Antitrust Issues in “Product-Hopping” Cases

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ABA Health Law Section

Maria Salgado
Principal, Cornerstone Research
Moderator

Ted Hassi
O’Melveny & Meyers

Christopher Holding
Goodwin Procter

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What is “Product Hopping”?

• Introduction of a line extension before generic competition.

• Patients encouraged (forced?) to switch from old product to the line extension.

• Generics cannot be automatically substituted for line extension.
The FTC’s View
FTC on “Product Hopping”

• “Product-hopping seems clearly to be an effort to game the rather intricate FDA rules ... The patentee is making a product change with no technological benefit solely in order to delay competition.”

  FTC’s D. Ct. Amicus Brief in Mylan
Types of Alleged Anticompetitive Conduct by Branded Pharmaceutical Companies

• Minor changes in product formulation, method of delivery, indications, or labeling.

• Promotions encourage switching to new product.

• Discontinue original product prior to generic entry.

• Recall supply of the original product prior to generic entry.

• Delete the “National Drug Code.”

• Raise the price of the old product.
Mylan v. Warner Chilcott (Doryx)

• Acne drug.

• Several product changes: capsules to tablets; the addition of tablet scoring.

• Warner Chilcott discontinued selling the prior version.

• Asked major customers to return inventory.

• Warner Chilcott won summary judgment.

• Mylan appealing to the Second Circuit.
Doryx: Good Facts

- Doryx was off patent—no patent cliff.

- Warner was not aware Mylan was coming to market.

- Court found no monopoly power; Doryx competes with other oral tetracyclines.

- Mylan got to market with its generic and stayed on the market after the brand stopped selling original dosages and moved to a different dosage.

- Mylan raised prices after Defendants moved to a new dosage.

- Mylan “opted” not to detail its product.

- Defendants offered procompetitive justifications for the product improvements; benefits were “undeniable.”
Doryx Decision

• Mylan “is thus a ‘victim’ of its own business strategy…”

• “Here, there was no exclusionary conduct. Mylan remains able to reach consumers through, inter alia, advertising, promotion, cost competition, or superior product development. Mylan instead seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan’s business plan by keeping older versions of branded Doryx on the market.”
NY v. Actavis / Forest Labs (Namenda)

• Namenda IR is a blockbuster Alzheimer’s treatment.

• Generic entry on IR was due July 2015, shortly before patent expiry. New XR was approved in 2010 but not launched until 2013.

• Forest first implemented a “soft switch” in July 2013, which was not challenged by the NY AG. Key elements of the first strategy:
  – Launching the XR
  – Stopping all marketing activity for the IR
  – Spending substantial sums marketing XR to doctors, caregivers, patients, and pharmacists
  – Selling XR at a discounted rate, making it considerably less expensive than the IR
  – Issuing rebates to health plans for the XR to make sure the copay for XR was not higher than for IR
Namenda’s Hard Switch

• By early 2014, with the soft switch strategy, only 30% of IR patients had converted to XR

• Forest changed strategy and implemented a “hard switch.” Key elements of the new strategy:
  – Publicly announcing that Forest would discontinue IR as of a certain date
  – Notifying FDA of the plan to discontinue IR
  – Publishing letters on the website urging healthcare providers and caregivers to discuss switching to XR with their patients
  – Asking the federal government to remove IR from the Medicare drug formulary list

• Forest executives: purpose is to avoid the “patent cliff”
New York AG Antitrust Suit

- NY AG files antitrust claims challenging “hard switch” as a form of monopoly maintenance and seeking a PI requiring Forest to continue marketing brand IR until generic entry occurs.

- Forest agrees to continue IR shipments pending decision.

- District Court enters preliminary injunction in December 2014. Forest must:
  - Continue selling IR until 30 days after generic IR entry can occur
  - Make the IR available on the same terms and conditions that were in place on the day after XR launched [i.e., the soft-switch terms]
  - Notify the market that IR would continue to be available

- Injunction upheld by the Second Circuit.
Namenda Decision

• Market definition not in dispute.

• Second circuit found the pulling of Namenda IR to be “coercive.”

• Preventing generic IR from competing under state drug substitution laws would likely thwart generic entry and competition.

• Switching costs an important consideration: “By removing Namenda IR from the market prior to generic IR entry, [Actavis] sought to deprive consumers of that choice. In this way, [Actavis] could avoid competing against lower-cost generics based on the merits.”

• Patients unlikely to switch back to generics after switching to XR.

• Defendants’ explicit purpose was to impede generic competition and to avoid the patent cliff—which occurs at the end of a drug’s exclusivity period when generics gain market share through state substitution laws.
Additional Considerations: Impact on Innovation and Welfare

- From 1989 to 2000, only 35% of the 1,035 new drug applications approved by the FDA were for new molecular entities.

- 54% of all approvals were for drugs with new dosage forms, route of administration, or that were combined with another active ingredient.

- Once-a-day treatments increase compliance.

- Patient compliance increases drug efficacy and therefore welfare.
Additional Considerations: Impact on Innovation and Welfare, cont’d.

- How do restrictions to “product hopping” strategies impact innovation?

- How can the impact on innovation be measured against the reduced generic competition?

- What is the net effect on welfare?
In the Face of a “Product-Hop,” Can the Reduced Generic Competition Be Prevented?

• Can generic manufacturers promote their product to physicians?
  – "What would be the effect on generic prices from these types of conduct?"
  – "Does it make sense for a generic to invest in such strategies, when even brands do not do so following patent expiration and generic entry?"

• Can insurers / PBMs incentivize generics through favorable formulary placement and prior authorization requirements?

• Can insurers and generic manufactures inform patients about generics or alternative therapeutic treatments?

• Is there a role for providers? How are they impacted by a “product hop.”

• What procompetitive justifications might suffice? Will they be credited, in the absence of bad intent evidence?
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