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Iqbal Plausibility in Pharmaceutical and Medical Device Litigation

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***Iqbal* “Plausibility” in Pharmaceutical and Medical Device Litigation**

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Judicial opinions construing and interpreting the technicalities of proper pleading may be bedside reading for the bench, the bar, and civil procedure enthusiasts, but rarely for those outside the legal circle. It is hardly the spice that energizes the cocktail party circuit. Not true with the United States Supreme Court’s decision in *Ashcroft v. Iqbal*, which examined the federal pleader’s burden to avoid a dismissal.¹ In fact, few decisions in recent memory have attracted as much popular attention, analysis, and angry debate as this opinion and its predecessor from two years earlier that it had sought to clarify, *Bell Atlantic Corp. v. Twombly*.² In tandem, these two decisions represent the Court’s resolve that speculation of wrongdoing will not be sufficient to unlock the doors to civil litigation in federal court. Instead, as *Iqbal* made firm, a plaintiff is now required to plead a claim that is factually “plausible” to avoid dismissal.

As the furious debate unleashed by *Iqbal* ricochets among the courts, practitioners, academics, and elected officials, assessing its impact has become a leading order of the day. One sector worthy of special attention in this pursuit is pharmaceutical and medical device litigation. It has been estimated that products regulated by the federal Food and Drug Administration account for approximately one-quarter of the entire consumer economy in the United States,³ an economic valuation once pegged at \$1.5

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* Assistant Professor of Law, Charleston School of Law. The concept for this Article originated with a chapter in *Top 20 Food and Drug Cases 2009*, published by the Food and Drug Law Institute in April 2010. I thank both the FDLI and John B. Reiss, Esquire for that opportunity. This Article was improved through the generosity of time and wise counsel graciously offered by six accomplished legal scholars: Professor Richard D. Freer, Professor David G. Owen, Professor Sheila B. Scheuerman, Professor Craig R. Senn, Professor Jay Tidmarsh, and Thomas E. Willging, Esquire. Finally, I thank William Gaskill, Charles S. Propst, and Kristin D. Smith for their outstanding research assistance. This Article is dedicated lovingly to the memory of my father, William Mathias Janssen, who passed away just as it was being published.

1. 129 S. Ct. 1937 (2009).

2. 550 U.S. 544 (2007).

3. See Richard Merrill, *FDA Regulatory Requirements as Tort Standards*, 12 J.L. & POL’Y 549, 557 (2004). Additionally, the federal government estimates that, in 2009, the total national health expenditure (encompassing not just pharmaceuticals and medical devices, but professional services as well) rose to \$2.5 trillion and represented a 17.3% share of the gross domestic product of

trillion.⁴ The value of the world pharmaceutical marketplace alone has been estimated to be \$750 billion.⁵ Domestically, 18 of the *Fortune 500* companies in 2010 were in the pharmaceutical or medical device industries,⁶ and 3 of the 30 companies comprising the current *Dow Jones Industrial Average* were pharmaceutical companies.⁷ Pharmaceutical and medicine manufacturing employs hundreds of thousands of wage and salaried employees.⁸ By any measure, the pharmaceutical and medical device marketplaces are vast. What *Iqbal* means to this sector, therefore, may have a relevance that far transcends the rarely dusty tomes of federal civil procedure law. It may influence a very broad swath of federal

the United States. See Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *National Health Expenditure Projections 2009–2019*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2009.pdf> (last visited Aug. 2, 2010).

4. See Douglas A. Grimm, *FDA, CLIA, or a "Reasonable Combination of Both": Toward Increased Regulatory Oversight of Genetic Testing*, 41 U.S.F. L. REV. 107, 113–14 & n.54 (2006) (citing Eve E. Slater, *Today's FDA*, 352 NEW ENG. J. MED. 293, 293 (2005)). Further discrimination within that regulatory category is elusive. As the agency's authorizing statute confirms, the FDA's regulatory net encompasses food, cosmetics, and biologics (and, now, tobacco), in addition to pharmaceuticals and medical devices. See Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301–399a (2006 & Supp. 2009).

5. See *IMS Health Lowers 2009 Global Pharmaceutical Market Forecast to 2.5–3.5 Percent Growth*, BUS. WIRE (Apr. 22, 2009), <http://www.allbusiness.com/economy-economic-indicators/economic-conditions-recovery/12305880-1.html>.

6. The 12 pharmaceutical companies with this distinction (with their *Fortune 500* rank) were: Johnson & Johnson (33); Pfizer (40); Abbott Laboratories (75); Merck (85); Eli Lilly (112); Bristol-Myers Squibb (114); Amgen (159); Gilead Sciences (324); Mylan (412); Genzyme (458); Allergan (459); and Biogen Idec (471). See FORTUNE, May 3, 2010, at F-39, available at <http://money.cnn.com/magazines/fortune/fortune500/2010/industries/21/index.html>. The six medical device companies with this distinction (with their *Fortune 500* rank) were: Medtronic (160); Baxter International (185); Boston Scientific (279); Becton Dickinson (312); Stryker (333); and St. Jude Medical (445). See FORTUNE, May 3, 2010, at F-38, available at <http://money.cnn.com/magazines/fortune/fortune500/2010/industries/195/index.html>.

7. These companies were Johnson & Johnson, Merck, and Pfizer. See *Dow Jones Industrial Average—Components*, DOW JONES AVERAGES, <http://www.djaverages.com/?view=industrial&page=components> (requires registration) (last visited July 2, 2010).

8. In 2008, for example, the Department of Labor counted almost 300,000 such employees in the pharmaceutical and medicines manufacturing industries. See Bureau of Labor Statistics, U.S. Dep't of Labor, *Career Guide to Industries: Pharmaceutical and Medicine Manufacturers*, BUREAU LAB. STAT., <http://www.bls.gov/oco/cg/cgs009.htm> (last modified Dec. 17, 2009). Interestingly, approximately 87% of these positions were “in establishments that employed more than 100 workers.” *Id.*

litigation that encompasses an equally broad (and critical) dimension of the nation’s life.

It is not this Article’s goal to condemn or applaud *Iqbal* or the pleading choices the Supreme Court made in deciding it. That effort has been undertaken by many others, and their formidable scholarship has already ably crystallized that debate. Instead, this Article’s objective is narrower—to assess whether *Iqbal* matters in pharmaceutical and medical device litigation and, if so, how and to what degree.

This Article begins with context. Part I introduces the legal landscape onto which *Iqbal* emerged. Part II retells the story of *Iqbal*, describing the facts of the decision, followed by the substance of the Supreme Court’s ruling. Part III reviews the message of *Iqbal* and the clarification it aspired to supply to federal pleaders and the courts. Part IV discusses the legal and non-legal reactions to the decision, including legislative proposals to overturn *Iqbal*. Part V surveys a few of the existing analytical and statistical studies seeking to divine the significance of *Iqbal* generally, over the full inventory of federal cases. Part VI probes the meaning of *Iqbal* in the specific context of pharmaceutical and medical device litigation, beginning with a description of the methodology used in this Article to make that assessment, proceeding to the results of this Article’s analysis of *Iqbal*’s effect in the 264 pharmaceutical and device opinions released during a period of more than 15 months since *Iqbal* was decided, and closing with a sampling of noteworthy judicial uses of the decision in this context. This Article finds that *Iqbal* has not had a dramatically recalibrating effect throughout pharmaceutical and medical device litigation: nearly 80% of the time, *Iqbal* did not drive the outcome of dismissal motions. But this Article also finds that summary pronouncements that brush *Iqbal* aside as entirely inconsequential may be just as incorrect: 20% is still a big number. However, a focused inspection of those cases where *Iqbal* seemed to make a difference reveals a pattern of their reducing incidence, no obviously explainable geographic concentrations, a frequent grant of amendment opportunities, and the presence of a possible, though modest, “information asymmetry.” This Article also finds that, in large measure, whatever *Iqbal* significance there seems to be within this pharmaceutical and medical device cohort cannot be verified; the apparent *Iqbal* difference might just be a new label for the prevailing “no-conclusions” pleading paradigm that has long reigned nationally among the lower federal courts.

I. PRELUDE TO CONTROVERSY: THE FEDERAL RULES, *CONLEY*, AND *TWOMBLY*

The Federal Rules of Civil Procedure codified a sea-change in federal practice when they first took effect in 1938.⁹ Beginning with the very first Rule, the new set of federal procedures aspired to end the archaic formalism that had bedeviled earlier litigation.¹⁰ The incumbent, strict pleading regimes had produced a rigidity in litigation procedure that the Rules' drafters concluded delayed the search for truth, or defeated it altogether with highly technical victories and losses.¹¹ That formula was rejected for the federal

9. This liberalizing codification, while the broadest, most far-reaching, and perhaps most familiar, was also certainly not the first. The federal equity rules had pioneered a more austere pleading regime a quarter-century earlier in 1912. See Rules of Practice for the Courts of Equity of the United States, 226 U.S. 627, 655 (1912) (promulgating Equity Rule 25, which prescribed that "it shall be sufficient that a bill in equity shall contain . . . a short and simple statement of the ultimate facts upon which the plaintiff asks relief, omitting any mere statement of evidence"); *id.* at 653 (promulgating Rule 18, which prescribed that, generally, "technical forms of pleadings in equity are abolished"). A number of states were tending in the same direction well before 1938. See CHARLES E. CLARK, HANDBOOK ON THE LAW OF CODE PLEADING 163 (1928) (reporting that, by 1928, notice pleading "is in use in a few courts and has been advocated for general adoption"). The tides of change had surely begun. See, e.g., Jay Tidmarsh, *Pound's Century, and Ours*, 81 NOTRE DAME L. REV. 513, 518 (2006) (commenting that young Roscoe Pound's 1906 speech to the American Bar Association decrying "mechanical jurisprudence" sparked "the beginning of the reform movement that led directly to the creation of the gold standard of modern procedure, the Federal Rules of Civil Procedure, in 1938"). Informed and impressed by these more isolated currents, the drafters of the Federal Rules of Civil Procedure completed the transformation with their national and universally applicable handiwork.

10. See FED. R. CIV. P. 1 (prescribing that the Rules "should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding"); see also FED. R. CIV. P. 8(d)(1) (prescribing that allegations "must be simple, concise, and direct," and that "[n]o technical form is required"); FED. R. CIV. P. 8(e) (prescribing that "[p]leadings must be construed so as to do justice"); FED. R. CIV. P. 84 (supplying accompanying forms to "illustrate the simplicity and brevity that these rules contemplate").

11. See 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1202, at 90 (3d ed. 2004) ("The whole grand scheme was premised on the assumption that by proceeding through a maze of rigid, and often numerous, stages of denial, avoidance, or demurrer, eventually the dispute would be reduced to a single issue of law or fact that would dispose of the case. The system was wonderfully scientific. It also proved to be excruciatingly slow, expensive, and unworkable. The system was better calculated to vindicate highly technical rules of pleading than it was to dispense justice.").

courts,¹² and in its place the drafters envisioned a far more austere role for pleadings—simple notice of the claim or defense being asserted (with the newly-minted and broad-reaching discovery rules inheriting the task of revealing the evidentiary facts to support those claims and defenses).¹³

In an early case decided just six years after the new Rules took effect, Judge Charles E. Clark examined a complaint prepared *pro se* by a plaintiff who spoke and wrote only limited English and who demanded relief in federal court for certain “bottles” of “tonics” from Italy “of great value” that had since “disappeared.”¹⁴ The defendant, the Port of New York Collector of Customs, had won a dismissal at the trial court level, having argued that the plaintiff’s allegations failed to “state facts sufficient to constitute a cause of action.”¹⁵ Judge Clark arrived to this task with unique qualifications—he not only had been the Dean of the Yale Law School before assuming his judgeship but also had served as the principal drafter of the new federal Rules.¹⁶ In reversing the complaint’s dismissal, Dean/Drafter/Judge Clark wrote: “Under the new rules of civil procedure, there is no pleading requirement of stating ‘facts sufficient to constitute a cause of action,’ but only that there be ‘a short and plain statement of the claim showing that the pleader is entitled to relief.’”¹⁷ Though “inartistically” stated, Judge Clark read the plaintiff’s complaint to have successfully alleged that a New York customs collector had somehow improperly done away with property belonging to the plaintiff.¹⁸

12. See *Conley v. Gibson*, 355 U.S. 41, 48 (1957) (“The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits.”); see also Jay Tidmarsh, *Resolving Cases “On the Merits,”* 87 DENV. U. L. REV. 407, 413–14 (2010) (“Notice pleading sought to eliminate the technical rigor of common-law and code pleading—a rigor that was thought to thwart the parties’ ability to obtain a decision based on substantive law.”).

13. See 5 WRIGHT & MILLER, *supra* note 11, § 1202, at 88–90; see also *Conley*, 355 U.S. at 47–48 (observing that the federal courts’ “simplified ‘notice pleading’ is made possible by the liberal opportunity for discovery and the other pretrial procedures established by the Rules to disclose more precisely the basis of both claim and defense and to define more narrowly the disputed facts and issues”).

14. See *Dioguardi v. Durning*, 139 F.2d 774, 774 (2d Cir. 1944).

15. *Id.*

16. See *Zahn v. Int’l Paper Co.*, 414 U.S. 291, 297 (1973) (identifying Judge Clark as “a principal architect of the Federal Rules of Civil Procedure”); Charles E. Clark, *Edson Sunderland and the Federal Rules of Civil Procedure*, 58 MICH. L. REV. 6, 6 intro. n. (1959).

17. *Dioguardi*, 139 F.2d at 775.

18. *Id.*

“[A]s it stands,” Judge Clark ended, “we do not see how the plaintiff may properly be deprived of his day in court to show what he obviously so firmly believes and what for present purposes defendant must be taken as admitting.”¹⁹

Thirteen years later, the Supreme Court had its opportunity to pass on the precision of Judge Clark’s construction of his new Federal Rules in *Conley v. Gibson*,²⁰ a lawsuit involving an allegation by black railroad employees that their union had failed to protect them against racially discriminatory employment actions. The trial court granted the union’s motion to dismiss, finding that the employees’ complaint failed to state a claim upon which relief could be granted.²¹ A unanimous Supreme Court reversed and, with a sweeping flourish, “follow[ed], of course, the accepted rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.”²² Because the employees’ complaint pleaded an allegation that, if proven, would establish a breach of the union’s duty, the Court ruled the dismissal to be improper.²³ The Court also rejected the union’s insistence that the employees had “failed to set forth specific facts to support its general allegations of discrimination.”²⁴ The Court responded curtly:

The decisive answer to this is that the Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim. To the contrary, all the Rules require is ‘a short and plain statement of the

19. *Id.* at 775; see also Charles E. Clark, *Pleading Under the Federal Rules*, 12 WYO. L. REV. 177, 181 (1958) (“What we require is a general statement of the case We do not require detail.”), *quoted in* RICHARD D. FREER & WENDY COLLINS PERDUE, *CIVIL PROCEDURE: CASES, MATERIALS, & QUESTIONS* 297 (5th ed. 2008).

20. 355 U.S. 41 (1957).

21. *Id.* at 43.

22. *Id.* at 45–46. As support for this “accepted rule,” the Court cited three court of appeals decisions, including Judge Clark’s opinion for the Second Circuit Court of Appeals in *Dioguardi*. See *id.* at 46 n.5.

23. *Id.* at 46 (“Here, the complaint alleged, in part, that petitioners were discharged wrongfully by the Railroad and that the Union, acting according to plan, refused to protect their jobs as it did those of white employees or to help them with their grievances all because they were Negroes. If these allegations are proven there has been a manifest breach of the Union’s statutory duty to represent fairly and without hostile discrimination all of the employees in the bargaining unit.”).

24. *Id.* at 47.

claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests.²⁵

And that is where the Supreme Court long left the matter. Year after year, case after case, federal courts at every level repeated the rote of beginning dismissal motion opinions by incanting the *Conley* mantra of no dismissals for pleading inadequacies unless it "appears beyond doubt" that the pleader could prove "no set of facts" entitling the pleader to a remedy.²⁶

Occasionally, the Supreme Court would reinforce the message of simplicity contemplated by the Federal Rules by repelling challenges by defendants to the sufficiency of certain pleadings. In *Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit*,²⁷ for example, the Court granted certiorari to resolve a circuit split as to whether an "enhanced pleading standard" ought to be imposed in civil rights cases against municipalities. "Perhaps," explained the unanimous Court, if the Rules "were rewritten today," that might well be the test.²⁸ But, the Court wrote, as currently drafted, Rule 8(a)(2) requires only "notice pleading"—that is, "a short and plain statement of the claim showing that the pleader is entitled to relief."²⁹ Although the Rules do provide for pleading enhancement in a very few instances,³⁰ no such enhancement appears in the Rules for municipal civil liability claims.³¹ If such claims are to be added to the list of enhanced pleadings, noted the Court, that result "must be obtained by the process of amending the Federal Rules, and not by judicial interpretation."³²

Later, in *Swierkiewicz v. Sorema N.A.*,³³ the Court rejected an employer's argument that wrongful termination complaints claiming national origin or age prejudice must allege specific

25. *Id.* (quoting FED. R. CIV. P. 8(a)(2)).

26. See 5 WRIGHT & MILLER, *supra* note 11, § 1215, at 203–06 n.12 (citing a sampling of the "wealth of judicial authority" supporting the proposition, and adding that "complete citation to the case law is neither feasible nor useful").

27. 507 U.S. 163 (1993).

28. *Id.* at 168.

29. *Id.* (quoting FED. R. CIV. P. 8(a)(2)).

30. See FED. R. CIV. P. 9(b) (to plead fraud and mistake, the "circumstances" must be stated "with particularity"); FED. R. CIV. P. 9(g) (to plead items of special damage, they must be "specifically stated").

31. Citing the settled interpretative tenet of "[e]xpressio unius est exclusio alterius," the Court rejected the invitation to judicially rewrite Rule 8(a) by adding to the drafters' list of enhanced pleading claims. *Leatherman*, 507 U.S. at 168.

32. *Id.* Until such time, wrote the Court, federal judges and parties "must rely on summary judgment and control of discovery to weed out unmeritorious claims sooner rather than later." *Id.* at 168–69.

33. 534 U.S. 506 (2002).

factual circumstances to support an inference of discrimination.³⁴ The Court held that such a view “conflicts” with Rule 8(a)(2)’s “simplified notice pleading standard,” which is designed merely to “give the defendant fair notice of what the plaintiff’s claim is and the grounds upon which it rests.”³⁵ Guided by that standard, the employee’s complaint had “easily satisfie[d]” the federal pleading rules: he alleged he was terminated on account of his national origin and age, and he detailed the events surrounding the termination, supplying both dates as well as the nationalities and ages of his replacement.³⁶ Whether the pleader appears likely (or unlikely) to succeed ultimately at trial is not the dismissal test, reminded the Court; instead, the “limited” task in ruling on a dismissal motion is only “whether the claimant is entitled to offer evidence to support the claims.”³⁷

Throughout this 70-year period following the adoption of the Federal Rules, the Court’s insistence on a simplified federal pleading standard, unsupplemented by judicial fiat, remained apparently steady. The large principles seemed fixed, and episodic efforts to tighten the pleading regimen were resisted summarily. But incantations of principles and tenets aside, among the lower federal courts—charged daily with ruling on dismissal motions—the notion of “simplified” federal pleading was evolving. Although the *Conley* mantra continued to be repeated, it came to lose an absolutist meaning.

Read literally, *Conley* would seem to forbid a court from ever dismissing any federal lawsuit unless, “beyond doubt,” there was just plain no earthly way at all a plaintiff could supply, obtain, develop, or discover facts to support the claim.³⁸ If that was truly to be the toll-booth into federal court, the toll-takers might as well

34. *Id.* at 511–12. The Court reminded litigants that circumstantially proving such discrimination in employment is only one way to prevail in such a case and that direct evidence of discrimination would not obligate the pleader to build the evidentiary foundation for circumstantial proof. “It thus seems incongruous to require a plaintiff, in order to survive a motion to dismiss, to plead more facts than he may ultimately need to prove to succeed on the merits if direct evidence of discrimination is discovered.” *Id.*

35. *Id.* at 512 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

36. *Id.* at 514.

37. *Id.* at 511 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)); accord *id.* at 515.

38. See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 561–62 (2007) (“On such a focused and literal reading of *Conley*’s ‘no set of facts,’ a wholly conclusory statement of claim would survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some ‘set of [undisclosed] facts’ to support recovery. . . . Mr. Micawber’s optimism would be enough.”).

go home. From this, the lower courts recoiled. Empathetic to the burgeoning transactional costs of civil discovery,³⁹ troubled by the specter of tolerating “shoot-first-and-let’s-see-what-we-find” pleadings,⁴⁰ and perhaps also informed by the unpredictably changeable trajectory of Rule 11 as a sanctioning tool to ward off improper pleading,⁴¹ the lower courts began to migrate—subtly

39. *Id.* at 559 (citing Frank H. Easterbrook, *Discovery as Abuse*, 69 B.U. L. REV. 635, 638 (1989)) (“[T]he threat of discovery expense will push cost-conscious defendants to settle even anemic cases . . .”); *see also* McGovern v. City of Phila., 554 F.3d 114, 121 n.5 (3d Cir. 2009) (remarking that the belief that discovery should be permitted to marshal facts necessary to plead a theory amounts to a “misguided” understanding of federal pleading). *See generally* Sheila B. Scheuerman, *The Consumer Fraud Class Action: Reining In Abuse By Requiring Plaintiffs to Allege Reliance as an Essential Element*, 43 HARV. J. ON LEGIS. 1, 39 (2006) (opining that, especially in class actions, an easier pleading and proof burden “creates an incentive to settle the case—not because the manufacturer has harmed the plaintiff, but because the case presents the risk of a bankrupting judgment”). *Cf.* *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) (“Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.”).

40. *See, e.g.*, *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996) (noting that a deferential federal pleading standard does not obligate a court “to swallow the plaintiff’s invective hook, line, and sinker; bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like need not be credited”); *see also* *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 190 (1st Cir. 1996) (observing that federal pleading obligations, while low, are “real” and are “not entirely a toothless tiger” (internal quotation marks omitted)).

41. Rule 11 was designed to achieve honesty in pleading by requiring federal attorneys to certify that every pleading they file has good grounds for support and is not filed simply to cause delay. *See* FED. R. CIV. P. 11. But the rule, as originally adopted, contained no specific punishments for offending behavior. *See also* 5A WRIGHT & MILLER, *supra* note 11, § 1331, at 459–60 (describing the original adoption history of Rule 11). In 1983, Rule 11 was meaningfully strengthened by amendment in an effort to combat perceived frivolous litigation and pretrial abuses that were weighing down the federal courts. *See id.* at 462–63. The amendments “had a dramatic effect on federal court practice and brought Rule 11, which previously had been virtually ignored, to the forefront of the consciousness of almost everyone who engaged in civil litigation in the federal courts. Its invocation and application were pervasive.” *Id.* at 473–74. Courts received the Rule enthusiastically and used it liberally. *Id.* at 480–81. In the years that followed, concerns grew that the advent of extensive collateral, “satellite” litigations—fighting over the application of Rule 11—threatened to “negat[e] whatever gains against frivolous litigation the [1983] amendment might have achieved through deterrence.” *Id.* at 485. The Rule was then amended again, in 1993, this time by modifying the perception that the device was primarily a fee-shifting one and establishing a 21-day “safe harbor” whereby offending attorneys were afforded the right to withdraw an improper pleading without judicial intervention. *See id.* at 495–96 (noting the drafters’ observation that, under the new Rule 11, sanctions “should not be used to compensate one of the parties, but ‘should ordinarily be paid into court as a

and then expressly—away from *Conley*.⁴² By the 1980s, this migration had become so settled and uncontroversial that the highly influential Judge Richard Posner could blithely remark that, though “the exceedingly forgiving attitude toward pleading deficiencies that was expressed . . . in *Conley v. Gibson* . . . continues to be quoted with approval, it has never been taken literally.”⁴³

Onto this reconfigured landscape the Supreme Court strode in May 2007 with its opinion in *Twombly*. The case involved an antitrust challenge to the behavior of four regional telephone operating companies. Divested from AT&T in 1984, seven

penalty”). Opponents decried the 1993 amendment as de-fanging the rule of its core benefit. *See* Amendments to the Federal Rules of Civil Procedure, 146 F.R.D. 401, 507–09 (Apr. 22, 1993) (Scalia, J., dissenting) (“In my view, those who file frivolous suits and pleadings should have no ‘safe harbor,’” and the “Rules should be solicitous of the abused (the courts and the opposing party), and not of the abuser”; that “the likelihood and the severity of punishment for those foolish enough not to seek refuge in the safe harbor” is decreased because sanctions are now discretionary, not mandatory, because compensatory sanctions should be reserved to “unusual circumstances,” and because even when awarded they are ordinarily “payable to the court.”); *see also id.* at 509 (“As seen from the viewpoint of the victim of an abusive litigator, these revisions convert Rule 11 from a means of obtaining compensation to an invitation to throw good money after bad. The net effect is to decrease the incentive on the part of the person best situated to alert the court to perversion of our civil justice system.”).

42. *See* 5 WRIGHT & MILLER, *supra* note 11, § 1216, at 220–27 (noting *Conley*, *Swierkiewicz*, “and a host of other cases” discussing pleading liberality, but acknowledging that the lower federal courts (in the years leading up to *Twombly* and *Iqbal*) enforced a pleading practice that had come to require that a complaint “contain either direct allegations on every material point necessary to sustain a recovery on any recognizable legal theory, even though that theory may not be the one suggested or intended by the pleader, or the pleading must contain allegations from which an inference fairly may be drawn by the district court that evidence on these material points will be available and introduced at trial”).

43. *Sutliff, Inc. v. Donovan Cos.*, 727 F.2d 648, 654 (7th Cir. 1984) (citations omitted), *overruled by* *Hammes v. AAMCO Transmissions, Inc.*, 33 F.3d 774 (7th Cir. 1994). Judge Posner’s conclusion, while perhaps unique in its flourish, was hardly unique in its substance. *See, e.g., Mann v. Boatright*, 477 F.3d 1140, 1148 (10th Cir. 2007) (remarking that it is not the court’s job “to stitch together cognizable claims for relief from the wholly deficient pleading”); *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003) (stating that, in testing pleadings, it is not the task of judges and litigants to “try to fish a gold coin from a bucket of mud”); *Gen. Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001) (“Liberal construction has its limits,” and “[c]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” (internal quotation marks omitted)).

regional companies had controlled, through authorized monopolies, 90% or more of the Nation’s local telephone service in the 48 contiguous states; after mergers and acquisitions, four companies remained.⁴⁴ When Congress withdrew approval for these regional monopolies in 1996, the companies were permitted to compete with one another.⁴⁵ But they didn’t. The plaintiffs brought a class action on behalf of local telephone and high speed Internet customers alleging an illegal restraint of trade in violation of the federal antitrust laws.⁴⁶ However, under the antitrust laws, parallel business conduct—even if consciously parallel—is not necessarily unlawful; what the antitrust laws forbid, instead, are “restraints effected by a contract, combination, or conspiracy.”⁴⁷ The plaintiffs in *Twombly* contended that such a contract, combination, or conspiracy could be fairly inferred from a few facts, including the very fact of the “common failure” of the regional companies to pursue “attractive business opportunit[ies]” in their competitors’ regions as well as a statement from one company’s senior executive that such competition “might be a good way to turn a quick dollar but that doesn’t make it right.”⁴⁸

The contest in *Twombly* centered on whether alleging such a proffered inference satisfied the federal pleading standards. A surprisingly united Court ruled that the pleading failed.⁴⁹ The majority accepted that the complaint’s allegations *were* consistent with an illegal conspiracy, but they *were also* just as consistent with “a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market.”⁵⁰ As far as inferences go, the Court found both inferences equally fairly drawn. Determining what to do with a pleading in such a case became one of the watershed decisions of 2007.

The Court in *Twombly* began by repeating Rule 8(a)(2)’s admonition that all federal pleading requires is “a short and plain statement of the claim showing that the pleader is entitled to relief.”⁵¹ Then it quoted *Conley* for the Rule’s purpose—to “give the defendant fair notice of what the . . . claim is and the grounds

44. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 549–50 & n.1 (2007).

45. *Id.* at 549–50.

46. *Id.* at 550.

47. *Id.* at 553 (quoting Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 775 (1984)).

48. *Id.* at 551.

49. The decision was 7–2. Justice David Souter wrote the majority opinion in *Twombly*, in which six of his fellow Justices joined. Only Justices Stevens and Ginsburg dissented. *Id.* at 547.

50. *Id.* at 554.

51. *Id.* at 555 (quoting FED. R. CIV. P. 8(a)(2)).

upon which it rests.”⁵² But the Court’s embrace of *Conley* stopped there. The Court turned to the other oft-quoted sentence from *Conley* that a federal complaint should not be dismissed “unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.”⁵³ That concept, mulled the Court, if “read in isolation” could mean that “any statement revealing the theory of the claim will suffice unless its factual impossibility may be shown from the face of the pleadings.”⁵⁴ The Court noted that such an outcome had caused “a good many judges and commentators” to “balk[] at taking the literal terms of the *Conley* passage as a pleading standard.”⁵⁵ Evidently, the time had come for the Supreme Court to join the balking: “*Conley*’s ‘no set of facts’ language has been questioned, criticized, and explained away long enough. . . . [A]fter puzzling the profession for 50 years, this famous observation has earned its retirement.”⁵⁶

Mindful of this evolved view of the *Conley* “no-set-of-facts” language, the motion to dismiss the *Twombly* plaintiffs’ complaint could not be denied cursorily simply because it was impossible to say, “beyond doubt,” that the plaintiffs could never unearth facts to prove their claim. Consequently, a more searching inspection of the allegations would be necessary.

The Court reemphasized that “detailed factual allegations” are not required in federal pleadings.⁵⁷ Yet nor would “labels and conclusions” or “a formulaic recitation of the elements of a cause

52. *Id.* (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

53. *Id.* at 561 (quoting *Conley*, 355 U.S. at 45–46).

54. *Id.*

55. *Id.* at 562 (providing a sample of citations); see *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 968 (9th Cir. 2009) (commenting that *Conley*, “read literally, set the bar too low”).

56. *Twombly*, 550 U.S. at 562–63. The Court did not discount the *Conley* language as mistaken, just misunderstood:

To be fair to the *Conley* Court, the passage should be understood in light of the opinion’s preceding summary of the complaint’s concrete allegations, which the Court quite reasonably understood as amply stating a claim for relief. . . . The phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint. . . . *Conley*, then, described the breadth of opportunity to prove what an adequate complaint claims, not the minimum standard of adequate pleading to govern a complaint’s survival.

Id.

57. *Id.* at 555. This liberality was expressly embraced in *Conley*, 355 U.S. at 47 (“[T]he Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim.”).

of action” suffice.⁵⁸ Instead, to “show” the “grounds” for an “entitle[ment] to relief,” the pleader must supply “enough” factual allegations “to raise a right to relief above the speculative level,”⁵⁹ or, as the Court later casted it, the pleading must “possess enough heft”⁶⁰ to “nudge[] . . . claims across the line from conceivable to plausible.”⁶¹ This “plausibility” inquiry, cautioned the Court, is not a judicial license to test for the probability or likelihood of success of a claim or defense; that sort of qualitative assessment of a pleader’s potential ability to prove the allegations, the Court admonished, is improper.⁶² Instead, the appropriate inquiry “simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence” to prove the allegations.⁶³ Drawing on earlier precedent to make the point, the Court explained that demanding “something beyond . . . mere possibility” is necessary “lest a plaintiff with ‘a largely groundless claim’ be 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

58. *Twombly*, 550 U.S. at 555.

59. *Id.* The requirements of a “showing” and an “entitle[ment] to relief” are both found in the language of Rule 8(a)(2) itself. *See* FED. R. CIV. P. 8(a)(2) (“A pleading that states a claim for relief must contain: . . . a short and plain statement of the claim *showing* that the pleader is *entitled to relief*.” (emphasis added)). *But see* Arthur R. Miller, *From Conley to Twombly to Iqbal: A Double Play on the Federal Rules of Civil Procedure*, 60 DUKE L.J. 1, 19 (2010) (assailing “the Court’s newly minted demand for a factual showing”). The majority found the requirement of a “showing” corroborative of its conclusion that an adequate factual presentation is essential. *See Twombly*, 550 U.S. at 555 n.3 (“Rule 8(a)(2) still requires a ‘showing,’ rather than a blanket assertion, of entitlement to relief. Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only ‘fair notice’ of the nature of the claim, but also ‘grounds’ on which the claim rests.”). The requirement of stating the “grounds” for a claim comes a bit more indirectly. The drafters expressly required a statement of “grounds” for invoking the court’s jurisdiction. *See* FED. R. CIV. P. 8(a)(1) (requiring “a short and plain statement of the grounds for the court’s jurisdiction”). But, as the quotation above confirms, that term is absent from the later obligation of pleading an entitlement to relief. Nevertheless, the obligation was installed, curiously, by no lesser an authority than the *Conley* Court itself. *See Conley*, 355 U.S. at 47 (“[A]ll the Rules require is ‘a short and plain statement of the claim’ that will give the defendant fair notice of what the plaintiff’s claim is *and the grounds upon which it rests*.” (emphasis added)). The *Conley* Court’s source for this “grounds” obligation is not expressly identified in the *Twombly* opinion.

60. *Twombly*, 550 U.S. at 557.

61. *Id.* at 570.

62. *Id.* at 556 (“[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and ‘that a recovery is very remote and unlikely.’” (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974))).

63. *Id.*

value.”⁶⁴ The “plausibility” inquiry, ended the Court, was thus squarely in line with its earlier federal pleading precedents.⁶⁵

Applying this “plausibility” inquiry to the *Twombly* plaintiffs’ complaint, the Court found that the allegations had not been “nudged” beyond the realm of the conceivable. Behavior by the regional telephone operating companies that was consciously parallel would, alone, not be enough to suggest an illegal conspiracy; likewise, a pleaded allegation of such behavior would,

64. *Id.* at 557–58 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). The Court rejected the proffer that “a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through ‘careful case management.’” *Id.* at 559. Citing experience among the lower federal courts (and, notably, the observations of Judge Posner), the Court was unimpressed that the opportunity for “careful case management” should allow a non-“plausible” claim to survive. *See id.* at 560 n.6 (“Given the system that we have, the hope of effective judicial supervision is slim: ‘The timing is all wrong. The plaintiff files a sketchy complaint (the Rules of Civil Procedure discourage fulsome documents), and discovery is launched. A judicial officer does not know the details of the case the parties will present and in theory *cannot* know the details. Discovery is used to find the details. The judicial officer always knows less than the parties, and the parties themselves may not know very well where they are going or what they expect to find. A magistrate supervising discovery does not—cannot—know the expected productivity of a given request, because the nature of the requester’s claim and the contents of the files (or head) of the adverse party are unknown. Judicial officers cannot measure the costs and benefits to the requester and so cannot isolate impositional requests.” (quoting Easterbrook, *supra* note 39, at 638–39)). That a litigation-costs-based concern prompted the *Twombly* result now seems fairly well accepted. *See, e.g., Swanson v. Citibank, N.A.*, 614 F.3d 400, 405 (7th Cir. 2010) (“We realize that one powerful reason that lies behind the Supreme Court’s concern about pleading standards is the cost of the discovery that will follow in any case that survives a motion to dismiss on the pleadings. . . . Too much chaff was moving ahead with the wheat.”); *id.* at 411 (Posner, J., dissenting in part) (“Behind both *Twombly* and *Iqbal* lurks a concern with asymmetric discovery burdens and the potential for extortionate litigation.”).

65. As discussed earlier, the Court found *Conley* not inconsistent with “plausibility,” but simply errantly (or too expansively) interpreted by the precedents that followed it. *See* discussion *supra* note 56. “Plausibility” was not inconsistent with *Leatherman*, reasoned the Court, because, unlike in *Leatherman*, which rejected unpromulgated, common law enhancements to the Rules’ pleading standard, the complaint in *Twombly* failed the baseline application of Rule 8(a)(2) “because it failed *in toto* to render plaintiffs’ entitlement to relief plausible.” *Twombly*, 550 U.S. at 569 n.14. “Plausibility” was not inconsistent with *Swierkiewicz*, explained the Court, because, unlike in *Swierkiewicz*, which reversed the imposition of an enhanced requirement of alleging “‘specific facts’ beyond those necessary to state [a] claim,” the complaint in *Twombly* failed because it lacked enough facts to meet the same baseline Rule 8(a)(2) requirement. *Id.* at 570.

alone, not be enough to infer an illegal conspiracy.⁶⁶ Nor could this gap be bridged by a conclusory allegation of a conspiratorial agreement: "when allegations of parallel conduct are set out in order to make a § 1 [antitrust] claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action."⁶⁷ Thus, absent "allegations plausibly suggesting (not merely consistent with)" an antitrust agreement, the threshold obligations of Rule 8(a)(2) had not been met.⁶⁸ Having therefore failed to meet the federal pleading threshold, the *Twombly* plaintiffs' complaint should have been dismissed.

By the summer of 2007, the federal pleading rules (once a sea-change themselves from prior pleading norms) seemed awash again in change. That December 1, 2007, heralded the arrival of the top-to-bottom "restyling" rewrite of every Federal Rule of Civil Procedure only added to the sense of dramatic federal procedural restructuring.⁶⁹ After *Twombly*, many questions seemed to remain. Was the *Twombly* "plausibility" rule simply a vague sentiment, or did it embody an actual, concrete test?⁷⁰ Was the *Twombly* "plausibility" rule limited to only antitrust cases, or perhaps to only exceptionally complex cases, or maybe to only

66. *Id.* at 556–57; *see also id.* at 568 ("[A] natural explanation for the noncompetition alleged is that the former Government-sanctioned monopolists were sitting tight, expecting their neighbors to do the same thing.").

67. *Id.* at 557.

68. *Id.*

69. The Rules restyling project was designed to "make [the Federal Rules of Civil Procedure] more easily understood and to make style and terminology consistent throughout the rules." FED. R. CIV. P. 1, advisory committee's note 1 to 2007 amendments. "[N]o changes in substantive meaning" were intended. *Id.* note 5. These reassurances were often small comfort to a Bench and Bar confronting the first top-to-bottom revamping of federal practice since the Rules were first promulgated during Franklin Delano Roosevelt's second term as president. *See generally* Jeremy Counseller, *Rooting for the Restyled Rules (Even Though I Opposed Them)*, 78 Miss. L.J. 519, 538–42 (2009) (discussing some of the fundamental concerns with the Restyling Project, including the incumbent transactional costs at implementation and the significant risk of even unintentional meaning changes).

70. *See, e.g.,* Moss v. U.S. Secret Serv., 572 F.3d 962, 968 (9th Cir. 2009) ("Much confusion accompanied the lower courts' initial engagement with *Twombly*."); Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233–34 (3d Cir. 2008) (noting that whether *Twombly* "materially alters" the federal notice pleading standard "is difficult to divine"); EEOC v. Concentra Health Servs., Inc., 496 F.3d 773, 776 (7th Cir. 2007) (remarking that *Twombly* "impose[s] two easy-to-clear hurdles"—fair notice to defendants of claims and grounds, and plausible allegations).

those with unique inference-laden allegations?⁷¹ How significant would the “plausibility” test prove to be in practice, and how was it to be applied?⁷² The Court’s decision in *Iqbal* two terms later provided some of the answers.

II. *ASHCROFT V. IQBAL*

Javaid Iqbal is a Muslim man from Pakistan.⁷³ Two months following the terror attacks of September 11, 2001, Iqbal was arrested by the Federal Bureau of Investigation (FBI) and the Immigration and Naturalization Service (INS) on charges of fraud concerning his identification documents and conspiracy to defraud the United States.⁷⁴ The FBI included Iqbal among a group of 184 people deemed to be of “high interest” in the investigation into identifying the assailants of the September 11, 2001 attacks and preventing future attacks.⁷⁵ This “high interest” group was detained in a Brooklyn, New York facility under restrictive conditions intended to deny them communication access to both

71. Early courts approached *Twombly* with some hesitation. *See* *Tamayo v. Blagojevich*, 526 F.3d 1074, 1082 (7th Cir. 2008) (cautioning care not to “over-read” or “under-read” the *Twombly* opinion). And courts remained timid in their predictions of *Twombly*’s application at its outer boundaries. *See* *Goldstein v. Pataki*, 516 F.3d 50, 56 (2d Cir. 2008) (stating that “we need not take this occasion to contemplate the outer limits” of *Twombly*). But within the year, courts seemed to have come to a firm consensus that the *Twombly* standard was not limited to antitrust cases, but applied more broadly. *See* STEVEN BAICKER-MCKEE ET AL., *FEDERAL CIVIL RULES HANDBOOK* 431 n.230 (2009) (providing a sample of cases).

72. *See, e.g.*, *Courie v. Alcoa Wheel & Forged Prods.*, 577 F.3d 625, 630 (6th Cir. 2009) (“Exactly how implausible is ‘implausible’ remains to be seen”); *Phillips*, 515 F.3d at 234 (noting that *Twombly* raises issues “not easily resolved” and is likely to be a source of controversy “for years to come”); *Concentra*, 496 F.3d at 776 (noting that *Twombly* “imposes two easy-to-clear hurdles”—fair notice to defendants of claims and grounds, and plausible allegations). Indeed, early indications from the Supreme Court suggested that “plausibility” might not have altered very much. In *Erickson v. Pardus*, decided shortly after *Twombly*, the Court summarily reversed the dismissal of a prisoner’s cruel and unusual punishment claim and the lower court’s characterization of the claim as “too conclusory” to satisfy *Twombly*: “Specific facts are not necessary; the statement need only ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” 551 U.S. 89, 93 (2007) (quoting *Twombly*, 550 U.S. at 555); *see also id.* at 93 (“It may in the final analysis be shown that the District Court was correct to grant respondents’ motion to dismiss. That is not the issue here, however. It was error . . . to conclude that the allegations in question . . . were too conclusory to establish for pleading purposes” for the plaintiff’s claim).

73. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1942 (2009).

74. *Id.* at 1943.

75. *Id.*

fellow prisoners and the outside world.⁷⁶ Iqbal was, two months later, relocated to an even higher security portion of the facility where he remained for six months before being returned to the general population.⁷⁷ During that period of special confinement, Iqbal alleged that he was severely physically and psychologically abused, by being kicked, punched, dragged, serially strip- and cavity-searched; verbally abused; denied access to adequate exercise, nutrition, and medical care; and denied prayer.⁷⁸ He did not contest his original arrest or his confinement among the general prison population⁷⁹ and ultimately pleaded guilty to criminal charges, served jail time, and was removed back to Pakistan.⁸⁰

Iqbal’s federal lawsuit named 53 defendants, including correctional officers, wardens, Bureau of Prison officials, and FBI agents.⁸¹ The sufficiency of the lawsuit against 51 of these 53 defendants was not contested in the Supreme Court, and the Justices had no occasion to consider or rule upon them.⁸²

The issue in the Supreme Court was a “narrower” one,⁸³ involving the two other named defendants. Iqbal had included in his lawsuit claims against then-Attorney General John Ashcroft and FBI Director Robert Mueller.⁸⁴ It was those allegations that were the Court’s focus. As summarized by the Court, Iqbal had alleged:

- that the FBI, under Mueller’s direction, “arrested and detained thousands of Arab Muslim men . . . as part of its investigation of the events of September 11”;

76. *Id.*

77. *Iqbal v. Hasty*, 490 F.3d 143, 148 (2d Cir. 2007), *rev’d and remanded sub nom. Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

78. *Iqbal*, 129 S. Ct. at 1944; *Elmaghraby v. Ashcroft*, No. 04-CV-01809-JG-SMG, 2005 WL 2375202, at *1 (E.D.N.Y. Sept. 27, 2005), *aff’d in part, rev’d in part, remanded in part sub nom. Iqbal v. Hasty*, 490 F.3d 143, 148 (2d Cir. 2007), *rev’d and remanded sub nom. Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

79. *Iqbal*, 129 S. Ct. at 1943, 1952.

80. *Id.* at 1943. Following his guilty plea, Iqbal was sentenced to 16 months incarceration. *See Elmaghraby*, 2005 WL 2375202, at *1 n.1.

81. *Elmaghraby*, 2005 WL 2375202, at *1.

82. The majority volunteered, however, that those accusations, though not before the Court for decision, had alleged “serious official misconduct” that could “demonstrate unconstitutional misconduct.” *Iqbal*, 129 S. Ct. at 1942; *id.* at 1952 (“It is important to note . . . that we express no opinion concerning the sufficiency of [Iqbal’s] complaint against the defendants who are not before us. [His] account of his prison ordeal alleges serious official misconduct that we need not address here.”).

83. *Id.* at 1942–43.

84. *Id.* at 1942.

- that “[t]he policy of holding post-September-11th detainees in highly restrictive conditions of confinement until they were ‘cleared’ by the FBI was approved by Defendants [Ashcroft and Mueller] in discussions in the weeks after September 11, 2001”;
- that Ashcroft and Mueller “each knew of, condoned, and willfully and maliciously agreed to subject” Iqbal “to harsh conditions of confinement ‘as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest’”;
- that Ashcroft was the “principal architect” of the policy; and
- that Mueller was “instrumental in [its] adoption, promulgation, and implementation.”⁸⁵

Ashcroft and Mueller moved to dismiss these allegations against them, contending that, as governmental officials, they were entitled to qualified immunity⁸⁶ and that Iqbal’s complaint failed to plead the type of facts necessary to overcome that immunity—namely, that they were personally involved in behavior that violated clearly established constitutional rights.⁸⁷ The trial court denied the motion,⁸⁸ and the court of appeals largely affirmed.⁸⁹ In a concurrence, one of the appellate court judges wrote of his

85. *Id.* at 1944. In the proceedings below, the Second Circuit noted a threshold incongruity with these allegations, although that did not impede the court’s reasoning. As a literal matter, Iqbal’s accusation that he was included in a mistreatment policy targeted at “Arab Muslim men” was encumbered by the evidently uncontested fact that, though a Muslim and a Pakistani, “he was not an Arab.” *Iqbal v. Hasty*, 490 F.3d 143, 148 n.2 (2d Cir. 2007), *rev’d and remanded sub nom.* *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). Construing the allegations more broadly than written, the court reasoned that Iqbal’s “claim is fairly to be understood as alleging unlawful treatment based on his ethnicity, even if not technically on a racial classification,” and, as such, “his allegations of what was done to Arab Muslims are fairly understood to mean that unlawful actions were taken against him because officials believed, perhaps, because of his appearance and his ethnicity, that he was an Arab.” *Id.*

86. Qualified immunity, the Court explained, “shields Government officials ‘from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights,’” and, as formulated by the Court, represents both “a defense to liability and a limited ‘entitlement not to stand trial or face the other burdens of litigation.’” *Iqbal*, 129 S. Ct. at 1945–46 (quoting *Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985); *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982)).

87. *Id.* at 1944.

88. *Elmaghraby v. Ashcroft*, No. 04-CV-01809-JG-SMG, 2005 WL 2375202, at *11 (E.D.N.Y. Sept. 27, 2005), *aff’d in part, rev’d in part, remanded in part sub nom.* *Iqbal v. Hasty*, 490 F.3d 143, 148 (2d Cir. 2007), *rev’d and remanded sub nom.* *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

89. *Hasty*, 490 F.3d at 147.

concern over exposing “high-ranking Government officials” to “the burdens of discovery on the basis of a complaint as nonspecific as” Iqbal’s, especially as those officials were responding to “a national and international security emergency unprecedented in the history of the American Republic.”⁹⁰ Commenting that existing precedent on the issue was “less than crystal clear,” the judge urged the Supreme Court to offer further guidance to the nation’s courts “at the earliest opportunity.”⁹¹ Embracing that suggestion, the Supreme Court accepted the case for review and reversed.

The Supreme Court ruled that Iqbal’s allegations against defendants Ashcroft and Mueller failed to satisfy Rule 8(a)(2) of the Federal Rules of Civil Procedure, which obligates pleaders to set forth “a short and plain statement of the claim showing that the pleader is entitled to relief.”⁹² Iqbal’s failure, reasoned the Court, was that, as pleaded, his allegations had not “nudged [his] claims . . . across the line from conceivable to plausible.”⁹³ This obligation to state a “plausible” claim in order to avoid dismissal was unfurled by the Court two terms earlier in the *Twombly* decision, where the Court distinguished pleadings that alleged facts merely “consistent with” liability from pleadings that alleged facts that allow a “reasonable inference” of liability.⁹⁴ Only the latter are “plausible” federal claims, and therefore only the latter can survive a motion to dismiss.⁹⁵

Applying these precepts to Iqbal’s lawsuit, the Court turned to his complaint. The Court began by discounting those allegations that it found to be mere conclusions of law, because, in assessing a motion to dismiss, only factual allegations are assumed to be true, and thus bald legal conclusions would not help Iqbal satisfy his

90. *Id.* at 179 (Cabrane, J., concurring). The concurrence was not entirely mollified by the potential for tailored discovery to abate the disruptive effect of lawsuits directed against high government officials.

Even with the discovery safeguards carefully laid out in Judge Newman’s [lead] opinion, it seems that little would prevent other plaintiffs claiming to be aggrieved by national security programs and policies of the federal government from following the blueprint laid out by this lawsuit to require officials charged with protecting our nation from future attacks to submit to prolonged and vexatious discovery processes.

Id.

91. *Id.* at 178.

92. FED. R. CIV. P. 8(a)(2).

93. *Iqbal*, 129 S. Ct. at 1950–51 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

94. *Twombly*, 550 U.S. at 557.

95. *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570).

Rule 8(a)(2) pleading duty.⁹⁶ Allegations that fell within this category, found the Court, were those pronouncing that Ashcroft and Mueller “knew of, condoned, and willfully and maliciously agreed” to subject him to abusive conditions “as a matter of policy,” solely for discriminatory reasons and not for penological ones, as well as those listing Ashcroft as the policy’s “principal architect” and Mueller as “instrumental” in the policy’s execution.⁹⁷ “These bare assertions,” offered the Court, “amount to nothing more than a ‘formulaic recitation of the elements’ of a constitutional discrimination claim,” and were therefore “conclusory and not entitled to be assumed true.”⁹⁸

What remained, then, was to search the complaint for those allegations found to be factual and, therefore, entitled to a presumption of truth. Allegations falling within this category, reasoned the Court, were those describing the arrest and detention of “thousands of Arab Muslim men” in the course of the FBI’s post-September 11 investigation, the confining of those detained in “highly restrictive conditions” until cleared by the FBI, and the approval of this policy by Ashcroft and Mueller.⁹⁹ Those allegations *were* indeed consistent with constitutionally forbidden behavior, wrote the Court, but were also equally consistent with legitimate law enforcement efforts to detect those suspected of a link to the Islamic fundamentalist organization responsible for the

96. *Id.* at 1949–50; *see id.* at 1950 (“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.”); *id.* at 1949 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”).

97. *Id.* at 1951.

98. *Id.* The Court added little further guidance to the task of divining the boundary between factual allegations (entitled to a presumption of accuracy) and legal conclusions (not entitled to that presumption). As the Court recounted, Iqbal had alleged that Ashcroft and Mueller “knew of, condoned, and willfully and maliciously agreed” to detain him under especially harsh conditions; had alleged that they did so “as a matter of policy”; had alleged that Ashcroft was the policy’s “principal architect” and Mueller its “instrumental” conduit for execution; had alleged that the policy was implemented “solely” on account of his “religion, race, and/or national origin”; and had alleged that, at least as implemented against him, the policy had “no legitimate penological interest.” *Id.* Although it may well have been the Supreme Court’s judgment that these contestations against Ashcroft and Mueller were unlikely to be provably true (though coming to such a conclusion was something the Court expressly denied it was doing, *see id.* (“To be clear, we do not reject these bald allegations on the ground that they are unrealistic or nonsensical.”)), it is not immediately apparent why they fall to the side as “bare assertions” rather than receive credit as “factual allegations.” In the end, and for this reason at least, Judge Cabranes’s plea for clarifying guidance from the Supreme Court remained not entirely realized.

99. *Id.*

criminal attacks under investigation.¹⁰⁰ In the course of that search, the Court observed that “[i]t should come as no surprise” that those efforts “would produce a disparate, incidental impact on Arab Muslims, even though the purpose of the policy was to target neither Arabs nor Muslims.”¹⁰¹ Confronted by two different interpretations of what the Court found to be Iqbal’s non-conclusory allegations of fact—one interpretation that would be unlawful and the other that would be lawful¹⁰²—the Court concluded that the inference that Ashcroft and Mueller had engaged in unconstitutional misconduct was not one that could plausibly be drawn from what Iqbal had pleaded.¹⁰³ Ergo, because Iqbal had failed to accomplish what Federal Rule of Civil Procedure 8(a)(2) commanded of him (namely, a complaint “showing” that he was “entitled to relief”), his pleading did not state a cognizable federal claim.¹⁰⁴ It was, therefore, dismissed.

III. HOW *IQBAL* MATTERS

Twenty years after his handiwork took effect, Judge Clark wrote that pleading under the new Federal Rules was “a beautiful nebulous thing.”¹⁰⁵ Though he may have had in mind a somewhat different message, his words have proven prescient indeed. With the benefit of two years’ worth of lower court work guessing and surmising about (in the course of interpreting and applying) the *Twombly* decision, the Supreme Court likely had much in view while crafting its *Iqbal* opinion.

On several fronts, the Court supplied a modicum of new clarity. First, the Court endeavored to end the uncertainty whether the “plausibility” approach announced in *Twombly* was to be limited to the context of antitrust and similarly intricate

100. *Id.*

101. *Id.*

102. *Id.* at 1952 (So limited, all that these selected factual allegations “plausibly suggest[] is that the nation’s top law enforcement officers, in the aftermath of a devastating terrorist attack, sought to keep suspected terrorists in the most secure conditions available until the suspects could be cleared of terrorist activity. [Iqbal] does not argue, nor can he, that such a motive would violate [defendants Ashcroft and Mueller’s] constitutional obligations.”).

103. *Id.* at 1951–52 (“As between th[e] ‘obvious alternative explanation’ for the arrests, . . . and the purposeful, invidious discrimination respondent asks us to infer, discrimination is not a plausible conclusion.”).

104. *See id.* at 1954.

105. Clark, *supra* note 19, at 181, *quoted in* FREER & PERDUE, *supra* note 19, at 297.

litigation.¹⁰⁶ It was not. Because the *Twombly* ruling was premised on an “interpretation and application of Rule 8,” the “plausibility” approach applied—just as Rule 8 itself did—to “all civil actions and proceedings in the United States district courts.”¹⁰⁷ This reinforcement eliminated the possibility of a recasting of the reach of *Twombly* and verified that the *Conley* “no-set-of-facts” model was, indeed, interred.¹⁰⁸ A claimant¹⁰⁹ can no longer expect that a pleading inadequacy (whatever that may mean) will be rescued by the notion that nothing ought to be dismissed in federal court unless it is, “beyond doubt,” simply and demonstrably impossible.

Second, the Court converted the *Twombly* principle into an *Iqbal* equation. As set out by the *Iqbal* Court, the “plausibility” inquiry progresses linearly through two steps, as a court examines a motion to dismiss contesting the adequacy of a pleading’s factual allegations. The examining court must begin by first identifying those pleaded allegations that are “no more than conclusions”; as to those, the court will not defer to their truth.¹¹⁰ Next, the court must then identify the “well-pleaded” factual allegations; as to those, the court will assume them to be true and will assess whether they (and only they) plausibly give rise to an entitlement to relief.¹¹¹

Third, the Court explicitly reaffirmed three legacy concepts that had seemed to be bedrock tenets of federal pleading, each of which is said to continue under the *Iqbal* regime. Federal pleaders had long been assured they were free of the duty to plead detailed factual allegations, and *Iqbal* declared this tenet unchanged.¹¹² Federal pleaders were also assured that their allegations of fact will

106. See, e.g., *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009) (citing cases, pre-*Iqbal*, for the proposition that *Twombly*’s holding “is likely limited to expensive, complicated litigation”).

107. *Iqbal*, 129 S. Ct. at 1953 (clarifying that the *Twombly* ruling “expounded the pleading standard for ‘all civil actions,’” and rejecting the suggestion that it should be limited only to antitrust claims as “not supported by *Twombly* and . . . incompatible with the Federal Rules of Civil Procedure”).

108. See discussion *supra* notes 53–56 and accompanying text.

109. “Claimant” is the more precise term. Because Rule 8(a)(2) encompasses any pleading that “states a claim for relief,” see FED. R. CIV. P. 8(a), there is little reason to believe that this paradigm will not apply (at least) to complaints, counterclaims, crossclaims, and third-party claims alike.

110. *Iqbal*, 129 S. Ct. at 1950.

111. *Id.*

112. See *id.* at 1949; see also *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 544 (2007); *Conley v. Gibson*, 355 U.S. 41, 47 (1957). The declaration may prove far less reassuring in practice. Without more precise guidance from the Court to enable litigants to confidently divine the line between uncredited “bare assertions” and qualifying “factual allegations,” more detailed federal pleadings can hardly be unexpected.

be assumed true, and *Iqbal* declared this tenet unchanged as well.¹¹³ Finally, federal pleaders were assured that they need not attempt to allege a case that seemed facially likely to win on the merits, and here, too, *Iqbal* reaffirmed the tenet.¹¹⁴

Fourth, the Court offered some sharpening of the concept of “plausibility.” The standard will not be satisfied by what the Court denominated as bald, non-factual conclusions of law—federal pleading “demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”¹¹⁵ That is not to say (we were reminded earlier) that legal conclusions are out of place in federal complaints: “a naked assertion . . . gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility of ‘entitle[ment] to relief.’”¹¹⁶ Again, where this distinction draws pivotal, and potentially decisive, importance is in isolating the point of judicial deference to the pleading. A complaint’s well-pleaded facts will be assumed true for purposes of a motion to dismiss; a complaint’s legal conclusions will not be.¹¹⁷ In other words, the work a pleading needs to do to survive a motion to dismiss is not work that can be done by its conclusions, but only by its factual allegations.¹¹⁸

Fifth, in gauging whether the standard is satisfied, the Court added that the assessment of “plausibility” is a “context-specific task” that obligates a reviewing court “to draw on its judicial experience and common sense.”¹¹⁹ This notion seems to validate the impression that the demands of “plausibility” can mutate depending on, among other factors, the precise allegations made and the type of case in which they are offered. A “plausible” car

113. See *Iqbal*, 129 S. Ct. at 1949–50 (noting that “for the purposes of a motion to dismiss we must take all of the factual allegations in the complaint as true”); see also *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993) (“We review . . . a decision granting a motion to dismiss, and therefore must accept as true all the factual allegations of the complaint.”). Like the admonition that detailed facts are not required, this reassurance is undermined by the same absence of reliability in assessing the boundary between legal conclusions and factual allegations.

114. See *Iqbal*, 129 S. Ct. at 1949. Left unaffected, therefore, seems to be the substantial body of pre-*Iqbal* and pre-*Twombly* federal case law that holds that the reviewing judge’s doubt or disbelief about the merits may not justify a dismissal. See STEVEN BAICKER-MCKEE ET AL., *FEDERAL CIVIL RULES HANDBOOK* 434 n.217, 437 nn.245–46 (2010) (collecting cases).

115. *Iqbal*, 129 S. Ct. at 1949.

116. *Twombly*, 550 U.S. at 557.

117. *Iqbal*, 129 S. Ct. at 1949–50.

118. See *id.* at 1949 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”).

119. *Id.* at 1950.

wreck lawsuit may be very simply and concisely pleaded.¹²⁰ Other types of claims likely require more substance.

Sixth, the “plausibility” standard remains a facial one and is defeated by a state of equipoise. A claimant’s task in preparing the complaint is to include “sufficient factual matter” so as to “state a claim to relief that is plausible on its face.”¹²¹ The *Iqbal* definition of “plausibility” is “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”¹²² An inference of liability is unreasonable—and therefore will not be made—if an inference of non-liability would, on the facts alleged, be just as fairly drawn.¹²³ In that resulting equipoise, the allegations (without more) are not

120. The Federal Rules are supplemented with an Appendix of Forms, which, according to Rule 84, “suffice under these rules and illustrate the simplicity and brevity that these rules contemplate.” FED. R. CIV. P. 84. At the time of the *Twombly* decision, Form 9 contained the text of a proper complaint for negligence. See FED. R. CIV. P. Form 9 (pre-2007 text) (“2. On June 1, 1936, in a public highway called Boylston Street in Boston, Massachusetts, defendant negligently drove a motor vehicle against plaintiff who was then crossing said highway. 3. As a result plaintiff was thrown down and had his leg broken and was otherwise injured, was prevented from transacting his business, suffered great pain of body and mind, and incurred expenses for medical attention and hospitalization in the sum of one thousand dollars.”). The majority in *Twombly*, while jousting with the dissenters, described why the *Twombly* complaint failed to meet the same federal pleading prerequisites that this Form 9 evidently satisfied:

Whereas the model form alleges that the defendant struck the plaintiff with his car while plaintiff was crossing a particular highway at a specified date and time, the complaint here furnishes no clue as to which of the [regional telephone operating companies] (much less which of their employees) supposedly agreed, or when and where the illicit agreement took place. A defendant wishing to prepare an answer in the simple fact pattern laid out in Form 9 would know what to answer; a defendant seeking to respond to plaintiffs’ conclusory allegations . . . would have little idea where to begin.

Twombly, 550 U.S. at 565 n.10. Note that, with the restyling of the Rules in December 2007, the forms, too, were altered; the restyled negligence complaint language appears in new Form 11. See generally discussion *supra* note 69 (discussing restyling project). The new text is even more austere. See FED. R. CIV. P. Form 11 (“2. On *date*, at *place*, the defendant negligently drove a motor vehicle against the plaintiff. 3. As a result, the plaintiff was physically injured, lost wages or income, suffered physical and mental pain, and incurred medical expenses of \$ ____.”).

121. *Iqbal*, 129 S. Ct. at 1449 (quoting *Twombly*, 550 U.S. at 570).

122. *Id.* at 1440 (quoting *Twombly*, 550 U.S. at 556).

123. *Id.* at 1449 (“The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.” (citing *Twombly*, 550 U.S. at 556)); *id.* (“Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” (quoting *Twombly*, 550 U.S. at 557)).

plausible, and no “showing” of an “entitle[ment] to relief” will have been made.¹²⁴

Whether these six points of clarification from *Iqbal* have made the “plausibility” standard more comprehensible and more cogently applied is a question to be answered by those lower courts now engaged in the process of trying to apply it. It is, however, hard to dispute the conclusion that, at least when calibrated against the *Conley* literal “no-set-of-facts” standard, the recasting seems significant. In his *Twombly* dissent, Justice John Paul Stevens remarked that “[u]nder the relaxed pleading standards of the Federal Rules, the idea was not to keep litigants out of court but rather to keep them in.”¹²⁵ His comment certainly seemed to mirror the tenor of the *Conley* decision’s “beyond doubt” threshold before a case could be dismissed.¹²⁶ Under the *Iqbal* paradigm, the point-of-departure now appears to have inverted—from *Conley*’s “cannot-be-dismissed-unless” message to *Iqbal*’s “cannot-avoid-dismissal-unless” message.¹²⁷ Whether, in practice, the *Conley*-to-*Iqbal* shift is truly as theoretically seismic as that is difficult to know for certain at this early stage, but as a comparison among competing theories, it is difficult to view it otherwise:

It used to be that, abiding by *Conley*’s lenient mandate, courts might not have dismissed a complaint, even after rejecting a pleader’s asserted legal theory, if the court were unable to positively confirm that there was no other theoretically possible claim that the pleader could have. In other words, unless the pleaded allegations actually *denied* the pleader any possible avenue for recovery, the complaint might not have been dismissed. After *Twombly*, the required inquiry seems to be an inverted version of the former one: now, a proper complaint must do more than merely *avoid foreclosing* all possible bases for recovery; it must instead affirmatively *suggest* an actual *entitlement to relief* by supplying allegations that push the claim about the level of mere speculation.¹²⁸

124. *Id.* at 1950.

125. *Twombly*, 550 U.S. at 575 (Stevens, J., dissenting).

126. *See Conley v. Gibson*, 355 U.S. 41, 45–46 (1957).

127. *See Iqbal*, 129 S. Ct. at 1950 (noting that “only a complaint that states a plausible claim for relief survives a motion to dismiss”).

128. BAICKER-MCKEE ET AL., *supra* note 114, at 437–38 (footnotes and citations omitted) (citing *Tamayo v. Blagojevich*, 526 F.3d 1074, 1084 (7th Cir. 2008)).

IV. THE BATTLE FOR *IQBAL*

The *Iqbal* and *Twombly* decisions do not suffer from a scarcity of critics. Criticism of the decisions has come from many corners, including the lower judiciary, the elected government, public interest groups, legal academia, and the popular press. For example, federal courts of appeals have questioned the precision of “implausibility” as a pleading test¹²⁹ and predicted that the standard is likely to be a source of controversy “for years to come.”¹³⁰ One United States Senator described *Iqbal* as evidence of the United States Supreme Court’s “well-documented disregard of precedent.”¹³¹ A senior National Association for the Advancement of Colored People (NAACP) representative denounced the decision as “nothing short of an assault on our democratic principles” that imposes “a significant barrier that operates to deny victims of discrimination their day in court.”¹³² One prominent law professor and federal procedure expert commented that *Iqbal* challenges the “twin commitments to an independent and accountable judiciary and to the institutions and values of democracy,”¹³³ and another distinguished constitutional scholar opined that the classic junior high school message that everyone has the right to a day in court “is becoming a myth.”¹³⁴ A *New York Times* editorial labeled the decision “lamentable,” contending that it makes it “significantly harder for Americans to assert their legal rights in federal court,” “allow[s] wrongdoers to avoid accountability,” and “gives judges excessive latitude to bury

129. See *Courie v. Alcoa Wheel & Forged Prods.*, 577 F.3d 625, 630 (6th Cir. 2009) (“Exactly how implausible is ‘implausible’ remains to be seen . . .”).

130. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008).

131. 155 CONG. REC. S11,219–21 (daily ed. Nov. 5, 2009) (statement of Senator Arlen Specter, including the *Iqbal* decision as among instances of the Supreme Court’s “well-documented disregard of precedent, which the Court took to new levels during its 2008 Term”).

132. *Has the Supreme Court Limited Americans’ Access to Courts? Hearing Before the S. Comm. on the Judiciary*, 111th Cong. 5 (2009) [hereinafter *Senate Judiciary Hearing*] (prepared statement of John Payton, President and Director-Counsel of NAACP Legal Defense & Educational Fund, Inc.), available at <http://judiciary.senate.gov/pdf/12-02-09%20Payton%20Testimony.pdf>, at 2.

133. *Id.* at 86 (prepared statement of University of Pennsylvania Law School Professor Stephen B. Burbank), available at <http://judiciary.senate.gov/pdf/12-02-09%20Burbank%20Testimony.pdf>, at 2.

134. Kim Briggeman, *Supreme Court’s Ashcroft Ruling Will Be One of Most-Cited Cases*, *UC-Irvine Law Dean Says*, *MISSOULIAN* (Missoula, Mont.), Mar. 9, 2010, available at http://missoulian.com/news/state-and-regional/article_f2c6be1a-2b3e-11df-827d-001cc4c03286.html (quoting remarks by University of California at Irvine School of Law Dean Erwin Chemerinsky).

cases based on their subjective views before the evidence emerges and can be fairly weighed.”¹³⁵

Two congressional bills propose to legislatively overrule the *Iqbal* decision. The United States Senate’s *Notice Pleading Restoration Act of 2009* proposes that, absent ensuing legislation or Rule amendment, federal courts may not dismiss complaints under Federal Rules of Civil Procedure 12(b)(6) or 12(e) “except upon the standards set forth . . . in *Conley v. Gibson*.”¹³⁶ The United States House of Representatives’ *Open Access to Courts Act of 2009* proposes that, absent ensuing legislation or Rule amendment, federal courts may not dismiss complaints under Federal Rules of Civil Procedure 12(b)(6), 12(c), or 12(e) “unless it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim which would entitle the plaintiff to relief,” and that in applying this standard, no dismissal may be based on the judge’s determination “that the factual contents of the complaint do not show the plaintiff’s claim to be plausible or are insufficient to warrant a reasonable inference that the defendant is liable for the misconduct alleged.”¹³⁷ Still other proposals, both legislative and Rule-based, continue to simmer.¹³⁸

This is not to say that *Iqbal* lacks for supporters. For example, the former United States Solicitor General who argued *Iqbal* before the Supreme Court insisted that the opinion fits “comfortably within [a] deeply-rooted body of precedent,” “represent[s] a natural application of existing law,” and “provide[s] important guidance to the lower courts in evaluating the sufficiency of pleadings.”¹³⁹ A legal scholar mused that the Supreme Court’s “plausibility” test “is remarkable only for its

135. Editorial, *Restoring Access to the Courts*, N.Y. TIMES, Dec. 22, 2009, at A40, available at <http://www.nytimes.com/2009/12/22/opinion/22tue3.html>.

136. S. 1504, 111th Cong. (2009) (introduced by Sen. Specter (D-Pa.)). As of early July 2010, this Bill remained with the Senate Committee on the Judiciary.

137. H.R. 4115, 111th Cong. (2009) (introduced by Rep. Nadler (D-N.Y.)). As of early August 2010, this Bill remained with the House Subcommittee on Courts and Competition Policy.

138. See Edward A. Hartnett, *Responding to Twombly and Iqbal: Where Do We Go from Here?*, 95 IOWA L. REV. BULL. 24 (2010), http://www.uiowa.edu/~ilr/bulletin/ILRB_95_Hartnett.pdf (surveying other proposed reworkings of the decisions). Professor Hartnett himself offers the thought-provoking addition of a new Rule 12(j) that would install a procedure for expressly invoking Rule 11(b)(3) and pleading based on a likelihood that evidentiary support for allegations would emerge from discovery. *Id.*

139. *Senate Judiciary Hearing*, *supra* note 132, at 194 (prepared statement of Gregory G. Garre, Partner, Latham & Watkins LLP and former U.S. Solicitor General), available at <http://judiciary.senate.gov/pdf/12-02-09%20Garre%20Testimony.pdf>, at 20.

unremarkability,” because it “actually did nothing to eviscerate, much less affect, Rule 8’s longstanding pleading pronouncement,” but, “[t]o the contrary, it reaffirmed it.”¹⁴⁰ A lengthy white paper assembled by leading representatives of the defense bar applauded *Iqbal* as judicial recognition of “systemic abuses and distortions” in a litigation system whose purpose “is the evaluation and adjudication of known claims, not the unfettered search for unknown claims,” and, consequently, it should not be “an unreasonable burden to require a plaintiff to know and identify facts that state a plausible claim in order to initiate a legal action.”¹⁴¹ A broad coalition from the Defense Research Institute earlier wrote that *Iqbal* “will have no effect on well-founded cases,” and attempting legislatively to dismantle the opinion “would impose a hefty ‘litigation tax’ on the engines of our economic growth, diverting scarce resources to litigation rather than job creation and impeding economic recovery at the worst possible time.”¹⁴² A nationally prominent drug and device attorney blogged that there is “nothing radical about requiring a plaintiff to have sufficient facts to plead a prima facie case before the courts will entertain the lawsuit,” that “[l]itigation is expensive, after all, especially discovery . . . [and] [m]ore should be required to set this machine in motion than the rote and fact-free pleading of the elements of any given cause of action.”¹⁴³ A senior representative from the support office from the Judicial Conference of the United States commented that the decision appears to be having “little or

140. Daniel R. Karon, “*‘Twas Three Years After Twombly and All Through the Bar, Not a Plaintiff Was Troubled from Near or from Far’—The Unremarkable Effect of the U.S. Supreme Court’s Re-Expressed Pleading Standard in Bell Atlantic Corp. v. Twombly*, 44 U.S.F. L. REV. 571, 572 (2010); see also *id.* at 600 (“Things are no different today than they were before *Twombly*, as *Twombly* merely reaffirmed Rule 8’s liberal pleading standard.”).

141. WHITE PAPER: RESHAPING THE RULES OF CIVIL PROCEDURE FOR THE 21ST CENTURY 37–38 (2010) [hereinafter WHITE PAPER], available at http://www.thefederation.org/documents/V60N3_WhitePaper.pdf (submitted to the 2010 Conference on Civil Litigation, Duke Law School, May 10–11, 2010, by (among others) the Lawyers for Civil Justice, the Defense Research Institute, the Federation of Defense and Corporate Counsel, and the International Association of Defense Counsel).

142. Letter from DRI Coal. to Subcomm. on Cts. & Competition Policy, H. Comm. on the Judiciary 3 (Dec. 15, 2009), available at <http://www.dri.org/DRI/webdocs/Iqbal%20Coalition%20Letter%20House%20Courts%20Subcmte%2012%2015%2009.pdf>.

143. James M. Beck & Mark Herrmann, *A Twombly of Scholarship*, DRUG & DEVICE L. BLOG (Oct. 12, 2009, 8:00 AM), <http://druganddevicelaw.blogspot.com/search/label/Iqbal>.

no impact” on federal dismissal rates, and was “very skeptical” that any problem exists.¹⁴⁴

Just as opponents press for a non-judicial un-making of the *Iqbal* decision, proponents press for its non-judicial, permanent codification. One proposal advocates replacing the current language of Rule 8(a)(2)—which commands all pleadings that state claims for relief to contain “a short and plain statement of the claim showing that the pleader is entitled to relief”—with new language that would require, instead, that such claims contain “a short and plain statement, made with particularity, of all material facts known to the pleading party that support the claim, creating a reasonable inference that the pleader is plausibly entitled to relief.”¹⁴⁵ And the battles rage on.

Perhaps the most intriguing opposition to *Iqbal* came in the opinion written by the four dissenting Justices in the case itself.¹⁴⁶ The dissent was written by Justice Souter, who had authored the *Twombly* majority opinion two years earlier. Although faulting the *Iqbal* majority for misapplying his *Twombly* standard, Justice Souter reiterated the “plausibility” inquiry of *Twombly* and did so without the slightest twinge of retreat: “Under *Twombly*, the relevant question is whether, assuming the factual allegations are true, the plaintiff has stated a ground for relief that is plausible. That is, in *Twombly*’s words, a plaintiff must ‘allege facts’ that, taken as true, are ‘suggestive of illegal conduct,’” and thus “‘a naked assertion . . . stops short of the line between possibility and plausibility.’”¹⁴⁷ His recounting of *Twombly* complete, Justice Souter concluded: “I do not understand the majority to disagree

144. Dave Lenckus, *Congress Eyes Pleading Standard*, BUS. INS., Nov. 9, 2009, available at <http://www.businessinsurance.com/article/20091108/ISSUE03/311089984> (requires subscription) (quoting John Rabiej, Chief of the Support Office for the Rules Committee of the U.S. Judicial Conference).

145. See WHITE PAPER, *supra* note 141, at 26. The term “material fact” is defined in the proposal as “one that is necessary to the claim and without which it could not be supported. As to facts pleaded on information and belief, the pleading party must set forth with particularity the factual information supporting the pleading party’s belief.” *Id.*

146. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1954 (2009) (Souter, J., dissenting, joined by Stevens, Ginsburg & Breyer, JJ.).

147. *Id.* at 1959–60. Evidently, this *Twombly* recitation did not dismay his fellow dissenting Justices, each of whom joined in the Souter dissent and only one of whom wrote separately. In that one separate opinion, Justice Breyer clarified his belief that it is “important to prevent unwarranted litigation from interfering with ‘the proper execution of the work of the Government,’” though he was unconvinced that the trial court would be unable to achieve that goal through structuring of discovery. See *id.* at 1961–62 (Breyer, J., dissenting).

with this understanding of ‘plausibility’ under *Twombly*.¹⁴⁸ Indeed, he agreed further with the majority that the two factual allegations on which it focused its decision, “standing alone, do not state a plausible entitlement to relief for unconstitutional discrimination.”¹⁴⁹ Thus, where Justice Souter (and, by apparent extension, the other three dissenting justices who joined in his opinion) parts company with the majority is not with its description and embrace of the “plausibility” test, but only with the particular result reached upon its application. In truth, there is a great deal of agreement with, and reaffirmation of, the *Twombly* “plausibility” standard in the *Iqbal* dissents.

The earlier dissent in *Twombly* had been far less timid. Justice Stevens, writing for himself and fellow dissenter Justice Ginsburg, offered that “[i]f *Conley*’s ‘no set of facts’ language is to be interred, let it not be without an eulogy.”¹⁵⁰ Justice Stevens noted the constancy with which the Supreme Court cited the *Conley* language, the volume of States that borrowed the standard for their dismissal motions, and the history of the development of liberalized federal pleading.¹⁵¹ Although acknowledging the majority’s concern about the size of the possible discovery burden the lawsuit might inflict,¹⁵² he emphasized that this potential for “‘sprawling, costly, and hugely time-consuming’ discovery . . . is no reason to throw the baby out with the bathwater.”¹⁵³ He would have concluded that the panoply of weapons in “a district court’s

148. *Id.* at 1960 (Souter, J., dissenting). In fact, in one respect, Justice Souter intimated even an extension to the “plausibility” standard he had crafted in *Twombly*. After noting the familiar principle that, on a motion to dismiss, “a court must take the allegations as true, no matter how skeptical the court may be,” *id.* at 1959, he acknowledged that this principle may, itself, not be an absolute one. He wrote: “The sole exception to this rule lies with allegations that are sufficiently fantastic to defy reality as we know it: claims about little green men, or the plaintiff’s recent trip to Pluto, or experiences in time travel.” *Id.* The notion that a claimant’s well-pleaded allegations of fact (not legal conclusions) could, under any circumstance, be subjectively disregarded by a court on a motion to dismiss is a place to which the majority opinions in neither *Iqbal* nor *Twombly* dared to go. Arguably, this suggestion—offered in the dissent—which would empower a judge to weigh how “sufficiently fantastic” a pleader’s *factual* allegations are (even before conducting the “plausibility” inquiry), may actually be a type of pleading heresy on which everyone might agree.

149. *Id.* at 1960.

150. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 577 (2007) (Stevens, J., dissenting).

151. *Id.* at 577–86.

152. *Id.* at 593 (“To be clear, if I had been the trial judge in this case, I would not have permitted the plaintiffs to engage in massive discovery based solely on the allegations in this complaint.”).

153. *Id.* at 593 n.13.

case-management arsenal” could be effectively brought to bear to minimize the discovery risk.¹⁵⁴ In concluding, Justice Stevens wrote: “Even if there is abundant evidence that the [antitrust conspiracy] allegation is untrue, directing that the case be dismissed without even looking at any of that evidence marks a fundamental—and unjustified—change in the character of pretrial practice.”¹⁵⁵

What remains to be explored, then, is whether such a momentous change in federal pleading practice has truly been signaled.

V. BROAD STUDIES OF THE IMPACT OF *IQBAL* ON THE FEDERAL COURTS

That the *Iqbal* decision is being cited frequently in resolving dismissal motions filed in pharmaceutical and medical device litigation is hardly surprising—it is the Supreme Court’s most recent articulation of the test for examining motions to dismiss against pleaders’ Rule 8 obligations. It would be surprising if the decision was *not* cited by lower courts as they rule on pending motions to dismiss.¹⁵⁶

But volume of citation is not the core issue. The core issue is dismissal behavior and tendency, and whether *Iqbal* has ushered in change. Sadly, the prospects for an answer based on raw statistics alone—at least one that is definitive, ultimately reliable, and widely accepted—are not good. The task itself explains this unencouraging outlook.

Any sound analysis would have to account for (and thus control for) a great many variables, some of which may be exceptionally difficult or frankly impossible to isolate, especially across a broad, national decisional universe. For example, to

154. *Id.*

155. *Id.* at 597.

156. Ergo, the mere fact of citation is unlikely to be a sound barometer for much. Because nearly all judicial opinions begin their analysis with a statement of the controlling legal standards, and because the United States Supreme Court has now, twice, offered recent statements concerning that standard, one would expect that nearly every federal disposition of a Rule 12(b)(6) motion to dismiss will cite to *Iqbal* or *Twombly*, or both. Indeed, according to an Administrative Office of the United States Courts study, as of late July 2010, the *Iqbal* decision had been cited in approximately 11,000 cases. See Memorandum from Andrea Kuperman to the Civil Rules Comm. & Standing Rules Comm. on Review of Case Law Applying *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, at 1 n.2 (July 26, 2010) [hereinafter Kuperman Memo], available at http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Iqbal_memo_072610.pdf; *infra* notes 165–68 and accompanying text (discussing this study in greater detail).

reliably assess—at a statistical level—whether application of the *Iqbal* standard is disposing of federal lawsuits at a greater pace than before would require not only a macro (arithmetic) understanding of the pre-“plausibility” and post-“plausibility” dismissal motion volumes, but also a micro, case-level understanding of the circumstances of each pre-“plausibility” and post-“plausibility” dismissal motion treatment. This latter examination would also need to consider the particulars of the claimed basis for the dismissal motion, so as to properly code those dismissals that are not *Iqbal*-prompted at all. For example, such case-level coding would segregate dismissal motions that challenge only the *legal* sufficiency (rather than factual sufficiency) of a claim,¹⁵⁷ or press a challenge that *blends* legal and factual sufficiency in an omnibus motion,¹⁵⁸ or that raise “*built-in*” defenses that constitute inherent, bright-line bars to recovery.¹⁵⁹ Also separated would be challenges that contest non-“entitlement-to-relief”-based rationales under Rule 12(b)¹⁶⁰ or that pursue

157. Such a legal challenge, premised on the actual unavailability of relief for the category of claim that the party is asserting (such as a claim by unmarried partners for loss of consortium (in a jurisdiction that requires marriage as a predicate for such claims) or by parents for “wrongful life” damages (in a jurisdiction that has refused to recognize such claims)), would seem to be something that a *Conley* analysis would absolutely permit. *See, e.g.*, *Waguespack v. Plivia USA, Inc.*, No. 10-692, 2010 WL 2086882, at *3 (E.D. La. May 24, 2010) (dismissing claims brought outside Louisiana’s exclusive, statutory products liability law); *Fellner v. Tri-Union Seafoods, LLC*, No. 06-CV-0688 (DMC), 2010 WL 1490927, at *4 (D.N.J. Apr. 13, 2010) (dismissing certain state law claims as having been subsumed by the state’s omnibus Products Liability Act).

158. Such a blending would challenge the researcher to segment any resulting ruling into the type of decision that *Conley* principles might tolerate, separate from the type of ruling that “plausibility” alone would allow.

159. One would expect that factual sufficiency challenges (even of the sort that fall squarely within the theoretical divide demarcated by *Conley* on the one side and *Iqbal* on the other) ought to be excluded from any analysis if the basis for the ruling (or, perhaps, even the motion filing itself) was premised on the pleader’s inclusion of gratuitous allegations or attached extrinsic materials that conflict with, and conclusively negate, the pleader’s stated allegations. *See Santana-Castro v. Toledo-Davila*, 579 F.3d 109, 113–14 (1st Cir. 2009) (noting that when the facts establishing affirmative defenses are obvious from the face of the pleadings, the defenses may be raised by dismissal motion); *Thompson v. Ill. Dep’t of Prof’l Regulation*, 300 F.3d 750, 754 (7th Cir. 2002) (“[W]here a plaintiff attaches documents and relies upon the documents to form the basis for a claim or part of a claim, dismissal is appropriate if the document negates the claim.”).

160. Properly excluded from any such study should also be dismissal rulings based on challenges *other* than Rule 8(a)(2) inadequacies, for example, contests over other Rule 12(b) defenses, such as motions seeking jurisdictional dismissals, dismissals for improperly laid (or inconvenient) venue, dismissals

dismissal for unrelated procedural failings¹⁶¹ or as a sanction for improper behavior.¹⁶² Dismissals entered for a litigant’s failure to contest the pending motion at all would be discounted,¹⁶³ as would dismissals upon the pleader’s consent.¹⁶⁴ In short, designing a genuinely reliable statistical analysis of the post-*Iqbal* effect that controls for all likely confounding variables would be a tall order. This is not to say that statistical study is not valuable, only that it is likely to supply an obscured peek at the true answer.

As of the date this Article goes to press, four examinations of *Iqbal* across the full spectrum of federal cases have been released,

for insufficient service or process, and dismissals for absent indispensable parties.

161. See, e.g., FED. R. CIV. P. 4(m) (dismissals for failure to serve within 120 days of filing).

162. See, e.g., FED. R. CIV. P. 37(b)(2)(A)(iii), (v) (authorizing striking of pleadings and dismissals for failure to obey discovery orders).

163. By local rule, various federal districts have embraced just such a dismissal vehicle. See, e.g., C.D. CAL. LOC. R. CIV. P. 7-12 (failure to timely file required motion papers “may be deemed consent to the granting or denial of the motion”); D.D.C. LOC. R. CIV. P. 7(b) (permitting court to treat motions as “conceded” if they have not been timely opposed by a memorandum of points and authorities); E.D. PA. LOC. R. CIV. P. 7.1(c) (permitting court to treat motions as “uncontested” if they have not been timely opposed by a brief in opposition). This Article’s examination of the pharmaceutical and medical device dismissal practice confirms that “consent”-based dismissals abound. See, e.g., *Sorrentino v. Barr Labs., Inc.*, No. 5:09-CV-0591 (GTS/RFT), 2010 WL 2026135, at *4 (N.D.N.Y. May 20, 2010) (dismissing complaint when plaintiff, in eight months, never filed opposition, and under local rules such a litigant “is deemed to have ‘consented’ to the legal arguments contained in that memorandum of law”); *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 538 (E.D. Pa. 2010) (granting motions to dismiss claims that plaintiffs failed to contest); *Redinger v. Stryker Corp.*, No. 5:10-CV-104, 2010 WL 908675, at *1–2 (N.D. Ohio Mar. 12, 2010) (granting motion to dismiss common law claims as “barred” and “abrogated” by Ohio’s comprehensive products liability statutory scheme, additionally noting that “Plaintiff has not filed an opposition to the motion”).

164. See *Lewis v. Pfizer Pharm. Co.*, Civ. No. 09-0283, 2010 WL 2545195, at *1 (W.D. La. June 18, 2010) (noting plaintiff’s lack of opposition and deeming motion unopposed); *Wendell v. Johnson & Johnson*, No. C-09-04124-CW, 2010 WL 2465456, at *3, *6 (N.D. Cal. June 14, 2010) (granting dismissal, upon plaintiffs’ consent, to certain counts and to punitive damages request); *King Drug Co.*, 702 F. Supp. 2d at 538 (granting motions to dismiss claims that plaintiffs voluntarily withdrew); *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668, 673 (W.D. La. 2010) (dismissing claims that plaintiff “acknowledged,” in both briefing and oral argument, were federally preempted); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 149, 167–68 (E.D. Pa. 2009) (dismissing claims under Pennsylvania and Texas law that plaintiffs “conceded”); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 631–32 & n.1 (E.D.N.C. 2009) (dismissing count, noting plaintiffs’ lack of opposition).

two statistical in nature and two otherwise. Each offers valuable insights in supplying the *Iqbal* answer.

A. The Administrative Office's August 2010 Electronic Data

The Statistics Division of the Administrative Office of the United States Courts posted in early August 2010 a set of data that tracked electronically collected statistical information from the computerized docketing systems of the nation's federal district courts.¹⁶⁵ The data show motion volumes and motion disposition volumes, by month, from January 2007 (about four months before the *Twombly* decision was released) through June 2010 (about 13 months after the *Iqbal* decision was released).¹⁶⁶ The data encompass all case and motion filing activity throughout the 94 federal district courts.

Upon isolating the raw totals for the four complete months preceding *Twombly* and comparing those raw totals to the first four complete months of data after *Iqbal* and then the 13 months of data after *Iqbal*, the results show as follows.¹⁶⁷

165. STATISTICS DIV., ADMIN. OFFICE OF THE U.S. COURTS, MOTIONS TO DISMISS: INFORMATION ON COLLECTION OF DATA (2010) [hereinafter AO DATA COLLECTION], available at http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Motions_to_Dismiss_081210.pdf. The compilers of this data volunteered a number of caveats: (a) the data collection was electronic only, and the underlying actual motions and orders were not read; (b) if transposition or other errors were made in entering docket data, those errors were neither identified nor corrected; (c) the data did not distinguish between the types of Rule 12 motions; (d) the data did not reflect whether dismissals were granted with or without prejudice, and if amendments were permitted, whether the amendments were successful in preserving the case; (e) the data did not exclude motions for which rulings will never be made (for example, with settlements); and (f) the data excludes Multi-District Litigation cases. *Id.* at 1.

166. The Administrative Office has been updating this posted data monthly; the data through June 2010 (as posted in August 2010) was the most current available as of the date this Article went to press.

167. The totals in this chart were assembled from the raw monthly data posted by the Administrative Office; any errors in data transposition or computation are the author's failings alone. The months used for this chart's data averaging were: Column A = January, February, March, and April 2007; Column B = June, July, August, and September 2009; Column C = June, July, August, September, October, November, and December 2009 and January, February, March, April, May, and June 2010. Three notations about this data are appropriate. First, the reported data begins with January 2007; statistics preceding that month are not included in the Administrative Office's electronically posted data. Second, the Administrative Office has been updating these data sets monthly. Those updates reveal that historical data has not remained fixed over time, but changes slightly with each monthly update. For example, comparing the historical data for two random months (September 2007

All Categories of Federal Cases (All Figures Given in Monthly Averages)			
Current Through A.O.’s August 12, 2010 Data	A. 4 months before Bell Atlantic v. Twombly	B. 4 months after Ashcroft v. Iqbal	C. 13 months after Ashcroft v. Iqbal
Total No. of Cases Filed:	17,979	21,150	20,086
No. of Motions to Dismiss Filed	6,184	7,653	7,414
% of Total Cases Where MTD Filed	34.38%	36.18%	37.00%
No. of Motions to Dismiss Granted	2,364	2,928	2,820
% of All Motions Where MTD Granted	38.24%	38.32%	37.98%
No. of Motions to Dismiss Denied	916	1,097	1,029
% of All Motions Where MTD Denied	14.80%	14.39%	13.86%
No. of Motions to Dismiss Mooted	271	398	382
% of All Motions Where MTD Mooted	4.38%	5.21%	5.14%
No. of Motions to Dismiss Partially Granted, Partially Denied	368	466	449
% of All Motions Where MTD Partially Granted, Partially Denied	5.91%	6.12%	6.04%

and October 2007) between the August 2010 data set released by the Administrative Office and the preceding July 2010 data set illustrates the point. The August 2010 data set shows 21,104 cases filed in October 2007; 5,796 motions to dismiss filed in September 2007; 2,401 motions granted in September 2007; and 787 motions denied in October 2007. The immediately preceding July 2010 data set shows 21,103 cases filed in October 2007; 5,795 motions to dismiss filed in September 2007; 2,396 motions granted in September 2007; and 786 motions denied in October 2007. *Compare* AO DATA COLLECTION, *supra* note 165 (July 7, 2010 data set) (on file with author), *with id.* (Aug. 12, 2010 data set) (on file with author). The monthly data used in compiling this chart were those posted by the Administrative Office on August 12, 2010. Third, it is not apparent from the posted data that the motion volumes are individually tracked to new cases filed, or that motion dispositions are individually tracked to new motions filed; rather, it appears that the data simply represent raw totals. This may impair the ability to draw sound conclusions regarding individual data totals. Nevertheless, the Administrative Office has used numerical comparisons from these data to measure the *Iqbal* effect on particular case populations, see *infra* note 273, and for this reason at least, the comparisons offered in this chart are useful.

As presented in this chart, this data is *not* limited to any particular category of case but encompasses the full universe of federal docket activity in the United States district courts.

This data is amenable to a few observations. First, the raw totals of newly filed motions to dismiss jumped meaningfully in the four months following the *Iqbal* decision when compared to the filing activity in the four months immediately preceding the *Twombly* decision, but that growth in numbers has stopped and begun to ebb through the 13 months after *Iqbal*. Second, the volume of dismissal motions granted likewise jumped in the four months following *Iqbal* when compared to the four months preceding *Twombly*, but that growth, too, seems to have stalled and begun to recede. Third, when measured against new-motion filing activity, the percentage of motions to dismiss that were granted has remained essentially level. In fact, when the data for the full last 13 months is considered, the percentage of motions granted has actually fallen to a point lower now than it was during the pre-*Twombly* period. Fourth, the number of motions to dismiss that were denied also rose significantly in the period after *Iqbal* as compared to the period before *Twombly*, but that growth has likewise now ended and the numbers have begun to recede. Whether these figures represent actual trends, or mere anomalies influenced by the small volumes of data and the brief window of time, remains unclear.¹⁶⁸

168. On this point, the susceptibility of these early *Iqbal*-related conclusions to change is demonstrated dramatically by the Administrative Office's tracking of two case populations of particular concern, "Civil Rights Employment Cases" and "Civil Rights Other Cases." Several months ago, the Administrative Office released its tracking data for those two populations measured in only the four-month windows pre-*Twombly* and post-*Iqbal*. That data showed no increase in the rates of motions granted post-*Iqbal* and, in fact, reported a decrease during that period. See AO DATA COLLECTION, *supra* note 165 (four-month version) (on file with author) (Civil Rights Employment Cases: pre-*Twombly* motions granted = 20% of cases and post-*Iqbal* motions granted = 16% of cases; Civil Rights Other Cases: pre-*Twombly* motions granted = 26% of cases and post-*Iqbal* motions granted = 25% of cases). However, when the Administrative Office released the same tracking data for the same two populations, but now measured in the 13-month windows pre-*Twombly* and post-*Iqbal*, the statistics had grown significantly. See *id.* (13-month version) (on file with author) (Civil Rights Employment Cases: pre-*Twombly* motions granted = 14% of cases and post-*Iqbal* motions granted = 16% of cases; Civil Rights Other Cases: pre-*Twombly* motions granted = 19% of cases and post-*Iqbal* motions granted = 25% of cases). Even here, though, making sense of the data still eludes us. As Judge Mark R. Kravitz reported in his May 2010 summary as Civil Rules Advisory Committee Chair: "These [civil rights] figures show a substantial increase in the percent of motions granted. But they cannot show the explanation—whether, for example, the increase is largely in types of pro se

B. The Judicial Conference’s July 2010 Case Law Survey Study

The United States Judicial Conference Standing Rules Committee and its Civil Rules Committee has been tracking *Iqbal* through a case analysis study, prepared by Andrea Kuperman.¹⁶⁹ The 340-page study summarized the holdings and reasoning of cases discussing and applying *Iqbal* through late July 2010.¹⁷⁰ Acknowledging the difficulty of drawing “generalized conclusions” at so early a stage in the development of the post-*Iqbal* case law, the study observed: “The case law to date does not appear to indicate that *Iqbal* has dramatically changed the application of the standards used to determine pleading sufficiency.”¹⁷¹ Instead, “the appellate courts are taking a subtle and context-specific approach to applying *Twombly* and *Iqbal* and are instructing the district courts to be careful in determining whether to dismiss a complaint.”¹⁷² The study commented further that the review of the developing case law “may suggest that *Twombly* and *Iqbal* are providing a new framework in which to analyze familiar pleading concepts, rather than an entirely new pleading standard.”¹⁷³

In summarizing the decision law through this period, the study offered several observations on patterns and similarities in some of the studied opinions:

- Some courts reaffirm that the federal “notice” pleading regime “remains intact”;
- Other courts commented that *Twombly* and *Iqbal* “have raised the bar for defeating a motion to dismiss based on

cases that survived under notice pleading only because judges felt helpless to dismiss, no matter how manifestly implausible the claim might be.” Memorandum from Hon. Mark R. Kravitz to Hon. Lee H. Rosenthal on the Report of the Civil Rules Advisory Comm. 3 (May 17, 2010) [hereinafter Kravitz Memo], available at <http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/CV05-2010.pdf>.

169. Kuperman Memo, *supra* note 156. Ms. Kuperman is the Rules Law Clerk for the Chair of the Judicial Conference Committee on Rules of Practice and Procedure. *Id.* at 1 n.1.

170. The study remains dynamic; Ms. Kuperman continues to update it regularly. She has noted that the focus of the updates has been “largely on appellate cases because as the number of cases applying *Iqbal* has grown, it has seemed appropriate to focus on appellate cases, which will guide district courts as to how to apply *Iqbal* in different contexts.” *Id.* at 1 n.2. The late-July version was the most current as this Article went to press.

171. *Id.* at 2.

172. *Id.*

173. *Id.* at 2–3.

failure to state a claim” (with one court suggesting that future plaintiffs may seek to avoid a federal forum);

- Some courts have dismissed pleadings after noting that the result would have been the same even before *Twombly* (although other courts have stated or implied the opposite);
- Many courts of appeals decisions focus on the “context-specific” nature of the *Iqbal* analysis, which, surmised the study’s author, “may give courts some flexibility to apply the analysis more leniently in cases where pleading with more detail may be difficult.”¹⁷⁴

Highlighting a recurring challenge present in any post-*Iqbal* analysis, the study noted:

While it seems likely that *Twombly* and *Iqbal* have resulted in screening out some claims that might have survived before those cases, it is difficult to determine from the case law whether meritorious claims are being screened under the *Iqbal* framework or whether the new framework is effectively working to sift out only those claims that lack merit earlier in the proceedings.¹⁷⁵

C. Professor Hatamyar’s October 2009 Empirical Study

One early empirical effort at assessing *Iqbal*’s impact is the study by Professor Patricia W. Hatamyar, who conducted an analysis of a randomized sampling of case opinions across the entire federal judiciary.¹⁷⁶ Professor Hatamyar endeavored to discern whether, as an empirical matter, there was a statistically significant change in the profile of federal motion to dismiss practice in the period before *Twombly*, during *Twombly*, and after *Iqbal*. She began with searches of the Westlaw database of electronically accessible case opinions, which yielded 6,010 cases applying *Conley* during the two-year period immediately before the *Twombly* decision was released, 6,319 cases applying *Twombly* during the two years after it was released, and 914 cases applying *Iqbal* during the three-and-a-half-month period between its release and her August 31, 2009 closing date selected for her article.¹⁷⁷ By randomized selection,¹⁷⁸ she next chose a sampling of 1,200 of these

174. *Id.*

175. *Id.* at 3.

176. Patricia W. Hatamyar, *The Tao of Pleading: Do Twombly and Iqbal Matter Empirically?*, 59 AM. U. L. REV. 553 (2010).

177. *See id.* at 584 n.200 (describing Westlaw search terms).

178. *See id.* at 584–85 (describing use of online random number generator).

13,243 opinions (500 from the 6,010-case *Conley* set, 500 from the 6,319-case *Twombly* set, and 200 from the 914-case *Iqbal* set).¹⁷⁹

From this sampling, Professor Hatamyar noted a sizable pre-existing, pre-*Twombly* dismissal rate, which then increased modestly after *Twombly* but seemed to grow meaningfully after *Iqbal*.¹⁸⁰ An excerpt of her first table of data follows:¹⁸¹

	Full Dismissal Granted, with prejudice	Full Dismissal Granted, without prejudice	Partial Dismissal Granted	Total of All Dismissals (full, partial, w/ & w/o prejudice)	Dismissal Denied	T O T A L
<i>Conley</i> Cases	40% (177)	6% (28)	28% (123)	74% (328)	26% (116)	444
<i>Twombly</i> Cases	39% (165)	9% (37)	30% (125)	78% (327)	23% (95)	422
<i>Iqbal</i> Cases	37% (64)	19% (33)	25% (44)	81% (141)	18% (32)	173

In summarizing the results of her multinomial logistic regression, Professor Hatamyar found that, “holding all other variables constant,” in the period after *Twombly* but before *Iqbal*, “the odds that a 12(b)(6) motion would be granted with leave to amend, rather than denied, were 1.81 times greater” than before *Twombly*, and that in the period after *Iqbal*, “the odds that a 12(b)(6) motion would be granted with leave to amend, rather than denied, were over four times greater” than before *Twombly*.¹⁸²

179. See *id.* at 584–85 (describing case gathering process). Professor Hatamyar later culled 161 cases from her originally gathered data set for various reasons, leaving her with 444 *Conley* cases, 422 *Twombly* cases, and 173 *Iqbal* cases. *Id.* at 585–87.

180. See *id.* at 598.

181. *Id.* at 598 tbl.1. Note, for ease of illustration, a sub-total column has been added to this summary chart, adding together dismissals granted with and without prejudice. The discussion here represents only the broadest summary of Professor Hatamyar’s impressive work, and the reader is directed to her article for the full content of her contributions. Any misattribution of the data here is the responsibility of the author, of course, and not Professor Hatamyar.

182. *Id.* at 556; see also *id.* at 598–99. As to dismissals granted without leave to amend, Professor Hatamyar’s study found that the incidence fell from before *Twombly* to after *Twombly* (from 40% to 39%) and from before *Iqbal* to after *Iqbal* (from 39% to 37%). *Id.* at 599. One especially noteworthy additional conclusion is her assessment that “*Twombly* and *Iqbal* are poised to have their

With so early a study, Professor Hatamyar warned her readers that “[b]ecause the *Iqbal* cases span only three months and are fewer in number than the *Conley* or *Twombly* cases, caution should be used in drawing inferences from the *Iqbal* data.”¹⁸³ This is, of course, no weakness of Professor Hatamyar’s impressive methodology but merely a product of the limitations borne of the recency and thin volumes of the then-available data. Her study was able to gather a 24-month set of *Conley* cases (from which she chose an 8.3% sampling (later diminished to 7.4%)); a 24-month set of *Twombly* cases (from which she chose a 7.9% sampling (later diminished to 6.7%)); but only a three-and-a-half-month set of *Iqbal* cases (from which she chose a 21% sampling (later diminished to 19%)). As a result of her time window, her *Iqbal* sampling reflected a sampling-to-gathered total representation that was almost three-times higher than the *Conley* and *Twombly* percentages, with the *Iqbal* sampling already bearing the disadvantage of spanning only about one-seventh of the calendar length that the *Conley* and *Twombly* gathered cases had spanned. Moreover, Professor Hatamyar further cautioned that any statistically significant conclusion drawn from this sampling was dependent on the inclusion of the *Iqbal* numbers. If those numbers were disregarded (for example, in preference for waiting for a more fulsome *Iqbal* dataset that mirrored the 24-month spans of the *Conley* and *Twombly* datasets), the differences prove to be “not large enough to reject the null hypothesis that *Twombly* alone had no effect on courts’ rulings on 12(b)(6) motions.”¹⁸⁴ Her cautionary advice notwithstanding, Professor Hatamyar’s study remains a formidable contribution to understanding *Iqbal*’s effect.

D. The Lee and Willging Federal Judicial Center Studies

The Federal Judicial Center has released two papers summarizing surveys with practicing attorneys who were asked to comment on *Iqbal*, *Twombly*, and the “plausibility” standard.

In the first paper, Senior Federal Judicial Center Researchers Emery G. Lee, III and Thomas E. Willging summarized the

greatest impact on civil rights cases, simply because those cases are by far the most likely type of case to be attacked by a 12(b)(6) motion.” *Id.* at 624.

183. *Id.* at 585; *see also id.* at 556 (“[T]he short time span and smaller number of *Iqbal* cases counsel caution in interpreting the data.”).

184. *Id.* at 600. Professor Hatamyar explained: “If the distribution of rulings includes only those cases decided under *Conley* and *Twombly* (without including the cases under *Iqbal*), there is an unacceptably high probability (35.9%) that the differences could have occurred by chance.” *Id.*

comments received during a survey conducted by the National Employment Lawyers Association, which sought to assess the impact of “plausibility” pleading on the law practices of employment attorneys.¹⁸⁵ More than 70% of those responding agreed that *Iqbal* and/or *Twombly* had “affected how [they] structure complaints in employment discrimination cases.”¹⁸⁶ When asked about the nature of that effect, the responders replied that they “include more factual allegations in the complaint than . . . prior to *Twombly/Iqbal*” (94.2% agreeing) and that they “have to respond to motions to dismiss that might not have been filed prior to *Twombly/Iqbal*” (74.6%).¹⁸⁷ Fewer than 15% of responders agreed that they “conduct more factual investigation” after *Twombly/Iqbal*, that they “screen cases more carefully” after *Twombly/Iqbal*, or that they “raise different claims” after *Twombly/Iqbal*.¹⁸⁸ Of those who had actually filed an employment discrimination case since the *Twombly* decision was released, only 7.2% agreed that a case had been dismissed “for failure to state a claim under the standard announced in *Twombly/Iqbal*.”¹⁸⁹

In the second paper, Willging and Lee reported on individual telephone interviews with 35 attorneys concerning their personal federal litigation experiences.¹⁹⁰ The interviewees were comprised of 16 who primarily represented plaintiffs, 12 who primarily represented defendants, and 7 who represented both about equally.¹⁹¹ Most agreed they had not “seen any impact” and

185. EMERY G. LEE, III & THOMAS E. WILLGING, FED. JUDICIAL CTR., ATTORNEY SATISFACTION WITH THE FEDERAL RULES OF CIVIL PROCEDURE: REPORT TO THE JUDICIAL CONFERENCE ADVISORY COMMITTEE ON CIVIL RULES 11–12 (2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1606885. The authors offered three caveats in assessing these responses. First, they noted that survey response rates “were relatively low.” *Id.* at 4. Second, they noted that the Association, due to its internal policies, did not share email addresses with the researchers, thus preventing the researchers from constructing their “own sampling design.” *Id.* Third, they noted that, as a consequence of both limitations, the survey responses “should only be taken as the views of the members who voluntarily took the time to respond.” *Id.*

186. *Id.* at 12. Almost 30% answered “no.” *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. THOMAS E. WILLGING & EMERY G. LEE, III, FED. JUDICIAL CTR., IN THEIR OWN WORDS: ATTORNEY VIEWS ABOUT COSTS AND PROCEDURES IN FEDERAL CIVIL LITIGATION 1–2 (2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1606866. The authors had sent email invitations to 75 attorneys (based on participation during an earlier Federal Judicial Center survey), of whom 35 participated in telephone interviews lasting between 20 and 30 minutes. *Id.*

191. *Id.* at 2.

“reported no effect” from *Twombly/Iqbal* in their practices, and “none of the attorneys identified an increase in the likelihood that [a Rule 12(b)(6)] motion would be granted.”¹⁹² Many interviewees did, however, note an increase in litigation costs occasioned by “the increased frequency of litigating 12(b)(6) motions.”¹⁹³ Most interviewees reported that “notice” pleading was already “rare” and often intentionally so based on “longstanding personal practice of pleading specific facts.”¹⁹⁴ Among the quoted comments were: “My complaints are detailed, for tactical reasons. . . . I want the reader, including the judge or more likely his clerk, to say to himself ‘Well, if he can prove this, he wins’”; “it is a good idea to put as much detail as possible into a complaint so as to make a good first impression on the judge”; “always included more than is necessary for notice pleadings, and we are generally very specific about the facts”; “never did notice pleading, always much more”; “I plead to influence the court”; and “I have a tendency to do fact pleading.”¹⁹⁵

E. The Utility of General Federal Data and Experience in Assessing the Pharmaceutical and Medical Device Experience

Opinions may differ on how accurately these four sources capture the actual post-*Iqbal* effect across the full spectrum of federal cases. However one chooses to credit those sources, two observations counsel special reserve in blindly extrapolating from these four studies (or any study broadly assessing *Iqbal* against all federal cases) into the pharmaceutical and medical device arena. First, pharmaceutical and medical device cases may just prove to be resistant to a reliable extension of uncontextualized data; this area of litigation involves a great many threshold legal challenges (often unique to this dispute type) that create case vulnerabilities that transcend many of the details behind the broad facts.¹⁹⁶

192. *Id.* at 25. One interviewee who represented both plaintiffs and defendants commented: “More motions to dismiss are being filed, but there are not more dismissals.” *Id.* at 26.

193. *Id.* at 25.

194. *Id.* at 27–28.

195. *Id.* at 28–29. Not all interviewees agreed with these sentiments, however, but their stories were the distinct minority: “Only two attorneys said that they routinely used notice pleading.” *Id.* at 29.

196. Federal preemption is one such threshold legal defense. *See infra* note 330 and accompanying text. But other threshold legal defenses abound in this sector. *See, e.g.*, *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341 (2001) (state law fraud-on-the-FDA claims are impliedly preempted under federal law); *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301 (Ala. 1984) (holding that under Alabama substantive law, prescription drug manufacturer’s duty to

Although pharmaceutical and medical device cases are unlikely the only category of litigation with this sort of uniqueness, it certainly distinguishes this sector from other less intricate and less regulatorily nuanced trial work. Second, the sector itself continues to change on its own, with the advent of new context-specific rulings (such as those probing the outer reaches of federal preemption theory).¹⁹⁷ For each of these reasons, the litigation realities in pharmaceutical and medical device disputes may, over time, come to reveal a different profile from that which is projectable nationally by extrapolating from the full volume of federal case statistics.

For this reason, a tailored study, examining pharmaceutical and medical device litigation uniquely, offers the best hope for correctly assessing *Iqbal*’s effect in this context. When complete, the results from that contextualized inspection may be susceptible to a measure of further collaboration from these four broad, general studies, but it will be the tailored analysis that drives the conclusions.

VI. *IQBAL* IN CONTEXT: IMPACT IN PHARMACEUTICAL AND MEDICAL DEVICE LITIGATION

Any doubts that the “plausibility” rule might not apply in civil litigation involving pharmaceutical and medical device disputes were dispelled by the Supreme Court in *Iqbal*.¹⁹⁸ In the time since *Iqbal* was released, a steady volume of pharmaceutical and medical

warn is limited to obligations to inform the prescribing physician); *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008) (holding that under New Jersey substantive law, a statutory claim under the state consumer fraud act cannot be maintained by prescription drug plaintiffs alleging product liability harm); *White v. Weiner*, 562 A.2d 378 (Pa. Super. Ct. 1989) (holding that under Pennsylvania substantive law, some warning duties are imposed only on final manufacturers, not bulk suppliers of pharmaceutical chemicals); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (holding that under Utah substantive law, all prescription drugs are declared unavoidably unsafe, and manufacturers of such drugs are not amenable to design defect claims).

197. See *infra* note 330 and accompanying text; see also *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (ruling that state law failure-to-warn claims are not preempted under federal law).

198. See *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1953 (2009) (clarifying that the *Twombly* ruling “expounded the pleading standard for ‘all civil actions,’” and rejecting suggestion that it should be limited only to antitrust claims as “not supported by *Twombly* and . . . incompatible with the Federal Rules of Civil Procedure”).

devices cases have cited the decision.¹⁹⁹ Fervent voices have argued why *Iqbal* portends a seismic change in the course of federal litigation; equally fervent voices insist just the opposite is true. In the pharmaceutical and medical device universe, who has been proven right?

Barely a year-and-a-half distant from the release of the *Iqbal* opinion, one must approach with great hesitation the task of extrapolating from so small and early a data set. Any such conclusions are vulnerable to the risk that the population of cases under examination may still be too small and the litigant/judicial responses still too evolving to avoid over-highlighting as “patterns” what fade significantly—or reconfigure entirely—as mere anomalies as a larger decisional population emerges. Nevertheless, limited by what the courts have generated to date, and mindful of the admonition against declaring early conclusions to be stonily reliable ones, certain observations can still be made.

A. This Article’s Methodology

The numerical data and analytical conclusions of this Article were derived from studying the cohort of 264 federal decisions that had resolved a post-*Iqbal* dispositive pleading motion involving the pharmaceutical or medical device industries. This cohort was gathered electronically, using the Westlaw *Allfeds* database.²⁰⁰ The

199. The mere fact of citation is unlikely to be a sound barometer for much. Because nearly all judicial opinions begin their analysis with a statement of the controlling legal standards, and because the United States Supreme Court has now, twice, offered recent statements concerning that standard, it is hardly surprising that nearly every federal disposition of a Rule 12(b)(6) motion to dismiss will cite to *Iqbal* or *Twombly*, or both. Indeed, according to an Administrative Office of the United States Courts study, as of May 25, 2010, the *Iqbal* decision had been cited in approximately 11,000 cases. See *supra* notes 165–68 and accompanying text; see also Kuperman Memo, *supra* note 156, at 1 n.2.

200. A research query was run weekly in the Westlaw *Allfeds* database, using this terms-and-connectors formulation: “(ASHCROFT /4 IQB*L) & (PHARMACEUTICAL (PRESCRIPTION /4 DRUG) (MEDICAL /3 DEVICE) F.D.A. (FOOD /3 DRUG /3 ADMINISTRATION) F.D.C.A. (FOOD /3 DRUG /5 COSMETIC)) & date(aft 5/18/2009)”. This query was designed to ensure that every pharmaceutical and medical device decision, available in this database, that cited *Iqbal* was collected. Because *Iqbal* confirmed that the “plausibility” standard—as announced in *Twombly*—applied in all civil cases, see *Iqbal*, 129 S. Ct. at 1953, a second research query was run to gather all *Twombly*-citing, post-*Iqbal* decisions in the pharmaceutical and medical device context that, though applying the “plausibility” test, chose to cite only to *Twombly* and not to *Iqbal*. That research query, also run weekly in the Westlaw *Allfeds* database, used this terms-and-connectors formulation: “date (aft 5/18/2009) & TWOMBLY & (PHARMACEUTICAL (PRESCRIPTION /4 DRUG) (MEDICAL /3 DEVICE)

search pursued citations only to decisions entered after the date of the *Iqbal* opinion (May 18, 2009). Although sound arguments can be made that even before *Iqbal*, it was quickly becoming settled that the *Twombly* “plausibility” standard applied to all civil cases (beyond narrowly limited categories like antitrust and especially complex or costly litigations), it was not until the *Iqbal* decision that the issue was squarely, incontestably made clear.²⁰¹ The search continued to gather cases through August 31, 2010. The total study period, therefore, spanned just under 15-and-a-half months.²⁰²

F.D.A. (FOOD /3 DRUG /3 ADMINISTRATION) F.D.C.A. (FOOD /3 DRUG /5 COSMETIC)) % (ASHCROFT /4 IQB*L).”

201. See discussion *supra* notes 106–09 and accompanying text. Well, perhaps “incontestably” and “clear” overshoot the mark a tiny bit. Barely three months after *Iqbal* was decided, Judge Posner (for a unanimous panel of the Seventh Circuit) affirmed a trial court’s grant of a motion to dismiss, but in closing the opinion, offered a few intriguing, passing observations. See *Smith v. Duffey*, 576 F.3d 336, 339–40 (7th Cir. 2009) (Posner, J.). The *Twombly* opinion, wrote the Judge, had been decided “in complex litigation,” and *Iqbal* had been decided in an official immunity context, neither of which was implicated in *Smith*. *Id.* Moreover, Justice Kennedy’s majority opinion in *Iqbal* had embraced the “plausibility” test by rejecting the curative prospects of specially-tailored discovery as “especially cold comfort in *this* pleading context, where we are impelled to give real content to the concept of qualified immunity for high-level officials who must be neither deterred nor detracted from the vigorous performance of their duties.” *Id.* at 340 (quoting *Iqbal*, 129 S. Ct. at 1954) (internal quotation marks omitted). Attentive to Justice Kennedy’s artful use of the word “this,” Judge Posner mused in his opinion’s final paragraph: “So maybe neither *Bell Atlantic* [*v. Twombly*] nor *Iqbal* governs here.” *Id.*; see also *Cooney v. Rossiter*, 583 F.3d 967, 971 (7th Cir. 2009) (Posner, J.) (noting that *Iqbal* teaches that “the height of the pleading requirement is relative to circumstances,” and that “[t]his case is not a complex litigation, and the two remaining defendants do not claim any immunity”; nevertheless, a “high standard of plausibility” was demanded because the case involved “a bitter custody fight” that alleged “a vast, encompassing conspiracy”); *Brace v. Massachusetts*, 673 F. Supp. 2d 36, 42 (D. Mass. 2009) (commenting that “[t]he heightened ‘plausibility’ pleading standard first articulated in *Twombly* and then re-stated in *Iqbal* might not be as universal as [some] . . . seem[] to contend”); *City of Springfield v. Comcast Cable Commc’n, Inc.*, 670 F. Supp. 2d 100, 108 n.7 (D. Mass. 2009) (citing Judge Posner’s *Smith* opinion and observing that “*Twombly*’s ‘plausibility’ test may not govern here,” though deciding on other grounds). But see *Boroff v. Alza Corp.*, 685 F. Supp. 2d 704, 707 (N.D. Ohio 2010) (“Judge Posner’s proposed (narrow) reading of *Iqbal* and *Twombly* holds obvious appeal to lawyers and judges familiar with the venerable *Conley* pleading standard. But it cannot be reconciled with the clear statement in *Iqbal* that the *Twombly* standard applies to ‘all civil actions.’”).

202. More precisely, the study period extended from May 19, 2009 through and including August 31, 2010. To ensure an ample opportunity for courts and Westlaw to post all of the late August 2010 opinions, this research continued for three weeks into September 2010.

This final cohort total was achieved by a careful culling of the raw electronic search results. Decisions where the search terms appeared in a plainly off-topic manner were culled.²⁰³ Also culled were pharmaceutical and medical device decisions resolving motions seeking relief for something other than a deficient pleading, such as discovery contests or summary judgment battles.²⁰⁴ Although motions seeking relief under Rule 12(b)(6) accounted for the overwhelming majority of the final cohort, a few other types of motions were nevertheless included in this study if they squarely assessed the Rule 8 adequacy of a pleading against the “plausibility” standard. Such motions included Rule 12(c) motions for judgment on the pleadings,²⁰⁵ Rule 15 motions seeking leave to amend,²⁰⁶ and motions to remand that asserted the absence of a viable claim upon which federal jurisdiction was premised.²⁰⁷

203. This culling eliminated only obviously inapplicable case decisions, where the query search terms appeared in ways that were not at all germane to this study, such as where the search terms (such as “pharmaceutical” or “medical device”) appeared simply in the titles of precedents the case was citing for other purposes, or where the terms appeared in background facts or other irrelevant contexts (such as where a litigant’s use of a “prescription drug” was recounted for other purposes or where an expert witness’s credentials as a former “FDA” employee were assessed). The frequent, but off-topic, case law citations to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005), are classic “cases” in point.

204. The courts’ citations to *Iqbal* in resolving motions for summary judgment are intriguing, but beyond the scope of this Article given the difference in evidentiary focus commanded by Rule 56 motions. See, e.g., *Am. Med. Sys., Inc. v. Laser Peripherals, LLC*, No. 08-4798 (JNE/FLN), 2010 WL 1957479, at *17 (D. Minn. May 13, 2010) (granting summary judgment on willful infringement claim for pleader’s failure to properly plead it under *Twombly*); *Williams v. Allergan USA, Inc.*, No. CV-09-1160-PHX-GMS, 2009 WL 3294873, at *4 (D. Ariz. Oct. 14, 2009) (granting summary judgment on preemption grounds, citing plaintiff’s failure to plead sufficient facts under *Twombly* to defeat it); *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 308 (E.D. Pa. 2009) (granting summary judgment on breach of express warranty claims, citing pleader’s failure under *Iqbal* to plead them).

205. See, e.g., *AstraZeneca AB v. Apotex Corp.*, Nos. 01-Civ.-9351, M-21-81 (BSJ), MDL No. 1291, 2010 WL 2541180, at *2 (S.D.N.Y. June 9, 2010) (noting that the Rule 12(c) test is the same as Rule 12(b)(6)); *Pettit v. SmithKline Beecham Corp.*, No. 2:09-cv-00602, 2010 WL 1463479, at *1–2 (S.D. Ohio Apr. 13, 2010) (noting that Rule 12(c) motions apply the Rule 12(b)(6) standard and *Iqbal*); *Cnty. of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 WHA, 2010 WL 1038464, at *4 (N.D. Cal. Mar. 19, 2010) (Rule 12(b)(6) and Rule 12(c) standards are the same); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 209 (E.D. Pa. 2009) (noting that Rule 12(c) motions employ the same standard as Rule 12(b)(6), including *Twombly*).

206. See, e.g., *Cent. Reg’l Emps. Benefit Fund v. Cephalon, Inc.*, Civ. No. 09-3418 (MLC), 2010 WL 1257790 (D.N.J. Mar. 29, 2010) (denying proposed

Finally, cases were also culled if they involved contests regarding the soundness of healthcare treatment and cases involving food products. These latter two culled categories—cases involving the service-side of medicine (e.g., professional healthcare delivery, healthcare facilities, healthcare insurance and managed care, healthcare regulation, healthcare administration, and pharmacy practices) and cases involving food and food products—are indisputably nationally-critical industry sectors worthy of careful post-*Iqbal* study, but they were beyond the scope of this Article. The focus of this Article’s examination remained exclusively on the product side of the pharmaceutical and medical device industry.

Expectedly, given the nature of the pharmaceutical and medical device industries, the resulting case population is dominated by products liability disputes, followed by antitrust contests, consumer fraud and securities claims, intellectual property disputes, contract claims, False Claims Act disputes, employment and ERISA claims, statutory and common law unfair trade practices claims, and a smattering of other litigation types. The precise categorical division of the cohort this Article studied follows:

Litigation Type	Cases
Products Liability	114
Antitrust	26
Consumer Fraud	24
Securities	18
Intellectual Property	16
Contract	11
False Claims (<i>Qui Tam</i>)	10
Employment	8
ERISA	6
Unfair Trade Practices	6
Regulatory Disputes	3

amendment for its failure to satisfy “plausibility” test); *Johnson & Johnson v. Guidant Corp.*, No. 06 Civ. 7685 (RJS), 2010 WL 571814 (S.D.N.Y. Feb. 16, 2010) (same).

207. See, e.g., *In re Prempro Prods. Liab. Litig.*, MDL Nos. 4:03-CV-01507-WRW, 4:10-CV-00409-WRW, 2010 WL 2884887 (E.D. Ark. July 20, 2010) (granting motion to remand, ruling that plaintiff had pleaded a cognizable claim against non-defense defendant); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, Nos. 3:09-md-02100-DRH-PMF, 3:10-CV-20095-DRH-PMF, MDL No. 2100, 2010 WL 1963202, at *4 (S.D. Ill. May 14, 2010) (denying motion to remand, ruling that diverse party had been fraudulently joined because plaintiff failed to plead plausible claim against that party).

Reimbursement Fraud	3
Tortious Interference	3
Bankruptcy	2
Food, Drug & Cosmetic Act Claims	2
Fiduciary Breach	2
Malpractice	2
Pricing Overcharges	2
Other (Constitutional Law, Contribution, False Statements, Tariff Act, Lender Liability, Unknown—1 each)	6
	264

With this case population assembled, the essential remaining task was to determine whether the emergence of the *Iqbal* dismissal test made a decisional difference in each case. To accomplish that assessment, five categorizing rules were adopted.

First, if the party resisting the dispositive pleading motion prevailed (that is, the court denied the motion), the case was recorded in a “no-difference” category. Plainly, that grouping judgment is accurate only as to the motion disposition outcome itself and, obviously, only for the case population examined; it is only to those extents that the grouping judgment is claimed. One might certainly argue that even in those cases where the dispositive motion was successfully resisted, the *Iqbal* “plausibility” standard could have meaningfully impacted the case nevertheless, by, for example, imposing on the pleader the costs of defending a motion that might never have been attempted before *Iqbal*, by ratcheting up the costs of that motion battle, or by forcing the pleader to incur additional expense in pretrial investigation and claim drafting.²⁰⁸ Likewise, one might argue that the grouping exercise itself may bear the flaw of an unrepairably understated denominator because it fails to capture those cases that attorneys refused to litigate out of concern for *Iqbal*.²⁰⁹ Neither of those potential weaknesses is

208. Anecdotal attorney survey solicitations tend to validate the existence of these sorts of added *Iqbal* costs in a general way (not focused peculiarly on pharmaceutical and medical device litigation). See, e.g., LEE & WILLGING, *supra* note 185, at 12 (reporting that 70.1% of respondents answered that *Twombly* and/or *Iqbal* had “affected their practices”; 94.2% of respondents answered that they “include more factual allegations in the complaint than I did prior to *Twombly/Iqbal*”; and 74.6% of respondents answered that they “have to respond to motions to dismiss that might not have been filed prior to *Twombly/Iqbal*”).

209. Anecdotal validation for this criticism exists as well. See, for example, Jeff Jeffrey, *Assessing the Changing World of Civil Procedure Post-‘Twombly,’ ‘Iqbal,’* NAT’L L.J. (June 21, 2010), <http://www.law.com/jsp/article.jsp?id=1202462842283>, which quotes leading plaintiff’s lawyer Elizabeth Cabraser as stating that “[t]he plausibility requirement has forced her to reject some cases

readily, practically assessable, unfortunately. Nonetheless, at its broadest level, assessing whether a post-*Iqbal* dispositive motion was defeated or not still represents a valuable tool of measurement; if a claimant was successful in resisting the motion under the *Iqbal* “plausibility” regime, than at least one can conclude that the most decisive post-*Iqbal* effect (the dismissal of the case) was avoided in that instance. This sub-category was labeled “no-difference (defeated).”

Second, if the contested pleading was dismissed on grounds that plainly did not hinge on the adoption of the *Iqbal* “plausibility” test, that case was recorded in a second “no-difference” category. This analysis was conducted cautiously, and restricted to two types of decisions—where the testing paradigm applied by the court was not Rule 8(a) and where the dispositive legal principles used by the court emanated from non-*Iqbal* pleading standards or otherwise erected impenetrable legal bars to recovery. For example, motions that challenged fraud claims, or claims in the nature of fraud, were all grouped within this category if they applied the fraud-based pleading enhancement standard. For those sorts of fraud-based claims, enhanced particularity in pleading was required not by operation of Rule 8(a), which *Iqbal* and *Twombly* had construed, but by the longstanding, preexisting mandate of Rule 9(b).²¹⁰ This is similarly true where an enhanced obligation was imposed by another federal law, such as securities fraud claims governed by the heightened pleading standards

that she might have taken on prior to [*Twombly* and *Iqbal*] because ‘often the truth is implausible on its face’” and that “[t]he cases that are never brought can be the cases that would be most important.” Curiously, however, one attorney survey solicitation suggests that this understatement—if indeed it exists—might be very modest. *See, e.g.,* LEE & WILLGING, *supra* note 185, at 12 (noting that fewer than 15% of respondents answered that, post-*Iqbal*, they conduct more pre-filing factual investigation than before, they screen cases more carefully with motions to dismiss in mind than before, or they raise different claims than before).

210. *See* FED. R. CIV. P. 9(b) (substantively requiring, since adoption in 1937, that a party alleging fraud “must state with particularity the circumstances constituting the fraud or mistake”); *see also* *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1954 (2009) (drawing a distinction between the “elevated pleading standard” of “particularity” required for fraud and mistake under Rule 9(b) and “the less rigid—though still operative—strictures of Rule 8” in all other instances); *United States ex rel. Stephens v. Tissue Sci. Labs., Inc.*, 664 F. Supp. 2d 1310, 1315 (N.D. Ga. 2009) (noting that when fraud claims are alleged, “a higher pleading standard” than *Twombly* applies). This Rule 9(b) enhancement may, itself, be further enhanced in certain contexts. *See United States ex rel. Laucirica v. Stryker Corp.*, No 1:09-CV-63, 2010 WL 1798321, at *4 (W.D. Mich. May 3, 2010) (“The Rule 9(b) requirements for a *qui tam* action are demanding . . .”).

imposed by the federal Private Securities Litigation Reform Act²¹¹ or shareholders' derivative act claims governed by the pleading requirements of Rule 23.1.²¹² Whether one agrees with or disagrees with a particular court's dismissal under Rule 9(b) or another statutorily enhanced pleading standard, one must concede that the inquiry being conducted is not an *Iqbal* Rule 8(a) one.²¹³ Likewise, motions that were granted in reliance upon non-pleading standards or other non-*Iqbal* legal bars to recovery were recorded in the "no-difference" category.²¹⁴ For example, within this category fell

211. 15 U.S.C. § 78u-4(b) (2006) (amended 2010); see *In re Cutura Sec. Litig.*, 610 F.3d 1103, 1107 (9th Cir. 2010) (outlining "heightened pleading standard" for securities fraud claims imposed by the federal Private Securities Litigation Reform Act); *In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1225 (N.D. Cal. 2009) (same). See generally *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 705 F. Supp. 2d 1088, 1098 (E.D. Mo. 2010) (noting that the "special heightened pleading rules" of the Act "[are] intended to eliminate abusive securities litigation and put an end to the practice of pleading 'fraud by hindsight'").

212. FED. R. CIV. P. 23.1(b)(3) (obligating pleaders to "state with particularity" their efforts in pursuing (or reasons for failing to pursue) compliant action from a board of directors); see *King v. Baldino*, 648 F. Supp. 2d 609, 616 (D. Del. 2009) (describing demand futility pleading obligations demanded by Rule 23.1); see also *In re Pfizer Inc. S'holder Derivative Litig.*, 09 Civ. 7822 (JSR), 2010 WL 2747447, at *8 (S.D.N.Y. July 13, 2010) (noting that "the standard under Rule 12(b)(6) is less stringent than that under Rule 23.1").

213. This is not to say that Rule 8(a) and Rule 9(b) are separated hermetically one from the other, at least as respects the "plausibility" inquiry. The emerging case law on the point confirms that such fixed lines of compartmentalization do not exist. See, e.g., *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291–93 (11th Cir. 2010) (ruling that pleading "does not plausibly, under *Twombly*, or particularly, under Rule 9(b)," meet pleader's obligations); *SEC v. Tambone*, 597 F.3d 436, 442 (1st Cir. 2010) (Rule 9(b) represents "an additional hurdle" beyond pleader's plausibility requirements); *Crichton v. Golden Rule Ins. Co.*, 576 F.3d 392, 395 (7th Cir. 2009) (noting that "[i]n addition" to plausibility, a pleader alleging fraud must satisfy Rule 9(b)). Nevertheless, the Rule 9(b) component of this equation remains a particularity-in-pleading one. See, e.g., *Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter*, 607 F.3d 1029, 1034 (5th Cir. 2010) (commenting that Rule 9(b) imposes the "additional burden" on a pleader alleging fraud to "lay out 'the who, what, when, where, and how'" of the fraud); *Mitec Partners, LLC v. U.S. Bank Nat'l Ass'n*, 605 F.3d 617, 622 (8th Cir. 2010) (same). A pleader who fails that independent claim-particularization obligation is already subject to dismissal, regardless of what a further "plausibility" inquiry would produce.

214. See, for example, *Rule v. Fort Dodge Animal Health, Inc.*, 607 F.3d 250, 252–53 (1st Cir. 2010), which dismissed an implied warranty of merchantability claim because there was no actual injury from the claimed misconduct (required under applicable law), and dismissed a Massachusetts Deceptive Trade Practices Act claim because the claimant suffered no economic injury (also required under applicable law). The opinion noted: "Although judges have some room to dispatch at this stage claims that are highly

motions in products cases that sought to dismiss state common law counts that had been abrogated by exclusive statutory remedies,²¹⁵ motions to dismiss counts that required special pre-filing notice that had not been given,²¹⁶ and motions to dismiss counts that were otherwise barred by definition under the elements of the pleaded cause of action.²¹⁷ Again, whether one agrees with or disagrees with a particular court’s interpretation of these laws or legal

implausible or pled only in conclusory terms, that wrinkle is not of importance in this case.” *Id.* at 252 (citation omitted); *see also* Waguespack v. Plivia USA, Inc., Civ. No. 10-692, 2010 WL 2086882, at *3 (E.D. La. May 24, 2010) (dismissing claims brought outside Louisiana’s exclusive statutory products liability law); Mascetti v. Zozulin, No. 3:09-cv-963 (PCD), 2010 WL 1644572, at *5 (D. Conn. Apr. 20, 2010) (dismissing claims as not cognizable against private (non-state) actors and as lacking a private right of action); Fellner v. Tri-Union Seafoods, LLC, No. 06-CV-0688 (DMC), 2010 WL 1490927 (D.N.J. Apr. 13, 2010) (dismissing certain state law claims as having been subsumed by the state’s omnibus Products Liability Act); Mutual Pharm. Co. v. Watson Pharm., Inc., Civ. No. 09-5421 (GEB), 2010 WL 446132 (D.N.J. Feb. 8, 2010) (dismissing state unfair competition law claims as not cognizable under pre-*Iqbal* state case authorities).

215. *See, e.g.,* Lewis v. Pfizer Pharm. Co., Civ. No. 09-0283, 2010 WL 2545195, at *12 (W.D. La. June 18, 2010) (dismissing common law claims abolished by Louisiana’s products liability statute); Redinger v. Stryker Corp., No. 5:10 CV 104, 2010 WL 908675, at *2–3 (N.D. Ohio Mar. 12, 2010) (same, Ohio’s statute); Washington v. Wyeth, Inc., No. 3:09-CV-01343, 2010 WL 450351, at *2 (W.D. La. Feb. 8, 2010) (same, Louisiana’s statute); Gainer v. Mylan Bertek Pharms., Inc., Civ. No. 09-690 (JNE/JSM), 2010 WL 154233, at *2 (D. Minn. Jan. 11, 2010) (same, Ohio’s statute).

216. *See, e.g.,* Mattson v. Bristol-Myers Squibb Co., Civ. No. 07-908 (FLW), 2009 WL 5216966, at *5–8 (D.N.J. Dec. 30, 2009) (dismissing California Consumer Legal Remedies Act claim for failure to provide mandatory statutory notice).

217. *See, e.g.,* Warren Gen. Hosp. v. Amgen, Inc., Civ. No. 09-4935 (SRC), 2010 WL 2326254, at *3–7 (D.N.J. June 7, 2010) (dismissing antitrust claim as barred under prior law, as contradicted by exhibits attached to complaint, and as defeated by concessions of counsel); Nelson v. Xacta 3000, Inc., Civ. No. 08-5426 (MLC), 2010 WL 1931251, at *9 (D.N.J. May 12, 2010) (dismissing unjust enrichment count because New Jersey does not recognize such a claim as an independent cause of action); *In re* Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., 692 F. Supp. 2d 1012, 1017–23 (S.D. Ill. 2010) (dismissing strict liability, negligence, and warning claims for absence of enforceable duty under Illinois law and as barred by state law warning theory and the learned intermediary doctrine, and dismissing warranty claim as lacking “transaction of goods” element essential under Illinois law); Cent. Reg’l Emps. Benefit Fund v. Cephalon, Inc., Civ. No. 09-3418 (MLC), 2009 WL 3245485, at *2–3 (D.N.J. Oct. 7, 2009) (dismissing New Jersey Consumer Fraud Act claims filed by third-party payors because they lacked “consumer” status necessary to relief under the statute).

principles, such dismissals are not *Iqbal*-reliant ones. This sub-category was labeled “no-difference (legal bar).”

Third, if a case straddled these first two categories—that is, the court denied a portion of the motion to dismiss and granted another portion in reliance on a non-*Iqbal* standard or legal bar—the case was grouped into the “no-difference (combined)” sub-category.²¹⁸

Fourth, unless a case fell within these first three categories (i.e., the dismissal motion was denied, was granted in reliance on a non-*Iqbal* pleading standard or legal bar, or both), the case was grouped into one of three final categories: “possible-difference,” “yes-difference,” or “mixed-difference.” In those cases, the dispositive effect of *Iqbal* on the decision was expressed directly or inferentially by the deciding court, or an *Iqbal* effect could not, for other reasons, be confidently ruled out. To reduce the level of subjectivity inherent in the classification choice between “possible-difference” and “yes-difference,” the analysis was an equally cautious one. The “yes-difference” category was reserved for only those cases where the court’s dismissal depended unmistakably on what it expressly or impliedly described as a change in pleading obligations under the *Iqbal* “plausibility” test.²¹⁹

Fifth, a “possible-difference” category was used where the court’s dismissal could not be confidently placed into either the

218. See, e.g., *Tethys Bioscience, Inc. v. Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.*, No. C 09-5155 CW, 2010 WL 2287474, at *1–8 (N.D. Cal. June 4, 2010) (denying dismissal of fiduciary breach claim because it was properly pleaded, but dismissing conversion count and certain categories of claimed damages as barred under California law); *In re Hydroxycut Mktg. & Sales Practices Litig.*, No. 09 MD-2087 BTM (AJB), 2010 WL 1734948, at *1–5 (S.D. Cal. Apr. 26, 2010) (denying dismissal of warranty count because it was properly pleaded, but dismissing New York General Business Law count for failure of essential element of transaction occurring within New York State); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524 (E.D. Pa. 2010) (denying dismissal of 10 of 17 counts, but dismissing remaining counts under prior law, lack of private right of action, and failure to send mandatory demand letter).

219. See, for example, *Gonzalez v. Bristol-Myers Squibb Co.*, Civ. No. 3:07-cv-00902 (FLW), 2009 WL 5216984 (D.N.J. Dec. 30, 2009), which dismissed a state law negligent misrepresentation claim because, beyond conclusorily alleging detrimental reliance, the plaintiff failed to plead any facts by which it could be inferred: “It is not enough for Plaintiff to set forth a formulaic recitation of the element without any factual support. Plaintiff’s allegation is clearly insufficient under the standard set forth in *Iqbal*.” *Id.* at *8. As framed and explained, the *Iqbal* opinion was essential to the district court’s dismissal decision in *Gonzalez*. Notwithstanding how the court described this effect, it might well be that another trial judge (or this same trial judge) would have reached an identical outcome without the “plausibility” test, but that conclusion cannot be fairly supported by the manner in which the case was decided. Consequently, the *Gonzalez* case (and those like it) was categorized in the “yes-difference” group.

“no-difference” or “yes-difference” category, and good (yet arguable) reasons existed both for and against a more definitive classification.²²⁰

Sixth, the final category, “mixed-difference,” was used where a portion of the court’s ruling fell within a “no-difference” category but another portion of the court’s ruling fell within the “possible-difference” or “yes-difference” categories.²²¹

Before embarking on a review of this Article’s results, a few comments on the reliability of performing this study on the basis of computer-retrievable opinions are in order. Thoughtful criticisms have been offered of studies premised on such material.²²² Without

220. See, for example, *Anthony v. Stryker Corp.*, No. 1:09-cv-2343, 2010 WL 1387790 (N.D. Ohio Mar. 31, 2010), which relied on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), to dismiss on preemption grounds where the pleader failed to establish that the state claims were “parallel” to federal violations. The pleader failed to mention the FDA or its regulations, to plead a basis that linked the medical device at issue with the origin of the recalled manufacturing error, or to plead how the claimed injuries were caused by the alleged wrongful act. A case like *Anthony* fell in the “possible-difference” category because of the enormity of the pleading failure the district court had identified, and the likelihood that even without the “plausibility” test, the trial judge, upon confronting such pleading omissions, would have granted a Rule 12(b)(6) dismissal. But that possibility, however likely it might be, remains just a possibility. For this reason, grouping in the “no-difference” category was foreclosed, and a “possible-difference” selection was made instead for *Anthony* and decisions like it.

221. See, for example, *Bayer Schera Pharma AG v. Sandoz, Inc.*, Nos. 08-Civ-03710 (PGG), 08-Civ-08112 (PGG), 2010 WL 1222012 (S.D.N.Y. Mar. 29, 2010), which dismissed an antitrust claim on market definition pleading failure based on prior precedent and dismissed a state unfair competition claim based on a state law interpretation that bad faith litigation does not qualify as unfair competition. But the case also dismissed a tortious interference claim: “Prior to *Iqbal*, New York district courts disagreed as to whether a plaintiff was required to identify specific business relationships in order to make out a claim for tortious interference with prospective economic advantage. After *Iqbal*, it is clear that a claim such as this—which merely ‘offers “labels and conclusions” [and] “a formulaic recitation of the elements of a cause of action”’—will not survive a motion to dismiss.” *Id.* at *8 (alteration in original) (citation omitted) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). Because a portion of the *Bayer Schera Pharma AG* decision would fall within the “no-difference” category and another portion would fall within the “yes-difference” category, the opinion (and those like it) was grouped in the “mixed-difference” category.

222. See, e.g., Kevin M. Clermont & Theodore Eisenberg, *CAFA Judicata: A Tale of Waste and Politics*, 156 U. PA. L. REV. 1553, 1558–60 (2008) (noting that “[i]n many situations, empirical research limited to published opinions is dangerous,” because they “represent only the very tip of the mass of grievances,” because “a rather small percentage of judicial decisions appear as published opinions,” and because the discretionary choice to publish or not results in “a skewed sample of judicial decisions”); Brian N. Lizotte, *Publish or Perish: The Electronic Availability of Summary Judgments by Eight District*

denigrating those perspectives, this Article's opinion-based focus is an appropriate and reliable foundation for this inquiry here, into the effect that *Iqbal* had on pharmaceutical and medical device litigation, for several reasons. First, as a cursory inspection of the footnotes in this Part VI confirms, a substantial number of the opinions within the studied cohort are technically "unpublished" and are likely to remain that way.²²³ Consequently, the degree to which the studied cohort here is under-representing the full data set is likely far less than a study limited to only Reporter-published decisions. Second, statistical analyses of the *Iqbal* effect may not represent a superior mode of assessment; indeed, that methodology has engendered its own critics, who decry such studies as functionally unreliable in their own right.²²⁴ Third, raw statistical formulations will often be unable to isolate out disposition details that, left uncultured, would incorrectly skew the study results.²²⁵ Fourth, in any event, non-opinion based examinations have been conducted generally, across the full volume of federal cases, and they are already available for review.²²⁶ Moreover, a non-opinion based study of pharmaceutical and medical device litigation is probably untenable, because the federal case inventory is electronically coded in only broad groupings and not by precise industry type.²²⁷ Fifth, pharmaceutical and medical device litigation may prove to be dispositionally unique, and therefore not reflective of broader studies across the entire federal judiciary.²²⁸

Courts, 2007 WIS. L. REV. 107, 121 ("[W]hen researchers studying the administration of the federal courts make conclusions based only on published opinions, those conclusions are based on incomplete, and biased, data." (footnote omitted)).

223. See Lizotte, *supra* note 222, at 120 (commenting that "[t]he term 'unpublished' is itself a bit of a misnomer" in the "age of the Internet" where "'unpublished' rarely means 'unavailable'").

224. See Kravitz Memo, *supra* note 168, at 4 (noting protests from a May 2010 Duke Law School conference "that mere statistics counting dismissal rates cannot count the things that truly count: the number of cases that, if not dismissed, would have survived to victory on the merits; the cases that are not filed; the diminution in private enforcement of essential public policies").

225. See *supra* notes 157–64 and accompanying text.

226. See, e.g., *supra* Part V.

227. See AO DATA COLLECTION, *supra* note 165 (coding cases in sweepingly broad categories, such as "Personal Injury," "Antitrust," "Patent," "Labor Laws," "Contracts," and the like). Consequently, to perform a non-opinion based study would require a personal examination of actual case files, which would not only be practically and economically prohibitive but also vulnerable to the same type of subjectivity in assessment that haunts all decision-based studies.

228. See *supra* notes 196–97 and accompanying text.

Sixth, though limited by the shortcomings of a potentially incomplete data set, it cannot convincingly be argued that decision-based studies are entirely bereft of insights.²²⁹ Case decisions constitute the working field for much of legal scholarship²³⁰ and are the engines often driving behavior and change.²³¹ So it is into those decisions that this Article now turns.

B. The Study Results

Of the 264 cases examined, only 11 were court of appeals rulings, and just two were bankruptcy court rulings.²³² The remaining 251 cases were district court decisions. Most of the decisions resolved Rule 12(b)(6) motions to dismiss a plaintiff’s complaint, filed by and opposed by represented parties—but not all. This Article’s study confirmed *Iqbal*’s application to

229. See Theodore Eisenberg & Geoffrey Miller, *The Role of Opt-Outs and Objectors in Class Action Litigation: Theoretical and Empirical Issues*, 57 VAND. L. REV. 1529, 1542 n.59 (2004) (“Although published opinions are not necessarily representative of the universe of all cases, however, they can lead to important insights.”); Theodore Eisenberg & Sheri Lynn Johnson, *The Effects of Intent: Do We Know How Legal Standards Work?*, 76 CORNELL L. REV. 1151, 1195 (1991) (“Although we acknowledge that published opinions . . . may not be representative of all underlying case findings, this does not mean that one must abandon hope of obtaining useful insights about an area of law from them.”).

230. See Eisenberg & Johnson, *supra* note 229, at 1195 (commenting that published opinions “for most scholars are the full population” and are what “most of us ever work from”).

231. See Clermont & Eisenberg, *supra* note 222, at 1560 (“Published opinions are the decisions that move the law.”); Theodore Eisenberg & James A. Henderson, Jr., *Products Liability Cases on Appeal: An Empirical Study*, 16 JUST. SYS. J. 117, 118 (1993) (“Studying published opinions remains valuable for both practical and theoretical reasons. Each litigant who is unsatisfied with the trial court’s disposition of a products liability case faces a decision whether to appeal. That decision is informed by an attorney’s assessment of the state of the law. Hence, published opinions heavily influence the decision of whether to file an appeal. Products liability law as developed in published opinions also guides corporate law departments and plaintiffs’ attorneys in deciding whether to bring, defend, or settle claims.” (footnote omitted)).

232. Those courts of appeals decisions are discussed below. See *infra* notes 236–38 and accompanying text. The two bankruptcy court decisions fell into “no-difference” categories. See *In re Apton Corp.*, 423 B.R. 76 (Bankr. D. Del. Jan. 27, 2010) (denying motion to dismiss in part, having found “plausibility” test satisfied; denying in part because Rule 9(b) is satisfied as to certain claims; granting in part because other claims fail to satisfy Rule 9(b); granting in part because other claims are contradicted by exhibits attached to complaint); *In re Qualia Clinical Serv., Inc.*, No. BK-09-80629TJM, Adv. No. A09-8041-TJM, 2009 WL 2868220 (Bankr. D. Neb. Sept. 1, 2009) (denying motion to dismiss, finding pleading sufficient under *Iqbal*).

pharmaceutical and medical device pleadings that were prepared by *pro se* litigants,²³³ that asserted counterclaims,²³⁴ and that were resolved on motions for judgments on the pleadings (with the courts noting that Rule 12(c) borrows the Rule 12(b)(6) standards).²³⁵

For ease of analysis, the cases were grouped into five 3-month intervals (although the first interval included the additional 13 post-*Iqbal* days from the month of May 2009). Thus, the first interval encompassed the last days of May 2009, along with June, July, and August 2009; the second interval encompassed September, October, and November 2009; the third interval encompassed December 2009 and January and February 2010; the fourth interval encompassed March, April, and May 2010; and the fifth and final interval encompassed June, July, and August 2010.

233. See *Sorrentino v. Barr Labs., Inc.*, No. 5:09-CV-0591 (GTS/RFT), 2010 WL 2026135, at *3 (N.D.N.Y. May 20, 2010) (“[T]he clarified plausibility standard that was articulated by the Supreme Court in *Twombly* governs *all* claims, including claims brought by *pro se* litigants (although the plausibility of those claims is to be assessed generously, in light of the special solicitude normally afforded *pro se* litigants).”); *Taylor v. Squibb Pharms., Civ. No. 09-4196 (FLW)*, 2010 WL 1133447, at *1 (D.N.J. Mar. 19, 2010) (“The Court need not, however, credit a *pro se* plaintiff’s ‘bald assertions’ or ‘legal conclusions.’”); see also *Tyler v. Bristol-Meyer Squibb*, No. 8:10CV107, 2010 WL 1664967 (D. Neb. Apr. 23, 2010); *Campbell v. Sebelius*, No. C09-1515JLR, 2010 WL 1576696 (W.D. Wash. Apr. 20, 2010); *Coleman v. State Sup. Ct.*, 697 F. Supp. 2d 493, 503 (S.D.N.Y. 2010); *Porter v. Fnu Thadani*, No. 10-cv-056-PB, 2010 WL 1052214 (D.N.H. Mar. 15, 2010); *Lewis v. Abbott Labs.*, No. 08-Civ-7480 (SCR/GAY), 2009 WL 2231701 (S.D.N.Y. July 24, 2009).

234. See *Pfizer v. Apotex Inc.*, Nos. 08-cv-7231, 09-cv-6053, 2010 WL 2649841, at *4, *14–15 (N.D. Ill. June 30, 2010); *AstraZeneca AB v. Mylan Labs. Inc.*, Nos. 00-Civ-6749, 03-Civ-6057, M-21-81 (B&J), MDL No. 1291, 2010 WL 2079722 (S.D.N.Y. May 19, 2010); *Everett Labs. Inc. v. River’s Edge Pharm., LLC*, Civ. No. 09-3458, 2010 WL 1424017, at *4–6 (D.N.J. Apr. 8, 2010); *Elan Pharma Int’l Ltd. v. Lupin Ltd.*, Civ. No. 09-1008 (JAG), 2010 WL 1372316 (D.N.J. Mar. 31, 2010); *Bayer Schera Pharma AG v. Sandoz, Inc.*, Nos. 08-Civ-03710 (PGG), 08-Civ-08112 (PGG), 2010 WL 1222012 (S.D.N.Y. Mar. 29, 2010); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 346 (D.N.J. Aug. 27, 2009).

235. See *McCoy v. Pfizer, Inc.*, No. 4:09-CV-496, 2010 WL 3365284, at *1 (E.D. Tex. Aug. 3, 2010); *AstraZeneca AB v. Apotex Corp.*, Nos. 01-Civ-9351, M-21-81 (BSJ), MDL No. 1291, 2010 WL 2541180, at *2 (S.D.N.Y. June 9, 2010); *Pettit v. SmithKline Beecham Corp.*, No. 2:09-cv-00602, 2010 WL 1463479, at *1–2 (S.D. Ohio. Apr. 13, 2010); *Cnty. of Santa Clara v. Astra USA, Inc.*, No. C-05-03740-WHA, 2010 WL 1038464, at *4 (N.D. Cal. Mar. 19, 2010); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 209 (E.D. Pa. 2009).

By category, the groupings (by interval periods) of this cohort of 264 pharmaceutical and medical device cases totaled as follows (with the numbers in parenthesis representing the percentage that each total represented for the designated interval):

<i>Iqbal</i> Grouping (All Cases)	May- Jun-July- Aug 2009	Sep- Oct- Nov 2009	Dec 2009 Jan- Feb 2010	Mar- Apr- May 2010	Jun- Jul- Aug 2010	Totals (All Intervals)
No- Difference (defeated)	8 (17.4%)	7 (25.9%)	15 (24.6%)	17 (23.3%)	18 (31.6%)	65 (24.6%)
No- Difference (legal bar)	20 (43.5%)	10 (37.0%)	20 (32.8%)	30 (41.1%)	15 (26.3%)	95 (36.0%)
No- Difference (combined)	9 (19.6%)	6 (22.2%)	9 (14.8%)	10 (13.7%)	14 (24.6%)	48 (18.2%)
Possible- Difference	2 (4.3%)	1 (3.7%)	8 (13.1%)	6 (8.2%)	4 (7.0%)	21 (8.0%)
Yes- Difference	1 (2.2%)	1 (3.7%)	2 (3.3%)	0 (0%)	0 (0%)	4 (1.5%)
Mixed- Difference	6 (13.0%)	2 (7.4%)	7 (11.5%)	10 (13.7%)	6 (10.5%)	31 (11.7%)
Totals: (all categories)	46	27	61	73	57	264

For a more accessible view of these results, the data can be conflated down into a natural pairing. When the three “no-difference” categories are folded together and the three remaining “possible-difference,” “yes-difference,” and “mixed-difference” categories are folded together, the resulting data appears like this:

<i>Iqbal</i> Grouping (All Cases)	May- Jun-July- Aug 2009	Sep- Oct- Nov 2009	Dec 2009 Jan- Feb 2010	Mar- Apr- May 2010	Jun- Jul- Aug 2010	Totals (All Intervals)
No- Difference (all categories)	37 (80.4%)	23 (85.2%)	44 (72.1%)	57 (78.1%)	47 (82.5%)	208 (78.8%)
Potential- Difference (all categories)	9 (19.6%)	4 (14.8%)	17 (27.9%)	16 (21.9%)	10 (17.5%)	56 (21.2%)
Totals: (all categories)	46	27	61	73	57	264

Readers will draw their own conclusions from these raw results; ample room for many different opinions on this data exists. Two conclusions seem defensible, or at least facially so. The notion that *Iqbal* is ushering in a veritable torrent of new dismissals in pharmaceutical and medical device litigation is an untenable conclusion to draw on the basis of this Article’s study. Almost 79% of the time, *Iqbal* simply did not affect dispositive pleading motions in this cohort of cases. But equally unconvincing seems to be the conclusion that *Iqbal*’s effect on pharmaceutical and medical device cases is so negligible as to be inconsequential. In about 21% of the cases studied, *Iqbal* was—based on language used in the opinions by the deciding courts—possibly impactful to all or part of the court’s disposition of a pending motion to dismiss. It hardly seems credible to discount as inconsequential anything that happens about 21% of the time.

This frequency is reasonably mirrored by the court of appeals data set, although that set suffers from the limitations of a much smaller sampling total. Nonetheless, of the 11 court of appeals decisions encompassed within this study, eight (72.7%) fell within the “no-difference” categories and only three (27.3%) fell within the remaining categories. The only “yes-difference” court of appeals opinion is also the second-earliest such decision, released on July 14, 2009, less than two months after *Iqbal*.²³⁶ The only “possible-difference” court of appeals opinion is a very brief affirmance of the dismissal of a claim that seems to have failed to even offer a formulaic recitation of elements.²³⁷ And the only “mixed-difference” court of appeals opinion was a two-judge “summary order” affirmance of an antitrust complaint that, in part, failed for the same conscious parallelism reason that had defeated *Twombly*.²³⁸ The raw court of appeals detail follows:

236. *Harris v. Amgen, Inc.*, 573 F.3d 728 (9th Cir. 2009). The opinion also represents the most cursory treatment of *Iqbal* among the 11 court of appeals cases. The lion’s share of the *Harris* opinion is devoted to reviewing (and reversing) the district court’s conclusion that the plaintiffs in this ERISA dispute lacked standing. *Id.* at 732–36. The remaining portion of the opinion reviews (and reverses) the district court’s denial of leave to amend. *Id.* at 736–37. In that second portion, in a footnote, the court of appeals noted that the trial judge had also found “that the Complaint made insufficient factual allegations.” *Id.* at 736 n.6. The court’s one-sentence treatment of that issue follows, preceding citations to both *Twombly* and *Iqbal*: “We agree with the district court that the Complaint does not contain factual allegations against the individual defendants sufficient ‘to raise a right to relief above the speculative level.’” *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1953 (2009)).

237. *Myers-Armstrong v. Actavis Totowa, LLC*, No. 09-16055, 2010 WL 2232652 (9th Cir. June 3, 2010). In this short, nine-paragraph decision, the Ninth Circuit Court of Appeals found the complaint failed to allege many of the elements essential to the various claims. *Id.* at *1–2. Although under the “plausibility” paradigm, “a formulaic recitation of the elements of a cause of action” does not suffice, it appears that the Ninth Circuit found the plaintiff in *Myers-Armstrong* to have failed to meet even that level of pleading. *Id.* (quoting *Twombly*, 550 U.S. at 555).

238. *RxUSA Wholesale Inc. v. Alcon Labs.*, No. 09-4406-CV, 2010 WL 3393737 (2d Cir. Aug. 30, 2010). In another unusual and short (four-paragraph) opinion, the Second Circuit Court of Appeals affirmed an antitrust dismissal that was “entirely conclusory” and that failed to “place its allegations of parallel conduct in a context that suggests a prior agreement.” *Id.* at *1. Not only is the opinion unpublished and labeled a “Summary Order,” it was also a two-judge dispositional panel, after one of the three panel judges recused. *Id.* at *1 n.1.

<i>Iqbal</i> Grouping (Court of Appeals cases only)	May- Jun-July- Aug 2009	Sep- Oct- Nov 2009	Dec 2009 Jan-Feb 2010	Mar- Apr- May 2010	Jun- Jul- Aug 2010	Totals (All Intervals)
No- Difference (defeated)	0 (0%)	2 (100%)	1 (100%)	0 (0%)	0 (0%)	3 (27.3%)
No- Difference (legal bar)	2 (66.7%)	0 (0%)	0 (0%)	1 (100%)	1 (25%)	4 (36.4%)
No- Difference (combined)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (9.1%)
Possible- Difference	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (9.1%)
Yes- Difference	1 (33.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (9.1%)
Mixed- Difference	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (9.1%)
Totals: (all categories)	3	2	1	1	4	11

The volume of the “no-difference” cases is informing, but it is the substance of the remaining cases that merits a deeper, more searching inspection. What do the cases comprising the three potential-difference categories teach? Those three categories—“possible-difference,” “yes-difference,” and “mixed-difference”—total 56 cases, representing 21.2% of the total pharmaceutical and medical device cohort of cases. As a group, they bear additional attributes that may enhance this Article’s assessment.

1. The “Difference” Cases—Timing

The fluctuation of this group of “possible-difference,” “yes-difference,” and “mixed-difference” cases over the five time intervals studied is noteworthy. In the interval immediately following the release of the *Iqbal* decision, 19.6% of the cases examined show a possible *Iqbal* effect. That percentage drops noticeably during the second interval to 14.8%, nearly doubles during the third interval to 27.9%, then diminishes during the

fourth interval to 21.9%, and fades again during the fifth interval to 17.5%—a level more than two points lower from where it had started. What might explain this rate of movement? Perhaps it is mere coincidence, portending nothing.

Or perhaps a clue to explain this fluctuation might lie in a recent study of federal court civil processing statistics performed by the Institute for the Advancement of the American Legal System at the University of Denver.²³⁹ This study of almost 8,000 federal district court cases that had closed over one 12-month period revealed a mean disposition time for Rule 12 dispositive motions of 129.78 days—in other words, on average, more than four months elapses between the date such a motion is filed and the date it is ruled upon.²⁴⁰ If that average were applied to this pharmaceutical and medical device case cohort, the motions that comprise the third interval period (the one revealing the dramatic jump in potential-dismissal cases) would have begun to be filed, on average, in late July 2009, just a few months after the *Iqbal* decision was released on May 18, 2009.²⁴¹

Mindful of that mean disposition time, the interval data fluctuations in pharmaceutical and medical device cases could be explained this way: a period of early quiescence during which litigants studied the *Iqbal* decision and busied themselves preparing new *Iqbal* motions, followed by a period marked by that higher number of such motions being filed, followed by, in due course, rulings by the district courts on those motions that reveal an initially sharpened use of Rule 8(a), with that sharpness now dulling back over time.

Whether this surmise proves accurate, only time will tell. But such a path would align with impressions from some of those attending a recent conference on federal practice: “Some thoughtful voices suggested that just one year after the *Iqbal* decision, practice is already settling down in patterns that reflect very little change in pleading standards. The increased flurry of

239. INST. FOR ADVANCEMENT OF AM. LEGAL SYS., CIVIL CASE PROCESSING IN THE FEDERAL DISTRICT COURTS: A 21ST CENTURY ANALYSIS (2009) [hereinafter IAALS STUDY], available at <http://www.du.edu/legalinstitute/pubs/PACER%20FINAL%201-21-09.pdf>. This study examined civil cases that closed during the pre-*Twombly*/pre-*Iqbal* period from October 1, 2005 through September 30, 2006 in the district courts of eight federal districts. *Id.* at 20–26 (noting data collection methodology from the districts of Arizona, Colorado, Delaware, Idaho, and Oregon, and from the Eastern District of Missouri, the Eastern District of Virginia, and the Western District of Wisconsin).

240. *Id.* at 48. The data reflect the mean disposition period for motions filed under Rules 12(b), 12(c), and 12(f).

241. The third interval begins with December 1, 2009. *See id.* at 40. July 24, 2000 is 130 days before December 1, 2009.

motions that tested the standards may well abate once this lesson is learned.”²⁴² Perhaps Seventh Circuit Judge Diane S. Sykes was also prescient, at least in the long-run, when she predicted that “most judges” would be “cautious in applying these standards.”²⁴³ Several recent appellate decisions seem to agree.²⁴⁴ This Article’s pharmaceutical and medical device case findings are, at the very least, not inconsistent with those impressions and the pattern they imagine.

In fact, the civil processing data actually dovetail with those impressions. The Institute for the Advancement of the American Legal System’s study found that, even in the pre-*Iqbal* and pre-*Twombly* period of October 2005 through September 2006, “[s]lightly less than 30% of all Rule 12 motions were denied in their entirety.”²⁴⁵ This Article’s study of pharmaceutical and medical device cases is roughly consistent with that finding during

242. See Kravitz Memo, *supra* note 168, at 4. The conference also heard competing views, which believed that access to the federal courts had been limited: “They protested that mere statistics counting dismissal rates cannot count the things that truly count: the number of cases that, if not dismissed, would have survived to victory on the merits; the cases that are not filed; the diminution in private enforcement of essential public policies.” *Id.*

243. See Jeffrey, *supra* note 209, which quoted Judge Sykes’s remarks at the American Constitution Society’s annual conference held in mid-June 2010, where she commented that “she could understand the ‘alarm’ of plaintiffs attorneys who may feel their clients face a higher threshold before they can file a complaint. But she went on to say that ‘eventually a body of case law will be developed to tell courts how heavy handed this standard needs to be.’ In the meantime she said, ‘I expect most judges to be cautious in applying these standards.’”

244. See *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 n.17 (3d Cir. 2010) (noting that, although originally believing the plausibility standard “repudiated” earlier Supreme Court precedent, the court is now “not so sure”); *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 119 (2d Cir. 2010) (noting that the *Twombly* opinion itself “belied” the notion that a heightened pleading standard is required); *Bissessur v. Ind. Univ. Bd. of Trs.*, 581 F.3d 599, 603 (7th Cir. 2009) (“Our system operates on a notice pleading standard; *Twombly* and its progeny do not change this fact.”). But see *al-Kidd v. Ashcroft*, 580 F.3d 949, 977 (9th Cir. 2009), *cert. granted in part*, 79 U.S.L.W. 3062 (U.S. 2010) (“Post-*Twombly* plaintiffs face a higher burden of pleading facts, and courts face greater uncertainty in evaluating complaints.”).

245. See IAALS STUDY, *supra* note 239, at 47–48 (“It is important to note that these statistics on Rule 12 motions reflect motions filed and decided prior to the U.S. Supreme Court’s 2007 decision in *Bell Atlantic v. Twombly*, which many scholars and practitioners believe may dramatically affect filing rates of Rule 12(b)(6) motions. However, contrary to some post-*Twombly* pronouncements that Rule 12(b)(6) had been in a sleepy state of relative disuse before the Supreme Court’s ruling, the data here suggest that motions to dismiss were in fact well-used by attorneys, and frequently granted by the district courts, in the pre-*Twombly* era.” (footnotes omitted)).

the second interval (25.9%), third interval (24.6%), fourth interval (23.6%), and fifth interval (31.6%).²⁴⁶ In short, during the first 15-and-a-half months after *Iqbal*, claimants were having roughly about the same rate of success in completely fending off pleading motions in pharmaceutical and medical device cases as all federal pleaders had before *Iqbal* (and, indeed, before *Twombly*).

The choice of syntax used by the courts in resolving dispositive pleadings motions in pharmaceutical and medical device cases suggests that many judges are interpreting *Iqbal* as not especially consequential. Some courts have described the “plausibility” test as merely “clarifying” existing dismissal standards,²⁴⁷ emphasizing that the obligations on federal pleaders remain “liberal” ones²⁴⁸ that have *not* been “heightened”²⁴⁹ or “changed,”²⁵⁰ and that the

246. See *supra* Part VI.B. During the first interval, the one encompassing the first three-and-a-half months after *Iqbal*, the rate of complete pleader victories ebbed to its lowest point, 17.4%, but then rebounded dramatically in the intervals that followed. See *supra* Part VI.B. This statistic is consistent with the notion that the courts originally may have given *Iqbal* an aggressive application in pharmaceutical and medical device cases and then quickly began retrenching from that inclination.

247. See *In re Schering-Plough ERISA Litig.*, No. 08-CV-1432 (DMC), 2010 WL 2667414, at *3 (D.N.J. June 29, 2010); *Sepracor Inc. v. Teva Pharms. USA, Inc.*, No. 09-cv-01302 (DMC) (MF), 2010 WL 2326262, at *4 (D.N.J. June 7, 2010); *CIBA Vision Corp. v. De Spirito*, No. 1:09-cv-01343-JOF, 2010 WL 553233, at *4 (N.D. Ga. Feb. 10, 2010); see also *Koch v. I-Flow Corp.*, 715 F. Supp. 2d 297, 302 (D.R.I. 2010) (commenting that *Iqbal* does “not mark a radical change in federal pleading standards, but rather a fine tuning of sorts”).

248. See *Pittsburgh Standard Spine Co. v. Lanx, Inc.*, No. 09-cv-01062-REB-MJW, 2010 WL 2604985, at *1 (D. Colo. June 28, 2010); *Crisp v. Stryker Corp.*, No. 5:09-cv-02212, 2010 WL 2076796, at *2 (N.D. Ohio. May 21, 2010).

249. See *Turner v. Mylan, Inc.*, No. 4:09-CV-1816-TIA, 2010 WL 1608852 (E.D. Mo. Apr. 20, 2010). The *Turner* decision is illustrative of judicial persistence with a very gentle approach to pleadings-testing, notwithstanding “plausibility.” In *Turner*, the court rejected the argument that the pleading failed *Iqbal* because it lacked specific allegations regarding the nature of the product’s failure:

[I]t would be rare for a plaintiff at the time of the filing of a complaint to have more factual information than . . . that the defendants designed, manufactured and marketed the specific product; that the decedent used the product properly for its intended use on a date certain; and that the product directly and proximately caused her death.

Id. at *2 (quoting *Houston v. Mylan, Inc.*, No. 8:09CV306 (D. Neb. Nov. 20, 2009)).

250. See *Elan Pharma Int’l Ltd. v. Lupin Ltd.*, Civ. No. 09-1008 (JAG), 2010 WL 1372316, at *4 (D.N.J. Mar. 31, 2010) (citing *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1357 n.4 (Fed. Cir. 2007)) (commenting that “the Federal Circuit considered whether the Supreme Court’s decision in *Twombly* changed the pleading requirements of Rule 8(a) in patent infringement actions, and concluded that it did not”).

obligation remains notice-pleading.²⁵¹ The “plausibility” inquiry, explained one court, erects “two easy-to-clear hurdles.”²⁵² A few courts even remarked that motions to dismiss are still viewed with “disfavor” and are “rarely granted.”²⁵³ Moving parties have been admonished that, notwithstanding the “plausibility” test, pleaders are still “not required to prove the merits of [their] claim at the pleading stage, but only to give fair notice,” with detail-seeking to follow during discovery.²⁵⁴ “[P]recise, detailed allegations” are still not required, insisted one court.²⁵⁵ A pleading that “lack[ed] detailed factual allegations” survived, explained another judge, because under the “plausibility” test, all those allegations are “treated as entirely accurate, however true or misguided a fact finder might ultimately find them to be.”²⁵⁶ Courts have refused to dismiss some pleadings even after characterizing them as “[c]ursory,”²⁵⁷ “minimal,”²⁵⁸ and “primarily . . . formulaic recitations.”²⁵⁹ Other

251. See *On-Site Screening, Inc. v. United States*, No. 09-C-6084, 2010 WL 3025039, at *2 (N.D. Ill. July 30, 2010) (“Our system operates on a notice pleading standard; *Twombly* and its progeny did not change this fact.”); *Genzyme Corp. v. Disc. Drugs Wis., Inc.*, No. 08-C-5151, 2010 WL 744275, at *2 (N.D. Ill. Feb. 26, 2010) (“[T]he notice pleading standard remains [intact].”); *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1376 (N.D. Ga. 2010) (citing *Twombly* and *Iqbal*, but noting that “[g]enerally, notice pleading is all that is required for a valid complaint”).

252. *Warsco v. Becton Dickinson & Co.*, No. 1:08-CV-5-TS, 2009 WL 1874375, at *2 (N.D. Ind. June 30, 2009).

253. See *Whitener v. Pliva, Inc.*, Civ. No. 10-1552, 2010 WL 3021866, at *2 (E.D. La. July 29, 2010) (citing 1997 and 1982 precedent, “viewed with disfavor and rarely granted”); *Jacobson v. Celgene Corp.*, Civ. No. 09-4329 (FSH) (PS), 2010 WL 1492869, at *5 (D.N.J. Apr. 14, 2010) (citing 1995 precedent, “district courts generally disfavor Rule 12(b)(6) motions”); *Brennon v. Pfizer, Inc.*, Civ. No. 09-1093, 2009 WL 2525180, at *2 (W.D. La. Aug. 17, 2009) (quoting 1982 precedent, “viewed with disfavor” and “rarely granted”). Some courts even persist in incanting the “no-set-of-facts” mantra from *Conley* that the Supreme Court “retired” in *Twombly*. See, e.g., *Ervin v. Guidant Corp.*, Civ. No. 08-03783, 2010 WL 3081306, at *2 (E.D. La. Aug. 5, 2010).

254. *Waguespack v. Plivia USA, Inc.*, Civ. No. 10-692, 2010 WL 2086882, at *3 (E.D. La. May 24, 2010); see also *Woodcock v. Mylan, Inc.*, 661 F. Supp. 2d 602, 612 (S.D.W. Va. 2009) (denying a dismissal, explaining that to rule otherwise “would be to impose a heightened pleading standard that would require the plaintiff to produce evidence before discovery has commenced”).

255. *Ivory v. Pfizer, Inc.*, Civ. No. 09-0072, 2009 WL 3230611, at *5 (W.D. La. Sept. 30, 2009).

256. *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2009 WL 2433468, at *8–9 (S.D.W. Va. Aug. 3, 2009).

257. See *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 379 (E.D.N.Y. 2010).

258. See *Fellner v. Tri-Union Seafoods, L.L.C.*, No. 06-CV-0688 (DMC), 2010 WL 1490927, at *7 (D.N.J. Apr. 13, 2010).

courts have rejected dismissal motions with a tint of exasperation, deriding that the contested allegations were “as specific as possible,”²⁶⁰ or musing that it was “not clear how much more specific the complaint could be.”²⁶¹ One judge discounted a movant’s contention that a pleading ought to be dismissed as “‘conclusory’ and implausible,” by explaining that such an argument represented “a premature attack on the factual merits.”²⁶² Yet another court rejected a defendant’s statute of limitations challenge, premised on the fact that the only conduct alleged against that defendant had occurred too long ago for the claim to still be ripe, by reasoning that it was nevertheless “plausible” that the pleaded conduct might have persisted long enough to preserve the timeliness of the claim.²⁶³ These sorts of analyses certainly seem to dovetail with the “cautious” application of *Iqbal* that Judge Sykes foresaw.

Nevertheless, although it is certainly true that courts, incanting the “plausibility” lingo, have found pharmaceutical and medical device pleadings to be sufficient to withstand the *Iqbal* dismissal inquiry,²⁶⁴ it is also true that courts have incanted the same

259. See *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 717 (C.D. Ill. 2010).

260. *Cruz v. Mylan, Inc.*, No. 8:09-CV-1106-T17-EAJ, 2010 WL 598688, at *4 (M.D. Fla. Feb. 17, 2010).

261. *Boroff v. Alza Corp.*, 685 F. Supp. 2d 704, 708 (N.D. Ohio 2010).

262. *Merix Pharm. Corp. v. EMS Acquisition Corp.*, No. 09-C-5871, 2010 WL 481247, at *8 (N.D. Ill. Feb. 4, 2010) (“A complaint need only allege damages; its failure to ‘establish’ them is no basis for dismissal. And neither is a defendant’s self-serving and *ex ante* conclusion that the plaintiff will be unable to prove damages when the burden of doing so arrives in due course.”).

263. See *Sales Bd. v. Pfizer, Inc.*, 644 F. Supp. 2d 1127, 1134–35 (D. Minn. 2009) (“Pfizer asserts that Sales Board’s claims are barred because the only act alleged in the Complaint attributable to Pfizer is the use of the ‘Strategic Selling Guide Featuring *Action Selling*’ at the first national sales training meeting in 2002. [The court had earlier noted that ‘the cut-off date for the statute of limitations is March 11, 2003.’] . . . In the Court’s experience, and as a matter of common sense, it is plausible that a selling guide ‘implemented’ at a large corporation’s national sale training meeting in 2002 would still be in use as of March 11, 2003.” (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009), and the Supreme Court’s admonition that the “plausibility” inquiry is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense”)).

264. See, e.g., *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1180 (9th Cir. 2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)) (finding allegations were sufficient “to ‘nudge[] [Appellants’] claim[s] across the line from conceivable to plausible”), *cert. granted*, 130 S. Ct. 3411 (2010); *Meijer, Inc. v. Ferring B.V.*, 585 F.3d 677, 693 (2d Cir. 2009) (finding allegations “sufficient to plausibly support a finding” of fraud, because the

language in dismissing pleadings.²⁶⁵ Other courts have acknowledged that *Iqbal* “modified”²⁶⁶ or “transformed”²⁶⁷ the dismissal standards, though they differ in assessing the degree of the change. Some see the change as modest,²⁶⁸ others as significant

“pleadings could plausibly lead to additional findings . . . which is all that is required at this stage of the litigation”); *Pettit v. SmithKline Beecham Corp.*, No. 2:09-cv-00602, 2010 WL 1463479, at *3 (S.D. Ohio Apr. 13, 2010) (finding allegations were “sufficient to state a plausible claim for relief”); *Ivory v. Pfizer, Inc.*, Civ. No. 09-0072, 2009 WL 3230611, at *3 (W.D. La. Sept. 30, 2009) (finding allegations “are more than sufficient ‘to raise a right to relief above the speculative level’”); *In re Actiq Sales & Mktg. Practices Litig.*, Nos. 07-4492, 09-431, 2009 WL 2581717, at *4 (E.D. Pa. Aug. 21, 2009) (finding complaint “sufficient to nudge the allegations over the line from that which is merely ‘speculative’ and ‘conceivable,’ to that which states ‘a claim to relief that is plausible on its face’”). In a curious discussion of the “plausibility” standard, the Ninth Circuit in *Siracusano* seemed to find that the existence of a pleading equipoise was proper cause for finding a challenged pleading sufficient. See *Siracusano*, 585 F.3d at 1183 (“[T]he inference that Appellees withheld the information regarding Zicam and anosmia intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation.”). In both *Twombly* and *Iqbal*, the Supreme Court seemed to embrace precisely the opposite conclusion: that the existence of a pleading equipoise—where the pleading is just as consistent with culpable conduct as with nonculpable conduct—should doom the complaint. Cf. *Iqbal*, 129 S. Ct. at 1951–52 (ruling that pleading fails where factual allegations are consistent with two different inferences, one of lawful conduct and one of unlawful conduct, and the latter inference cannot be plausibly drawn); *Twombly*, 550 U.S. at 557 (ruling that pleading fails where allegations are “merely consistent with” unlawful conduct, rather than “plausibly suggesting” unlawful conduct).

265. See, e.g., *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2010 WL 2464746, at *8 (D.N.J. June 9, 2010) (dismissing claims as “[f]ar from plausible” and “based purely on speculation and suspicion”); *Peterson v. Breg, Inc.*, No. 2:09-cv-2044 JWS, 2010 WL 2044248, at *2 (D. Ariz. Apr. 29, 2010) (dismissing claims that lack factual allegations “plausibly suggestive of a claim entitling [them] to relief”); *Burks v. Abbott Labs.*, Civ. No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *3 (D. Minn. Apr. 20, 2010) (dismissing allegations that are “a formulaic recitation” of elements and “legal conclusions”); *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSx), 2010 WL 1339948, at *3 (C.D. Cal. Mar. 30, 2010) (dismissing claims that “plead nothing more than the sheer possibility” of a claim); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 418 (D. Del. 2010) (dismissing claims that do not rise “above the speculative level”).

266. See *In re Qualia Clinical Serv., Inc.*, No. BK-09-80629TJM, Adv. No. A09-8041-TJM, 2009 WL 2868220, at *1 (Bankr. D. Neb. Sept. 1, 2009).

267. *Geesey v. Stryker Corp.*, Civ. No. 09-2988, 2010 WL 3069630, at *2 (E.D. Pa. Aug. 4, 2010).

268. See *United States ex rel. Laucirica v. Stryker Corp.*, No. 1:09-CV-63, 2010 WL 1798321, at *3 (W.D. Mich. May 3, 2010) (noting that the “plausibility” test “does not change the notice-pleading standards” but does

in imposing a “more stringent”²⁶⁹ or “heightened” standard,²⁷⁰ and others as representing “a radical change in the long-thought to have been settled pleading requirements derived from *Conley v. Gibson*.”²⁷¹

The explanation offered for the timing trend identified here may prove, over time, to have been mistaken. But this much is certain: claimants who face dispositive pleadings attacks in pharmaceutical and medical device litigation are having a greater rate of success in completely defeating those motions today than federal pleaders had in the year before the “plausibility” test arrived with *Twombly*, and they are losing such motions today at the lowest rate since *Iqbal* was decided.

2. The “Difference” Cases—Geographic Concentrations

When examined geographically, the concentrations of these 56 “possible-difference,” “yes-difference,” and “mixed-difference” cases are unsurprising, with New Jersey and Pennsylvania as possible exceptions. The table below identifies the sources of these 56 cases by originating district and lists those districts’ respective percentages of the total volume of all federal civil cases pending as of September 30, 2009.²⁷²

“take[] a step away from the long-standing ‘no-set-of-facts’ standard established by *Conley*”); see also *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1381 (N.D. Ga. 2010) (“In the post-*Twombly* world, the complaint is judged as it is and not on whether a set of facts could be imagined that would support the claim.”).

269. See *Johns v. Bayer Corp.*, No. 09-CV-1935-DMS (JMA), 2010 WL 2573493, at *3 (S.D. Cal. June 24, 2010) (noting the “more stringent” standard, but finding the pleading sufficient).

270. See *Albergo v. Immunosyn Corp.*, No. 09-CV-2653-DMS (AJB), 2010 WL 3339398, at *2 (S.D. Cal. Aug. 24, 2010) (noting that in *Iqbal* and *Twombly*, “the Supreme Court established a more stringent standard of review for 12(b)(6) motions”), amended, 2010 WL 3895364 (S.D. Cal. Sept. 30, 2010); *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *4 (W.D. Pa. June 16, 2010) (noting that the standard “seemingly shifted from simple notice pleading to a more heightened form of pleading”); *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 715, 718 (C.D. Ill. 2010) (noting “heightened” standard, but finding pleading sufficient).

271. *Pa. Emp. Benefit Trust Fund v. Zeneca*, 710 F. Supp. 2d 458, 479 (D. Del. 2010).

272. According to the Administrative Office of the United States Courts, the total number of pending civil cases as of September 30, 2009 was 306,816. See ADMIN. OFFICE OF U.S. COURTS, JUDICIAL BUSINESS OF THE UNITED STATES COURTS: 2009 ANNUAL REPORT OF THE DIRECTOR 138 tbl.C-1 (2010), available at <http://www.uscourts.gov/Statistics/JudicialBusiness/JudicialBusiness.aspx?>

Jurisdiction	Jurisdiction's % of Federal Civil Cases	Possible / Yes / Mixed Cases	Source Details
U.S. Courts of Appeals	n/a	3	9th Cir.=2 (origin = N.D. Cal.=2) 2d Cir.=1 (origin = E.D.N.Y.=1)
New Jersey (all)	1.95%	12	D.N.J.=12
California (ND, CD, ED)	8.09%	8	N.D.Cal.=4; E.D.Cal.=2; C.D.Cal.=2
New York (SD)	7.52%	6	S.D.N.Y.=6
Ohio (ND, SD)	2.70%	4	N.D.Ohio=3; S.D.Ohio=1
Illinois (ND, CD)	3.01%	3	C.D.Ill.=2; N.D.Ill.=1
Arizona (all)	0.98%	2	D.Az.=2
Georgia (ND)	1.06%	2	N.D.Ga.=2
Minnesota (all)	1.17%	2	D.Minn.=2
Pennsylvania (WD, ED)	21.6%	2	W.D.Pa.=1; E.D.Pa.=1
Texas (ND)	1.08%	2	N.D.Tex.=2
Wisconsin (WD)	0.14%	2	W.D.Wis.=2
Alabama (MD)	0.32%	1	M.D.Ala.=1
Colorado (all)	0.75%	1	D.Colo.=1
Delaware (all)	0.43%	1	D.Del.=1
Court of Int'l Claims (all)	n/a	1	C.I.T.=1
Missouri (ED)	0.73%	1	E.D.Mo.=1
North Carolina (MD)	0.27%	1	M.D.N.C.=1
Vermont (all)	0.10%	1	D.Vt.=1
Washington (WD)	0.69%	1	W.D.Wash.=1

With the exception of New Jersey and Pennsylvania, the concentrations of the “possible-difference,” “yes-difference,” and “mixed-difference” cases relate rationally to the volume levels of civil cases each jurisdiction processes. For example, with the exceptions of New Jersey and Pennsylvania, the two highest sources of these “possible-difference,” “yes-difference,” and “mixed-difference” cases—California and New York (eight cases and six cases, respectively)—also accounted for the highest

doc=/uscourts/Statistics/JudicialBusiness/2009/appendices/C01Sep09.pdf. The individual jurisdiction source data is drawn from this report. *See id.*

percentage of the Nation's federal civil case inventory as of September 30, 2009, with each state's implicated districts accounting for more than 7.5% of the total inventory.²⁷³ As that share of the federal judiciary inventory fell, so, too, did the number of "possible-difference," "yes-difference," and "mixed-difference" cases. The next two largest inventory shares, Ohio and Illinois (each with between 2.5% and 3%), also have the next highest total of these cases (four and three, respectively).²⁷⁴ Three of the next four largest inventory shares, Arizona, Georgia, and Minnesota (with approximately 1% each), also have the next highest total of these cases (two each).²⁷⁵ Finally, most jurisdictions having less than 1% of the federal civil case inventory each had one case in the "possible-difference," "yes-difference," and "mixed-difference" set.²⁷⁶

New Jersey and Pennsylvania remain obvious outliers in this trend. New Jersey has a disproportionately high number of "possible-difference," "yes-difference," and "mixed-difference" cases (12) in relation to its percentage of the federal inventory (1.95%).²⁷⁷ But New Jersey also had a unique distinction within

273. See *id.* (California (N.D., C.D., E.D.): 24,811 / 306,816 = 8.09%; New York (S.D.): 23,073 / 306,816 = 7.52%). Although not truly decisions with a "source" in California, the two court of appeals decisions in this set are both Ninth Circuit opinions that originated in California district courts. See *Myers-Armstrong v. Actavis Totowa, LLC*, No. C 08-04741 WHA, 2009 WL 1082026 (N.D. Cal. Apr. 22, 2009), *aff'd*, 382 F. App'x 545 (9th Cir. 2010) (originating from the Northern District of California); *Harris v. Amgen, Inc.*, 573 F.3d 728 (9th Cir. 2009) (originating from the Central District of California).

274. See ADMIN. OFFICE OF U.S. COURTS, *supra* note 272, at 138 tbl.C-1 (Ohio (N.D., S.D.): 8,286 / 306,816 = 2.70%; Illinois (N.D., C.D.): 9,240 cases / 306,816 = 3.01%).

275. See *id.* (Arizona: 3,014 / 306,816 = 0.98%; Georgia (N.D.): 3,250 cases / 306,816 = 1.06%; Minnesota: 3,593 cases / 306,816 = 1.17%). The fourth jurisdiction—the Western District of Wisconsin—had two cases but one of the smallest shares of the federal civil case inventory (0.14%). *Id.* (430 cases / 306,816 = 0.14%). Because the Wisconsin case volume is so small (two cases) and the outlying nature so modest (between a more-than-1% jurisdiction (having two cases) and a less-than-1% jurisdiction (having one case)), this anomaly does not materially undermine this trend.

276. See *id.* (Alabama (M.D.): 989 / 306,816 = 0.32%; Colorado: 2,305 / 306,816 = 0.75%; Delaware: 1,330 / 306,816 = 0.43%; Missouri (E.D.): 2,248 / 306,816 = 0.73%; North Carolina (M.D.): 843 / 306,816 = 0.27%; Vermont: 292 / 306,816 = 0.10%; Washington (W.D.): 2,121 / 306,816 = 0.69%). The only outlier in this group, the Northern District of Texas, was just over the 1% mark, at 1.08%. See *id.* (Texas (N.D.): 3,303 / 306,816 = 1.08%). As with Wisconsin, this modest, one-group-removed anomaly does not materially undermine the trend.

277. See ADMIN. OFFICE OF U.S. COURTS, *supra* note 272, at 138 tbl.C-1 (New Jersey: 5,968 / 306,816 = 1.95%).

the entire pharmaceutical and medical device cohort—on December 30, 2009, the District of New Jersey released 16 separate Plavix products liability opinions, of which seven were “possible-difference,” “yes-difference,” and “mixed-difference” cases. This temporally concentrated release of qualifying opinions was not detected in any other judicial district or state, nor did it occur again in New Jersey either before or after December 30, 2009. Efforts to further explain that New Jersey anomaly (by examining the nature of the Plavix claims, the manner in which they were pleaded, or otherwise) have been unavailing.²⁷⁸ Conversely, the Western and Eastern Districts of Pennsylvania have a disproportionately low number of “possible-difference,” “yes-difference,” and “mixed-difference” cases (2) in relation to their percentage of the federal inventory (21.6%).²⁷⁹ Efforts to further explain the Pennsylvania anomaly were equally unavailing.

Beyond observing that the “possible-difference,” “yes-difference,” and “mixed-difference” categories seem generally to concentrate in higher proportion in those jurisdictions handling larger volumes of federal civil cases (New Jersey and Pennsylvania excepted), no further conclusions from this geographic spread seem obvious.

3. The “Difference” Cases—Amendment Possibility

Although the “possible-difference,” “yes-difference,” and “mixed-difference” cases all (obviously) involved full or partial dismissals, the pleaders were not expressly foreclosed from re-pleading in the substantial majority of them. In 29 of these 56 cases, the dismissing court either confirmed that the dismissal was without prejudice or granted the pleader explicit leave to amend. In another 13 of these cases, the dismissing court did not directly rule whether future amendments would be permitted or future motions for leave considered (thus, the opportunity for a re-pleading in those cases could not be discounted). In the 14 remaining cases, the court’s dismissal was expressly with prejudice. The incidence

278. But one final New Jersey observation can be offered. If this single-day December 30, 2009 anomaly in New Jersey were discounted, and only the “routine” volume of cases were examined, the state would have had five “possible-difference,” “yes-difference,” and “mixed-difference” cases. Given the state’s volume of the federal civil inventory (1.95%), that total is still a bit higher than the 2–3% experienced in Ohio and Illinois (four and three cases, respectively), but the difference obviously becomes far less pronounced. *See id.* (New Jersey: 5,968 / 306,816 = 1.95%).

279. *See* ADMIN. OFFICE OF U.S. COURTS, *supra* note 272, at 138 tbl.C-1 (Pennsylvania (W.D., E.D.): 66,268 / 306,816 = 21.6%).

of this type of result, a with-prejudice dismissal in a “difference” case, was small—it occurred in only 5.3% of the 264 cases in the pharmaceutical and medical device cohort. But the severity can hardly be overstated; these types of with-prejudice dismissals undoubtedly represent the most aggressive *Iqbal* outcome possible—the loss of a claim, based on a pleading failure, without an ability to try again. For this reason, these 14 cases warrant further examination.

In three of these 14 cases, the with-prejudice dismissals were ordered only as to those portions of the products liability cases that the district courts found to be inarguably barred by controlling law;²⁸⁰ as to all other dismissed claims in the cases, the courts’ dismissals were without prejudice.²⁸¹ In another case, the district court dismissed with prejudice an ERISA fiduciary duty dispute, largely by rejecting the plaintiffs’ posited legal theory: the court found implausible allegations that a pharmaceutical company retirement plan committee had breached fiduciary duties owed to employee–investors, because, under existing law, neither a committee member’s personal decision to sell shares of that stock nor the company’s conduct in submitting stock reports would state cognizable ERISA claims.²⁸² As to each of these first four cases,

280. See *Redden v. Smith & Nephew, Inc.*, No. 3:09-CV-1380-L, 2010 WL 2944598, at *6 (N.D. Tex. July 26, 2010) (dismissing fiduciary duty claim with prejudice because, under Texas law, cognizable claim requires that fiduciary status pre-exist agreement at issue, and the plaintiffs admit it did not); *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSx), 2010 WL 1339948, at *4, *6–7 (C.D. Cal. Mar. 30, 2010) (dismissing breach of warranty claims with prejudice because California law denies privity (an essential element in California for warranty claims) in prescription pharmaceutical and medical device cases because “the transaction is between the manufacturer and the physician, not the patient”; also granting motion to strike, with prejudice, design defect claims, failure to warn public or FDA claims, constructive trust claims, and injunction claims as all barred under state law); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 789–90 (D. Minn. 2009) (dismissing claims with prejudice as “obviously preempted” on their face).

281. See *Redden*, 2010 WL 2944598, at *6 (dismissing contract and defamation claims without prejudice); *Adams*, 2010 WL 1339948, at *6–7 (dismissing defect theories, time-barred claims, fraud and misrepresentation claims, and consumer fraud act claims without prejudice); *Riley*, 625 F. Supp. 2d at 780–90 (dismissing manufacturing defect, failure to warn, fraud, express warranty, and loss of consortium claims without prejudice).

282. *Herrera v. Wyeth*, No. 08 Civ. 4688 (RJS), 2010 WL 1028163 (S.D.N.Y. Mar. 17, 2010). The court did invite the plaintiffs’ counsel to explain how the complaint might be amended to cure its deficiencies and, after listening to counsel, the court concluded that most of the proffered amendments would be futile and the one that could be meaningful might be entertained, upon a fuller explanation to the court. *Id.* at *8.

the severity of the with-prejudice dismissals may be muted by the legally untenable nature of the proposed claims.

In another four of the cases, the with-prejudice dismissal was premised (at least in part) on the pleaders' repeated failures to cure the perceived deficiencies.²⁸³ Notwithstanding the with-prejudice culling, there were surviving claims in three of these four cases that would proceed to discovery.²⁸⁴ Here, too, the severity of these dismissals may be understood by the court simply tiring of repeated pleading revisions and by a desire to bring seriatim re-volleying to a final close.²⁸⁵

In two other cases, the with-prejudice dismissals were based in part on the pleaders' failure to request leave to amend.²⁸⁶

283. See *Burks v. Abbott Labs.*, Civ. No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *3–9 (D. Minn. Apr. 20, 2010) (dismissing with prejudice both the manufacturing defect and design defect claims after the fifth try, and dismissing with prejudice the express warranty claim as barred under state law); *CIBA Vision Corp. v. De Spirito*, No. 1:09-cv-01343-JOF, 2010 WL 553233, at *9–10 (N.D. Ga. Feb. 10, 2010) (dismissing claim without granting pleader a fourth try); *Schultz v. TomoTherapy Inc.*, 676 F. Supp. 2d 780, 794 (W.D. Wis. 2009) (dismissing the still-deficient re-pleaded portion of a formerly dismissed claim, this time with prejudice, where claim theory remained unsupported by the factual allegations in the complaint); *Frey v. Novartis Pharm. Corp.*, 642 F. Supp. 2d 787, 789–96 (S.D. Ohio 2009) (denying leave to file second amended complaint, and dismissing manufacturing defect, design defect, and supplier liability counts).

284. See *Burks*, 2010 WL 1576779, at *2–9 (dismissing with prejudice manufacturing defect, design defect, and express warranty claims, but preserving failure to warn claim); *Schultz*, 676 F. Supp. 2d at 784–94 (dismissing certain '33 Act and '34 Act securities fraud claims, but preserving other '33 Act and '34 Act claims); *Frey*, 642 F. Supp. 2d at 789–96 (dismissing manufacturing defect, design defect, and supplier liability counts, but preserving failure to warn and express warranty claims). In the fourth case, dismissed in its entirety, the court faulted the pleader for scarcely trying. See *CIBA Vision Corp.*, 2010 WL 553233, at *9–10, which faults the claimant for having “not made any effort to bring his counterclaims up to the standards articulated in *Twombly* and *Iqbal*,” and notes, as an example, that the pleader’s opposition brief “contains only two legal citations.” “There simply has been no effort by Defendant to explain to Plaintiff or the court why the vague and conclusory allegations raised in his counterclaims are sufficient . . .” *Id.*

285. This notion, although unjust from the perspective of those who are dismissed, is not wholly foreign in the law. See *Baldwin v. Iowa State Traveling Men’s Ass’n*, 283 U.S. 522, 525–26 (1931) (refusing to permit collateral attack on personal jurisdiction loss, reasoning that “[p]ublic policy dictates that there be an end of litigation; that those who have contested an issue shall be bound by the result of the contest”).

286. See *RxUSA Wholesale Inc. v. Alcon Labs.*, No. 09-4406-CV, 2010 WL 3393737, at *2 (2d Cir. Aug. 30, 2010) (refusing leave to amend because pleader did not seek it and because amendment found to be futile); *In re Pfizer Inc. S’holder Derivative Litig.*, No. 09 Civ. 7822 (JSR), 2010 WL 2747447, at *8–11 (S.D.N.Y. July 13, 2010) (refusing leave to amend because pleaders did

In two further cases, the pleaders actually acknowledged that the defendants moving for a with-prejudice dismissal in anesthetic products cases had not, in fact, manufactured the particular anesthetic product allegedly used by the patient–plaintiff.²⁸⁷ Nevertheless, both pleaders opposed dismissal, arguing that the medical records might possibly have been filled out inaccurately and that the brand name on the forms might be a sort of healthcare-shorthand for any anesthetic of this type.²⁸⁸ That these claims were dismissed may not be surprising; that the claims were dismissed with prejudice and without some modest period of post-filing discovery could be denounced as stark.²⁸⁹ One could certainly imagine a highly industrious plaintiff finding the brand-name notation on a medical record, learning about the possible healthcare-shorthand use of that name, and still needing discovery to ferret out the healthcare provider’s purchasing records to confirm which manufacturer’s product was at issue. Indeed, other courts, confronting nearly identical motions to dismiss involving similar products, granted dismissal without prejudice.²⁹⁰

not seek it and because the court read pleaders’ allegations of federal securities non-disclosure, fiduciary duty, and unjust enrichment claims to be self-defeating).

287. See *Timmons v. Linvatec Corp.*, 263 F.R.D. 582 (C.D. Cal. 2010) (where the pleader alleges injury from an unnamed anesthetic, agrees that medical records reveal that “Marcaine” was used, and does not dispute that the moving defendant did not distribute, manufacture, or sell it); *Combs v. Stryker Corp.*, No. 2:09-cv-02018-JAM-GGH, 2009 WL 4929110, at *2 (E.D. Cal. Dec. 14, 2009) (where the pleader alleges injury from “Marcaine” anesthetic, but concedes that the moving defendant did not distribute or sell it).

288. See *Timmons*, 263 F.R.D. at 583 (noting the plaintiffs’ argument that “they sued the eight anesthetic manufacturer defendants in this case on the ground that one of them may have manufactured the [anesthetic] administered to [the plaintiff]”); *Combs*, 2009 WL 4929110, at *2 (noting plaintiffs’ argument that “one cannot trust the brand name that is written in the medical records” and that the plaintiff “could have been given any one of a number of anesthetic drugs”).

289. In both cases, the pleaders urged the court to forebear (or at least to forebear a with-prejudice dismissal) until after discovery. See *Timmons*, 263 F.R.D. at 585 (“Plaintiffs request discovery in order to identify the anesthetic used, arguing that discovery may reveal which one of the eight anesthetic manufacturer defendants they sued, if any, manufactured the anesthetic Mrs. Timmons received.”); *Combs*, 2009 WL 4929110, at *2 (“They ask the Court not to dismiss their claims against Defendants at this time, or to do so without prejudice so that claims may be re-filed, should discovery reveal that the drug given to Julie was actually not Marcaine but rather another drug . . . which was distributed and sold by Defendants during the relevant time period.”).

290. See *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *16–17 (W.D. Pa. June 16, 2010) (also a Marcaine case; granting

Nonetheless, one of the courts noted that familiar pleading procedures may permit a plaintiff, when confronting a situation such as this, to use fictitious-name practice to preserve the pleading but in a manner that avoids imposing unwarranted costs on that group of named defendants who will bear no liability to the plaintiff.²⁹¹ This procedural opportunity, the manner of the pleading, and the claimants' inability to convince their courts that they had made diligent pre-filing efforts in attempting to unearth accurate product information may all explain the courts' use of with-prejudice dismissals in these cases.²⁹²

Finally, in the last two cases, the court dismissed with prejudice products claims as federally preempted, finding that the pleaders had failed to allege why the allegations survived under the "parallel claims" preemption exception recently embraced by the Supreme Court.²⁹³ This use of a with-prejudice dismissal, prior to limited discovery, also seems aggressive. In one of the two cases, the court did, however, examine individually each of the factual allegations offered by plaintiff in support of his theory, and noted

three-week leave-to-amend period); *Peterson v. Breg, Inc.*, No. 2:09-cv-2044 JWS, 2010 WL 2044248, at *2–3 (D. Ariz. Apr. 29, 2010) (anesthetic and pain pump case; granting 30-day leave-to-amend period); *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSx), 2010 WL 1339948, at *3 (C.D. Cal. Mar. 30, 2010) (anesthetic and pain pump case; granting leave to amend); *Haskins v. Zimmer Holdings Inc.*, No. 1:09-CV-236, 2010 WL 342552, at *2 (D. Vt. Jan. 29, 2010) (anesthetic and pain pump case; granting three-week leave-to-amend period).

291. See *Timmons*, 263 F.R.D. at 585 n.1 ("If Plaintiffs were uncertain, as they admit they are, about the identity of the entity who manufactured the anesthetic administered to Mrs. Timmons, yet concerned about the running of the statute of limitations, they should have proceeded against fictitious 'Doe' defendants, as permitted under California law."). Pursuing informal discovery from the healthcare providers or seeking pre-filing discovery under Rule 27 may be other resources as well. See FED. R. CIV. P. 27(a) (allowing petitions to perpetuate testimony before federal lawsuit is filed).

292. But cf. *Peterson*, 2010 WL 2044248, at *3 (granting leave-to-amend notwithstanding that pleaders "fail to suggest what steps, if any, they would take to identify the appropriate defendant that they have not taken since the complaint was filed, and the court is not persuaded that additional time would assist plaintiffs in identifying the appropriate defendants").

293. See *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *4–11 (D. Colo. May 12, 2010) (magistrate judge's recommendation), *adopted*, 2010 WL 2543570 (D. Colo. June 22, 2010) (finding allegations insufficient to permit a plausible "parallel claim" analysis that would avoid federal preemption, as required under *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008)); *Anthony v. Stryker Corp.*, No. 1:09-cv-2343, 2010 WL 1387790, at *2–4 (N.D. Ohio Mar. 31, 2010) (same finding).

why each could not rescue his claim.²⁹⁴ The second of the two cases, a with-prejudice dismissal of a *pro se* plaintiff on nuanced federal preemption grounds, is less easily understood.²⁹⁵

Whatever judgment one may pass on these with-prejudice dismissals—an unfavorable one (because the claimant was defeated without discovery) or a favorable one (because the defendant and the judiciary were saved further expense on a claim lacking an evident factual basis)—the incidence of these with-prejudice dismissals is small. There remains a pronounced tendency among *Iqbal*-dismissing courts in the pharmaceutical and medical device cohort to not foreclose a pleader’s opportunity—at least once—to conform to the “plausibility” standard.

4. The “Difference” Cases—Information Asymmetry

Although prevalent, this re-pleading opportunity would prove hollow if the *Iqbal*-producing dismissals result from what is now being called an “information asymmetry”—where the factual detail necessary to produce a “plausible” claim is either outside the informal reach of the pleader, or worse still, only in the possession of the adverse party for which the formal discovery rules may prove the only lawful path to access.²⁹⁶ Cases bearing evidence of this sort of “information asymmetry” predicament might be present among these 51 “possible-difference,” “yes-difference,” and “mixed-difference” cases. But, if it exists, the incidence of this predicament appears in the minority of cases.

In about half of “possible-difference,” “yes-difference,” and “mixed-difference” cases (27 out of 56), the detail that the courts held to be missing from the challenged pleading related to information well within the pleaders’ apparent reach (and, sometimes, exclusively within the pleaders’ reach). In seven cases,

294. The plaintiff in *Anthony* had pointed to the fact that the defendant had received two warning letters concerning certain of its products from the FDA, but the court found this allegation insufficient because the plaintiff had not alleged a link between his particular product and the conduct for which the defendant was warned. *Anthony*, 2010 WL 1387790, at *4 (“Without more detailed factual allegations, Anthony’s complaint does not cross the critical threshold that distinguishes the speculative from the plausible.”).

295. See *Franklin*, 2010 WL 2543579, at *3 (noting the plaintiff’s current *pro se* status, although also noting that the pleading at issue was prepared by counsel during a period when the plaintiff was represented).

296. See, e.g., A. Benjamin Spencer, *Plausibility Pleading*, 49 B.C. L. REV. 431, 459 & n.153 (2008) (defining “information asymmetry”); Howard M. Wasserman, *Iqbal, Procedural Mismatches, and Civil Rights Litigation*, 14 LEWIS & CLARK L. REV. 157, 168 (2010) (explaining “information asymmetry”).

the pleaders' counts for product misrepresentation were dismissed for failing to allege what the actual claimed misrepresentation was, and what the pleader actually did in reliance.²⁹⁷ Likewise, a tortious interference claim was dismissed when the pleader failed to identify the business relationships that were purportedly interfered with;²⁹⁸ a defamation and breach of contract claim was dismissed when the pleaders failed to identify the defaming content or the contractual damages they had lost;²⁹⁹ an intentional infliction of emotional distress claim was dismissed when the pleader failed to describe the details of the psychically-injuring event;³⁰⁰ warranty and warning claims were dismissed when the pleader failed to identify the warranty and omitted warnings;³⁰¹ a contract claim was dismissed when the pleader failed to set out the contract;³⁰² a trade dress claim was dismissed when the pleader

297. See *Money v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1100 (FLW), 2009 WL 5216987, at *9–10 (D.N.J. Dec. 30, 2009); *Gonzalez v. Bristol-Myers Squibb Co.*, No. 3:07-cv-00902 (FLW), 2009 WL 5216984, at *7–8 (D.N.J. Dec. 30, 2009); *Smith v. Bristol-Myers Squibb Co.*, No. 3:06-cv-6053 (FLW), 2009 WL 5216982, at *10 (D.N.J. Dec. 30, 2009); *Bunting v. Bristol-Myers Squibb Co.*, No. 3:06-cv-6052 (FLW), 2009 WL 5216981, at *9 (D.N.J. Dec. 30, 2009); *Mayberry v. Bristol-Myers Squibb Co.*, Nos. 07-942 (FLW), 07-1099 (FLW), 2009 WL 5216968, at *11 (D.N.J. Dec. 30, 2009); *Barge v. Bristol-Myers Squibb Co.*, No. 03:07-cv-00783 (FLW), 2009 WL 5206127, at *11 (D.N.J. Dec. 30, 2009); *Robinson v. Bristol-Myers Squibb Co.*, No. 3:07-cv-267 (FLW), 2009 WL 5206126, at *9 (D.N.J. Dec. 30, 2009).

298. See *Bayer Schera Pharma AG v. Sandoz, Inc.*, Nos. 08 Civ. 03710 (PGG), 08 Civ. 08112 (PGG), 2010 WL 1222012, at *8 (S.D.N.Y. Mar. 29, 2010). In fact, the court noted that the fatally missing detail may have been intentionally withheld by the pleader, a strategy the court faulted as an error in judgment:

Sandoz argues that it could not identify specific business relationships because of “the strict confidentiality ascribed to contracts for the supply of API [active pharmaceutical ingredients] in the pharmaceutical industry.” Protection of trade secrets or other proprietary information can, of course, be accomplished through entry of a protective order and/or a sealing order. In any event, confidentiality concerns do not excuse a failure to plead the elements of a cause of action.

Id. at *8 n.13 (alteration in original) (internal citation omitted).

299. See *Redden v. Smith & Nephew, Inc.*, No. 3:09-CV-1380-L, 2010 WL 2944598, at *3–5 (N.D. Tex. July 26, 2010).

300. See *Earl v. H.D. Smith Wholesale Drug Co.*, No. 08-3224, 2009 WL 1871929, at *3 (C.D. Ill. June 23, 2009) (ruling that, because the nature of the psychologically-injuring event must be examined, the omission of the details “dooms her claim”).

301. See *Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 271423, at *4–5 (N.D. Cal. Jan. 20, 2010).

302. See *Genzyme Corp. v. Disc. Drugs Wis., Inc.*, No. 08 C 5151, 2010 WL 744275, at *4 (N.D. Ill. Feb. 26, 2010) (“Under *Iqbal*, it is not enough for the complaint merely to state, ‘Defendant and Plaintiff formed a new contract,’

failed to describe the contents of the claimed trade dress;³⁰³ a patent-based antitrust claim was dismissed when the pleader failed to allege which patents it alleged to be improperly listed and why they were invalid;³⁰⁴ a securities law and fiduciary duty claim was dismissed when the pleader failed to identify the wrongful omissions from proxies and other financial reports;³⁰⁵ an unfair competition claim was dismissed for failing to specify the allegedly wrongful acts;³⁰⁶ a tariff claim by the federal government was dismissed for failing to describe what tariff wrongdoings each defendant was accused of committing;³⁰⁷ and a claim that a product was "worthless" was dismissed when the pleader failed to explain why.³⁰⁸ A curious claim that a "bank-based transactional corporate conspiracy" was afoot to impose "bioweaponized H1N1 influenza vaccinations" was also dismissed for the pleader's failure to describe her own specific resulting injury.³⁰⁹ In six other cases, the pleaders expressly or impliedly acknowledged access to the details the court declared missing³¹⁰ or were granted a brief additional

'Defendant breached the new contract it had with Plaintiff,' or 'Plaintiff and Defendant modified their original contract.' The complaint must provide factual grounds sufficient to make the formation of a new or modified contract plausible on its face.").

303. See *Sleep Sci. Partners v. Lieberman*, No. 09-04200 CW, 2010 WL 1881770, at *2–6 (N.D. Cal. May 10, 2010) (also dismissing a copyright infringement claim for failing to plead the prerequisite of preregistration or registration).

304. See *AstraZeneca AB v. Mylan Labs. Inc.*, Nos. 00 Civ. 6749, 03 Civ. 6057, M-21-81 (BSJ), MDL No. 1291, 2010 WL 2079722, at *5–6 (S.D.N.Y. May 19, 2010).

305. See *In re Pfizer Inc. S'holder Derivative Litig.*, No. 09 Civ. 7822 (JSR), 2010 WL 2747447, at *8–11 (S.D.N.Y. July 13, 2010). The court also dismissed the pleaders' unjust enrichment count because the only alleged enrichment (executive salaries, benefits, and bonuses) would not qualify under that equity claim, absent some further allegation of improper purpose. *Id.* at *11.

306. See *Myers-Armstrong v. Actavis Totowa, LLC*, No. 09-16055, 2010 WL 2232652, at *1 (9th Cir. June 3, 2010).

307. See *United States v. Scotia Pharm. Ltd.*, 2009 WL 1410437, at *6 (Ct. Int'l Trade May 20, 2009).

308. See *Nelson v. Xacta 3000 Inc.*, No. 08-5426 (MLC), 2009 WL 4119176, at *6–7 (D.N.J. Nov. 24, 2009).

309. See *Campbell v. Sebelius*, No. C09-1515JLR, 2010 WL 1576696, at *2–4 (W.D. Wash. Apr. 20, 2010) (pressing claim under the Declaration of Independence and the First, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth, and Fourteenth Amendments to the United States Constitution).

310. See *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSx), 2010 WL 1339948, at *3 (C.D. Cal. Mar. 30, 2010) (pleader acknowledges access to certain information omitted from original pleading); *Haskins v. Zimmer Holdings Inc.*, No. 1:09-CV-236, 2010 WL 342552, at *1 (D. Vt. Jan. 29, 2010)

period to go discover the missing information.³¹¹ In two cases, the court faulted the pleaders for simply inattentive or mistaken drafting.³¹² In each of these cases, it would appear that the deficient pleaders had ready, easy access to the *Iqbal* antidote. None of these cases appears to implicate an information asymmetry situation.

In six of the remaining “possible-difference,” “yes-difference,” and “mixed-difference” cases, the fatally missing factual detail seems to be classically accessible through pre-filing expert investigation and analysis. For example, in several antitrust, Lanham Act, and unfair competition cases, the pleaders were faulted for failing to specify the allegedly unlawful resulting market impacts.³¹³ In a products case, the pleader was faulted for

(pleader acknowledges access to missing data from recently-received operative note); *Gilmore v. DJO Inc.*, 663 F. Supp. 2d 856, 862 (D. Ariz. Oct. 15, 2009) (pleader obtained missing information from newly-acquired medical records); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 418 (D. Del. 2010) (pleader demonstrated ability to plead proper inducement to infringement claim as to one patent, but failed to do so for second patent); *Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 2465456, at *3–6 (N.D. Cal. June 14, 2010) (in amendment, pleader demonstrates ability to plead in detail against one defendant, and now must do the same as to other defendants).

311. *See Peterson v. Breg, Inc.*, No. 2:09-cv-2044 JWS, 2010 WL 2044248, at *3 (D. Ariz. Apr. 29, 2010) (granted another 30 days).

312. *See In re Fosamax Prods. Liab. Litig.*, No. 09 Civ. 1412 (JFK), 2010 WL 1654156, at *2 (S.D.N.Y. Apr. 9, 2010) (finding what appears to be a simple cut-and-paste problem, the court notes the pleader’s omission of any factual allegations against the moving defendants, “as if she clumsily copied these factual allegations from one of the many complaints in this multi-district litigation that asserts claims solely against” another defendant); *see also Harris v. Amgen, Inc.*, 573 F.3d 728, 737 (9th Cir. 2009) (expressing belief that the pleader can cure detail and misidentification pleading problems).

313. *See Everett Labs. Inc. v. River’s Edge Pharm., LLC*, Civ. No. 09-3458 (JLL), 2010 WL 1424017, at *5–6 (D.N.J. Apr. 8, 2010) (in Lanham Act / unfair competition claim, faulting pleader for failing to specify why contested conduct would be unfairly uncompetitive or confusing to consumers); *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371, 1376–79 (N.D. Ga. 2010) (in antitrust claim, faulting pleader for failing to support unreasonable restraint of trade theory); *CIBA Vision Corp. v. De Spirito*, No. 1:09-cv-01343-JOF, 2010 WL 553233, at *5–10 (N.D. Ga. Feb. 10, 2010) (in antitrust case, faulting pleader for failing to explain why alleged competitive behavior was improper); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09-3854 MMC, 2009 WL 4723739, at *5 (N.D. Cal. Dec. 2, 2009) (in antitrust case involving public companies, faulting pleader for failing to list the competitors and their sales volumes within the relevant industry market to show the possibility of a market dominance); *Synergetics USA, Inc. v. Alcon Labs., Inc.*, No. 08 Civ. 3669

failing to specify how the alleged product defect was factually linked to the alleged injury.³¹⁴ Again, in each of these cases, the specificity held to be missing was likely already in the pleader’s pre-filing investigative and case-assessment file (or probably should have been). Consequently, none of these cases appear to implicate the information asymmetry predicament.

In another of the “possible-difference,” “yes-difference,” and “mixed-difference” cases, a state law personal injury products claim was initially dismissed because the pleader had alleged indecisively that the plaintiff’s decedent, a clinical trial patient, had died either because of exposure to defendant Abbott Laboratories’ drug, exposure to another experimental product, or exposure to a combination of both.³¹⁵ Upon re-pleading, the defendant again moved to dismiss for, among other reasons, a continued failure to meet the *Iqbal* “plausibility” standard. This time, the district court denied the motion.³¹⁶ In arguing for another dismissal, the defendant aimed the court’s attention squarely on the absence of pleaded facts as to both the prescribing physician’s and the manufacturing defendant’s state of knowledge—an obvious “information asymmetry” situation.³¹⁷ Notwithstanding *Iqbal*, the court was unpersuaded:

As Abbott contends, because the case involves prescription drugs, the critical causation element is what Ms. Mohr’s [the plaintiff’s decedent] physician, not Ms. Mohr, would have done differently with a different warning. It is difficult to know, prior to discovery, whether Ms. Mohr’s physician would have prescribed [the challenged drug] if there were additional warnings.³¹⁸

(DLC), 2009 WL 1564113, at *4 (S.D.N.Y. June 4, 2009) (same, failing to allege the defendant’s power or dominance in market).

314. See *In re Heparin*, No. 3:09HC60137, 2010 WL 547322, at *2–3 (N.D. Ohio Feb. 9, 2010) (pleader claimed that manufacturer produced kinked dialysis tubing, but failed to factually connect that defect to the decedent’s actual cause of death).

315. *Mohr v. Targeted Genetics, Inc.*, No. 09-3170, 2009 WL 4021153, at *3 (C.D. Ill. Nov. 18, 2009) (finding allegations “do not meet the *Iqbal* standard” because they amount to “little more than the ‘magic words’ which are typically used to support a product liability claim” and lack “specific facts which establish tortious conduct”). Again, in *Mohr*, the claim’s weakness that seemed to trouble the court was the pleader’s inability to link the defendant’s drug with the alleged injury, an omission that might also have been corrected by an expert’s review.

316. *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 721 n.6 (C.D. Ill. 2010).

317. *Id.*

318. *Id.* at 718 (citations omitted).

[As to Abbott's state of knowledge:] Although this is a very close issue, the Court at this stage of the litigation is unable to conclude that . . . [dismissal is warranted.] It is not yet apparent when Abbott learned of the information that prompted the FDA to require additional warnings It may be that the package insert . . . was sufficient based on the information Abbott had at the time and dismissal is thus appropriate. . . . When the complaint's allegations are accepted as true, however, the Court finds that Plaintiff has alleged enough facts to assert a plausible claim. Presumably, the discovery process will yield information

. . . .³¹⁹
Citing *Iqbal*, Abbott suggests that Plaintiff has not asserted enough facts to be entitled to discovery. However, a plaintiff cannot be expected to allege facts of which—through no fault of its own—it is not yet aware. Moreover, the Court must still draw all reasonable inferences in the Plaintiff's favor.³²⁰

In sum, in testing the re-pleaded claim, the trial court not only noted the spectre of “information asymmetry,” but relied, in part, on that very disability to explain denying the motion to dismiss—all the while citing *Iqbal* and discussing the “plausibility” pleading standard.³²¹

This leaves 22 “possible-difference,” “yes-difference,” and “mixed-difference” cases (8.3% of the pharmaceutical and medical device cohort) that seem to present the information asymmetry predicament in cases where the “plausibility” test appears material to the disposition.

In eight of those cases, the factual detail that the courts declared missing might be obtained through discovery from an adversary. Two failure-to-warn products claims were dismissed because the pleader failed to include sufficient factual allegations concerning the defendants' state of knowledge of the claimed risk³²² and their actual promotion behavior.³²³ Two versions of the

319. *Id.* at 721.

320. *Id.* at 721 n.6 (citations omitted).

321. This court was not alone in focusing on an “information asymmetry” to deny an *Iqbal* challenge. *See, e.g., In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2009 WL 2433468, at *10 (S.D.W. Va. Aug. 3, 2009) (“The exact relationship between the defendants, their knowledge of material events, the timing of their receipt of that knowledge, and the impact those fact intensive questions may have on the application of the unsettled, governing law all counsel in favor of allowing the challenged Counts to proceed to discovery.”).

322. *See Redinger v. Stryker Corp.*, No. 5:10 CV 104, 2010 WL 1995829, at *3 (N.D. Ohio May 19, 2010) (“Plaintiff has alleged no factual particulars

same securities fraud complaint were dismissed because the pleaders failed to explain why public offering statements concerning order backlogs were misleading, a lack of detail that might well have been remediable only through discovery from the defendant.³²⁴ Three ERISA breach of fiduciary duty cases were dismissed because the pleaders failed to detail how the defendants assumed fiduciary-level status or how they misbehaved as fiduciaries, or both.³²⁵ One employment discrimination claim was

supporting a plausible conclusion that there was inadequate warning or instruction under [Ohio statutory law].”). Here, again, reasonable minds can differ on the point. Under the controlling law, the Ohio Product Liability Act, a warning or instruction is considered “defective” if the defending manufacturer “knew or, in the exercise of reasonable care, should have known” about an unwarned-against risk. *Id.* at *2 (quoting OHIO REV. CODE ANN. § 2307.76(A)(1)(a), (2)(a) (West 2004)). Although actual knowledge certainly may present an “information asymmetry” dilemma, the alternative “should have known” analysis might well have been supplied by a consulted industry expert.

323. See *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 784–85 (D. Minn. 2009) (finding allegations capable of escaping federal preemption only if the defendant was promoting in a certain off-label manner, knew of the relevant risks to the plaintiff, and failed to properly warn of those, and faulting pleader for failing to allege those facts). The court in *Riley* also dismissed an express warranty claim that allegedly had occurred after the fact, reasoning that the pleader would have to explain how such a claimed warranty could have formed the basis for the bargain (a required showing under the controlling law). *Id.* at 788.

324. See *Schultz v. TomoTherapy Inc.*, Nos. 08-cv-314-slc, 08-cv-342-slc, 2009 WL 2032372, at *14 (W.D. Wis. July 9, 2009) (dismissing portion of ’33 Act claim in first amended complaint, but granting leave to amend notwithstanding judge’s belief that “[i]t seems unlikely that plaintiffs could revivify this claim (they would have to uncover many more multi-unit orders in the backlog to establish that it was misleading)"); *Schultz v. TomoTherapy Inc.*, 676 F. Supp. 2d 780, 786 (W.D. Wis. 2009) (dismissing of same portion of ’33 Act claim in second amended complaint, noting that “[r]egardless whether plaintiffs *might* be able to unearth additional delayed orders if they were able to perform discovery, nothing about the allegations in the complaint suggests that additional discovery could be expected to lead to those results”).

325. See *Crocker v. KV Pharm. Co.*, No. 4:09-CV-198 (CEJ), 2010 WL 1257671, at *16, *25 (E.D. Mo. Mar. 24, 2010) (dismissing fiduciary claim that company directors had become retirement plan fiduciaries based on lack of detail about degree of control they exercised over plan’s investments, and dismissing fiduciary claim against other defendants for lack of allegations of actual conduct that breached fiduciary duties); *Precision CPAP, Inc. v. Jackson Hosp.*, No. 2:05 cv 1096-MHT, 2010 WL 797170, at *6–14 (M.D. Ala. Mar. 8, 2010) (dismissing on similar grounds); *Herrera v. Wyeth*, No. 08 Civ. 4688 (RJS), 2010 WL 1028163, at *6–7 (S.D.N.Y. Mar. 17, 2010) (dismissing fiduciary claims based on absence of allegations as to how individual members of company retirement committee behaved with their own personal shares of stock).

dismissed when the pleader failed to better allege the unlawful motivation behind her termination.³²⁶

In five other cases, the detail declared to be lacking would seem to be of a nature accessible largely through discovery of non-parties. Three of the anesthetic cases discussed earlier fall into this category, where the pleaders sued numerous potential defendants, justifying their over-pleading on an uncertainty as to the identity of the actual anesthetic they received due to healthcare-shorthand use of the brand name; the confirming details that allow for a positive product identification likely could be learned from discovery of the specific healthcare providers who implanted the anesthetic devices.³²⁷ In two other cases, consumer fraud claims were dismissed because the pleaders had not sufficiently alleged the link between the claimed misrepresentations and the plaintiffs' injuries, a detail that might only be learned from the prescribing physicians who would be in the position to explain whether those misrepresentations had actually influenced the prescribing decision.³²⁸

Finally, in the remaining nine cases, the missing detail might be supplied through discovery from a combination of adversaries and non-parties. In seven of these cases, the pleaders were faulted for failing to allege enough about the manufacturing process or design of a pharmaceutical or medical device. Thus, in two of the cases, product defect claims were dismissed because the pleaders lacked depth in their allegations about the nature of the precise defect in manufacturing or the nature of the precise defect in product design.³²⁹ Similarly, in the other five cases, the court found

326. See *Taylor v. Squibb Pharm.*, Civ. No. 09-4196 (FLW), 2010 WL 1133447, at *3 (D.N.J. Mar. 19, 2010) (dismissing claim because, among other failures, pleader failed to explain how she was discharged due to her race and that her replacement was not a member of her same protected class).

327. See *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *16–17 (W.D. Pa. June 16, 2010); *Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 583–85 (C.D. Cal. 2010); *Combs v. Stryker Corp.*, No. 2:09-cv-02018-JAM-GGH, 2009 WL 4929110, at *2 (E.D. Cal. Dec. 14, 2009). For a further discussion of these and other similar cases, see generally *supra* notes 288–93 and accompanying text.

328. See *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2010 WL 2464746, at *6–8 (D.N.J. June 9, 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2010 WL 2346624, at *8–14 (D.N.J. June 9, 2010).

329. See *Burks v. Abbott Labs.*, Civ. No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *3 (D. Minn. Apr. 20, 2010) (faulting pleader for, *inter alia*, not alleging “any facts describing or identifying defendants’ manufacturing specifications or standards” and, therefore, pleader failed “to allege facts describing how defendants’ products deviated from such specifications or standards”); *Frey v. Novartis Pharm. Corp.*, 642 F. Supp. 2d 787, 795 (S.D.

that the pleaders had failed to defeat federal preemption of their claims because they had not adequately alleged what specific federal law the particular product’s manufacturing, design, or sale had violated.³³⁰ (In 2008, the Supreme Court ruled that certain state law claims against medical device manufacturers may be barred under federal preemption theory *unless* the claims in the case are doing nothing more than imposing a state law duty that is “parallel” to duties the manufacturers already have to meet under existing federal law.)³³¹ In both sets of cases, the missing details might have been sought through discovery from the product manufacturers, product designers, and the healthcare providers. The final two cases in this group were antitrust claims that the

Ohio 2009) (faulting pleaders for, *inter alia*, “a formulaic recitation of the elements” and failing to allege “any facts that would permit the Court to conclude that there was a defect in the design or formulation of [the medicine] and that the defect was the proximate cause of [the plaintiff’s] alleged injuries”).

330. See *Bass v. Stryker Corp.*, No. 4:09-CV-632-Y, 2010 WL 3431637, at *5 (N.D. Tex. Aug. 31, 2010) (“Plaintiff has not specifically alleged how Defendants have failed to meet [federal device-approval] specifications or that such a failure has even occurred.”); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (magistrate judge’s recommendation), *adopted*, 2010 WL 2543570 (D. Colo. June 22, 2010) (“Plaintiff ‘cannot simply incant the magic words “[defendant] violated FDA regulations” in order to avoid preemption.’ . . . Merely alleging that Defendant generally failed to comply with federal requirements is insufficient to overcome the preemptive reach [of federal law] without some factual detail as to why Defendant violated federal regulations.” (quoting *In re Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009))); *Anthony v. Stryker Corp.*, No. 1:09-cv-2343, 2010 WL 1387790, at *4 (N.D. Ohio Mar. 31, 2010) (“Although Anthony did allege Stryker’s deviation from ‘manufacturing performance standards’ in the complaint, Anthony did not specifically mention either the FDA or its regulations” nor did plaintiff “plead any facts that would lead this court to plausibly infer that Stryker’s noncompliance with FDA regulations led to his injury.”); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *15 (M.D.N.C. Aug. 5, 2009) (“[The plaintiff] has not alleged any particular non-conclusory link between that alleged wrongdoing and his particular injuries, let alone a causal one, as he would ultimately be required to do before he is entitled to recover anything from [defendant]. Thus, at this point, the Court is left with nothing more than a mere ‘suspicion’ that Plaintiff may have a legally cognizable claim, which . . . is insufficient to survive a motion to dismiss.”); *Prudhel v. Endologix, Inc.*, Civ. No. S-09-0661 LKK/KJM, 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009) (“Although plaintiffs[] generally allege that many violations of federal requirements occur, to state a parallel claim, a federal violation must be a predicate to the theory of liability.”).

331. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 329 (2008) (construing preemption language in the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360c–360k (2006 & Supp. 2009)).

courts faulted for failing to supply either the context necessary to suggest an agreement in restraint of trade³³² or anything more than a conclusory allegation of co-conspirator status.³³³

Do these last 22 cases bear the hallmarks of a genuine information asymmetry? That may depend on whom you ask.

A lawyer hoping to prosecute such a case on a client's behalf might answer with a resounding "yes," that the information the courts are now demanding under the mantra of *Iqbal* unquestionably necessitates the discovery process to pry it loose from the sources where it naturally lies hidden. To demand an *Iqbal* level of specificity before discovery, that lawyer would argue, is to relegate plaintiffs to fighting blind, with both hands bound, in an unfamiliar dark room. And it will be the clients who suffer, as tall procedural hurdles allow the wealthy, insidious wrongdoers to scamper away.³³⁴

The lawyer asked to defend against such a case might answer with an equally resounding "no," that these are not meritorious cases where the key evidence is being squirreled away, but rather

332. RxUSA Wholesale Inc. v. Alcon Labs., No. 09-4406-CV, 2010 WL 3393737, at *1 (2d Cir. Aug. 30, 2010) (finding pleading to be "entirely conclusory" and failing to "place its allegations of parallel conduct in a context that suggests a prior agreement").

333. *In re Blood Reagents Antitrust Litig.*, MDL No. 09-2081, 2010 WL 3364218, at *8 (E.D. Pa. Aug. 23, 2010). Interestingly, the antitrust pleading in *Blood Reagents* was sufficient to repel dismissal motions filed by two of the three alleged co-conspirators, even when measured expressly against the "plausibility" standard. *See id.* at *8 ("Twombly increased the burden antitrust plaintiffs must bear in order to satisfy Rule 8(a). However, it does not require 'heightened fact pleading of specifics' and expressly disclaimed an approach focusing on the probability that a complaint's allegations will ultimately be vindicated. Whether plaintiffs are able to actually prove their allegations or not, the Complaint's charge of a conspiracy between Immucor and Ortho-Clinical is set within a context that renders it plausible." (citation omitted)). The co-conspiracy claim against the third defendant, Johnson & Johnson Health Care Systems, failed because the sole allegation against it was a single paragraph describing its business services; no allegations of its role in the conspiracy were offered. *Id.*

334. This view of *Iqbal* is vindicated by forgiving interpretations and applications of *Iqbal*'s tenets. *See, e.g.,* Waguespack v. Plivia USA, Inc., Civ. No. 10-692, 2010 WL 2086882, at *3 (E.D. La. May 24, 2010). In *Waguespack*, the defendant objected to a products liability claim as implausible because it had failed to allege when and why the plaintiff was prescribed the challenged drug, the dosage used, the length of use, the identity of the manufacturer, and the details of the claimed deviation from manufacturer standards. *Id.* at *2. The court was wholly unimpressed—details aside, the defendants had received all they were entitled to receive, just "notice." The pleading adequately informed them "that defendants manufactured a drug which plaintiff took that caused him harm because there was something wrong with the drug about which doctors and patients were not warned." *Id.* at *3.

are rank litigation “guesses” in search of basic confirmation during an increasingly expensive discovery process. That lawyer would argue that in cases such as these, the claimants have no real idea whether their claims have any merit or not, and the proposed litigation process is just a journey where the plaintiffs, the defendants, and the courts adventure along together on a quest to see whether any facts exist to support empty hunches. To this view, a non-*Iqbal* litigation paradigm is an only modestly more expensive Powerball ticket—simply buying a chance for a possible payday.³³⁵

Partisans’ advocacy aside, this Article’s examination of the “possible-difference,” “yes-difference,” and “mixed-difference” cases reveals that the instances of arguable “information asymmetry” are infrequent; they appeared in only 8.3% of the cases in the cohort. Moreover, at least in the context of the pharmaceutical and medical device cohort, the phrase “information asymmetry” proved to be a bit of an incomplete gloss itself. In the 22 cases discussed above, probable sources of important factual information certainly included the litigants’ adversaries and non-parties. It may even be true that adversaries and non-parties represented the primary sources of the core evidentiary material. But it must also be true that other sources of that same information (or suggestive of that same information) existed to have justified the decision to file in the first place.³³⁶ So, properly understood within this cohort, *Iqbal* does not present a true “information asymmetry” predicament (even in the worst of situations) as much

335. This view of *Iqbal* is vindicated by a stern interpretation and exacting application of *Iqbal*’s tenets. See, e.g., *Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 585 (C.D. Cal. 2010). In *Timmons*, one of the anesthetic cases discussed *supra* in notes 288–93 and accompanying text, the pleaders entreated the court for post-filing discovery, so as to enable them to determine which of the many defendants they had sued was actually the one responsible for their claimed injury. The court was wholly unimpressed:

[A] plaintiff who fails to meet the pleading requirements of Rule 8 is not entitled to conduct discovery with the hope that it might then permit her to state a claim. Further, allowing plaintiffs to file first and investigate later, as Plaintiffs here have done, would be contrary to Rule 11(b), which mandates an “inquiry reasonable under the circumstances” into the evidentiary support for all factual contentions prior to filing a pleading.

Id. (citations to *Iqbal* and *Twombly* omitted).

336. See FED. R. CIV. P. 11(b)(3) (“By presenting to the court a pleading . . . an attorney or unrepresented party certifies that to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable under the circumstances . . . the factual circumstances have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery . . .”).

as an enhanced obligation on pleaders to explain more lucidly and convincingly what caused them to believe that their pleadings comported with Rule 11 at the time they were filed.³³⁷ In any event, the polarity of this concept is not as reliable as one might think. Contrary to popular belief, incanting “information asymmetry” is not a privilege reserved just to plaintiffs; defendants, too, have invoked the notion (albeit in an opposing formulation) to *incite* a dismissal where the pleaders clearly possessed access to essential details but omitted including them in their claims.³³⁸

337. This construction of *Iqbal* also finds support in the pharmaceutical and medical device case law. *See, e.g., In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 693 (2d Cir. 2009), *cert. denied sub nom. Ferring B.V. v. Meijer, Inc.*, 130 S. Ct. 3505 (2010) (“[T]he plaintiffs’ pleadings could plausibly lead to additional findings that would satisfy [the implicated legal standard], which is all that is required at this stage of the litigation.”); *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 721 n.6 (C.D. Ill. 2010) (“Citing *Iqbal*, Abbott suggests that Plaintiff has not asserted enough facts to be entitled to discovery. . . . However, a plaintiff cannot be expected to allege facts of which—through no fault of its own—it is not yet aware. Moreover, the Court must still draw all reasonable inferences in the Plaintiff’s favor. Based on the number of deaths . . . , it may be reasonable to infer that stronger warnings should have been incorporated into Humira’s label before the FDA ordered such warnings in September 2008.” (citation omitted)); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D. Pa. 2009) (“[T]he Court recognizes that the amended complaint is short on specifics However, the Court finds that the amended complaint contains facts that raise a reasonable expectation that discovery will reveal evidence” to support the allegations.); *cf. Schultz v. TomoTherapy Inc.*, 676 F. Supp. 2d 780, 786 (W.D. Wis. 2009) (“Regardless whether plaintiffs *might* be able to unearth additional [supporting facts] if they were able to perform discovery, nothing about the allegations in the complaint suggests that additional discovery could be expected to lead to those results.”). In fact, this seems to have been one of the animating messages of the whole “plausibility” concept. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 559 (2007) (“Probably, then, it is only by taking care to require allegations that reach the level suggesting conspiracy that we can hope to avoid the potentially enormous expense of discovery in cases with no ‘reasonably founded hope that the [discovery] process will reveal relevant evidence’ to support [the pleaded claim].” (first alteration in original) (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)) (internal quotation marks omitted)).

338. *See Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *8 (W.D. Pa. June 16, 2010) (dismissing negligence claims, noting that “Plaintiff is the only party who has access to the various medical and insurance records that would allow her to properly identify what drug was administered”); *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2009 WL 3740648, at *18 (N.D. Cal. Nov. 6, 2009) (“The facts needed to adequately state claims under these statutory and common law provisions have always been within plaintiffs’ and their treating physicians’ knowledge. The court provided plaintiffs with an opportunity to gather and allege the requisite facts. Their failure to do so justifies dismissing the claims with prejudice.”).

5. The “Difference” Cases—Was There an Iqbal Difference?

This Article now comes, at last, to its central question. Had *Iqbal* never been decided, would the outcomes in these “possible-difference,” “yes-difference,” and “mixed-difference” cases have been substantively different under the prevailing local, pre-*Iqbal* circuit-level approaches to assessing dispositive pleading motions? The question is at once pivotal to gauging the importance of *Iqbal* to this cohort of cases, yet also largely unanswerable. Be that as it may, there is no doubt that the uncertainty points in both directions.

The real answer may lie back with the lower federal judiciary’s longstanding migration away from one implied *Conley* principle and its oft-recounted embrace of that principle’s antithesis—that a pleader’s bald announcement of elements can survive dismissal.³³⁹ Indeed, throughout this pharmaceutical and medical device cohort of cases has appeared the recurring, frequently dispositive criticism of the *conclusory* nature of the rejected pleadings.³⁴⁰ Setting aside for a moment the puzzling notion of claim “plausibility,” the vulnerability of federal cases pleaded in conclusory fashion had, long before *Iqbal*, been recognized by every circuit in the federal judiciary.³⁴¹ This settled practice of discounting legally conclusory

339. See *supra* notes 38–43 and accompanying text.

340. See, e.g., *RxUSA Wholesale Inc. v. Alcon Labs.*, No. 09-4406-CV, 2010 WL 3393737, at *1 (2d Cir. Aug. 30, 2010) (“entirely conclusory”); *Redinger v. Stryker Corp.*, No. 5:10 CV 104, 2010 WL 1995829, at *3 (N.D. Ohio May 19, 2010) (“completely bereft of any factual allegation”); *Bayer Schera Pharma AG v. Sandoz, Inc.*, Nos. 08 Civ. 03710 (PGG), 08 Civ. 08112 (PGG), 2010 WL 1222012, at *8 (S.D.N.Y. Mar. 29, 2010) (“a formulaic recitation of the elements of a cause of action’ will not survive a motion to dismiss” (internal quotation marks omitted)); *Money v. Bristol-Meyers Squibb Co.*, No. 3:07-cv-110 (FLW), 2009 WL 5216987, at *9 (D.N.J. Dec. 30, 2009) (“amount to nothing more than conclusory allegations”); *Gonzalez v. Bristol-Meyers Squibb Co.*, No. 3:07-cv-00902 (FLW), 2009 WL 5216984, at *8 (D.N.J. Dec. 30, 2009) (“not enough . . . to set forth a formulaic recitation of the element without any factual support”); *Smith v. Bristol-Meyers Squibb Co.*, No. 3:06-cv-6053 (FLW), 2009 WL 5216982, at *10 (D.N.J. Dec. 30, 2009) (“[plaintiff] failed to plead anything other than bald conclusory allegations”).

341. See, e.g., *Redondo-Borges v. U.S. Dep’t of Hous. & Urban Dev.*, 421 F.3d 1, 9 (1st Cir. 2005) (“The fact that notice pleading governs at the Rule 12(b)(6) stage does not save the plaintiffs’ conclusory allegation. . . . Even within the generous confines of notice pleading, courts must continue to ‘eschew . . . reliance on bald assertions [and] unsupportable conclusions.’” (alteration in original) (quoting *Chongris v. Bd. of Appeals*, 811 F.2d 36, 37 (1st Cir. 1987))); *Achtman v. Kirby, McInerney & Squire, LLP*, 464 F.3d 328, 337 (2d Cir. 2006) (“[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to [defeat] a motion to dismiss.” (second alteration in original) (citation and internal quotation marks omitted)); *Evancho v. Fisher*,

allegations also does not seem like some naked, intemperate (though nationally uniform) remolding of the federal pleading paradigm; to the contrary, lofty support for such an approach both pre-dates and post-dates the *Conley* decision.³⁴² Indeed, perhaps even Judge Clark himself can be counted among the supporters.³⁴³

423 F.3d 347, 351 (3d Cir. 2005) (“[A] court need not credit either ‘bald assertions’ or ‘legal conclusions’ in a complaint when deciding a motion to dismiss.”); *Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) (“The pleader may not evade [Rule 12(b)(6)] requirements by merely alleging a bare legal conclusion” (alteration in original) (citation and internal quotation marks omitted)); *Rios v. City of Del Rio*, 444 F.3d 417, 421 (5th Cir. 2006) (“[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” (citation and internal quotation marks omitted)); *Mezibov v. Allen*, 411 F.3d 712, 716 (6th Cir. 2005) (“[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.”); *Cnty. of McHenry v. Ins. Co. of the W.*, 438 F.3d 813, 818 (7th Cir. 2006) (noting that the court “‘will not invent legal arguments for litigants,’ and is ‘not obliged to accept as true legal conclusions or unsupported conclusions of fact’” (citations omitted)); *Ashley v. U.S. Dep’t of Interior*, 408 F.3d 997, 1000 (8th Cir. 2005) (“[W]e need not accept as true their legal conclusions even if they are ‘cast in the form of factual allegations’” (citations omitted)); *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001), *amended*, 275 F.3d 1187 (9th Cir. 2004) (“Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.”); *Tal v. Hogan*, 453 F.3d 1244, 1252 (10th Cir. 2006) (“A motion to dismiss under Fed. R. Civ. P. 12(b)(6) ‘admits all well-pleaded facts in the complaint as distinguished from conclusory allegations.’” (citation omitted)); *Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1263 (11th Cir. 2004) (“To survive a motion to dismiss, plaintiffs must do more than merely state legal conclusions; they are required to allege some specific factual bases for those conclusions or face dismissal of their claims.”); *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002) (“[W]e accept neither ‘inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint,’ nor ‘legal conclusions cast in the form of factual allegations.’” (citation omitted)); *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1355 (Fed. Cir. 1991) (“Allegations of legal conclusions are insufficient to withstand a motion to dismiss.”).

342. See, e.g., *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (“Although for the purposes of this motion to dismiss we must take all the factual allegations in the complaint as true, we are not bound to accept as true a legal conclusion couched as a factual allegation.”); *Newport News Shipbuilding & Dry Dock Co. v. Schauffler*, 303 U.S. 54, 57 (1938) (Brandeis, J.) (“The company insists that, since the case was heard on motion to dismiss the bill which alleges that the company is not engaged in interstate or foreign commerce and its relations to its employees do not affect such commerce, these allegations must be accepted as true. The motion admits as facts allegations describing the manner in which the business is carried on, but not legal conclusions from those facts. The allegations that interstate or foreign commerce is not involved are conclusions of law.”). Indeed, in October 1955, the Advisory Committee on Rules for Civil Procedure wrote to the Supreme Court to explain its decision *not* to amend Rule 8(a) so as

If the mortal error in most of the “possible-difference,” “yes-difference,” and “mixed-difference” cases was a conclusorily pleaded claim, one must confront the possibility (if not the probability) that existing, pre-*Iqbal* federal precedent could have fairly guided these same courts to reach the very same results.³⁴⁴ If there were any doubts about the reasonableness of such a suggestion, the actual language of many of the pharmaceutical and medical device cases dispels it. In case after case within this cohort, the deciding judges recounted the “conclusions-do-not-

to more plainly verify that federal pleaders are obligated to include factual detail in their federal pleadings; the Committee refused because the Rule as written, they believed, already enjoyed that clarity. *See* ADVISORY COMM. ON RULES FOR CIVIL PROCEDURE, PROPOSED AMENDMENTS TO THE RULES OF CIVIL PROCEDURE FOR THE UNITED STATES COURTS (1955), *reprinted in* 12A CHARLES ALAN WRIGHT ET AL., *FEDERAL PRACTICE AND PROCEDURE* 654–55 (4th ed. 2010) (“That Rule 8(a) envisages the statement of circumstances, occurrences, and events in support of the claim presented is clearly indicated,” and “as it stands, the rule . . . requires the pleader to disclose adequate information as the basis of his claim for relief as distinguished from a bare averment that he wants relief and is entitled to it.”). It is equally true that the boundary between factual allegations and legal conclusions is not, in all cases, well marked out or easily deciphered. *See* Miller, *supra* note 59, at 24 (“The fact–legal conclusion dichotomy presented by *Twombly*’s first step is shadowy at best. Worse, the categories are likely to generate motion practice unrelated to the merits.”).

343. *See* CLARK, *supra* note 9, at 157 (“No rule of thumb is possible, but in general it may be said that the pleader should not content himself with alleging merely the final and ultimate conclusion which the court is to make in deciding the case for him. He should go at least one step further back and allege the circumstances from which this conclusion directly followed.”); *see also* WHITE PAPER, *supra* note 141, at 6. It has been reported that Judge Clark “did not believe in a total abandonment of the requirement of allegations of specific fact in pleadings.” *Id.* (quoting RICHARD L. MARCUS ET AL., *CIVIL PROCEDURE: A MODERN APPROACH* 133 (4th ed. 2005)). In fact, he “insisted that there were limits to the generality of pleading allowed under the Federal Rules. A bare allegation that the defendant had injured the plaintiff through negligence, he said, would not suffice.” WHITE PAPER, *supra* note 141, at 6 (quoting Michael E. Smith, *Judge Charles E. Clark and the Federal Rules of Civil Procedure*, 85 *YALE L.J.* 914, 917–18 (1976)). Interestingly, the 1955 Civil Rules Advisory Committee seemed entirely unimpressed by those critics who were then characterizing Judge Clark’s opinion in *Dioguardi* as a validation of fact-free pleading in federal courts. That decision, schooled the Committee, “was not based on any holding that a pleader is not required to supply information disclosing a ground for relief. The complaint in that case stated a plethora of facts and the court so construed them as to sustain the validity of the pleading.” ADVISORY COMM. ON RULES FOR CIVIL PROCEDURE, *supra* note 342, at 655.

344. *See generally* Kuperman Memo, *supra* note 156, at 2 (noting that “some of the post-*Iqbal* cases dismissing complaints note that those complaints would have been deficient even before *Twombly* and *Iqbal*”).

count” principle, and did so, time after time, by quoting or citing pre-*Iqbal* and pre-*Twombly* case precedent from within their own circuits.³⁴⁵

345. See, e.g., *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 28 (1st Cir. 2009) (citing 1987 precedent (and *Iqbal*) for the proposition that “we are under no obligation to credit [the pleader’s] conclusory allegations, which simply parrot the elements of the statute”); *Bass v. Stryker Corp.*, No. 4:09-CV-632-Y, 2010 WL 3431637, at *2 (N.D. Tex. Aug. 31, 2010) (citing 1992 and 1982 precedent for the proposition that plaintiffs must “plead specific facts, not mere conclusory allegations, to avoid dismissal” and “[t]he court must accept as true all well-pleaded, non-conclusory allegations”); *Ferring Pharm., Inc. v. River’s Edge Pharm., LLC*, Civ. No. AW-09-02601, 2010 WL 3087419, at *2 (D. Md. Aug. 6, 2010) (citing *Papasan*, and precedent from 1999 and 1979, for the proposition that courts “need not . . . accept unsupported legal allegations, legal conclusions couched as factual allegations, or conclusory factual allegations devoid of any reference to actual events” (citations omitted)); *In re Mirapex Prods. Liab. Litig.*, Civ. Nos. 07-MD-1836 (JMR/FLN), 10-485 (JMR/FLN), 10-486 (JMR/FLN), 2010 WL 3385251, at *2 (D. Minn. Aug. 4, 2010) (citing 1998 precedent for the proposition that “[t]o avoid dismissal, a complaint must allege facts sufficient to state a claim as a matter of law and may not merely state legal conclusions”); *Redden v. Smith & Nephew, Inc.*, Civ. No. 3:09-CV-1380-L, 2010 WL 2944598, at *3 (N.D. Tex. July 26, 2010) (citing 2005 precedent for the proposition that “a court is not to strain to find inferences favorable to the plaintiff and is not to accept conclusory allegations, unwarranted deductions, or legal conclusions”); *Zafarana v. Pfizer Inc.*, Civ. No. 09-cv-4026, 2010 WL 2854170, at *4 (E.D. Pa. July 20, 2010) (citing *Papasan* as precedent for the proposition that courts are “not required to blindly accept ‘a legal conclusion couched as a factual allegation’”); *Pittsburgh Standard Spine Co. v. Lanx, Inc.*, No. 09-cv-01062-RED-MJM, 2010 WL 2604985, at *1 (D. Colo. June 28, 2010) (citing 1993 and 2002 precedent for the proposition that “conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss”); *In re Mirapex Prods. Liab. Litig.*, No. 07-MD-1836 (JMR/FLN), Civ. No. 09-807 (JMR/FLN), 2010 WL 2520567, at *1 (D. Minn. May 28, 2010) (citing 1998 precedent for the proposition that “a complaint must allege facts sufficient to state a claim as a matter of law and may not merely state legal conclusions”); *In re Budeprion XL Mktg. & Sales Litig.*, MDL No. 2107, No. 09-md-2107, 2010 WL 2135625, at *5 (E.D. Pa. May 26, 2010) (citing 1997 precedent (and *Iqbal*) for the proposition that courts need not “credit ‘bald assertions’ or ‘legal conclusions’ when deciding a motion to dismiss”); *Crisp v. Stryker Corp.*, No. 5:09-cv-02212, 2010 WL 2076796, at *2 (N.D. Ohio May 21, 2010) (citing 2006 precedent for the proposition that “more than the bare assertion of legal conclusions” is required, and instead “the complaint must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory”); *Pettit v. SmithKline Beecham Corp.*, No. 2:09-cv-00602, 2010 WL 1463479, at *2 (S.D. Ohio Apr. 13, 2010) (citing 1993 precedent for the proposition that “[a]lthough liberal, the Rule 12(b)(6) standard requires more than the bare assertion of legal conclusions to survive a motion to dismiss”); *Taylor v. Squibb Pharm.*, Civ. No. 09-4196 (FLW), 2010 WL 1133447, at *1 (D.N.J. Mar. 19, 2010) (citing 1997 precedent for the proposition that courts need not “credit a *pro se* plaintiff’s ‘bald assertions’ or ‘legal conclusions’”); *Gallien v. Proctor & Gamble Pharm., Inc.*, No. 09 Civ. 6903

So, in the end, *Iqbal* does seem to have made a difference in about 21% of the cases studied in this pharmaceutical and medical device cohort because the deciding courts wrote or implied that it did. Left unaddressed by those deciding courts was the companion question of whether the outcome would have been any different had then-prevailing circuit precedent, rather than *Iqbal*, been applied to test the pleading. For this cohort of studied cases, the

(JFK), 2010 WL 768937, at *1 (S.D.N.Y. Mar. 5, 2010) (citing the United States Supreme Court’s opinion in *Papasan* for the proposition that courts need not “accept as true conclusory allegations or ‘a legal conclusion couched as a factual allegation’”); *Wyeth v. Sun Pharm. Indus.*, No. 09-11726, 2010 WL 746394, at *2 (E.D. Mich. Mar. 2, 2010) (citing 1999 precedent for the proposition that although “this standard is decidedly liberal, it requires more than the bare assertion of legal conclusions”); *Mitchell v. Proctor & Gamble*, No. 2:09-CV-426, 2010 WL 728222, at *1 (S.D. Ohio Mar. 1, 2010) (citing 1993 precedent for the proposition that “[a]lthough liberal, the Rule 12(b)(6) standard requires more than the bare assertion of legal conclusions to survive a motion to dismiss”); *Krywokulski v. Ethicon, Inc.*, No. 8:09-CV-980-T-30MAP, 2010 WL 326166, at *1 (M.D. Fla. Jan. 21, 2010) (citing 2003 precedent for the proposition that “‘conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts’ will subject a complaint to dismissal”); *Redden v. Smith & Nephew, Inc.*, No. 3:09-CV-1380-L, 2010 WL 184428, at *2 (N.D. Tex. Jan. 19, 2010) (citing 2005 precedent for the proposition that “a court is not to strain to find inferences favorable to the plaintiff and is not to accept conclusory allegations, unwarranted deductions, or legal conclusions”); *Williams v. Bausch & Lomb Co.*, No. 2:08-cv-910, 2009 WL 2983080, at *2 (S.D. Ohio Sept. 14, 2009) (citing both 1971 precedent and *Twombly* for the proposition that “[a]lthough the court must apply a liberal construction of the complaint in favor of the party opposing the motion to dismiss, a court will not accept conclusions of law or unwarranted inferences of fact cast in the form of factual allegations”); *Somerville v. Stryker Orthopaedics*, No. C 08-02443 JSW, 2009 WL 2901591, at *1 (N.D. Cal. Sept. 4, 2009) (citing 1988 precedent for the proposition that “[c]onclusory allegations without more are insufficient to defeat a motion to dismiss for failure to state a claim upon which relief may be granted”); *William Beaumont Hosp. v. Medtronic, Inc.*, No. 09-CV-11941, 2009 WL 2849546, at *2 (E.D. Mich. Aug. 31, 2009) (citing 1996 precedent (and *Iqbal*) for the proposition that the dismissal standard of review, “[t]hough decidedly generous, . . . does require more than the bare assertion of legal conclusions”); *In re Neurontin Antitrust Litig.*, MDL No. 1479, Master File No. 02-1390, Civ. Nos. 02-1830 (FSH), 02-2731 (FSH), 02-5583 (FSH), 2009 WL 2751029, at *7 (D.N.J. Aug. 28, 2009) (citing 1989 and 1997 precedent (and *Twombly*) for the proposition that “a court does not need to credit a complaint’s ‘bald assertions’ or ‘legal conclusions’”); *Prudhel v. Endologix, Inc.*, No. Civ. S-09-0661 LKK/KJM, 2009 WL 2045559, at *3 (E.D. Cal. July 9, 2009) (citing 1981 precedent for the proposition that “the court does not accept as true unreasonable inferences or conclusory legal allegations cast in the form of factual allegations”); *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 107 (D. Mass. 2009) (citing 1984 and 1991 precedent for the proposition that “conclusory allegations are not sufficient”).

lower federal judiciary's universal adoption of the "conclusions-do-not-count" principle suggests that the answer to that unaddressed question is "no."

6. A Sampling of Iqbal's Use in Pharmaceutical and Medical Device Cases

No opinion-level study of the *Iqbal* effect would be complete without examining *how* the courts are using *Iqbal* in pharmaceutical and medical device litigation. Comprehensively cataloguing all of *Iqbal*'s uses within this cohort of cases would tax even the most intrigued reader's patience. But a sampling of some of those applications is revealing and illustrates just how creatively *Iqbal* is being invoked. The short synopses that follow discuss a few of the more noteworthy uses of the *Iqbal* standard in this case cohort.

a. Products Liability—Alternatively Pleading Causation

As discussed earlier, the *Iqbal* decision was cited as authority for dismissing strict liability and wrongful death claims against the manufacturer of a prescription drug administered to a clinical trial patient.³⁴⁶ In the original *Mohr v. Targeted Genetics, Inc.* opinion,³⁴⁷ the court surveyed "the proverbial 'laundry list' of elements of a product-liability case" alleged against the defendant, and ruled that "they do not meet the *Iqbal* standard."³⁴⁸ The plaintiff had alleged harm caused by the defendant's drug, or by the experimental gene therapy drug that was the subject of the clinical trial, or by a combination of the two.³⁴⁹ Such a pleading failed the *Iqbal* inquiry, ruled the court, because it "alleged no specific facts which establish tortious conduct" by the defendant.³⁵⁰

346. See *supra* notes 315–21 and accompanying text.

347. No. 09-3170, 2009 WL 4021153 (C.D. Ill. Nov. 18, 2009). As explained earlier, the pleader survived an *Iqbal* dismissal motion on repleading. See *Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 721 n.6 (C.D. Ill. 2010).

348. *Mohr*, 2009 WL 4021153, at *3.

349. *Id.*

350. *Id.* As a matter of *proof*, the court surely was correct. See DAVID G. OWEN, PRODUCTS LIABILITY LAW 766 (2d ed. 2008) ("In every products liability case, the plaintiff must establish the central element of causation—that the plaintiff's harm resulted, at least in part, from some defect in a product that the defendant manufactured or sold."). The operative question in *Mohr* was whether that *proof* must be previewed definitively in the pleadings in an alternatively liable, multiple defendant setting.

This *Mohr* opinion raises the intriguing question of how far, if at all, the Supreme Court might envision the incursion of its “plausibility” equipoise concept into the alternative pleading principle. A key failing the Court detected in both the *Twombly* and *Iqbal* pleadings seems to be their inability to discount the possibility of a non-liability-producing explanation for their potentially-liability-producing accusations.³⁵¹ Read narrowly, the same failing will necessarily appear in many alternatively pleaded causation allegations like *Mohr*—either the drug manufacturer is culpable or, if not, then the experimental gene therapy producer is.³⁵² The very existence of each alternatively pleaded factual scenario competes against, and thereby presumably undermines, the “plausibility” of the other by creating an equipoise between liability and non-liability for each of the alternatively-pleaded causation sources. The *Mohr* court’s reasoning implies that, in such a situation, the *Iqbal* “plausibility” standard could be assigned a role in testing the alternative pleadings and, so assigned, would likely be expected to defeat the pleading.³⁵³ That result, an

351. See *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1951–52 (2009) (“As between th[e] ‘obvious alternative explanation’ for the arrests [of Muslims, namely the expected ‘disparate, incidental impact’ on that ethnic group during the post-9/11 investigation] . . . and the purposeful, invidious discrimination respondent asks us to infer, discrimination is not a plausible conclusion.”); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 568 (2007) (“[A] natural explanation for the noncompetition alleged is that the former Government-sponsored monopolists were sitting tight, expecting their neighbors to do the same thing.”).

352. The principle of alternative pleading has long been recognized in federal pleading practice. See FED. R. CIV. P. 8(d)(2) (“A party may set out 2 or more statements of a claim or defense alternatively If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.”).

353. The *Mohr* court is not alone. See *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *7 (W.D. Pa. June 16, 2010) (rejecting pleader’s contention, in an unknown-anesthetic-supplier case, that “Fed. R. Civ. P. 8(d) permits her to plead in the alternative, as she is unable to identify the exact [anesthetic] manufacturer”). But nor has the *Mohr* analysis been embraced everywhere. The District of Rhode Island, for example, ruled that “plausibility” does not undermine a pleader’s entitlement under Rule 8(d) to assert alternative or hypothetical claims, and the familiar product liability litigation practice of joining all potentially liable defendants survives *Iqbal*. *Koch v. I-Flow Corp.*, No. 09-441 S, 2010 WL 2265670, at *3–4 (D.R.I. June 7, 2010) (noting that the need for alternative pleadings “typically arises when the substance of plaintiff’s claim indicates that plaintiff is entitled to relief from someone, but the plaintiff does not know which of two or more defendants is liable,” that “*Twombly* and *Iqbal* do not mark a radical change in federal pleadings standards,” and that although the pleader “will ultimately be required to identify” the culpable manufacturer, “at this stage of the litigation . . . [the plaintiff] has made out facially plausible claims against each Defendant, alternatively” (citations and internal quotation marks omitted)); see also *In re Prempro Prods. Liab. Litig.*, MDL Nos. 4:03-CV-01507-WRW, 4:10-CV-00409-WRW, 2010 WL 2884887,

extension of the “plausibility” standard, may cause very little disruption in existing alternative-pleading practice when the pleader is privy to the underlying facts,³⁵⁴ but a far more meaningful adjustment when the underlying facts are honestly unknown (and alternative pleading would have been otherwise proper).³⁵⁵

b. Products Liability—Alternatively Pleading Product Identification

The “unknown-anesthetic-supplier” cases discussed earlier are emblematic of *Iqbal*’s use by some courts in dismissing pharmaceutical products liability complaints for failure to allege a factually plausible product identification against the named defendants.³⁵⁶ For example, in *Dittman v. DJO, LLC*,³⁵⁷ the court tested a complaint alleging injury from negligent warning and

at *2 (E.D. Ark. July 20, 2010) (finding alternative claim properly pleaded, commenting that “the real question is not whether Plaintiffs presented inconsistent theories, it is whether the allegations presented are adequately pleaded”).

354. See *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 407 (S.D.N.Y. 2001) (“[The alternative pleading rule does not] grant[] plaintiffs license to plead inconsistent *assertions of facts* within the allegations that serve as the factual predicates for an independent, unitary claim. Internally conflicting factual assertions that constitute integral components of a claim must be distinguished from a permissible alternative statement embodying a theory of a whole sufficient claim. . . . [The Rule] could not coherently contemplate that plaintiffs pressing a claim of fraud would be allowed to make a factual assertion in one paragraph of the complaint declaring that they were not aware of some material information, and in another part of the same claim concede that they relied detrimentally upon that same factual representation as the basis for recovery. Under these circumstances, such conflicting allegations would be deemed admissions that undermine plaintiffs’ statement of the elements of a sufficient claim.” (citations omitted)).

355. See 5 WRIGHT & MILLER, *supra* note 11, § 1285, at 741 (“A party . . . should not set forth inconsistent, or alternative, or hypothetical statements in the pleadings unless, after a reasonable inquiry, the pleader legitimately is in doubt about the factual background or legal theories supporting the claims or defenses or is otherwise justified in pleading in this fashion and the pleader can represent that he is not doing so for an improper purpose. However, the obligations imposed by Rule 11 should not be construed to force a party to choose any single factual or legal theory in the pleadings to the exclusion of all others when that party is honestly uncertain as to what might be produced in the discovery process and what the evidence will show.” (footnotes omitted)).

356. See also *supra* notes 287–92 and accompanying text.

357. No. 08-cv-02791-WDM-KLM, 2009 WL 3246128 (D. Colo. Oct. 5, 2009).

testing (among other claims) of an anesthetic-loaded, implanted pain pump. Although the plaintiff had named two anesthetic manufacturers, the complaint did “not identify which specific medication was allegedly used during his procedure or directly allege that any of these defendants were the actual manufacturer of the drug that caused his injury.”³⁵⁸ Quoting *Iqbal*, the court described the plausibility standard as “ask[ing] for more than a sheer possibility that a defendant has acted unlawfully.”³⁵⁹ Pleading facts that are “merely consistent with” liability fail this test.³⁶⁰ Because the plausibility threshold had not been crossed, reasoned the court, the pleading must be dismissed:

Plaintiff has no facts, only speculation, on which to base his claim that defendants’ products caused or contributed to his injury. This mere possibility, *i.e.*, that the medicine used could have been made by these defendants, rather than by any number of other manufacturers of anesthesia drugs, is not adequate to state a claim under the prevailing standards as set forth by *Twombly* and *Iqbal*.³⁶¹

This sort of *Iqbal* application, however, is not universally received; other courts that have considered it have rejected it.³⁶²

Like alternatively pleaded causation, the injection of *Iqbal* to justify the pre-discovery dismissal of a products liability lawsuit on alternatively-pleaded product identification grounds may signal, for several jurisdictions, a substantial departure from prior dismissal motion practice.³⁶³

358. *Id.* at *1.

359. *Id.* at *2 (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)).

360. *Id.* (quoting *Iqbal*, 129 S. Ct. at 1949).

361. *Id.* at *3. As noted above, other courts have reached the same results. See *supra* notes 287–92, 327 and accompanying text. Again, as a matter of *proof*, the court’s conclusion is beyond reproach. See OWEN, *supra* note 350, at 768 (“[I]f a plaintiff cannot prove that the accident product was more likely produced or sold by the defendant, a jury will not be permitted to speculate on this crucial issue of identification, and the plaintiff’s case will usually fail.”).

362. See, e.g., *In re Prempro Prods. Liab. Litig.*, MDL Nos. 4:03-CV-01507-WRW, 4:10-CV-00409-WRW, 2010 WL 2884887, at *2 (E.D. Ark. July 20, 2010) (“[T]he real question is not whether Plaintiffs presented inconsistent theories, it is whether the allegations presented are adequately pleaded.”).

363. See, e.g., *Garcia v. Pfizer, Inc.*, 268 Fed. App’x 270, 271 (5th Cir. 2008) (describing process of post-complaint product identification discovery, leading to amended complaint and, later, to post-discovery summary judgment challenge); *In re Brooklyn Navy Yard Asbestos Litig.*, 971 F.2d 831, 844 (2d Cir. 1992) (noting dismissal, at trial, of defendant for lack of product identification); *Menne v. Celotex Corp.*, 861 F.2d 1453, 1457 n.5 (10th Cir. 1988) (noting that product identification defense was resolved at trial by jury). But see *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217,

c. Products Liability—Selecting a “Defect” Theory

The *Iqbal* decision was cited as authority in testing whether a plaintiff is now obligated to choose among, and then plead, a specific theory of defect in a product liability lawsuit. In *Krywokulski v. Ethicon, Inc.*,³⁶⁴ a surgical patient sued the manufacturer of a surgical mesh hernia patch for strict liability and negligence when the product failed. The defendants claimed that *Iqbal* (and *Twombly*) “placed a higher pleading burden upon plaintiffs to survive a Rule 12(b)(6) . . . dismissal.”³⁶⁵ More precisely, the defendants argued that *Iqbal* changed Florida state law that, formerly, had not required a strict liability pleader to choose the theory of defect (e.g., manufacturing defect, design defect, or warning defect) or to articulate the facts supporting the claimed defect.³⁶⁶ Although citing liberally from both *Iqbal* and *Twombly*, the court rejected the defendants’ position. Florida’s pleading law had not been altered by *Iqbal*; pleaders in the state still were not obligated to elect their strict liability defect theory at the pleading stage, and an enhanced pleading obligation to settle on a precise defect theory in drug and device cases did not exist.³⁶⁷ Nevertheless, the court did rule that in pleading a negligence claim, a mere incantation that defendants had, and breached, some unspecified duty of care did not suffice; additional factual definition of that claim was required.³⁶⁸

The *Krywokulski* decision illustrates how litigants are pressing *Iqbal* as a source for greater product defect particularization at the pleading stage, and meeting limited, but some, success in doing so. Ultimately, the court in *Krywokulski* was able to harmonize *Iqbal* with existing pleading practice.³⁶⁹ How other courts will respond to

1225 (9th Cir. 2006) (discussing dismissal process for multidistrict litigation claimants unable to plead specific product identification).

364. No. 8:09-CV-980-T-30MAP, 2010 WL 326166 (M.D. Fla. Jan. 21, 2010).

365. *Id.* at *2.

366. *Id.* at *2–3.

367. *Id.* at *3.

368. *Id.* at *3–4. Even here, however, the court based its dismissal of the negligence count on preexisting state substantive law that had long pre-dated *Iqbal*. *Id.* at *4 (quoting *Jennings v. BIC Corp.*, 181 F.3d 1250, 1256–57 (11th Cir. 1999)).

369. The court in *Krywokulski* is not alone in this regard. In a multidistrict litigation pretrial resolution of an attack on a Master Consolidated Complaint in a cardiac drug products liability litigation, the court in *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2009 WL 2433468 (S.D.W. Va. Aug. 3, 2009),

similar pleading invitations will clarify whether *Iqbal* represents a true change in defect-particularization standards.

d. Products Liability—Conclusory Pleading of “Defect”

The *Iqbal* decision was cited as authority for dismissing products liability claims that alleged the nature of a product’s defect but did so only in an element-recounting, factually conclusory fashion. In *Frey v. Novartis Pharmaceuticals Corp.*,³⁷⁰ a patient sued the manufacturer of an anticonvulsant medication for manufacturing, design, and warning defects that caused her injury. Her manufacturing defect claim pleaded that the company had “failed to design, manufacture, test, and control the quality of [the drug] such that when it left the control of the Defendant, it deviated in a material way from the design specifications, formula or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula or performance standards.”³⁷¹ Similarly, her design claim contended that “the risks created by [the drug] exceeded its benefits and that a practical and technically feasible alternative design was available which would have prevented the harm alleged without substantially impairing the product’s usefulness or intended purpose.”³⁷² Finally, her warning claim alleged an

inadequate warning or instruction at the time of marketing and post-marketing because defendants knew, or in the exercise of reasonable care should have known, about a risk associated with the product that caused the harm alleged, and defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk.³⁷³

likewise found that allegations of failure to warn, manufacturing and design defect, and negligence per se survived an *Iqbal* inquiry.

370. 642 F. Supp. 2d 787 (S.D. Ohio 2009).

371. *Id.* at 790. This language tracked, effectively verbatim, the language of the applicable statutory law, the Ohio Product Liability Act. *See id.* at 792–93 (quoting statutorily approved manufacturing defect elements, OHIO REV. CODE ANN. § 2307.74 (West 2004)).

372. *Id.* at 790 (paraphrasing pleaded allegations); *see also id.* at 793 (quoting statutorily approved design defect elements, OHIO REV. CODE ANN. § 2307.75 (West Supp. 2008)).

373. *Id.* at 790 (paraphrasing pleaded allegations); *see also id.* at 793 (quoting statutorily approved warning defect elements, OHIO REV. CODE ANN. § 2307.76 (West 2004)).

The company moved to dismiss only the manufacturing and design counts and did not challenge the adequacy of the warning count.³⁷⁴ In very brief discussions, the court granted the dismissals. Plaintiffs' allegations, wrote the court, "fail[ed] to state a plausible claim for relief" and "fall far short of the sufficiency standard set forth in *Twombly*" because they do "nothing more than provide a formulaic recitation of the elements of a claim under the statute."³⁷⁵

That this sort of element-only pleading would have survived under the pre-"plausibility" pleading regime might be doubtful, but it is also uncontested that *Iqbal* has added to the arsenal defendants are using—sometimes successfully—to explain why such conclusory allegations are insufficient and must be dismissed.³⁷⁶

e. Products Liability—Escaping Federal Preemption

Also as discussed earlier, the *Iqbal* decision has been cited in cases as authority for dismissing medical device complaints that failed to supply the factual allegations to support a "parallel" claim that might escape federal Medical Device Amendment preemption.³⁷⁷ For example, in *Ilaraza v. Medtronic, Inc.*,³⁷⁸ the plaintiff claimed an injury from an implanted medical pump, and alleged that the defendant failed to manufacture the product in compliance with federally prescribed Current Good Manufacturing Practices. However, because the plaintiff's pleading did "nothing more than recite unsupported violations of general regulations, and fail[ed] to tie such allegations to the injuries alleged, the complaint [wa]s properly dismissed."³⁷⁹ Other courts have applied *Iqbal* to

374. *Id.* at 791. This strategy is curious, and given the summary dismissal and associated reasoning from the court, the defendant might, in retrospect, have sought to prevail on all three theories.

375. *Id.* at 795.

376. The *Frey* court is not alone. See *Burks v. Abbott Labs.*, Civ. No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *3 (D. Minn. Apr. 20, 2010) (faulting pleader for, among other things, not alleging "any facts describing or identifying defendants' manufacturing specifications or standards" and, therefore, pleader failed "to allege facts describing how defendants' products deviated from such specifications or standards").

377. See *supra* notes 330–31 and accompanying text.

378. 677 F. Supp. 2d 582 (E.D.N.Y. Dec. 28, 2009).

379. *Id.* at 588. The Court quoted *Twombly* for the proposition that federal pleading requirements "require dismissal of complaints that do nothing more than engage in a 'formulaic recitation of the elements of a cause of action.'" *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

find preemption under similar reasoning.³⁸⁰ In doing so, one court expressly questioned whether the practice of pleading “upon information and belief” survived in the wake of the “plausibility” standard, at least in the preemption context.³⁸¹

Whether *Iqbal* has wrought a meaningful change in this category of medical device litigation hinges at least on the nature of the dismissal challenge. A claim that is facially preempted under existing federal authorities would seem to implicate the paradigmatic *Conley* situation: “beyond doubt,” such a plaintiff

380. See, e.g., *Bass v. Stryker Corp.*, No. 4:09-CV-632-Y, 2010 WL 3431637, at *5 (N.D. Tex. Aug. 31, 2010) (“Plaintiff has not specifically alleged how Defendants have failed to meet [federal device-approval] specifications or that such a failure has even occurred.”); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (“[The pleader] ‘cannot simply incant the magic words ‘Medtronic violated FDA regulations’ in order to avoid preemption.’ . . . Merely alleging that Defendant generally failed to comply with federal requirements is insufficient to overcome the preemptive reach of [federal law] without some factual detail as to why Defendant violated federal regulations.” (citation omitted)); *Anthony v. Stryker Corp.*, No. 1:09-cv-2343, 2010 WL 1387790, at *4 (N.D. Ohio Mar. 31, 2010) (observing that pleader “did not specifically mention either the FDA or its regulations” nor “plead any facts that would lead this court to plausibly infer that Stryker’s noncompliance with FDA regulations led to his injury”); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009) (finding that pleader “provides no facts in support of his conclusory allegations, instead relying on the doctrine of *res ipsa loquitur*—a doctrine that would seem to be soundly refuted by *Riegel*” and, therefore, granting motion); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *15 (M.D.N.C. Aug. 5, 2009) (ruling that because pleader “has not alleged any particular non-conclusory link between th[e] alleged wrongdoing and his particular injuries,” the court was “left with nothing more than a mere ‘suspicion’ that Plaintiff may have a legally cognizable claim, which . . . is insufficient to survive a motion to dismiss”); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) (explaining that “[t]he generalized allegations made in plaintiff’s complaint call for . . . amplification here as the relationship between defendants’ federal violations and plaintiff’s injury seems implausible”); see also *Prudhel v. Endologix, Inc.*, No. Civ. S-09-0661-LKK/KJM, 2009 WL 2045559, at *9 (E.D. Cal. July 9, 2009) (noting that courts are “divided as to what *Twombly* requires of a plaintiff seeking to plead a parallel claim,” but finding no need to cast its lot as between the competing views because, under either approach, certain claims failed and others survived).

381. See *Funk*, 673 F. Supp. 2d at 525 (“Whether an allegation based solely on information and belief is sufficient, after *Twombly*, to survive a motion to dismiss is unclear.”). Although the court in *Funk* did not resolutely answer this question, after mulling over language from *Twombly* and several Circuit-level opinions, the court tended toward the conclusion that information-and-belief pleading was at least newly circumscribed under the “plausibility” regime. See *id.* (“Accordingly, this court reviews allegations based upon information and belief under *Twombly*’s 12(b)(6) formulation requiring sufficient fact pleading to make a claim plausible.”).

would be unable to marshal any “set of facts in support of his claim which would entitle him to relief.”³⁸² A baldly conclusory listing of federal standards, coupled with an equally conclusory pronouncement of an unspecified violation (or series of violations), is where *Iqbal*’s effect is most likely to be asserted, but even there such a pleading might well have triggered a dismissal under the lower federal courts’ pre-*Iqbal* practice of rejecting cursory and unembellished declarations of liability.³⁸³

f. Antitrust—Paradigmatic “Plausibility”

In a return to the litigation origins of the plausibility standard that hearkened back to the *Twombly* context, the *Iqbal* decision was cited in dismissing an antitrust complaint that challenged the Pfizer–Wyeth merger. In *Golden Gate Pharmacy Services, Inc. v. Pfizer, Inc.*,³⁸⁴ the court faulted the pleading for failing to properly allege the relevant product market, a prerequisite for antitrust claims: “Plaintiffs fail to allege . . . even as a conclusion, let alone the requisite facts to support a finding, that all prescription drugs are ‘reasonably interchangeable by consumers for the same purposes.’”³⁸⁵ The court’s conclusion in *Golden Gate Pharmacy* that the pleader had failed to allege a requisite element to support relief under the chosen antitrust theory could well have resulted in a functionally identical dismissal without the *Iqbal* inquiry.³⁸⁶ On another occasion, the *Iqbal* decision was cited as authority for dismissing an antitrust case that lacked factual content. In *RxUSA Wholesale, Inc. v. Alcon Laboratories, Inc.*,³⁸⁷ the court dismissed a portion of the antitrust claim, as in *Golden Gate Pharmacy*, for

382. See *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957).

383. See *supra* notes 339–45 and accompanying text (discussing migration by the courts of appeals away from a literal *Conley* standard well before *Iqbal* and *Twombly*).

384. No. C-09-3854-MMC, 2009 WL 3320272 (N.D. Cal. Oct. 14, 2009).

385. *Id.* at *1 (“An allegation that a product market exists must be, as with any element of a claim, supported by ‘sufficient factual matter’” (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009))).

386. See 5 WRIGHT & MILLER, *supra* note 11, § 1216, at 220–27 (years before *Twombly*, noting that federal pleading principles require that “the complaint must contain either direct allegations on every material point necessary to sustain a recovery on any recognizable legal theory, even though that they may not be the one suggested or intended by the pleader, or the pleading must contain allegations from which an inference fairly may be drawn by the district court that evidence on these material points will be available and introduced at trial”).

387. 661 F. Supp. 2d 218 (E.D.N.Y. 2009).

failure to satisfy element foundations,³⁸⁸ but other portions of the antitrust claim for failing to supply an adequate factual context to verify plausibility.³⁸⁹ Other similar antitrust examples abound.³⁹⁰ Clearly, “plausibility” is retaining a vibrant presence in the antitrust context where this concept first began.

g. Consumer Fraud—Showing the Elements

The *Iqbal* decision was cited as authority for dismissing claims under state law consumer protection, false advertising, and unfair competition statutes. In *Brownfield v. Bayer Corp.*,³⁹¹ the plaintiffs filed a putative class action against the manufacturer of a prescription oral contraceptive that, they claimed, had been misrepresented in consumer advertising. The court dismissed the state law claims for lack of standing, finding that the plaintiffs had failed to plead that they actually viewed the challenged advertising, that they purchased the product in reliance on the advertising, and that they were injured as a result.³⁹² Because, citing *Iqbal*, “[o]nly

388. *Id.* at 227–28 (dismissing Section 2 refusal to deal claims because the pleader failed to allege that it was a competitor of the defendants or had ever engaged in business with them).

389. *See, e.g., id.* at 231 (“The Complaint contains no allegations as to when the alleged conspiracy began, where it occurred, or what statements the Manufacturing Defendants made to one another. . . . Under *Twombly*, as well as controlling Second Circuit precedent, such conclusory allegations are insufficient to state a claim.”); *id.* at 232 (“Because Plaintiff’s allegations are not ‘placed in a context that raises a suggestion of a preceding agreement, [but] merely [suggests] parallel conduct that could just as well be independent action,’ Plaintiff’s allegations of parallel conduct fail to allege a conspiracy claim under Section 1.” (citation to *Twombly* omitted)). An interesting artifact of the *RxUSA Wholesale* decision is the confirmation that an *Iqbal* failure on federal antitrust claims may, for that reason, also defeat a state law antitrust claim. *See id.* at 234 (“Because plaintiff’s federal antitrust claims have been dismissed, Plaintiff’s claims under the Donnelly Act [New York General Business Law that declares as illegal all contracts, agreements, arrangements, or combinations whereby a monopoly is established] are dismissed as well.”).

390. *See In re Blood Reagents Antitrust Litig.*, MDL No. 09-2081, 2010 WL 3364218, at *8 (E.D. Pa. Aug. 23, 2010) (faulting pleader for failing to allege any allegations of conspiratorial involvement); *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1376–79 (N.D. Ga. Feb. 22, 2010) (faulting pleader for failing to support unreasonable restraint of trade theory); *CIBA Vision Corp. v. De Spirito*, No. 1:09-cv-01343-JOF, 2010 WL 553233, at *5–10 (N.D. Ga. Feb. 10, 2010) (faulting pleader for failing to explain why alleged competitive behavior was improper); *Synergetics USA, Inc. v. Alcon Labs., Inc.*, No. 08-CIV-3669 (DLC), 2009 WL 1564113, at *4 (S.D.N.Y. June 4, 2009) (faulting pleader for failing to specify defendant’s power or dominance in market).

391. No. 2:09-cv-00444-JAM-GGH, 2009 WL 1953035 (E.D. Cal. July 6, 2009).

392. *Id.* at *4.

a complaint that states a plausible claim for relief survives a motion to dismiss,” the court struck the pleading.³⁹³ This decision tends to square with prior federal practice. Although the pleading in *Brownfield* might have survived a literal *Conley* inquiry (because the allegations do not affirmatively deny viewing, reliance, and injury), the failure to allege the baseline requisites for a claimed cause of action would probably have doomed the state law claims well before “plausibility” arrived.³⁹⁴

C. The Study Conclusions

So, who has been proven right? Is *Iqbal* actually making a difference in pharmaceutical and medical device litigation?

This Article’s study undermines the view that *Iqbal*’s effect is dramatic throughout pharmaceutical and medical device litigation. Its effect, however characterized, was not felt in nearly 79% of the cases in this cohort. But this Article’s study also does not confirm that *Iqbal*’s effect was negligible and wholly inconsequential. In about 21% of the cases examined, the deciding courts either expressly or impliedly relied on *Iqbal* to grant a full or partial dismissal.

Giving meaning to that 21% has proven to be a bit more elusive, though some conclusions are fairly drawn. The rates of grants and denials reveal a trend. Plaintiffs confronting dispositive pleadings attacks in this litigation context are succeeding in completely resisting those motions at a greater rate today than federal pleaders generally in the year before *Twombly* first announced the “plausibility” test and are losing such motions today at the lowest rate since *Iqbal* was decided. The incidence of a with-prejudice dismissal in an *Iqbal*-affected disposition is small, only 5.3% of the 264 cases studied. Most often, dismissed pleaders are invited to replead (or at least are not expressly precluded from seeking to replead). In a comparably small percentage of the cases (8.3%), a potential “information asymmetry” was identified in an *Iqbal*-affected disposition, but those pleaders’ deficiencies were often not so much a lack of information as a lack of explanation of the pre-filing investigative efforts that unearthed the right to sue in the first place. Those dismissals might well have been identical had the deciding court used Rule 11(b)(3), rather than “plausibility,” to explain the results.

In the end, confounding this analysis is the prevailing, pre-*Iqbal* recitation by every federal judicial circuit that a pleader’s

393. *Id.*

394. *See supra* note 386.

conclusory allegations should not be accepted as true when ruling on Rule 12(b)(6) motions to dismiss.³⁹⁵ If that pre-existing, pre-*Iqbal* principle had been applied, rather than *Iqbal* itself, the candid conclusion may well be that nothing has changed at all. If that is truly the case, then *Iqbal* did not usher in some new federal paradigm as regards conclusorily pleaded claims; it simply validated a practice long-followed throughout the federal courts.³⁹⁶ One apt to criticize *Iqbal* (at least as it relates to legal conclusions) might better argue not that the Supreme Court used *Iqbal* as an instrument of great change, but that the Court *failed* to use it as an instrument of great change by neglecting to overturn the prevailing federal approach to legal conclusions.

In any event, if one is inclined to see in *Iqbal* the harbinger of momentous change in federal pleading, an arrival greeted either alarmingly (in fear of meritorious cases lost) or warmly (in appreciation for unmeritorious cases purged),³⁹⁷ the cause for either alarm or delight is waning. This Article’s study finds that the prevalence of the courts’ use of *Iqbal* to dismiss cases has tapered off meaningfully in pharmaceutical and medical device litigation.

The four broad *Iqbal* studies that predated this Article offer a modicum of corroboration to the pharmaceutical and medical device findings noted here. Both this Article and the data assembled by the Administrative Office of the United States

395. See *supra* note 341 and accompanying text.

396. See *Bissessur v. Ind. Univ. Bd. of Trs.*, 581 F.3d 599, 603–04 (7th Cir. 2009). The court remarked:

Our system operates on a notice pleading standard; *Twombly* and its progeny do not change this fact. A defendant is owed “fair notice of what the . . . claim is and the grounds upon which it rests.” [Conley v. Gibson, 355 U.S. 41, 47 (1957).] Under *Conley*, just as under *Twombly*, it is not enough to give a threadbare recitation of the elements of a claim without factual support. A plaintiff may not escape dismissal on a contract claim, for example, by stating that he had a contract with the defendant, gave the defendant consideration, and the defendant breached the contract. What was the contract? The promises made? The consideration? The nature of the breach? . . . Allowing [such a] case to proceed absent factual allegations that match the bare-bones recitation of the claims’ elements would sanction a fishing expedition costing both parties, and the court, valuable time and resources.

Id. (further citations omitted).

397. And were this view correct, the advent of change would not, in itself, have likely earned Judge Clark’s condemnation. He seemed to recoil from the notion that even disruptive change was, for that reason alone, to be unwelcomed. See CLARK, *supra* note 9, at 31 (“[U]nless pleading rules are subject to constant examination and revaluation, they petrify and become hindrances, not aids, to the administration of justice. Many lawyers are disturbed by the idea that the rules of practice must be changed. There is always strife for that delusive certainty in the law.”).

Courts tend to show that post-*Iqbal* motion filings rose meaningfully, but the rate of motions granted post-*Iqbal* is not dramatically higher than before (and, indeed, has seemed to recede).³⁹⁸ Both this Article and the Judicial Conference's study conclude that the case law decided to date does not reveal a dramatic post-*Iqbal* change in federal pleading practice among the lower federal courts.³⁹⁹ Both this Article and Professor Hatamyar's study found a very substantial rate of post-*Iqbal* dismissals in the period immediately after the release of the *Iqbal* opinion and, among dismissals, a heavy weighting towards those of the without-prejudice variety.⁴⁰⁰ Both this Article and the Federal Judicial Center studies detected only a modest (if any) post-*Iqbal* impact on motions to dismiss experience in litigation.⁴⁰¹

CONCLUSION

Few battles over federal civil procedure have ever drawn out the vigor as the fight over *Iqbal* and claim "plausibility." The language of the tumult is impassioned. Opponents of *Iqbal* decry it (and *Twombly*, its predecessor) as "serious mistakes" that are "at odds with premises underlying the Federal Rules, with precedent, and with congressional expectations"⁴⁰² and that "marks a continued retreat from the principles of citizen access, private enforcement of public policies, and equality of litigant treatment in

398. See *supra* notes 165–68 and accompanying text.

399. See *supra* notes 169–75 and accompanying text.

400. See *supra* notes 176–84 and accompanying text. To be precise, Professor Hatamyar's study of a sampling of all federal cases found a dismissal rate (full and partial dismissals, and both with and without prejudice) of 81% in the three-and-a-half months immediately following *Iqbal*. See Hatamyar, *supra* note 176, at 598 tbl.1. This Article finds a dismissal rate among pharmaceutical and medical device cases at an 82.6% rate during the same period. See *supra* Part VI.B (noting first interval rate for completely defeated motions at 17.4%). This Article also finds that this dismissal rate fell off meaningfully as the distance from *Iqbal* grew, to the 61.7% rate recorded for the fifth time interval measured (June, July, and August 2010). Whether Professor Hatamyar's study would have found a similar pattern across the full spectrum of federal cases in the 12 additional months following the close of her research is unknown.

401. In the first study, lawyers who filed a post-*Twombly* employment discrimination case reported suffering a "plausibility"-based dismissal just 7.2% of the time. See *supra* notes 185–89 and accompanying text. In the second study, most of those interviewed reported that they have not "seen any impact" or have seen "no impact" in their practices from "plausibility." See *supra* notes 190–95 and accompanying text.

402. Senate Judiciary Hearing, *supra* note 132, at 101, 104, available at <http://judiciary.senate.gov/pdf/12-02-09%20Burbank%20Testimony.pdf>, at 17, 20 (statement of Professor Burbank).

favor of corporate interests and concentrated wealth.”⁴⁰³ Proponents of *Iqbal* applaud it, in pharmaceutical and medical device products cases at least, for at last policing a more thorough pre-filing investigation, which “means looking through the medical records . . . [,] . . . interviewing the prescriber . . . [,] engaging an expert witness, and getting at least a preliminary opinion,” all of which “means significant curtailment of litigation by word processor”—a result “that’s just great.”⁴⁰⁴

This Article studied the actual effect of *Iqbal* on the cohort of more than 264 federal pharmaceutical and medical device cases of every type, released from the day of the decision in *Iqbal* through August 31, 2010. The results of that study of more than 15 months of case law suggest that *Iqbal* is not having a dramatic impact on this cohort, although its impact cannot be conclusively dismissed as inconsequential either. There have been aggressive applications of *Iqbal* on occasion. In the 21.2% of the time when *Iqbal* appears facially to be impactful, a closer examination reveals that this observed effect is, in large measure, decreasing in incidence, coupled with an ability for correction, and frequently avoidable through accessible sources of information. Moreover, this Article cannot rule out that even those perceived effects may be phantoms, because repeated, longstanding, and frequently cited federal precedent among the lower federal courts may well have led to functionally identical results even without *Iqbal*’s emergence. Nevertheless, validly assessing the true impact of *Iqbal* on pharmaceutical and medical device litigation (or, for that matter, federal litigation generally) remains a risky business. The *Iqbal* opinion is still too new, the hard data surrounding its use too thin, the steadied nature of its application too uncertain, and the legislative efforts to unwork it too unknown.

The vibrancy of this battle will likely persist for many years to come. What this Article has found (at least as to the data available as it was written) is that the drama of the debate does not quite echo in the pharmaceutical and medical device experience of the courthouse.

403. Miller, *supra* note 59, at 10.

404. James M. Beck, *Once More into the Breach*, DRUG & DEVICE L. BLOG (Mar. 18, 2010, 5:47 PM), <http://druganddevicelaw.blogspot.com/2010/03/once-more-into-breach.html>.