

The Treatment of Pharmaceutical Life Cycle Management Strategies In the European Commission's Pharmaceutical Sector Inquiry Final Report: An American Perspective

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Last month, the European Commission issued its long-awaited Pharmaceutical Sector Inquiry Final Report, which claims to examine “the reasons for observed delays in the entry of generic medicines . . . and the apparent decline in innovation as measured by the number of new medicines coming to the market.” (21)¹ To search for those “reasons,” the Report focused on the competitive relationships between research-based “originator companies” and generic drug companies, while consciously ignoring “other important factors – apart from company behaviour – [that] could have contributed to a decline in innovation,” such as “increased scientific complexities” and regulatory changes, primarily at the U.S. Food and Drug Administration, that have increased the risks of developing new drugs. (15, 21)

The Report concludes that originator companies use a so-called “tool box” of measures designed to delay and deter the entry of generic drugs, including patent acquisitions; patent settlements, and other agreements with generics; disputes and litigation with generic companies; intervening in regulatory proceedings concerning marketing authorizations, pricing, and reimbursement for drugs; promotional activities; and patenting, launching, and promoting “Second Generation Products.” (24)

This article addresses the Report's suggestion that originator companies may be guilty of anticompetitive conduct when they patent, and then promote, Second Generation Products in order to compete against generic competitors – *i.e.*, when they engage in common product life cycle management strategies. The conclusion is that the Report has not uncovered conduct, and the EC has not articulated a theory, that could reasonably support any sort of enforcement or remedial action.

Introduction

The EC begins its discussion of pharmaceutical life cycle management strategies by briefly acknowledging that “incremental research” can “lead to significant improvements” in a variety of ways. (987) Then, while claiming not to “question incremental innovation as such,” the Report immediately reveals its focus: “the launch of a second generation product can . . . delay the market entry of a generic products corresponding to the first generation product.” (988)

Originator companies often launch second generation . . . products shortly before loss of exclusivity of the first generation product, which is sometimes combined with the withdrawal of the initial product from the market. This is accompanied by intensive marketing efforts . . . to switch . . . prescriptions and patients to the new product. Thus, when the initial product loses exclusivity, generic companies may not rely on their generic versions being prescribed and their viability is threatened. (989)

If the Commission were discussing any other industry, it would be unthinkable to suggest that life cycle management strategies like this are anticompetitive. Consumer product companies routinely make continuous incremental improvements to their products. The improvements are often not significant – but are nonetheless promoted as “new and improved”; the old product is withdrawn; and the market decides the merits of the improvement. If the incremental improvement is covered by a patent, so much the better. No one seriously argues that patenting

incremental improvements is anticompetitive because that protection creates the motivation to invest in R&D to find the improvement in the first place.

The Commission also sympathetically quotes a generic drug company as follows: “In some cases we develop a product, but by the time we come to launch, the market has completely gone or switched to another molecule and our opportunity has diminished.” (1087)

Once again, such a complaint by any other type of consumer products company would be met with derision. Why should consumers be deprived of the benefits that drove them to switch to the new molecule? To protect the profits of a competitor that chooses not to innovate, but instead to follow a strategy of copying the innovator’s products – a strategy that carries the inherent risk of ending up trying to sell yesterday’s newspaper?

So why does the Commission treat the pharmaceutical industry differently? The easy answer is that unlike the consumer products company, the innovative drug company is presumed to be a monopolist – even though the Report recognizes that often, many drugs compete to treat the same conditions – and its conduct designed to maintain that monopoly. But even if we indulge the assumption that the originator company has monopoly power, one must ask why market power makes a difference to the question of whether the introduction and promotion of Second Generation Products is anticompetitive.

This is a key question. A recent theme of U.S. antitrust law is that when an allegation of monopolization is based on conduct that we frequently observe in competitive markets – and therefore, can be presumed to have procompetitive benefits – we need to understand clearly why we would condemn such presumptively procompetitive conduct when it is engaged in by a monopolist. The Report, however, fails to do so and instead, implies that harm to a generic company’s business is anticompetitive harm. Using the language of U.S. antitrust cases, the Report confuses harm to competitors with harm to competition. A few examples stand out.

1. The Report takes a suspicious view of the fact that many secondary patents issue, and many Second Generation Products are introduced, shortly before the expiration of patent protection for First Generation Products. (1027-31, Fig. 138) This suggests, the Commission implies, an intent to impede generic entry. (1122 et seq.) But an equally fair reading of these facts – and one that originator and generic companies alike expressed to the Commission (92) – is that these temporal relationships demonstrate that the competition presented by imminent generic entry spurs innovation. That is unambiguously a consumer benefit, even if the innovator is a monopolist.

2. Likewise, the Commission seems bothered by evidence that, “Especially in the year before loss of exclusivity of the first product, one could see a switch of the marketing and promotion budget towards the second generation product.” (1039) It is difficult to see what troubles the Commission here. The problem cannot be the cessation of promotional support for the First Generation Product. Even when no Second Generation Product is imminent, innovator drug companies usually stop promoting products that are about to lose patent protection. (247, Fig. 34) And, of course, there is no legal principle that requires a company – even a monopolist – to promote a product that is about to lose sales for reasons that no amount of additional promotion can prevent.

This suggests, then, that the problem the Commission sees is the innovator company’s promotion of its new product. But promoting a new product is clearly procompetitive, not anticompetitive – even if the new product is introduced by a monopolist.

3. Finally, the Report quotes the following complaints by generic companies:

“[O]riginator companies *withdraw* first generation products and switch to second generation products. They claim that such withdrawals before generic market entry leave doctors and patients with *no other choice* than to switch to the second generation product.” (1045)(emphasis added)

As noted above, consumer products companies almost always withdraw older products upon the introduction of “new and improved” products, so that consumers are left with “no other choice.” In this instance, however, the fact that the originator company is assumed to be a monopolist *may* make a difference to the analysis. The effect on the consumer of a product withdrawal is clearly different in a monopolized market than in a competitive one.

That is the question examined in the balance of this paper. When – and under what legal theory – could an alleged pharmaceutical monopolist have an obligation to keep an old product on the market, after it introduces a new one?

Relevant U.S. Law

U.S. law has some – but not much – experience with this question, in two antitrust decisions in which innovator drug companies that were about to lose patent protection on one product, introduced a second, allegedly similar product – and then switched patients from the first to the second before patent expiration. These cases, brought under Section 2 of the Sherman Act, have been called “product switching” or “product hopping” cases.

One case is *Abbott Labs. v. Teva Pharmaceuticals, USA, Inc.*,² in which the court denied a motion to dismiss; the other is *Walgreen Co. v. AstraZeneca Pharmaceuticals*,³ in which the court granted that motion. Both cases relied heavily on the 1979 decision in *Berkey Photo, Inc. v. Eastman Kodak Co.*,⁴ and so we will start with a discussion of that case.

Berkey Photo v. Kodak

In *Berkey Photo*, Kodak was found to have monopolies in both a camera market and a film market. Before 1972, Kodak sold the Instamatic 126 camera system, comprised of the 126 camera and Kodacolor X film, formatted for the 126 camera. In 1972, Kodak introduced a new camera system, comprised of the Instamatic 110 camera and Kodacolor II film, formatted for the 110 camera.

Berkey Photo alleged that the new film, Kodacolor II, was actually *inferior* to the old film – and that if Kodak had simply reformatted the old film to fit the new camera, consumers would have been better off. Berkey alleged that the simultaneous introduction of the 110 camera and the inferior Kodacolor II film, together with a campaign that aggressively advertised them jointly, enabled Kodak to garner more camera sales – including sales that Berkey would have made – than if Kodak had reformatted the old film to fit the new camera. Because Kodacolor II was not necessary to produce satisfactory photographs with the new camera, Berkey claimed, these sales gains represented an unlawful maintenance of a monopoly.

The court rejected that claim and in doing so, made comments that were repeated in the *Abbott* and *Walgreen* cases.

First, the court famously stated that “any firm, even a monopolist, may generally bring its products to market whenever and however it chooses,”⁵ adding in a footnote that in cases involving product introductions, “it is not the product introduction itself, but some associated conduct, that supplies the violation.”⁶

Second, it said that Berkey's allegation that the new film was inferior to the old was irrelevant because the market, not courts, should decide which product would be successful, "so long as that success was not based on any form of coercion. . . . [C]onsumers . . . were not compelled to purchase Kodacolor II [the new film] *especially since Kodak did not remove any other films from the market when it introduced the new one.*"⁷ The court then added a footnote:

[T]he situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing the film in the [earlier] 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera . . . In such a case, the technological desirability of the product change might bear on the question of monopolistic intent.⁸

The court did not elaborate on this point, which suggests the possibility that monopolists may have an obligation to keep old versions of a product on the market. Nor did the court articulate any antitrust principle that would create such an obligation. Nor is such an obligation self-evident. After all, what if Kodak had simply stopped making the old camera system in favor of the new camera system, like P&G stops making old Pampers® when it introduces new Pampers? Although Kodak's consumers may become alienated, under what theory would Kodak be required to continue producing the old package of products? And why would the question of Kodacolor II's alleged inferiority become relevant?

Walgreen v. AstraZeneca

In *Walgreen*, plaintiffs alleged that AstraZeneca (AZ) switched patients from Prilosec®, which was about to lose patent protection, to Nexium®, which they claimed was "virtually identical" to Prilosec but had patent protection. The court granted AZ's motion to dismiss, finding that the plaintiffs had not alleged any "exclusionary" conduct, an essential element of a Sherman Act Section 2 claim, principally because AZ had not withdrawn Prilosec from the market. The court said:

[H]ere, there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices. It introduced a new drug to compete with already-established drugs – both its own and others' – and with the generic substitutes for at least one of the established drugs.⁹

The court made three other findings that respond to the European Commission's skepticism about Second Generation Products. First, citing *Berkey Photo*, the court found that the allegation that Nexium was "virtually identical" to Prilosec added nothing to the allegations because it was up to the market to decide which product was preferred.

Second, the court was not moved by inflammatory allegations about AZ's "enormously expensive . . . advertising campaign," recognizing that marketing, even by a monopolist, is procompetitive.

Third, the court found that plaintiffs had not alleged antitrust injury. "The fact 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."¹⁰ That is, the fact that, after the introduction of a Second Generation Product, generic companies "may not rely on their generic versions being prescribed" (989) merely reflects a business strategy that has left it trying to sell yesterday's newspaper.

Abbott v. Teva

The story line in *Abbott v. Teva* was long and complicated, but can be distilled as follows:

1. Teva filed for approval to sell generic copies of Abbott's product TriCor®, and Abbott sued for patent infringement.
2. The patent infringement case was not going well for Abbott, but before it was over, Abbott introduced a lower dose and different formulation of TriCor, and withdrew the old version.
3. Teva then filed for approval to sell the new version of TriCor; Abbott sued for patent infringement; the suit again was not going well; and Abbott did the same thing again – it introduced a lower dose version of the drug and withdrew the old version.
4. Teva brought an antitrust case, alleging also that when Abbott withdrew the previous versions of TriCor, it changed the drug data file code for those products to “obsolete” – with the alleged effect of preventing prescriptions written for TriCor from being filled generically.

The court denied Abbott's motion to dismiss. It rejected Abbott's argument that the introduction of new products is per se legal, citing *Berkey Photo's* footnote that the analysis is “completely different” if the introduction has restricted consumer choice. And it rejected Abbott's argument that it had no obligation to let the generics “free ride on the TriCor brand,” finding that Teva had not alleged a failure to help, but rather, that Abbott had affirmatively blocked its entry by changing the drug data code.

Conclusions

The U.S. cases teach three apparent propositions. First, obtaining secondary patents, introducing new products, and aggressively promoting them are all inherently procompetitive. Incremental improvements are the norm and should not be treated as “second class” innovations.

Second, the merits of Second Generation Products relative to older products should be decided by markets, not courts or agencies.

Third, despite language in *Berkey Photo* and *Abbott* that casts the issue as the legality of a new product introduction, a careful reading shows that none of the courts were bothered by the introduction of new products. Instead, the courts focused on the consequences of withdrawing the old products, including consequences that flow from market and regulatory structures. Thus, in *Berkey*, the court was concerned that Kodak might “stop[] producing film for the old camera, thereby compelling camera purchasers to buy the new one”; in *Abbott*, the court worried that by withdrawing earlier versions of TriCor and changing the drug data file code to “obsolete,” prescriptions for the old version could not be filled with available generic equivalents; but in *Walgreen*, the court found no exclusionary conduct because there was no product withdrawal.

Indeed, the *Walgreen* case appears to create a “safe harbor”: If the innovator keeps its old product on the market, the introduction of a new product cannot expose it to antitrust liability, regardless of when (relative to patent expiration) it introduces the new product, how aggressively it promotes it over the old one, or the relative merits of the two products. This rule – which is directly at odds with the Commission's suspicions about patenting and promoting Second Generation Products – respects the procompetitive benefits of product life cycle strategies and recognizes that markets, and not courts or enforcement agencies, should decide winners and losers.

But while *Walgreen* creates a “safe harbor,” it does not answer the question, “What legal theory might obligate a monopolist to keep an old product on the market?”

The only case law that remotely suggests such an obligation involves interoperable products. These cases are exemplified by the IBM peripherals litigation of the late 1970s,¹¹ where IBM's central processing units created markets for IBM-compatible peripheral devices. When IBM

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changed its CPU design, the peripheral manufacturers' products were sometimes rendered obsolete, and they sued, alleging that IBM's product changes were intended to stifle competition in the peripherals market. The result of those and similar cases, however, is a general rule that a monopolist may upgrade its product without fear of legal exposure to rivals who have chosen to make products that are interoperable with the outmoded one. The limited exception is when (a) the monopolist knew that the new product was no better than the old, and (b) it developed the new product *solely* to stifle competition.¹² Nothing in the EC's Report suggests such conduct.

Moreover, the analogy here is that if the availability of a generic drug to consumers is dependent on the first generation drug product remaining on the market – like an interoperable product is dependent on the host product – then an obligation to keep the first generation drug on the market might attach.

That analogy, however, does not “fit” the European pharmaceutical industry. Most important, the Commission's Report notes that recent changes in law allow generic products to enter European markets, even if the originator has withdrawn the market authorizations for those products.¹³ Consequently, there is no “interoperability” between the first generation product and the generic product, and the factual predicate for the application of this theory to European pharmaceutical markets does not exist. Accordingly, there appears to be no principled basis on which to attack life cycle strategies as “anticompetitive.”

In addition, there are many valid reasons to withdraw old products, such as avoiding consumer confusion, capturing cost savings, simplifying product lines, or building a brand. Requiring a monopolist to keep its products on the market despite these legitimate reasons not to do so smacks of requiring a monopolist to help its competitors, an obligation that the U.S. Supreme Court rejected in the *Trinko* case.¹⁴

Thus, the argument for obligating a monopolist to keep old products on the market is extremely thin. In any event, to the extent product withdrawals *do* block generic entry, the solution clearly should be to tweak the regulatory scheme, not to impose antitrust liability on the inherently procompetitive conduct of patenting, introducing, and promoting Second Generation Products.

In sum, the European Commission is wrong to view Second Generation Products with suspicion. Incremental innovation should be highly valued, and there is no factual predicate or legal theory to support treating innovator companies' use of Second Generation Products to compete with generic drug companies as “unfair.”

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¹ Citations to “(xxx)” refer to paragraph numbers in the Pharmaceutical Sector Inquiry Final Report (July 8, 2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf and

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf.

² 532 F. Supp. 2d 408 (D. Del. 2006).

³ 534 F. Supp. 2d 146 (D.D.C. 2008). The author represented AstraZeneca in the *Walgreen* case.

⁴ 603 F.2d 263 (2d Cir. 1979).

⁵ 603 F.2d at 286.

⁶ Id. at 286, n. 30.

⁷ Id. at 287 (emphasis added).

⁸ Id. at 287, n. 39.

⁹ 534 F. Supp. 2d at 151.

¹⁰ Id. at 152.

¹¹ See *ILC Peripherals Corp. v. IBM*, 458 F. Supp. 423 (D.C. Calif. 1978), *aff'd*, 613 F.2d 727 (9th Cir. 1979); *Transamerica Computer Co. v. IBM*, 481 F. Supp. 965 (N.D. Cal. 1979), *aff'd*, 698 F. 2d 1377 (9th Cir. 1983).

¹² IIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶776, 287 (3d ed. 2008).

¹³ Council Directive 2004/27/EC, Art. 10(1), 2004 O.J. (L136) 39.

¹⁴ *Verizon Comm. Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).