14-4624(cv)

United States Court of Appeals for the Second Circuit

STATE OF NEW YORK, by and through
ERIC T. SCHNEIDERMAN, Attorney General

Plaintiff-Appellee,

v.

ACTAVIS PLC & FOREST LABORATORIES, LLC

Defendants – Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK (SWEET, D.J.)

AMICUS RECKITT BENCKISER PHARMACEUTICALS, INC.'S BRIEF IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

Kevin D. McDonald
Mark R. Lentz
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Thomas Demitrack
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, OH 44114-1190
Telephone: (216) 586-3939
Facsimile: (216) 579-0212

Attorneys for Amicus Reckitt Benckiser Pharmaceuticals, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Reckitt Benckiser Pharmaceuticals, Inc. states that it is an indirectly, wholly-owned subsidiary of Invidior plc, a publicly traded company. There are no publicly held corporations that own 10% or more of Invidior plc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES AND RULES

OTHER AUTHORITIES

STATEMENT OF AMICUS'S INTEREST

Reckitt Beckiser Pharmaceuticals, Inc.[1] sells Suboxone®, the first opioid-dependence treatment approved for use outside a treatment facility. Reckitt originally sold Suboxone in a tablet form, which was packaged in a single bottle. Because Suboxone is itself an opioid, it is subject to abuse and potentially lethal when exposed to children. Reckitt subsequently developed a different dosage form, Suboxone film, which could be packaged in individual, child-resistant containers. After studies showed that the risk of pediatric exposure was *eight times* greater with tablets than with film, Reckitt withdrew its branded tablets shortly after generics entered the market.

Reckitt is defending an antitrust suit alleging that its introduction of film and withdrawal of tablets constituted acts of monopolization. Although the allegations in that case are in some respects different from those here, Reckitt has a direct interest in the proper antitrust analysis of the type of product innovation at issue here. Reckitt's brief is filed with all parties' consent.

[1] No one other than Reckitt and its counsel either (a) authored any part of this brief or (b) contributed money to its preparation or submission.

INTRODUCTION

In one respect, this is a case of first impression for this Court. No court has ever ordered a company to resume selling a product that it used to sell, rather than a new product that it prefers to sell, solely to benefit certain competitors who the court believes "cannot compete effectively" with the new product. (SA-80.) In all other respects, however, this case involves the simple application of established principles of antitrust law that should have guided the district court's analysis below, but did not.

It is well established, for example, that there are but "rare instances in which a dominant firm may incur antitrust liability for purely unilateral conduct." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009). Nor is there doubt that "any firm, even a monopolist, may generally bring its products to market whenever and however it chooses." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979). Likewise, the Supreme Court stated nearly a century ago that, having brought a product to market, "the Sherman Act 'does not restrict the long recognized right of a trader … freely to exercise his own independent discretion as to the parties with whom he will deal," or whether he will deal at all. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004) (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)); *see also, e.g.*, *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d

370, 376 (7th Cir. 1986) (Posner, J.) ("withdraw[ing]" a "helping hand" does not violate § 2).

The Supreme Court has repeatedly held, moreover, that the regulatory policies underlying other statutes, whether wise or foolish, do not change the obligations of an alleged monopolist to deal with its rivals or support their competitive preferences. *See, e.g.*, *Linkline*, 555 U.S. at 450; *Trinko*, 540 U.S. at 415-16. And prior to the order below, there was agreement that the introduction of a genuine product innovation was not only consistent with but encouraged by the antitrust laws, no matter how devastating the impact on the innovator's rivals. IIIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 781e, at 325 (3d ed. 2008) ("[N]o responsible commentator proposes to subordinate the public and consumer interest in better products to the preservation of less inventive rivals.").

But these principles were simply disregarded – indeed rendered irrelevant – by the district court's analysis. The impropriety of that result as a matter of *competition* law is reflected in the "but for" world the court's order would create. It is not a world in which generics compete on an equal footing against Forest – product against product, salesperson against salesperson, price against price. Instead, under the injunction, generics somehow have the right to compete without "generally market[ing]" their products. (SA-79.) At the same time, however, Forest is *legally compelled* to market its products – even those it deems less

desirable for patients – and to price them in a way that the court – not the market – deems acceptable. Forest must do this not for its own sake, but all so that when a physician prescribes Forest's product, the sale will go not to Forest but to a generic substitute.

Perhaps, somewhere, there is a policy that could mandate such a world, but it would not employ the word competition. The district court's decision reveals that generics' preferred method of competition is not having to compete at all. Antitrust has long recognized that such free-riding "is the antithesis of competition." *Olympia*, 797 F.2d at 378.

For all of the reasons in Forest's principal brief – including the lack of irreparable harm, Forest's patent rights, the lack of exclusionary conduct or antitrust injury, and the vagueness of the injunction – the district court's injunction must be vacated. Reckitt writes separately to highlight three of the fundamental antitrust fallacies contained within the district court's opinion.

First, and most important, the district court applied the wrong § 2 standard to evaluate exclusionary conduct. Specifically, the district court applied a balancing test contrary to binding Supreme Court and Circuit precedent. The Supreme Court has "repeatedly emphasized the importance of clear rules in antitrust law," *Linkline*, 555 U.S. at 452, and this Court has defined the anticompetitive conduct proscribed by § 2 to be "conduct without a legitimate

business purpose." *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 124 (2d Cir. 2007) (citation omitted). Such conduct, this Court emphasized, must be economically irrational, in that it "makes sense only because it eliminates competition." *Id.*

But rather than apply this clear test, the district court followed the D.C. Circuit in importing a § 1 balancing test, which weighs an action's pro-competitive benefits against its anti-competitive effects, to apply to § 2 claims. *See United States v. Microsoft*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (en banc). In doing so, the district court ignored the rule that "[c]oncerted activity subject to § 1 is judged more sternly than unilateral activity under § 2." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 767-68 (1984). This Circuit has never adopted *Microsoft*'s balancing test, and other circuit courts and commentators have castigated it with good reason: the test is not only unprecedented, but unadministrable. *See, e.g.*, *Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury.").

Second, even if § 2 claims were subject to such an amorphous balancing test, reversal would still be necessary because, in weighing the purported anticompetitive effects of Forest's actions, the district court conflated regulatory

controls with the free-market competition that antitrust law protects. The advantages that generics receive from state substitution laws do not create new federal antitrust obligations. They are simply regulatory limits on the market, like rent controls. *Trinko* and *Linkline* rejected the argument that such regulations expand "the duty of a monopolist to refrain from exclusionary practices." *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 399 (7th Cir. 2000) (Wood, J.). By equating a reduction in generic substitution with a reduction in competition, the district court traduced the fundamental principle that "the antitrust laws … were enacted for 'the protection of *competition*, not *competitors*.'" *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

Indeed, the district court could not have been more clear that its injunction was intended to benefit certain competitors (generics) from the consequences of a new product:

> Defendants are entitled to a just return on their investment in Namenda IR, but having enjoyed that return for over a decade, the law now requires them to allow generic competitors a fair opportunity to compete using state substitution laws.

(SA-95-96.) To the contrary, however, the Supreme Court in *Trinko* and other decisions has repeatedly rejected attempts to impose on alleged monopolists the duty to be "fair" to other rivals. *See, e.g.*, *Linkline*, 555 U.S. at 454 (rejecting claim that the monopolist's pricing failed to "leave its rivals a 'fair' or 'adequate' margin with which to compete"); *Weyerhaeuser Co. v. Ross-Simmons Hardwood*

Lumber Co., 549 U.S. 312, 317 (2007) (rejecting claim that monopolist's purchase of inputs prevented plaintiffs "from obtaining the [inputs] they needed at a fair price"). The desire of New York and the district court to have generics prosper at the expense of Forest may seem socially beneficial to some, but it is the antithesis of competition.

Finally, confirming the dual errors of following *Microsoft* and confusing regulations with competition, the district court's injunction is facially unadministrable. The injunction does not specify what actions will cause Forest to be held in contempt, and when Forest sought clarification, the district court simply said: "Good luck." Such a vague order not only violates due process and Rule 65(d), it also manifests the problem with attempting to convert a state regulatory regime into a federal antitrust duty to deal with consumers: "No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise." *Trinko*, 540 U.S. at 415 (citation omitted).

******

The district court's unprecedented injunction diminishes the incentive of Reckitt and all others who engage in research for the purpose of improving their products. *See id.* at 407-08. That may be the goal of New York's substitution law, but "reducing the incentive both sides have to innovate, invest, and expand … [is] inconsistent with the goals of antitrust." *Novell v. Microsoft Corp.*, 731 F.3d 1064,

1073 (10th Cir. 2013). As shown below, simply applying the correct antitrust standard mandates reversal, without the need to reach Forest's unquestioned patent rights or the proper equitable standard for issuance of such a mandatory injunction.

I. FOREST'S CONDUCT WAS NOT EXCLUSIONARY UNDER THE PROPER SECTION TWO STANDARD

A critical threshold question before this Court is how antitrust law defines exclusionary conduct in determining the offense of monopolization. That is, what standard applies under § 2 to measure the "rare instances in which a dominant firm may incur antitrust liability for purely unilateral conduct"? *Linkline*, 555 U.S. at 448.

The court below applied a § 2 balancing test – the so-called *Microsoft* test – that is contrary to binding precedent both in this Court and in the Supreme Court. Under this test, no innovator's unilateral decision to improve or replace a product through innovation is safe from antitrust liability if a jury later concludes that the impact on other competitors who prefer not to compete with the innovative product is too severe. That is not the law. When the correct analysis of exclusionary conduct is identified and applied, the district court's error is made manifest.

A. The *Microsoft* Balancing Test Used By The District Court Has No Foundation In Section Two Precedent

It is well-settled that § 2 prohibits the acquisition or maintenance of "monopoly power through anticompetitive exclusionary conduct." (SA-107.)

Exclusionary conduct, in turn, is "conduct *without* a legitimate business purpose that makes sense *only* because it eliminates competition." *Port Dock*, 507 F.3d at 124 (emphases added). Thus, conduct justified by *any* legitimate business purpose is not prohibited by § 2, regardless of how severely it affects competition. *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.").

This rule makes sense. A competitor that saves itself or earns even one additional dollar makes itself stronger and better able to compete in the future. "This is the rule of the marketplace and is precisely the sort of competition that promotes the consumer interests that the Sherman Act aims to foster." *Copperweld*, 467 U.S. at 767; *see id.* ("It is not enough that a single firm appears to 'restrain trade' unreasonably, for even a vigorous competitor may leave that impression."). As a result, unilateral conduct claimed to be exclusionary "doesn't violate section 2 if valid business reasons exist for that refusal." *Novell*, 731 F.3d at 1075; *see* Gregory J. Werden, *Indentifying Exclusionary Conduct Under Section 2: The 'No Economic Sense' Test*, 73 Antitrust L.J. 413, 424-25 (2006).

The district court did not apply this standard, nor pretend that it could be met on this record. There is no serious argument that Forest's introduction of a once-daily formulation or its withdrawal of its prior product (as to which it was about to

lose 90% of its sales) was irrational.[2] The courts have explained that all sellers have a legitimate interest in ensuring that the fruits of their competitive efforts are not taken to benefit their rivals. "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." *Trinko*, 540 U.S. at 407-08; *see, e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 867 (D.C. Cir. 2008) (alleged monopolist was under no obligation to continue selling a drug product "in competition with [its own] branded product").

But the court below was able to disregard these justifications because it adopted the wrong monopolization standard. Instead of applying this Court's

---

[2] New York's attempt to claim that Forest sacrificed short-term profits by withdrawing its IR product misses the point of the "no economic sense" test, as the Tenth Circuit explained in *Novell*:

> Of course, firms routinely sacrifice short-term profits for lots of legitimate reasons that enhance consumer welfare (think promotional discounts).… [A] monopolist might wish to withdraw from a prior course of dealing and suffer a short-term profit loss in order to pursue perfectly procompetitive ends — say, *to pursue an innovative replacement product of its own*.… To avoid penalizing normal competitive conduct, then, we require proof not just that the monopolist decided to forsake short-term profits.… Put simply, the monopolist's conduct must be *irrational* but for its anticompetitive effect.

731 F.3d at 1075 (emphases added) (citing, *inter alia*, Areeda & Hovenkamp, *supra*, ¶ 651).

decisions in *Port Dock* and *Berkey Photo*, the court stated that "[t]he D.C. Circuit case *United States v. Microsoft* lays out a useful framework for determining whether Defendants have engaged in anticompetitive conduct." (SA-115.) The court then described *Microsoft*'s "rule of reason" balancing test, under which a plaintiff may prove with respect any justification proffered for the unilateral conduct – no matter how legitimate – "that the anticompetitive harm of the conduct outweighs its precompetitive effect." (SA-116.) But this balancing test is indistinguishable from the test of liability under § 1 of the Sherman Act, which proscribes the limit on *concerted* action, not unilateral conduct. By importing a § 1 test to apply to § 2 claims, *Microsoft* ignored the rule that "[c]oncerted activity subject to § 1 is judged more sternly than unilateral activity under § 2." *Copperweld*, 467 U.S. at 768.

The D.C. Circuit based its test on cases dating back to 1911, and none more recent than 1980, *see* 253 F.3d at 58-59, thus ignoring that "[o]pinion about … monopolization has undergone an evolution." *Olympia Equip.*, 797 F.2d at 375.

> Forty years ago it was thought that even a firm with a lawful monopoly … could not be allowed to defend its monopoly against would-be competitors by tactics otherwise legitimate; it had to exercise special restraint …. Later, as the emphasis of antitrust policy shifted from the protection of competition as a process of rivalry to the protection of competition as a means of promoting economic efficiency, … it became recognized that the lawful monopolist should be free to compete like everyone else; otherwise the antitrust laws would be holding an umbrella over inefficient competitors.

Id. (citing *Berkey*, 603 F.2d 263 and numerous other cases). Thus, today, "it is clear that a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or otherwise pulling its competitive punches." *Id.* But that is the opposite of what the court held below. Under this injunction, Forest must pull its competitive punches if they deny its rivals a "fair opportunity" to free ride under state substitution laws. Under a test of monopolization as boundless as *Microsoft*, "[i]f a monopolist so much as expanded its facilities to meet anticipated demand, or failed to keep its prices high enough to permit less efficient rivals to stay afloat, it could find itself held liable under section 2." *Novell*, 731 F.3d at 1072.

In *Allied Orthopedic*, the Ninth Circuit specifically addressed the flaws in the *Microsoft* balancing test. Rejecting a § 2 challenge to a change in product design, *Allied Orthopedic* held that there "is no room in this [§ 2] analysis for balancing the benefits or worth of a product improvement against its anticompetitive effects." 592 F.3d at 1000.

> To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the "right" amount of innovation, which would maximize social gains and minimize competitive injury. A seemingly minor technological improvement today can lead to much greater advances in the future.

Id. The Ninth Circuit concluded that its precedents, and this Court's *Berkey* case,

"counsel strongly against such a [balancing] test," and noted that even the D.C. Circuit "has not yet attempted to apply it." *Id.*; *see also* Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 Berkeley Tech. L.J. 1, 52 (2012) ("[The DC Circuit's balancing] test is also opaque, and its only saving grace … is that the court has had no occasion to apply it.").

Moreover, even if *Microsoft*'s balancing test could have been supported when that case was decided (it could not), it plainly has not survived the multiple § 2 decisions the Supreme Court has since handed down. Had the Court applied the district court's balancing standard in *Trinko*, it would not have affirmed but reversed, holding that a jury was necessary to balance the defendant's right to refuse to assist competitors against the competitors' need for that assistance. Likewise, the *Linkline* Court would not have dismissed, but instead called for a jury to balance the defendant's unilateral right to set its wholesale and retail prices against the difficulties its rivals experienced due to the resulting "price squeeze." But these claims were dismissed without such balancing, because modern antitrust law recognizes that "even a monopolist is entitled to compete; it need not lie down and play dead." *Goldwasser*, 222 F.3d at 397.

Perhaps the most vivid acknowledgment that *Microsoft*'s § 2 test cannot survive *Trinko* came in *MetroNet Services Corp. v. Qwest Corp.*, 383 F.3d 1124 (9th Cir. 2004). In *MetroNet*, the Ninth Circuit had originally reversed summary

judgment in favor of the antitrust defendant, relying on *Microsoft*'s balancing test to send the case to a jury. *See* 329 F.3d 986, 1008 (9th Cir. 2003). After the Supreme Court vacated and remanded in light of *Trinko*, *see* 540 U.S. 1147 (2004), the Ninth Circuit affirmed summary judgment because the defendant "was attempting to increase its short-term profits," never once mentioning *Microsoft* or its balancing test. 383 F.3d at 1132.

Because the district court applied the wrong § 2 standard, its injunction must be vacated.

B. Section Two Precedent Instructs That Forest's Conduct Was Not Exclusionary

When judged by the correct § 2 standard, moreover, it is beyond question that Forest's conduct was proper.

1. Introducing a new product by definition increases competition in the relevant market. *See, e.g.*, *Eon Labs Mfg., Inc. v. Watson Pharms., Inc.*, 164 F. Supp. 2d 350, 358 (S.D.N.Y. 2001). Consumers, not antitrust courts or juries, determine whether the new product is desirable. *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir. 1976) ("Any other conclusion would enmesh the courts in a technical inquiry into the justifiability of product innovations."); *Medtronic Minimed Inc. v. Smiths Med. MD Inc.*, 371 F. Supp. 2d 578, 589 (D. Del. 2005) ("[I]t is not the role of the courts to determine how companies should innovate."). For that reason, introduction of a product that

enhances consumer choice is absolutely protected by the antitrust laws. *See, e.g.*, *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 369 (9th Cir. 1988) (A long "line of 'product innovation' cases has consistently rejected antitrust liability for a monopolist's decision about when or whether to market new products."); *AstraZeneca AB v. Mylan Labs. Inc.*, No. 00-6749, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010) ("[T]he alleged conduct – introducing new products – is generally considered pro-competitive.").

Walgreen Co. v. AstraZeneca Pharmaceuticals, LP, 534 F. Supp. 2d 146 (D.D.C. 2008), is strikingly on point. There, the district court dismissed a complaint alleging that AstraZeneca's introduction of Nexium – alleged to be interchangeable with its former Prilosec drug – was anticompetitive:

> Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace. New products are not capable of affecting competitors' market share unless consumers prefer the new product, regardless of whether that product is superior, equivalent, or inferior to existing products.

Id. at 151 (discussing *Berkey*, 603 F.2d at 287).

2. Conversely, the withdrawal of a product does restrict consumer choice. But – as the case miscited by the district court actually held – withdrawal still does not constitute exclusionary conduct. "[T]he antitrust laws do not preclude any manufacturer from independently discontinuing a product line …." *Glen Holly Entm't Inc. v. Tektronix Inc.*, 352 F.3d 367, 372 (9th Cir. 2003).

That is because antitrust laws impose negative, not affirmative, duties; they protect, but do not require, competition. Indeed, the premise of the entire refusal-to-deal *corpus* is "the Sherman Act 'does not restrict the long recognized right of a trader … freely to exercise his own independent discretion as to the parties with whom he will deal," or whether he will deal at all. *Trinko*, 540 U.S. at 408. That body of cases, moreover, reinforces the conclusion that even "an apparent legitimate business reason" will suffice to preclude antitrust liability. *Port Dock*, 507 F.3d at 126; *see also, e.g.*, *Novell*, 731 F.3d at 1076 (rejecting antitrust claims based on Microsoft's withdrawal of support for competitor's applications because "all the evidence suggest that Microsoft's decision came about as a result of a desire to maximize the company's immediate and overall profits"); *Olympia Equip.*, 797 F.2d at 376 ("If a monopolist does extend a helping hand, though not required to do so, and later withdraws it as happened in this case, does he incur antitrust liability? We think not.").

Meijer is particularly instructive. There, the court rejected an antitrust claim based on a branded pharmaceutical company's withdrawal of its own generic product, reasoning: "There is no provision of law that would have required Biovail and Forest to sell … a generic version of Diltiazem HCl in competition with Biovail's branded product …." 533 F.3d at 867; *see Schor v. Abbott Labs.*, 457 F.3d 608, 610 (7th Cir. 2006) (rejecting antitrust claim based on pricing of

pharmaceuticals because "antitrust law does not require monopolists to cooperate with rivals by selling them products that would help the rivals to compete"). Likewise, here, antitrust law does not compel Forest to compete with itself, or to help generics once they enter.

To the extent the court below found other district court cases holding to the contrary, they too erroneously relied on *Microsoft*'s balancing test. Only one of the cases, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) [*Tricor*], merits extended analysis because of its potential similarity to Forest's conduct. There, however, the defendant not only withdrew its old drug, but also *repurchased* supplies of that drug from pharmacies. *Id.* at 418. That additional conduct made no economic sense other than through foreclosure of generics. Thus, the *Abbott* court later "distinguished the 'offending conduct of the defendants at bar from that of [*Walgreen*], finding that defendants at bar were charged with 'eliminating choices available to the consumer' by *'repurchas[ing]* all existing prior formulations' of TriCor®." *TriCor*, No. 02-1512, 2008 BL 305552, at *1 (D. Del. Aug. 18, 2008) (emphasis added). Here, in contrast, Forest did not take this extra, irrational step to exclude generics, who will be free to compete for every Namenda sale once they enter the market as shown below.

C. The Lack Of Exclusionary Conduct Is Confirmed By The Lack Of Antitrust Injury

Even if New York's "regulatory gaming" theory could satisfy the proper § 2

test for exclusionary conduct, it would still fail for lack of antitrust injury. That is because the harm alleged by New York and found by the district court – generics' inability to "compete effectively" against Namenda XR®, (SA-80) – is precisely the type of injury rejected by the Supreme Court in *Brunswick*.

Antitrust injury doctrine requires a plaintiff to connect the alleged injury to an actual reduction in competition. As the Supreme Court has explained:

> Conduct in violation of the antitrust laws may have three effects, often interwoven: In some respects the conduct may reduce competition, in other respects it may increase competition, and in still other respects effects may be neutral as to competition. The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a *competition-reducing* aspect or effect of the defendant's behavior.

Atl. Richfield Co. v. USA-Petroleum Co., 495 U.S. 328, 343-44 (1990) (original emphasis). The need for careful application of this principle is underscored here, because rivals will always be "hurt" by the need to compete with new products. But that injury is not caused by the "competition-reducing" aspect of the conduct.

New York does not, and cannot, complain that Forest's introduction of Namenda XR® delayed the entry of generic Namenda IR. Likewise, the district court did not, and could not, find that the presence of Namenda XR will *exclude* generics after Forest's patent and regulatory exclusivities expire. Thus, after July 2015, consumers will be free to choose between generic Namenda IR and Forest's Namenda XR.

Instead, the harm found by the district court is that the presence of Namenda XR will "reduce the Namenda IR market" after generics enter, causing the generics to make fewer sales than they would in the absence of Namenda XR. (SA-86.)[3] But *Brunswick* expressly rejected such claims of antitrust injury based upon the presence of *more* competitors in the market. There, the plaintiffs' claim was premised on the theory that, but for an illegal merger by Brunswick, they would not have had to compete with certain Brunswick bowling allies. Although the merger was indeed illegal, the Court nonetheless rejected the antitrust claim. *Id.* at 488. The Court reasoned that the merger was not illegal because the competition between the alleys would remain, thus the plaintiffs' injury did not "flow[] from that which makes defendants' acts unlawful." *Id.* at 489.

So too here, the injury found by the district court was caused not by any exclusion of generics, but because it gives consumers another choice that generics – like the plaintiffs in *Brunswick* – find inconvenient. But generics are free to price or market their generic versions of Namenda IR in any way that they deem appropriate to compete. *See* Devlin & Jacobs, *supra*, 27 Berkeley Tech. L.J. at 41 ("[I]n cases where a product design fetters, but does not eliminate, competitors' ability to offer rival goods to consumers, the new design should be immune from

[3] Notably, this reliance on a "Namenda IR market" ignores the district court's own finding that the relevant antitrust market consists of all memantine products. (SA-104.)

antitrust challenge.") Any doctor or patient who prefers generic Namenda IR over Forest's Namenda XR® may choose it immediately, and any pharmacist or health care plan is free to try to convince them to do so. After July, the continued presence of Namenda XR® thus cannot be competition-reducing. In brief, the competitive process is intact.

The district court's contrary holding was based on its solicitude for generic's "typical[]" or "general[]" practice not to "market" their drugs. (SA-78-79.) As discussed in § II below, however, that practice is not protected by antitrust law. To be sure, *Microsoft* found that barring rivals from "cost-efficient" means of distribution is sufficient. 253 F.3d at 64. But that statement – for which *Microsoft* cited no authority – does not and cannot "displace" the inquiry into whether Forest had a legitimate business justification for its conduct. *Novell*, 731 F.3d at 1079; *see Multistate Legal Studies v. Harcourt Brace Jovanovich Legal & Prof'l Pubs., Inc.*, 63 F.3d 1540, 1553 n. 12 (10th Cir.1995) ("raising rivals' costs" inquiry examines whether there is "a legitimate business justification"). In any event, no principle of antitrust law would require Forest to "subsidiz[e] its competitors' selling costs." *Olympia*, 797 F.2d at 375; *see also id.* at 377-78 (competitors have "no right under antitrust law to take a free ride on its competitor's sales force.").

To hold otherwise would be to convert Forest's branded Namenda IR into some kind of essential facility, even though the Supreme Court has "never

recognized such a doctrine." *Trinko*, 540 U.S. at 411. Moreover, even in the pre-*Trinko* cases where this Court recognized the essential-facilities doctrine, it correctly recognized that "a plaintiff must show more than inconvenience, *or even some economic loss*; he must show that an alternative to the facility is not feasible." *Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 570 (2d Cir. 1990) (emphasis added); *see also, e.g.*, *Midw. Gas Servs., Inc. v. Ind. Gas Co.*, 317 F.3d 703, 714 (7th Cir. 2003) ("[T]he most economical route is not an essential facility when other routes are available."); *Sanjuan v. Am. Bd. of Psych. & Neurology, Inc.*, 40 F.3d 247, 251(7th Cir. 1994) ("The claim that a practice reduces (particular) producers' incomes has nothing to do with the antitrust laws ….").[4]

Here, neither New York nor generics could possibly make such a showing. The district court's factual findings demonstrate that generics are able to compete against brands even without automatic substitution. (SA-80-81.) And the Lipitor example provided by the district court is not the only one; Forest lists others where generics captured a majority of the market. (Dkt. No. 108-1 at 53.)

The remarkable lesson that the district court drew from these examples is that "[n]on-AB-rated generic drugs are not able to compete *effectively*" because they did not capture 80-90% of the market automatically. (SA-80 (emphasis

[4] Moreover, Forest's patent rights would preclude any argument that Namenda IR is an essential facility. *Eatoni Ergonomics, Inc. v. Research In Motion Co.*, 486 F. App'x 186, 190 (2d Cir. 2012).

added).) But antitrust law protects the right to compete, it does not create any right to win (or, in the district court's words, "compete effectively"). And nothing Forest has done in any way limits generics' ability to compete for Namenda sales once they enter the market. The generics may elect not to market their products or otherwise compete against Forest, but there is no restraint on the competitive process that requires them to do so, or protects them from their choice.

In sum, New York makes no claim that generics will not be free to compete for every Namenda sale that occurs. Nothing is alleged that would stop any physician from prescribing generic Namenda IR for any patient once that product enters the market. Where, as in *Brunswick* and *Eon Labs*, the alleged injury "flows" from the presence of more, rather than fewer, competitors, the antitrust claim fails.

II. STATE GENERIC SUBSTITUTION LAWS PLACE RESTRICTIONS ON FREE COMPETITION; THEY DO NOT REDEFINE IT.

Even if the district court were somehow permitted to balance procompetitive and anticompetitive effects as part of its § 2 analysis, it erred fundamentally in treating the regulatory benefits conferred on generic companies under state substitution laws as *competitive* benefits deserving of special protection under the antitrust laws. Indeed, the court made plain that it viewed the Hatch-Waxman Act, and specifically state generic substitution laws, as a means of competition protected by the antitrust laws. It condemned Forest for "violat[ing] the *spirit* of

the Hatch-Waxman Act," as well as "fighting back against," "gam[ing]," and "thwarting" – but notably not violating – "*state substitution laws*." (SA-72, 77, 118, 135 (emphases added).) Moreover, in summarizing its legal conclusions, the district court held that antitrust "law now requires [Forest] to allow generic competitors a fair opportunity to compete *using state substitution laws*." (SA-95-96 (emphasis added).) The court below thus committed the fallacy of confusing regulation with competition, precisely the mistake against which the Supreme Court warned in *Trinko* and *Linkline*.

A. *Trinko* And *Linkline* Expose The Error Of Conflating State Generic Substitution Laws With Competition On The Merits

State generic substitution laws cannot create federal antitrust obligations. A federal statute defines the term "antitrust laws." *See* 15 U.S.C. § 12. That definition is referenced in the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(D)(i)(V). But neither of these provisions mentions state generic substitution laws. State generic substitution laws thus are not antitrust laws.

Nor do they even reflect competition policy. Instead – as the location of New York's law confirms – generic substitution laws reflect *health-care* policy. *See* N.Y. Pub. Health Law § 206(o)(1); N.Y. Educ. Law § 6810(6). That policy may or may not be wise, as New York legislators are currently debating. (*See* Dkt. No. 108-1 at 12-13.) But even if it reflects sound health-care policy, the reduction in costs stemming from these regulations – like the reduced costs from rent

controls or other regulatory price ceilings – has nothing to do with competition, and nothing to do with antitrust. *Cf. Fisher v. City of Berkeley*, 475 U.S. 260, 264 (1986) (rejecting antitrust challenge to rent-control ordinance, reasoning that "the function of government may often be to tamper with free markets, correcting their failures and aiding their victims").

In fact, like most price controls, generic substitution laws operate in a manner antithetical to antitrust's objectives. "State generic substitution laws aim to encourage *generic* drug sales." (SA-24 (emphasis added).) Showing such solicitude to a specific sort of competitor contravenes the fundamental antitrust goal of "protect[ing] *competition*, not *competitors*." *Brunswick*, 429 U.S. at 488.

In two recent cases, the Supreme Court has confirmed that regulations assisting certain competitors do not create new federal antitrust obligations. *Trinko* affirmed the dismissal of § 2 complaint against Verizon, despite the allegation that Verizon had breached its statutory obligation to assist local exchange carriers. *See* 540 U.S. at 415-16 ("The Sherman Act … does not does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). And *Linkline* likewise affirmed the dismissal of a § 2 complaint against AT&T, despite allegations that it had set wholesale prices too high. *See* 555 U.S. at 450 ("[A]ny such duty arises only from FCC regulations, not from the Sherman Act.").

Together, *Trinko* and *Linkline* demonstrate that regulations favoring certain competitors – even regulations designed to "eliminate … monopolies," *Trinko*, 540 U.S. at 415 – do not amend the antitrust laws. The district court's "fundamental fallacy" is its conclusion that the opportunities certain states afford generics "are coterminous with the duty of a monopolist to refrain from exclusionary practices. They are not." *Goldwasser*, 222 F.3d at 399.

In sum, forcing generics to actually compete for sales is, in the district court's own words, precisely "what the antitrust laws require, not a cognizable harm." (SA-133.) Even an erroneous balancing test must balance effects on competition, not effects on New York's healthcare policies.

B. Treating Generic Substitution Laws As An Antitrust Obligation Ignores Dynamic Competition And Harms Consumers

That error, moreover, is compounded by the static focus of generic substitution laws. Those regulations focus on drugs currently on the market, ignoring drugs in development or yet to be discovered. The district court's injunction will thus reduce the incentives for both brands *and generics* to innovate, to the ultimate detriment of consumers.

Brands. The loss of incentives to branded companies like Forest is obvious. Even with "aggressive marketing and pricing practices," brands responding to generic entry by introducing marginal improvements will have limited ability to overcome "the inertia that causes most patients and physicians to resist changing

medicines." (SA-73.) In other words, every "switch-resistant" user that the district court described as a lost "market opportunity for generics" will instead become a lost market opportunity for brands. (SA-112, 88.) And even if brands succeed in converting these users after "years" of efforts (SA-73), antitrust law will then obligate brands to – on pain of treble damages – ensure that generics recapture 80% of these hard-earned gains within three months. (SA-48.) Brands' return-on-investment for marginal improvements will thus be significantly reduced, and their investment into research for such improvements will be reduced accordingly. In short, by erecting a barrier to exit, the district court also created a barrier to entry.

Generics. The effect on generics is less obvious, but nonetheless real. In fact, the court's injunction favors the generics who wish to sell IR at the expense of the multiple generics seeking approval to market XR. (*See* SA-37.) Thus, if Forest were able to convert only 20% of memantine market to Namenda XR® without a hard switch, then the multiple generics already seeking to market XR could expect to capture only a single-digit market share. That result will reduce generics' incentive to prosecute the costly patent litigation necessary to bring an ANDA product to market before expiration of the brand's intellectual property rights.

Consumers. Reducing the incentives to introduce incremental product improvements ultimately hurts consumers. Here, for example, the district court found that Namenda XR® represents "an improved version" that increases patient

compliance and reduces caregiver burdens. (SA-35-36.) But any future innovator in Forest's position will have significantly less inventive to invest in the research necessary to accomplish this benefit. This result is especially troubling because marginal product improvements constitute more than half of new, FDA-approved drugs. *See* Nat'l Inst. For Health Care Mgmt., *Changing Patterns of Pharmaceutical Innovation* 8-9 (2002).

Nor will consumers be deprived of only marginal improvements. Again, this case presents a perfect example. Without Namenda XR®, Forest could not have created Namzaric®, the breakthrough combination of the two known Alzheimer's treatments. More generally, as the Ninth Circuit has noted, the small steps taken in marginal improvements like Namenda XR® often provide the momentum for great leaps like Namzaric: "A seemingly minor technological improvement today can lead to much greater advances in the future." *Allied Orthopedic*, 592 F.3d at 1000.

In sum, elevating the static focus of generic substitution laws into an antitrust obligation ignores dynamic competition and reduces *all* pharmaceutical companies' incentives to innovate. *See* IIIB Areeda & Hovenkamp, *supra*, ¶ 781e, at 319-320 ("[G]iven that the payoff for R&D is even more speculative than for other investments[,] …. a society concerned with its productivity would not wish to instruct firms that they undertake R&D at the peril of treble damage antitrust liability."). The district court's injunction is contrary to both the law and the facts,

and will hurt consumers in the long run.

> [That the] business model on which generic-drug companies operate, of course, does not allow for such [marketing] expenditures … should not change the nature of the antitrust inquiry. …
>
> The key insight here is that policymakers should not distort well-established antitrust rules in order to solve what is, at heart, a regulatory problem.

Devlin & Jacobs, *supra*, 27 Berkeley Tech. L.J. at 51.

III. THE INDEFINITE INJUNCTION REFLECTS THE ERROR OF CREATING A SECTION 2 DUTY TO SELL

The analysis above suffices to demonstrate why antitrust law alone requires reversal of the district court's injunction, without reaching Forest's patent rights or the appropriate equitable standard for such an injunction. Reckitt also will not repeat Forest's explanation of why the injunction's vagueness violates due process, (*see* Dkt. No. 108-1 at 56-60), other than to note that "reliance on the good faith of the parties to work out any ambiguities … is not a workable substitute" for compliance with Rule 65(d). *Sebago Lake Camps, Inc. v. Simpson*, 434 A.2d 519, 523 (Me. 1981).

Instead, Reckitt will simply provide examples of the types of questions that the injunctions leaves unanswered, and an explanation for that vagueness. To wit:

- In February 2015, Forest discovers that a distributor it had supplied with Namenda IR from July 2013 onwards did not practice safe storage. Does the injunction prohibit Forest from terminating its dealings without approaching the Court to modify the injunction?

- In April 2015, Forest discovers that its detailers had been promoting

off-label uses of Namenda IR. Does the injunction require Forest to continue to do so absent modification?

- Finally, after generic entry, the district court found that Forest must lower prices or expect lower sales volumes. (SA-28.) Does the injunction prohibit Forest from drawing down inventory below the mean level it maintained between July 2013 and December 2014? The median? Some other level?

The injunction does not answer these questions, or the countless others that may arise, because no district court judge could or should take up the day-to-day management of Forest's business.

Antitrust law has long recognized this institutional incapacity. That was the entire point of § III.C of the *Linkline* opinion. *See* 555 U.S. at 452-55 ("The problem should be deemed irremedia[ble] by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency."). The impossibility of framing an injunction specific enough to comply with Rule 65(d), yet flexible enough to adapt to the day-to-day circumstances confronting businesses operating in an already heavily-regulated environment, simply confirms that the district court's antitrust analysis ignored the Supreme Court's guidance.

CONCLUSION

For the foregoing reasons, as well as those in Forest's opening brief, Reckitt urges this Court to reverse the district court's unprecedented and unwise injunction.

Respectfully submitted,

Dated: January 15, 2015

/s/ Thomas Demitrack
Thomas Demitrack

Kevin D. McDonald
Mark R. Lentz
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Thomas Demitrack
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, OH 44114-1190
Telephone: (216) 586-3939
Facsimile: (216) 579-0212

Attorneys for Amicus Reckitt Benckiser Pharmaceticals, Inc.

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) because this brief contains 6,999 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).
2. This brief complies with the typeface limitation of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14 point Times New Roman font

/s/ Thomas Demitrack
Thomas Demitrack

Thomas Demitrack
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, OH 44114-1190
Telephone: (216) 586-3939
Facsimile: (216) 579-0212

Attorney for Amicus Reckitt Benckiser Pharmaceticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2015, the undersigned filed a true and correct copy of the foregoing Amicus Reckitt Benckiser Pharmaceuticals, Inc.'s Brief in Support of Defendants-Appellants and Reversal with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all counsel of record, including the individuals below. I further certify that on this same date I have e-mailed and mailed via overnight courier the requisite copies of the same document to:

James Andrew Kent
Anisha Dasgupta
New York State Office of the Attorney General
120 Broadway
New York, NY 10271
Tel.: (212) 416-8262
Fax.: (212) 416-6015

George T. Conway III
WACHTELL, LIPTON, ROSEN & KATZ
51 West 52nd Street
New York, NY 10019
Tel.: (212) 403-1000
Fax: (212) 403-2000

Lisa S. Blatt
Sarah M. Harris
Robert A. DeRise
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004
Tel.: (202) 942-5000
Fax: (202) 942-5999

J. Mark Gidley
Peter J. Carney
Claire A. DeLelle
WHITE & CASE LLP
701 Thirteenth Street, N.W.
Washington, D.C. 20005
Tel.: (202) 626-3600
Fax: (202) 639-9355

Jack E. Pace III
Martin M. Toto
WHITE & CASE LLP
1155 6th Avenue
New York, NY 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113

Dated: January 15, 2015

/s/ Thomas Demitrack
Thomas Demitrack