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Understanding and Un-Tying Product Hopping Litigation, Part II: A Reply to Carrier and Shadowen

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IN THE FALL 2018 ISSUE OF *ANTITRUST*, Michael A. Carrier and Steve D. Shadowen respond to our Summer 2018 article, Doryx, Namenda, *and Coercion: Understanding and Un-Tying Product-Hopping Litigation*.[1] Carrier and Shadowen agree with our conclusion that the "hard switch"/"soft switch" distinction relied on by several antitrust plaintiffs and the Second Circuit in *Namenda* is unprincipled.[2] But we disagree with Carrier and Shadowen over what to do about that. In our Summer 2018 article, we concluded that the emptiness of the "hard switch"/"soft switch" distinction called into question the entire premise that pharmaceutical "product hopping" is anticompetitive. Carrier and Shadowen argue instead that *all transitions* from old products to new products (both hard and soft switches) should be illegal, except in isolated instances in which the branded pharmaceutical manufacturer takes extreme steps to assist its generic competitors.

In addition, Carrier and Shadowen frame their proposed test of product-hopping legality as a response to a test we did not propose. We reiterate here the conclusions of our earlier analysis of product hopping and describe some of the substantive and practical problems of the Carrier-Shadowen test.

The "Coercion" Test

Carrier and Shadowen argue that we "applaud" the courts' reliance on a "coercion" test in product-hopping cases and are "overstat[ing our] case" by citing examples of courts applying such a test.[3] Carrier and Shadowen then take the opportunity to propose their alternative to the coercion test.

But we never endorsed the use of a coercion requirement in product-hopping cases. Instead, we explored the origin of the "coercion" test used in product-hopping cases in an effort to determine why courts began requiring coercion in the first place.[4] Then, after finding that the coercion requirement comes from the case law on product-tying arrangements, we explored what that heritage might mean for today's analysis of product hopping.[5] Finally, because a core part of the alleged coercion underlying tying is deception of customers, we proposed a standard for evaluating product hopping that is consistent with its heritage: product hopping should be considered potentially anticompetitive when it is deceptive, i.e., when the proposed innovation is a sham and therefore disrupts "competition on the merits."[6] Carrier and Shadowen do not call into question our finding that courts today are applying a coercion test borrowed from tying cases to assess claims of product hopping. Nor do they provide a reason why the latest iteration of the coercion test should not have the same focus on consumer deception that was the focus of those earlier tying cases.

Nonetheless, Carrier and Shadowen make several provocative points in support of their proposed product-hopping test, and we address those points briefly below.

The "Price Disconnect"

Carrier and Shadowen argue that a coercion test is too narrow and propose expanding considerably the scope of what courts should consider a "product hop."[7] They argue that antitrust scrutiny is appropriate for *all* product reformulations, even where no customers were coerced, because of the "price disconnect" in pharmaceutical sales: "But *every* product hop that occurs in a price-disconnected market, regardless of any traditional 'coercion,' justifies scrutiny."[8] Carrier and Shadowen argue that, unlike in other industries, where customers can be trusted to make an efficient purchase decision based on price and quality, "no one" in the pharmaceutical purchasing chain makes a price-quality assessment when purchasing medicine.[9] Carrier and Shadowen contend that "the person who chooses [the doctor, they claim] does not pay, and the person who pays [the patient, they claim] does not choose."[10] For the reasons summarized in our article, we disagree with Carrier and Shadowen that patients do not play an important role in deciding what medicine they should take and that the parties paying for medicine "do[] not choose" the products.[11]

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For example, if Carrier and Shadowen are right, then why do pharmaceutical companies spend billions of dollars a year marketing directly to patients (e.g., television advertisements)? What about treatment areas like contraceptives, where generic drugs use their own trademarked brand names intended to create brand loyalty among patients? And if the true health care payors have no say in the selection of the product, then what explains the formularies created by insurance companies and pharmacy benefits managers (PBMs) to define the range of substitutable drugs for which an insurer will reimburse patients? And if PBMs do not influence product selection, then what explains the billions of dollars in rebates extracted by PBMs from pharmaceutical manufacturers every year for favorable formulary placement? We leave those questions for the readers to answer.

The Regulatory-Regime "Cheat Sheet"

Carrier and Shadowen point to the Hatch-Waxman Act and state substitution laws as a "cheat sheet" for how courts should "balance marginal product improvements against significant harms to generic competition."[12] But they decline to acknowledge that, in addition to encouraging generic competition, the Hatch-Waxman Act also was designed to incentivize brand name pharmaceutical manufacturers to invest in research and development and launch new brand name drugs. Carrier and Shadowen cite language from the Second Circuit's *Namenda* opinion regarding the "goals" of the Hatch-Waxman Act but do not cite the Second Circuit's acknowledgement that "Hatch-Waxman was designed to serve the dual purposes of both encouraging generic drug competition in order to lower drug prices *and incentivizing brand drug manufacturers to innovate through patent extensions*."[13] Because one of the goals of the Hatch-Waxman Act is to encourage branded pharmaceutical manufacturers to innovate, it is not surprising that Congress has not chosen to amend the Act to address the objections to product reformulations that Carrier and Shadowen describe.

Carrier and Shadowen do not take on in a meaningful way our point that Congress has the ability to modify the Hatch-Waxman Act to address "product hopping" but has never done so.[14] As discussed by the district court in *Doryx* and affirmed by the Third Circuit, Congress's decision not to legislate in the product-hopping area likely is a conscious one, reflecting at least in part an awareness that one regulatory misstep could discourage pharmaceutical companies from investing in important research and development:

> [T]he Act is silent on product hopping. . . . Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not. Courts should not seek to substitute their "legislative judgment" for that of Congress.[15]

Even now, with the issue of drug pricing front and center for federal lawmakers, the various proposals to address alleged efforts to impede generic competition have targeted things like FDA Citizen Petitions and alleged refusals to cooperate in developing REMS[16] protocols, and not "product hopping."[17]

The "Carrier-Shadowen Test"

Concerned that courts may not be giving appropriate attention to the "price disconnect" and are too enamored of the difference between "soft" and "hard" switches, Carrier and Shadowen propose a new test for assessing product-hopping claims. Their proposed test (1) expands the definition of a product hop subject to antitrust liability, (2) proposes two safe harbors for companies introducing new pharmaceutical products, and (3) applies a "no-economic sense" test to determine if a brand manufacturer had "anticompetitive intent" in introducing a new version of a drug.[18]

We share Carrier and Shadowen's desire for clarity in product-hopping case law but note a few problems with their test. The most significant is their definition of product hopping. They propose antitrust scrutiny of product hopping based on a broad definition of the potentially illegal conduct: "Product hopping consists of a drug company's reformulation of its product and encouragement of doctors to switch prescriptions to the reformulated product."[19] This definition includes situations in which the manufacturer continues to make and sell both the new and old versions of its medicine. No court has defined product hopping this broadly. In fact, even the Second Circuit in *Namenda*, which Carrier and Shadowen applaud for its reference to a potential "price disconnect" in pharmaceuticals, made clear that companies are free to introduce new versions of their products and encourage doctors to prescribe those products over older versions.[20] The introduction of a new formulation of a drug (and any other product for that matter) is always followed by efforts to promote that drug, which efforts typically include both retaining existing customers and growing the market (e.g., getting existing iPhone users, as well as Samsung users, to switch to a new version of the iPhone). That is not anticompetitive conduct; it is routine business strategy and likely a legal requirement for the many publicly traded pharmaceutical companies with fiduciary obligations to their stockholders.

Carrier and Shadowen also propose two "safe harbors" for alleged product hoppers.[21] But those "safe harbors" are little more than antitrust gerrymandering—redrawing the lines of what is considered permissible under the antitrust laws in a manner that would condemn more conduct than what is prohibited by *Doryx*, *Namenda*, and other cases. For the first safe harbor, Carrier and Shadowen propose a four-year "Generic Window" that begins 18 months before the first generic manufacturer submits its abbreviated new drug application (ANDA).[22] Any reformulation before that window, Carrier and Shadowen predict, is unlikely to have been intended to impair generic competition and thus should be immune from antitrust challenge.[23] Setting aside the difficulties in evaluating a party's intent in any analysis of anti-

While we agree that antitrust courts should evaluate alleged anticompetitive conduct in part based on the circumstances existing at the time the conduct took place, we do not suggest that courts become blind to subsequent competitive effects of conduct.

competitive effects[24]—if a defendant does not want to defeat its rivals, that is when antitrust red flags should go up—we are concerned that this safe harbor can be used only retrospectively. That is, in most situations, a brand manufacturer will not know when a generic manufacturer is going to file an ANDA. So looking at the timing of the manufacturer's reformulation may not tell you anything about the manufacturer's intent, let alone whether the reformulation prevented generic competition. In addition, whether a generic manufacturer files an ANDA within 18 months of the brand's reformulation (thus removing the brand manufacturer from the safe harbor) is out of the brand manufacturer's control. ANDAs are aspirational, and a chance at defeating a brand's safe harbor (and recovering treble damages) only would encourage generic manufacturers to file more speculative ANDAs earlier.

The second proposed safe harbor, which allows for reformulations after generic entry,[25] also would expand the scope of antitrust liability well beyond the current case law, which at this time does not require a brand to wait until actual generic entry to launch a new version of an existing drug or withdraw an older version. The product-hopping cases to date are clear that once the applicable patents expire, and generics have *the ability* to enter (regardless of whether they actually do), the brand manufacturer is free to reformulate and discontinue old versions of its drug. And this rule makes sense. Otherwise, brand manufacturers would be stuck devoting resources to manufacturing old versions of their drugs in perpetuity, waiting not only until generic competition was possible, but also until an unidentified generic manufacturer (outside the brand manufacturer's control) became capable of obtaining FDA approval and manufacturing a generic version. But what if it takes months or years for a generic company to reach that point, through no fault of the brand manufacturer? That sort of uncertainty and open-ended obligation to manufacture is something antitrust courts rightly have sought to avoid.[26]

In the final step of the Carrier-Shadowen test, conduct that meets the author's definition of product hopping and falls outside the proposed safe harbors would undergo a "no-economic-sense" test.[27] Under this test, if the brand manufacturer invested more money reformulating the drug than the manufacturer expected to earn in excess of its current sales, then the brand manufacturer violated the antitrust laws.[28] "The no-economic-sense inquiry," the authors claim, "offers an economic test to determine whether the monopolist's sole motive was to impair competition. If a firm undertakes conduct that makes no economic sense, then its 'anticompetitive intent' can be 'unambiguously inferred.'"[29] This framework, Carrier and Shadowen propose, would replace the antitrust rule of reason applied in product-hopping cases like *Doryx* and *Namenda* and in other Sherman Act Section 2 cases like *Microsoft*.[30]

Again, setting aside that a brand manufacturer's intent offers little help in assessing anticompetitive effects,[31] we fear that replacing the standard rule of reason with a no-economic-sense test improperly would ignore the procompetitive benefits of a reformulation. What if, for example, the brand manufacturer spent $100 million developing a new version of a product with the expectation that the reformulated product would attract only $99 million in new sales, but the new product ends up a blockbuster? What if the new drug ended up generating $500 million in new sales or curing a devastating disease? Practitioners in pharmaceutical antitrust litigation should concede that these hypotheticals are not fanciful. While Carrier and Shadowen seem to envision a contemporaneous analysis by the manufacturer of whether its product reformulation is a "genuine" one, no pharmaceutical manufacturer has a crystal ball. These companies often do not know whether and to what extent the market will accept their new product—sales forecasts are often more art than science.

But under the no-economic-sense test proposed by Carrier and Shadowen, those procompetitive benefits of the reformulation would be irrelevant because the test evaluates only what a party estimated it would earn, and not what actually happened. While we agree that antitrust courts should evaluate alleged anticompetitive conduct in part based on the circumstances existing at the time the conduct took place,[32] we do not suggest that courts become blind to subsequent competitive effects of conduct. The current rule of reason framework permits this larger view, empowering a court to weigh any anticompetitive effects of a product reformulation against, among other things, the benefits of the new version.[33] Moreover, replacing the rule of reason with a test designed only to evaluate a party's "intent," as opposed to any actual anticompetitive effects of its conduct, would turn years of antitrust law on its head. While Carrier and Shadowen may believe that intent to defeat one's competitors alone is worthy of treble-damages liability, the law still requires antitrust plaintiffs to prove actual conduct with anticompetitive effects that outweigh the procompetitive benefits.

Conclusion

Somewhat ironically, the Carrier-Shadowen test would require pharmaceutical manufacturers to act in a manner that seems anticompetitive—or at least restricts competition on the merits. Carrier and Shadowen make clear that, under

their test, even if a brand manufacturer launched a new version of a drug but continued to sell the old version for the benefit of generic competitors, the brand manufacturer could not encourage doctors and patients to use the new version.[34] That would be the case under the Carrier-Shadowen test even if the new version had clear benefits, such as longer-acting ingredients and a reduced pill burden. Instead, the brand manufacturer would need to pay for a sales force and other resources to market both the new version and old version "equally."[35]

Setting aside any objections to forcing affirmative conduct for the benefit of a competitor—as well as any potential First Amendment problems with forced commercial speech—a requirement that the branded manufacturer "promotes the original and reformulated products equally"[36] seems difficult to enforce and impossible to comply with. Thus an "equal" promotion requirement would impose new costs on branded firms without any accompanying comfort that incurring those costs would help the firm avoid an antitrust lawsuit.

Under the Carrier-Shadowen test, every new version of brand-name medicine would run the risk of treble damages antitrust liability (and years of litigation expense and business disruption) unless it qualified for a safe harbor that depended on the conduct of generic competitors outside the brand manufacturer's control.[37] For that reason and others, we remain concerned that the Carrier-Shadowen test, and the uncertainty created by a lack of clear guidance from the courts hearing product-hopping cases, discourages innovation in an industry literally vital to the health of the economy. ■

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1 Michael A. Carrier & Steve D. Shadowen, *A Non-Coercive Economic Approach to Product Hopping*, ANTITRUST, Fall 2018, at 102.

2 *Id.* at 106.

3 *Id.* at 102. Carrier and Shadowen also take issue with our inclusion of *TriCor* and *Asacol* as cases in which the court applied a coercion requirement. But the court in *TriCor* indeed invoked the same coercion standard relied on in *Namenda*, even citing the same cases. *See, e.g.*, Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 421 (D. Del. 2006) ("[W]hen the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate. . . . In the absence of free consumer choice, the basis for judicial deference is removed."). Similarly, in *Asacol*, the court expressly indicated that the theory plaintiffs were advancing, and that the court was considering at the summary judgment stage, was "in line with the Second Circuit's decision in" *Namenda*, which required plaintiff to establish that a "monopolist combine[d] product withdrawal with some other conduct, the overall effect is which to *coerce consumers* rather than persuade them on the merits." *In re* Asacol Antitrust Litig., 323 F.R.D. 451, 487 (D. Mass. 2017) (emphasis added). It is also worth noting that *TriCor* is a District of Delaware case that predated *Doryx* and thus was overruled by the Third Circuit Court's *Doryx* decision in 2015.

4 Jack E. Pace III & Kevin C. Adam, Doryx, Namenda, *and Coercion: Understanding and Un-Tying Product Hopping Litigation*, ANTITRUST, Summer 2018, at 26–28.

5 *See id.*

6 *See id.* at 28.

7 *See* Carrier & Shadowen, *supra* note 1, at 104–06.

8 *See id.* at 102; *see also* 104–05.

9 *See id.* at 102.

10 *Id.*

11 *See* Adam & Pace, *supra* note 4, at 25.

12 *See* Carrier & Shadowen, *supra* note 1, at 103–04.

13 New York v. Actavis PLC, 787 F.3d 638, 644 (2d Cir. 2015).

14 *See* Carrier & Shadowen, *supra* note 1, at 103–04.

15 Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at *43–44 (E.D. Pa. Apr. 16, 2015).

16 "REMS" stands for "Risk Evaluation and Mitigation Strategies." *See* 21 U.S.C. § 355-1.

17 *See generally* Bulleit et al., *The Trump Administration's Latest Drug Pricing Initiatives*, LAW360 (Jan. 14, 2019).

18 *See* Carrier & Shadowen, *supra* note 1, at 104–06.

19 *Id.* at 102; *see also id.* at 104.

20 *Actavis*, 787 F.3d at 654 ("As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.").

21 *See* Carrier & Shadowen, *supra* note 1, at 105.

22 *Id.*

23 *Id.*

24 *See, e.g.*, Levine v. Central Florida Med. Affiliates, Inc., 72 F.3d 1538, 1552 (11th Cir. 1996) ("The rule of reason analysis is concerned with the actual or likely effects of defendants' behavior, not with the intent behind that behavior.") (citing U.S. Healthcare, Inc. v. Healthsource, Inc., 986 F.2d 589, 596 (1st Cir. 1993) ("[E]ffects are . . . the central concern of the antitrust laws," and intent is but "a clue")); *see also* General Leaseways, Inc. v. National Truck Leasing Ass'n, 744 F.2d 588, 595–96 (7th Cir. 1984) ("We attach rather little weight to internal company documents used to show anticompetitive intent, because, though they sometimes dazzle a jury, they cast only a dim light on what ought to be the central question in an antitrust case: actual or probable anticompetitive effect.").

25 *See* Carrier & Shadowen, *supra* note 1, at 105.

26 *See* United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001) ("[T]he challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it.").

27 *See* Carrier & Shadowen, *supra* note 1, at 106.

28 *See id.* at 105–06.

29 *See id.* at 105.

30 *See id.* at 106.

31 *See supra* note 24.

32 *See, e.g.*, Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1306 (11th Cir. 2003) ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.") (citing Polk Bros. v. Forest City Enters., 776 F.2d 185, 189 (7th Cir. 1985)); *see generally* Franklin Fisher & R. Craig Romaine, *Janis Joplin's Yearbook and the Theory of Damages*, 5 J. ACCT., AUDITING & FIN. 145 (1990).

33 *See, e.g.*, *Microsoft Corp.*, 253 F.3d at 59.

34 *See* Carrier & Shadowen, *supra* note 1, at 104–05.

35 *See id.* at 104.

36 *See id.*

37 The district court in *Doryx* raised a similar concern with the theory plaintiffs advanced in that case, which shares a number of similarities with the approach Carrier and Shadowen advocate here. *See Mylan*, 2015 U.S. Dist. LEXIS 50026, at *43 ("Mylan's theory also risks slowing or even stopping pharmaceutical innovation. The 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.").