CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
December 2015 (1)

Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation

Douglas H. Ginsburg, Koren W. Wong-Ervin, & Joshua D. Wright

George Mason University School of Law

www.competitionpolicyinternational.com

Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation

Douglas H. Ginsburg, Koren W. Wong-Ervin, & Joshua D. Wright [1]

I. INTRODUCTION

Product hopping refers to the situation in which a brand name drug manufacturer seeks to switch demand from a drug Product A, with expiring patent protection, to drug Product B, which is usually a modified version of Product A but has a longer term of patent protection remaining. The theory that product hopping violates the antitrust laws contemplates the circumstance in which any consumer welfare gains associated with shifting consumer demand to the newer and putatively improved Product B is outweighed by the consumer harm associated with delaying generic entry until Product B no longer has patent protection.

Therefore, application of the antitrust laws to govern product hopping requires antitrust agencies or courts to weigh the consumer welfare gain from a change in product design—in this case, a new drug formulation—against the consumer welfare loss from forgone price competition. Competition law is not a suitable instrument for micromanaging product design and innovation in this way.

Several courts have now addressed the appropriateness of applying antitrust scrutiny to product hopping. At least one court has effectively held product hopping *per se* lawful, explaining that it does not constitute exclusionary conduct under the antitrust laws because the generic company is still free to compete and is "able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development."[2]

---

[1] Douglas H. Ginsburg is a Senior Judge on the U.S. Court of Appeals for the District of Columbia, Professor of Law at George Mason University School of Law, and Chairman of the International Advisory Committee at George Mason University School of Law's Global Antitrust Institute. Koren W. Wong-Ervin is Director of the Global Antitrust Institute. Joshua D. Wright is a Professor of Law at George Mason University School of Law and Executive Director of the Global Antitrust Institute. The authors thank Lindsey Edwards for her research assistance.

[2] Mylan Pharm., Inc. v. Warner Chilcott Public Ltd. Co., 2015 WL 1736957 at *14 (E.D. Pa. 2015) (rejecting a claim of anticompetitive product switching upon finding, among other things, that the alleged product switch did not amount to exclusionary conduct). *But see* New York v. Actavis PLC, 787 F.3d 638 (2nd Cir. 2015). The court of appeals in *Actavis* held the trial court did not abuse its discretion by issuing a preliminary injunction that barred a brand company from withdrawing its branded drug from the market. In so holding, the court credited the trial court's finding that "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers" (*Actavis* at 655-58) and then held that U.S. antitrust law "requires [brand companies] to allow generic competitors a fair opportunity to compete using state substitution laws" (*id.* at 658). The district court's finding is not supported by empirical evidence and its statement of the law is contrary to the teaching of the United States Supreme Court, which has explicitly held that the antitrust laws do not impose a general duty to aid one's rivals. *See* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415 (2004).

Indeed, the issue is not that generic companies cannot compete but rather that they cannot take advantage of automatic state substitution laws, which allow—or in some states require—a pharmacist to substitute a bioequivalent (or "AB-rated") generic drug when presented with a prescription for its brand equivalent, unless a physician directs or the patient requests otherwise. But, as the court in *Mylan* explained, brand companies "have no duty to facilitate" a generic company's free-riding on the brands' promotional efforts by keeping older versions of their product on the market, and antitrust law does not require that a generic company be permitted to distribute its product through automatic substitution laws.[3]

Considering the potential for significant consumer benefits from even small changes in product design, coupled with antitrust agencies and courts being ill-equipped to displace the judgments of consumers (and, with regard to drugs, their doctors) about the value of a new product design, product hopping should be *per se* lawful absent objective evidence that Product B is a sham innovation with zero or negative consumer welfare effects. In short, while it is plausible that product hopping may under narrowly defined circumstances constitute exclusionary conduct, applying a standard antitrust law analysis (with the possibility of treble damages) is likely to deter innovation that would have benefitted consumers.

II. "SOFT" VERSUS "HARD" SWITCHES

It is important to distinguish between a "hard" switch, removing Product A from the market and the formulary list so that generic companies cannot take advantage of automatic substitution laws, and a "soft" switch, allowing Product A to remain on the market and the formulary list while aggressively attempting to persuade patients and doctors to switch to Product B, by means such as offering rebates and other discounts.

Though it is plausible that a hard switch may—under certain narrowly defined circumstances, such as the introduction of a sham innovation that confers no benefits upon any consumers—constitute exclusionary conduct, a soft switch amounts to no more than competition on the merits. As the Court of Appeals for the Second Circuit recently explained, "[a]s long as [the brand] sought to persuade patients and their doctors to switch from [Product A to Product B] while both were on the market (the soft switch) and with generic . . . drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives."[4] In short, imposing an antitrust law sanction on soft switches would punish the very type of competition the antitrust laws are intended to promote.

III. THE SIGNIFICANT BENEFITS TO CONSUMERS FROM INCREMENTAL INNOVATIONS

It is well-established that innovations, including even small changes in product design or relatively minor therapeutic improvements, can generate significant consumer benefits, and that such changes are consistent with the normal competitive process. For example, new drug formulations may involve changes that appear small but are of significant benefit to consumers

[3] *Mylan*, 2015 WL 1736957 at *14.

[4] *Actavis,* 787 F.3d at 654; *see also* Walgreen Co. v. AstraZeneca Pharm., 534 F. Supp. 2d 146, 152 (D.D.C. 2008) (dismissing allegations that the brand company's soft switch amounted to anticompetitive conduct, holding "that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action").

or are critical stepping-stones to potentially life-saving inventions.[5] Potential antitrust liability for introducing new formulations or introducing minor product design changes risks chilling future innovation that could yield significant consumer benefits.

IV. THE IMPORTANCE OF ALLOWING CONSUMERS TO DETERMINE THE VALUE OF NEW PRODUCT INNOVATIONS

Antitrust law is not a suitable instrument for micromanaging product design and innovation. Imposing antitrust liability upon new product introductions requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition. Not only are agencies and courts ill-equipped to make such determinations, but it is also unclear whether the balancing contemplated by a rule prohibiting anticompetitive product hopping can be done at all.

Courts in the United States have recognized these difficulties. As a United States district court recently explained, "[t]he prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs."[6] The courts of appeals have advised against applying an antitrust law sanction to product design decisions more generally. For example, the Ninth Circuit Court of Appeals has cautioned that "[t]o weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury."[7] Similarly, the Court of Appeals for the Second Circuit warned that "no one can determine with any reasonable assurance whether one product is 'superior.'"[8]

---

[5] *See, e.g.*, Jerry A. Hausman, *Valuation of New Goods Under Perfect and Imperfect Competition* in THE ECONOMICS OF NEW GOODS (Timothy F. Bresnahan & Robert J. Gordon eds., 1996); Ernst R. Berndt, Iain M. Cockburn & Karen A. Grépin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24(2) PHARMACOECONOMICS 69-86 (2006) (studying data on drug utilization by diagnosis for the period 1999-2004 combined with data on the approval histories of three important classes of drugs, and finding that incremental innovation to existing pharmaceutical products in the form of new dosages, formulations, and indications account for a substantial share of drug utilization and associated economic and medical benefits; also finding that all three drug classes studied have seen the approval of numerous new indications, some targeting markedly distinct populations from that of the original indication, significantly expanding the economic and medical benefits of these drugs).

[6] *Mylan*, 2015 WL 1736957 at *16.

[7] Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP, 592 F.3d 991, 1000 (9th Cir. 2010); *see also* United States v. Microsoft Corp., 147 F.3d 935, 948 (1998) ("Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law."). On the difficulties associated with assessing the optimal amount of innovation from an antitrust perspective, see Douglas H. Ginsburg & Joshua D. Wright, *Dynamic Analysis and the Limits of Antitrust Institutions*, 78 ANTITRUST L.J. 1, 12 (2012); Joshua D. Wright, *Antitrust, Multi-Dimensional Competition, and Innovation: Do We Have an Antitrust-Relevant Theory of Competition* in REGULATING INNOVATION: COMPETITION POLICY AND PATENT LAW UNDER UNCERTAINTY (Geoffrey A. Manne & Joshua D. Wright eds., Cambridge Univ. Press, 2009).

[8] Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 (2d Cir. 1979).

Even the most economically sophisticated competition agencies are not equipped to make such determinations and to displace consumers' judgment about the value of a product design change. The economic analysis upon which the theory of antitrust liability for product hopping is premised requires the agency or court to assess the tradeoff between the benefits to diverse consumers of a new pharmaceutical formulation and the premium those consumers pay for the new branded product relative to the hypothetical price for the generic version of the old formulation. This is a complex and difficult task rendered even more difficult because what appears to be a minor product improvement can generate a significant gain in consumer welfare.

Relying upon a competition agency to engage in *ex post* valuation of a product design change, and to weigh it against the welfare loss from the associated reduction in competition, can only reduce the overall incentive to innovate and distort the remaining incentive toward blockbuster innovations and away from reformulations that may result in incremental but significant consumer benefits.

It is important to note that a product-hopping antitrust theory does not merely contemplate agencies and courts engaging in their own complex analysis of the value of product design changes; it means agencies and courts substituting their judgment for that of consumers in the marketplace. An anticompetitive product-hopping theory assumes consumers—here, both prescribing doctors and their patients—are incapable of determining the value of a pharmaceutical product improvement and adequately responding in their own best interests.

This approach assumes, remarkably, that pharmaceutical markets are so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations and should be forced to defer to the judgment of a competition agency or court as to whether the premium charged for the innovative version of the drug is worth whatever benefit it confers.

V. CONCLUSION

As a threshold matter, it is questionable whether product hopping can ever amount to exclusionary conduct under the antitrust laws given that the generic company is still free to compete, but just cannot free-ride through state substitution laws. The one exception may be for sham innovations, i.e., a reformulation that has no or negative consumer welfare benefits. When regulators and courts encounter a sham innovation they do not need to weigh the increased cost to consumers against the consumer benefit ordinarily associated with a new product because the benefit is nil.

Extending the idea that product hopping is anticompetitive with respect to a reformulation that benefits consumers, however, necessarily would require just that weighing of costs and benefits and, as a result, would place agencies and courts in the position of making economic value judgments that are (i) methodologically doubtful, (ii) fall outside the traditional scope of competition analysis, and (iii) are based upon the premise that consumers (and their doctors) cannot be relied upon to make their own assessments of the value of new products and reformulations.