In Re: Humira (Adalimumab) Antitrust Litigation

United States District Court for the Northern District of Illinois
465 F. Supp. 3d 811
June 8, 2020

No. 19 CV 1873.

Plaintiffs include: *Blue Cross Blue Shield of Louisiana; UFCW Local 1500 Welfare Fund; Locals 302 & 612 of the International Union of Operating Engineers-Employers Construction Industry Health and Security Trust Fund; Mayor and City Council of Baltimore; Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Kentucky Laborers District Council Health and Welfare Fund; St. Paul Electrical Workers' Health Plan and Law Enforcement Health Benefits Inc.*

Defendants include: *AbbVie Inc.; Abbvie Biotechnology Ltd.; Amgen Inc.; Samsung Bioepis Co., Ltd.; Mylan Inc.; Mylan Pharmaceuticals, Inc.; Sandoz, Inc.; Pfizer Inc.; Momenta Pharmaceuticals, Inc.*

Judge Manish S. SHAH:

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). Originally developed for rheumatoid arthritis, Humira is now used to treat a variety of autoimmune disorders ranging from Crohn's disease to plaque psoriasis.

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

Humira's active ingredient is an antibody called "adalimumab." 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 drug—Humira—in 2002. 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. The '382 patent expired on December 31, 2016.

The plaintiffs in this lawsuit—indirect purchasers of Humira, including the City of Baltimore , an insurance trust fund for Miami Police Department officers , and a Minnesota-based employee welfare benefit plan for plumbers, pipefitters, and other workers in the pipe trades industries , 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. {Biosimilars are to biologics what generics are to small molecule drugs. Small molecule drugs are those made from chemical processes.} 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.), forcing them to agree to delay their market entry in return for licensing agreements that cut through AbbVie's patent thicket.

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 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 U.S. Dist. LEXIS 473, 1995 WL 389822, at *11 (N.D. Ill. Feb. 15, 1995). 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. 35 U.S.C. § 120; 37 C.F.R. § 1.78(d). {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).} 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.* The catch is that if the new claims are simple, obvious variations on the invention described in the

original application, the applicant "generally must" 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. 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). If the application is 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). Manufacturers often charge supracompetitive prices during this period in order to recoup their research and development costs and obtain a profit.

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). 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). 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). Once approved, the biosimilar can be marketed to the public—assuming the drug is not also patented. Prices tend to drop shortly after a new biosimilar is introduced.

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). 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). 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). 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).

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). 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. 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). More than 90% of those patents were issued in 2014 or later, despite the fact that Humira was first marketed in 2002.

In the process, AbbVie relied heavily on continuation applications. 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. AbbVie's 100-plus Humira-related patents can be traced back to twenty root patents, forming twenty patent trees. 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.

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. Twelve of those fifteen root patents were filed after 2006. 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. 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.

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. 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.

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. 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. Some of AbbVie's other patents are invalid because they claim methods that were already in the prior art.

When the Patent Trial and Appeal Board heard challenges to five of AbbVie's Humira-related patents, it ruled that three were invalid. AbbVie terminated the other two before the board reached any final determination.

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." He added that the bulk of AbbVie's IP strategy was to "make it more difficult for a biosimilar to follow behind." In an email to investors, AbbVie's CEO noted that market entry for any Humira biosimilars would likely be delayed because patent litigation takes more than four years and at-risk launches are rare.

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. During the patent dance, AbbVie identified sixty-six patents that it believed Amjevita would infringe. 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. By August of 2016, Amgen and AbbVie had finished the patent dance and AbbVie had filed suit. One month later, the FDA approved Amgen's abbreviated application to market Amjevita. On December 31, 2016, the '382 patent expired. Amgen did not launch at risk.

One year into litigation, in the fall of 2017, Amgen and AbbVie settled. At the time, a bench trial was scheduled to start in the fall of 2019. Any appeal would have taken (on average) at least another year to resolve. The terms of the settlement are confidential, but AbbVie's press release made clear that Amgen had agreed to drop its patent challenges and delay Amjevita's market entry until January of 2023. (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. AbbVie filed under seal copies of its settlement agreements with Amgen, and, in response, plaintiffs dropped their claims that Amgen's *de facto* five months of exclusivity constituted a reverse payment.)

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. Each agreed to U.S. market entry dates ranging from June 30, 2023 (Samsung Bioepis) to December 15, 2023 (Coherus). 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, with Sandoz after AbbVie had initiated litigation but before Sandoz had responded to the complaint and with Boehringer only after it had responded to AbbVie's infringement complaint and asserted counterclaims seeking to invalidate many of AbbVie's patents. In the process, AbbVie occasionally asserted patents for which there was not even an arguable claim of infringement. Only four of the biosimilar manufacturers that settled with AbbVie (Amgen, Samsung Bioepis, Sandoz, and Boehringer) ever received FDA approval to market their biosimilars. Only two (Amgen and Boehringer) received approval before they had entered into settlement agreements with AbbVie.

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. 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.

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. The judge issued an

order finding that AbbVie "made every effort to shield the claims of its patents from scrutiny." 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. 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. 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. Samsung Bioepis's and Sandoz's agreements contained the same European early entry date (October 16, 2018). That date coincided with the expiration of AbbVie's European patent for adalimumab.

The early European entry dates were extremely valuable to Amgen, Samsung Bioepis, and Sandoz. 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. AbbVie's motive was to keep prices in the U.S. artificially high for as long as possible. 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).

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."

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."

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.), Count III asserts a market-allocation-agreement theory of liability under § 1 of the Sherman Act against all defendants, and Count V asserts a violation of § 2 of the Sherman Act against AbbVie. 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, 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, and Count VI asserts a monopolization theory of liability under state antitrust laws (and consumer protection laws that prohibit anticompetitive conduct) against AbbVie. Lastly, Count VII asserts violations of state laws that prohibit unfair and unconscionable conduct against AbbVie. For purposes of the Sherman Act claims, the complaint defines the relevant geographic market as the United States, and alleges that AbbVie maintains 100% of the relevant market share for adalimumab.

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. 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 *Prof'l 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. 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.

[*The court rejected the plaintiffs' §2 monopolization claims because of* Noerr-Pennington *immunity, which protects from antitrust liability actions that constitute legitimate petitioning of the government. The court additionally rejected the §2 claims because of a lack of antitrust injury, referring to part 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. NCAA*, 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. NCAA*, 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. 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) and a market-allocation theory (i.e., AbbVie allocated to itself the U.S. market and allocated to the other defendants the European market).

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. The result is that, in the interim, consumers in the U.S. are "subsidizing competition in Europe."

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. 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.

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-Hayes 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 uninfringed 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. NCAA*, 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. {It is not always necessary to determine which of the three categories of analysis should be applied when ruling on a motion to dismiss. 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.}

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 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). Plaintiffs no longer allege that AbbVie granted any exclusivity to Amgen. 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.

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 Pharms., 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. Appx. 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 Antritrust 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) onto the biosimilar companies, while buying AbbVie even more lucrative monopoly time in the U.S. (worth billions of dollars in revenue for AbbVie).

{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. 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," 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). 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.}

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 U.S. Dist. LEXIS 127748, 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 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 U.S. Dist. LEXIS 127748, 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," 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-Hayes 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 & Commer. Workers Local 1776 & Participating Employers 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*).

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 alleged the existence of an agreement that restrained competition.

{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.}

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.* 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. 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.

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. [Plaintiffs' opposition to defendants' motions to dismiss] at 64 (citing *United Food & Commer. Workers Local 1776 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.*, 868 F.3d 132, 2017 WL 3529114 (3d Cir. 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," its patent applications "dubious," says that some of the patents were "obvious in light of prior art," and identifies four patents that were issued as the result of material misrepresentations and omissions to the USPTO. But the complaint never alleges that all of AbbVie's patents were invalid or not infringed. *See, e.g.*, [Plaintiffs' complaint] ¶ 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. Instead, they say it is enough that a "great many of the patents were invalid or not infringed," and that, as a result, at least one of the biosimilar manufacturers could have prevailed in the underlying litigation. 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. {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"). But for the reasons discussed with regard to the alternative settlement theory below, that claim is possible—not plausible.}

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). 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 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). Nondefendant Boehringer's infringement suit was scheduled to go to trial in October of 2020 when it settled in May of 2019. 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, 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. 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. Boehringer spent twenty months waiting for the underlying patent litigation to wrap up without launching. As the complaint points out, the reason for their delay was AbbVie's patent thicket, which was "impassable."~ Launching while the underlying patent litigation was ongoing posed an enormous risk. ~([T]he 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, 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, Samsung Bioepis, and Sandoz, 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. 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.~

–#–

NOTES ABOUT THE EDITING OF THIS CASE: *The superscript tilde (~) denotes an ellipsis. A few insertions were made with brackets. Citations were removed without notation. Footnotes were eliminated. Some text from footnotes was inserted into the main text as in curly brackets or parentheses.*