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# ON UNKNOWN OPPORTUNITIES AND PERILS: REFLECTIONS ON CARRIER AND MINNITI'S "BIOLOGICS: THE NEW ANTITRUST FRONTIER"

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[W]e stand today on the edge of a New Frontier—the frontier of the 1960s—a frontier of unknown opportunities and perils—the frontier of unfilled hopes and unfilled threats. . . . Beyond that frontier are the uncharted areas of science and space, unsolved problems of peace and war, unconquered pockets of ignorance and prejudice, unanswered questions of poverty and surplus.<sup>1</sup>

—Senator John F. Kennedy

## INTRODUCTION

The word “frontier” can be defined as “[t]hat part of a country which forms the border of its settled or inhabited regions,”<sup>2</sup> or more figuratively as “a border between what is known and what is not . . . .”<sup>3</sup> Consistent with President Kennedy’s address as quoted above, frontiers (whether spatial, temporal, or metaphorical) can present us with a host of unknown opportunities and perils. Nonetheless, as the political scientist Philip Tetlock has shown, some individuals (whom Tetlock refers to as “superforecasters”) share certain traits and mental habits—among them intellectual curiosity, openness to a wide variety of competing views, numeracy, and a resistance to all-encompassing theories of how the world works—that enable them with some consistency to see a bit past the temporal frontier and thus to predict future political or other events with greater accuracy than many professional pundits.<sup>4</sup> But, even these superfore-

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1. Senator John F. Kennedy, Address Accepting the Democratic Party Nomination for the Presidency of the United States at the Democratic National Convention (July 15, 1960), <http://www.presidency.ucsb.edu/ws/index.php?pid=25966>.

2. *Frontier IV.b*, OXFORD ENGLISH DICTIONARY (2017).

3. *Frontier*, CAMBRIDGE ENGLISH DICTIONARY (2017).

4. See PHILIP E. TETLOCK & DAN GARDNER, SUPERFORECASTING: THE ART AND SCIENCE OF PREDICTION 191–92 (2015).

casters, as they would be the first to admit, are not infallible. And, as Nassim Nicholas Taleb observes, some events are best thought of as “black swans”—consequential events that are unimaginable, or at least highly improbable, in advance<sup>5</sup>—for which little if anything can be done to prepare ourselves. At times the frontier can be breached, perhaps, but never fully tamed.

It is with these thoughts in mind that I approach Michael A. Carrier and Carl J. Minniti III’s new article, *Biologics: The New Antitrust Frontier*.<sup>6</sup> The authors’ principal task is to predict what antitrust problems will arise from conduct on the part of biologic and biosimilar drug manufacturers in the near future and how these problems will differ (in terms of frequency and severity) from the more familiar issues arising from discovery, regulation, and marketing of small-molecule compounds. From this article, I would guess that Carrier and Minniti would fare well as superforecasters. Their analysis is thoughtful, based on a vast array of sources, and reflects a keen awareness of what can and cannot yet be known; I also find their recommendations for addressing these looming issues largely persuasive. Nevertheless, at what is still an early stage in the development of biologic and biosimilar drugs, exactly how the possible threats to competition and innovation will play out remains to some degree both unknown and unknowable. Also, while it is important to protect biologic and biosimilar drugs as best we can, the ability to foresee the future surely will be outpaced by the ingenuity of industry participants, for good or for ill, in responding to ever-changing technological and market conditions.

In Part I of this essay, I discuss what Carrier and Minniti might have termed the (comparatively) easy cases—those the frequency of which we can predict, probably with a fair degree of confidence, and for which the courts have more-or-less standard analytic frameworks at their disposal. The two principal examples here are reverse payment settlements and product hopping. Part II will discuss cases that may prove a bit more difficult both to predict and to address—though I will argue that, even here, courts may not find it quite as hard as Carrier and Minniti fear to craft appropriate standards. Part III concludes.

## I. EASY CASES

Although it may seem perverse for me to classify reverse-payment settlements and product hopping as easy cases, in the present context the label ar-

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5. See NASSIM NICHOLAS TALEB, *THE BLACK SWAN: THE IMPACT OF THE HIGHLY IMPROBABLE* xxiii (2d ed. 2011). The concept is not all that dissimilar to Donald Rumsfeld’s famous “unknown unknowns.” See Donald Rumsfeld, U.S. Sec’y of Defense, Dep’t of Defense News Briefing (Feb. 12, 2002), <http://archive.defense.gov/Transcripts/Transcript.aspx?TranscriptID=2636>; see also SUSAN HAACK, *EVIDENCE MATTERS: SCIENCE, PROOF, AND TRUTH IN THE LAW* 234 (2014) (stating that, “from a strictly epistemological perspective . . . Secretary Rumsfeld had a genuinely important point . . . there may be evidence we don’t have that we don’t even realize is relevant”); TETLOCK & GARDNER, *supra* note 4, at 237–42 (challenging Taleb’s black swan thesis).

6. Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1.

guably fits: but first a little terminology. A reverse-payment settlement occurs when a brand-name drug company settles patent litigation against a generic firm that, pursuant to the terms of the Hatch-Waxman Act, has filed an abbreviated new drug application (“ANDA”) covering a bioequivalent version of the brand-name drug, on terms that involve consideration flowing from the brand-name plaintiff to the generic drug company defendant.<sup>7</sup> Product hopping, as Carrier and Minniti observe, arises when a drug company “switches from one version of a drug (say, capsule) to another (say, tablet).”<sup>8</sup> Neither practice is necessarily anticompetitive. Although on its face a reverse-payment settlement looks as if the brand-name firm is paying the generic to exit the market (a practice that in other contexts would be a *per se* violation of Sherman Act § 1), in the peculiar setting of Hatch-Waxman litigation such a settlement might reflect nothing more than the brand-name firm’s desire to avoid litigation costs and the fact that, at the time litigation commences, the defendant has sold no infringing products (and thus has not caused the plaintiff to suffer any damages). Moreover, a settlement would be procompetitive if it resulted in quicker generic entry than if the brand-name firm had prevailed in the infringement litigation.<sup>9</sup> Similarly, product hopping might enhance consumer welfare if the new formulation or dosage of an existing drug is, say, longer lasting or easier to digest. On the other hand, if a reverse payment exceeds the amount of the plaintiff’s forgone litigation costs—or if the product hop is made not to benefit patients but rather to preserve market share, by switching hard-to-switch-back patients to a new drug just before a generic substitute hits the market—these practices can preserve monopoly power without offering corresponding welfare benefits. Antitrust courts that discern whether the pro- or anticompetitive consequences of such practices are likely to dominate therefore face the unenviable task of fashioning rules that are both administrable and that avoid generating too many false positives (condemning conduct that actually promotes innovation) or false negatives (exonerating conduct that on balance harms consumers). Nonetheless, in recent cases courts have made strides in developing standards, which (in my view, at least) are both workable and, on balance, reasonable. In *FTC v. Actavis, Inc.*, for example, the Supreme Court held that reverse-payment settlements are subject to antitrust scrutiny under the rule of reason while also attempting to isolate the inquiry by strongly suggesting that payments in excess of forgone litigation costs should be highly scrutinized.<sup>10</sup> Additionally, while the Supreme Court thus far has not addressed product hopping, some of the

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7. See *id.* at 20–21.

8. *Id.* at 28.

9. For further discussion, see THOMAS F. COTTER, PATENT WARS: HOW PATENTS IMPACT OUR DAILY LIVES ch. 6 (forthcoming 2018).

10. 570 U.S. 136, 155–58 (2013). The appellate decisions construing *Actavis* have concluded, among other things, that a “payment” from brand-name to generic can consist of any benefit, such as an agreement not to market an authorized generic. See *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251–53 (3d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549–53 (1st Cir. 2016); *King Drug Co. of Florence v. SmithKline Beecham Corp.*, 791 F.3d 388, 412–13 (3d Cir. 2015). But see *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 160–63 (3d Cir. 2017) (interpreting *Actavis* somewhat more narrowly by recognizing risk aversion as a reason for a large reverse payment).

more recent lower court decisions (again correctly, in my view) have viewed the brand-name firm's outright withdrawal of an earlier version of a drug, which can make it difficult for generic firms to compete due to (among other things) regulatory constraints on substituting generic for brand-name drugs, as an indicium of potentially anticompetitive effects.<sup>11</sup>

In any event, with respect to biologic and biosimilar drugs, Carrier and Minniti make a persuasive case that reverse payments and anticompetitive product hopping probably will be less frequent than in the small-molecule setting, and that no major change in the law is needed to address issues when they do arise. As for the first of these, Carrier and Minniti argue that reverse payments will be less frequent in the biosimilar context because (1) biosimilar entry is likely to have less of an impact on the biologic firm's profits than generic entry has on the brand-name company's profits; (2) relatedly, biologics will enjoy substantial first-mover advantages; and (3) challengers can readily petition for *inter partes* review ("IPRs") to challenge the validity of biologic patents before the Patent Trial and Appeal Board ("PTAB").<sup>12</sup> This third point assumes that the U.S. Supreme Court will not find IPRs to be unconstitutional in the pending *Oil States* case<sup>13</sup>—an assumption I think is likely to be correct, though as of this writing is uncertain—and that Congress will not amend the patent law to immunize drug companies from IPRs, as some have proposed.<sup>14</sup> For similar reasons, Carrier and Minniti believe that product hopping will be less likely because the complexity of biosimilars makes product hopping itself more difficult; the FDA is not authorized to provide for additional regulatory exclusivities with regard to follow-on products (as it is for small-molecule drugs); and as above the price impact of biosimilar competition will be more muted.<sup>15</sup> Thus, while courts should apply or adapt existing legal standards to reverse payments or product hopping involving biosimilars, the legal framework for doing so already exists, and the phenomena themselves may occur rather infrequently in any event.

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11. See, e.g., *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 658–60 (2d Cir. 2015); *Abbott Labs. v. Teva Pharms. USA* 432 F. Supp. 2d 408, 430–31 (D. Del. 2006). But see *Mylan Pharms. Inc. v. Warner Chilcot Public Ltd.*, 838 F.3d 421, 438–41 (3d Cir. 2016) (affirming judgment for defendants). Carrier and Minniti suggest that current standards would be improved, however, if courts went a bit further and adopted a "no-economic-sense test" for evaluating product hopping. See Carrier & Minniti, *supra* note 6, at 33–34.

12. See Carrier & Minniti, *supra* note 6, at 21–28.

13. See *Oil States Energy Servs. v. Greene's Energy Grp.* 137 S. Ct. 2239 (2017) (granting certiorari).

14. See, e.g., Matthew Bultman, *Pharma Lobby Wants Some Patents Exempt From AIA Review*, LAW360 (July 16, 2015, 7:43 PM), <https://www.law360.com/articles/680005/pharma-lobby-wants-some-patents-exempt-from-aia-review>.

15. See Carrier & Minniti, *supra* note 6, at 28–35. For similar reasons, the authors also believe that there will be fewer sham citizen petitions, since the inherent complexity of biologic and biosimilar drugs will raise legitimate concerns about safety. See *id.* at 55–64.

## II. HARDER CASES

Among the harder cases Carrier and Minniti foresee are those involving regulatory abuse and Risk Evaluation and Mitigation Strategies (“REMs”). In this regard, Carrier and Minniti note that biologic firms can subvert the regulatory process by, for example, disclosing patents late in the process rather than as part of the so-called patent “dance”<sup>16</sup> and (as small-molecule firms also sometimes do) using the REMS designation as a reason for refusing to share with competitors the samples needed for reverse engineering.<sup>17</sup> These practices are genuinely difficult to address using the standard tools of antitrust, which as a general matter impose no liability for the legitimate assertion of intellectual property rights and refrain from condemning unilateral refusals to deal (*especially* when it comes to intellectual property).<sup>18</sup> Still, as Carrier and Minniti point out, the existing case law may provide some tools for addressing perceived abuses. Specifically, although the Supreme Court contemplated a lesser role for antitrust in regulated industries in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,<sup>19</sup> its holding arguably is of less effect where—as in the present context, where the FDA cannot *compel* drug companies to provide samples to rivals—the agency lacks the power to prevent the regulated entity from engaging in anticompetitive conduct.<sup>20</sup> In addition, the Court’s earlier decision in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*<sup>21</sup> can be read as standing for the proposition that withdrawing a benefit previously afforded a competitor solely to expand monopoly power can be a violation of § 2.<sup>22</sup> Finally, *Actavis* (the reverse-payments case) clearly holds that an attempt to enforce the potential exclusionary scope of one’s patent is not *per se* immune from antitrust scrutiny.<sup>23</sup>

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16. *See id.* at 35–48.

17. *See id.* at 49–55.

18. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325–28 (Fed. Cir. 2000) (indicating that a refusal to license IP does not violate § 2, unless the IP owner has fraudulently procured the IP or engaged in sham petitioning); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1356–62 (Fed. Cir. 1999) (articulating the same reasoning). Some other cases take a slightly more expansive view, for example by permitting the claim to go forward if the refusal to license had no legitimate business justification. *See United States v. Microsoft Corp.*, 253 F.3d 34, 62–67 (D.C. Cir. 2001); *Image Tech. Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1218–20 (9th Cir. 1997); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1187 n.64 (1st Cir. 1994), *abrogated on other grounds by Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154 (2010).

19. 540 U.S. 398 (2004).

20. *See id.* at 412 (“One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny. Where, by contrast, ‘[t]here is nothing built into the regulatory scheme which performs the antitrust function’ . . . the benefits of antitrust are worth its sometimes considerable disadvantages.”) (citations omitted); Carrier & Minniti, *supra* note 6, at 50–51.

21. 472 U.S. 585 (1985).

22. *See id.* at 610–11 (“[T]he evidence supports an inference that Ski Co. was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival.”).

23. *See F.T.C. v. Actavis, Inc.*, 570 U.S. 13, 148 (2013) (“[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than

At the same time, however, *Trinko* cautions against undermining the incentive to innovate by imposing a duty to share,<sup>24</sup> and in the present context courts might invoke this concern to avoid extending liability frontiers too far. Focusing on the incentive to invent nevertheless suggests a potentially interesting thought experiment, if nothing else: What if courts applied the principle that restraints on trade (or unilateral conduct on the part of a monopolist) are unlawful unless the pro-competitive benefits outweigh the anticompetitive costs? Put another way, what if courts were to condemn any agreements or conduct relating to patented drugs that were not reasonably necessary either to recoup the cost of past, or to induce investment in future, research and development (“R&D”)? For example, suppose it were established that the cost of developing a particular biologic drug (taking into account the need to make up for research that does not pan out, the cost of capital, and all other costs that drug companies necessarily must incur to stay in business) was \$3 billion.<sup>25</sup> Would it make sense to condemn any effort to enforce the patent on such a drug once that cost has been recouped?

The answer to this question, in my view, is emphatically no. Such a standard would be extremely difficult to administer, and U.S. antitrust law (generally for good reasons<sup>26</sup>) traditionally has shied away from condemning monopoly exploitation, as opposed to monopoly expansion or maintenance.<sup>27</sup> Moreover, a thorough analysis would need to take into account the countervailing procompetitive benefits of patents in terms of stimulating not only invention but also disclosure and other potentially beneficial consequences<sup>28</sup> as well as consider any other possible unintended consequences (e.g., encouraging trade secrecy over patents) of extending liability beyond its traditional bounds. But perhaps a more modest approach would be defensible. Maybe we shouldn't worry about forcing patent owners to share samples, for example, or to assert their patents in a timely fashion, if we can be confident that the cost of the subject drug already has been recouped many times over.<sup>29</sup> The idea seems not too

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by measuring them against procompetitive antitrust policies as well. . . . [C]ontrary to the [lower court's] view that the only pertinent question is whether ‘the settlement agreement . . . fall[s] within’ the legitimate ‘scope’ of the patent’s ‘exclusionary potential,’ . . . this Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”)

24. See *Trinko*, 540 U.S. at 407–08 (“Compelling . . . firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.”).

25. See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) (estimating the drug companies’ average cost per approved, self-originated new chemical entity/new biologic entity from the synthesis or isolation of the compound through the completion of Phase III trials at \$2.558 billion in 2013 dollars). I discuss whether this estimate is representative of all drugs, and some of the evidence presented in other studies, in COTTER, *supra* note 9, at ch. 6.

26. See, e.g., Thomas F. Cotter, *Patent Holdup, Patent Remedies, and Antitrust Responses*, 34 J. CORP. L. 1151, 1156–59 (2009).

27. See, e.g., *Rambus, Inc. v. FTC*, 522 F.3d 456, 466–68 (D.C. Cir. 2008).

28. See COTTER, *supra* note 9, at ch. 1.

29. See Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 319–20 (2016) (arguing that the U.S. government should require the compulsory licensing of some drugs pursuant to 28 U.S.C. § 1498, subject to the conditions that (1)

far removed from proposals put forward over the years by Ian Ayres and Paul Klemperer, who have argued that constraining monopolists from charging their profit-maximizing monopoly price often would enhance social welfare, because the last increment of profit attributable to that price harms consumers to a much greater extent than it benefits the monopolist.<sup>30</sup> Whether considerations of this sort could be turned into a workable legal standard nevertheless is a fair question. How many times over should patent owners be allowed to recoup their investment, for example? Could they lawfully be forced to disclose their R&D costs—a closely guarded trade secret—as a condition of avoiding antitrust liability? Nevertheless, at least in some cases confidence that the patent owner has been compensated over and again perhaps could form part of the background assumptions against which antitrust litigation operates—and arguably could bolster the intuition that forced sharing is not *always* something to be condemned for fear of killing off incentives.

Yet another hard case might involve disparagement as a potential antitrust offense. As Carrier and Minniti note:

Given the nature of competition between brands and generics, there have been few antitrust cases challenging disparagement. Brands are not likely to falsely injure near-identical generics, which garner sales not from advertising campaigns but from state substitution laws. In contrast, promotion, marketing, and the education of stakeholders will be crucial to the coming biosimilar wave, which could implicate disparagement and require courts to address novel antitrust theories.<sup>31</sup>

As a result, they argue that “[u]nlike the relationship between brands and generics, competition between biologics and biosimilars will require marketing and advertising to differentiate products, which increases the likelihood of disparagement,” and that “[b]iologic manufacturers . . . may seek to influence, or even intimidate, prescribers by exaggerating the differences with biosimilars . . . .”<sup>32</sup> Carrier and Minniti nevertheless express concern that, given

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the price charged for the drug greatly exceeds its “risk-adjusted R&D costs plus a reasonable profit,” and (2) “the magnitude of potential public health gain” promises “significant population-wide benefits”). Perhaps such considerations also could play a role in determining when other conduct biologic and other drug companies may engage in, such as exclusive dealing arrangements and bundled discounts, pose a risk of unnecessary anti-competitive harm. For recent discussion, see, e.g., Jonathan D. Rockoff, *Pfizer Alleges J&J Thwarted Competition to Remicade*, in *Legal Test of Biotech-Drug Copies*, WALL ST. J., <https://www.wsj.com/articles/pfizer-files-antitrust-lawsuit-alleging-j-j-thwarted-use-of-biosimilar-rival-to-remicade-1505913080> (last updated Sept. 20, 2017, 6:20 PM); Jonathan D. Rockoff, *Shire Alleged Allergan Blocked Drug from Medicare Contracts*, WALL ST. J., <https://www.wsj.com/articles/shire-alleges-allergan-blocked-drug-from-medicare-contracts-1506957534> (last updated Oct. 2, 2017, 2:00 PM); Arlene Weintraub, *Shire, Pfizer Antitrust Lawsuits Could Rewrite the Rules for Formulary Contracts: Report*, FIERCEPHARMA (Oct. 10, 2017, 10:49 AM), <https://www.fiercepharma.com/legal/pharma-antitrust-lawsuits-could-change-rules-for-formulary-contracts-report>; see also Jonathan M. Jacobson, *A Note on Loyalty Discounts*, ANTITRUST SOURCE (June 2010), [https://www.americanbar.org/content/dam/aba/publishing/antitrust\\_source/Jun10\\_Jacobson6\\_24f.authcheckdam.pdf](https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Jun10_Jacobson6_24f.authcheckdam.pdf).

30. Ian Ayres, *Pushing the Envelope: Antitrust Implications of the Envelope Theorem*, 17 MISS. C.L. REV. 21, 23–24 (1996); Ian Ayres & Paul Klemperer, *Limiting Patentees’ Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 989–90 (1999).

31. Carrier & Minniti, *supra* note 6, at 64 (internal citations omitted).

32. *Id.* at 69.

the comparative novelty of disparagement serving as the basis for antitrust claims and hostility with which some courts have responded to such claims when asserted,<sup>33</sup> biosimilar firms that assert such theories could face substantial legal impediments—though, at the end of the day, they seem to believe that courts generally would be receptive, given the right set of facts.<sup>34</sup>

If anything, I am actually more sanguine than Carrier and Minitti that courts will recognize disparagement as potentially anticompetitive conduct when the facts so warrant. To be sure—and I say this as someone who for many years has written and taught courses in both antitrust and unfair competition law—it does not appear common for litigants to base antitrust claims on competitors' alleged commission of unfair competition torts (such as disparagement, false advertising, or trade secret misappropriation).<sup>35</sup> This might seem odd to an outsider to these fields, because these torts surely can cause competitors and consumers to suffer substantial harm; but the reason they only rarely result in antitrust liability is that such conduct typically does not enable the tortfeasor to acquire sufficient market share or otherwise distort the market to the extent necessary to form the basis for antitrust liability. But there is no categorical reason to assume that this will always be the case. In other contexts, deception sometimes has served as a basis for imposing antitrust liability,<sup>36</sup> and as Carrier and Minitti note some circuits have explicitly held that disparagement that has the effect of excluding competitors can violate § 2.<sup>37</sup> The fact that some courts have appeared (perhaps overly) skeptical of such claims should not distract others from applying mainstream antitrust principles when the facts so require.

### III. CONCLUSION

Carrier and Minitti have done a fine job predicting the likely genesis of antitrust disputes surrounding biologic drugs and presenting reasoned argu-

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33. See, e.g., *Sanderson v. Culligan Int'l Co.*, 415 F.3d 620, 623–24 (7th Cir. 2005) (Easterbrook, J.) (stating that “[f]alse statements about a rival’s goods do not curtail output in either the short or the long run,” and that “[c]ommercial speech is not actionable under the antitrust laws”) (cited in Carrier & Minitti, *supra* note 6, at 65 n.506).

34. See Carrier & Minitti, *supra* note 6, at 69–71.

35. See, e.g., 1 HERBERT HOVENKAMP ET AL., ANTITRUST AND IP § 11.5, at 11-84–11-85 (3d ed. 2017) (discussing the much-maligned *Pick-Barth* doctrine, under which an act of infringement or unfair competition might be deemed a per se violation of the antitrust laws, and stating that the circumstances in which such an act “impermissibly helps a party to acquire or maintain market power” are “extremely rare”).

36. See *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 314 (3d Cir. 2007) (holding that a patentee’s intentionally false promise to license standard-essential technology on FRAND terms could be actionable misconduct); *Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 795 (6th Cir. 2002) (affirming a judgment that misrepresentations concerning the strength of the plaintiff’s brand excluded competitors); *United States v. Microsoft Corp.*, 253 F.3d 34, 76–77 (D.C. Cir. 2001) (concluding that Microsoft’s “campaign to deceive developers” was “exclusionary, in violation of the Sherman Act”); cf. *Rambus Inc. v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008) (noting these cases, but also that (consistent with the text above) “an otherwise lawful monopolist’s use of deception simply to obtain higher prices normally has no particular tendency to exclude rivals and thus to diminish competition”).

37. See, e.g., *Nat’l Ass’n of Pharm. Mfrs. v. Ayerst Labs.*, 850 F.2d 904 (2d Cir. 1988) (discussed in Carrier & Minitti, *supra* note 6, at 65–66). This opinion was authored by the judge I clerked for during the term I clerked.

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ments for how the courts should respond to such disputes. Nevertheless, as I suggested at the beginning, the future is almost certain to surprise us in ways we cannot foresee. Given sufficient time, I suspect that biologic drug manufacturers will develop other practices (perhaps scarcely imaginable at present) to test the boundaries of the patent/antitrust law interface. In addressing these issues, should they arise, courts will do well to follow the lead of *Carrier* and *Minniti* in paying close attention to the facts, critically examining the economic consequences, and keeping an open mind concerning which practices do (or do not) push too far.

I will conclude nonetheless with a note of caution: namely, that it's important to not lose sight of the fact that antitrust is only one piece of the healthcare-pricing puzzle. As I have noted elsewhere,<sup>38</sup> the estimated cost of anticompetitive conduct (as it relates to drugs) is only a small fraction of all the U.S. annually spends on healthcare generally (or even on drugs specifically)—and what we spend, on a per-capita basis, on drugs and other health-related products and services dwarfs just about every other developed nation on the planet. To find solutions, policymakers will have to grapple with more fundamental issues in the way drugs and other aspects of healthcare are financed, priced, and allocated. Predicting what such reforms, should they occur at all, might look like over the course of twenty or thirty years nevertheless would require much more foresight than any one of us individually, or perhaps even collectively, possesses. At the end of the day, then, forecasts like *Carrier* and *Minniti*'s can be useful in preparing for the future as it relates to antitrust and biologics; but other, more important, unknowns simply may remain unknown for quite some time to come. The frontier beyond the frontier eludes our grasp.

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38. For extended discussion, see COTTER, *supra* note 9, at ch. 6.