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Law360's Product-Hopping Cheat Sheet For 2015

By **Melissa Lipman**

Law360, New York (March 13, 2015, 4:45 PM EDT) -- Despite a decade of litigation over so-called product-hopping, the Second Circuit will become the first appellate court to weigh whether pharmaceutical companies' efforts to preserve profits from blockbuster brands facing expiring patents can amount to an antitrust violation.

The Second Circuit is set to hear oral arguments April 13 over whether a federal judge erred in granting New York's attorney general a preliminary injunction forcing Actavis PLC and its Forest Laboratories LLC unit to keep selling an older version of the Alzheimer's drug Namenda until generic-drug challengers can enter the market.

Whatever the appeals court concludes **will have significant repercussions** for the industry generally and for a handful of other pending cases making similar claims over drugmakers' efforts to move the market to a new version of a treatment to avoid the steep drop in profits that follows patent expiration and generic market entry.

Here, Law360 takes a look at the key cases so far.

Case: Abbott Laboratories et al. v. Teva Pharmaceutical Industries Ltd.
Court: U.S. District Court for the District of Delaware, U.S. District Judge Kent Jordan
Drug: TriCor, cholesterol treatment
Was the old version pulled from the market?: Yes
Status: Settled after motion to dismiss denied

One of the biggest and most successful product-hopping cases targeted Abbott Laboratories and Fournier Industrie et Sante over their repeated reformulations of cholesterol treatment TriCor.

Generic-drug makers the pair had sued for patent infringement as well as purchasers and eventually two dozen states accused the companies of cutting off sales of the original formulation of the drug and buying back remaining stocks in order to thwart automatic generic substitution for the treatment.

In 2006, a Delaware federal judge **refused to dismiss the antitrust claims** over the reformulations, citing the landmark Microsoft Corp. monopolization case and the regulatory restrictions within the pharmaceutical market.

The judge pointed out that even though the generic-drug makers could still sell their version of the original formulation of the drug, it was enough for the plaintiffs to allege that Abbott

and Fournier's reformulation and withdrawal of the old versions of the drug kept the generic-drug companies from offering substitutes for the current formulation of TriCor.

Abbott eventually **agreed to pay $250 million** to settle the class actions and reached a $22.5 million deal with the states in 2010.

Case: Walgreen Co. et al. v. AstraZeneca Pharmaceuticals LP et al.
Court: District of Columbia, U.S. District Judge Richard W. Roberts
Drug: Prilosec, heartburn treatment
Was the old version pulled from the market?: No
Status: Dismissed

Private plaintiffs had far less success with suits challenging AstraZeneca PLC's switch from Prilosec, whose patent protection expired in 2001, to a similar drug called Nexium and an over-the-counter version of the older heartburn treatment.

The U.S. Food and Drug Administration had granted AstraZeneca exclusive rights to sell Prilosec without a prescription from 2003 through mid-2006, and Nexium remained under patent protection until 2014.

AstraZeneca, however, never pulled Prilosec from the shelves.

Even though the plaintiffs in the Prilosec suit pointed once again to the Microsoft ruling and the TriCor decision, the D.C. federal judge overseeing the case **found the analogy a failed one**. The difference, the judge reasoned, was that because AstraZeneca continued to sell the older product it had done nothing to limit consumer choice.

Case: Mylan Pharmaceuticals Inc. et al. v. Warner Chilcott PLC et al.
Court: Eastern District of Pennsylvania, U.S. District Judge Paul S. Diamond
Drug: Doryx, oral antibiotic acne treatment
Was the old version pulled from the market?: Yes — but the judge didn't mention it in his ruling
Status: Partially settled; pending summary judgment motion

In 2013, a Pennsylvania federal judge **refused to dismiss product-hopping claims** against Warner Chilcott PLC brought by Mylan Pharmaceuticals and a host of purchasers over acne medication Doryx.

The court voiced skepticism about the plaintiffs' claims that the multiple reformulations of the drug amounted to an antitrust violation but called efforts to nix the case premature and denied the defendants' motion to dismiss without prejudice. Warner pulled the older version of the drug from shelves, according to the plaintiffs, but the judge made no explicit mention of that in his order.

After the indirect purchasers lost their bid for class certification in late 2013, both the direct and indirect purchasers ended up signing settlements. Warner, which is now owned by Actavis, **agreed to pay the direct purchasers** $15 million and the indirect purchasers $8 million.

Mylan, however, is still pursuing the case and is now **fighting for summary judgment**. The generics maker recently pointed the court to the preliminary injunction ruling in the Namenda case.

Case: In re: Suboxone Antitrust Litigation
Court: Eastern District of Pennsylvania, U.S. District Judge Mitchell Goldberg
Drug: Suboxone, opiate addiction treatment
Was the drug pulled from the market?: Yes
Status: Pending motion for reconsideration on motion to dismiss

Filed in 2013, this multidistrict litigation brought by private purchasers accuses Reckitt Benckiser Inc. of using product-hopping to thwart generic-drug competition for opiate addiction treatment Suboxone.

The company reformulated the drug from a tablet to a film, withdrew the old product from the market just as generics were able to begin sales and started claiming the tablets had safety issues, according to the plaintiffs.

Even though Reckitt didn't have a patent on the drug, the FDA deemed the product an orphan drug and granted the company seven years of exclusivity. The company then began developing and seeking patents for a film formulation of the drug, according to the suit.

In December, Judge Goldberg **refused to dismiss the case**, saying that allegations that Reckitt paired its introduction of the reformulated product with sufficiently "coercive" measures that limited consumer choice were enough for the case to go forward. The judge has not yet ruled on Reckitt's **motion for reconsideration**.

The Federal Trade Commission **is also looking into** whether Reckitt abused its monopoly to switch the market to the new version of the drug and filed sham petitions with the FDA.

Case: New York v. Actavis PLC et al.
Court: Second Circuit
Drug: Namenda, Alzheimer's treatment
Was the drug pulled from the market?: Yes — that was the plan
Status: Awaiting oral argument

New York Attorney General Eric Schneiderman **sued Actavis and Forest in September**, saying that they planned to pull the drug from the market after few patients initially made the transition from the twice-a-day immediate release version of the Alzheimer's treatment to a once-a-day extended release version.

Forest initially said in early 2014 that it would discontinue Namenda IR entirely in August but eventually shifted its plan amid the state investigation and supply problems with Namenda XR so that the older version of the drug would only be available through a specialty mail-order pharmacy with a prescription and a doctor's statement that it was medically necessary for the patient to keep using it.

In December, however, U.S. District Judge Robert W. Sweet intervened, **granting the state** a preliminary injunction requiring the companies to keep the immediate release version of the drug on the market. Once again, the court looked to the Microsoft ruling among others to justify ruling for the plaintiffs.

The court noted that just because the companies no longer planned to fully withdraw the drug from the market didn't mean they weren't restricting generic competition.

Case: In re: Opana ER Antitrust Litigation
Court: Northern District of Illinois, U.S. District Judge Harry D. Leinenweber

Drug: Opana ER, painkiller
Was the drug pulled from the market?: Yes
Status: Consolidated into multidistrict litigation

The most recently filed case combines pay-for-delay allegations with product-hopping claims.

Six putative class actions accusing Endo Pharmaceuticals Inc. of paying Impax Laboratories Inc. more than $112 million to delay a generic version of Endo's opioid pain medication Opana ER **were consolidated** in Illinois in December.

The suits **maintain that the settlement** gave Endo enough time to move the market to a newer version of the drug. With the additional two-year delay in generic launch from the pay-for-delay deal, Endo had enough time to secure approval for Opana ER CRF — a more crush-resistant form of the drug — and to stop selling the older version of the product to force doctors to start prescribing the newer, protected version, according to one complaint.

A consolidated complaint has not yet been filed.

--Additional reporting by Linda Chiem and Kelly Knaub. Editing by Katherine Rautenberg and Brian Baresch.

Correction: A previous version of this article incorrectly stated the original form of the product at issue in the Doryx case. The error has been corrected.