

## A PRODUCT-HOP, SKIP, AND JUMP IN 2017<sup>1</sup>

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January 2017 started with marked activity at the federal district court level in the antitrust area of pharmaceutical product-hopping. In the Eastern District of Pennsylvania, New Jersey-based generic drug maker Amneal Pharmaceuticals was permitted to advance in its suit against Indivior PLC, a British company specializing in the treatment of opioid addiction.<sup>2</sup> In the District of Delaware, generic pharmaceutical manufacturer Apotex Inc. and Japanese drug manufacturer Kyorin Pharmaceutical Co. Ltd. jointly filed a stipulation to stay proceedings upon reaching an agreement with Kyorin from suit after an initial battle involving multiple drug makers accused of trying to extend the market for Allergan Inc.'s pinkeye treatment, Zymar.<sup>3</sup> This and other activity underscores that perceived

product-hopping conduct by pharmaceutical companies near the expiration of a brand name drug's patent life may remain a targeted focus for antitrust enforcement in 2017.

### I. A CIRCUIT SPLIT: ACTAVIS AND MYLAN

The legality of product-hopping is still unclear given the distinction between the Second Circuit's 2015 treatment of product-hopping in *N.Y. ex rel. Schneiderman v. Actavis PLC*<sup>4</sup> versus the Third Circuit's 2016 rejection of antitrust claims in *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*<sup>5</sup>

In *Actavis*, the Second Circuit affirmed the district court's grant of a preliminary injunction preventing brand firm Forest (now part of Actavis) from withdrawing its original Alzheimer's drug Namenda Immediate Release (IR) from the market. Forest planned to replace Namenda IR with Namenda Extended Release (XR), which would have changed the administration method from twice a day to once a day.

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<sup>2</sup> See *In re: Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, case no. 2:13-md-02445. See also Dan Packel, "Amneal Sees Key Suboxone Product-Hopping Claims Advance," Law360, [https://www.law360.com/ip/articles/877503/amneal-sees-key-suboxone-product-hopping-claims-advance?nl\\_pk=3c925521-b976-4301-8fe1-49caad957179&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=ip](https://www.law360.com/ip/articles/877503/amneal-sees-key-suboxone-product-hopping-claims-advance?nl_pk=3c925521-b976-4301-8fe1-49caad957179&utm_source=newsletter&utm_medium=email&utm_campaign=ip) (Jan. 4, 2017).

<sup>3</sup> See *Apotex Inc. et al v. Allergan Inc.*, case no. 1:12-cv-00196. See also Kelly Knaub, "Kyorin to Settle Apotex Pinkeye Meds Product-Hopping Suit," Law360, [https://www.law360.com/ip/articles/878407/kyorin-to-settle-apotex-pinkeye-meds-product-hopping-suit?nl\\_pk=3c925521-b976-4301-8fe1-49caad957179&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=ip](https://www.law360.com/ip/articles/878407/kyorin-to-settle-apotex-pinkeye-meds-product-hopping-suit?nl_pk=3c925521-b976-4301-8fe1-49caad957179&utm_source=newsletter&utm_medium=email&utm_campaign=ip) (Jan. 6, 2017).

<sup>4</sup> 787 F.3d 638 (2d Cir. 2015).

<sup>5</sup> 838 F.3d 421 (3d Cir. 2016).

The Second Circuit found that while “neither product withdrawal nor product improvement alone is anticompetitive,” such *combination* of activity gives the overall effect that would coerce consumers rather than persuade them on the merits.<sup>6</sup> According to the court, when a monopolist *combines* product withdrawal *with some other conduct*, the overall effect of which is to impede competition and coerce consumers rather than persuade them on the merits, its actions are anticompetitive, which is a violation of Section 2 of the Sherman Act, related to attempted and actual monopolization.<sup>7</sup> Specifically, the Second Circuit emphasized that removing Namenda IR from the market prior to the entry of generics—in *combination* with introducing Namenda XR—forced Alzheimer’s patients to switch to Namenda XR, to which generic IR is not therapeutically equivalent. This basically deprived doctors and consumers the right to choose between once-daily Namenda XR versus a twice-daily therapy using less expensive generic IR.

In *Mylan*, the Third Circuit examined whether Warner Chilcott’s behavior violated Sections 1 and 2 of the Sherman Act when it stopped selling capsule versions of its acne-treating drug Doryx to wholesalers and effectively forced the market to replace the capsules with a new tablet version.<sup>8</sup> In its initial suit, Mylan alleged that Warner Chilcott made four anticompetitive “hops”—

in 2005, it changed from 75 mg and 100 mg capsules to 75 mg and 100 mg tablets; in 2008, it introduced a single-scored 150 mg tablet; in 2009, it added a single score to 75 mg and 100 mg tablets; and in 2011, it changed from single-score to dual-score on the 150 mg tablet. The District Court found that Warner Chilcott did indeed make product “hops” to primarily delay generic market entry, but concluded Mylan’s antitrust claims failed as a matter of law, especially regarding Section 2, because there was insufficient evidence to show Warner Chilcott had monopoly power in the relevant market.

The Third Circuit agreed with the District Court’s analysis of Section 2, finding that Mylan failed to provide direct evidence of Warner Chilcott’s monopoly power and too narrowly defined the relevant market as only related to generic and brand-name Doryx. Further, there was also evidence of pro-competitive purposes to Warner Chilcott’s product changes, addressing issues like safety and shelf-life problems with the capsule version. The Third Circuit rejected the argument that large profit margins alone were evidence of monopoly power. Similarly, the Third Circuit rejected Mylan’s contention that Warner Chilcott’s conduct was an illegal restraint of trade, in violation of Section 1 of the Sherman Act, because Mylan failed to prove the product hops were anticompetitive.

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<sup>6</sup> *Actavis*, 787 F.3d at 653–54.

<sup>7</sup> § 2 of the Sherman Act states: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . .”

<sup>8</sup> § 1 of the Sherman Act states: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. . . .”

The circuit split suggests that the particular facts of any product-hopping case may ultimately affect a court's ruling,<sup>9</sup> and that product-hopping can also be viewed in an innovative light.<sup>10</sup> While some argue that product-hopping negatively impacts consumers, it arguably also incentivizes consumer education programs and could decrease costs faced by manufacturers.

## II. AMNEAL AND APOTEX

Against the backdrop of this divide in circuit court opinions, two 2017 cases illustrate that activity in the area continues to be far from settled.

In *In re: Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, Plaintiff Amneal's claims alleged that Defendant Indivior, an affiliate of Reckitt Benckiser, Inc., engaged in deceptive and antitrust conduct that made it difficult for generic drug makers to obtain the necessary approval from the United States Food and Drug Administration (FDA), delaying generic entry into the market. Specifically, Indivior engaged in product-hopping by reformulating its prescription brand name drug, Suboxone<sup>®</sup>, used to treat opioid

addiction, from an older tablet version to a newly patent-protected film version that is administered under the tongue or inside the cheek.<sup>11</sup>

Amneal alleged that Indivior, knowing that its period of exclusivity for Suboxone tablets was ending, anticompetitively developed and marketed its new film product to maintain its monopoly in the Suboxone market in violation of Section 2 of the Sherman Act. Amneal contended that Suboxone film had equivalent bioavailability as Suboxone tablets, i.e., the products release the same amount of active ingredients into a patient's bloodstream, and that Indivior launched fraudulent sales and marketing campaigns against the tablet form once the FDA approved Suboxone film.<sup>12</sup> While Indivior has asked the district court to dismiss the case under *Mylan*, arguing that similar claims have been unsuccessful, the case is currently pending in the Eastern District of Pennsylvania.<sup>13</sup>

In *Apotex Inc. et al v. Allergan Inc.*, Apotex brought suit alleging that Kyrib and other drug makers, like Senju Pharmaceutical Co. Ltd. and Allergan Inc., violated federal antitrust laws by trying to shift the market of

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<sup>9</sup> Mark A. Ford et. al., "3rd Circ. Weights In on Product-Hopping," Law360, [https://www.wilmerhale.com/uploadedFiles/Shared\\_Content/Editorial/Publications/Documents/2016-11-03-3rd-Circ-Weights-In-On-Product-Hopping.pdf](https://www.wilmerhale.com/uploadedFiles/Shared_Content/Editorial/Publications/Documents/2016-11-03-3rd-Circ-Weights-In-On-Product-Hopping.pdf) (Oct. 31, 2016).

<sup>10</sup> See Benjamin M. Miller, Product Hopping: Monopolization or Innovation?, B.U.J. Sci. & Tech. L., vol. 22 89-120.

<sup>11</sup> <http://www.suboxone.com/treatment/suboxone-film>.

<sup>12</sup> See generally *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 677 (E.D. Pa. 2014), on reconsideration in part sub nom. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015).

<sup>13</sup> See Eric Kroh, "Indivior Must Face Suboxone Product-Hop Suit, States Say," Law360, <https://www.law360.com/articles/886718> (Jan. 31, 2017).

Zymar, a pinkeye medication. The alleged shift was from Zymar, which was developed in the mid-1990s and contained a 0.3% concentration of antibiotic gatifloxacin, to a new formulation, Zymaxid, which increased the amount of gatifloxacin to 0.5% concentration. Apotex, who had received final FDA approval to sell a generic version of the 0.3% gatifloxacin ophthalmic solution in August 2011, claimed Zymaxid was functionally the same as Zymar.

Apotex alleged that Allergan was aware of studies conducted by Senju that demonstrated the 0.5% concentration formulation did not show an increase in efficacy as compared to the 0.3% concentration formulation. Thus, Apotex claimed that Allergan illegally maintained its monopoly power and conspired to monopolize the market for gatifloxacin ophthalmic solutions in violation of Section 2 of the Sherman Act, as well as engaged in anticompetitive conduct that placed an unreasonable restraint of trade in violation of Section 1 of the Sherman Act.<sup>14</sup> However, on April 26, 2017, the Delaware district court dismissed the suit after the parties reached a settlement agreement.<sup>15</sup>

### III. ROOM FOR PRODUCT EDUCATION?

Despite the issues raised in recent case law, product-hopping—the launch of a new brand formulation coinciding with the removal of an old, almost-expired formulation—may provide consumers with

an opportunity for product education. New pharmaceutical product releases are accompanied by marketing and education investments,<sup>16</sup> including safety risks and new benefits. Through such marketing, choice and responsibility *can* actually lie with patients and physicians.

The frequent counterargument to this has been that when a brand name firm pulls its older formulation from shelves, such conduct robs consumers of the chance to use a bioequivalent generic. But at the same time, because a launch of a newer formulation, as fully paid by the brand name manufacturer, highlights to consumers the difference between new generation versus the old generation. Such marketing is only provided by brand name firms, and not generics. However, if a generic brand were to enter the market, it would not incentivize the brand name company to conduct education and marketing programs.

Just as the Third Circuit in *Mylan* found that the new formulation of Doryx tablets addressed credible and important aspects like shelf-life, the tablet form needed new advertising and marketing support to inform consumers of its benefits—whether or not those benefits are different or just a ruse to mask functional similarity. Nevertheless, without such educational information, paid by Warner Chilcott, consumers and doctors may not be aware of previously existing deficiencies in the original formulation. Such

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<sup>14</sup> See generally *Apotex Inc. et al v. Allergan Inc.*, 1:12-cv-00196-SLR (D. Del 2012), Complaint.

<sup>15</sup> See Eric Kroh, “Allergan Settles Apotex Pinkeye Meds Product-Hopping Suit,” *Law360*,

<https://www.law360.com/articles/917311> (Apr. 26, 2017).

<sup>16</sup> See Benjamin M. Miller, *Product Hopping: Monopolization or Innovation?*, *B.U.J. Sci. & Tech. L.*, vol. 22 89-120.

educational marketing could also encourage doctors to consider similar properties in other drugs they may be prescribing to patients.

Highlighting the (alleged) benefits of the new formulation as least gives consumers a chance to acknowledge differences between the legacy product and the new product. Of course, the ultimate choice or lack thereof still depends on whether or not the brand name manufacturer can successfully pull its legacy product from market before the launch of a generic. Likewise, generic drug companies, in addition to showing that a brand name has market power within the relevant market, may have to combat and point out that the proposed benefits of a new brand name formulation are, in fact, not substantial enough to mask functional similarity.