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Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground

Guy V. Amoresano

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I. INTRODUCTION

Various efforts by brand name pharmaceutical companies to preserve market share when faced with impending competition from generic substitutes have given rise to considerable antitrust litigation in recent years.¹ A new front is now opening in this ongoing war. Federal Trade Commission (FTC)² personnel have observed that they are examining the strategy employed by some brand name manufacturers of making changes to the branded product, usually in formulation, dosage or labeling (collectively hereafter reformulation), on the eve of generic launch in order to prevent the ready substitution of the generic for the brand.³ Recently, antitrust cases have been brought against at least two brand drug manufacturers for employing a reformulation strategy to forestall generic competition.⁴ A decision last year by the United States District Court for the District of Delaware denying a motion to dismiss one of those cases may well give traction to this new front and embolden the FTC and private litigants to pursue it.⁵ This article examines that decision and discusses the question of whether the antitrust laws are the appropriate vehicle for promoting the public policy goals embodied in state drug product selection laws.

II. BACKGROUND

Consideration of the antitrust significance of last minute changes to a branded drug to forestall generic substitution requires a brief review of certain background legal principles that provide the context for the analysis. To begin with, the competitive landscape immediately prior to generic entry is often one marked by an expiring patent monopoly. Thus, from an antitrust perspective, two things are generally true: first, immediately prior to generic entry, the branded drug enjoys a lawful monopoly⁶ and, second, attempts to maintain that monopoly beyond the

* Mr. Amoresano is Director, Business & Commercial Litigation, with Gibbons P.C., Newark, NJ.

¹ The recent retail price war in generic drug sales started by Wal-Mart will likely widen the gap between branded drug prices and generic prices, adding further impetus for antitrust scrutiny of efforts to forestall generic competition.

² The FTC shares jurisdiction with the United States Department of Justice, Antitrust Division for enforcement of federal antitrust law. *See* 15 U.S.C §§ 41, et seq. Of the two, the FTC has taken the lead in recent years with respect to antitrust issues affecting the pharmaceutical industry.

³ FTC Staff, Informal, Unpublished Remarks Before the 2006 American Bar Association 54th Antitrust Law Spring Meeting.

⁴ *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp.2d 408 (D. Del. (2006)); *Walgreen Co., et al. v. AstraZeneca Pharmaceuticals L.P, et al.*, Civ. Action No. 1:06-cv-02084-RWR (D. Del. (12/07/2006)).

⁵ *Abbott Labs*, *supra* note 4.

⁶ Congress's power to grant patent monopolies is found in Article I, section 8 of the Constitution, and mere acquisition of a patent monopoly, even if it gives rise to an economic monopoly, does not violate the Sherman Act. *See, e.g.*, *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. (1981)), *cert. denied*, 455 U.S. 1016 (1982). In *Illinois Tool Works Inc. v. Independent Ins., Inc.*, 547 U.S. 1 (2006), the Supreme Court recently held that monopoly power (a/k/a market power) cannot be presumed merely from the presence of a patent. This article is intended to address those instances in which the antitrust plaintiff can plead and prove that the brand drug manufacturer has market power in the product market for its drug.

expiration of the patent can constitute the offense of monopolization in violation Section 2 of the Sherman Act.⁷

The second important backdrop to the reformulation battle is the generic drug market entry procedures found in The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).⁸ Much has been written about the competitive pros and cons of the Hatch-Waxman Act, and a full exploration of those is outside the scope of this article. For purposes of the present discussion, the significant feature of the Hatch-Waxman Act is the congressional attempt to encourage generic manufacturers to quickly bring generics to market by streamlining the Food and Drug Administration (FDA) approval process and by providing the first approved generic with a 180-day exclusivity period before additional generic suppliers may enter the market. To obtain FDA approval to market a new, branded drug, the manufacturer must first file with FDA a detailed New Drug Application (NDA), with the drug's safety and efficacy data. The Hatch-Waxman Act allows subsequent manufacturers of generic substitutes for the approved drug to submit instead an Abbreviated New Drug Application (ANDA), simply incorporating the safety and efficacy data submitted in the NDA for the branded drug. The first generic manufacturer to file an ANDA is granted a 180-day exclusivity period to market the generic substitute before other generics may be approved.⁹

The final piece of the legal backdrop is found in the generic substitution laws enacted by each state. FDA and the FTC worked together to promulgate a Model Drug Product Selection Act (Model Act) in 1979,¹⁰ and some form of drug product selection (DPS) law was ultimately adopted in each state (hereinafter DPS Laws). These DPS laws either require or permit pharmacies to fill prescriptions for branded drugs with their less expensive generic substitutes, absent explicit direction from the prescribing physicians to the contrary. Significantly, for purposes of the issues addressed in this article, DPS laws modeled after the Model Act permit this generic substitution at the pharmacy only if the generic drug is so-called "AB-rated" by FDA, meaning that it is both bioequivalent to the brand and in the same dosage, strength and form. The stated purpose of FDA and the FTC in promulgating the Model Act was to "facilitate drug product selection" and "stimulate price competition."¹¹

Taking all of this background into consideration, the standard progression of events in the absence of competitive (or anticompetition) maneuvering by the brand manufacturer is this: 1) the brand manufacturer obtains an approved NDA for its new drug; 2) the brand manufacturer enjoys a lawful monopoly over the new drug for the life of its patent, and the lawful monopoly pricing that results; 3) as the patent is expiring (or because of the absence of a valid blocking patent), a generic manufacturer gets an approved ANDA for a generic, "AB-rated" substitute for the branded drug; 4) the generic manufacturer launches the generic substitute, invariably resulting in an immediate decline in the drug's average cost and a loss of some of the brand's market share to the generic; and 5) the generic manufacturer reaps the rewards of a 180-day exclusive on the sale of generics before other, competing generic manufacturers may enter the market.

⁷ Section 2 of the Sherman Act prohibits monopolization or attempted monopolization of any part of interstate commerce, 15 U.S.C. § 2.

⁸ 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271 and 278.

⁹ See generally *Abbot Labs*, 432 F. Supp.2d at 414-415 (discussion of the operation of the Hatch-Waxman Act).

¹⁰ See *Drug Product Selection*, Staff Report to the FTC, at 49-50 (Jan. 1979).

¹¹ *Id.* at 291.

III. REFORMULATION STRATEGY

The alleged generic entry inhibiting strategy employed by brand manufacturers that has received the greatest amount of antitrust scrutiny so far has been the tactic of suing the generic manufacturer and asserting that the generic infringes the brand's unexpired patents. Then, the brand manufacturer settles the infringement suit under terms that to the FTC appear to sometimes amount to compensating the generic manufacturer for delaying launch of the generic drug.¹² The FTC has been aggressively scrutinizing patent litigation settlements between brand name and generic suppliers that the FTC contends have included agreements to postpone generic entry.¹³ Thus, antitrust challenges to such a strategy have been focused on its effect in delaying the generic drug from being sold at all. The reformulation strategy, on the other hand, does not prevent the generic manufacturer from bringing its drug to market, but instead prevents that drug from being dispensed by pharmacists as an AB-rated substitute to fill prescriptions written for the brand drug. This strategy is illustrated in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*¹⁴

Abbott Labs concerned Abbott's TriCor brand of fenofibrate, a drug used to treat high triglyceride levels. TriCor's formulation was patented, and Abbott received approval of its NDA in 1998 to sell TriCor in capsule form. In 1999, Teva¹⁵ filed an ANDA for 67mg and 200mg fenofibrate capsules. Abbott brought a patent infringement claim against Teva that Abbott eventually lost. The filing of the patent case, however, had the effect of triggering a statutory automatic stay of Teva's ANDA approval under the Hatch-Waxman Act.¹⁶

Before losing its patent claims, and while the ANDA approval stay was in effect, Abbott sought and obtained an approved NDA for a new TriCor fenofibrate formulation: 54mg and 160mg tablets. Abbott then pulled the old TriCor capsules from the market and changed the code for the old TriCor® capsules in the National Drug Date File (NDDF) to "obsolete." Following Teva's submission of ANDAs for generic equivalents of the new tablet formulations of TriCor, Abbott obtained yet another approved NDA for 145mg and 48mg tablets, as well as a label change removing the requirement that the drug be taken with food. As before, Abbott pulled the old tablets from the market and changed the NDDF code.¹⁷

The practical effect of Abbott's strategy was this: while the Teva drug was approved for sale by FDA, it was no longer an AB-rated generic substitute for any formulation of TriCor being sold by Abbott. Thus, while Teva was free to sell its brand of fenofibrate, and doctors were free to prescribe it by name, pharmacists could not dispense the Teva drug when TriCor was prescribed. As an alleged result, Teva was only able to make modest sales of its fenofibrate drug, under its own Lofibra brand.

¹² See, e.g., *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1067 (11th Cir. (2005)), *cert. denied*, 2006 WL 1725862 (2006).

¹³ See, e.g., *id.* A second strategy being employed by the brand name companies, that of launching their own "authorized generic," is also receiving attention as a possible attempt to chill the incentive for generic drug development. FTC Commissioner Jon Leibowitz, Remarks Before the Senate Special Committee on Aging, (July 21, 2006).

¹⁴ 432 F. Supp.2d 408 (D. Del. (2006)).

¹⁵ The ANDA was actually filed by Novopharm, LTD, Teva's predecessor in interest, and the litigation concerned the conduct not only of Abbott but also of its licensees. For ease of reference, this article refers to the parties aligned with Abbott collectively as "Abbott," and the parties aligned with Teva collectively as "Teva."

¹⁶ Teva's eventual antitrust allegations against Abbott also included the allegation that Abbott's patent claims were a sham. These allegations are outside the scope of this article.

¹⁷ 432 F. Supp. at 416-18.

IV. TEVA'S MONOPOLIZATION CLAIMS

Among other things, Teva reacted to Abbott's strategy by bringing claims against Abbott in the U.S. District Court for the District of Delaware for unlawful monopolization of the fenofibrate market in violation of Section 2 of the Sherman Act. Teva alleged that through its strategy of sequential reformulation, relabeling and NDDF coding, Abbott had foreclosed Teva from the most cost-effective means of competition with TriCor, i.e., through generic substitution. Teva alleged that the changes made by Abbott to TriCor were not true product enhancements, but merely an artifice to deprive Teva's product of an AB equivalency rating, and thus prevent substitution by pharmacists. In response, by way of a motion to dismiss Teva's antitrust claims, Abbott argued that even a monopolist is entitled to preserve market share by introducing new products, that Teva was not prevented from selling its version of fenofibrate and that Abbott was not required to help Teva to "free-ride on the TriCor brand."¹⁸

V. ABBOTT COURT'S DECISION

In their respective briefing on Abbott's motion to dismiss, Abbott and Teva proposed competing legal standards against which to measure the antitrust legality of Abbott's reformulation strategy. Teva, in reliance on such cases as *United States v. Microsoft*,¹⁹ and *In re IBM Peripheral EDP Devices Antitrust Litigation*²⁰ proposed a test by which the court should assess and weigh the actual benefits of the product design changes against the anticompetitive harm they inflicted.²¹ Abbott, on the other hand, drew upon the Second Circuit's well known decision in *Berkey Photo, Inc. v. Eastman Kodak Co.*²² and upon Professors Areeda and Hovenkamp's leading antitrust treatise for the proposition that courts are ill suited to distinguish between helpful and harmful innovation, a task better left to the marketplace, and that antitrust liability for design changes should, therefore, only be entertained when "the innovator knew before introducing the improvement into the market that it was absolutely no better than the prior version, and that the only purpose of the innovation was to eliminate the complementary product of a rival."²³

Accepting the test proposed by Teva and rejecting the stricter standard of proof espoused by Abbott, the district court denied the motion to dismiss. Relying principally on *Microsoft* and on dicta in a footnote in *Berkey Photo*, the district court reasoned that the judicial deference to a monopolist's design choices espoused in *Berkey Photo* was appropriate only where unfettered consumer choice would essentially permit consumers to vote with their feet by rejecting the new product.²⁴ In contrast, based on Teva's allegations, the court observed that by reason of Abbott's conduct in removing its old TriCor formulations from the market, Abbott had eliminated consumer choice. As a result, the court concluded that judicial

¹⁸ *Id.* at 418-420, 423-424.

¹⁹ 253 F.3d 34 (D.C. Cir. (2001)).

²⁰ 481 F. Supp. 965 (N.D. Col. (1979)), *aff'd*, 698 F.2d 1377 (9th Cir. (1983)).

²¹ Abbott Labs, *supra* note 4, Teva's Answering Brief in Opposition to Abbott's and Fournier's Motion to Dismiss Counterclaims, at 23-26 (filed (12/02/05)).

²² 603 F.2d 263 (2d Cir. (1979)).

²³ Abbott Labs, *supra* note 4, Defendants' Memorandum of Law in Support of Their Consolidated Motion to Dismiss Plaintiffs' Complaints at 9-11 (filed 10/19/05) (quoting 3A Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 776d (2d ed. (2002)).

²⁴ 432 F. Supp.2d at 421-422.

evaluation of the benefits of the product changes — an evaluation eschewed by the *Berkey Photo* court—was appropriate. In short, the court concluded that Abbott’s antitrust liability should hinge on whether the actual benefits of the product redesign outweighed its anticompetition harm.²⁵

The court also rejected Abbott’s contention that its reformulation strategy could not be labeled anticompetitive because it did not prevent Teva from selling its fenofibrate under its own brand. The court reasoned that Teva need not prove that it was foreclosed from all avenues of competition if it was barred “from the cost-efficient ones.” In this case, the court observed, generic substitution was alleged to be the foreclosed cost-efficient competitive avenue. Thus, Abbott’s action had the alleged effect of blocking generic substitution and “such conduct, which results in consumer coercion, is potentially anticompetitive.”²⁶

VI. DISCUSSION

Because the *Abbott Labs* court was grappling with a case of apparent first impression, it is not at all surprising that it would deny a motion to dismiss at the pleading stage in favor of ultimately resolving thorny antitrust issues on a more complete factual record. With that said, there are aspects of the court’s reasoning that are troublesome, and a more critical analysis of both the standard of proof and the alleged competitive harm is called for when the full record is developed. While the court’s yardstick for determining whether to grant *Berkey Photo* type deference to a monopolist’s design choices was a sound one, i.e., the presence or absence of consumer coercion, its application of that yardstick to Abbott’s reformulation strategy appears flawed. Ultimately, the court’s approach to the reformulation strategy may operate more to enforce the policy objectives of state DPS laws than to promote free market competition in the classic antitrust sense.

The *Abbott Labs* court correctly observed that the reluctance of the *Berkey Photo* court to embark upon a judicial evaluation of the pros and cons of a monopolist’s design choices was predicated on that court’s view that, in the absence of coercion, it is “of no importance that a judge or jury may later regard” the newly designed product as inferior (or at least no better), if the product has been accepted by consumers in the marketplace.²⁷ “If consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and ‘antitrust should not interfere when an invention pleases customers.’”²⁸ The *Abbott Labs* court concluded, however, that if consumer coercion is present, then the marketplace based reason for the deferential standard of *Berkey Photo* is absent. In the presence of coercion, the court reasoned that judicial evaluation of the alleged benefit of the product redesign becomes appropriate and that antitrust liability may be found when the anticompetitive effects of the redesign outweigh the benefits of that design.

The *Abbott Labs* court’s conclusion that deference to a monopolist’s design choices is inappropriate in the presence of consumer coercion appears well grounded. Language in *Berkey Photo* itself suggests the need for greater scrutiny when coercion is present,²⁹ and, as the *Abbott Labs* court observed, the *Microsoft* court

²⁵ . *Id.* at 422.

²⁶ *Id.* at 423-424.

²⁷ *Id.* at 421 (quoting *Berkey Photo*, *supra* note 22, at 287).

²⁸ *Id.* (quoting *Areeda & Hovenkamp*, *supra* note 23, ¶ 776d).

²⁹ *Berkey Photo*, *supra* note 22, at 263 & n. 39. The coercive conduct hypothesized by the *Berkey Photo* court, however, was very different than anything alleged by Teva. The court hypothesized a scenario under which Kodak, having invented a new camera and associated film size, ceased supplying another film size for which it was a monopoly source and without which competing cameras would be useless.

in fact applied a non-deferential balancing test when faced with coercive practices.³⁰ The difficulty with the *Abbott Labs* opinion, however, is found in its conclusion that Teva's allegations reflected any true "consumer coercion." Nowhere does the *Abbott Labs* court identify who the consumers are who were coerced and exactly how their choices were limited by anything Abbott did. When discussing buying behaviors and choices in the pharmaceutical industry, the two actors of greatest significance on the demand side of the equation are the physicians who write the prescriptions and the third-party payors (i.e., insurers, managed care companies, etc.) who pay for them. Absent from the court's opinion is any discussion of how the competitive choices of either of these two demand sources were affected by Abbott's reformulation strategy. Once Teva launched its formulation of fenofibrate, physicians were presumably free to prescribe it by name instead of TriCor. Perhaps more importantly, managed care companies and the pharmacy benefit management firms that exert considerable influence over the prescribing behavior of physicians were free to make Teva's Lofibra brand of fenofibrate the preferred choice in their approved formularies that their network physicians must consult when writing prescriptions. In short, if the new TriCor formulations were not, in the eyes of those who actually drive pharmaceutical product demand, desirable despite the presence of a less expensive Teva brand with a different dosage and delivery system, those "buyers" had the very same ability to vote with their feet that led the *Berkey Photo* court to reject the prospect of judicial evaluation of the pros and cons of product innovation.

The alleged lack of "unfettered consumer choice" identified by the *Abbott Labs* court was the inability to choose "between fenofibrate formulations" because Abbott removed its old formulation from the market. However, both the new Abbott formulation for TriCor and the old formulation, represented by the Teva's Lofibra product, were available for physicians to prescribe. In short, the Abbott court's departure from the teaching of *Berkey Photo*, to the extent it rests on some element of consumer coercion, seems flawed. At bottom, it appears that the true gravamen of Teva's allegations in *Abbott Labs* was not that consumer choice (through the prescribing physician) was restricted but that an overt choice was *required*. That is, the net effect of the reformulation strategy was that for Teva to sell its version of fenofibrate, the physician had to consciously *choose* Teva's product *by name*. What Teva lost was not the ability to compete for that choice, but the ability to have sales automatically redirected to it by pharmacists when the prescribing physician wrote "TriCor." Teva's allegations themselves suggested just such a theory of its competitive harm, averring that Teva "does not employ—and ... should not need to employ—an extensive marketing department like those utilized by brand-name companies."³¹ On balance, the stricter standard of proof proposed by Abbott—that of *Berkey Photo* type deference to product design choices—seems therefore more appropriate. The "balancing test" standard employed by the court invites excessive judicial tampering with product design, under circumstances where plaintiff's allegations do not reflect a true restriction of consumer choice.³²

³⁰ Microsoft, *supra* note 19, at 64-66 ("Judicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful."). The design changes at issue in Microsoft had the effect of technologically impairing the ability of a rival's internet browser software to be installed on computers running Microsoft Windows® in place of Microsoft's own browser software.

³¹ Abbott Labs, *supra* note 4, Teva Counterclaims ¶ 79.

³² It must be noted here that the Abbott Labs court may well have denied Abbott's motion to dismiss, even if the stricter standard of proof advanced by Abbott had been adopted. It was plainly Teva's contention that the TriCor® reformulations represented no improvement at all over the prior

Apart from the question of what standard is to be applied in measuring the legality of a reformulation strategy, future courts should also be mindful of the difference between what may be sound healthcare regulatory policy, on the one hand, and the proper role of the antitrust laws on the other. The *Abbott Labs* court's analysis of the reformulation strategy is perhaps better understood as an effort to promote the generic drug substitution goals embodied in state DPS laws, rather than an effort to promote unfettered competition across all dimensions of the competitive spectrum, including non-price competition. DPS laws were enacted in part because the physicians who drive pharmaceutical demand are largely not price-sensitive, and thus more responsive to other competitive weapons in a drug seller's arsenal, including name recognition, brand loyalty, marketing prowess and the like. The DPS laws thus sought to inject a more price-sensitive selection process into a market that was naturally dominated by non-price competition. Given the exploding cost of healthcare in general, this governmental tinkering with the industry's natural competitive dynamic is sound policy, but the use of the antitrust laws to enforce that policy is somewhat strained.

That a course of conduct may have the effect of impairing the government regulatory objective, embodied in DPS laws, to promote the buying of generic drugs does not necessarily yield the conclusion that it is "anticompetitive" in the antitrust sense. As a matter of regulatory policy, one may well argue forcefully that a brand manufacturer's deliberate avoidance of automatic generic substitution is undesirable. But, that is very different from saying that it is anticompetitive. It is not at all unusual for firms in any industry to go to great lengths to achieve differentiation, real or perceived, between their product and those of their competitors. "Commoditization" of one's product — that is, the perception that one's product and those of one's competitors are entirely fungible — is something many businesses seek to avoid through the promotion of the perceived quality of their brand and of loyalty to that brand. Goodwill, name recognition and brand loyalty are all features of open market competition. Governmentally required substitution of one product when another is requested is not. That does not mean that the governmentally required substitution is not desirable in this context. It likely is very desirable. But, it is not a feature of free market competition, the deliberate avoidance of which can comfortably be termed anticompetitive.

At least one plausible view of a reformulation strategy like that employed by Abbott is that it is an attempt to *force* competition across *all* competitive dimensions, including brand loyalty, marketing prowess, quality (perceived or actual), corporate reputation and the like, by deliberately avoiding triggering legislation that itself supplants that broad spectrum of competition in favor of price-only decision making. When the *Abbott Labs* court and future courts are eventually called upon to grapple with these issues on a full record, they should more carefully distinguish between what may be desirable healthcare regulatory policy and what is sound antitrust analysis. To the extent that reformulation strategies are perceived to run afoul of a legislative desire to promote generic substitution, the courts should think critically about whether or not the antitrust laws are the appropriate vehicle for

product and that they were introduced solely to thwart Teva's generic entry. Moreover, Teva's claims against Abbott included the allegation that Abbott's two patent infringement actions against Teva were a sham. At least on a motion to dismiss, Teva's allegations, taken as a whole, may well have risen to the level necessary to satisfy the very test that Abbott espoused. Counsel for brand name manufacturers might do well to suggest a somewhat less overtly aggressive approach to a patent litigation plus reformulation strategy than that reflected in Teva's allegations against Abbott.

addressing the problem. It may be that a more appropriate approach to the issues raised by reformulation strategies is to leave it to FDA and the state legislatures to determine if some modification of FDA "AB rating" guidelines and state DPS Laws is prudent to address scenarios in which inconsequential reformulations affect the speed of generic drug market entry.

In the meantime, counsel for brand name pharmaceutical companies must take notice that under the vagaries of a "balancing test" like that espoused in *Abbott Labs*, almost any product reformulation that occurs on the eve of generic entry runs the substantial risk of embroiling the brand manufacturer in antitrust litigation in which it will be forced to justify the benefits of the change to a judge and jury. In fact, the *Abbott Labs* decision may already be spawning new attacks on the reformulation strategy. In December 2006, a group of retail pharmacy chains filed a putative class action against AstraZeneca Pharmaceuticals L.P. for allegedly using a reformulation strategy to forestall generic competition with its blockbuster heartburn medication, Prilosec. The complaint alleges that on the eve of generic market entry AstraZeneca launched Nexium, a drug with only a minor, insignificant molecular difference from Prilosec, and then undertook a series of actions to shift buyers from Prilosec to Nexium to avoid competition from would-be generic substitutes for Prilosec.³³ More antitrust attacks on the reformulation strategy are sure to follow.

VII. CONCLUSION

Brand drug manufacturers whose patent law monopolies expire will continue to develop competitive strategies to preserve market share in the face of new competition. Those strategies may predictably rely on the non-price dimensions of competition over which the brand manufacturers enjoy an advantage. State DPS laws may well reflect a legislative desire to give primacy to the price dimension of competition by relieving generic manufacturers of the usual costs and burdens of non-price competition in the areas of name recognition, brand loyalty and marketing prowess. A brand manufacturer that deliberately avoids triggering those DPS laws may be impairing that legislative policy choice. Such a strategy, however, cannot necessarily be termed anticompetitive, if the strategy is properly understood to force competition across all competitive dimensions, including non-price factors. This is not to say that particular implementations of the reformulation strategy may not run afoul of the antitrust laws. Rather, courts should be careful to determine whether the conduct in question actually forecloses entry of a competitive product, or merely avoids triggering legislation that gives the new entrant an advantage it would not otherwise enjoy. If entry is not foreclosed, then judicial second-guessing of the manufacturer's design-choices is ill-advised for the reasons expressed in *Berkey Photo*. Under those circumstances, the more deferential test for antitrust illegality announced in *Berkey Photo* is more appropriate. If the ability to avoid triggering DPS laws is undesirable from a regulatory policy perspective, that problem should be left to FDA and state legislatures to fix, not addressed by a misapplication of the antitrust laws.

³³ Walgreens, *supra* note 4.