THE ANTITRUST LOGIC OF BIOLOGICS

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For scholars and general readers interested in the intersection of intellectual property, pharmaceutical regulation, antitrust, and science, Professor Michael Carrier and Mr. Carl Minniti have provided a great service in their article "Biologics: The New Antitrust Frontier." Biologics is a relatively new frontier for medical prevention, diagnosis, and treatment, and it is an even newer frontier for various fields of law. While pharmaceutical development has traditionally initiated from "small molecules," or chemical compositions that interact with the body's chemistry, biologics are "large molecules," a mix of living and chemical matter that target a human's biochemistry. Whether through vaccines, gene therapies, human cells for transplantation, or allergenic extracts—to borrow just a few examples from the Food and Drug Administration ("FDA") website—biologics raise challenging regulatory and legal questions for designing competitive markets to deliver the promised medical products. These questions, however, are not completely new. Experience with generic pharmaceuticals from the small molecule world inform the analysis in the Carrier-Minniti article. Nevertheless, past experience, does not translate readily into future performance.

Like most readers, I did not approach the Carrier-Minniti article with a science background. I hope most readers are comfortable with science and not put off by it. Carrier and Minniti explain well what biologics are and how they differ from traditional pharmaceuticals. The differences are relevant for legal policy for two reasons.

First, the costs of inventing and producing biologics are much higher, both in terms of the investment of time and money, than the costs associated with small molecules. Costs are a relative measure and are not sufficient to justify a different regulatory scheme between big and small molecules. As the authors point out, however, the benefits from big molecule development are greater than what medical research has gleaned

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from small molecule research. A different benefit-cost calculation supports a different assessment of regulatory structures.

Second, biologics are more difficult to copy than small molecules. As a result, the development of a competitive generic industry is more tenuous for biologics than for traditional pharmaceuticals. As far as nomenclature, the analogue to generic pharmaceuticals in the world of biologics is biosimilars. The innovative name, however, tells us little about the appropriate regulation. More difficulty in imitation might mean a lesser need for patent protection and more scrutiny of anticompetitive patent uses. At the same time, more difficulty in imitation might mean greater reliance on trade secrets, making the intellectual property rights more complex in assessing the regulatory space.

Carrier and Minniti do not discuss trade secret law in great detail; that would be the subject of an important follow-up paper. Their paper instead identifies the key legal issues arising in the legal construction of "small molecule" therapies. These issues include reverse payment settlements, citizen petitions challenging generic—or biosimilar—entry, and refusals to share samples for risk and safety assessment. I will not assess all of these issues in much detail. Out of personal interest, however, I will focus on one: antitrust liability for disparagement. The authors identify the problem of disparaging biosimilars as a tactic to deter and inhibit entry. For the rest of this comment, I will make the case for why such disparagement in the biologic and other contexts should be the basis for an antitrust claim, *Retractable Technologies, Inc. v. Becton Dickerson & Co.*

I. BACKGROUND

In its decision in *F.T.C. v. Actavis, Inc.*,[1] the Supreme Court resolved a circuit split that vexed practitioners and policy makers confronted with a tension between antitrust and patent law. Prior to the Court's resolution, circuits were split on when a settlement agreement between a pharmaceutical patent owner and a potential generic drug manufacturer delaying entry by the generic violated antitrust laws. The circuits were split three ways. Some circuits held the agreement to be *per se* legal since promotion of settlement is desirable policy if the patent owner was acting within the scope of the patent.[2] Other circuits held the agreement to be *per se* illegal since delay of entry of a competitor creates anticompetitive harms.[3] Other circuits held that the antitrust scrutiny of the agreement should occur on a case-by-case basis under the rule of reason, requiring a balancing of competitive harms and benefits.[4]

1. 570 U.S. 136 (2013).
2. *See, e.g.*, Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005).
3. *See, e.g.*, In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).
4. *See, e.g.*, In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012).

The Supreme Court adopted the rule of reason, bringing some certainty to this circuit split affecting business relations in the sizeable pharmaceutical industry. While the rule of reason invites a case-by-case judicial analysis rather than a clear-cut rule, the Court's decision emphasized the appropriateness of antitrust scrutiny of patent rights. The opinion also set forth identifiable facts whose presence would lead to a finding of an antitrust violation. A twenty-year uncertainty in the law was given much needed clarity and invited further consideration of the intersection between antitrust and intellectual property laws.

II. CIRCUIT SPLIT: DISPARAGEMENT AS AN ANTITRUST VIOLATION

As indicated in the background to the *Actavis* case, the circuits are split three ways on the issue of disparagement as an antitrust violation. Some courts hold that disparaging commercial speech can be the basis for a claim of monopolization or attempted monopolization under the Sherman Act. These courts would allow a plaintiff to bring a Sherman Act claim if the plaintiff can meet a multi-factor test. Other courts would create a presumption against a Sherman Act claim based on disparaging commercial speech. These courts, however, would allow the plaintiff to overcome the presumption. Finally, the Fifth Circuit in *Retractable Technologies, Inc. v. Becton Dickerson & Co.*[5] ("the RTI case") follows the Seventh Circuit in holding that disparaging commercial speech is *per se* legal under the Sherman Act.

This split is analogous to that in *Actavis*: with circuits representing the range from *per se* legality to various forms of the rule of reason. Likewise, this split creates uncertainty on the scope of liability for disparaging commercial speech and the reach of the antitrust laws. While the uncertainty in *Actavis* affected only the pharmaceutical industry and the place of generic entry, the one represented in RTI's case affects a range of industries, not limited to the medical device and retractable needle industries factually at issue here. This broad reach makes the Court's review more urgent as companies in all industries make decisions of how to reconcile Lanham Act and Sherman Act claims.

In fact, the cases giving rise to the circuit split have arisen in high technology industries in which intellectual property is involved in defining markets. Among ten reported decisions that address the issue of whether product disparagement and false advertising claims preclude a Sherman Act claim, five courts found that the Sherman Act claim was not precluded. These decisions involved disputes in the field of telecommunications;[6] medical devices;[7] generic drugs;[8] hospital services;[9] and travel

5. 842 F.3d 883 (5th Cir. 2016).

6. *See* Caribbean Broad Sys., Ltd. v. Cable & Wireless P.L.C., 148 F.3d 1080, 1087 (D.C. Cir. 1998) (adopting a multi-factor test).

booking systems.[10] Some of remaining cases finding preclusion were in assorted sectors lacking a technology component: beauty products;[11] medical board review;[12] bar review preparation services.[13] The cases from the Seventh Circuit where preclusion was found as a *per se* rule involved high technology industries: medical devices[14] and water purification systems.[15]

This pattern of cases rejecting preclusion reflects the situation where established companies challenge new market entrants, technologies, and products through disparaging statements. These statements serve to prevent entry of new and innovative firms in the marketplace, thereby preventing competition. Difficulties in challenging the anticompetitive effects of product disparagement, even if limited to certain industries, impede innovation and the benefits to the economy, society, and consumers of dynamically competitive markets. The circuit split casts a shadow not only on industries broadly but also on competitive processes fueling innovation and consumer-oriented product improvements. The Fifth Circuit, by adopting the Seventh Circuit *per se* rule of preclusion, has a greater differential impact on technology-based industries than the more flexible approaches of circuits like the District of Columbia, Third, and Eighth Circuits, which look at the effect on market competition of product disparagement and false advertising on a case-by-case basis.

Like the split leading to the grant of certiorari in *Actavis*, the split over the antitrust treatment of disparagement raises reviewable questions of innovation and competition policy. These questions are ones of national importance, further mandating the Court to reconcile the uncertainties created by a circuit split.

III. ANALYZING BIOLOGICS UNDER THE CIRCUIT SPLIT

In its decision in *Actavis*, the Supreme Court overturned a lower court ruling that patent ownership created a near-immunity against antitrust review. The Court's ruling, however, maintained the view that "the antitrust laws do not negate the patentee's right to exclude others from

7. *See* Lenox McLaren Surgical Corp. v. Medtronic, Inc., 762 F.3d 1114, 1127–28 (10th Cir. 2014) (applying a *de minimis* test).

8. *See* Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs., 850 F.2d 904, 916 (2d Cir. 1988) (applying a *de minimis* test).

9. *See* W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 108–09 (3d Cir. 2010) (applying multi-factor test).

10. *See* Int'l Travel Arrangers, Inc. v. W. Airlines, Inc., 623 F.2d 1255, 1269–70 (8th Cir. 1980).

11. *See* Duty Free Ams., Inc. v. Estee Lauder Cos., 797 F.3d 1248, 1268–69 (11th Cir. 2015) (applying a *de minimis* test).

12. *See* Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 370 (6th Cir. 2003) (applying a *de minimis* test).

13. *See* Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc., 108 F.3d 1147, 1152 (9th Cir. 1997) (applying *de minimis* test).

14. *See* Mercatus Grp., LLC v. Lake Forest Hosp., 641 F.3d 834, 851–52 (7th Cir. 2011).

15. *See* Sanderson v. Culligan Int'l Co., 415 F.3d 620, 624 (7th Cir. 2005).

patent property" and that "the commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist."[16] The Court's ruling, however, emphasized the centrality of competition even within the system of exclusionary rights created by patent law. "[I]t would be incongruous," the Supreme Court wrote, "to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[17] Commitment to antitrust policy in the environment of intellectual property was at the core of the Court's ruling in concluding: "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."[18]

In a typical case involving biologics, one company has created biosimilars on several innovative means of medical diagnosis or treatment. The innovative company, however, seeks antitrust review of several disparaging statements about the inventions that were found to be acts of false advertising under the Lanham Act. Instead of seeking shelter under a settlement agreement, a disparaging company seeks immunity from antitrust review on the grounds that product disparagement cannot be anticompetitive. The Fifth Circuit would affirm this erroneous argument by ruling that "absent a demonstration that a competitor's false advertisements had the potential to eliminate, or did in fact eliminate, competition, an antitrust lawsuit will not lie."[19] In *Becton Dickinson*, the RTI case, the Fifth Circuit further concluded: "a business that is maligned by a competitor's false advertising may counter with its own advertising to expose the dishonest competitor and turn the tables competitively against the malefactor. Far from restricting competition, then, false or misleading advertising generally sets competition into motion."[20] Thus, the Fifth Circuit has adopted a shelter from antitrust scrutiny based in the Lanham Act analogous to the shelter created under patent law overturned by the Supreme Court in *Actavis*.

Not only does the Lanham Act shelter prevent biosimilars from developing its antitrust case against a disparaging company, it also creates a safe harbor for all monopolists who seek to avoid antitrust scrutiny. False advertising can allow a firm to maintain market power by diverting customers at all links in a distribution chain from a competitor's product. Such diversion can block entry to the marketplace that harms not only the competitor, but also the competitive process. Scholars have expressed

16. In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000).
17. F.T.C. v. Actavis, Inc., 570 U.S. 136 (2013).
18. *Id.*
19. Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016).
20. *Id.* (internal citations omitted).

this threat to the competitive process well. "Modern businesses are well aware of the threat of disruptive outsiders and, left unchecked, will do their utmost to prevent future waves of creative destruction from threatening the status quo."[21] Becton Dickinson's false advertising went beyond mere disparagement of a competitor. It was precisely a tactic to prevent threats to the market status quo from competitive entry of innovative products. The Fifth Circuit rule prevents judicial review of these harms to competition and the process of innovation through the creation of a shelter under the Lanham Act.

As one commentator, has noted:

> Product disparagement, depending on its motivating origins, can either nurture or spoil a competitive environment. Disparagement motivated by a rivalry grounded in truthful, accurate information is welcome competitive conduct and should be encouraged as a matter of public policy. To the extent such disparagement reveals accurate distinctions with respect to product characteristics and qualities, it cultivates a vigorous, competitive environment. However, product disparagement fueled by a rivalry driven by deception and misinformation is unacceptable and should be discouraged as a matter of public policy.[22]

The Sherman Act gives legal content to this "matter of public policy." By protecting competition, the Sherman Act acts to drive innovation and the entry of new firms with innovative products. It is not enough to say that innovative companies like RTI need to compete more aggressively in the advertising market. False statements hurt competition in the product market, and more aggressive competition in countering speech does not mitigate competitive losses in the distribution of new products. The Fifth Circuit's Darwinian view of competition ignores how statements can block innovation. Only antitrust scrutiny of competitive harms can address the abuse of monopoly power through false statements. By granting the certiorari petition, the Supreme Court can restore "a vision for competition policy that rewards innovation, innovators, and entrepreneurs but which does not allow successful firms to block subsequent innovation that may threaten them in the future."[23]

In *Actavis*, the Supreme Court demonstrated, according to one scholar, that "antitrust and patent laws may reside in separate provisions of the United States Code, but they are not independent of each other."[24] The Court, in ruling against a patent shelter for antitrust scrutiny, af-

21. Spencer Weber Waller & Matthew Sag, *Promoting Innovation*, 100 IOWA L. REV. 2223, 2224 (2015).

22. Kevin S. Marshall, *Product Disparagement Under the Sherman Act, Its Nurturing and Injurious Effects to Competition, and the Tension Between Jurisprudential Economics and Microeconomics*, 46 SANTA CLARA L. REV. 231, 253–54 (2006).

23. Waller & Sag, *supra* note 21, at 2228.

24. Shubha Ghosh, *Convergence?*, 15 MINN. J.L. SCI. & TECH. 95, 106 (2014).

firmed implicitly that "market competition drives innovation, and patent law should be applied with that principle in mind."[25] Similarly, the Fifth Circuit has created a wall between the Lanham Act and the Sherman Act. Thus, the Supreme Court should grant RTI's certiorari petition to tear down the wall, judiciously and thoughtfully, as it did with the wall created by lower courts prior to the *Actavis* decision.

IV. REMOVE THE WALL BETWEEN THE SHERMAN ACT AND THE LANHAM ACT

The false advertising safe harbor allows any large company with market power to block upstart companies, large or small, from entering a marketplace by shifting the domain of competition from the marketplace for products to the marketplace for advertising. This diversion not only changes the rules of the game but the game itself. The advertising marketplace has anticompetitive spillovers in the marketplace for innovative products. Scrutiny under the Sherman Act is necessary to prevent these anticompetitive spillovers. The Fifth Circuit ruling serves only to reinforce them.

Scholars of innovation identify risk taking as the key to innovation. Professor Robert Gordon summarizes the experience of innovators over time:

> [I]nnovators, particularly when acting by themselves or in small partnerships, are the ultimate risk-takers. Their inventions may lead them to create large firms, or their inventions may be supplanted by alternatives that are more efficient and perform better. Or they may have a promising idea and fail to find a source of funding for development of their ideas. Invention at the level of the individual is "anything but mechanical, automatic, and predictable. Chance plays a tremendous role.[26]

Nowhere is deceptive and exclusionary conduct by a competitor considered as one of the risks that an innovator has to endure. The Lanham Act and the Sherman Act serve to protect innovators from conduct that is harmful to business development. When deceptive conduct is also exclusionary, the Sherman Act should be available to protect the competitive process of innovation. The Fifth Circuit has prevented innovators from allowing the Sherman Act to fulfill its critical role in the innovation process.

Professor Gordon identifies the pharmaceutical industry as one of the key sectors where innovation will be critical in the current technology revolution shaping the economy. He notes that "pharmaceutical research has reached a brick wall of rapidly increasing costs and declining bene-

25. *Id.* at 107.
26. Robert J. Gordon, THE RISE AND FALL OF AMERICAN GROWTH 570 (2016).

fits."[27] He includes medical advances within this claim. Although Professor Gordon points to regulatory burdens as raising the costs of medical innovation, he also points to the rise of large firms and the decline of a democratic culture of innovation fostered by the patent system.[28]

The Sherman Act preserves the competitive and democratic dynamics of markets. Rules like that adopted by the Fifth Circuit that allow large firms to increase the costs for innovators in bringing new products to market without antitrust review should be scrutinized. Accordingly, it is imperative for the Supreme Court to grant the certiorari petition in order to preserve the competitive, innovation-driven landscape in all sectors of the economy.

The Fifth Circuit concluded without much analysis that the Lanham Act precludes a Sherman Act claim. It rested this conclusion on a rigid distinction "between business torts, which harm competitors, and truly anticompetitive activities, which harm the market."[29] According to the Fifth Circuit, citing the Seventh, "[i]f [a competitor's statements about another] should be false or misleading or incomplete or just plain mistaken, the remedy is not antitrust litigation but more speech—the marketplace of ideas."[30] The Fifth Circuit explains, citing its own precedent: "[t]he thrust of antitrust law is to prevent restraints on competition. Unfair competition is still competition and the purpose of the law of unfair competition is to impose restraints on that competition."[31]

To summarize, the lower appellate court's conclusions rest on preconceived notions of different types of competition as subject matter for the Lanham and Sherman Acts respectively. But competition is competition whether occurring through speech or through the distribution of products. It is true that as a matter of law that the Lanham Act and the Sherman Act protect different interests in the competitive marketplace, but that cannot be enough to have the first preclude the second. The Fifth Circuit attempts to draw a clear, unbridgeable boundary between the Lanham Act and the Sherman Act by raising the standard under which an antitrust claim may arise from product disparagement by a dominant competitor. Under the terms of the lower court opinion, an antitrust trust claim is not stated "absent a demonstration that a competitor's false advertisements had the potential to eliminate, or did in fact eliminate, competition, an antitrust lawsuit will not lie."[32] Furthermore, citing its own precedent, the Fifth Circuit expounds that a false advertising claim may give rise to one under antitrust when a competitor engages in "[a]dvertising that creates barriers to entry in a market constitutes preda-

27. *Id.* at 594.
28. *Id.* at 574.
29. Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016).
30. *Id.* at 894 (internal citations omitted).
31. *Id.* at 895 (internal citations omitted).
32. *Id.*

tory behavior of the type the antitrust laws are designed to prevent."[33] Under this high standard, the lower court dismisses without further scrutiny factual arguments RTI raised to show barriers to entry created by BD's product disparagement and false advertisement.

The Fifth Circuit's reasoning raises the standard for a monopolization or attempted monopolization claim to cases where competition is either eliminated completely or is nearly eliminated. Such a high standard is inconsistent with the holdings of the Supreme Court that a dominant firm "may not be liable for attempted monopolization under § 2 of the Sherman Act absent proof of a dangerous probability that they would monopolize a particular market and specific intent to monopolize."[34] Dangerous probability of success is a lower bar than the requirement that conduct has "the potential to eliminate."

V. COMPARING THE RTI CASE TO *POM WONDERFUL*

The Fifth Circuit opinion contains a questionable conclusion about preclusion of claims that seems to waiver on its own terms. The Supreme Court should clarify this ambiguity in light of its own recent precedent. As the Court has stated: "When two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other."[35] At issue in the POM case was the preclusion of a Lanham Act by the labelling review requirements of the Food, Drug, and Cosmetic Act (FDCA). The Court, after careful review of the policies underlying the two Acts and their respective language, concluded that the FDCA did not preclude a Lanham Act claim. Such careful review is mandated in RTI's case. The Fifth Circuit's analysis creates an unnecessary and readily cured ambiguity in the law that affects innovation and competitive markets.

Coca-Cola, in its dispute with POM Wonderful, challenged a claim that its labelling of pomegranate juice bottles constituted acts of false advertising and unfair competition in violation of the Lanham Act. Since the FDA had approved Coca-Cola's labels, the company argued that compliance with the FDCA precluded the Lanham Act. The Supreme Court recognized the need to harmonize the two statutes but rejected as a matter of course Coca-Cola's conclusion as to preclusion. Instead, the Court looked to the language and policies of the statutes as a basis for harmonization. Thus, the Court ought to grant RTI's certiorari petition to continue the process of harmonization of the Lanham Act with other federal statutes.

33. *Id.* (citations omitted).
34. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 459 (1993).
35. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014).

Judicial review is not only necessary but also readily applicable following the methodology in the *POM Wonderful* opinion. There, the Court began with the statutory analysis to see if there was specific language for preclusion. As the FDCA did not have language precluding a Lanham Act claim, analogously the Lanham Act does not include language precluding a claim under the Sherman Act. Furthermore, just as the FDCA labeling requirements were found to complement the Lanham Act in protecting consumers, so the Lanham Act and Sherman Act complement each other. As the Court stated in *POM Wonderful*: "The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers."[36]

As the Court notably stated about antitrust injury: "The antitrust laws, however, were enacted for 'the protection of *competition,* not *competitors.*'"[37] These two foundational policies complement each other. Protection for consumers as enforced by competitors prohibits harms that arise from consumer deception. Protection of competition extends to harms that arise when a dominant firm creates barriers to entry by diverting customers from innovative firms and products that are attempting to enter the market. Given the lack of language supporting preclusion and the complementary policies, the Fifth Circuit was in error in precluding the Sherman Act claim. The Supreme Court can readily resolve this error by providing a more careful analysis of the two statutes, following its reasoning in the *POM Wonderful* decision.

Should the Court grant the certiorari petition, it need not address arguments raised by POM Wonderful and Coca-Cola as to fundamental questions of statutory interpretation. Specifically, there is no argument in RTI's petition regarding the "genuine irreconcilable conflict" between statutory schemes. The Supreme Court did not address them in its *POM Wonderful* opinion and need not do so here. Furthermore, the decisions of several circuits harmonizing the Sherman Act and Lanham Act would undermine any argument in favor of an irreconcilable conflict between them. Scholars also urgently support antitrust claims based on deceptive conduct by dominant firms. As one scholar states:

> Prosecuting a monopolist's anticompetitive deception furthers the legislative aims of competition law. Given deception's social and economic harms, its lack of redeeming economic benefits or cognizable efficiencies, and the importance of trust in the marketplace, a hard line is warranted.

36. *Id.* at 2234.

37. Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 115 (1986) (internal citations omitted).

> The danger today is not that courts will punish deception under the Sherman Act. Rather, the danger is that the courts will not. In advancing their peculiar social policies on deceptive commercial speech and competition generally, courts that do not punish a monopolist's anticompetitive deception contravene the Act's legislative aim.[38]

The Fifth Circuit erred in concluding that the Lanham Act precluded a Sherman Act claim without the detailed analysis of preclusion engaged in by the Court in *POM Wonderful.* The error should be corrected to provide clarity for the competitive process of innovation.

VI. CONCLUSION

Biologics are a new frontier for antitrust law. One area where the law can be developed is in the antitrust treatment of disparagement. Given the chemical and biological complexity of biosimilars, disparagement can occur readily and with harmful market consequences. Carrier and Minniti carefully identify this problem. I commend the authors for their work and encourage efforts to correct the current law that creates an antitrust safe-harbor for disparaging statements of competing and innovative products.

38. Maurice E. Stucke, *How Do (and Should) Competition Authorities Treat A Dominant Firm's Deception?*, 63 SMU L. REV. 1069, 1122 (2010).