No. 14-1243

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

In Re: Lamictal Direct Purchaser Antitrust Litigation

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO., INC., on behalf of itself and all others similarly situated,

Plaintiffs-Appellants,

v.

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS, USA

Defendants-Appellees.

On Appeal from the United States District Court
for the District Of New Jersey
Civ. Action No. 2:12-cv-00995 (Hon. William H. Walls, District Judge)

BRIEF *AMICUS CURIAE* OF THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF DEFENDANTS-APPELLEES URGING AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel certifies that the National Association of Manufacturers ("NAM") is a nonprofit trade association representing small and large manufacturers in a wide range of industrial sectors and in all 50 states. The NAM is the preeminent U.S. manufacturers' association as well as the nation's largest industrial trade association. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

Dated: June 3, 2014

/s/ Daniel Francis
Daniel Francis

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INTEREST OF *AMICUS CURIAE*

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing more than 12,000 members, including large and small manufacturers from every industrial sector and from every state. Manufacturing employs nearly 12 million men and women, contributes more than $1.8 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for two-thirds of private-sector research and development. The NAM is a powerful voice for the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

This litigation raises issues of direct concern to the NAM and American industry as a whole. Members of the NAM are innovators, patent holders, and patent challengers, as well as purchasers and consumers of patented articles and technologies: in other words, voices from every side of patent controversies and from almost every area of the economy. Accordingly, the NAM and its membership have a strong interest in the development of legal rules that enable parties to efficiently resolve disputes, avoid lengthy and burdensome litigation, and focus on the development and commercialization of new technologies.

All parties, including counsel for Plaintiffs-Appellants, have consented to the filing of this brief. No party (or counsel for a party) authored this brief in

whole or in part. No party (or counsel for a party) contributed money that was intended to fund preparing or submitting this brief. No person other than the NAM and its members have contributed money that was intended to fund preparing or submitting this brief. Defendant-Appellee GlaxoSmithKline is a member of the NAM.

INTRODUCTION AND SUMMARY OF ARGUMENT

In this antitrust challenge to a patent settlement, Plaintiffs-Appellants ("Plaintiffs") take aim at the use of exclusive licenses as tools for the settlement of patent litigation. Specifically, Plaintiffs argue that, if an antitrust complaint alleges that a settlement agreement includes a limited exclusive license (*i.e.*, a license agreement allowing a generic to enter during the term of a patent holder's exclusive rights, while also allowing the patent holder to compete with the generic by continuing to market and sell its branded drug), then that allegation *without more* states a "plausible" theory of competitive harm. Moreover, Plaintiffs argue, such a claim "is not to be resolved on a motion to dismiss" under Fed. R. Civ. P. 12(b)(6), and must proceed to discovery.[1]

This is neither good law nor good policy. Plaintiffs here advocate, in effect, for a *per se* rule that motions to dismiss should be denied whenever parties go beyond simple "early entry" settlements and enter into exclusive licensing agreements as part of a patent settlement. But this ignores: (1) the extraordinary burdens and risks of patent litigation, which have created an urgent need to encourage and facilitate the private settlement of patent disputes; (2) elementary principles of negotiation economics, which make dispute resolution much more likely when the parties can negotiate over more than a single variable (such as an

[1] Brief for Plaintiffs-Appellants and Joint Appendix, Volume I of II ("Plaintiffs-Appellants' Appeal Brief") at 35 (Apr. 21, 2014), Doc. No. 003111594224.

"early entry" date) and can structure licensing arrangements to include other variables beside entry date (such as the scope of an exclusive license); and (3) the practical reality that, unless Rule 12(b)(6) is applied rigorously to antitrust claims, the threat of having to litigate a rule-of-reason antitrust case can discourage parties from reaching procompetitive settlements and force them into protracted and inefficient litigation.

In the world as Plaintiffs would have it, patent holders and patent challengers would face an impossible choice between expensive, burdensome patent litigation (as opponents), and expensive, burdensome antitrust litigation (as co-defendants). This Court should reject that no-win proposition. Companies should remain free to structure patent settlement agreements without fear of speculative antitrust litigation. And where, as here, a plaintiff alleges nothing more than a limited exclusive license in a settlement, courts should recognize that there is no plausible theory of competitive harm and grant a motion to dismiss.

In the view of the NAM, this outcome—as well as the holdings and policy concerns articulated by the Supreme Court in *Twombly* and *Iqbal*—would be served by requiring, on a motion to dismiss, that:

(1) an antitrust plaintiff must allege a theory of competitive harm that rises above merely "conceivable" or "possible" to reach the higher standard of a "plausible" claim, as *Twombly* and *Iqbal* require; and

(2) an antitrust plaintiff must satisfy this standard by plausibly alleging something more than facts that are competitively neutral (such as fully exclusive patent licensing agreements that simply substitute the licensee for the licensor), or actively procompetitive (such as limited exclusive patent licensing agreements that create new competition between licensor and licensee).

BACKGROUND

I. Patent Litigation.

Commercial litigation of any kind is often expensive and burdensome, but patent litigation is particularly so. It promises exceptional technical complexities, voluminous discovery, significant expert work, and enormous costs.

Patent litigation is particularly expensive. The Supreme Court has recognized that "patent litigation is particularly complex, and particularly costly."[2] A chorus of federal courts have agreed, with one noting that "patent litigation is the slowest and most expensive litigation in the United States."[3] Very simply, "the costs of patent litigation are enormous with an average patent case costing upwards of $3 million for each side."[4]

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[2] *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2243 (2013). *See also, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334 (1971) ("[P]atent litigation is a very costly process[.]").

[3] *DeLaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006). *See also, e.g., Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) ("Patent infringement . . . is already notorious for its complexity and high cost.") (quoting *amicus* brief filed by the American Bar Association) (internal quotation marks omitted); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) ("Patent litigation breeds a litany of direct and indirect costs[.]"); *United States v. FMC Corp.*, 717 F.2d 775, 787 (3d Cir. 1983) ("Patent litigation is very expensive.").

[4] *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376–77 (Fed. Cir. 2011) (Moore, J., concurring).

In 2013, the American Intellectual Property Law Association ("AIPLA") quantified the average costs for patent infringement litigation of all varieties as follows:

Figure 1: Average Patent Litigation Costs

Amount in controversy	Average costs through end of discovery	Average costs through trial
< $1,000,000	$530,000	$970,000
$1,000,000 – $10,000,000	$1,200,000	$2,100,000
$1,000,000 – $25,000,000	$1,700,000	$2,800,000
$10,000,000 – $25,000,000	$2,200,000	$3,600,000
> $25,000,000	$3,600,000	$5,900,000

Source: AIPLA, 2013 *Report of the Economic Survey*.[5]

Patent litigation is particularly lengthy. "Patent litigations are among the longest, most time-consuming types of civil actions."[6] A comprehensive patent litigation study by PricewaterhouseCoopers in 2013 found that, since 2005, the *average* patent litigation has taken approximately 30 months from filing to trial,

[5] The costs identified by AIPLA include outside and local counsel, associates, paralegal services, travel and living expenses, fees and costs for court reporters, copies, couriers, exhibit preparation, analytical testing, expert witnesses, translators, surveys, jury advisors, and similar expenses. They exclude costs relating to settlements and damages.

[6] *Ohio Willow Wood Co.*, 629 F.3d at 1376–77 (Moore, J., concurring) (noting that "[a]s of 2009, 384 patent cases had been pending in the district courts for three years or more") (citation omitted).

with a "slight upward trend" since 2004.[7] This figure is almost 15% higher than the average for all civil litigation.[8] And the largest cases take longest to get to trial: between 1995 and 2012, the median damages award in litigated patent cases coming to trial within two years was $3.6 million; for cases taking four years or longer, median damages were $17.3 million.[9]

Patent litigation is particularly uncertain. Despite the arduous and costly nature of the patent litigation enterprise, the process remains "inherently uncertain."[10] In part, this is a function of the dense, technical nature of patent litigation, which forces a generalist judge or lay jury to "venture into a jungle of technology, conflicting expert testimony, technical evidence, and technical arguments."[11] For juries in particular—which overwhelmingly decide the highest-

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[7] PricewaterhouseCoopers LLP, *2013 Patent Litigation Study* (1995–2012), 21 (June 2013), *available at* http://www.pwc.com/us/en/forensic-services/publications/2013-patent-litigation-study.jhtml ("PwC Report").

[8] U.S. Courts, *Judicial Business of the U.S. Courts: Annual Report of the Director*, Chart T-3 (Median Time Intervals From Filing to Trial for Civil Cases in Which Trials Were Completed, by District) (2013), *available at* http://www.uscourts.gov/Statistics/JudicialBusiness/2013/statistical-tables-us-district-courts-trials.aspx.

[9] PwC Report, 22.

[10] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2005).

[11] Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme*, *in* LITIGATION STRATEGIES HANDBOOK 41 (Barry L. Grossman & Gary M. Hoffman, eds. 2000).

value cases[12]—the problem can be very serious. One district court has suggested that "patent cases may well be the most difficult for [juries] to understand both as to the evidence and the law."[13] And "[m]ock jury deliberations show that jurors often confuse one patent with another and will sometimes confuse which party is the plaintiff and which is the defendant."[14] High reversal rates in patent cases further increase the uncertainty of the process.[15] As the Seventh Circuit has put it with dry understatement, patent litigation is a "somewhat uncertain venture," and "[i]n the interest of candor, be it said that the outcome of patent litigation cannot be forecast with scientific exactitude."[16]

Uncertainty for courts and juries means uncertain outcomes for litigants. In the 15 district courts identified in the PwC Report as most favorable to patent holders, the success rate for patent holders varied between 19.6% and 57.5%.[17]

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[12] *See* PwC Report, 10.

[13] *Cooper Indus., Inc. v. Juno Lighting, Inc.*, No. 85 C 7243, 1987 WL 15086, at *6 (N.D. Ill. 1987), *aff'd* 826 F.2d 1073 (Fed. Cir. 1987).

[14] Chu & Lipner, *supra* n.12, at 43.

[15] *See, e.g.*, *DeLaventura*, 417 F. Supp. 2d at 153 n.7 (noting that district court reversal rates in patent litigation cases "once reached 42%").

[16] *Russell v. J. P. Seeburg Corp.*, 123 F.2d 509, 512 (7th Cir. 1941) (parentheses omitted).

[17] PwC Report, 23. Favorability to patent holders was based on a combination of time-to-trial, success rates, and median damages awards.

Before the 25 federal judges deciding the greatest number of patent litigations between 1995 and 2012, success rates varied between 0.0% and 84.6%.[18]

Uncertainties are most costly when the stakes at issue are high, and the stakes in patent litigation could scarcely be higher. The median damages award in patent litigation in 2012 was $9.5 million.[19] Three of the largest jury awards of all time in patent litigation date from the last few years: *Monsanto v. DuPont* ($1 billion), *Apple v. Samsung* ($1.05 billion), and *Carnegie Mellon University v. Marvell* ($1.17 billion).[20]

The problem is getting worse, not better. These burdens loom even larger because the volume of patent litigation is *increasing*. The PwC Report noted in 2013 that suits increased 29% from 2011 to 2012 (the most recent year covered by the report), reaching an unprecedented 5,189 suits.[21]

ANDA litigation is unusually burdensome. ANDA litigation—the type of patent litigation between GSK and Teva that led to the settlement at issue here—is

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[18] *Id.* at 30.

[19] *Id.* at 7.

[20] *See Monsanto Co. v. E.I. DuPont de Nemours & Co.*, Case No. 4:09-CV-00686, 2012 WL 5397601, at *2 (E.D. Mo. Nov. 2, 2012); *Apple Inc. v. Samsung Elecs. Co.*, Case No. 11-CV-01846, 2012 WL 4078433 (N.D. Cal. Aug. 24, 2012); *Carnegie Mellon Univ. v. Marvell Tech. Grp.*, Case No. 2:09-cv-00290, 2012 WL 7991311 (W.D. Pa. Dec. 26, 2012). These damages figures are initial jury verdicts only, and do not reflect subsequent *vacatur*, modification, appeals, etc.

[21] PwC Report, 6.

both particularly expensive (one study cited by the U.S. Supreme Court in *Actavis* noted that "litigation expenses can raise the expense of an ANDA to around $10 million"[22]) and particularly unpredictable (with annual success rates since 2006 varying between 22% and 83%[23]). It is also proliferating: 17 cases were decided between 1995 and 2000; 43 between 2001 and 2006; and 77 between 2007 and 2012.[24] Moreover, Paragraph IV certifications are exceptionally likely to result in litigation: an FTC review of ANDA filings between 1992 and 2000 concluded that they led to litigation in 75% of cases.[25]

II. Patent Settlements and the Importance of Flexibility.

In this light, the prospect of playing the patent litigation game is unappealing. Both parties face mounting costs and fees, uncertainty about their rights (sometimes for years), and lost revenues.[26] Purchasers and consumers suffer

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[22] Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011). *See also, e.g.*, H. Keeto Sabharwal et al., *Management of an ANDA Litigation in* ANDA LITIGATION: STRATEGIES AND TACTICS FOR PHARMACEUTICAL PATENT LITIGATORS 540 (2012).

[23] PwC Report, 28.

[24] *Id.* at 27.

[25] Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 373 (2010).

[26] Patent challengers lose revenue when an allegedly-infringing product is barred from the market; patent holders lose revenue when an infringing product competes improperly within the scope of a valid patent.

too: litigation can mean years of delay before a desirable product or technology reaches the market, and costs and risks that translate into higher prices. In most cases, the best way to escape or avoid this quagmire is a settlement agreement among the parties, if one can be reached.

The importance of patent settlements. "[P]ublic policy wisely encourages settlements."[27] Settlement agreements allow parties "to avoid litigation costs, to reduce uncertainty, and to maintain ongoing commercial relationships."[28] This is particularly important in the patent context, in light of the peculiar burdens and costs described above. Thus, "the Federal Circuit has repeatedly expressed the view that there is a strong public interest in settlement of patent litigation."[29]

Moreover, for some entities—including non-profit entities, small businesses, universities, and others—settlement agreements can provide not just an attractive and efficient alternative to litigation, but the *only* realistic mechanism through which their rights can be asserted and accommodated. As Justice Powell once observed, litigation costs can bar the courtroom door: a party may simply be

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[27] *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

[28] *Id*.

[29] *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 477 (Fed. Cir. 1991). *See also, e.g., Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 172 (2d Cir. 2012) (recognizing the "strong judicial policy favoring the settlement of litigation, including patent litigation").

unable to litigate to the bitter end.[30] When litigation costs are abnormally high—as in the patent context—settlement agreements may offer the only alternative to the all-or-nothing proposition of litigating to verdict.

Of course, these considerations are not unique to patent cases. "Parties to litigation and the public as a whole have an interest—often an overriding one—in settlement rather than exhaustion of protracted court proceedings."[31] The litigation process is both expensive and wasteful,[32] and as one appellate judge has observed, e-discovery excesses "have made the formal trial process less attractive than almost any alternative."[33] But the magnitude of the patent litigation burden makes the policy imperatives particularly strong.

It is therefore unsurprising that parties settle *much* more often than they litigate to judgment. One author has calculated that, between 1991 and 2011,

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[30] *Delta Air Lines, Inc. v. August*, 450 U.S. 346, 363 n.1 (1981) ("Unfortunately, the cost of litigation in this country—furthered by discovery procedures susceptible to gross abuse—has reached the point where many persons and entities simply cannot afford to litigate even the most meritorious claim or defense.") (Powell, J., concurring).

[31] *Id.* at 363.

[32] *See generally* Lawyers for Civil Justice et al., *Statement on Litigation Cost Survey of Major Companies* (2010), *available at* http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Duke%20Materials/Library/Litigation%20Cost%20Survey%20of%20Major%20Companies.pdf.

[33] Hon. Patrick Higginbotham, *The Disappearing Trial and Why We Should Care*, RAND REVIEW (Summer 2004), *available at* http://www.rand.org/pubs/periodicals/rand-review/issues/summer2004/28.html.

"parties settled about 95% of patent actions [filed in federal district court]. For every action litigated to the bitter end, the parties settled 19 actions. And this is merely the observable tip of the iceberg. For every dispute that resulted in litigation, many others were resolved without filing a complaint."[34]

The importance of flexibility, and multiple variables, in settlement design. In general, settlements are possible when parties can find a solution that offers value to each party, compared to the alternatives of litigating to verdict or conceding. The likelihood of settlement varies in proportion with the breadth of alternatives at the parties' disposal: the wider the choice among structures and models for negotiation and agreement, the easier it is to find a settlement.[35]

In particular, negotiating parties find it harder to reach an agreement when only a single variable is at issue. In such a situation—for example, when a patent holder and a patent challenger are negotiating *solely* over the date on which the generic will enter the market—the parties are locked in a zero-sum game in which a marginal gain for one party (*e.g.*, one day earlier or later) means a marginal loss for the other. One more apple for me is one fewer apple for you, even if we value

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[34] JOHN W. SCHLICHER, SETTLEMENT OF PATENT LITIGATION AND DISPUTES: IMPROVING DECISIONS AND AGREEMENTS TO SETTLE AND LICENSE 5 (ABA 2011).

[35] *See, e.g.*, HOWARD RAIFFA ET AL., NEGOTIATION ANALYSIS: THE SCIENCE AND ART OF COLLABORATIVE DECISION MAKING 402 (2002) ("[T]he more alternative courses of action considered by decision makers, the better the payoff to that decision is likely to be.").

apples differently. This dynamic presents an economic and psychological barrier to deal-making.

By contrast, as more variables are added to the negotiation, the opportunity to reach an agreement improves. If we are negotiating over oranges as well as apples, and if we value them differently, we may be able to exchange an apple for an orange, leaving us *both* better off. Thus, the prospects for a successful negotiation can turn on whether the parties can find trades of this kind that exploit their divergent valuations of different variables. Judge Posner has recognized this principle:

> A negotiation is more likely to be successful when there are several issues to be resolved ("integrative bargaining") rather than just one, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war.[36]

Thus, if settlements are to be facilitated, parties should not be confined to single-variable negotiations (such as a negotiation between patent holder and generic entrant focused only on the date of generic entry) but, rather, permitted and encouraged to explore alternative variables (such as the scope and terms of a license, including any degree of exclusivity).

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[36] *Duffy Tool & Stamping, L.L.C. v. N.L.R.B.*, 233 F.3d 995, 998 (7th Cir. 2000) (citing HOWARD RAIFFA, THE ART AND SCIENCE OF NEGOTIATION, 97–103, 131–32 (1982)).

III. The Role and Significance of Exclusive Licenses.

The "No-AG Commitment" is simply a limited exclusive license. Plaintiffs make much of what they call the "No-AG Commitment" in this case. But, in economic substance, this simply amounts to a short-term exclusive license that substitutes the licensee (Teva), for the licensor (GSK), with the addition of a competition-creating carveout that allows the licensor to continue to compete with the licensee through its branded drug Lamictal. As a matter of economics, this is *more* competitive than a fully exclusive license; it is therefore described in this brief as a "limited exclusive license."

Exclusive licenses are common. Exclusive licenses are ubiquitous. One 2011 study found that exclusive licenses represent 66% of all patent licenses issued by commercial licensors; 84% of all patent licenses in the life sciences sector; and 94% of all patent licenses issued by universities.[37]

Exclusive licenses are procompetitive. Moreover, as a matter of economics, exclusive licenses help to efficiently align the incentives of licensor and licensee. As a result, they are associated in practice with procompetitive collaboration and investment. The 2011 study found that exclusive licenses are more than twice as likely as non-exclusive licenses to be accompanied by a grant of equity interest in

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[37] Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 BUS. ECON. 229, 237 (2011).

the licensee.[38] The World Intellectual Property Organization has recognized that "most potential licensees would seek exclusivity" in cases where the licensee will make significant investment.[39] Courts also recognize the benefits of exclusive licenses.[40]

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[38] *Id.* *See also*, *e.g.*, Thomas C. Meyers, *Field-of-Use Restrictions as Precompetitive Elements in Patent and Know-How Licensing Agreements in the United States and the European Communities*, 12 NW. J. INT'L L. & BUS. 364, 373–74 (1991) (" Exclusive dealing arrangements between licensors and licensees can . . . alleviate the risks of sunk costs to investors in patented technology."); Patrick W. Schmitz, *Exclusive Versus Non-Exclusive Licensing Strategies and Moral Hazard*, 97 ECON. LETTERS 208, 212 (2007) ("[W]hen . . . effort costs are small it is optimal to provide an exclusive license and implement high effort[.]").

[39] WORLD INTELLECTUAL PROPERTY ORGANIZATION, EXCHANGING VALUE: NEGOTIATING TECHNOLOGY LICENSING AGREEMENTS: A TRAINING MANUAL 48 (2005), *available at* http://www.wipo.int/export/sites/www/sme/en/documents/pdf/technology_licensing.pdf; *see also*, *e.g.*, BRIAN G. BRUNSVOLD ET AL., DRAFTING PATENT LICENSE AGREEMENTS 62 (7th ed. 2012) ("Grant of an exclusive license for a limited time is a common incentive for an early licensee who may have to invest heavily in product and market development.").

[40] *See, e.g.*, *Am. Needle, Inc. v. New Orleans La. Saints*, Case No. 04-cv-7806, 2014 WL 1364022, at *1 (N.D. Ill. Apr. 7, 2014) ("[D]efendants contend that the exclusive license arrangement encouraged additional licensee commitment and had numerous procompetitive effects, including improvements in product design, quality, distribution, and coordination of styles with other apparel items. These contentions are sufficiently supported by evidence and expert opinion to be facially plausible."). *See also*, *e.g.*, *Ralph C. Wilson Indus., Inc. v. Am. Broad. Cos., Inc.*, 598 F. Supp. 694, 706 (N.D. Cal. 1984) ("Exclusive licenses promote competition among suppliers by providing an incentive to maximize the number of programs offered and by maximizing the supplier's revenues from the licenses.") (footnote omitted).

IV. The Lamictal Patent Settlement and Litigation.

The key facts in this case are few, simple, and far from unusual. GSK holds patents for lamotrigine (the active ingredient in its branded drug Lamictal). Teva subsequently developed generic lamotrigine tablets and chewables, and then filed an ANDA with a Paragraph IV certification that GSK's patents were invalid and/or not infringed. As a result, in August 2002, GSK sued Teva in federal district court for patent infringement.[41] On February 16, 2005, GSK and Teva reached an agreement to settle that litigation ("Lamictal Settlement"), which provided, in part:

- ***Early entry (~43 months) for Teva's generic lamotrigine chewables.*** GSK granted Teva an exclusive license (subject to a carveout for GSK's branded Lamictal products) to market and sell generic lamotrigine chewables beginning in June 2005, roughly 43 months before the termination of GSK's exclusive rights.[42]
- ***Early entry (~6 months) for Teva's generic lamotrigine tablets, with exclusive license.*** GSK granted Teva an exclusive license (subject to a carveout for GSK's branded Lamictal products) to market and sell generic

[41] Brief of Defendant-Appellee GlaxoSmithKline LLC ("GSK Appeal Brief") at 2–7 (May 27, 2014), Doc. No. 003111630881.

[42] *Id.* at 7.

lamotrigine tablets beginning in July 2008, roughly 6 months before the termination of GSK's exclusive rights.[43]

GSK used the carveout to compete with Teva, dropping the price of its branded Lamictal to a generic price level.[44] Thus, the settlement facilitated vigorous price competition between the companies' drugs.[45]

[43] *Id.* at 7–8. GSK's exclusive rights in this context included a term of pediatric exclusivity awarded by the FDA. *Id.* at 8.

[44] *Id.* at 11–12.

[45] *Id.* at 36.

ARGUMENT

I. Limited Exclusive Licenses Like the Lamictal Settlement Are Not Market Allocation Agreements.

Plaintiffs in this case characterize patent settlements like the Lamictal Settlement—in which a patent holder exclusively licenses a generic entrant, while retaining a limited carveout to allow direct competition with that entrant—as "analytically indistinguishable from a classic market allocation agreement[.]"[46] But agreements of this kind neither resemble market allocation agreements nor have comparable effects. To the contrary, such agreements provide companies with a valuable settlement tool.[47]

Plaintiffs aim to justify their characterization of the Lamictal Settlement by describing the terms as "reciprocal agreements among the Defendants not to compete with each other," alleging specifically that "Teva agreed not to launch its generic product and compete with GSK's branded drug for three years and in exchange GSK agreed not to market an authorized generic and compete with Teva once Teva's generic product comes to market, including even after the [relevant]

[46] Plaintiffs-Appellants' Appeal Brief, 20.

[47] *See supra*, Background § II.

patent expired."[48] Thus, Plaintiffs argue, the agreement is of a type that has "long been condemned . . . as *per se* unlawful."[49]

But this strained analogy to a market-allocation agreement is wrong because it omits a crucial piece of the puzzle: *the patent*.[50] Plaintiffs' analysis presupposes a counterfactual world in which patent holder and generic entrant (here, GSK and Teva) begin from a position of full competition with one another—*i.e.*, a world without patent rights. But this assumes away the most important fact: absent the agreement, the parties would not be competing at all. Where one party holds a lawfully obtained patent, as GSK does here, there can be *no* lawful competition within the scope of the patent absent: (a) judicial invalidation of the patent, which—as explained above—involves expensive, time-consuming, uncertain, and inefficient litigation; and (b) settlement and licensing, which is exactly what the parties did here. Against this counterfactual world of lawful monopoly, far from *harming* competition—like a market allocation agreement—the Lamictal Settlement here *augments* it.

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[48] Plaintiffs-Appellants' Appeal Brief, 20.

[49] *Id.* at 20–21.

[50] In this case, the analogy omits not just the patent itself but also the exclusive right conferred by the FDA's grant of pediatric exclusivity following the expiration of the patent. For convenience, pediatric exclusivity is not discussed separately herein. Just like a patent, it is a statutory right that can be waived or licensed.

This ignore-the-patent logic—which would turn a simple, competitively neutral exclusive patent license into a *per se* illegal market allocation—should be rejected. Settling parties should be encouraged to take advantage of efficient licensing mechanisms, without summoning the specter of antitrust illegality by invoking ill-fitting labels.

II. Limited Exclusive Licenses are Procompetitive, Lawful, and Desirable.

Plaintiffs suggest that limited exclusive licenses—like those in the Lamictal Settlement—can, even without more, present significant dangers to competition. Thus, Plaintiffs argue, every exclusive license should be subject to antitrust litigation and full-blown rule-of-reason discovery. But, as explained below: (a) as a matter of ***economics***, limited exclusive licenses like those in the Lamictal Settlement, without more, are procompetitive and do not harm competition; (b) as a matter of ***law***, an antitrust complaint alleging only a limited exclusive license does not plausibly allege harm to competition, and should be dismissed under Rule 12(b)(6); and (c) as a matter of ***policy***, limited exclusive licenses of this kind should be encouraged, not disfavored, by courts and antitrust agencies.

A. Limited Exclusive Licenses are Procompetitive.

Although Plaintiffs recognize the antitrust principle that agreements should be judged on their economic substance, not their form, they offer little analysis of competitive effects. But an allegation that a patent holder has issued one or more

limited exclusive licenses to a generic entrant (however those licenses are characterized) does not suggest—still less *plausibly* suggest—that competition has been harmed.

Under the rule of reason, the decisive economic question is whether the relevant conduct leads to a significant impairment of competition. If so, it must be justified by a showing of sufficient procompetitive benefits; if not (*i.e.*, if it is competitively neutral or beneficial), it is lawful, without more.[51] The complaint here alleged conduct that was *good*, not bad, for competition.

Specifically, in this case, GSK held exclusive rights for lamotrigine (through a combination of patent rights and pediatric exclusivity) that lasted for a certain period of time. Suppose for simplicity that this was ten years. Consider three hypothetical scenarios:

- **Scenario 1.** Suppose that GSK granted *no licenses*. In this scenario, it would be a single strict monopolist supplier of lamotrigine for the full ten-year term. Following the expiration of GSK's exclusive rights, full competition would take place. This is the typical outcome when a patent is issued: short-term monopoly is Congress's reward for innovation.

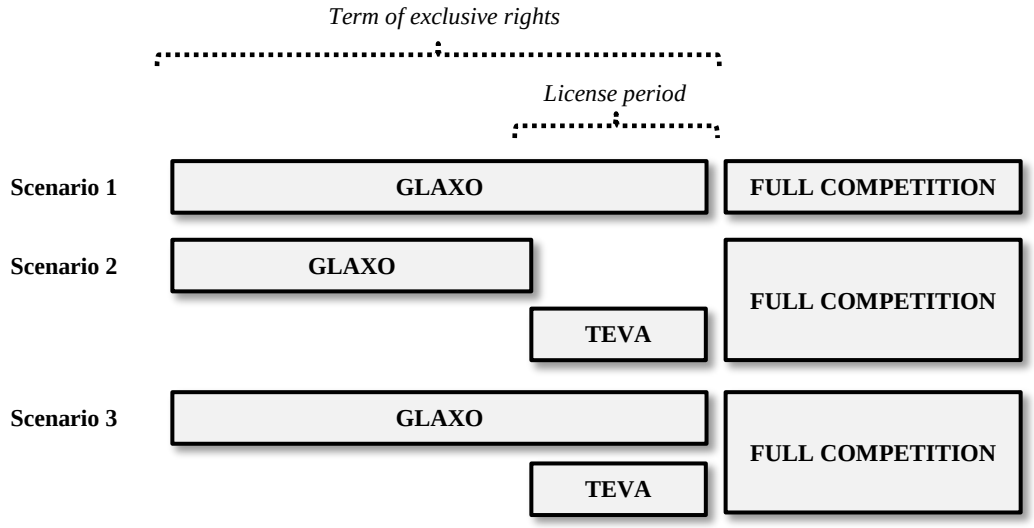
[51] *See, e.g., Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1553 n.18 (11th Cir. 1996) ("Because we hold that Dr. Levine has failed to establish any anticompetitive effect, *we need not reach the second part of the rule of reason analysis* and decide whether the defendants' conduct may be excused by some procompetitive benefit or justification.") (emphasis added).

- **Scenario 2.** Now suppose that GSK granted a *single exclusive license* to Teva to begin at a certain point (say, three years before the end of the exclusivity period). In this scenario, GSK would be a strict monopolist supplier for the first seven years, and Teva would be a strict monopolist supplier for the final three years. Following the expiration of GSK's exclusive rights, full competition would take place. This outcome, in which at all times there is a single monopolist supplier of lamotrigine over the full ten-year term, is *competitively identical* to Scenario 1: one competitor is substituted for another, with no change to the structure of the market. There can be no antitrust liability in this situation, because there is no harm to competition compared to the counterfactual.[52]
- **Scenario 3.** Finally, suppose that GSK granted the same license as in Scenario 2, but *subject to a carveout* that preserved limited rights for GSK to continue to market and sell lamotrigine as well (for example, a carveout that allowed GSK to compete using its branded drug, Lamictal). In this scenario, GSK would be a strict monopolist until the start of the license term. But from the start of the license until the expiration of GSK's exclusive rights, Teva and GSK would compete. The outcome is therefore *increased*

[52] *See, e.g.*, Brief of Appellees Teva Pharmaceutical Indus., Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva Appeal Brief") at 40 (May 27, 2014), Doc. No. 003111631120 (citing cases approving exclusive licenses under the antitrust laws).

competition compared with both Scenario 1 and Scenario 2—two suppliers instead of one.

Figure 2: Three Competitive Hypotheticals



Scenario 3 is the Lamictal Settlement, except that entry by Teva occurred here 43, not 36, months before the end of GSK's exclusive rights for chewables, and 6 months before for tablets. And, as the above demonstrates, the result is *more* competition, not less, than the counterfactual patent monopoly—which, of course, is presumed valid under the Patent Act.[53]

As noted above, the common and procompetitive nature of exclusive licenses has been widely recognized. Indeed, one district court reviewing the Lamictal Settlement itself noted that it allowed "early procompetitive generic competition for lamotrigine tablets . . . *which competition otherwise would not*

[53] 35 U.S.C. § 282(a).

have existed until the expiration of [GSK's exclusive rights]."[54] Moreover, the competitive effects of this license are not simply a matter of theory, but are reflected in the record, which shows that GSK in fact competed aggressively with Teva on price through the carveout.[55] In other words, GSK competed with its branded drug *just as if* it had released an authorized generic, confirming that the theoretical outcome (vigorous competition) was realized in this case.

Parties attempting to settle complex patent litigation should have the opportunity to negotiate across as many variables as possible. Given that exclusive licenses do not harm competition—and instead promote it—parties should be permitted and encouraged to use them if they find it efficient to do so.

B. Limited Exclusive Licenses are Lawful Under the Antitrust Laws.

Plaintiffs argue that the Lamictal Settlement constituted a "reverse payment agreement"[56] and, as such, should be subject to a "rule of reason analysis . . . after the completion of discovery."[57] Plaintiffs even take the view that rule-of-reason

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[54] Stipulation and Order of Dismissal at 2, *SmithKline Beecham Corp. v. Teva Pharm. USA, Inc.*, Case No. 02-cv-03779 (D.N.J. Apr. 6, 2005), ECF No. 89 (emphasis added).

[55] GSK Appeal Brief, 12–13.

[56] Plaintiffs-Appellants' Appeal Brief, 21–32.

[57] *Id.* at 34.

claims like this one may not be disposed of on a motion to dismiss.[58] This is neither good law nor good economics, and certainly it does not promote good policy. If, as Plaintiffs contend, a plaintiff need only point to the existence of an exclusive (or limited exclusive) license in a patent settlement to receive a free pass through Rule 12(b)(6) into discovery, antitrust complaints under Section 1 will become cheap lottery tickets, with dismal consequences for both defendants and the courts. But this is not the law.

The core of the U.S. Supreme Court's decision in *Twombly* was an insistence that lower courts apply meaningful scrutiny, *at the motion to dismiss stage*, to be sure that an antitrust plaintiff has articulated a theory of competitive harm that is not merely conceivable or possible, but actually *plausible*, before the parties should be forced to undergo the rigors and agonies of antitrust discovery. Only specific and plausible factual allegations of anticompetitive harm can justify allowing "a potentially massive factual controversy to proceed."[59] In announcing this rule, the Court warned against allowing "a plaintiff with a largely groundless claim be[ing] allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement [value]".[60]

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[58] *Id.* at 35 ("Whether Plaintiffs will be able ultimately to prove their case under a rule of reason analysis is not to be resolved on a motion to dismiss.").

[59] *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

[60] *Twombly*, 550 U.S. at 557–58 (internal quotation marks omitted).

In this case, Plaintiffs attempt to reach this plausibility threshold by pointing to the limited exclusive licenses in the Lamictal Settlement.[61] But that is not enough. As a threshold matter, as Defendants-Appellees correctly point out, even *fully* exclusive licenses are expressly authorized by the Patent Act,[62] and have been repeatedly validated under the antitrust laws.[63] And *limited* exclusive licenses of a patent—whether labeled "No AG Commitments" or anything else—*promote* competition by replacing one competitor with two. And even if the Plaintiffs could—somehow—articulate a theoretical possibility of lost competition from such agreements in general, there was certainly no harm to competition *in this case*, where the branded drug competed vigorously on price, just like a generic.

Thus, without allegations that, if true, would make harm to competition actually *plausible* in this case, there is no case to answer under the rule of reason.

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[61] *See, e.g.*, Plaintiffs-Appellants' Appeal Brief, 25 ("[T]here can be no question that a No-AG agreement has substantial anticompetitive effects, both insofar as it induces the generic to delay entering the market and because it eliminates the only potential source of generic price competition during the 180-day exclusivity period.").

[62] 35 U.S.C. § 261 ("The . . . patentee . . . may . . . grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

[63] *See, e.g.*, *Parrish v. Nat'l Football League Players Ass'n*, 534 F. Supp. 2d 1081, 1092 (N.D. Cal. 2007) ("The mere existence of an exclusive deal between the NFLPA and its licensees does not violate the antitrust laws or significantly threaten competition.").

Far from the "automatic discovery" rule posited by Plaintiffs, the claim can and should be dismissed under Rule 12.

Nor can a plaintiff assemble a plausible antitrust claim on facts like these by describing a limited exclusive license as a "payment" for delayed entry.[64] In settlements of this kind, as explained above, entry is *accelerated*, not delayed, by comparison with the counterfactual patent monopoly. Thus, the agreement itself is procompetitive. Moreover, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."[65] Plaintiffs argue, in effect, for a *per se* rule that presumes unlawful any patent settlement that goes beyond an early entry date unless discovery shows otherwise: a rule that would turn virtually *every* patent settlement into a rule-of-reason antitrust case waiting to be filed. But, as explained below, that would be an undesirable policy outcome; moreover, the antitrust laws do not allow harm to competition to be inferred from allegations of competitively neutral (or beneficial) facts.

That is the principal teaching of *Twombly*, which emphasized the need to "avoid the potentially enormous expense of discovery in cases with no reasonably

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[64] *See, e.g.*, Plaintiffs-Appellants' Appeal Brief, 22 ("Teva received consideration for its agreement to delay competition and the consideration took the form of a No-AG Agreement").

[65] *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) (emphasis in original).

founded hope that the discovery process will reveal relevant evidence to support a § 1 claim."[66] It also is consistent with the practice of the Third Circuit, and federal courts across the country, which routinely dismiss rule-of-reason claims where the complaint does not state allegations that, if true, would plausibly suggest harm to competition.[67]

Finally, nothing in the Supreme Court's holding in *Actavis* changes this analysis. In *Actavis* the Court focused on settlements involving "large and unjustified" payments for delay, which are not present here.[68] Indeed, the *Actavis* Court expressly contrasted such settlements with agreements—like the Lamictal Settlement at issue here—that "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[69]

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[66] *Twombly*, 550 U.S. at 559–60 (internal quotation marks, citation, and brackets omitted).

[67] *See, e.g.*, *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 230 (3d Cir. 2011); *see also, e.g.*, *Havoco of Am., Ltd. v. Shell Oil Co.*, 626 F.2d 549, 557–59 (7th Cir. 1980) (dismissing Section 1 claim where "allegations as to anticompetitive effect, even when judged by the placable standards . . . [applicable under the old *Conley* standard, which the Supreme Court rejected and heightened in *Twombly*,] were deficient"); *Universal Grading Serv. v. eBay, Inc.*, No. C-09-2755, 2011 WL 846060, at *6 (N.D. Cal. Mar. 8, 2011) ("Plaintiffs must allege facts supporting a plausible claim of harm to competition.").

[68] *F.T.C. v. Actavis*, 133 S. Ct. 2223, 2236–37 (2013).

[69] *Id.* at 2237.

C. Limited Exclusive Licenses Offer a Desirable Alternative to Litigation.

Finally, Plaintiffs' approach is bad policy. As explained above, litigation to the bitter end is seldom efficient for patent holders or patent challengers, requiring as it does an investment of many years and many millions of dollars in exchange for, at best, a very uncertain outcome. And it is seldom in the interests of purchasers or consumers, who often must wait for products and technologies to reach the market and who may ultimately bear, in the form of higher prices, the risks and costs of litigation. As a result, companies across the economy—like the members of the NAM and those similarly situated—benefit when courts and agencies articulate and apply rules that facilitate settlement rather than those that discourage it.

As explained above, settlement is easier and more likely when parties have a wide range of tools at their disposal. The Supreme Court and the FTC have recognized that an "early entry only" settlement does not violate the antitrust laws—presumably because such an agreement can only augment competition, without harming it.[70] The same logic applies here. The terms of the Lamictal Settlement promise new entry and new competitive pressure without a

[70] *Id.*; Op. of the Comm'n, *In the matter of Schering-Plough Corp., et al.*, FTC Docket No. 9297, 35 ("Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack.").

countervailing risk of harm to competition. For that reason, such agreements do not violate the rule of reason. And, crucially, they offer more opportunities than a simple single-variable "early entry only" settlement for the parties to negotiate over variables and parameters and, by exchanging apples for oranges, find an efficient resolution.

Plaintiffs here seek to put patent holders and patent challengers alike in an impossible and inefficient bind. On the one hand, if the parties fight to the death in a patent court, the prospect of lengthy, expensive, and uncertain patent litigation beckons; on the other, if the parties work to craft an agreement that offers value to both, lengthy, expensive, and uncertain antitrust litigation will follow—particularly if, as Plaintiffs hope, it is enough to intone the words "rule of reason" in order to defeat a motion to dismiss.[71] Meanwhile, federal courts would be pressed into service as micro-managers of every settlement.

This Court should decline Plaintiffs' invitation. It should do here what the U.S. Supreme Court did in *Actavis*: when an agreement cannot harm competition,

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[71] *Compare, e.g.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with a treble damages penalty [for antitrust liability] would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose.") (footnote omitted).

and only offers competitive benefits, the Court should say so. Expressly recognizing that licenses like those in the Lamictal Settlement are neutral at worst, and procompetitive at best, will provide valuable guidance to parties searching for a way to both create business value and avoid litigation. *Amicus* submits that this would be an efficient, procompetitive, and desirable outcome.

CONCLUSION

For the foregoing reasons the National Association of Manufacturers urges this Court to affirm the opinion of the district court.

June 3, 2014

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2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 pt. Times New Roman.

Dated: June 3, 2014

/s/ Daniel Francis
Daniel Francis

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I, Daniel Francis, certify that on this 3rd day of June, 2014, I caused seven (7) copies of this Brief of *Amicus Curiae*, the National Association of Manufacturers, to be dispatched via overnight delivery to the Clerk of the Court for the United States Court of Appeals for the Third Circuit, and filed and served an electronic copy of the brief via CM/ECF for all counsel of record. I certify that counsel of record for the parties are filing users of the Court's CM/ECF system.

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