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Provigil: A Commentary

By DANIEL A. CRANE*

No issue has attracted more antitrust scholarship over the past decade than the skirmishing between branded and generic drug manufacturers. The battles have raged over a variety of legal terrain, including patent law, FDA regulation, the Hatch-Waxman Act,¹ and antitrust law. Just as troubling—or perhaps more troubling—than the generic/branded battles have been their truces, legal settlements that have allegedly resulted in unlawful market division and impeded entry by other generics.

The stakes are obviously enormous. Static efficiency losses, occasioned by monopolistic overcharges by branded and generic firms, perhaps run into the billions. Equally or more important are the dynamic efficiency implications. In recent years we have seen a dramatic and troubling slowing in the pace and importance of pioneer drug applications. Recently, the Obama Administration announced that it had become so concerned about the lethargic pace of new drugs that the administration is starting a new billion-dollar drug development center.² Whether the drug wars between pioneer firms and generics have anything to do with this innovation lethargy, and, if so, what effect the drug wars have on the pace of innovation, are weighty matters of public concern.

Michael Carrier's case study on Provigil³ offers new support for the view that Big Pharma is to blame for stymieing competition,

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

2. Gardiner Harris, *Citing Slow Pace of New Drugs, US to Open \$1b Development Center*, NEW YORK TIMES, Jan. 23, 2011, available at http://www.boston.com/lifestyle/health/articles/2011/01/23/citing_slow_pace_of_new_drugs_us_to_open_1b_development_center/.

3. Michael Carrier, *Povigil: A Case Study of Anticompetitive Behavior*, 3 HAST. SCI. & TECH. L. J. 441 (2011).

retarding innovation, and inflating prices in the drug industry. Carrier argues that Cephalon was able to thwart generic entry by a combination of anticompetitive strategies. It entered into a reverse payment settlement agreement with generics seeking to enter the market. These settlements purported to allow generic entry before the expiration of the patent period, but, according to Carrier, the promise of early entry was negated by the second prong of Cephalon's anticompetitive strategy. During the time that it had bought by the patent settlement, Cephalon rolled out a new sleep disorder drug—Nuvigil—supposedly to frustrate generic entry.

Since the purpose of Carrier's case study is presumably not merely to support legal action against Cephalon but to motivate continued scrutiny of Big Pharma's patent practices and perhaps a change in the governing legal or regulatory norms, it is worth taking a minute to assess his claims and ponder the wisdom of generalizing from them to broader public policy prescriptions. Having already spilled considerable ink on the patent settlements issue,⁴ I will focus my commentary on Carrier's "product hopping" claims—essentially, that Cephalon rolled out Nuvigil merely to thwart competition. Since I have no expertise with the relevant products and no particular dog in the fight between Cephalon and its antagonists, I limit myself to three very general observations about the case study and its ostensible morals for public policy.

First, it is noteworthy that, upon introducing Nuvigil, Cephalon did not withdraw Provigil from the market. Cephalon still offers Provigil today. In 2012, Provigil will become available in generic form. Carrier dismisses the significance of Cephalon's decision to keep Provigil, noting that Cephalon raised the price of Provigil to induce customers to switch to Nuvigil when the latter became available. Carrier seems to assume that once customers switch to Nuvigil, they will not switch back to a lower-priced generic Provigil.

But that is an empirical question that has not yet been tested, since generic Provigil is not yet available. One blogger has noted that "[i]f generic Provigil was to hit the market, patients who converted to Nuvigil would likely be pressured by payers to switch back to a

4. Daniel A. Crane, *Antitrust Regulation of Patent Settlements*, in ISSUES IN COMPETITION POLICY (Dale Collins ed., 2009); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements: A Reply to Hovenkamp, Janis & Lemley*, 88 MINN. L. REV. 698 (2004); Daniel A. Crane, *Per Se Illegality for Reverse Payment Settlements?*, 61 ALA. L. REV. 575 (2010) (book review symposium, invited contribution); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002).

cheaper Provigil generic.”⁵ Time will tell what effect the advent of generic Provigil will have on Provigil and Nuvigil prices and sales. For now, observe that the driving assumption in Carrier’s case study—that a switch to Nuvigil is a one-way street—remains to be tested.

It’s no answer to say that Cephalon’s pricing strategy evidences Cephalon’s hope to switch customers to Nuvigil. Of course Cephalon hopes to persuade customers that they are better off with a higher price product that will remain in patent for years to come. The question is whether customers will find Nuvigil sufficiently better than generic Provigil—a question that we can’t yet answer.

Second, and relatedly, part of the reason that we don’t know what will happen when generic Provigil hits the market is that it’s hard to tell how great the advantages of Nuvigil over Provigil actually are. Carrier dismisses the benefits as small, but there seems to be a case that the benefits are substantial, at least for some patients. Nuvigil is longer acting, has more rapid onset, and has fewer side effects.⁶ It may be more effective for some patients in treating sleep disorders, and have benefits for conditions beyond sleep disorders including ADHD, depression, bipolar depression, anxiety, and schizophrenia.⁷

Are these possible benefits sufficient to justify the purchase of Nuvigil once a generic and substantially less expensive version of Provigil becomes available? That will surely be a patient-specific issue,⁸ and only the availability of generic Provigil will answer the question. As far as I can tell, the case has yet to be made that customers will continue to pay for higher priced Nuvigil because of lock in or that Nuvigil isn’t worth its future price premium over generic Provigil.

This brings me to my third concern with Carrier’s case study—the implicit suggestion that courts should get into the business of scrutinizing “product hopping.” Alarming, there is precedent for such judicial second guessing of pharmaceutical product changes. In

5. Evelyn Pringle, *The Rise and Fall of Provigil – Part II*, SALIENT NEWS (Sept. 21, 2010, 5:00 AM), available at <http://www.salient-news.com/2010/09/provogil-cephalon/>.

6. See David Rosenberg, *Nuvigil May Have Major Advantages Compared to Provigil*, GERSON LEHRMAN GROUP (June 21, 2007), available at <http://www.glgroup.com/News/Nuvigil-may-have-major-advantages-compared-to-Provigil-12978.html>.

7. *Id.*

8. See generally RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 118–19 (2006) (discussing patient heterogeneity and consequences for regulation of drug availability).

Abbott Laboratories v. Teva Pharmaceuticals,⁹ the federal district court in Delaware confronted a claim that the branded manufacturer of Tricor, an anti-cholesterol drug, blocked generic entry by switching the product's formulation from capsule to tablet form.¹⁰ This formulation switch allegedly prevented pharmacies from making generic substitution of Tricor prescriptions.¹¹ The district court ruled that the plaintiff-competitors had stated a monopolization claim. Indeed, the court held that plaintiffs could pursue a product hopping claim even if it turned out that the new formulation was superior to the old formulation and that there were procompetitive reasons for the introduction of the new formulation:

[A]n antitrust inquiry into the benefits provided by Defendants' product changes is appropriate. Contrary to Defendants' assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.¹²

The implications of this ruling are disturbing. Suppose that you are the general counsel of a branded pharmaceutical company whose product managers want to know whether they can change the formulation of one of their drugs. Suppose that there are likely patient benefits from the change, but also some risk that generic competitors will see the change as a form of "product hopping" that could stymie their entry into the market. Your job as general counsel is to assess the probability that a jury of twelve retired postal workers (metaphorically) would conclude years after the fact that the potentially life-saving benefits to some patients were outweighed by the harms to competition from "product hopping." In the event the jury reached the conclusion that harms outweighed benefits, they would enter a lost profits damages award to competitors and an overcharge damages award to a class action of consumers that would each be automatically trebled (and attorneys' fees to the plaintiffs

9. 432 F. Supp. 2d 408 (D. Del. 2006).

10. *Id.* at 416.

11. *Id.*

12. *Id.* at 422.

automatically granted). Assuming an even mildly risk-averse class of general counsels, one has to worry about the innovation effects of a product hopping liability rule.

If there is a silver lining to the *Abbott* opinion it is the court's apparent recognition that if Abbott had kept the old formulation on the market when it introduced the new formulation, any anticompetitive effect on consumers would have arisen from consumer choice and therefore would not have been actionable.¹³ If such a rule were adopted, then Cephalon would be off the hook for product hopping, since it left Provigil on the market when it introduced Nuvigil. Alas, Carrier's case study seems designed to draw even that constraint on product hopping liability into question.

Time will tell whether consumers prefer cheap generic Provigil to expensive patented Nuvigil. Hopefully, the courts will not take it upon themselves to make that decision in the place of consumers.

13. *Id.* at 421–22.