American Medical Association Journal of Ethics

August 2015, Volume 17, Number 8: 760-762

HEALTH LAW

A Legal Test for the Pharmaceutical Company Practice of "Product Hopping"

Tobin Klusty

In September 2014, the New York Attorney General filed a claim in federal court alleging that the pharmaceutical company Actavis was violating federal and state antitrust laws by preventing competition through a practice known as "product hopping." Product hopping occurs when a pharmaceutical company discontinues an old formulation of a drug whose patent expiration date has passed or is approaching in an attempt to force consumers to change to the drug's new—and newly patented—formulation. Patents protect pharmaceutical companies from generic drug manufacturing competition for 20 years, assuming the patent is not extended [1]. After the patent's expiration, competitors are free to use the drug's formula to manufacture generic versions as a cheaper option. Fearing large profit losses with the availability of generic versions, some pharmaceutical companies seek separate patents for new formulations of the patented drug. Minor changes, like the switch from a two-a-day to a one-a-day pill, can qualify for a new drug patent [2]. Following patent approval, the pharmaceutical company makes a push for use of the new formulation.

Patients are more likely to be reliant on a drug when few drugs are available for their particular ailment. Under such circumstances, discontinuation of an old formulation effectively forces people to use the new formulation. By the time the patent for the old formulation of the drug expires and generic versions become available, users often have become reliant on the new formulation of the drug. If the new formulation has a different dosage, strength, or delivery mechanism than the old formulation, most state drug substitution laws prevent pharmacists from replacing the new formulation with generic versions of the old formulation [3]. Thus a successful "product hop" can extend a pharmaceutical company's monopoly for a drug for another 20 years—effectively stifling competition—and companies can hop several times within a single drug line.

New York v. Actavis addresses Actavis's use of product hopping for the prescription drug Namenda [3]. Actavis, through its subsidiary Forest Laboratories LLC, marketed and sold Namenda IR, a twice-daily prescription drug used to treat Alzheimer's disease [3]. Namenda is Actavis's largest revenue generator, and it is the only memantine drug approved by the FDA to treat Alzheimer's disease [4]. With Namenda IR's patent set to expire in July 2015, Actavis released a once-daily version named Namenda XR and attempted to persuade consumers to switch from Namenda IR to Namenda XR by offering rebates and discounted rates for Namenda XR and heavily promoting the switch

to the healthcare community [5]. Due to concerns that patients would not switch to Namenda XR if IR was still available, Actavis announced that it would no longer produce Namenda IR, forcing consumers to switch to the once-daily Namenda XR because generic versions of Namenda IR had not yet hit the market [5]. Due to state drug substitution laws, pharmacists in most states will be unable to automatically switch patients from the once-daily Namenda XR to generic versions of the twice-daily Namenda IR, effectively prolonging Actavis's monopoly on memantine treatments for Alzheimer's disease until Namenda XR's patent expires in 2029 [3]. Actavis's marketing strategy led New York's Attorney General to bring suit in the United States District Court for the Southern District of New York.

New York's attorney general claimed that Actavis violated federal and state antitrust laws by preventing generic competition through product hopping [3]. The claim included a preliminary injunction, which requested that the federal court prevent Actavis from stopping the production and sale of Namenda IR (the older formulation). The district court granted New York's request for the preliminary injunction, requiring Actavis to continue production of Namenda IR until one month after generic versions entered the market. Actavis filed an expedited appeal with the United States Court of Appeals for the Second Circuit, which affirmed the district court's ruling [3].

The Second Circuit's ruling was unusual for a few reasons. First, the injunction forces Actavis to continue producing Namenda IR and dictates that its terms of sale cannot be changed. Antitrust law, under the Sherman Antitrust Act [6], does not normally require companies to assist competitors in the market, but the Second Circuit found that Actavis's product hopping strategy disallowed fair competition. The ruling referred to public comments from Actavis's CEO indicating that Actavis's purpose was to thwart competition rather than promote competitive technology: "We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity" [7] and "what we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users" [8]. The only way to prevent irreparable harm to both competition and consumers, according to the district court and the Second Circuit, was to reverse Actavis's product-hopping strategy.

Secondly, the decision did not give weight to the potential benefits Namenda XR offered to consumers that Namenda IR did not. The Second Circuit did not quantify the strength of Namenda XR's benefits because Actavis's market strategy coercively forced patients and doctors to use XR without being able to weigh the benefits themselves [9]. In other words, Actavis's purposeful restriction of fair competition prevented it from arguing that Namenda XR's benefit to consumers warranted the removal of Namenda IR from the market.

While the Second Circuit's ruling forbids the use of product hopping as an anticompetitive and coercive marketing strategy, the conflict between preventing anticompetitive practices and encouraging innovation is still left murky, especially since most district courts are handling the issue without guidance from the higher courts. With the lack of precedent, more circuit courts are likely to decide the legality of product hopping. In the interim, Actavis is expected to appeal the Second Circuit's decision to enforce production of Namenda IR. A decision forcing production of a discontinued drug is unprecedented and may warrant the US Supreme Court to agree to review the decision per Actavis's appeal. For now, all that can be concluded is that the product hopping strategy is forbidden by the Second Circuit if there is evidence that the strategy is coercive and used to restrict fair competition.

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Tobin Klusty is pursuing his JD at DePaul University College of Law in Chicago. His research focuses on the intersection of health law and civil rights, and he also has an interest in public policy.

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ISSN 2376-6980