Nos. 14-2071 & 15-1250

IN THE

United States Court of Appeals

FOR THE FIRST CIRCUIT

In Re: Loestrin 24 FE Antitrust Litigation

On Appeal from the United States District Court
for the District of Rhode Island

Brief *Amicus Curiae* of the National Association of Manufacturers in Support of Defendants-Appellees Urging Affirmance

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Dated: August 27, 2015

CORPORATE DISCLOSURE STATEMENT

The National Association of Manufacturers ("NAM") is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards. The NAM has no parent company, and no publicly held company has a 10% or greater ownership interest in the NAM.

/s/ Daniel S. Francis
Daniel Francis

Dated: August 27, 2015

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 12 million men and women, contributes roughly $2.1 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. Its mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth.

[1] All parties have consented to the filing of this brief. No counsel for any party authored this brief in whole or in part. No party funded the preparation or submission of this brief. Neither any party, nor any party's counsel, nor any other person contributed money to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In this appeal, the Court is invited to create a special new rule for the antitrust analysis of Paragraph IV patent settlements on a motion to dismiss. Under the rule proposed by the End-Payor Plaintiffs (together with the Direct Purchaser Plaintiffs, "Plaintiffs"), an antitrust complaint will automatically survive a motion to dismiss—and trigger an avalanche of antitrust discovery—if that complaint alleges that the settlement fits, in whole or part, into a formalistic category called an "actionable payment," involving: (1) a transfer of "value" from the patentee to the generic infringer; and (2) the value transferred is something that the generic infringer could not have obtained in Paragraph IV litigation. E.P. App. Br. 24, 27–32.[2] But that is not the law. Such a rule would have disastrous consequences for patent holders, patent challengers, and purchasers of patented articles alike—*all* of which are included in the NAM's broad membership.

Looming in the background of this case is the reality that patent litigation is a notoriously expensive, lengthy, and uncertain process for all participants, whatever the merits. *See* below 5–9. In the pharmaceutical sector, the costs, risks, and delays of litigation can mean higher prices and longer waits for consumers awaiting crucial therapeutic drugs. Thus, the ability of patent holders and patent

[2] Page references for all docketed documents, including Warner Defendants' Appeal Brief ("W. Def. App. Br."), Lupin Defendants' Appeal Brief ("L. Def. App. Br."), Direct Purchasers' Appeal Brief, ("D.P. App. Br."), and End-Payors' Appeal Brief, ("E.P. App. Br."), refer to those on the top margin, not the bottom.

challengers to reach settlement agreements is a vital social good that must be protected. *See* below 9–13.

But the threat of antitrust litigation—even on a speculative or meritless theory—can be a powerful obstacle to the conclusion of such settlement agreements. There is a grave risk that patentees will be forced to choose between lengthy, expensive patent litigation if they do *not* settle with a generic infringer, and lengthy, expensive antitrust litigation if they *do*. That is not a prospect that anyone should welcome. Thus, while patent settlements are not immune from antitrust challenge—as the Supreme Court held in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)—the role of Fed. R. Civ. P. 12(b)(6) in screening out claims that are not pleaded with requisite rigor, is of vital importance. The Supreme Court emphasized this very point, in the specific context of antitrust litigation, in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558–60 (2007). The costs of patent and antitrust litigation are too high—and the liberty to reach mutually rational settlements is too important—to ignore or undermine *Twombly* here.

In this case, Plaintiffs invite the Court to infer a "plausible" antitrust claim—and an automatic license to proceed to antitrust discovery—from agreements that are commonplace and procompetitive. But nothing in *Actavis* counsels or supports that outcome.

Instead, the Court should do what *Actavis* and *Twombly* prescribe: *first*, analyze antitrust attacks on patent settlements under the standard antitrust framework, as *Actavis* commands, by applying the rule of reason; *second*, require, on a motion to dismiss, the discipline demanded by *Twombly*; and, *third*, disfavor the inference of antitrust wrongdoing from commonplace, procompetitive agreements.

The liberty to craft rational and flexible instruments of dispute resolution is crucial for companies of all kinds, and to the users and consumers (both large and small) who buy—and often depend upon—patented products and services. It should be protected, not undermined.

BACKGROUND

I. Patent Litigation

Patent litigation is among the most burdensome forms of commercial litigation, distinguished by technical complexity, voluminous discovery, reliance on expert evidence, and long and costly proceedings.

Patent litigation is particularly expensive. The Supreme Court has recognized that "patent litigation is particularly complex, and particularly costly."[3] A chorus of federal courts has agreed, with one noting that "patent litigation is the slowest and most expensive litigation in the United States."[4] Very simply, "the costs of patent litigation are enormous with an average patent case costing upwards of $3 million for each side."[5] In 2015, the American Intellectual Property Law Association ("AIPLA") quantified the median costs for patent infringement litigation of all varieties as follows:

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[3] *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[.]").

[4] *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. F.T.C.* 402 F.3d 1056, 1075 (11th Cir. 2005) ("[P]atent infringement 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.").

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

Figure 1: Median Patent Litigation Costs

Amount in controversy	Costs through end of discovery	All costs
< $1,000,000	$400,000	$600,000
$1,000,000 – $10,000,000	$950,000	$2,000,000
$10,000,000 – $25,000,000	$1,900,000	$3,100,000
> $25,000,000	$3,000,000	$5,000,000

Source: AIPLA, 2015 *Report of the Economic Survey*, 37.[6]

Abbreviated New Drug Application ("ANDA") litigation—the type of patent litigation that led to the settlement at issue here—is notoriously expensive: one study cited by the *Actavis* Court noted that "litigation expenses can raise the expense of an ANDA to around $10 million."[7] Moreover, Paragraph IV certifications are exceptionally likely to result in litigation: an FTC review of

[6] The costs identified by AIPLA include outside legal and paralegal services, local counsel, associates, paralegals, travel and living expenses, fees and costs for court reporters, photocopies, courier services, exhibit preparation, analytical testing, expert witnesses, translators, surveys, jury advisors, and similar expenses. They exclude costs relating to settlements and damages. AIPLA, 2015 *Report of the Economic Survey*, 3.

[7] 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., *Managing an ANDA Litigation, in ANDA Litigation: Strategies And Tactics For Pharmaceutical Patent Litigators* 540 (2012).

ANDA filings between 1992 and 2000 concluded that they led to litigation in 75% of cases.[8]

Patent litigation is particularly lengthy. "Patent litigations are among the longest, most time-consuming types of civil actions."[9] A 2015 PricewaterhouseCoopers report ("PwC Report") estimated that the average patent litigation takes about 2.4 *years* to get from filing to trial.[10]

Patent litigation is particularly uncertain. Despite the arduous and costly nature of patent litigation, the process remains "inherently uncertain."[11] In part, this is a function of the dense, technical nature of patent litigation, which forces a generalist judge or lay jury to "venture out into a jungle of technology, conflicting expert testimony, technical evidence, and technical arguments."[12] In cases involving juries in particular—which decided 67% of non-ANDA patent

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

[9] *Ohio Willow Wood Co.*, 629 F.3d at 1376 (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).

[10] PricewaterhouseCoopers, *2015 Patent Litigation Study* 14, *available at* http://www.pwc.com/us/en/forensic-services/publications/patent-litigation-study.jhtml.

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

[12] Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme*, in *Patent Litigation Strategies Handbook* 41 (Barry L. Grossman & Gary M. Hoffman, eds. 2000).

infringement litigation over the last five years,[13] and which "almost always" try high-stakes patent cases[14]—the problem can be very serious. One court has suggested that "patent cases may well be the most difficult for [juries] to understand both as to the evidence and the law."[15] 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."[16] Before the 10 federal judges deciding the greatest number of patent litigations between 1995 and 2014, overall success rates varied between 9% and 73%.[17] And a striking 52% of appealed cases are modified in some regard on appeal.[18] As the Seventh Circuit put it: "[i]n the interest of candor, be it said that the outcome of patent litigation cannot be forecast with scientific exactitude."[19]

Uncertainties are most costly when the stakes at issue are high, and the stakes in patent litigation are very high. The *median* damages award in patent

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[13] PwC Report 6.

[14] *Id.* 7.

[15] *Cooper Indus., Inc. v. Juno Lighting, Inc.*, No. 85 C 7243, 1987 WL 15086, at *6 (N.D. Ill. Jan. 28, 1987), *aff'd* 826 F.2d 1073 (Fed. Cir. 1987).

[16] Chu & Lipner, *Adopting A Case Theme*, at 43.

[17] PwC Report 18.

[18] *Id.* 19.

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

litigation in 2014 was $2.0 million.[20] 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).[21] 2014 saw a $467 million award in *Masimo Corp. v. Phillips Electronics*,[22] and a settlement between Medtronic and Edwards Lifesciences for around $1.15 billion.[23]

II. Patent Settlements

The importance of patent settlements. "[P]ublic policy wisely encourages settlements."[24] Settlement agreements allow parties "to avoid litigation costs, to reduce uncertainty, and to maintain ongoing commercial relationships. . . ."[25] This is particularly important in the patent context, in light of the burdens and costs

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[20] PwC Report 4.

[21] *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.

[22] Andrew Khouri, *Court upholds Masimo's victory in patent suit against Philips units*, L.A. TIMES (May 19, 2015), *available at* http://www.latimes.com/business/la-fi-masimo-award-20150520-story.html.

[23] PwC Report 5.

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

[25] *Id.*

described above. Thus, "the Federal Circuit has repeatedly expressed the view that there is a strong public interest in settlement of patent litigation."[26]

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 unable to litigate to the bitter end.[27] And 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. The litigation process is both expensive and wasteful,[28] and as one appellate judge has observed,

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[26] *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"); *Fidelity & Guar. Ins. Co. v. Star Equip. Corp.*, 541 F.3d 1, 5 (1st Cir. 2008) ("Settlement agreements enjoy great favor with the courts as a preferred alternative to costly, time-consuming litigation.") (citation and internal quotation marks omitted).

[27] *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).

[28] *See generally* Lawyers for Civil Justice et al., *Statement on Litigation Cost Survey of Major Companies* (2010), *available at*

e-discovery excesses "have made the formal trial process less attractive than almost any alternative."[29] 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, "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."[30]

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. Crucially, 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 create gains

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http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Duke%20Materials/Library/Litigation%20Cost%20Survey%20of%20Major%20Companies.pdf.

[29] Hon. Patrick Higginbotham, *The Disappearing Trial and Why We Should Care*, RAND REVIEW 3 (Summer 2004), *available at* http://www.rand.org/pubs/periodicals/rand-review/issues/summer2004/28.html.

[30] John W. Schlicher, *Settlement of Patent Litigation and Disputes: Improving Decisions and Agreements to Settle and License* 5 (ABA 2011).

from trade or Pareto improvements that are rational for *all* parties.[31] Conversely, limiting the forms that a settlement can take makes settlement more difficult—and litigation harder to avoid.

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 generic infringer are negotiating *solely* over the date on which the generic will enter—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 apples differently. This creates an economic and psychological barrier to agreement.

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. As Judge Posner put it:

> 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

[31] *See generally*, *e.g.*, Robert S. Pindyck & Daniel L. Rubinfeld, *Microeconomics*, 590–91 (2009); Howard Raiffa, et al, *Negotiation Analysis: The Science and Art of Collaborative Decision Making* 402 (2002).

> parties feel they are getting more from peace than from war.[32]

Thus, if settlements are to be facilitated, parties should not be confined to negotiations over a single variable only (such as the date of generic entry) but, rather, permitted and encouraged to explore alternative variables (such as licensing or other forms of cooperation).

III. Exclusive Licenses and Commercial Cooperation

Plaintiffs in this case focus mainly on two features of the agreements concluded by Warner Chilcott: (1) a so-called "no-AG" agreement, pursuant to which Warner Chilcott "agreed not to launch an authorized generic ("AG") during the first 180 days that Watson's generic Loestrin 24 was on the market" (a period corresponding to the last six months of Warner Chilcott's patent term), and not to license other generics during that time, D.P. App. Br. 28–29; and (2) commercial cooperation agreements, involving cooperation in the sale and marketing of certain other pharmaceuticals, D.P. App. Br. 29, E.P. App. Br. 17.[33] But both types of agreement are, in economic substance, commonplace and procompetitive.

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[32] *Duffy Tool & Stamping, L.L.C. v. N.L.R.B.*, 233 F.3d 995, 998 (7th Cir. 2000) (emphasis added) (citing Raiffa, *The Art and Science of Negotiation*, 97–103, 131–32).

[33] The complaints refer to additional agreements, including a so-called "acceleration clause," E.P. App. Br. 20–21, but those described in the text are those that are challenged by both set of Plaintiffs. *See* D.P. App. Br. 30 n.18.

A. The "No-AG" Agreement: The Limited Exclusive License

What Plaintiffs call a "No-AG" agreement in this case is, in economic substance, simply a short-term limited exclusive license. It has two elements. The *first* element substitutes the generic (Watson), for the patentee (Warner Chilcott) for a short period of time: this is, obviously, competitively neutral.[34] The *second* element introduces a competition-*creating* carveout allowing Warner Chilcott to compete with Watson through its branded drug Loestrin: this is procompetitive. As described below, 26–28, this is *more* procompetitive than a fully exclusive license: it is therefore described in this brief as a "limited exclusive license."

Exclusive licenses are common. Even *fully* 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.[35]

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

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[34] The period of time in this case appears to be six months: Direct Purchaser Plaintiffs characterize it as a "delay" in generic entry rather than an "early" entry, D.P. App. Br. 35–36, but of course this assumes away the patent, which must, under the Patent Act, be presumed valid. 35 U.S.C. § 282(a) ("A patent shall be presumed valid.").

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

investment.[36] The World Intellectual Property Organization has recognized that "most potential licensees would seek exclusivity" when the licensee will make significant investment.[37] Courts, too, recognize their economic benefits.[38]

B. Commercial Collaboration

Plaintiffs in this case also point to collaborative marketing, sales, or "co-promotion" agreements, and make much of their alleged profitability. *See*, *e.g.*, D.P. App. Br. 29; E.P. App. Br. 17, 22. But it is elementary that commercial cooperation, even between competing companies, is frequently efficient and

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[36] *See*, *e.g.*, *Spinelli v. NFL*, Case No. 13-Civ-7398, 2015 WL 1433370, at *25 (S.D.N.Y. Mar 27, 2015) ("[B]ecause the benefits of exclusive licensing agreements are well-recognized, the Second Circuit has stated that these arrangements are presumptively legal.") (citation and internal quotation marks omitted).

[37] 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.

[38] *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).

procompetitive. This is widely recognized by courts and agencies alike.[39] And when cooperation *is* efficient—*i.e.*, "value creating"—it is frequently profitable for the participating companies as a result. (Indeed, if it were not, they would not do it.) There is nothing unusual or inherently troubling about the fact that a commercial cooperation is "valuable" or "profitable" for the participants.

Importantly—and precisely *because* efficient commercial cooperation can be profitable for both parties (as well as for end-consumers)—it offers a valuable tool for crafting resolutions to commercial disputes. "Win-win" agreements like these avoid zero-sum dynamics (which, as noted above, can present a formidable barrier to settlement) and offer a way to make an agreement acceptable to *both* parties. Such transactions are not just permitted but are favored by the efficiency-seeking policies underpinning the antitrust laws.[40]

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[39] *See*, *e.g.*, U.S. Dept. of Justice & FTC, *Antitrust Guidelines for Collaborations Among Competitors* § 2.1 (Potential Procompetitive Benefits) (Apr. 2000), *available at* www.justice.gov/atr/public/guidelines/305027.pdf; *Akanthos Capital Mgmt., LLC v. Atlanticus Holdings Corp.*, 734 F.3d 1269, 1277 (11th Cir. 2013) ("[M]any agreements that bring together competitors are procompetitive[.]").

[40] *See*, *e.g.*, *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10 (1st Cir. 1999) (emphasizing, in the standing context, the importance of "'ensur[ing] that suits inapposite to the goals of the antitrust laws are not litigated and that persons operating in the market do not restrict procompetitive behavior because of a fear of antitrust liability'") (quoting *Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1449 (11th Cir.1991)).

ARGUMENT

I. In An Antitrust Challenge To A Patent Settlement, Courts Must Ask: (1) Which Antitrust Standard Applies (Applying *Actavis*); And Then (2) Whether The Complaint Has Plausibly Alleged A Claim Under That Standard (Applying *Twombly*).

Much of the parties' appellate briefing in this case has focused on the interpretation of *Actavis*. But the Court should begin with, and should not lose sight of, the basic analytical framework into which *Actavis* fits. A court reviewing an antitrust challenge to a patent settlement (or, for that matter, any other agreement) must ask, and distinguish carefully between, two questions: *first*, the antitrust standard of review (*per se*, quick look, rule of reason, or immunity); and, *second*, the factual sufficiency of the complaint to withstand a motion to dismiss.

The *Actavis* decision focused on the first question (*i.e.*, the antitrust standard of review). It answered it by confirming that the rule of reason—the default and most lenient standard of antitrust review, requiring a plaintiff to show actual anticompetitive effects in excess of any procompetitive benefits—applies to the antitrust scrutiny of patent settlements. *Actavis*, 13 S.Ct. at 2237–38. In so doing, the *Actavis* Court confirmed that a patent settlement should be treated like any other agreement, rejecting both the more demanding standard sought by the FTC and the Eleventh Circuit's *de facto* immunity standard. *Id.* at 2237.

While the *Actavis* Court explained in detail its reasoning for rejecting "near automatic antitrust immunity" for patent settlements, *id.*, and identified various

ways in which anticompetitive effects could *in principle* arise from such agreements, the *Actavis* Court said remarkably little about the second question (*i.e.*, what factual allegations are sufficient under *Twombly* to survive a motion to dismiss). That question continues to be governed by the Supreme Court's decisions in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), which require that a complaint state a "plausible" claim for relief in order to survive dismissal. *See*, *e.g.*, *Twombly*, 550 U.S. at 556–57.

Plaintiffs in this case focus strongly on what, in their view, constitutes an "unlawful payment" after *Actavis*. *See*, *e.g.*, E.P. App. Br. 27–32. That view is mistaken, as described below. But this Court should *begin* by recognizing that the "plausibility" standard under Rule 12(b)(6) is defined by *Twombly*, not *Actavis*, and that failure to meet that standard justifies affirming the District Court here.[41]

II. Under *Twombly*, "Plausibility" Turns On Specific Allegations of Anticompetitive Effect, Not Plaintiffs' Formalistic Presumptions.

By virtually ignoring the plausibility criterion, Plaintiffs in this case effectively argue that *Actavis* set up a formalistic exception to *Twombly* by immunizing against dismissal any allegation that the patentee paid value to the

[41] *See, e.g.*, *Aguilar v. U.S. Immigration & Customs Enforcement Div. of Dep't of Homeland Sec.*, 510 F.3d 1, 8 (1st Cir. 2007) ("[W]e may affirm an order of dismissal on any ground made apparent by the record (whether or not relied upon by the lower court)."); *see also*, *e.g.*, *MacDonald v. Town of Eastham*, 745 F.3d 8, 11 (1st Cir. 2014); *Wilson v. HSBC Mortg. Servs., Inc.*, 744 F.3d 1, 7 (1st Cir. 2014).

generic infringer in a form that it could not have obtained if it had prevailed in Paragraph IV litigation. E.P. App. Br. 24, 27. But that is wrong: and if adopted, it would nullify the motion to dismiss as a tool for scrutinizing antitrust challenges to patent settlements. Nowhere did *Actavis* hold that alleging certain forms of agreement was enough, without more, to state a plausible antitrust claim.

A. *Actavis* Did Not Establish A Formalistic Exception To *Twombly*.

Plaintiffs misstate—and appear to wholly misunderstand—the impact of *Actavis*. End-Payor Plaintiffs appear to argue that *Actavis* created a formalistic category of "actionable payments," such that a plaintiff who alleges the existence of such a "payment" gets a free pass through a motion to dismiss and into the process of antitrust discovery. E.P. App. Br. 24. And they allege that this category of "payments" includes: (1) any transfer of "value" from patentee to generic infringer; if (2) the "value" is something the generic infringer could not have obtained through Paragraph IV litigation. E.P. App. Br. 24, 27. Direct Purchasers seem to have something similar in mind. D.P. App. Br. 37–43. But this reading turns *Actavis* on its head, and ignores the basic difference between the antitrust standard and the plausibility threshold.

Actavis was centrally about whether and to what extent patent settlements enjoy immunity from antitrust scrutiny, as the Court was at pains to make clear. *See*, *e.g.*, *Actavis*, 133 S.Ct. at 2230, 2233, 2237. By contrast, the *Actavis* Court

said very little, and even *less* that was clear, about the application of the motion to dismiss "plausibility" standard to patent settlements at all. As the District Court recognized on remand in that case, *Twombly* still governs that standard. *In re Androgel Antitrust Litigation (No. II)*, Case No. 1:09–MD–2084–TWT, 2014 WL 1600331, at *3 (N.D. Ga. Apr. 21, 2014). But what *Actavis does* teach is that formalistic presumptions, special pleading, and automatic rules should be rejected in favor of a detailed, fact-specific, economic analysis of a claim. Plaintiffs apparently seek to avoid that rigor here by proposing formalistic shortcuts. That will not do.

Under the antitrust laws, there is no magic in any formalistic category of "payments," and certainly there is none for the purposes of the plausibility analysis required under *Twombly*. As the Direct Purchasers accurately note, what matters is economic substance, not transactional form. D.P. App. Br. 40 & n.23 (citing cases). The antitrust laws respond to changes in the competitive structure of the market, not to payments or transfers of value as such, which are themselves competitively neutral. The End-Payor Plaintiffs are simply wrong on this elementary point when they state that *Actavis* held that "a payment . . . can be anticompetitive" or that the *Actavis* Court "defined an unlawful payment[.]" E.P.

App. Br. 27.[42] There is no such thing as an unlawful payment as such, and if there were, *Actavis*—which focused on the antitrust standard of review, not factual sufficiency under Rule 12—did not define it.

The question in each case is simply whether the antitrust complaint has alleged enough *facts* to make an overall anticompetitive effect plausible. What is crucial is not what the patentee pays, it is what it pays *for*: and the structure and form of a payment is only of any analytical significance to the extent that it suggests, in all the circumstances, that what is being paid *for* is an anticompetitive agreement. *See*, *e.g.*, *Actavis*, 133 S. Ct. at 2229 (describing allegations about the "true point of the payments"), 2237 (noting that "one who makes such a payment may be unable to explain or justify it").

In *Actavis* itself the Court was confronted with mysterious large payments, alleged to be for services of "little value." *Id.* at 2229. That, among other things, arguably suggested that the payments in that case were in exchange for an anticompetitive agreement.[43] But, by contrast, when the facts alleged amount to

[42] The Direct Purchasers also seem to miss this point when describing allegedly anticompetitive *payments*. D.P. App. Br. 28–29.

[43] This is the significance of the "fair value" concept. *Actavis*, 133 S.Ct. at 2236. In the absence of non-conclusory allegations showing that the terms of a settlement are something other than "fair value"— in other words, that a transfer of value is suspiciously "large" for what it is exchanged for, *id.* at 2235–37—there is no reason to infer anticompetitive effects, and no plausible claim.

commonplace, procompetitive conduct, the complaint supports no inference of wrongdoing. Plaintiffs seem to miss that elementary truth here.

The discipline of the *Twombly* standard is vital to avoid forcing parties into the impossible choice between patent litigation and antitrust litigation described above. *Actavis* did not dilute—or even discuss—that standard.

B. Plaintiffs' Rule Would Significantly Increase Litigation.

Plaintiffs' proposal also would lead to a dramatic increase in litigation in general, and antitrust *discovery* in particular. The proffered rule (*i.e.*, value + something unobtainable in Paragraph IV litigation = denial of a motion to dismiss) would effectively neuter Rule 12(b)(6).

Consider the first limb: the requirement that the patentee pay "value" to the generic infringer. Because of the unique configuration of Paragraph IV litigation, the respective incentives of the parties will *almost always* favor such a payment of "value" from the patentee to the generic infringer. The patentee in such a case faces virtually all the risk and has everything to lose. Given the notorious expense, length, and (particularly) the uncertainty of patent litigation (*see* above 5–9)—as well as the reality that discovery and litigation costs in an invalidity challenge will bear *much* more heavily on the patentee than the generic infringer—a patentee that faces even a weak claim of invalidity may very rationally be willing to pay a great

deal to fend off the challenge and protect its expected, and Congressionally ordained, period of exclusivity.[44]

Conversely, the generic infringer holds what amounts to a lottery ticket offering the prospect of a huge windfall, and is in a strong position to demand an exorbitant settlement. Moreover, it has much less to lose from litigation. And because a Paragraph IV filing triggers infringement litigation *before* the generic infringer has entered, the patentee virtually never has a damages claim as countervailing leverage. The obvious result: *patentee pays generic infringer*. Such a payment is not an aberration giving grounds for concern: it is an inherent consequence of the system that Congress has established.

In the second limb of the test, the Court is asked to infer antitrust concern when the "value" transferred is something that the generic infringer could not have obtained by prevailing in the Paragraph IV litigation. E.P. App. Br. 27. But the *only* thing that the generic infringer could obtain in Paragraph IV litigation is invalidation of the patent and a right to early entry. Thus, Plaintiffs invite this Court to prescribe a rule that patentees who want to settle a challenge *must* give up part of their statutory patent term—and *may not* give up anything else—in order to

[44] For example, if a generic infringer has even a 15% or 20% chance of prevailing on an invalidity claim against a billion-dollar patent—quite possible in view of the uncertainty of patent litigation, *see* above 7–9—a patentee might very rationally choose to pay *hundreds of millions* of dollars to settle without ever doubting the validity of its patent.

reach a settlement. Failure to do so would mean not just automatic antitrust litigation, but *automatic antitrust discovery*: the very process that the Supreme Court set out to limit in *Twombly* due to its exceptional expense and burden.

That cannot be the law. There is no sound reason in law or economics to dictate the formal structure of a settlement on pain of antitrust discovery. And there is no reason of logic, law, or economics to apply different liability presumptions when a patentee offers the generic infringer days of the patent term, on the one hand, and when it offers dollars, magic beans, or procompetitive cooperation deals, on the other. End-Payor Plaintiffs are simply wrong when they claim that "[w]hen the brand manufacturer pays with something that the generic manufacturer could not have obtained even if it had won the patent case . . . a court can be sure that the generic's exclusion from the market did not result solely from the patent's strength." E.P. App. Br. 30–31.

Moreover, forcing parties to structure their settlements according to such a straitjacketed standard would senselessly elevate formalism over the kind of fact-specific claim analysis the Supreme Court commanded in *Actavis* and *Twombly* alike. And it would ignore the crucial insight that flexibility over terms and forms

of settlement is frequently central to the chances of reaching an agreement.[45] *See* above 11–13.

In sum: Plaintiffs' approach here would arbitrarily and undesirably "short-circuit" *Twombly* in patent settlement cases.

III. Agreements Like Those Alleged Here Are Lawful, Procompetitive, and Commonplace, and Should Not Be Discouraged.

As the previous two sections have demonstrated, courts reviewing an antitrust challenge to a patent settlement should demand a complaint that "plausibly" states a claim under the antitrust standard that the Supreme Court confirmed in *Actavis*: the rule of reason. 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.[46] The remaining question in *this* case is therefore whether alleging the existence of agreements like those to which Plaintiffs point here—(1)

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[45] In particular, where the patentee and the generic infringer differ on their estimate of the strength or value of the patent (as they very easily might, given informational asymmetries and the fact that, by hypothesis, they are approaching litigation over the issue), it will not be remotely efficient to force the parties to bargain solely over early entry.

[46] *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).

limited exclusive licenses and (2) "valuable" cooperation agreements—constitutes a plausible allegation of overall anticompetitive effects.

It does not. If agreements like this are enough, without more, to state a "plausible" antitrust claim, there will be no end to the litigation that is automatically allowed to proceed into antitrust discovery. Such agreements are lawful, they are procompetitive, and they are common. To transmute them into free passes to discovery would significantly expand patent and antitrust litigation while deterring settlement: not just in the pharmaceutical industry, but in *all* sectors of the economy, for these agreements are ubiquitous.

The point is not that these agreements can *never* be anticompetitive. It is that they typically are not; that pointing to them does not suffice without more to state a plausible antitrust claim; and that the steep costs of "false positives"—unnecessary litigation and foregone settlements—will ultimately fall on the shoulders of consumers.

A. Limited Exclusive Licenses Are Procompetitive and Lawful

As explained at length above, 13–15, *fully* exclusive licenses are extremely common and are generally procompetitive or competitively neutral. And the type of agreement alleged here is even better for competition.

This can be shown in three steps. *First*, suppose that the patentee granted *no* licenses. It would remain a sole supplier for the duration of its patent term. This

is, obviously, the "default" competitive situation that Congress has ordained by creating the patent system.

Second, suppose the patentee now grants an *exclusive license* to another company for some of the patent term. The licensee would simply replace the patentee: no change in competitive conditions. This is competitively identical to the first step.

Third, suppose the patentee grants an exclusive license to another company for a period of time, just as in the second step, but this time subject to a carveout that allows the patentee to compete against the licensee as long as it does not do so with a generic. That is obviously a competitive *improvement* on the first and second step: that is, a move from first step to third is procompetitive overall.

Plaintiffs here allege *just such an agreement*, which they call a "No-AG" agreement. *See*, *e.g.*, D.P. App. Br. 28. But, as the foregoing analysis demonstrates, the result is *more* competition, not less, than the counterfactual patent monopoly (which, importantly, is presumed valid under the Patent Act[47]) and *more* competition than under an exclusive license (which, as noted above, is typically procompetitive or neutral,[48] and which is in any event specifically

[47] 35 U.S.C. § 282(a).

[48] *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.").

contemplated by the Patent Act[49]). Limited exclusive licenses like the one at issue here—whether labeled "No-AG" agreements or anything else—*promote* competition by replacing one competitor with two.

B. Commercial Cooperation Is Procompetitive and Lawful.

Nor is the existence of a valuable commercial cooperation arrangement in a patent settlement—like those allegedly at issue here (D.P. App. Br. 29–30)—grounds to infer antitrust liability. Such agreements are extremely common and, as noted above, are routinely procompetitive. Moreover, whether they are "valuable" or not says nothing about their effect on competition: profits are just as likely to arise from complementarities and efficiencies as from monopoly power. Innuendo about profitability is irrelevant. *Compare* D.P. App. Br. 29–30 (commercial cooperation was "worth tens of millions of dollars" to Watson and "lucrative" to Lupin and Mylan); E.P. App. Br. 22 (deals were "of substantial value" to Lupin).

Twombly teaches that it is not enough to plead facts *consistent* with unlawful anticompetitive effects: a plaintiff must make sufficient factual allegations to make a claim *plausible*. Pointing to profitable co-promotion arrangements and the like cannot suffice: not unless every commercial collaboration is to become a ground for antitrust suspicion simply because of the very factor—profitability—that most naturally suggests that the activity itself is an efficient response to market demand.

[49] 35 U.S.C. § 261.

Parties attempting to settle complex patent litigation should have the opportunity to negotiate across as many variables as possible. Neither exclusive licenses nor commercial cooperation agreements are inherently harmful to competition: parties should be permitted and encouraged to use them when they find it efficient to do so, not punished with speculative antitrust litigation.

IV. Conclusion

The burdens of patent litigation—and, for that matter, antitrust litigation—are vast and well documented. When a mutually rational alternative to litigation can be devised, benefits accrue to *all* parties, ultimately reaching consumers in the form of lower prices. And as both economic theory and practical experience counsel, flexibility in structuring settlement agreements is a central factor—sometimes *the decisive factor*—in determining whether a settlement can be agreed.

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, lengthy, expensive, and uncertain patent litigation beckons; on the other, if the parties work to craft an agreement that offers mutual value, lengthy, expensive, and uncertain antitrust litigation will follow. Plaintiffs would leave open only the straitjacketed solution of giving up some of the patent term conferred by Congress, and nothing else, in a settlement. And they would press federal courts into service as micro-managers of every patent settlement.

Plaintiffs invite the Court to depart from the careful teachings of *Actavis* and *Twombly* and to make this vision a unique reality in the First Circuit. But in the interests of all—innovators, patent holders, patent challengers, and those that use and consume patented articles—the Court should decline this invitation to neuter Rule 12(b)(6), and should insist instead on the rigor that the Supreme Court has demanded.

The decision of the District Court should be **AFFIRMED**.

Respectfully submitted,

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Dated: August 27, 2015

CERTIFICATE OF COMPLIANCE

I hereby certify, that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 6916 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B) (iii). I further certify that this brief complies with Fed. R. App. P. 32(a)(5) and Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14 point Times New Roman Font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of August, 2015, I electronically filed and served an electronic copy of the foregoing brief through the Court's CM/ECF system. I certify that counsel of record for the parties are filing users of the Court's CM/ECF system.

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