. v. Chemists and Druggists Association, Goa*, MRTP C-127/2009/DGIR4/28; *Vedant Bio Sciences v. Chemists & Druggists Association of Baroda*, Case No. C-87/2009/DGIR; *M/s Santuka Associates Pvt. Ltd. v. All India Organization of Chemists and Druggists and Ors.*, Case No. 20/2011; *M/s Sandhya Drug Agency v. Assam Drug Dealers Association and Ors.*, Case No. 41/2011; *M/s Peeveear Medical Agencies, Kerala v. All India Organization of Chemists and Druggists and Ors.*, Case No. 30/2011; *M/s Arora Medical Hall, Ferozepur vs Chemists & Druggists Association, Ferozepur & Ors.*, Case No. 60/2012; *In Re: Bengal Chemist and Druggist Association*, *Suo moto* Case No. 02 of 2012 and Ref. Case No. 01 of 2013; and *Collective boycott/refusal to deal by the Chemists & Druggists Association, Goa (CDAG), M/s Glenmark Company and, M/s Wockhardt Ltd.*, *Suo moto* Case No. 05/2013.

[6] This means that once it is established that a conduct falls under Section 3(3), the burden then shifts to the defendant to rebut this presumption. *See, Reliance Big Entertainment Private Limited v. Tamil Nadu Film Exhibitors Association*, Case No. 78/2011.

[7] Section 27 of the Competition Act.

[8] *See,* Chemists & Druggists Association, Ferozepur, *supra* n. 5; and In Re: Bengal Chemist, *supra* n. 5. Section 48 of the Competition Act empowers the CCI to hold individual officers personally liable for the anticompetitive conduct of the defendant company. As per orders passed until November 19, 2014, cases where action under Section 48 has been taken, all except one, have been in relation to chemists and druggists.

[9] Public Notice dated 31 January 2014, *available at* http://cci.gov.in/May2011/OrderOfCommission/PublicNotice/PublicNotice-DrugsAndMedicines.pdf

B. Merger Enforcement—The Abbreviated Assessment

Mergers and acquisitions are collectively referred to as combinations under the Competition Act.[10] Section 6 of the Competition Act prohibits those combinations that cause, or are likely to cause, an appreciable adverse effect on competition ("AAEC") in India and requires that such combinations are treated as void. Importantly, the regime is suspensory, which means that transactions subject to merger control review by the CCI cannot be concluded until merger clearance in India has been obtained or a review period of 210 calendar days has passed, whichever comes first.[11]

As per the provisions of the Competition Act, on receipt of a notification, the CCI is required to form a *prima facie* opinion on whether the combination causes, or is likely to cause, an AAEC in the relevant market in India within a period of 30 days,[12] more commonly known as the Phase I review process. At the end of the Phase I review period, in case the CCI forms a *prima facie* opinion that a combination causes, or is likely to cause, an AAEC, a detailed investigation will follow and the standstill obligation will continue until a final decision is reached by the CCI or a review period of 210 calendar days has passed.[13] This is Phase II review of the investigation process.

Merger enforcement in India has generally been non-controversial. Until as recently as 2014, the CCI cleared all cases within Phase I review, including cases relating to the pharma sector. In fact, their assessment seemed to indicate that pharma was a more or less competitive sector, primarily looking outbound, with insignificant impact in India.[14] At most, the only issues in this sector were in relation to non-compete clauses. Following the EU ancillary restraints doctrine, the CCI has permitted non-compete clauses that are "necessary" and "reasonable" to the transaction. Additionally, in line with the benchmark provided in the EU ancillary restraint guidelines, such clauses spanning across a period of more than four years were found to be excessive.[15]

Notably, contrary to the practice followed in other jurisdictions, the CCI refrained from arriving at a definitive market definition when assessing these cases, despite some of them being horizontal mergers.[16] The primary reason for this approach seemed to be the insignificant impact of the transactions in India as most of these cases related to entities that primarily exported.[17]

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[10] Section 5 of the Competition Act.

[11] Section 31 of the Competition Act.

[12] Section 29 of the Competition Act read with Regulation 19(1), Competition Commission of India (Procedure in regard to the transaction of Business relating to Combinations) Regulations, 2011 (Combination Regulations). Combination Regulations further supplement provisions relating to merger control under the Competition Act.

[13] Section 29 and 31 of the Competition Act.

[14] For instance *see*, *Notice given by Meiji Seika Pharma Co., Ltd.*, C-2014/07/189; *Notice given by Mylan Inc.*, C-2013/04/116; and *Notice for Acquisition filed by Orchid Chemicals & Pharmaceuticals Limited and Hospira Healthcare India Private Limited*, C-2012/09/79.

[15] Mylan Inc., *Id;* Orchid Chemicals, *Id.*

[16] *Id.*

[17] *Supra* n. 14.

It was only in the *Elder/Torrent*[18] case where the CCI undertook a more detailed analysis and, for the first time, defined the relevant market based on the therapeutic category of the products. Nevertheless, save for the non-compete clauses, no competition issues were observed here either.

Interestingly, in 2014 the CCI initiated its first phase II investigation in the Sun/Ranbaxy[19] merger. This case relates to a proposed merger between Sun Pharmaceuticals and Ranbaxy Laboratories. If approved, the merger is believed to create the fifth largest generics manufacturer in the world and the largest in India. The CCI formed a *prima facie* opinion that the deal is likely to cause an AAEC and consequently commenced an in-depth investigation.[20] Moreover, the CCI also sought public comments—yet again a first for merger enforcement in India.

Presumably, the CCI—as in the *Elder/Torrent* case—took a narrower approach to market definition when arriving at this conclusion. The assessment of the CCI seems to be based on the premise that proposed combination would result in Sun Pharma having a market share of more than 40 percent for at least 25 drugs. Out of these, for nine drugs its market share could be more than 65 percent.[21] Had the CCI taken its earlier approach, the transaction would have posed minimal concerns since the aggregate market share, post-transaction, seems to amounts to 9.2 percent[22] in the pharmaceutical sector.

IV. FUTURE TRENDS

Given these recent developments in Indian competition jurisprudence, enforcement trends in the coming future are likely to have exponential bearings on the pharmaceutical sector.

A. Merger Enforcement—A Meticulous Assessment

With gradual maturity, it is only natural that merger enforcement would be more nuanced in the coming future. The *Sun/Ranbaxy* case is clearly illustrative of such a trend. Importantly, this case is indicative of an increased scrutiny as opposed to the earlier somewhat ambivalent disposition in pharma cases.

Predictably this trend is most reflected in the CCI's approach to market definition. As mentioned above, recent decisional practice illustrates a more microscopic market definition as typically observed in more mature jurisdictions. The concept of defining a pharmaceutical market on the basis of therapeutic categorization—if not at a narrower level—seems to be the new basis. In fact, if required, the CCI could also adopt a narrower categorization.[23] A direct consequence of this approach is a more detailed assessment at the *prima facie* stage.

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[18] Notice for acquisition given by Torrent Pharmaceuticals Limited and Elder Pharmaceuticals Limited, C-2014/01/148, ¶ 9.

[19] *Supra* n. 2.

[20] Section 29 of the Competition Act provides for the procedure to be followed where the CCI takes a *prima facie* opinion that the proposed combination is likely to cause an AAEC.

[21] http://articles.economictimes.indiatimes.com/2014-10-18/news/55172874_1_competition-watchdog-sun-ranbaxy-competition-law.

[22] *See,* http://cci.gov.in/May2011/Home/C-2014-05-170-Form-IV.pdf.

[23] *See,* for instance, Elder/Torrent case, *supra* n. 18, where the CCI also considered the possibility of defining the market a molecular level, ¶ 9.

Here it is important to note that even during a Phase I review, the CCI is empowered to make additional inquiries if it feels that the information provided by the parties is insufficient.[24] The CCI in such situations typically issues a defect notice seeking further information, which, in turn, stops the clock till the requisite information is provided.[25] This often results in a merger assessment spanning across a period which is longer than the exact 30 days provided for a Phase I review, or the ultimate 210 days limit within which the CCI is mandated to complete its review.[26] With respect to pharma cases, the CCI, even with its abbreviated assessment, often has taken longer than actual 30 calendar days to arrive at a *prima facie* opinion.[27] Predictably, a detailed scrutiny is more than likely to translate into a longer review period.

B. Anticompetitive Agreements—Casting a Wider Net

As discussed above, with respect to anticompetitive agreements, only the distribution chain has been subject to CCI's scrutiny so far. However, the CCI is expected to broaden its assessment and focus on pharmaceutical manufacturers. In fact, taking its cue from the United States and EU, the CCI is believed to have already started looking at usual suspects and is investigating alleged pay-for-delay agreements entered into by pharmaceutical companies.[28]

Here it is important to note that India has borrowed heavily from EU jurisprudence.[29] Resultantly, such agreements if established, in all probability, will be deemed *per se* anticompetitive under Section 3(3) of the Competition Act.

C. The Trickle-Down Effect—Collaboration Agreements

The focus on manufacturers is likely to trickle down to an assessment of other forms of agreements. The pharmaceutical sector happens to be one of the few sectors where cooperation agreements between various manufacturers are commonplace. Such agreements are typically co-marketing or co-branding agreements between various manufacturers. While such agreements between competitors are traditionally frowned upon, in this industry they are generally believed to be efficiency enhancing and therefore permissible.

India is no exception to such agreements.[30] However, to date none of these agreements has been scrutinized under the Competition Act. Nevertheless, the probability of such

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[24] Regulations 14(3) and 19(2), Combination Regulations.

[25] Proviso to Regulation 19(2) of the Combination Regulations.

[26] *Supra* n. 13.

[27] For instance in Mylan Inc., *supra* n. 14, notification was made on April 1, 2013 while an order was passed on June 22, 2013. Similarly in Elder case, *supra* n. 18, notification was made on January 13, 2014 while an order was passed on March 26, 2014.

[28] *See* http://www.livemint.com/Companies/RVVDhRh7oTfpqlIphkb6jM/CCI-to-scan-drug-patent-settlements.html.

[29] *In Automobiles Dealers Association, Hathras, UP v. Global Automobiles & Others, Case No. 33/2011,* the CCI relied on the EU guidelines on vertical restraints when assessing a vertical agreement under the Competition Act. Similarly, the COMPAT in *M/s Excel Corps and Others v. Competition Commission and others, Appeal No. 79 of 2012; 80 of 2012; and 81 of 2012 (against In Re: Aluminium Phosphide Tablets Manufacturers, Suo-moto case No. 2/2011),* relied on guidelines in the EU and Office of Fair Trading, U.K. to propound the definition of relevant turnover.

[30] For instance *see* http://www.emcure.co.in/business_marketing.asp; http://economictimes.indiatimes.com/glaxosmithkline-pharmaceuticals-ltd/infocompanyhistory/companyid-

agreements also being reviewed is imminent. The assessment of these agreements is likely to be rather contentious. Given the emulation of EU jurisprudence, one would expect the CCI to follow a similar approach and generally adopt an effects-based analysis in these cases. However, unlike in the European Union, the Competition Act draws a clear distinction between horizontal, vertical, and all other forms of agreements.[31] Consequently, such agreements are likely to be assessed within the purview of Section 3(3) of the Competition Act.

Since these cases represent uncharted territory, it is difficult to predict what approach the CCI is likely to take. Typically an effects-based assessment has been reserved only for agreements other than horizontal agreements. Nevertheless, given the general efficiency-enhancing nature of such agreements, it is highly probable that the CCI will also assess these agreements under the rule of reason approach.

D. Abuse of Dominance—An India Specific Enforcement

As already mentioned, Indian literature is rather sparse regarding abuse of dominance cases relating to the pharma sector. Nevertheless, given the importance and nature of this sector, it is reasonable to expect cases relating to this category as well.

While probable trends seem to be ostensibly similar to the ones present in other jurisdictions, enforcement of competition law in India will, in all probability, cause significant divergence.

Section 4 of the Competition Act proscribes abuse of dominance by an enterprise. It is in these cases where the CCI has significantly diverged from international jurisdictions and taken an India-specific approach in enforcement.[32] Arguably, the main reason for this prevailing position can be attributed to its consumer-centric priorities. The approach taken by the CCI seems to concentrate on directly protecting consumer interests; as opposed to it being a necessary corollary of unbridled competition in the market. As a result, these priorities have yielded to the traditionally formalistic approach, particularly in abuse of dominance cases. For instance, under the current regime, both exclusionary and exploitative practices are considered to be an abuse.[33] In fact, exploitative conducts like excessive pricing and unfair conditions on consumers have taken a center stage in abuse of dominance cases in India.[34] Additionally, "special responsibility" has been accorded to a dominant enterprise under the Competition Act.[35]

13715.cms; http://www.livemint.com/Companies/l1UJr9if0JCTeKm8VEWFGJ/Cipla-to-partner-with-MSD-Pharma-to-sell-HIV-drug-in-India.html.

[31] *Mr. Ramakant Kini v. Dr. L.H. Hiranandani Hospital, Powai, Mumbai,* Case No. 39/2012, ¶ 9.

[32] *MCX Stock Exchange Ltd. v. National Stock Exchange of India Limited,* Case No. 13/2009, ¶ 10.80.

[33] *Belaire Owners' Association v. DLF Limited, HUDA & Others*, Case No. 19/2010, the CCI held that monopolization by the developer—by imposing unfair terms and conditions on the consumers—was illegal under Section 4. The conduct considered anticompetitive in this case was an exploitative conduct. On the other hand, in the NSE case, *id.,* the CCI was of the view that the conduct price predation by the dominant firm—to the exclusion of its competitors—amounted to abuse of dominance. This offense was also upheld by the COMPAT in National Stock Exchange of India Ltd., *id*.

[34] *Shri Shamsher Kataria v. Honda Siel Cars India Ltd. & Ors.*, Case No. 03/2011.

[35] *National Stock Exchange of India Ltd. v. Competition Commission of India & Ors.,* Appeal No. 15 of 2011, ¶ 69.

While this approach is reflected in all cases, it is likely to be even more conspicuous in the pharma sector.

It is important to remember that, in India, it is the end-consumers that bear the primary burden of healthcare expenditure. In such a scenario, it is only expected for competition policy in India to give credence to the generic sector and take a circumspect approach regarding innovator/originator companies. In light of this landscape, abuse of dominance cases are more than likely to be focused on strategies adopted by originator companies.

As mentioned, dominant undertakings have been accorded a special responsibility; in essence implying a higher level of scrutiny in the conduct of such entities. Predictably, this responsibility would be even greater in cases relating to innovator/originator companies—typically perceived as companies already armed with multiple intellectual property rights ("IPR") protections giving them monopoly rights. Any conduct of such companies that either results in an increase in price or delay of generic competitors will draw heavy scrutiny—necessitating an approach similar to Caesar's wife, i.e. to remain above all suspicion.

With respect to possible conducts likely to be the subject matter of review, impact on consumers is bound to be the most important factor, which implies pricing will be one of the most contentious issues. Thus, questionable conduct would typically comprise of strategies that relate to originator companies' pricing their own products and, more importantly, strategies adopted to delay the entry of generics into the market.

Finally, no discussion of enforcement in the pharma sector is close to being complete without talking about the imminent interface between intellectual property law and competition law. Patent strategies, adopted by innovator companies, to delay entry of generics are perhaps the quintessence of abusive conduct specific to this sector. Naturally, such strategies would also be subject to detailed assessment under the Competition Act.

V. CONCLUSION

The CCI has on numerous occasions stressed the need to ensure competitive neutrality across sectors in the economy. Its commitment to ensure competition across sectors can be seen in the advocacy initiatives undertaken by the CCI.[36] In this vein, the CCI has typically focused on particular industries that it believes have a direct impact on the economy and consumers.

What is perhaps interesting to note is that while these priorities seem to be suggestive of a robust enforcement in an industry such as the pharma sector, the CCI has surprisingly taken a rather deferred approach to date. This is perhaps more demonstrative of the yet nascent state of Indian competition law rather than it being a low priority for the CCI. As is typical of a developing jurisdiction, it is only natural to expect a shift in focus from the so-called "smokestack industries" to sectors that deal with more complex and intricate issues like the pharmaceutical industry.

[36] Per its Newsletter, Volume 5: April-June 2013, *available at* http://cci.gov.in/Newsletter/newsletterjuly2013.pdf.