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

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

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## 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.