

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

IN RE: HUMIRA (ADALIMUMAB)
ANTITRUST LITIGATION

No. 19 CV 1873

Judge Manish S. Shah

MEMORANDUM OPINION AND ORDER

Defendant AbbVie Inc. makes a lot of money selling the prescription drug Humira. One reason for Humira's profitability is that AbbVie's Humira-related patents (more than a hundred) make it difficult (if not impossible) to sell competing drugs. Another reason may be that the Food and Drug Administration's lengthy approval process imposes additional costs on competitors hoping to reach the market. Still a third reason might be the expensive, complicated, and contentious patent infringement litigation that often follows on the heels of FDA approval.

Plaintiffs, indirect purchasers of Humira, allege a different reason: AbbVie cornered the market for Humira (and other biosimilar drugs) through anticompetitive conduct. They say that AbbVie (and its subsidiary, AbbVie Biotechnology, Ltd.) applied for, obtained, and asserted patents to gain the power it needed to elbow its competitors (the other defendants in this case, Amgen, Inc., Samsung Bioepis Co., Ltd., and Sandoz, Inc.) out of the Humira market in the United States (in violation of § 2 of the Sherman Act) and then entered into agreements with those competitors to keep their competing drugs off the market (in violation of § 1). In return, AbbVie gave

those competitors permission to market their drugs in Europe (where AbbVie also possessed an imposing patent portfolio that blocked competition).

The legal and regulatory backdrop for patented biologic drugs, together with a well-resourced litigation strategy, gave AbbVie the ability to maintain control over Humira. Plaintiffs say that AbbVie's plan to extend its power over Humira amounts to a scheme to violate federal and state antitrust laws. But what plaintiffs describe is not an antitrust violation. AbbVie has exploited advantages conferred on it through lawful practices and to the extent this has kept prices high for Humira, existing antitrust doctrine does not prohibit it. Much of AbbVie's petitioning was protected by the *Noerr-Pennington* doctrine, and plaintiffs' theory of antitrust injury is too speculative. Because the federal antitrust claims fail, the state antitrust claims fail, too. And although the complaint is lengthy and detailed, its application to state statutes that prohibit unfair and unconscionable conduct falls short. The complaint is dismissed without prejudice.

I. Legal Standards

A complaint must contain a short and plain statement that plausibly suggests a right to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009); Fed. R. Civ. P. 8(a)(2). In ruling on a motion to dismiss, a court must accept all factual allegations in the complaint as true and draw all reasonable inferences in plaintiffs' favor, but need not accept legal conclusions, bare assertions, or conclusory allegations. *Iqbal*, 556 U.S. at 680–82. The complaint does not need to include detailed factual allegations, but it must provide more than labels and formulaic recitations of the elements of the cause

of action, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and must “present a story that holds together.” *Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010). If a complaint pleads facts that are “merely consistent with” liability, it “stops short of the line between possibility and plausibility of entitlement to relief.” *Iqbal*, 556 U.S. at 678.

II. Facts

A. Humira and the ’382 Patent

Humira is an anti-inflammatory biologic (a drug derived from living organisms that helps slow down overactive immune systems). [109] ¶¶ 2, 32, 77.¹ Originally developed for rheumatoid arthritis, Humira is now used to treat a variety of autoimmune disorders ranging from Crohn’s disease to plaque psoriasis. *Id.* ¶ 81.

Humira generated almost \$20 billion in worldwide sales in 2018 alone and more than \$56 billion in the United States between 2012 and 2018, *id.* ¶ 84, making it the best-selling drug in the country. *Id.* ¶¶ 2, 84. Its sales dollars come not from volume, but from price: a one-month prescription of Humira injections costs about \$4,500. *See id.* ¶ 84.

Humira’s active ingredient is an antibody called “adalimumab.” *See id.* ¶¶ 77–78. Abbott Laboratories bought the patent for adalimumab (U.S. Patent No. 6,090,382, originally assigned to BASF AG in 2000) and used it to launch a new

¹ Bracketed numbers refer to entries on the district court docket. The facts are taken from the consolidated class action complaint, [109], plaintiffs’ opposition to defendants’ motions to dismiss, [144], and, where noted, from sources outside of those documents through judicial notice.

drug—Humira—in 2002. *Id.* ¶¶ 78–80. Abbott sold Humira throughout the world for eleven years before passing the patent off to its spin-off biologic and branded drug business, AbbVie, Inc. *Id.* ¶ 87. The '382 patent expired on December 31, 2016. *Id.* ¶ 78.

The plaintiffs in this lawsuit—indirect purchasers of Humira, including the City of Baltimore, *id.* ¶ 13, an insurance trust fund for Miami Police Department officers, *id.* ¶ 14, and a Minnesota-based employee welfare benefit plan for plumbers, pipefitters, and other workers in the pipe trades industries, *id.* ¶ 15, among others—say that, in the months and years leading up to the expiration of the '382 patent, AbbVie created a thicket of intellectual property protection so dense that it prevented would-be challengers from entering the market with cheaper biosimilar alternatives.² *See id.* ¶¶ 4–9. Then, plaintiffs say, defendants AbbVie Inc. and AbbVie Biotechnology Ltd. used that intellectual property as leverage during negotiations with the other defendants (Amgen, Inc., Samsung Bioepis Co., Ltd., and Sandoz, Inc.³), forcing them to agree to delay their market entry in return for licensing agreements that cut through AbbVie's patent thicket. *Id.* ¶¶ 4, 7.

B. The Patent System

Anyone who invents or discovers any new and useful machine, manufacture, or composition of matter (e.g., a new drug) may apply for a patent from the United

² Biosimilars are to biologics what generics are to small molecule drugs. *See* [109] ¶ 47. Small molecule drugs are those made from chemical processes. *See id.* ¶¶ 32, 47.

³ Fresenius Kabi USA LLC was originally named as a defendant but was dismissed shortly before the filing of the motion to dismiss. *See* [120].

States Patent and Trademark Office. *See* 35 U.S.C. § 101. Once issued, the patent comes with an exclusive right to make, use, and sell the invention in the United States. 35 U.S.C. § 154(a). This “limited monopoly,” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014), lasts for twenty years. 35 U.S.C. § 154(a)(2). *But see* P. Areeda & H. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* § 704a (4th ed. 2019) (Areeda & Hovenkamp) (a patent is more akin to a property right than a monopoly because the “great majority” of patents do not confer sufficient market power to dominate a properly defined market).

Novel inventions are those not disclosed in the prior art. 35 U.S.C. § 102(a). The prior art includes anything that has already been patented or described in a printed publication, or that is in public use, on sale to the public, or otherwise available to the public. *Id.* The patent application process is nonadversarial and relies on applicants to abide by their duty of disclosure, candor, and good faith. 37 C.F.R. § 1.56(a); *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, No. 93 C 5106, 1995 WL 389822, at *11 (N.D. Ill. Feb. 15, 1995). *See also* [109] ¶ 58. If the applicant does not disclose (and the examiner does not find) all of the pertinent prior art, patents may issue to underserving inventions.

As prior art accumulates, applicants face an increasingly crowded space. There are, however, ways to navigate around some of that prior art. For instance, inventors are granted a one-year grace period to file their patent applications after any public disclosure of their own invention. 35 U.S.C. § 102(b)(1). Continuation applications

offer another work around: any applicant with a pending application may later tack on new, related claims.⁴ 35 U.S.C. § 120; 37 C.F.R. § 1.78(d). If the new claims are sufficiently related to the original claim, they are backdated and do not have to account for any prior art developed after the original application's filing date. *Id.* See also [109] ¶¶ 55–56. The catch is that if the new claims are simple, obvious variations on the invention described in the original application, the applicant “generally must” ([109] ¶ 56) file a terminal disclaimer (*see* 37 C.F.R. § 1.321(b)) relinquishing any portion of the new claim's term that would extend beyond the expiration date of the patent that is the subject of the pending application. [109] ¶ 56. In other words, if the applicant wants to use the original filing date for a simple and obvious variation on the original invention, the applicant has to accept the original expiration date, too. *See id.*

C. The Food and Drug Administration's Approval Process

Manufacturers that want to bring a new drug (patented or not) to market must first receive approval from the Food and Drug Administration. *See* 21 U.S.C. § 355; 42 U.S.C. § 262(a). Different kinds of drugs require different kinds of approvals. *See id.* The process for biologic drugs starts when a manufacturer submits a “Biologic License Application” demonstrating that its new drug is (among other things) “safe, pure, and potent.” 42 U.S.C. § 262(a)(2)(C)(i). *See also* [109] ¶ 35. If the application is

⁴ The claims “define the exact boundaries beyond which no member of the public may pass without invading the exclusive rights of the patentee.” *Nat'l Carbon Co. v. W. Shade Cloth Co.*, 93 F.2d 94, 96 (7th Cir. 1937). Claims force the patentee to “define precisely what his invention is.” *White v. Dunbar*, 119 U.S. 47, 52 (1886).

approved, the manufacturer enjoys a period of exclusivity during which it is the only entity that can market the drug for the approved purpose. 42 U.S.C. § 262(k)(7). *See also* [109] ¶ 34. Manufacturers often charge supracompetitive prices during this period in order to recoup their research and development costs and obtain a profit. [109] ¶ 34.

Eventually, that exclusivity ends. One way it can end is when a different manufacturer designs a biosimilar and submits (and has approved) an “Abbreviated Biologic License Application.” 42 U.S.C. §§ 262(k)(2)(A), (k)(6). *See also* [109] ¶¶ 39–40. Abbreviated applications piggyback on existing approvals by identifying an approved reference biologic and demonstrating that there is no “clinically meaningful difference” between the reference biologic and the proposed biosimilar. 42 U.S.C. §§ 262(k)(2)(B), (k)(4). *See also* [109] ¶ 39. Biosimilar manufacturers have to wait four years from the date the reference biologic was approved before submitting an abbreviated application, and the FDA has to wait twelve years from that same date before approving any abbreviated applications. 42 U.S.C. §§ 262(k)(7)(A), (B). *See also* [109] ¶ 41. Once approved, the biosimilar can be marketed to the public—assuming the drug is not also patented. [109] ¶ 41. Prices tend to drop shortly after a new biosimilar is introduced. *See id.* ¶¶ 43–45.

Often, the drug is patented. The regulatory framework sets out a five-step series of required prelitigation exchanges (sometimes called the “patent dance”) aimed at resolving patent disputes between the biosimilar manufacturer (the “applicant”) and the reference biologic’s manufacturer (the “sponsor”). 42 U.S.C.

§ 262(l). *See also* [109] ¶ 61. Once the FDA accepts the application for review, the applicant is required to send information about its biosimilar to the sponsor (step one), *see* 42 U.S.C. § 262(l)(2), the sponsor must send back a list of the patents (if any) that it believes would be infringed if the biosimilar was put on the market (step two), *see* 42 U.S.C. § 262(l)(3)(A), the applicant explains why it believes those patents are invalid, unenforceable, or would not be infringed (step three), *see* 42 U.S.C. § 262(l)(3)(B), and the sponsor responds (step four). *See* 42 U.S.C. § 262(l)(3)(C). *See also* [109] ¶¶ 62–66. At the fifth step the applicant tells the sponsor the number of patents it would like test in litigation, and then both sides simultaneously exchange a list of patents. *See* 42 U.S.C. § 262(l)(5); [109] ¶ 67. The sponsor then must initiate a lawsuit to determine the validity of the patents that appear on both lists (which, at most, includes double the number identified by the applicant, assuming no overlap). *See* 42 U.S.C. § 262(l)(6); [109] ¶¶ 65–67.

At that point, the applicant has to decide whether to launch “at risk” by putting its biosimilar on the market notwithstanding the prospect of a large damages award against it in patent litigation. Unlike the Hatch-Waxman Act (which governs small molecule drugs and imposes an automatic 30-month stay on FDA approval whenever a brand-name manufacturer files an infringement lawsuit (and meets other prerequisites), *see* 21 U.S.C. § 355(j)(5)(B)(iii)), the Biologics Price Competition and Innovation Act allows the FDA to approve an abbreviated biologic application despite a pending infringement suit and only requires the applicant to give the sponsor 180-days’ notice before launching. 42 U.S.C. § 262(l)(8)(A). *See also* [109] ¶¶ 69–70. But

even if the biosimilar manufacturer decides to launch at risk, the sponsor can still file a second lawsuit seeking a preliminary injunction (sometimes referred to as “second phase” litigation). 42 U.S.C. § 262(l)(8)(B).

D. AbbVie’s Patents

In the lead up to the expiration of the ’382 patent, AbbVie started applying for Humira-related patents. [109] ¶ 90. It sought patents on not only the many uses of Humira but also the process for manufacturing it and the ingredients and formulations that AbbVie anticipated its competition might seek to employ. *Id.* One estimate suggests that AbbVie filed a total of 247 patent applications related to Humira and obtained 132 patents (a batting average of .534). *Id.* ¶ 99. More than 90% of those patents were issued in 2014 or later, despite the fact that Humira was first marketed in 2002. *Id.* ¶ 4.

In the process, AbbVie relied heavily on continuation applications. *See id.* ¶¶ 99–100. For instance, AbbVie used one application from 2002 (U.S. Patent Application 10/22,140) to serve as the basis for twenty-two continuation applications, all of which would have been barred by prior art but-for their ability to relate back. *Id.* ¶¶ 102–104. AbbVie’s 100-plus Humira-related patents can be traced back to twenty root patents, forming twenty patent trees. *Id.* ¶¶ 130–131. By targeting the root patents that lie at the base of these trees, plaintiffs say they can quickly identify whole swaths of AbbVie’s IP portfolio that should not have issued. *See id.* ¶¶ 107, 131, 132.

For instance, fifteen of those trees are rooted in formulation and manufacturing process patents that, together, serve as the source of eighty-four of AbbVie's Humira-related patents. *Id.* ¶ 131. Twelve of those fifteen root patents were filed after 2006. *Id.* ¶ 132. Humira launched on New Year's eve of 2002, meaning AbbVie had until the first day of 2004 (the end of the one-year grace period) to apply for any patent describing a formulation or manufacturing process that was used to make Humira when it launched. *Id.* ¶¶ 126–128; 35 U.S.C. § 102(a)(1). As a result, the twelve patents filed after 2006 (and the nearly sixty patents that were issued as a result of continuation applications based on those underlying patents) are invalid because they describe inventions that were not novel when the patents issued. [109] ¶¶ 132–140.

Plaintiffs add that any formulation patent that describes a variant of Humira, (i.e., one that does not describe Humira as it was approved by the FDA) should not be used to block biosimilars of Humira. *Id.* ¶ 129. And, plaintiffs reason, any manufacturing process that was not used to make Humira when it launched must not be necessary to make Humira, meaning it should be no bar to making a biosimilar. *Id.*

AbbVie's wrongdoing was not limited to its continuation applications. For instance, AbbVie withheld information from the United States Patent and Trademark Office, such as the fact that it had already been using a way to make and sell a certain product for several years when it told the Patent and Trademark Office that the method was not obvious. *Id.* ¶ 114. And while prosecuting another patent,

AbbVie filed a declaration affirming that a certain process was unexpected to be successful despite earlier disclosures that suggested the process was not only likely to be successful but was in fact the standard method for achieving that result. *Id.* ¶¶ 115–120. Some of AbbVie’s other patents are invalid because they claim methods that were already in the prior art. *Id.* ¶¶ 109–113.

When the Patent Trial and Appeal Board heard challenges to five of AbbVie’s Humira-related patents, it ruled that three were invalid. [109] ¶ 108. AbbVie terminated the other two before the board reached any final determination. *Id.*⁵

At the same time that AbbVie was obtaining these patents, its executives were discussing AbbVie’s broader IP strategy with investors. For instance, in 2014, AbbVie’s CFO said that AbbVie was “obviously not very specific about what” it was putting into its “very robust collection of IP” because “with a product as important and as attractive as Humira, you do everything you can on the IP front to ensure that you’ve protected it to the best you can.” *Id.* ¶ 90. He added that the bulk of AbbVie’s IP strategy was to “make it more difficult for a biosimilar to follow behind.” *Id.* In an email to investors, AbbVie’s CEO noted that market entry for any Humira biosimilars

⁵ In its motion to dismiss, AbbVie adds that, on thirteen occasions that plaintiffs neglect to mention, the Patent Trial and Appeal Board declined to initiate *inter partes* review of AbbVie’s patents, finding that there was no reasonable likelihood that the challengers of AbbVie’s patents (among them defendants Amgen and Sandoz and nondefendant Coherus) would succeed. [124] at 17–18. Plaintiffs do not object to AbbVie’s request to take judicial notice of these decisions. [144]. The decisions are public court documents and beyond reasonable dispute. Fed. R. Evid. 201(b); *White v. Keely*, 814 F.3d 883, 886 (7th Cir. 2016); *Finjan, Inc. v. Blue Coat Sys., Inc.*, 2016 WL 7732542, at *1 n.1 (N.D. Cal. July 25, 2016); [124-1]; [124-2]; [124-3]; [124-4]; [124-5]; [124-6]; [124-7]; [124-8]; [124-9]; [124-10]; [124-11]; [124-12]; [124-13]. I take notice of them.

would likely be delayed because patent litigation takes more than four years and at-risk launches are rare. *Id.* ¶ 94.

E. The Other Defendants' Applications for Biosimilars and the U.S. Market Settlements

As AbbVie pursued new patents, its competitors applied for FDA approval to manufacture biosimilars. Amgen filed the first abbreviated biologic application for its biosimilar, Amjevita, in November of 2015. [109] ¶ 142. During the patent dance, AbbVie identified sixty-six patents that it believed Amjevita would infringe. *Id.* ¶ 143. Amgen responded by saying that it believed sixty-five of those patents (all but the original '382 patent) were invalid, and that it did not plan to market Amjevita until the '382 patent expired. *See id.* ¶¶ 140–146. By August of 2016, Amgen and AbbVie had finished the patent dance and AbbVie had filed suit. *Id.* ¶ 148. One month later, the FDA approved Amgen's abbreviated application to market Amjevita. *Id.* ¶ 149. On December 31, 2016, the '382 patent expired. *Id.* ¶ 78. Amgen did not launch at risk. *See id.* ¶¶ 149–51.

One year into litigation, in the fall of 2017, Amgen and AbbVie settled. *Id.* ¶ 151. At the time, a bench trial was scheduled to start in the fall of 2019. *Id.* ¶ 150. Any appeal would have taken (on average) at least another year to resolve.⁶ *See* [125] at 3 n.3. The terms of the settlement are confidential, but AbbVie's press release made

⁶ Plaintiffs do not object to judicial notice of the fact that patent appeals, on average, take more than one year to complete. *See* [125] at 3 n.3; U.S. Court of Appeals for the Federal Circuit, Median Disposition Time for Cases Decided by Merits Panels, 2009–2018, available at http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/06_Med_Disposition_Time_MERITS_table_-_Final.pdf (last visited June 4, 2020); [144].

clear that Amgen had agreed to drop its patent challenges and delay Amjevita's market entry until January of 2023. *Id.* ¶ 151.⁷

AbbVie reached similar settlement agreements with eight other manufacturers seeking to market Humira biosimilars, including defendants Samsung Bioepis and Sandoz and nondefendants Mylan, Fresenius, Momenta, Pfizer, Coherus, and Boehringer. [109] ¶¶ 157–184. Each agreed to U.S. market entry dates ranging from June 30, 2023 (Samsung Bioepis) to December 15, 2023 (Coherus). *Id.* ¶¶ 157–184, 211. AbbVie reached these settlements at different stages of its disputes with these companies. It settled with Samsung Bioepis before that company even filed its abbreviated application, *id.* ¶ 157, with Sandoz after AbbVie had initiated litigation but before Sandoz had responded to the complaint, *id.* ¶ 170, and with Boehringer only after it had responded to AbbVie's infringement complaint and asserted counterclaims seeking to invalidate many of AbbVie's patents. *Id.* ¶¶ 183–84. In the process, AbbVie occasionally asserted patents for which there was not even an arguable claim of infringement. *Id.* ¶ 167. Only four of the biosimilar manufacturers that settled with AbbVie (Amgen, Samsung Bioepis, Sandoz, and Boehringer) ever received FDA approval to market their biosimilars. *Id.* ¶ 211. Only two (Amgen and Boehringer) received approval before they had entered into settlement agreements with AbbVie. *Id.*

⁷ The complaint alleges that AbbVie promised to not let any other manufacturer enter the market until the end of June 2023, ensuring Amgen a five-month period of (semi) exclusivity worth nearly a billion dollars. [109] ¶¶ 151, 153, 154. AbbVie filed under seal copies of its settlement agreements with Amgen, [124-14]; [124-15]; [126-1]; [126-2], and, in response, plaintiffs dropped their claims that Amgen's *de facto* five months of exclusivity constituted a reverse payment. [144] at 46 n.15.

F. The European Market Settlements

At the same time, in Europe, plaintiffs say that AbbVie took advantage of a more fractured patent system (and a type of European patent application similar to the continuation application, known as a “divisional application”) to pressure the biosimilar defendants into settling there, too. *See id.* ¶¶ 185–89. AbbVie’s strategy in Europe was to abandon or withdraw patents as soon as they were challenged in one jurisdiction and then use its pending applications in other jurisdictions as the basis for divisional applications that covered much the same material it had just abandoned. *Id.* ¶¶ 185–90.

For instance, when Samsung Bioepis and another company challenged two of AbbVie’s patents in the U.K., AbbVie decided to abandon those patents rather than risk an adverse judicial verdict that could have been used to preclusive effect elsewhere. [109] ¶¶ 191–192. The judge issued an order finding that AbbVie “made every effort to shield the claims of its patents from scrutiny.” *Id.* ¶ 199. AbbVie then turned around and filed divisional patents in other countries covering much the same subject matter as that in the patents it had just abandoned. *Id.* ¶ 198. As a result, AbbVie was able to extend the life of its patent protection for Humira in Europe.

The settlements AbbVie entered into in the U.S. included European market entry dates. *See id.* ¶ 203. AbbVie’s agreement with Amgen allowed Amgen to enter the European market in October of 2018—more than four years before Amgen’s January 2023 date for the U.S. market. *Id.* Samsung Bioepis’s and Sandoz’s agreements contained the same European early entry date (October 16, 2018). *Id.*

That date coincided with the expiration of AbbVie’s European patent for adalimumab. *Id.*

The early European entry dates were extremely valuable to Amgen, Samsung Bioepis, and Sandoz. *Id.* ¶ 205. And plaintiffs say that AbbVie used those early European entry dates as bargaining chips during negotiations over the entry dates for the U.S. market, inducing Amgen, Samsung Bioepis, and Sandoz to delay their U.S. market entry by offering the *quid pro quo* of earlier entry dates in Europe. [109] ¶ 206. AbbVie’s motive was to keep prices in the U.S. artificially high for as long as possible. *Id.* ¶ 207. It succeeded: the cost of Humira to treat arthritis in the U.S. remains 50% more expensive than the cost of the same treatment in Spain (and 155% more expensive than in Switzerland). *Id.* ¶ 207.

G. The Claims in the Consolidated Complaint

Plaintiffs bring class action claims on behalf of two representative classes. The first seeks injunctive relief and is defined as, “[a]ll entities in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Humira, other than for resale, from December 31, 2016, through the present.” [109] ¶ 224.

The second seeks damages and is defined as, “[a]ll entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Humira, other than for resale,” in thirty-one states and the District of Columbia, “from December 31, 2016, through the present, for consumption by their members, employees, insureds, participants, or beneficiaries.” *Id.* ¶ 225.

The complaint has seven counts, seeking injunctive relief under federal law and damages under state law. Count I asserts a pay-for-delay theory of liability under § 1 of the Sherman Act against all defendants (i.e., AbbVie, Inc., AbbVie Biotechnology, Ltd., Amgen, Inc., Samsung Bioepis Co., Ltd., and Sandoz, Inc.), [109] ¶¶ 261–68, Count III asserts a market-allocation-agreement theory of liability under § 1 of the Sherman Act against all defendants, *id.* ¶¶ 279–85, and Count V asserts a violation of § 2 of the Sherman Act against AbbVie. *Id.* ¶¶ 295–300. Each federal antitrust claim comes with its state-law analog: Count II asserts a pay-for-delay theory of liability under state antitrust laws (and consumer protection laws that prohibit anticompetitive conduct) against all defendants, *id.* ¶¶ 269–78, Count IV asserts a market-allocation-agreement theory of liability under state antitrust laws (and consumer protection laws that prohibit anticompetitive conduct) against all defendants, *id.* ¶¶ 286–94, and Count VI asserts a monopolization theory of liability under state antitrust laws (and consumer protection laws that prohibit anticompetitive conduct) against AbbVie. *Id.* ¶¶ 301–08. Lastly, Count VII asserts violations of state laws that prohibit unfair and unconscionable conduct against AbbVie. *Id.* ¶¶ 309–406. For purposes of the Sherman Act claims, the complaint defines the relevant geographic market as the United States, *id.* ¶ 236, and alleges that AbbVie maintains 100% of the relevant market share for adalimumab. *Id.* ¶ 238.

III. Analysis

Defendants move to dismiss the complaint. With regard to the § 2 claims, AbbVie says there is nothing illegal about amassing a broad portfolio of legitimate

patents and that, even if a few were issued erroneously, the *Noerr–Pennington* doctrine immunizes them from liability. With regard to the § 1 claims, defendants say that the settlements at issue do not violate antitrust law because they: allow AbbVie’s competitors to enter the market before the expiration of AbbVie’s patents, do not involve any reverse payments from AbbVie (the patentee) to Amgen, Samsung Bioepis, and Sandoz (the alleged infringers), and only divvy up the market in ways consistent with AbbVie’s patent rights. Third, with regard to both the § 1 and § 2 claims, defendants argue that if a single one of AbbVie’s patents is valid, that patent would have prevented plaintiffs from entering the market at all. Defendants’ unlawful conduct was only the but-for cause of plaintiffs’ alleged injury if defendants obtained every single one of their patents unlawfully. And that, defendants say, is not plausible. Lastly, defendants advance arguments particular to each of the dozens of state-law claims.

Amgen, Samsung Bioepis, and Sandoz add that they had to enter into the settlement agreements because their only other choices were years of expensive litigation over an impassable patent thicket or an at-risk launch likely to result in a hefty damages award. They say the complaint’s assessment of their bargaining position is too rosy and that their negotiated entry dates did not harm competition.

As plaintiffs recognize, theirs is a new kind of antitrust claim. [144] at 28–35. Although the § 2 claim in some ways resembles the one asserted in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, which held that obtaining a patent by fraud can violate § 2 of the Sherman Act, 382 U.S. 172, 174 (1965), and the one

asserted in *Profl Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, which assigned antitrust liability to “objectively baseless” petitioning that falls outside the protection of the *Noerr–Pennington* doctrine, 508 U.S. 49, 51 (1993) (“*PRE*”), plaintiffs disclaim reliance on those cases. [144] at 26 n.3, 38. And while the § 1 claims rely heavily on *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 141 (2013), which calls for scrutiny of settlement agreements that require patent holders to pay money to alleged infringers (rather than the other way around), those claims bump against a sentence in *Actavis* that approved of settlements where the only reverse payment is an agreement permitting the alleged infringer to “enter the patentee’s market prior to the patent’s expiration.” *Id.* at 158.

The complaint brings together a disparate set of aggressive but mostly protected actions to allege a scheme to harm competition and maintain high prices. The allegations—even when considered broadly and together for their potential to restrain trade—fall short of alleging the kind of competitive harm remedied by antitrust law.

A. The § 2 Claims Against AbbVie and AbbVie Biotechnology Ltd.

Section 2 of the Sherman Act prohibits the wrongful monopolization of interstate trade or commerce. 15 U.S.C. § 2. In order to state a claim under § 2, a plaintiff must allege “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or

historic accident.” *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966); *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 854 (7th Cir. 2011).

This complaint proposes a new theory of § 2 antitrust liability. Plaintiffs’ claim is not that AbbVie obtained its patents by knowing and willful fraud. [144] at 27 n.4; *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012). Nor is their claim that it was anticompetitive to accumulate a large portfolio of patents. [144] at 26 n.3; *Automatic Radio Mfg. Co. v. Hazeltine Research*, 339 U.S. 827, 829 (1950). Nor is their claim that any one of AbbVie’s petitioning activities was “objectively baseless.” [144] at 38; *PRE*, 508 U.S. at 51.

Instead, the complaint alleges that AbbVie abused its monopoly over the U.S. market for adalimumab (which includes Humira and its biosimilars) when it gummed up progress toward lower prices by obtaining and asserting “swaths of invalid, unenforceable, or noninfringed patents without regard to the patents’ merits.” [109] ¶¶ 236–38; [144] at 44. By repeatedly and aggressively asserting this patent thicket during a lengthy, detailed regulatory process (and subsequent infringement litigation), AbbVie was able to delay its competitors and avoid any real examination of the patents’ validity long enough to reap a few more years’ worth of monopoly profit on its lucrative, patent-protected product, Humira. *Id.* at 44–45.

Both the patent and antitrust laws aim to encourage innovation, industry, and competition. *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1575 (Fed. Cir. 1990); U.S. Const. art. I, § 8, cl. 8. The former does this by dangling the carrot of a limited and temporary right to exclude others from practicing a patented invention

and the latter by prohibiting “conduct which unfairly tends to destroy competition itself.” *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). Even though patents operate like limited exceptions to the Sherman Act, they do “not wholly insulate the patent owner from the antitrust laws.” *Atari Games Corp.*, 897 F.2d at 1576. And since it is unlawful to use monopoly power—however lawfully obtained—to “foreclose competition, to gain a competitive advantage, or to destroy a competitor,” *United States v. Griffith*, 334 U.S. 100, 107 (1948), *overruled on other grounds by Copperweld Corp. v. Ind. Tube Corp.*, 467 U.S. 752 (1984), it is in some instances unlawful to use patents in ways that foreclose competition. *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948).

Plaintiffs say one such example is when a patentee acquires and asserts whole tracts of questionable patents as part of a bad-faith, intentional effort to prop up the market for an existing, expiring patented product. Their theory depends on another old premise: that petitioning the government (during patent prosecutions, the FDA approval process, and in the courts) can violate the antitrust laws if, in reality, that petitioning is nothing more than a sham meant to inhibit competition. Antitrust liability has long attached wherever there was a “pattern of baseless, repetitive claims” that shows the “administrative and judicial processes have been abused.” *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972) (citations omitted). Although the First Amendment protects the right to petition the government, *see E. R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965), it does

not protect exercising that right as the “means or the pretext for achieving substantive evils which the legislature has the power to control.” *California Motor*, 404 U.S. at 515 (citations omitted). But because immunized conduct cannot be aggregated with nonimmunized conduct without nullifying the immunity, it is necessary to identify protected and unprotected conduct. *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 839 (7th Cir. 2011) (the first step is to “identify any conduct that is immunized,” and then, after that, to “consider the evidence of the remaining challenged conduct in the aggregate to see if it is sufficient to support antitrust liability”).⁸

In *California Motor*, the Court recognized that “a pattern of baseless, repetitive claims” instituted “without probable cause, and regardless of the merits” falls outside of *Noerr–Pennington* protection. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972). *PRE* articulates a two-part test for identifying sham litigation: “[f]irst, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993). If the lawsuit is objectively baseless, then the court asks, “whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor, through

⁸ The *Noerr–Pennington* doctrine may be applied at the motion-to-dismiss stage. See *Metro Cable Co. v. CATV of Rockford, Inc.*, 516 F.2d 220, 222 (7th Cir. 1975) (affirming district court’s dismissal of the complaint on *Noerr–Pennington* grounds). See also *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 7 (1st Cir. 2018); *Armstrong Surgical Ctr., Inc. v. Armstrong Cty. Mem’l Hosp.*, 185 F.3d 154, 164 (3d Cir. 1999); *Mark Aero, Inc. v. Trans World Airlines, Inc.*, 580 F.2d 288, 290 (8th Cir. 1978); *Oregon Nat. Res. Council v. Mohla*, 944 F.2d 531, 533 (9th Cir. 1991); *GF Gaming Corp. v. City of Black Hawk, Colo.*, 405 F.3d 876, 884 (10th Cir. 2005).

the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.” *Id.* at 60–61 (cleaned up).

Some courts have cabined the “objectively baseless” requirement from *PRE* to situations where it was only necessary to assess whether a single action constituted sham petitioning. *Primetime 24 Joint Venture v. Nat’l Broad., Co.*, 219 F.3d 92, 101 (2d Cir. 2000); *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015); *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354, 363 (4th Cir. 2013); *USS-POSCO Indus. v. Contra Costa Cty. Bldg. & Const. Trades Council, AFL-CIO*, 31 F.3d 800, 810–11 (9th Cir. 1994). Plaintiffs rely on this line of cases to argue that AbbVie’s serial use of legal process does not need to meet *PRE*’s objectively baseless requirement (and that, instead, a more flexible test should be used to determine whether AbbVie’s actions fell outside of *Noerr–Pennington*’s protection). *See* [144] at 42.

In *U.S. Futures Exch., L.L.C. v. Bd. of Trade of the City of Chicago, Inc.*, 953 F.3d 955, 958 (7th Cir. 2020), *reh’g and reh’g en banc denied* (Apr. 23, 2020)—decided after briefing here—plaintiffs’ theory (dubbed a “delay theory”) invoked both the fraudulent misrepresentation and sham lawsuit exceptions to *Noerr–Pennington*. *Id.* at 959. The court first found that the fraudulent misrepresentation exception did not apply because the proceedings at issue were legislative. *Id.* at 963. Then, the court held that the “objectively reasonable” requirement from *PRE* applies to the sham lawsuit exception whether the allegations involve a single instance of sham petitioning or a series. *Id.* at 963–65. *See also Puerto Rico Tel. Co., Inc. v. San Juan*

Cable LLC, 874 F.3d 767, 769 (1st Cir. 2017). Any lawsuit “reasonably calculated to elicit a favorable outcome” is objectively reasonable, and any “successful action self-proves its reasonableness.” *Id.* at 963 (citations omitted). Because the subjective prong of *PRE* only comes into play once the objective prong is satisfied, the plaintiff in *U.S. Futures* was unable to prove that the proceedings were a sham “merely by showing that its competitor’s purposes were to delay the plaintiff’s entry into the market.” *Id.* at 965 (quoting *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365 (1991)) (cleaned up).⁹

The claim here involves adjudicative proceedings. AbbVie’s alleged transgressions occurred in three venues: patent prosecutions and *inter partes* review proceedings before the United States Patent and Trademark Office, the biologic licensing process before the Food and Drug Administration, and patent infringement actions in federal district court. *See* [109] ¶¶ 32–43, 54–70. The last of those three is quintessentially adjudicative. Proceedings before the Patent and Trademark Office are also adjudicative. The PTO reviews patent applications submitted by interested parties often represented by counsel with specialized legal training, engages in formal fact-finding based on submissions made pursuant to duties of disclosure, candor, and

⁹ *U.S. Futures* applied the objectively baseless test from *PRE* for two reasons: (1) that is the test to apply whenever the allegations involve a pattern of sham lawsuits, *id.* at 965, and (2) the conduct alleged involved a single proceeding within which the defendants were accused of making multiple filings, a situation which does not normally qualify as a “pattern.” *See id.* at 965–66. Although the allegations here are characterized by a wide-ranging pattern of patent prosecutions, BPCIA exchanges, and federal litigation, *U.S. Futures* holds that the same test applies to that conduct, too.

good faith, and issues decisions subject to definite standards and judicial review. *See* [109] ¶¶ 54–58; 37 C.F.R. § 1.56(a).

The proceedings before the Food and Drug Administration are also adjudicative. Members of Congress have been critical of AbbVie’s conduct before the Food and Drug Administration and some have even introduced legislation that could stymie AbbVie’s efforts to obtain similar patent thickets in the future. *See* [109] ¶¶ 214–223. But those actions say nothing about the character of the FDA’s process. The FDA reviews applications for new drugs submitted in nonadversarial processes marked by strict guidelines. *See id.* ¶¶ 32–43. That formalized review looks at a wealth of technical information and is guided by standards set forth by federal law. *See, e.g.*, [109] ¶ 40; 42 U.S.C. § 262.

Plaintiffs’ claim is not one under *PRE*. [144] at 38. But under *U.S. Futures*, AbbVie’s conduct is protected by *Noerr–Pennington* (and not subject to antitrust scrutiny) unless its petitions—its patent applications, patent dance exchanges, and the lawsuits that followed—were objectively baseless. *U.S. Futures Exch.*, 953 F.3d at 958. It is not enough to describe “numerous flaws in AbbVie’s patents and its assertion of them.” *See* [144] at 38. Plaintiffs have to allege that AbbVie’s petitioning was objectively baseless.

The question then becomes whether plaintiffs have plausibly alleged objectively baseless conduct.¹⁰ AbbVie’s rate of success with its patent applications—

¹⁰ *See Michael v. Letchinger*, No. 10 C 3897, 2011 WL 3471082, at *11 (N.D. Ill. Aug. 5, 2011) (applying plausibility standard to an allegation that a zoning and building code lawsuit was objectively baseless); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-MD-2343, 2013 WL 2181185, at *22 (E.D. Tenn. May 20, 2013) (applying plausibility standard to claims of a

more than half (53.4%) of AbbVie’s patent applications resulted in patents, [109] ¶ 99—is not “irrelevant,” [144] at 43; it compels the conclusion, as a matter of law, that more than half of AbbVie’s patent applications were not objectively baseless. *U.S. Futures Exch.*, 953 F.3d at 963–64 (“a successful action self-proves its reasonableness”). It is also not the product of guesswork—that rate is apparent on the face of the complaint. The allegations about AbbVie’s petitioning of the USPTO are not plausible acts of sham petitioning.

Even in circuits that apply the type of more flexible test plaintiffs say should be applied here, a batting average of .534 would be too high to plausibly allege sham petitioning as a matter of law. Compare *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354, 365 (4th Cir. 2013) (one out of fourteen (7%) success rate suggests a sham) with *USS-POSCO*, 31 F.3d at 811 (no sham litigation when fifteen of twenty-nine (52%) of the lawsuits were successful); *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1046–47 (9th Cir. 2009) (no sham litigation when seven out of seventeen (41%) of the lawsuits were successful and where, in the other ten, the defendants had plausible arguments on which they could have prevailed); *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F.Supp.2d 221, 224 (S.D.N.Y. 2002) (no sham litigation when “claims

series of objectively baseless sham petitioning under *California Motor Transport Co.*); *Inserra Supermarkets, Inc. v. Stop & Shop Supermarket Co., LLC*, No. 16-CV-01697, 2017 WL 3189029, at *3 (D.N.J. July 27, 2017) (same).

of infringement of four of the six asserted patents ... proceed[ed] beyond summary judgment, and two of the four ... proceed[ed] through trial”).¹¹

AbbVie’s success rate during *inter partes* review was even higher, and establishes that AbbVie’s conduct there was not objectively baseless, either. Although the Patent Trial and Appeal Board found invalid three of the five AbbVie patents that it reviewed (and even though AbbVie terminated the other two before a final determination could be reached), [109] ¶ 108, the PTAB declined to initiate *inter partes* review with regard to thirteen of AbbVie’s other patents, finding there was no reasonable likelihood that the parties challenging AbbVie’s patents would succeed on even one of the challenged claims. *See supra* n.5; 35 U.S.C. § 314. True, patents cannot be challenged for failing to account for prior art during *inter partes* review, and even when AbbVie succeeded in convincing the PTAB to decline to initiate *inter partes* review, that success did not result in a finding that AbbVie’s patents were valid. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 n.3 (Fed. Cir. 1988); *In re TLI Commc’ns LLC Patent Litig.*, 87 F.Supp.3d 773, 781, 804 (E.D. Va. 2015) (finding patent invalid under § 101 after an *inter partes* review petition was denied), *aff’d*, 823

¹¹ The complaint also contains allegations that AbbVie made material misrepresentations and omissions to the USPTO during the prosecution of its patents. [109] ¶ 114. But the complaint does not assert a *Walker Process* claim, [144] at 27 n.4, likely because these plaintiffs would lack standing to do so. *Farag v. Health Care Serv. Corp.*, 2017 WL 2868999, at *6 (N.D. Ill. July 5, 2017). In the end, even if plaintiffs could pursue a misrepresentation theory (while disclaiming reliance on *Walker Process*), plaintiffs effectively concede that not all of AbbVie’s patents are invalid and they do not intend to prove that AbbVie’s conduct was objectively baseless. That is enough to establish *Noerr–Pennington* protection for AbbVie’s conduct before the USPTO.

F.3d 607 (Fed. Cir. 2016).¹² But the high success rate—thirteen out of eighteen, or 72.2%—renders implausible the allegation that AbbVie’s submissions to the PTAB during those *inter partes* review proceedings were objectively baseless (at least without some other factual allegation to overcome that observation). AbbVie’s petitioning before the USPTO and the PTAB is protected by *Noerr–Pennington*.¹³

To the degree the complaint describes a kernel of objectively baseless petitioning, it is what happened during the patent dances.¹⁴ There, AbbVie allegedly

¹² Plaintiffs identify another argument that could not have been advanced during *inter partes* review and that diminishes any suggestion that AbbVie’s patent portfolio is legitimate: because AbbVie had to describe in its original patent application the best mode contemplated for carrying out the invention (i.e., adalimumab), 35 U.S.C. § 112(a), the formulation and manufacturing patents that post-date the original adalimumab patent cannot possibly have prevented biosimilar competitors from coming to market. [144] at 39–40. As a result, plaintiffs say AbbVie should be estopped from asserting that those patents ever could have prevented biosimilar competitors from coming to market. *Id.* at 40. But even if AbbVie could not point to some of its patents as barriers to biosimilar entry, plaintiffs’ theory remains that the entire thicket and conduct surrounding the thicket restrained competition. Picking at some of the patents as legally irrelevant to biosimilar manufacturing because of the original patent’s best-mode disclosure is just another way to say that AbbVie made unreasonable representations during the patent dance. But that the thicket and surrounding conduct were not as formidable as they may have seemed is a minor point given plaintiffs’ overarching claim, and raises the question of how plausible it is to glean concrete harm to consumers from the biosimilar manufacturers’ analysis of risk when taking on AbbVie’s patents.

¹³ To the extent AbbVie’s petitioning before the USPTO and PTAB was unsuccessful, that petitioning did not give rise to an antitrust injury. *See* § III.C. AbbVie’s patent applications required no response from any of the biosimilar manufacturers and were not so numerous that it is plausible to allege that their sheer volume intimidated AbbVie’s sophisticated competitors into forgoing the production of biosimilars (especially not to the degree those petitions were objectively baseless), and plaintiffs have not alleged that any of AbbVie’s submissions during the *inter partes* reviews were objectively baseless. *See* [109] ¶ 108.

¹⁴ Actually, the exchanges that take place between applicants and reference product sponsors during the patent dance portion of the FDA’s biosimilar application process might not qualify as petitioning at all, since neither party is (at that moment) asking the government to do anything. *See Freeman v. Lasky, Haas & Cohler*, 410 F.3d 1180, 1184 (9th Cir. 2005) (“discovery is merely communication between parties as an aid to litigation,” and is not a petition because it is not “in any sense a communication to the court,” although “conduct incidental to” a petition is protected if the petition itself is protected). Still, as discussed below, plaintiffs fail to allege a § 2 claim because most of the conduct upon which their

asserted without basis that if Amgen launched its biosimilar, it would infringe no less than sixty-six of AbbVie's patents. [109] ¶ 143. When Amgen disagreed, AbbVie failed to address Amgen's concerns and declined to elaborate (even after Amgen repeatedly notified AbbVie of its failures to respond). *Id.* ¶¶ 144–147. During AbbVie's prelitigation exchanges with Sandoz, AbbVie listed nine formulation patents that specified the use of a buffer system with ingredients that were in neither Sandoz's biosimilar nor Humira—i.e., that were objectively baseless to assert. *See also id.* ¶¶ 167–168. AbbVie also listed patents that were not infringed or that had been invalidated during its patent dance with Boehringer. [109] ¶ 180.

AbbVie's presumptively valid patents were not presumptively infringed,¹⁵ and unlike the proceedings before the USPTO and the PTAB, no neutral third party ever decided who was successful in these pre-litigation exchanges. Only successful petitioning self-proves its reasonableness, *see U.S. Futures Exch.*, 953 F.3d at 963, and AbbVie's patent dance exchanges were not successful, so they may still have been objectively baseless. *But see Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d

allegations are based was immunized, and because plaintiffs' theory depends on considering AbbVie's conduct as a whole. *See* [144] at 44–45. *See also MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1155 n.114 (7th Cir. 1983).

¹⁵ Even if patentees are presumed to enforce their patents in good faith, *see C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (the law "recognizes a presumption that the assertion of a duly granted patent is made in good faith"), that presumption is evidentiary, *id.*, and evidentiary presumptions do not overcome plausible allegations at the pleading stage. *See also Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1371 (Fed. Cir. 2002) ("if the party challenging such statements under state or federal law presents clear and convincing evidence that the infringement allegations are objectively false, and that the patentee made them in bad faith, viz., with knowledge of their incorrectness or falsity, or disregard for either, the statements are actionable and are not protected by the existence of a patent").

1338, 1345 (Fed. Cir. 2014) (“it will be a rare case in which a patentee’s assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation”). And without a high success rate to make AbbVie’s actions appear reasonable, it remains plausible that at least some of the assertions AbbVie made during the patent dances were objectively baseless.

One difference between AbbVie’s patent applications to the USPTO and its responses during the patent dance is that AbbVie did not initiate the patent dance—the challengers did. *Kaiser Found. Health Plan, Inc. v. Abbott Labs.*, 552 F.3d 1033, 1047 (9th Cir. 2009) (“[i]t is true that Abbott was litigious, but ... [t]he volume of Abbott’s suits was dependent on the number of generic companies attempting to enter the ... marketplace, a matter over which Abbott had no control”). Nonetheless, AbbVie participated. It was not forced to assert any patents at all during the patent dance (and it certainly was not forced to assert patents that were invalid or not infringed). AbbVie’s conduct during the patent dances was not protected by *Noerr–Pennington*. What effect AbbVie’s actions during the patent dance had on the market for Humira is another question. *See* § III.C below.

With regard to the infringement litigation that followed, AbbVie’s right to pursue those lawsuits was not without limitation. *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F.Supp.2d 986, 992–93 (N.D. Ill. 2003), *dismissed*, 104 Fed. App’x 178 (Fed. Cir. 2004) (anyone with a patent not obtained by fraud enjoys a presumption of validity that entitles them “to sue alleged infringers, and to settle with them,

whatever [their] private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment”). One potential problem for plaintiffs is that AbbVie was required by law to bring those infringement suits, 42 U.S.C. § 262(l)(6) (“not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent”), which gives AbbVie an objectively reasonable basis for bringing them. *See Kaiser Found. Health Plan, Inc.*, 552 F.3d at 1047.

In any event, each of the lawsuits was settled on terms that foreclose a finding of objective baselessness. When a lawsuit terminates in a settlement that provides substantial value to an antitrust defendant accused of initiating that lawsuit as a sham, that lawsuit is objectively reasonable. *See New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007); *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008).

AbbVie settled its suit with Amgen roughly one year after it began, agreeing to allow Amgen to enter the U.S. market five years before the expiration of AbbVie’s U.S. patents. [109] ¶ 151. It then entered into similar settlements with other biosimilar applicants, all of which contemplated U.S. market entry dates during calendar year 2023. *See id.* ¶¶ 157, 160, 170, 173–176, 184. At least with regard to plaintiffs’ § 2 claims, looking just at the allegations in the complaint, these settlements (all of which required concessions from both sides) render unreasonable

any inference that the litigation that preceded them was an objectively baseless sham maintained by AbbVie to extend the patent-backed monopoly it had obtained in the market for Humira.

The foregoing raises the question as to what conduct should be considered part of the alleged overarching scheme to destroy competition and what parts should be swept aside as lawful petitioning. There is a risk that by focusing only on each individual action in a series, a broader pattern of anticompetitive conduct might escape policing and remedy. Plaintiffs must be given the “full benefit of [their] proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each,” but at the same time, conduct immunized from antitrust liability cannot be aggregated with nonimmunized conduct without nullifying the immunity. *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 839 (7th Cir. 2011) (quoting *Cont’l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)). *See also City of Anaheim v. S. California Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) (considering the “synergistic effect” of the “mixture of the elements”).

Here, the vast majority of the alleged scheme is immunized from antitrust scrutiny, and what’s left are a few sharp elbows thrown at sophisticated competitors participating in regulated patent and biologic-drug regimes. Some of AbbVie’s conduct was not immunized by the *Noerr-Pennington* doctrine—including what plaintiffs allege to be the heart of their monopolization claim—but much of what preceded and followed that conduct was immunized, which makes the entirety of

alleged monopolization scheme immune, because plaintiffs' theory depends on all the components of AbbVie's conduct as the means to suppress competition. [144] at 44–45.

Unlike many of the cases that have considered a series of allegedly sham petitions, these claims involve the patent system. That difference is all the more reason to decline to recognize plaintiffs' new theory of antitrust liability. Patents are entitled to a presumption of validity, 35 U.S.C. § 282(a), and even though that presumption is not so strong as to make patents “completely unassailable,” *Chicago Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452, 458 (7th Cir. 1975), it is a presumption rightly based on the “expertise of patent examiners presumed to have done their job.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992). The patent prosecution system is no doubt imperfect, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1331 (Fed. Cir. 2018) (Dyk, J., concurring) (noting that the USPTO is an agency with “finite resources that sometimes issues patents in error”), but even if it is so broken that patent examiners are having the wool pulled over their eyes more than half the time by applicants acting mostly nonfraudulently and with disregard for their applications' chances of success, the proper fix is not to use antitrust doctrine to launch a collateral attack on 132 patents, thirteen *inter partes* review determinations, multiple patent dance exchanges and at least two patent infringement lawsuits. Doing so will not revamp the FDA's biologics application process or the USPTO's drug patenting process. *See Areeda & Hovenkamp*, §§ 221, 704b4 (“the patent system might be thought to be ...

in need of reform,” but “the antitrust laws were not designed to repair other government regulatory processes”).

The cases plaintiffs cite in support of their new theory of antitrust liability are unconvincing and distinguishable. *In re Neurontin Antitrust Litigation* is inconsistent with *U.S. Futures*, 953 F.3d 955, 958 (7th Cir. 2020), and, in any event, plaintiffs there firmly alleged that the petitioning in question was objectively baseless. No. 02-1390, 2009 WL 2751029, at *18–*23 (D.N.J. Aug. 28, 2009). So did the plaintiffs in *Nuance Commc’ns, Inc. v. Omilia Nat. Language Sols., Ltd.* No. CV 19-11438-PBS, 2020 WL 2198362 (D. Mass. May 6, 2020); [167]. Here, plaintiffs disclaim any intent to prove objectively baseless conduct. And in *Nuance Communications*, there was no basis for assessing the merits of the § 2 claim at the motion-to-dismiss stage, 2020 WL 2198362 at *5, while here, the vast majority of the petitioning has already proved itself reasonable. *U.S. Futures Exch.*, 953 F.3d at 963.

Also distinguishable are the cases addressing the practice of “pooling” existing patents. In *Kobe, Inc. v. Dempsey Pump Co.*, the defendants were accused of purchasing large numbers of patents from the entities to whom the patents had been issued. 198 F.2d 416, 420 (10th Cir. 1952). *See also Intellectual Ventures I LLC v. Capital One Financial Corp.*, 99 F.Supp.3d 610, 626 (D. Md. 2015) (the alleged conduct at issue there was the intentional acquisition of “a massive patent portfolio”). The practice of “pooling” patents does not involve petitioning the government, it involves a series of private transactions, and defendants’ First Amendment right to petition the government for internally developed patents (and, to a certain degree, for

FDA approval) is what protects most of their activity from suit here. Areeda & Hovenkamp, § 704c (“we would never hold internal patent development to be a § 2 exclusionary practice because we do not wish to discourage innovation, even by monopolists”). *See also Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F.Supp.2d 408, 429 (D. Del. 2006) (“*Kobe* ... is contrary to more recent pronouncements by the Supreme Court concerning *Noerr* immunity”); *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1107 (6th Cir. 1989) (dismissing antitrust action when allegation was that one company raised barriers to entering a market by acquiring companies that held patents relevant to the industry). Pooling patents also facilitates collusion among competitors, *Princo Corp. v. ITC*, 616 F.3d 1318, 1334–35 (Fed. Cir. 2010) (en banc), which is not at issue in AbbVie’s patent-development conduct. And plaintiffs’ reliance on *Dairy Foods Inc. v. Dairy Maid Prod. Co-op.* is misplaced because *Dairy Foods* was decided before *California Motor* and *PRE*. 297 F.2d 805, 809 (7th Cir. 1961).

Lastly, plaintiffs say the rule of reason should be applied to their § 2 claims, that they need only make out a prima facie case of anticompetitive effect, and that any procompetitive justifications must be assessed later. *See In re Opana ER Antitrust Litig.*, 162 F.Supp.3d 704, 719 (N.D. Ill. 2016). The rule of reason analysis involves an “inquiry into market power and market structure designed to assess the ... actual effect” of the contract, combination, or conspiracy, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984), or, in § 2 cases, of an alleged monopolization. *Hennessy Indus. Inc. v. FMC Corp.*, 779 F.2d 402, 404–05 (7th Cir. 1985). With regard to the conduct immunized by the *Noerr–Pennington* doctrine, rule

of reason analysis is not necessary. *See Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 357 (7th Cir. 1990). And since so much of the conduct in question is immunized, and since the only parts that may not have been are inseparable from the alleged § 2 scheme, the claim fails. *See Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 839 (7th Cir. 2011) (cautioning against aggregating conduct to nullify immunity). But even if AbbVie's nonimmunized conduct is sufficient to be a standalone scheme of monopolization, the complaint still fails for lack of an antitrust injury because it is not plausible that AbbVie's nonimmunized conduct intimidated the other defendants into delaying the launch of their biosimilars (or otherwise caused any antitrust injury). *See* § III.C below.

B. The § 1 Claims Against all Defendants

Section 1 of the Sherman Act declares illegal “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce.” 15 U.S.C. § 1. In order to state a claim under § 1, plaintiffs must plead “(1) a contract, combination, or conspiracy; (2) a resultant unreasonable restraint of trade in [a] relevant market; and (3) an accompanying injury.” *Deppe v. Nat’l Collegiate Athletic Ass’n*, 893 F.3d 498, 501 (7th Cir. 2018). When assessing whether a particular restraint enhances or inhibits competition, courts apply three categories of analysis: per se, quick-look, and rule of reason. *Agnew v. Nat’l Collegiate Athletic Ass’n*, 683 F.3d 328, 335 (7th Cir. 2012). All three are “meant to answer the same question: whether or not the challenged restraint enhances competition.” *Id.* (quotations omitted).

Per se analysis is applied when a “practice facially appears to be one that would always or almost always tend to restrict competition and decrease output,” such as horizontal price fixing and output limitations. *Id.* at 336. The quick-look approach asks whether an “observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect.” *Id.* (quoting *California Dental Ass’n v. F.T.C.*, 526 U.S. 756, 770 (1999)). If legitimate, procompetitive justifications for facially anticompetitive behavior are found, then rule of reason analysis may be necessary. *Id.* Under the rule of reason, plaintiffs must allege that “an agreement or contract has an anticompetitive effect on a given market within a given geographic area.” *Id.* at 335.

The complaint alleges that AbbVie, Amgen, Samsung Bioepis, and Sandoz violated § 1 when they entered into settlement agreements that required the latter three defendants to temporarily give up their efforts to introduce biosimilars in the U.S. market in return for near-immediate permission to launch their biosimilars in Europe. [109] ¶¶ 141–212. Plaintiffs say that those agreements violated § 1 under both a pay-for-delay theory (i.e., AbbVie paid off its competitors to buy itself more time as a monopolist), *id.* ¶¶ 261–68, and a market-allocation theory (i.e., AbbVie allocated to itself the U.S. market and allocated to the other defendants the European market). *Id.* ¶¶ 279–85.

These agreements do not justify per se treatment because they are not facially anticompetitive in any way that would always or almost always tend to restrict competition. The agreements do not set prices for Humira and its biosimilars, nor do

they include terms setting the quantity of Humira (or its biosimilars) that is to be sold in the market. *See Agnew*, 683 F.3d at 336 (“[h]orizontal price fixing and output limitation are classic examples of behavior that is considered anticompetitive per se”). Even reverse-payment patent settlement agreements that involve cash payments from the patentee to the alleged infringer do not usually receive per se treatment, *see FTC v. Actavis, Inc.*, 570 U.S. 136, 158–59 (2013), and the types of agreements at issue here—which involve two sets of early entry dates in two different regions—are even less facially restrictive because they do not involve a cash payment in return for a promise to keep a competing product off the market.

Market allocation agreements, however, are “classic examples” of per se § 1 violations. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972). In a market allocation agreement, competitors at the same level of a market “allocate territories in order to minimize competition.” *Id.* For instance, in *Palmer v. BRG of Georgia, Inc.*, it was a per se violation of § 1 for BRG to promise not to provide bar review courses outside of Georgia in return for a promise from its competitor to not provide bar review courses inside of Georgia. 498 U.S. 46, 47 (1990). *See also Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 152 F.3d 588, 591 (7th Cir. 1998) (the defendants “entered into agreements with competitors to stay out of each other’s territories”).

According to plaintiffs, the European entry dates are the quid pro quo for the U.S. market entry dates, and for the period that falls between the two, AbbVie effectively allocated to itself the U.S. market while allocating to the other defendants

the European market. [144] at 47–48. The result is that, in the interim, consumers in the U.S. are “subsidizing competition in Europe.” *Id.* at 48.

One difference between the usual market allocation agreement and the one alleged here is that there is no allegation that AbbVie planned to stop selling Humira in Europe after Amgen, Sandoz, Samsung Bioepis, and the others introduced their biosimilars. *See* [109] ¶¶ 203, 205, 209. That does not necessarily sink plaintiffs’ claim. *Areeda & Hovenkamp*, § 2030c; *Blackburn v. Sweeney*, 53 F.3d 825, 827 (7th Cir. 1995) (“[t]o fit under the *per se* rule” a horizontal, market-allocation agreement “need not foreclose all possible avenues of competition”). For instance, in *United States v. Topco*, one of the geographic restrictions that was found *per se* unlawful did not completely bar sales in the geographic region but placed some parties at a disadvantage in that region. 405 U.S. 596, 601–02 (1972).

The first difference here is that this complaint mentions no such disadvantages in either the U.S. or Europe. There is no allegation that Amgen, Sandoz, Samsung Bioepis, or the others could only market their biosimilar in Europe (or in the U.S.) using a certain label, or to certain kinds of doctors, or for a certain price, or by using certain kinds of advertisements. Once the entry dates passed, all competitors were free to compete on level ground. *See* [109] ¶¶ 203–204.

The second (and bigger) difference is that AbbVie is asserting patents. Patents come with the right to selectively license the patent “to the whole or any specific part of the United States.” 35 U.S.C. § 261; *Areeda & Hovenkamp*, § 704b4 (“a patent dispute that settles with a market division license agreement will be approved, and

the courts repeatedly state that they are loath to inquire into such things as whether the patents in question are valid”). A patentee may also issue territorial licenses that allow competitors to sell patented products in some foreign countries but not others (and not in the U.S.). *Dunlop Co. v. Kelsey-Haynes Co.*, 484 F.2d 407, 417 (6th Cir. 1973). *See also* Areeda & Hovenkamp, § 2044a1 (the Patent Act does not protect horizontal territorial divisions that do not involve the transfer of intellectual property rights unless the agreement resolves a bona fide intellectual property dispute, in which case the agreement receives “special consideration”); § 2045a (“[A]ssuming a genuine dispute, the outcome of even a settlement agreement producing a per se antitrust violation might be no more anticompetitive than the outcome of litigation.”).

Market allocation agreements are not free from per se treatment just because they involve intellectual property licenses, *see United States v. Sealy, Inc.*, 388 U.S. 350, 351, 357–59 (1967), but patents are different from other types of intellectual property when it comes to geographic restrictions, and an agreement to permit entry into a market previously protected by a patent does not become a per se invalid market allocation agreement just because it is specific to one territory (or one country). 35 U.S.C. § 261; Areeda & Hovenkamp, § 2044a1 (the “most obvious” reading of the Patent Act is that, “where the patentee also makes the manufactured product in a territory, the statute explicitly authorizes a form of ‘horizontal’ territorial division that would be illegal per se if done in the absence of an intellectual property license”). The settlement agreements here are not market-allocation agreements, as that term is understood for per se treatment.

In any event, per se treatment is disfavored for novel theories of antitrust violations like this one. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (“Per se treatment is appropriate once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.”) (citations omitted); *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607–08 (1972) (“[i]t is only after considerable experience with certain business relationships that courts classify them as per se violations of the Sherman Act”). The agreements are not per se unlawful under § 1.

The quick-look test is not the right test, either, because an observer with a rudimentary understanding of economics would not conclude that the agreements have an anticompetitive effect. *California Dental Ass’n v. F.T.C.*, 526 U.S. 756, 770 (1999). AbbVie’s intellectual property portfolio contains many Humira-related patents, and competitors Amgen, Sandoz, and Samsung Bioepis are all seeking to introduce drugs that are (by design) very similar to Humira. An agreement that allows competitors to enter markets from which there is a chance they would otherwise be excluded is not on its face anticompetitive. Even if the rudimentary economist is informed that most of the patents are likely invalid and un infringed and being asserted without regard to their validity, there are still legitimate, procompetitive justifications for the agreements that require full rule of reason analysis (for instance, the agreements provide certainty to both parties and avoid further litigation costs). *See Agnew v. Nat’l Collegiate Athletic Ass’n*, 683 F.3d 328, 335 (7th Cir. 2012). Because a “great likelihood of anticompetitive effect” cannot

“easily be ascertained,” *California Dental*, 526 U.S. at 770, the quick look test is not right for these agreements, either.

The rule of reason is a better fit, although the question at this stage is simply whether there is a plausible claim for a restraint on competition.¹⁶ Reverse-payment settlements (where the patentee pays the alleged infringer rather than the other way around) trigger § 1 antitrust scrutiny and rule of reason analysis. *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013). In *Actavis*, the patent holder settled its infringement claims against a generic drug manufacturer. *Id.* at 144–45. In the settlement, the patent holder paid the alleged infringer and the alleged infringer agreed to delay its entry into the market. *Id.* at 145. That “unusual” form of settlement, where an alleged infringer received money to stay away from the patent holder’s market, raised the concern that the agreement had an adverse effect on competition. *Id.* at 147–48, 152. Ordinarily, a patent holder has some entitlement to monopoly profits for the duration of its patent and consumers benefit from a deal to allow a competitor to enter the market before the patent expires. *Id.* at 153–54. But the *Actavis* settlement suggested that the patents were at risk and that the patentee purchased an opportunity to keep prices set at its preferred level—sharing monopoly profits with a competitor without

¹⁶ It is not always necessary to determine which of the three categories of analysis should be applied when ruling on a motion to dismiss. *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F.Supp.3d 730, 754 (N.D. Ill. 2019), *reconsideration denied*, No. 17 C 50107, 2019 WL 2763181 (N.D. Ill. May 3, 2019). *See also* Areeda & Hovenkamp, § 305(e) (“Often ... the decision about which rule is to be employed will await facts that are developed only in discovery.”) But there are no facts that need to be developed before determining which rule to apply here. The plaintiffs have alleged in their complaint the basic terms of the agreements and how they affected the market. *See* [109] ¶¶ 157–210.

consumer gains. *Id.* at 154. “In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects.” *Id.* at 159.

Although scrutiny of such settlements can lead to “time-consuming, complex, and expensive litigation,” the Court rejected a blanket rule immunizing reverse-payment patent-infringement settlements from antitrust scrutiny. Procompetitive justifications (e.g., the avoidance of litigation costs) can be examined and accounted for as part of the rule of reason analysis. *Id.* at 156. And fears that it would be expensive and time-consuming to assess the value of the underlying patent claim are mitigated by the fact that it is “normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham ...).” *Id.* at 157. The size of the reverse payment can serve as a proxy for the patent’s weakness without forcing a court to conduct a “detailed exploration of the validity of the patent itself.” *Id.* at 157–58. A rule of reason analysis would not be cumbersome when the size of the payment suggests that the patentee possessed the market power it needed to bring about anticompetitive harm. *Id.* at 157.

To avoid deterring settlements because of exposure to antitrust liability, the Court noted an important exception. Parties remain free to settle on other terms—for example, “by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.” *Id.* at 158.

The settlements here and their context are different than in *Actavis*. The *Actavis* settlement and its Hatch-Waxman Act context conferred limited exclusivity on the alleged infringer (*Actavis*, the generic manufacturer that was the first to file an abbreviated application), thereby allowing a patent monopoly to be shared, but not open to competition. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 155 (2013). Here, Amgen was not the only party to pursue litigation and reach an agreement for an early U.S. market-entry date—the complaint mentions eight other companies that followed closely on its heels (Samsung Bioepis, Mylan, Sandoz, Fresenius, Momenta, Pfizer, Coherus, and Boehringer). See [109] ¶¶ 141–184. Plaintiffs no longer allege that AbbVie granted any exclusivity to Amgen. *Id.* ¶ 155; see [126-1]; [126-2]; [144] at 46 n.15. Concerns that settlements like the one at issue here allow for sharing of monopoly profits to the detriment of consumers are undermined by the allegation that a wave of challengers stands waiting in the wings to sell adalimumab, and that none of them was forced to wait longer than the first-filer because of a settlement agreement. [109] ¶¶ 141–184; [144] at 46 n.15.

On their face, the U.S. settlements here are settlements that allow for early entry without a payment. *Actavis* identifies a settlement that allows early entry but without the patentee paying a competitor to stay out of the market as one type of agreement that is not an antitrust problem. *Actavis, Inc.*, 570 U.S. at 158. This makes sense because such settlements increase competition by cutting monopolies short. For instance, in *Asahi Glass Co. v. Pentech Pharm., Inc.*, a patentee had reached a settlement with a competitor that allowed that competitor to sell one of the patentee's

drugs in Puerto Rico immediately and, in the rest of the U.S., as soon as any other generic version hit the market. 289 F.Supp.2d 986, 992–93 (N.D. Ill. 2003), *dismissed*, 104 Fed. App'x 178 (Fed. Cir. 2004). There was no antitrust violation because the only “payment” was competition itself. *Id.* at 994 (“the ‘payment’ of Puerto Rico ... increased the competition there”). Since the payment was permission to start competing a little earlier than the competitor otherwise had the right to, and because the agreement did not extend any existing monopolies, there was no § 2 antitrust violation. *See id.* That logic aligns with the Supreme Court’s decision to name early entry settlement agreements as examples of permissible settlements. *See Actavis*, 570 U.S. at 158. The U.S. settlement agreements are not reverse-payment agreements subject to *Actavis* antitrust scrutiny.

The fact that the settlements did not involve a direct payment is not determinative. *See In re Aggrenox Antitrust Litig.*, 94 F.Supp.3d 224, 242–243 (D. Conn. 2015). *See also King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015); *In re Opana ER Antitrust Litig.*, 162 F.Supp.3d 704, 718 (N.D. Ill. 2016) (when considering whether a settlement constitutes a large and unjustified reverse payment, the various payments cannot be examined in isolation); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F.Supp.3d 307, 331 (D.R.I. 2017). Plaintiffs allege that there was a reverse payment, just not one within the infringement litigation settlement agreements. AbbVie paid the biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market. In exchange, the biosimilar companies agreed to settle the infringement

litigation with an AbbVie-friendly U.S. early entry date. The package deals conferred large European revenue streams (hundreds of millions of dollars, [144] at 53) onto the biosimilar companies, while buying AbbVie even more lucrative monopoly time in the U.S. (worth billions of dollars in revenue for AbbVie, [109] ¶ 204).¹⁷

Nevertheless, and notwithstanding the allegation that this exchange was for the purpose of unnecessarily perpetuating AbbVie's patent monopoly, the package of global patent settlements were not an *Actavis*-like unlawful reverse-payment. They provided one early entry date for the European market and a different early entry date for the U.S. market—both permissible under *Actavis*. See *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 RA, 2015 WL 5610752, at *17 (S.D.N.Y. Sept. 22, 2015) *vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017) (when “[b]oth ... licenses [are] permissible settlement terms under *Actavis* ... the simultaneous grant of both does not render either license unlawful”). The European deals were early

¹⁷ The defendants challenge the plausibility of plaintiffs' allegation that there was a quid pro quo in the U.S. and European agreements. Mylan and Boehringer agreed to roughly the same U.S. market entry dates as the other biosimilar manufacturers despite not accepting an early European entry date. [109] ¶¶ 177–84, 203. That undermines the inference that those European early entry dates were worth all that much or were a bargaining chip in the U.S. settlements. Similarly, AbbVie points out that it only has three European patents, that those three patents “protect indications for adalimumab for only four diseases, leaving at least five other diseases for which Humira is approved unguarded by patents in Europe,” [124] at 36–37, and so the European patents were not a valuable barrier to competition. And the complaint itself alleges that AbbVie's European adalimumab patent expired on the same day that the agreements allowed Amgen, Samsung Bioepis, and Sandoz to enter the European market, further undermining the implication that the European early entry dates were worth all that much (or that they were “early” at all). [109] ¶ 203. But at this stage, I put aside potential inconsistencies and accept plaintiffs' factual allegation of an exchange. The complaint alleges that AbbVie's conduct rendered it difficult (if not impossible) to sell competing biosimilars in Europe absent the agreements in question, and concluding otherwise would require drawing an inference in AbbVie's favor. See [109] ¶¶ 185–202.

entry settlements of the kind that did not worry the Court in *Actavis*, as were the U.S. settlements. The transfer of value, as large as it was, did not have the hallmarks of an unjustified and otherwise inexplicable payment because the package either increased competition or preserved an anticompetitive status quo. *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *16 (“*Actavis* does not provide a legal basis for restricting negotiated settlement terms where they do not restrain competition”). The effect of the payment was to increase, not restrain competition by bringing competitors into the market when patents otherwise prohibited the competition.

There is also a broader reason to uphold these agreements under antitrust review: encouraging patent litigants to settle worldwide patent disputes. Any early entry date in one region could always be considered a transfer of value in return for a later entry date in another region. Plaintiffs assure the court that “[i]t is the particular circumstances of AbbVie’s patent gamesmanship ... that, taken together with the contemporaneously executed settlement agreements, creates the violation,” [144] at 59–60, but they do not elaborate. Although certain aspects of this settlement agreement might take it outside the norm (the alleged value of the European early entry dates, for one), it is not unlawful to enter into agreements that have been explicitly recognized by the Supreme Court as not a matter for antitrust concern, *Actavis*, 570 U.S. at 152, that implement a right included in the bundle of rights awarded to patent holders, 35 U.S.C. § 261; *Dunlop Co. v. Kelsey-Haynes Co.*, 484

F.2d 407, 417–18 (6th Cir. 1973), and that play an important role in making global patent settlement agreements easier.

In *King Drug Co. of Florence v. Smithkline Beecham Corp.*, Smithkline induced Teva Pharmaceuticals to give up a challenge to Smithkline’s patent by promising Teva two things: (1) an early entry into the generic market and (2) that Smithkline would not produce an authorized generic of its own. 791 F.3d 388, 393–94 (3d Cir. 2015). Finding that this “no AG” agreement represented an “unusual, unexplained reverse transfer of considerable value,” the Third Circuit found that the agreement may have violated the antitrust laws because “the source of the benefit to the claimed infringer [was] something costly to the patentee.” *Id.* at 394, 405. When a brand name manufacturer agrees to not produce a generic, consumers lose and the market for the brand name drug (and its generics) becomes less competitive than it would have been absent the agreement. The difference here is that when AbbVie agreed to let Amgen, Sandoz, and Samsung Bioepis enter the European and U.S. markets earlier than they might have been able to otherwise, consumers won and the market for Humira (and its generics) became more competitive. These agreements were decidedly not “as harmful as those resulting from reverse payments of cash.” *Id.* at 405. *See also United Food & Commercial Workers Local 1776 & Participating Emp’rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F.Supp.3d 1052, 1067–68 (N.D. Cal. 2014) (recognizing that agreements that increase competition fall outside the scope of *Actavis*).¹⁸

¹⁸ Plaintiffs also rely on *Tawfilis v. Allergan, Inc.*, 157 F.Supp.3d 853, 862 (C.D. Cal. 2015). Although it found allegations of anticompetitive injury arising from a licensing agreement

In both *King Drug*, and *In re Lipitor Antitrust Litig.*, the Third Circuit acknowledged that it might not be appropriate to justify anticompetitive effects in one market with procompetitive effects in another. *King Drug*, 791 F.3d at 409 n.34; *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256 n.12 (3d Cir. 2017). But both cases ultimately turned on the sufficiency of the complaint's allegation that a patent holder made an unjustified transfer of value to an alleged infringer in a manner suggestive of competitive harm. *In re Lipitor Antitrust Litig.*, 868 F.3d at 239; *King Drug Co. of Florence*, 791 F.3d at 392.

Like *King Drug* and *In re Lipitor*, this case doesn't depend on the competitive benefits in one market (Europe) justifying the effects in another (the U.S.). The issue is whether the complaint alleges a patent settlement that has *Actavis*-like anticompetitive features and that warrants further scrutiny under the rule of reason. Unlike *King Drug* and *In re Lipitor*, the complaint here does not. The U.S. settlements were on terms consistent with *Actavis*'s notion of a competitively legitimate settlement, and while part of the bargain included the European deals, that part was also consistent with a permissible early entry settlement. The settlement terms, when taken together, involve transfers of value from the patentee to the alleged infringer. But because all the agreements are of a type specifically permitted by *Actavis*, and because they deliver value to consumers, plaintiffs have not plausibly

between competitors to be plausible, that case makes no mention of *Actavis* and is neither binding nor persuasive here.

alleged the existence of an agreement that restrained competition.¹⁹ Both of plaintiffs’ § 1 claims (for market allocation and pay-for-delay) against all of the defendants—AbbVie, Amgen, Samsung Bioepis, and Sandoz—are dismissed.

C. Antitrust Injury

Sections 4 and 16 of the Clayton Act provide for private rights of action (for damages and injunctive relief, respectively) in antitrust cases. 15 U.S.C. §§ 15, 26; *Indiana Grocery, Inc. v. Super Valu Stores, Inc.*, 864 F.2d 1409, 1419 (7th Cir. 1989); *Sw. Suburban Bd. of Realtors, Inc. v. Beverly Area Planning Ass’n*, 830 F.2d 1374, 1377–78 (7th Cir. 1987); *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 112–13 (1986). Both require that plaintiffs suffer an “antitrust injury.” *Id.* Antitrust injury analysis “focuses on the *type* of injury claimed by a *particular* plaintiff and demands that it be an ‘antitrust injury.’” *Indiana Grocery*, 864 F.2d at 1419 (emphasis in original). An antitrust injury is any “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). The injury must be “the type of loss that the claimed violations ... would be likely to cause.” *Id.*

¹⁹ Although it is “normally not necessary to litigate patent validity to answer the antitrust question,” *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 157 (2013), plaintiffs’ theory here does require a detailed exploration of both the validity of hundreds of patents (some of which have already been the subject of extensive infringement litigation and other disputes before the USPTO and PTAB) and whether those patents were infringed. That makes the European revenue conferred on the biosimilar companies a far less helpful proxy for market power because the alleged reverse-payment has to be measured against the global litigation risks and the approximate strength of hundreds of AbbVie’s patents (plus AbbVie’s intellectual property portfolio in Europe). In other words, the allegations here require even more expensive and time-consuming litigation than in *Actavis*, and this further suggests that plaintiffs’ theory pushes antitrust doctrine into unintended overlap with the patent regime.

The injury requirement applies to both plaintiffs' § 1 and § 2 claims. *See Indiana Grocery, Inc.*, 864 F.2d at 1419 (the antitrust injury requirement comes from § 4 of the Clayton Act, which is what grants plaintiffs the right to bring a private right of action under both § 1 and § 2 of the Sherman Act).

Antitrust injury analysis involves a two-step causation inquiry. *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 395 (7th Cir. 1993). After delineating the “*type* of interests protected by the antitrust laws,” the court must determine whether the “violation was the cause-in-fact of the injury: that ‘but for’ the violation, the injury would not have occurred.” *Id.* (emphasis in original). The illegality need only be a material cause of the injury and plaintiffs need not prove that there was no other potential cause of the injury. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969). The injury must flow directly from the anticompetitive aspect of the practice under scrutiny. *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1065 (7th Cir. 2019).

There is no hard-and-fast rule against deciding the question of antitrust injury at the pleading stage. *See McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1061 (7th Cir. 2019) (upholding dismissal on antitrust injury grounds at the motion to dismiss stage); *Midwest Gas Servs., Inc. v. Indiana Gas Co.*, 317 F.3d 703, 712–13 (7th Cir. 2003) (same). Dismissal is appropriate if the claim “rests at bottom on some abstract conception or speculative measure of harm.” *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 543 (1983).

The type of antitrust injury that plaintiffs allege they suffered is monopoly prices. Plaintiffs claim they paid monopoly prices for Humira during a period of time when, but-for the alleged unlawful conduct, competition would have driven prices lower. Higher prices are one of the “principles vices” proscribed by the antitrust laws, *McGarry & McGarry, LLC*, 937 F.3d at 1065, so the allegations satisfy the first part of the causation test. *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 395 (7th Cir. 1993).

Plaintiffs advance two sets of allegations to demonstrate that defendants’ conduct was the cause-in-fact of the monopoly prices: one set pertains to the underlying infringement litigation and the other pertains to the settlement agreements. With regard to the litigation, plaintiffs allege that, if the biosimilar manufacturers had pursued the underlying infringement suits, they could have prevailed and, by invalidating the patents that were preventing them from entering the market, entered the market even sooner than they are now able to under their settlement agreements, driving prices down. [144] at 64–67. With regard to the alternative settlement theory, plaintiffs allege that if AbbVie had asserted only those patents that were valid and infringed (i.e., fewer patents), the biosimilars’ bargaining position would have been stronger and the biosimilar manufacturers would have been able to negotiate earlier entry dates. [144] at 63.

The allegations about what might have happened in the underlying infringement litigation are too speculative and would require legal and factual determinations that go beyond judicially manageable limits. *Associated Gen.*

Contractors, 459 U.S. at 543; *Greater Rockford*, 998 F.2d at 394 (indirect and speculative injuries cannot support a private antitrust lawsuit). In order to allege cause-in-fact, plaintiffs must allege that “the injury would not have occurred” absent the alleged unlawful conduct. *Greater Rockford*, 998 F.2d at 395. With regard to the underlying infringement litigation, plaintiffs are not willing to go that far. Instead, they argue that at least one of the biosimilar defendants could—not would—have prevailed in one of the underlying infringement suits. [144] at 64 (citing *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA*, 296 F.Supp.3d 1142, 1155 (N.D. Cal. 2017) (requiring “some evidence” of the patents’ invalidity “is not the same as requiring plaintiffs to prove that the generic defendant *would have* won, only that it *could have*” won in the underlying infringement suit) (emphasis in original)). Plaintiffs’ position has some support: at the pleading stage the question is “*could* these things have happened, not *did* they happen.” *Carlson v. CSX Transp., Inc.*, 758 F.3d 819, 826–27 (7th Cir. 2014). But when it comes to this proposed alternative history, plaintiffs’ use of the word “could” instead of “would” is not merely semantic; it signals that they do not intend to prove that prices were going to fall but-for the litigation. They have conceived of a world where that might have happened, but conceivable falls short of plausible. *Id.* at 826.

The first problem with the litigation theory is that it only takes one valid, infringed patent to render all the rest—whether invalid, infringed, or not—irrelevant for purposes of cause-in-fact analysis. If a drug is not able to launch because

launching would infringe even a single patent, then the “injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch.” *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017), *judgment entered sub nom. In re Wellbutrin XL Antitrust Litig.*, No. 15-2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (“[t]he absence of competition from Canadian sources in the domestic prescription drug market ... is caused by the federal statutory and regulatory scheme adopted by the U.S. government, not by the conduct of the defendants,” and, “[c]onsequently, the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy”). If the reason the biosimilar manufacturers could not make it to market was that AbbVie had a patent that prevented them from doing so, it was the patent—and not AbbVie’s other conduct—that was the but-for cause of the monopoly prices.

Against that backdrop, plaintiffs’ theory of antitrust injury is not plausible. The complaint calls many of AbbVie’s patents “weak,” [109] ¶ 6, its patent applications “dubious,” *id.* ¶ 185, says that some of the patents were “obvious in light of prior art,” *id.* ¶ 107, and identifies four patents that were issued as the result of material misrepresentations and omissions to the USPTO. *Id.* ¶¶ 114–20. But the complaint never alleges that all of AbbVie’s patents were invalid or not infringed. *See, e.g.*, [109] ¶ 107 (“many” of AbbVie’s patents do not withstand scrutiny), ¶ 112 (all of the formulation patents are invalid in light of prior art), ¶¶ 130–132 (of AbbVie’s more than 100 patents covering adalimumab, each can be traced back to twenty

patents, two-thirds of which fail the novelty requirement), ¶ 134 (“the majority” of AbbVie’s formulation and manufacturing/process patents fail other requirements), ¶ 140 (AbbVie should be precluded from asserting any formulation and manufacturing patents filed after February 1996). Confirming as much in their response, plaintiffs say they do not need to allege that all of AbbVie’s patents were invalid or infringed. *See* [144] at 62. Instead, they say it is enough that a “great many of the patents were invalid or not infringed,” [144] at 65, and that, as a result, at least one of the biosimilar manufacturers could have prevailed in the underlying litigation. [144] at 64. But without identifying which patent at issue in the litigation was going to be declared invalid or committing to a clear pathway to establish how prices would have fallen if the biosimilars had stuck it out in the global patent fight against AbbVie, plaintiffs’ complaint leaves the defendants (and the reader) without notice of their claim.²⁰

The second problem is that litigation takes time. In the case of complex patent portfolios, it can take a lot of time. For instance, when Amgen and AbbVie settled their infringement suit, trial was still two years away (they settled in September of 2017, at which point trial was scheduled for November of 2019). *See* [109] ¶¶ 148–51. Plaintiffs’ theory requires them to allege that trial would have taken place as scheduled, that Amgen would have prevailed, and that any appeal would have

²⁰ Plaintiffs say that under their alternative settlement theory, the biosimilar companies had significant leverage and could have obtained licenses for any patents that were valid and infringed (i.e., “blocking patents”). [144] at 67. But for the reasons discussed with regard to the alternative settlement theory below, that claim is possible—not plausible.

resolved in time for Amgen’s biosimilar to hit the market before January 31, 2023 (the market entry date Amgen received under its settlement agreement). [144] at 66. Nondefendant Boehringer’s infringement suit was scheduled to go to trial in October of 2020 when it settled in May of 2019. [109] ¶¶ 181, 183–84. And since no trial date had been set in either Samsung Bioepis’s or Sandoz’s patent infringement suits when they settled in April and October of 2018, respectively, [109] ¶¶ 157, 170, plaintiffs are left to allege it was “likely” that their trials would have been scheduled and would have concluded—and that any appeal would have been resolved—early enough to allow them to bring their biosimilars to market before their June (Samsung Bioepis) and September (Sandoz) 2023 entry dates. [144] at 66; [109] ¶¶ 83–84, 148–51, 157, 170. Nothing in the complaint demonstrates a basis to predict the requisite timing to establish plaintiffs’ injury.

Alternatively, the biosimilar manufacturers might have launched at risk. According to the complaint, the only two biosimilar companies that received FDA approval before settling (Amgen and Boehringer) chose not to launch at risk. *See* [109] ¶¶ 149, 151, 182, 184, 211. Boehringer spent twenty months waiting for the underlying patent litigation to wrap up without launching. *See id.* ¶¶ 182, 184.²¹ As the complaint points out, the reason for their delay was AbbVie’s patent thicket, which was “impassable.” [109] ¶ 9. *See also supra*, n.5 (thirteen of the eighteen

²¹ Plaintiffs did not allege that any of the biosimilar manufacturers sent notice to AbbVie that they intended to market their biosimilar, which suggests those manufacturers may not have launched their biosimilars anyway. *See* 42 U.S.C. § 262(l)(8)(A) & (B); [124] at 47; [150] at 26. But plaintiffs were not required to account in their complaint for all of AbbVie’s alternative scenarios, and I draw the reasonable inference in plaintiffs’ favor that there was no technical barrier to launching at risk.

petitions for *inter partes* review had failed to punch a hole through the thicket). Launching while the underlying patent litigation was ongoing posed an enormous risk. *See id.* ¶¶ 86, 97 (the potential damages were “crushing”). And while plaintiffs acknowledge that phase-two litigation often poses a significant final barrier for biosimilar manufacturers hoping to reach the market, *see* [144] at 45, they say nothing about what it was that they think Boehringer or Amgen (or Samsung Bioepis and Sandoz) might have done to get their biosimilars to market before 2023 if they had tried launching at risk and AbbVie had initiated second-phase litigation seeking an injunction. With regard to the potential at-risk launches, too, plaintiffs’ theory rests on speculative guesses about what hypothetically competitive biosimilar manufacturers might have done.

Amgen, [125] at 5–6, Samsung Bioepis, [130] at 5–6, and Sandoz, [131] at 3–4, all argue that the complaint does not plausibly allege that, but-for their allegedly illegal agreements, the patent litigation would have concluded in time for consumers to have been able to buy their biosimilars any sooner than they will be able to under the existing agreements. I agree. The complaint requires drawing a conclusion that rests on too many inferences and reveals a theory of antitrust injury that is speculative as a matter of law.

The alternative settlement theory fares no better. Plaintiffs say that all they have to allege is that, but-for AbbVie’s conduct, the biosimilar manufacturers could have obtained earlier U.S. market entry dates than they did. [144] at 67. But the allegations in the complaint do not make plaintiffs’ hypothesis plausible. The

complaint alleges that the defendants entered into settlements. As discussed above, these settlements are not anti-competitive reverse payments of the kind that worried the Court in *Actavis*. Another way to see that these agreements do not suggest antitrust liability is to focus on the question of antitrust injury. As alleged, AbbVie and the biosimilar defendants agreed to early entry in Europe in exchange for favorable (to AbbVie) early entry in the United States. But to allege injury, plaintiffs must still plausibly allege that but for that agreement, the biosimilars would have entered sooner—that they had the kind of leverage over AbbVie’s patents to negotiate licenses or settlements even more favorable to them (and to consumers) than the compromise they agreed to. Given that AbbVie’s IP portfolio was “impassable,” its patents had survived thirteen *inter partes* review challenges, and that all it would have taken was one valid and infringed patent to preclude market entry until that patent’s expiration, it is not plausible that these agreements prevented an even earlier entry date in the U.S. market for a biosimilar. *See Kroger Co. v. Sanofi-Aventis*, 701 F.Supp.2d 938, 957 (S.D. Ohio 2010) (“an injury deriving from the failure to reach a hypothetical procompetitive agreement is ‘nothing but speculation.’” (quoting *Associated Gen. Contractors*, 459 U.S. at 543)).

Antitrust injury is a prerequisite for all of plaintiffs’ federal antitrust claims against not only AbbVie but also defendants Amgen, Samsung Bioepis, and Sandoz. Because plaintiffs have failed to plausibly allege that the but-for cause of Humira’s monopoly prices was the biosimilar manufacturers’ failure to pursue infringement litigation to its conclusion, AbbVie’s unlawful assertion of its patent thicket, or the

biosimilar manufacturers' failure to use the leverage that they apparently didn't know they had to reach an agreement to enter the market sooner than they did, all of the federal antitrust claims in the complaint fail.

D. State Law Claims

Plaintiffs' state-law claims are spread across four counts.²² Counts II and IV assert pay-for-delay and market-allocation-agreement theories of liability under antitrust laws from twenty-seven states. [109] ¶¶ 269–78, 286–94. Count VI asserts a monopolization theory of liability under the antitrust laws of twenty-three states. [109] ¶¶ 301–08.

Counts II, IV, and VI also list six states' consumer protection laws. *See id.* [109] ¶¶ 276, 292, 306 (citing Alaska Stat. Ann. § 45.50.471; Cal. Bus. & Prof. Code §§ 17200, *et seq.*; Fla. Stat. §§ 501.201 *et seq.*; Ga. Code Ann. § 10-1-393; S.C. Code Ann. §§ 39-5-20, *et seq.*; Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*). According to the complaint, these state consumer protection laws prohibit both anticompetitive conduct, [109] ¶¶ 276, 292, and monopolization. *Id.* ¶ 306. Count VII asserts violations of sixteen states' laws that prohibit unfair and unconscionable conduct. *Id.*

²² Subject-matter jurisdiction exists over the state-law claims because the amount in controversy exceeds \$5,000,000, *see, e.g.*, [109] ¶ 251, and because at least one member of the proposed class of plaintiffs is a citizen of a state different from at least one of the defendants. *Id.* ¶¶ 14–24, 224–225; 28 U.S.C. § 1332(d)(2).

¶¶ 309–406. Five of the same six consumer protection laws cited in Counts II, IV, and VI also appear in Count VII. *Id.* ¶¶ 317, 327, 339, 346, 391.²³

Both AbbVie and plaintiffs agree that if the federal antitrust claims are dismissed, the state-law antitrust claims should be dismissed, too. [124] at 49–50; [144] at 74 (“[t]he defendants are correct that the plaintiffs’ state law antitrust claims ... should be dismissed if their federal antitrust claims are dismissed”). I dismiss plaintiffs’ state-law antitrust claims for the same reasons I dismissed the federal antitrust claims.

Plaintiffs also agree that if their federal antitrust claims are dismissed, the state law antitrust claims brought pursuant to consumer protection statutes should be dismissed, too. [144] at 74. Accordingly, those claims are dismissed, and that resolves the last of the claims asserted against Amgen, Samsung Bioepis, and Sandoz.

With regard to the claims in the complaint under the heading, “unfair and unconscionable conduct,” *id.* ¶¶ 309–406, AbbVie says that all of plaintiffs’ state-law

²³ Plaintiffs’ statutory labels are not controlling. For instance, plaintiffs cite Alaska Stat. Ann. § 45.50.471, which they describe first as a “state consumer protection law[] that prohibit[s] anticompetitive conduct,” [109] ¶¶ 276, 292, second, as a “state consumer protection law[] that prohibit[s] monopolization,” *id.* ¶ 306, and third, as a state law that prohibits “unfair and unconscionable conduct.” *Id.* ¶¶ 309–10, 317. The statute does not contain the words anticompetitive, monopoly, or unconscionable, and pertains to deceptive acts and practices more akin to trademark infringement than antitrust violations. *See, e.g.*, Alaska Stat. Ann. § 45.50.471(b)(1). Alaska’s antitrust laws are codified elsewhere. *See, e.g.*, Alaska Stat. Ann. § 45.50.562. That being said, plaintiffs do not have to cite the right laws in their complaint. *N.A.A.C.P. v. Am. Family Mut. Ins. Co.*, 978 F.2d 287, 292 (7th Cir. 1992) (a complaint “should limn the grievance and demand relief” and “need not identify the law on which the claim rests”); *Beaton v. SpeedyPC Software*, 907 F.3d 1018, 1023 (7th Cir. 2018), *cert. denied*, 139 S. Ct. 1465 (2019) (“plaintiffs do not need to plead legal theories”). What matters is whether they have stated a claim upon which relief can be granted and provided defendants with “fair notice of what the ... claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); Fed. R. Civ. P. 8(a).

consumer protection claims fail because they are “inextricably linked” to plaintiffs’ antitrust claims. [124] at 53–54. But just because plaintiffs used certain factual allegations to support their antitrust claims does not mean that they cannot use those same factual allegations to support their unfair and unconscionable conduct claims. AbbVie also argues that if the conduct in the complaint fails to allege an antitrust violation, then it must also fail to allege any unfair or unconscionable act or practice. [124] at 53. But many of the state laws that form the basis of plaintiffs’ unfair and unconscionable conduct claims are modeled after the Federal Trade Commission Act, which is broader than § 1 and § 2 of the Sherman Act. *See, e.g.*, Fla. Stat. Ann. § 501.204(2); 15 U.S.C. § 45; *Fed. Trade Comm’n v. R.F. Keppel & Bro.*, 291 U.S. 304, 310 (1934) (the Federal Trade Commission Act was “aimed at all the familiar methods of law violation which prosecutions under the Sherman Act had disclosed,” but “also had a broader purpose”) (citations omitted). There are unfair or unconscionable acts that are not contracts or combinations in restraint of trade or unlawful monopolies.

But because the complaint is shaped by its antitrust theories, once those theories fall out of the case it becomes difficult to assess how the allegations satisfy the unfair or unconscionable standards of various states’ laws. AbbVie is entitled to “fair notice of what the ... claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); Fed. R. Civ. P. 8(a). The first few hundred paragraphs of the complaint contain detailed allegations about AbbVie’s conduct, and the complaint recaps the relevant portions of those factual allegations generally before invoking state consumer protection statutes. [109] ¶¶ 310–316. But at bottom,

the complaint lists various states' consumer protection laws and asserts that AbbVie's conduct was unfair and unconscionable without ever explaining (or even implying) what was unfair or unconscionable about AbbVie's conduct beyond its potential to restrain competition or effect an unlawful monopoly (both of which it fails to allege plausibly). The complaint says the conduct violated public policy and there was a gross disparity between price and value, but never offers an explanation beyond invoking the words of the statutes. In some cases that may be enough to tell the defendant what it is defending against. A complaint need only "limn the grievance and demand relief." *N.A.A.C.P. v. Am. Family Mut. Ins. Co.*, 978 F.2d 287, 292 (7th Cir. 1992). It does not have to "identify the law on which the claim rests." *Id.*; *Beaton*, 907 F.3d at 1023 (7th Cir. 2018) ("plaintiffs do not need to plead legal theories").

But the problem here is that read as a whole, the complaint sounds in antitrust, and once it is understood to not state such a claim, something more (perhaps not much) must be offered other than statutory language or quotations from state caselaw to understand why the nonactionable antitrust conduct happens to limn the grievance of state prohibitions against unfairness or unconscionability. *Noerr–Pennington* may affect the viability of these state-law claims, too, because it is rooted in the First Amendment. *See, e.g., Green Mountain Realty Corp. v. Fifth Estate Tower, LLC*, 161 N.H. 78, 89 (2010) (applying that doctrine in the context of New Hampshire's unfair and unconscionable conduct statute); *Curtis Pub. Co. v. Butts*, 388 U.S. 130, 149 (1967) (the First Amendment applies to the states through the Fourteenth Amendment). Incorporating large swaths of allegations that describe

activity protected by the First Amendment further makes it difficult to separate the unfair and unconscionable from nonactionable conduct. Count VII is dismissed without prejudice for failure to give adequate notice of the claim. Because plaintiffs may be able to cure this problem, some additional state-specific issues merit resolution to give plaintiffs additional guidance going forward.

1. *Alaska*

Section 45.50.471 of the Alaska Unfair Trade Practices and Consumer Act prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.” [109] ¶¶ 276a, 292a, 306a, 317; Alaska Stat. Ann. § 45.50.471. *See also* Alaska Stat. Ann. § 45.50.531 (providing a private right of action for acts declared unlawful under § 45.50.471).

Only buyers that purchase products directly from the antitrust violator may bring claims against that party for damages. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 735–38 (1977). Some states have enacted “*Illinois Brick* repealer” statutes that allow indirect purchasers to sue for money damages. *See McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1064 (7th Cir. 2019). Alaska’s repealer statute only partially repealed *Illinois Brick*. *See* Alaska Stat. Ann. § 45.50.577(i). As a result, the attorney general is the only person who can bring an antitrust claim for damages on behalf of indirect purchasers under Alaska’s Restraint of Trade Act.

Alaska Stat. Ann. §§ 45.50.462–45.50.470, 45.50.577(i); *In re Lidoderm Antitrust Litig.*, 103 F.Supp.3d 1155, 1163 (N.D. Cal. 2015).

“No court has construed Alaska’s consumer protection statute to permit claims based on alleged antitrust and monopolization conduct by indirect purchasers.” *In re Lidoderm Antitrust Litig.*, 103 F.Supp.3d at 1163. Doing so would allow plaintiffs to circumvent Alaska’s partial indirect purchaser bar by proceeding under Alaska’s more general consumer protection statute. *See In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 516 F.Supp.2d 1072, 1108 (N.D. Cal. 2007). The better reading of the Act, considered in conjunction with Alaska’s Restraint of Trade Act, is that it precludes plaintiffs from bringing claims as indirect purchasers even under a non-antitrust unfair practices theory.

2. *California*

California’s Unfair Competition Law defines unfair competition to include “unlawful, unfair or fraudulent business act[s] or practice[s] and unfair, deceptive, untrue or misleading advertising.” Cal. Bus. & Prof. Code § 17200. In the last paragraph of their California-law-based unfair and unconscionable conduct allegations, plaintiffs allege that, as a result of AbbVie’s wrongful conduct, AbbVie was unjustly enriched. [109] ¶ 332. As AbbVie points out, California law does not recognize an independent cause of action for unjust enrichment. *Hill v. Roll Int’l Corp.*, 195 Cal.App.4th 1295, 1307 (2011) (“Unjust enrichment is not a cause of action, just a restitution claim”); *United Food & Commercial Workers Local 1776 &*

Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F.Supp.3d 1052, 1091 (N.D. Cal. 2014).

But plaintiffs have not brought a cause of action for unjust enrichment, they seek equitable relief in the form of restitution and disgorgement. [109] ¶¶ 327–32. In addition to borrowing violations from other laws, *De La Torre v. CashCall, Inc.*, 854 F.3d 1082, 1085 (9th Cir. 2017), California’s Unfair Competition Law provides its own unique cause of action. *See Cel-Tech Commc’ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 180 (1999) (a “practice may be deemed unfair even if not specifically proscribed by some other law”). AbbVie’s argument that the claim is a prohibited unjust enrichment claim is not well taken and would not be an impediment to an amended complaint.

3. *District of Columbia*

The District of Columbia’s Consumer Protection Act makes it unlawful for “any person to engage in an unfair or deceptive trade practice.” D.C. Code Ann. § 28-3904. It was “designed to police trade practices arising only out of consumer-merchant relationships,” *Ford v. Chartone, Inc.*, 908 A.2d 72, 80–81 (D.C. App. 2006) (citations omitted), and covers only the “ultimate retail transaction between the final distributor and the individual member of the consuming public.” *Adam A. Weschler & Son, Inc. v. Klank*, 561 A.2d 1003, 1005 (D.C. App. 1989). Since plaintiffs here are indirect purchasers that reimburse their members, the transactions do not qualify under the statute. *See also In re Lidoderm Antitrust Litig.*, 103 F.Supp.3d 1155,

1164–65 (N.D. Cal. 2015) (dismissing CPPA claim brought by end-payor plaintiff). *But see In re Remicade Antitrust Litig.*, 345 F.Supp.3d 566, 588 (E.D. Pa. 2018).

The code also defines a consumer as “any person who ... does or would purchase ... or receive consumer goods or services, including as co-obligor or surety, or does or would otherwise provide the economic demand for a trade practice.” D.C. Code Ann. § 28-3901(2)(A). The plaintiffs here do not purchase or receive Humira. They also do not provide the economic demand for Humira—they reimburse the people that provide the economic demand for Humira. *See* [109] ¶¶ 13–17, 225. The people that suffer from the ailments that Humira treats provide the demand. Plaintiffs have not alleged that they are co-obligors or sureties of the people that provide the demand for Humira. *See id.* ¶¶ 333–38. (That being said, plaintiffs have adequately alleged that AbbVie is a merchant within the meaning of the Consumer Protection Act because they have alleged that AbbVie sells a broad range of drugs all over the United States at volumes that plausibly suggest they sell with regularity in the District of Columbia. [109] ¶¶ 19, 84; D.C. Code Ann. § 28-3901(a)(3). The District of Columbia’s Consumer Protection Act does not reach the transactions at issue.

4. *Georgia*

Georgia’s Fair Business Practices Act prohibits “[u]nfair or deceptive acts or practices in the conduct of consumer transaction[s].” Ga. Code Ann. § 10-1-393; [109] ¶¶ 276d, 292d, 306d, 346–350. In order to bring a suit under that statute, plaintiffs have to provide defendants with a written demand “identifying the claimant and reasonably describing the unfair or deceptive act or practice relied upon and the

injury suffered” at least thirty days before filing suit, but not if “the prospective respondent does not maintain a place of business or does not keep assets within the state.” Ga. Code Ann. § 10-1-399(b).

The complaint does not say whether notice was provided, but as plaintiffs point out in their opposition, the complaint also does not say that AbbVie maintains an office in Georgia. The notice provision is to be liberally construed, *Amin v. Mercedes-Benz USA, LLC*, 301 F.Supp.3d 1277, 1292 (N.D. Ga. 2018), and a reasonable inference drawn from the factual allegations in the complaint is that AbbVie does not maintain an office in Georgia, meaning that no notice was required.

5. *Illinois*

The Illinois Consumer Fraud and Deceptive Business Practices Act declares unlawful all “[u]nfair methods of competition and unfair or deceptive acts or practices, ... in the conduct of any trade or commerce ... whether any person has in fact been misled, deceived or damaged thereby.” 815 Ill. Comp. Stat. Ann. 505/2; [109] ¶¶ 351–54. Illinois has adopted an *Illinois Brick* repealer statute that permits indirect purchasers to sue for antitrust money damages. *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1064 (7th Cir. 2019); 740 Ill. Comp. Stat. Ann. 10/7(2). However, that statute prohibits class action antitrust claims brought by indirect purchasers. 740 Ill. Comp. Stat. § 10/7(2).

Even though in some states where *Illinois Brick* has been repealed, some courts have allowed suits brought by indirect purchasers under consumer protection statutes based on conduct that might also qualify as a violation of that state’s

antitrust statutes, *see, e.g., Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100, 104 (Fla. Dist. Ct. App. 1996); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F.Supp.3d 814, 842–43 (E.D. Pa. 2019), the law in Illinois is different. Plaintiffs’ claim under the Illinois Consumer Fraud and Deceptive Business Practices Act is a class action. [109] ¶¶ 252, 254–55. Permitting plaintiffs to bring a class action based on conduct that more closely approximates an antitrust violation under a broader consumer protection statute would allow them to make an “end run around the Illinois legislature’s determination” that such actions should not be permitted. *In re Flonase Antitrust Litig.*, 692 F.Supp.2d 524, 539 (E.D. Pa. 2010). Plaintiffs cannot assert what are “essentially antitrust claims in the guise of a claim under the Illinois consumer protection statute,” *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 162 (E.D. Pa. 2009), especially when doing so allows them to avoid a provision of Illinois law that would otherwise bar this particular type of suit. 740 Ill. Comp. Stat. § 10/7(2). *See also Appraisers Coalition v. Appraisal Institute*, 845 F.Supp. 592, 609 (N.D. Ill. 1994) (dismissing consumer protection claims because they only “alleged violations of the Sherman and Clayton Acts”).

6. *Nevada*

Much like Georgia’s statute, the Nevada Deceptive Trade Practices Act mandates that any person bringing an action under the statute “shall, simultaneously with the filing of the complaint with the court, mail a copy of the complaint to the Attorney General.” Nev. Rev. Stat. Ann. § 598A.210(3). As pointed out in the plaintiffs’ opposition, several plaintiffs sent the required notice to the

Nevada Attorney General. [145-1] at 22–23. *See also Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012) (when opposing a Rule 12(b)(6) motion, plaintiffs “may submit materials outside the pleadings to illustrate the facts the [plaintiff] expects to be able to prove,” so long as those “new elaborations” are consistent with the complaint”). The Attorney General notice requirement is not a basis to dismiss the Nevada statutory claim.

7. *New Hampshire*

New Hampshire’s Deceptive Trade Practices Act declares unlawful “any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state.” N.H. Rev. Stat. Ann. § 358-A:2; [109] ¶¶ 367–372. The words “trade” and “commerce” include the sale of any “thing of value, wherever situate,” and “any trade or commerce directly or indirectly affecting the people of” New Hampshire. N.H. Rev. Stat. Ann. § 358-A:1(II).

The statute is phrased broadly to include the sale of goods no matter where those goods are located and includes within its purview commerce that indirectly affects the people of New Hampshire. *See LaChance v. U.S. Smokeless Tobacco Co.*, 156 N.H. 88, 94–96 (2007) (declining to prohibit the bringing of antitrust-type actions under New Hampshire’s Deceptive Trade Practices Act and finding that the legislature intended a “broad sweep”). The offending conduct does not need to occur within New Hampshire so long as it had an effect on the people of that state. *In re Packaged Seafood Prod. Antitrust Litig.*, 242 F.Supp.3d 1033, 1081 (S.D. Cal. 2017); *In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F.Supp.3d 418, 438 (E.D. Va. 2019) (“a

nationwide pattern of conduct that resulted in consumers in each of the challenged jurisdiction[s] purchasing [a drug] at elevated prices adequately pleads sufficient intrastate connections” for purposes of a claim under New Hampshire’s Deceptive Trade Practices Act) (citations omitted); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F.Supp.2d 198, 231 (S.D.N.Y. 2012) (denying motion to dismiss because the complaint alleged that the putative plaintiffs “located in New Hampshire had to pay higher prices ... because of [the] alleged deception”). *But see Pacamor Bearings, Inc. v. Minebea Co.*, 918 F.Supp. 491, 504 (D.N.H. 1996) (“the statute is only applicable if the offending conduct took place within the territorial borders of the state”); *In re Flash Memory Antitrust Litig.*, 643 F.Supp.2d 1133, 1159 (N.D. Cal. 2009). Even if New Hampshire’s statute requires that the offending conduct take place within New Hampshire’s borders, it is enough to allege that the defendants introduced overpriced products into New Hampshire markets. *In re Chocolate Confectionary Antitrust Litig.*, 749 F.Supp.2d 224, 235 (M.D. Pa. 2010).

The complaint alleges that AbbVie’s conduct “substantially affected New Hampshire’s trade and commerce.” [109] ¶ 370. Elsewhere, it includes allegations that plausibly suggest that Humira was introduced into the New Hampshire market, such as the allegation that AbbVie made more than \$56 billion selling Humira throughout the United States during a six-year period. *Id.* ¶ 84. Although Count VII

is dismissed for other reasons, it adequately pleads the requisite effect in New Hampshire.

8. *North Carolina*

North Carolina's Unfair Trade and Business Practices Act declares unlawful all "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." N.C. Gen. Stat. Ann. § 75-1.1; [109] ¶¶ 379–84. The Act addresses "primarily local concerns." *The "In" Porters, S.A. v. Hanes Printables, Inc.*, 663 F.Supp. 494, 502 (M.D.N.C. 1987); *ITCO Corp. v. Michelin Tire Corp., Commercial Div.*, 722 F.2d 42, 48 n.9 (4th Cir. 1983). Actions that have only an "incidental local effect" fall outside its reach. *The "In" Porters*, 663 F.Supp. at 502; *In re Refrigerant Compressors Antitrust Litig.*, No. 2:09-MD-02042, 2013 WL 1431756, at *19 (E.D. Mich. Apr. 9, 2013).

That statute does not, however, require "substantial effects" on intrastate commerce. See N.C. Gen. Stat. Ann. § 75-1.1. And unlike in *The "In" Porters, S.A.*, 663 F.Supp. at 502, the plaintiffs here include at least a few people that purchased Humira in the state of North Carolina. [109] ¶ 382. That is enough to satisfy the "primarily local" aims of North Carolina's Unfair Trade and Business Practices Act. *In re Lidoderm Antitrust Litig.*, 103 F.Supp.3d 1155, 1174 (N.D. Cal. 2015); *Hosp. Auth. of Metro. Gov't of Nashville v. Momenta Pharm., Inc.*, 353 F.Supp.3d 678, 695 (M.D. Tenn. 2018) (it is enough to plead intrastate effects that caused supracompetitive process in the relevant jurisdiction); *In re Ductile Pipe Iron Pipe Fittings (DIPF) Indirect Purchaser Antitrust Litig.*, 2013 WL 5503308, at *22 (D.N.J.

Oct. 2, 2013). The alleged aggregate effect of those purchases was more than incidental. *See In re Remicade Antitrust Litig.*, 345 F.Supp.3d 566, 586 (E.D. Pa. 2018) (allegations that defendants had monopolized the market for a drug, “resulting in North Carolina purchasers paying artificially inflated prices” for that drug, was enough to survive a motion to dismiss).

9. *Utah*

Utah’s Consumer Sales Practices Act declares unlawful any “unconscionable act or practice by a supplier in connection with a consumer transaction ... whether it occurs before, during, or after the transaction.” Utah Code Ann. § 13-11-5(1); [109] ¶¶ 395–401. In Utah, the term “unconscionable ... defies precise definition,” and Utah courts “assess the circumstances of each particular case in light of the twofold purpose of the doctrine, prevention of oppression and of unfair surprise.” *Woodhaven Apartments v. Washington*, 942 P.2d 918, 924 (Utah 1997) (quoting *Res. Mgmt. Co. v. Weston Ranch & Livestock Co.*, 706 P.2d 1028, 1041 (Utah 1985)).

In the few cases where Utah courts have interpreted the statute, they have consistently looked to contract principles to define its terms. *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F.Supp.2d 160, 204 (D. Me. 2004); *In re Interior Molded Doors Indirect Purchaser Antitrust Litig.*, No. 3:18-CV-00850-JAG, 2020 WL 2110931, at *3 (E.D. Va. May 4, 2020); *Imperial Mobile Home Park, L.L.C. v. Kelsch*, No. 971591-CA, 1998 WL 1758393, at *1 (Utah Ct. App. Nov. 27, 1998) (plaintiffs generally must allege “gross bargaining power inequality or oppressive contractual terms”).

The Utah-based claim alleged here, which is brought against AbbVie only, is based on AbbVie’s alleged patent-related conduct. *See* [109] ¶¶ 310–316, 401. The fact that the patent-related conduct in question did not relate to a contract is not determinative. What matters is whether AbbVie’s alleged conduct qualifies as unconscionable, as Utah’s courts have interpreted that term. The problem for plaintiffs is that AbbVie’s alleged patent-related conduct did not involve either gross bargaining power or oppression. *Imperial Mobile Home Park*, 1998 WL 1758393 at *1. Nor have plaintiffs alleged facts that show procedural unconscionability (i.e., that plaintiffs did not have “a reasonable opportunity to read and understand the terms of the contract,” *Woodhaven Apartments*, 942 P.2d at 925), or substantive unconscionability (i.e., facts that show a disparity in bargaining power “so great as to shock the conscience,” *id.* (citations omitted)).

Utah’s Consumer Sales Practices Act is not limited to contract disputes, but it is limited to conduct that is “unconscionable,” and the complaint fails to allege conduct that qualifies as unconscionable as that word has been interpreted by Utah courts.

10. *West Virginia*

West Virginia’s Consumer Credit and Protection Act declares unlawful “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” W. Va. Code Ann. § 46A-6-104; [109] ¶¶ 402–406. At least when consumers allege that a purchase was made because of a misrepresentation, the Act “does not extend to prescription drug purchases,” because

physicians protect consumers when they intervene in that decision-making process. *White v. Wyeth*, 227 W.Va. 131, 141 (2010). Here, plaintiffs' allegations are not based on any alleged misrepresentations to consumers, but to the degree any of AbbVie's conduct involved misrepresentations to patent examiners, the claims fail for the same reason the claims failed in *White v. Wyeth*: a trained third-party intervened before consumers were affected. 227 W.Va. 131, 140–41.

IV. Conclusion

Defendants' motion to dismiss [123] is granted. The complaint is dismissed without prejudice and with leave to file an amended complaint. *Barry Aviation Inc. v. Land O'Lakes Mun. Airport Comm'n*, 377 F.3d 682, 687 (7th Cir. 2004); *Runnion ex rel. Runnion v. Girl Scouts of Greater Chicago & Nw. Indiana*, 786 F.3d 510, 518 (7th Cir. 2015). Plaintiffs shall file a status report on June 29, 2020, with a statement of whether they intend to file an amended complaint, or if they instead prefer that the dismissal convert to a dismissal with prejudice so they may seek appellate review.

ENTER:



Manish S. Shah
United States District Judge

Date: June 8, 2020