UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: HUMIRA (ADALIMUMAB) ANTITRUST LITIGATION	Case No. 1:19-cv-1873 Hon. Manish S. Shah Magistrate Judge Jeffrey Cummings JURY TRIAL DEMANDED

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Plaintiffs' Complaint seeks to upend the well-settled balance between the patent and antitrust laws. Plaintiffs' theories would label conduct as illegal that the Supreme Court has held to be lawful; usher in the end of any international early-entry patent settlement unless it provides for the same world-wide entry date; and chill medical and therapeutic innovation—precisely the opposite of what the patent laws and Sherman Act were intended to promote. The Court should reject Plaintiffs' bid to rewrite antitrust law and to claim illegal conduct where there is none.

AbbVie, like all innovator pharmaceutical companies, protects its inventions with patents. When its scientists achieve a breakthrough, AbbVie discloses its inventions to the public by filing patent applications. With respect to adalimumab (the active ingredient in AbbVie's biologic drug Humira®), AbbVie conducted extensive research and, consequently, has applied for, and the United States Patent Office has granted, dozens of U.S. patents. The Patent Office has recognized the validity of numerous AbbVie adalimumab patents in post-grant challenges, expressly finding that no reasonable likelihood exists that the challenger would be able to invalidate them. And although the U.S. Food and Drug Administration (FDA) approved two competitors to Humira, called adalimumab biosimilars, neither competitor launched its drug in the United States while engaged in patent infringement litigation with AbbVie, faced with the risk of infringing AbbVie's patents.

Instead, in the face of AbbVie's lawful patents—and after AbbVie prevailed in numerous post-grant proceedings—Defendants Amgen, Sandoz, and Samsung Bioepis ("Bioepis") (collectively, the "biosimilar Defendants"), as well as six non-parties, each settled their disputes with AbbVie by entering into patent license agreements. As the Complaint acknowledges, the licenses allow competitors to market adalimumab biosimilars in the United States beginning in 2023—years ***before*** dozens of AbbVie's U.S. patents will expire. *See* Compl. ¶¶ 91, 211. Some—but not all—of these biosimilar companies also signed agreements to license AbbVie's European

patents (where AbbVie had active, unexpired patents covering only four of nine approved uses of Humira), which permitted entry beginning in 2018. The biosimilar companies agreed to pay AbbVie a royalty in return; AbbVie has not made, and will not make, any payments to the other parties. This is precisely how patent licensing is supposed to work.

Against this backdrop, Plaintiffs assert three novel antitrust theories—each of which fails as a matter of law. *First*, Plaintiffs allege AbbVie created an unlawful monopoly when it obtained "too many" patents, supposedly creating barriers to entry via an unlawfully large "patent thicket" (Counts V and VI). But no law limits the number of patents an entity may apply for or hold. To the contrary, the Supreme Court has been clear that the "mere accumulation of patents, ***no matter how many***, is not in and of itself illegal." *Automatic Radio Mfg. Co. v. Hazeltine Research*, 339 U.S. 827, 834 (1950) (emphasis added), *overruled in part on other grounds by Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). Plaintiffs fail to plausibly plead any exception to the presumption that the acquisition and ownership of patents is lawful. In any event, *Noerr–Pennington* shields AbbVie's alleged patent-related conduct from antitrust liability, further requiring dismissal.

Second, Plaintiffs allege that AbbVie unlawfully "paid" the biosimilar Defendants by granting to them early access to the European market via license (Counts I and II), Compl. ¶ 211, and that AbbVie and the biosimilar Defendants unlawfully "allocated the markets for Humira and its biosimilars between the United States and Europe" (Counts III and IV), *id*. ¶ 206. ***No court*** has ever adopted Plaintiffs' novel theories. The Supreme Court has been clear that early-entry-only settlements, as here, stand "in contrast" to settlements that provide for a "reverse payment" (a payment flowing from the patent holder to the licensee), and only the latter are subject to antitrust scrutiny. As the Court stressed, parties "may ... settle ... by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration" without triggering antitrust scrutiny. *FTC v. Actavis, Inc.*, 570 U.S. 136, 152 (2013). Even the Complaint characterizes the challenged

settlements as early-entry-only agreements, enabling competition in ***both*** the United States and Europe. *See* Compl. ¶ 9. The benefit to the biosimilars is not any payment from AbbVie; it is only resolution of patent-infringement disputes, replacing uncertainty with date-certain entry. Plaintiffs cannot overcome *Actavis* by reframing the settlements as market allocation agreements, particularly where AbbVie continues to sell Humira in both Europe and the United States.

Third, Plaintiffs characterize the settlement between AbbVie and Amgen as an unlawful reverse payment, alleging that "AbbVie agreed not to settle with any other manufacturers on terms that would let them enter the market at the same time as Amgen, or for five months thereafter" (Counts I and II). *Id.* ¶ 153. This allegation is demonstrably false. The settlements between AbbVie and Amgen, incorporated by reference into the Complaint, contain no such agreement concerning exclusivity, and, in fact, [redacted]

Fourth, Plaintiffs have not adequately pleaded antitrust injury—i.e., that any alleged anticompetitive conduct was the but-for and proximate cause of the biosimilar companies staying off the market—for any of their claims. Plaintiffs have not alleged any facts to indicate that any biosimilars would be available in the United States today if not for Defendants' alleged conduct. Plaintiffs do not allege that any biosimilar Defendant would have prevailed in patent disputes against AbbVie, instead pleading that AbbVie's patent portfolio presented an "impassable" barrier to biosimilar entry. *Id.* ¶ 9. Nor do Plaintiffs allege that any biosimilar Defendant would have launched an adalimumab biosimilar "at risk" if it had not settled. Plaintiffs instead allege that the risk of doing so would have been prohibitive. *Id.* ¶¶ 86, 94. Indeed, rather than plead that any biosimilar Defendant "planned to launch" at the "very first opportunity as soon as the FDA gave the final green light," *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 756 (E.D. Pa. 2014), Plaintiffs plead the opposite. The Complaint shows that Amgen's adalimumab biosimilar had

FDA approval for more than a year before Amgen settled, and yet Amgen did not attempt to launch at risk during that time even though there was no court order or statute preventing it from doing so. *See* Compl. ¶¶ 149, 151. Absent plausible allegations that any biosimilar company would have entered the market but-for the alleged anticompetitive conduct, Counts I-VII must be dismissed.

Finally, Plaintiffs assert their own thicket of state antitrust and consumer protection claims (Counts II, IV, VI, and VII). These state-law claims are predicated upon, and accordingly fail alongside, Plaintiffs' federal claims. Many are also deficient under the state laws themselves.

Put simply, Plaintiffs have not identified any conduct that violates the antitrust laws. The Court should dismiss the Complaint in its entirety with prejudice.

BACKGROUND

I. ADALIMUMAB AND ABBVIE'S PATENT PORTFOLIO

In 2002, the FDA approved Humira, a biologic drug used to reduce inflammation in patients with severe autoimmune diseases. Compl. ¶ 2. The active ingredient in Humira is adalimumab, a genetically engineered fully human antibody. AbbVie scientists engaged in extensive research and development leading to breakthroughs in the formulation of Humira, new methods of treatment, new manufacturing processes, and new compositions of adalimumab with various profiles. AbbVie conducted more than 100 clinical trials, and the FDA approved Humira to treat 10 diseases: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, hidradenitis suppurativa, uveitis, and plaque psoriasis. *Id.* ¶¶ 80-81.

AbbVie's efforts and investment into researching and improving Humira have yielded a portfolio of more than 100 U.S. patents. *Id.* ¶ 4. U.S. Patent No. 9,096,666—which expires in 2027, *see id.* ¶¶ 148, 181—exemplifies the nature of AbbVie's ongoing research and development work. That patent protects a purer form of adalimumab than the form found in early versions of

Humira. *See generally* US Patent No. 9,096,666.[1] Adalimumab is manufactured using a cell culture process whereby a desired compound is grown in a host cell medium. AbbVie determined that a particular "host cell protein" (HCP), or contaminant, persisted in its final Humira product and, under certain conditions, was converting to an active enzyme that cut adalimumab into fragments. Because the "[f]ailure to identify and sufficiently remove HCPs from [adalimumab] may lead to reduced efficacy and/or adverse patient reactions," *id*. col. 45, ll. 23, AbbVie developed "assays" (tests) to detect and measure HCPs during the manufacturing process, *id.* col. 109-14. AbbVie used those assays to pioneer a multi-step purification process to produce adalimumab "substantially free" of HCPs, *id*. col. 10, ll. 49, resulting in a cleaner drug.

AbbVie also maintains patent protection abroad for its adalimumab-related discoveries, including in the European Union (EU). Compl. ¶ 190. AbbVie's European patents, however, are fewer in number and narrower in scope than its U.S. patents. Plaintiffs allege that AbbVie has only two relevant European patents that "remain in force today," *id.*, and that those two patents cover an adalimumab biosimilar marketed for only three approved diseases (rheumatoid arthritis, Crohn's disease, and ulcerative colitis).[2] Plaintiffs do not allege AbbVie has any active patents in Europe that cover an adalimumab biosimilar marketed for psoriasis, psoriatic arthritis, ankylosing spondylitis, or juvenile idiopathic arthritis—meaning that competitors could immediately enter the EU market upon regulatory approval for these uses. This is in contrast to the United States, where AbbVie has significant and broad patent protection, regardless of which indications a biosimilar would be labeled for, well beyond 2023. *Id*. ¶ 91.

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[1] It is "'well-established that a court may take judicial notice of patents or patent applications.'" *Cascades AV LLC v. Evertz Microsystems Ltd.*, 335 F. Supp. 3d 1088, 1091 n.2 (N.D. Ill. 2018) (quoting *Anderson v. Kimberly-Clark Corp.*, 570 F. App'x 927, 932 n.3 (Fed. Cir. 2014)).

[2] A third European patent covers one additional disease (hidradenitis suppurativa), but that still leaves five of nine diseases for which AbbVie lacks patent protection in Europe.

II. ABBVIE SUCCESSFULLY DEFENDED CHALLENGES TO ITS PATENTS

Following Humira's success, Defendants Amgen, Sandoz, and Bioepis, and non-parties Mylan, Momenta, Fresenius, Pfizer, Coherus, and Boehringer, developed adalimumab biosimilars. Faced with liability for infringing AbbVie's patents, several biosimilar companies challenged the patents by petitioning the Patent Trial and Appeal Board (PTAB) to institute *inter partes* review (IPR). *See* Compl. ¶ 108. IPR "allows a third party to ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). The burden of proof in IPR proceedings is less stringent than in civil litigation. An IPR petitioner need prove a patent invalid only by a preponderance of evidence, whereas a plaintiff in federal court must prove invalidity by clear and convincing evidence. 35 U.S.C. § 316(e); *see Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). The standard for the PTAB to institute an IPR (i.e., to begin a review of a patent's validity) is even less stringent; an IPR petitioner need only convince the PTAB that "there is a reasonable likelihood that [it] would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 114(a). In other words, when PTAB denies a competitor's petition to institute an IPR challenge, PTAB has found no reasonable likelihood that any of the challenged claims could be invalidated.

Plaintiffs discuss the IPR process generally, *see* Compl. ¶¶ 73-76, and identify five instances when the PTAB instituted IPR for three AbbVie patents, *id.* ¶ 108, but they do not tell the full story. Critically, Plaintiffs omit reference to AbbVie's repeated IPR successes with respect to its adalimumab patents. The full story is that from 2016 to 2018, the PTAB issued 20 decisions

in IPR petitions involving AbbVie's patents. It ***denied*** institution (i.e., ruled for AbbVie) ***13 times*** and instituted IPR only seven times.[3]

Amgen was the first company to petition for IPR, and did so for two of AbbVie's adalimumab formulation patents. The PTAB denied institution for both, holding that "Amgen has not established a reasonable likelihood of prevailing with respect to at least one challenged claim" of the subject patents. Ex. 1, IPR2015-01514 (PTAB Jan. 14, 2015) (US Patent No. 8,916,157); Ex. 2, IPR2015-01517 (PTAB Jan. 14, 2016) (U.S. Patent No. 8,916,158). The PTAB likewise denied institution of 11 other IPRs filed by Coherus and Sandoz, agreeing with AbbVie that the petitioners had not demonstrated that "there [was] a reasonable likelihood that [the patent challengers] would prevail with respect to at least 1 of the claims challenged in [their] petition[s]." Ex. 3-13. In sum, for the 13 denials, in more than 250 pages of reasoning, the PTAB rejected 21 theories of invalidity based on 29 prior art references for 169 unique claims across nine AbbVie patents. *See* Ex. 1-13. Of particular relevance to Plaintiffs' allegations, more than half (seven) of the denied petitions pertained to patents expiring after 2023.[4]

III. PATENT LITIGATION FRAMEWORK FOR BIOSIMILARS

The Biologics Price Competition and Innovation Act (BPCIA) governs the application and approval processes for biosimilar drugs to enter the U.S. market and provides another avenue for

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[3] The Court may "take[ ] judicial notice of the PTAB's decisions on whether to institute IPR." *Finjan, Inc. v. Blue Coat Sys., Inc.*, 2016 WL 7732542, at *1 n.1 (N.D. Cal. July 25, 2016); *see, e.g.*, *Procter & Gamble Co. v. Team Techs., Inc.*, 2014 WL 12656554, at *10 n.4 (S.D. Ohio July 3, 2014) ("This Court takes judicial notice of the fact of the PTAB's decision rejecting Clio's petition for IPR of the claims containing HOM Limitations."). The thirteen petitions for which PTAB denied institution of IPR are: Ex. 1 & 2, IPR2015-01514, -01517 (PTAB Jan. 14, 2016) (filed by Amgen); Ex. 3, IPR2016-01018 (PTAB Nov. 7, 2016) (filed by Coherus); Ex. 4-7, IPR2017-00822, -00823, -01008, -01009 (PTAB Sept. 7, 2017) (filed by Coherus); Ex. 8 & 9, IPR2017-01823, -01824 (PTAB Feb. 9, 2018) (filed by Sandoz); Ex. 10 & 11, IPR2017-01987, -01988 (PTAB Mar. 9, 2018) (filed by Sandoz); Ex. 12, IPR2018-00002 (PTAB May 3, 2018) (filed by Sandoz); and Ex. 13, IPR2018-00156 (PTAB June 5, 2018) (filed by Sandoz).

[4] U.S. Patent Nos. 9,085,619 (expiring 2028) (4 petitions); 9,512,216 (expiring 2025) (2 petitions); and 9,187,559 (expiring 2025).

biosimilar companies to challenge the validity of biologic patents. Among other things, the BPCIA facilitates a series of exchanges between an applicant seeking FDA approval of a biosimilar (e.g., Amgen) and the patent holder for the reference product (the "reference product sponsor," e.g., AbbVie). It directs the biosimilar applicant and reference product sponsor to exchange "list[s] of patents for which [they] believe[ ] a claim of patent infringement could reasonably be asserted." 42 U.S.C. §§ 262(*l*)(3)(A)(i), (B)(i). Then, the applicant responds with "a detailed statement" describing "on a claim by claim basis, the factual and legal basis" for why the patents are "invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product." *Id.* § 262(*l*)(3)(B). The reference product sponsor must respond with a reciprocal statement on the validity and enforceability of the patents, and whether they "will be infringed by the commercial marketing of the biological product." *Id.* § 262(*l*)(3)(C). To the extent there is a dispute about whether the biosimilar will infringe the reference product sponsor's patents, the BPCIA provides a process for determining the scope of first-stage patent litigation through which the biosimilar applicant can limit the number of patents that can be asserted. *See id.* §§ 262(*l*)(4)(A), (5)(A).

The BPCIA differs from the Hatch-Waxman Act—its predecessor for non-biologic generic drugs—in at least one critical respect. Hatch-Waxman provides for an automatic 30-month stay of FDA approval for generics whenever a brand-name manufacturer (the Hatch-Waxman analogue of a reference product sponsor) files an infringement lawsuit, assuming the relevant prerequisites are met. *See* 21 U.S.C. § 355(j)(5)(B)(iii). By contrast, the BPCIA does not provide for any automatic stay. Thus, biosimilar manufacturers can seek and obtain FDA approval and, after providing the reference product sponsor with 180 days' notice, may market and sell their product even while patent litigation with the reference product sponsor is ongoing, unless the reference product sponsor obtains a preliminary injunction.

IV. ABBVIE'S EARLY-ENTRY-ONLY SETTLEMENTS WITH BIOSIMILARS

As companies developed adalimumab biosimilars and sought FDA approval, AbbVie asserted its patent rights in the United States by engaging in BPCIA exchanges, defending against IPR challenges, and filing patent-infringement lawsuits. *See* Compl. ¶¶ 148, 169, 181. AbbVie and certain biosimilar manufacturers also engaged in patent disputes in Europe, where AbbVie had less patent protection. *Id*. ¶¶ 185-202. Ultimately, AbbVie entered into separate early-entry-only settlements with several biosimilars, including the biosimilar Defendants.

A. Amgen Litigation and Settlement

Amgen was the first company to seek FDA approval for an adalimumab biosimilar, filing an application in November 2015 for AMJEVITA® (adalimumab-atto). Compl. ¶¶ 141-42. As part of the BPCIA exchanges, AbbVie identified 61 patents for which it "believe[d] a claim of patent infringement could reasonably be asserted," *see* 42 U.S.C. §§ 262(*l*)(3)(A)(i), (*l*)(7), and provided a nearly 1,500-page statement stating that those patents were valid and explaining that Amgen's biosimilar product would infringe the patents. Pursuant to the BPCIA, Amgen limited the number of patents in the first wave of litigation to six per side. Five of the six patents identified by Amgen expire after 2023, including U.S. Patent No. 9,359,434, which expires in 2033. In August 2016, following exchanges of the parties' lists, which included two overlapping patents, AbbVie sued Amgen for patent infringement on 10 patents, including one for which the PTAB had already ***denied*** institution of IPR (U.S. Patent No. 8,916,157, *see* Ex. 1). Ex. 14 at Ex. C.

On September 23, 2016, less than two months after AbbVie filed suit, the FDA approved Amgen's biosimilar AMJEVITA for sale in the United States. *Id.* ¶ 149. Despite having FDA approval, Amgen did not attempt to take AMJEVITA to market, and the Complaint includes no allegation that Amgen made plans or intended to do so while it litigated against AbbVie. Of course, the Complaint also fails to acknowledge the judicially noticeable facts that, by the time

AbbVie sued Amgen, the PTAB already had denied institution of Amgen's two petitions for IPR, and in the 13 months after AbbVie filed suit, the PTAB denied institution of another five IPR petitions directed to AbbVie's adalimumab patents that were filed by Coherus. *See* Ex. 3-7.

On September 28, 2017, AbbVie and Amgen settled their disputes. Compl. ¶ 151. AbbVie agreed to license its adalimumab patents so Amgen could sell AMJEVITA in the United States beginning on January 31, 2023, *id.*—more than 10 years ***before*** the expiration of U.S. Patent No. 9,359,434, which Amgen introduced into the litigation, *see id.* ¶ 148. In a separate agreement, AbbVie agreed to license its European patents to Amgen beginning in 2018, *id.* ¶ 203. The agreements require Amgen to pay royalties to AbbVie for AMJEVITA sales in the United States and sales for patented indications in Europe. *See* Ex. 14 § 5.4 (U.S. Agreement); Ex. 15 §§ 5.3-5.5 (EU Agreement). The agreements do not contain any payment from AbbVie to Amgen. The U.S. agreement notes that Amgen [redacted] Ex. 14 § 4.2. And like its U.S. counterpart, the EU agreement states that it resulted from [redacted] Ex. 15 at 2. Importantly, there is ***no*** agreement regarding a five-month exclusivity period for Amgen in the United States. *Compare* Compl. ¶ 156, *with* Ex. 14, 15.

B. License Agreements With Other Biosimilar Companies

Following the Amgen settlements, the PTAB acted on Sandoz's six petitions for IPR for six different AbbVie patents, denying four. *See* Ex. 8-11. That made AbbVie's U.S. patent position even stronger. AbbVie then entered licensing agreements with Bioepis in April 2018. Compl. ¶ 157. The Complaint alleges that the U.S. settlement provided Bioepis with a license to enter the U.S. market in June 2023, *id.* ¶¶ 158, 203—but notably does not allege that Bioepis would have entered the U.S. market prior to that date in the absence of settlement. At the time of settlement, Bioepis had not sought FDA approval for its biosimilar Hadlima. *Id.* ¶ 157.

After AbbVie and Bioepis executed their license agreements, the PTAB denied Sandoz's two remaining petitions for IPR, on two different AbbVie patents, both of which expire in 2025. Ex. 12, 13. That again strengthened AbbVie's U.S. patent position. Following these denials, Defendant Sandoz and nonparties Mylan, Momenta, Fresenius, Pfizer, Coherus, and Boehringer entered into U.S. licensing agreements with AbbVie that Plaintiffs allege mirror Amgen's and Bioepis's, but with U.S. market entry dates ranging from July 2023 to December 2023, with Sandoz's U.S. license beginning in September 2023. *See* Compl. ¶ 211. The Complaint does not allege that, absent the settlement, Sandoz would have entered the U.S. market prior to the licensed entry date, or that Sandoz had any plan to do so. And while Plaintiffs allege that nonparties Mylan and Boehringer entered into settlements with early-entry licenses in the United States, they notably do not allege that either company is licensed by AbbVie for early entry in Europe—highlighting the merits of the 2023 U.S. entry date on its own. *Compare id.* ¶¶ 160, 184, 203.[5]

Nonparty Boehringer, like Amgen, received FDA approval for its adalimumab biosimilar long before settling with AbbVie. *See id.* ¶ 182 (August 2017 FDA approval), ¶ 184 (May 2019 settlement). But during the 20 months when Boehringer could have sought to bring its biosimilar to market—a market opportunity that Plaintiffs allege would have been worth more than $2 billion annually to a biosimilar company, *see id.* ¶ 154—Boehringer, like Amgen, chose not to launch at risk while infringement litigation was ongoing. And as with Amgen, Sandoz, and Bioepis, the Complaint does not allege that Boehringer took any steps toward marketing and selling its biosimilar in the United States.

[5] The announcements of the settlements with Boehringer and Mylan that Plaintiffs reference confirm that the settlements did not extend to Europe. *See* Ex. 16, 17. The Court may consider these announcements referenced in the Complaint on a motion to dismiss. *See D.M. Robinson Chiropractic, S.C. v. Encompass Ins. Co. of Am.*, 2013 WL 1286696, at *3 n.3 (N.D. Ill. Mar. 28, 2013) (taking judicial notice of press release); *Patel v. Parnes*, 253 F.R.D. 531, 546-47 (C.D. Cal. 2008) (same; citing cases).

LEGAL STANDARD

A complaint must be dismissed if it fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Although courts generally accept as true a complaint's well-pleaded allegations, "bare assertions" that "amount to nothing more than a formulaic recitation of the elements" "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 680-81 (2009). A complaint "must be dismissed" where it merely pleads allegations that are "not only compatible with, but indeed [are] more likely explained by, lawful" conduct. *Id.* at 680.

ARGUMENT

Plaintiffs allege that Defendants violated the Sherman Act and various state law analogues in three ways: (1) AbbVie monopolized the market for adalimumab by creating an alleged "patent thicket," Compl. ¶ 4; (2) each Defendant entered into pay-for-delay agreements whereby AbbVie allowed each biosimilar Defendant to enter the European market "early" in 2018 in exchange for accepting a delayed U.S. entry date, *id.* ¶ 8, and "allocated" the U.S. and European markets, *id.* ¶ 9; and (3) AbbVie and Amgen entered into a pay-for-delay agreement whereby AbbVie provided Amgen five months of biosimilar exclusivity on the U.S. market, *id.* ¶ 7. All three theories fail to plead unlawful conduct and antitrust injury. The Complaint should be dismissed with prejudice because these deficiencies cannot be cured through amendment.

I. PLAINTIFFS' "PATENT THICKET" CLAIMS FAIL TO ALLEGE UNLAWFUL ANTICOMPETITIVE CONDUCT

Plaintiffs allege that AbbVie monopolized the market for adalimumab by creating an unlawful "patent thicket." *Id.* ¶ 85. Plaintiffs' "patent thicket" allegations, however, fail to plead unlawful conduct for three independent reasons: (1) the mere accumulation of patents is not unlawful; (2) Plaintiffs' attempts to challenge a subset of AbbVie's patents are insufficient to create antitrust liability; and (3) AbbVie's alleged patent-related conduct is immune from antitrust liability. Counts V and VI, which are directed to AbbVie alone, fail as a matter of law.

A. Plaintiffs Allege Lawful Conduct, Not An Unlawful Monopoly

Plaintiffs contend that AbbVie violated Section 2 by "obtain[ing] as many patents as it could," as opposed to the "few" patents that Plaintiffs want this Court to decide would have been enough. *See* Compl. ¶¶ 90, 95. But as a matter of law, the "mere accumulation of patents, ***no matter how many***, is not in and of itself illegal." *Automatic Radio*, 339 U.S. at 834 (emphasis added). Nor could such conduct possibly even implicate the Sherman Act: "Mere procurement of a patent ... cannot without more affect the welfare of the consumer," and, therefore, "cannot in itself violate the antitrust laws." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1418 n.16 (Fed. Cir. 1987); *see, e.g.*, *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 2013 WL 6682981, at *7 (E.D. Va. Dec. 18, 2013) ("Lacking [ ] is any fact-based explanation concerning why IV's acquisition of presumed valid patents becomes unlawful"); *cf. SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1212 (2d Cir. 1981) (with respect to Clayton Act § 7 claim, "[w]here a company has acquired patents lawfully, it must be entitled to hold them free from the threat of antitrust liability for the [duration] that the patent laws provide"). That is so even where patents are viewed as "an impenetrable barrier" to market entry. *See Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1107 (6th Cir. 1989) (affirming dismissal of antirust claim).

To hold otherwise would invite courts to engage in arbitrary and unworkable line-drawing in response to the question: *how many patents are too many*? Federal courts have appropriately resisted that type of subjective judicial intervention. *See Intellectual Ventures*, 2013 WL 6682981 at *7 (dismissing monopolization claim where the plaintiff failed to allege "at what point [the defendant's] enforcement of multiple patents becomes unlawful monopoly power"); *cf. Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (concluding it is unworkable for federal courts to "act as central planners, identifying the proper price, quantity, and other terms of dealing" in context of Section 2).

B. Plaintiffs Have Not Pleaded An Exception To AbbVie's Lawful Conduct

Plaintiffs cannot transform AbbVie's lawful patenting practices into antitrust violations by challenging the validity of some of AbbVie's adalimumab patents. Plaintiffs allege that AbbVie's 100+ patents are "weak[ ]," Compl. ¶ 6, "dubious," *id.* ¶ 185, and "overlapping," *id.* at 36, and that certain patents are "obvious in light of prior art," *id.* ¶ 107.a, and not "novel" or "enabled," *id.* ¶¶ 133-34. Plaintiffs copied many of these "challenges" directly from IPR petitions that the PTAB declined to institute. *Compare id.* ¶ 110 n.48 (citing Goodman & Gilman and Hanuer), *with* Ex. 13 (same, among others), *and* Compl. ¶ 113 n.49-51 (citing van de Putte, Barrera, and Remington), *with* Ex. 8 (same, among others). None creates antitrust liability.

There is a limited exception to the general rule that the acquisition and assertion of patents cannot give rise to antitrust liability—where a patent was "obtained by ***fraud*** on the Patent Office." *Walker Process Equipment, Inc. v. Food Machinery & Chem Corp.*, 382 U.S. 172, 173 (1965) (emphasis added).[6] The law does not recognize any of the validity challenges that Plaintiffs make to AbbVie's patents as implicating antitrust liability. Even if a court found ***all*** of AbbVie's patents invalid under 35 U.S.C. §§ 102, 103, or 112, that still would be insufficient for purposes of pleading a Section 2 claim: "[T]he [Supreme] Court made clear that the invalidity of [a] patent [is] not sufficient" to create antitrust liability. *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012); *see Bendix Corp. v. Balax, Inc.*, 471 F.2d 149, 154 (7th Cir. 1972) ("[T]he fact of invalidity has no probative value in the case in attempting to establish any antitrust violation."); *e.g.*, *Advanced Ion Beam Tech., Inc. v. Varian Semiconductor Equip. Assocs., Inc.*, 721 F. Supp. 2d 62, 76 (D. Mass. 2010) (no antitrust liability where defendant alleged inventors "knew that one or more of the claims contained therein was anticipated" by prior art).

[6] The only other conceivable exception is the "sham exception" to *Noerr–Pennington* immunity, which, as discussed below, Plaintiffs do not even plead and could not plead in any event.

Notably, Plaintiffs do not allege *Walker Process* fraud as to any AbbVie patent. While one plaintiff asserted a *Walker Process* claim in its original complaint, *see* No. 1:19-cv-2674, Dkt. No. 1 at 70 (N.D. Ill.), Plaintiffs do not assert that claim now, and the Court need not consider Plaintiffs' patent challenges. Plaintiffs' omission makes sense given that they lack standing to assert *Walker Process* fraud, and—even if they had standing—they could not plausibly plead it.

First, as indirect purchasers, *see* Compl. ¶¶ 224-25, not as parties against whom AbbVie sought to enforce its patents, Plaintiffs lack standing to challenge the patents. "[A] party whose only connection to the patentee is as an indirect purchaser of products" lacks standing to assert *Walker Process* fraud. *Farag v. Health Care Serv. Corp.*, 2017 WL 2868999, at *6 (N.D. Ill. July 5, 2017) (granting 12(b)(1) motion); *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *18 (D.N.J. Mar. 1, 2007) (granting 12(b)(6) motion: "If this Court were to conclude that *indirect* purchasers had standing to bring *Walker Process* claims, it would turn antitrust policy on its head.").

Second, Plaintiffs' allegations touching on the prosecution of AbbVie's patents fall short of satisfying Rule 9(b)'s pleading standards. At most, Plaintiffs assert—for four patents only—that AbbVie made "material misrepresentations and omissions" to the Patent Office. Compl. at 41; *id.* ¶¶ 114-20 (U.S. Patent Nos. 8,093,045; 8,911,964; 9,090,867; and 9,018,361). But that is insufficient to plead fraud in this context, which requires four elements: "(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Plaintiffs do not allege—and certainly not with the specificity required by Rule 9(b)—that any statement or omission was deliberate, made with deceptive intent, relied on by the examiner, or the but-for cause of patent issuance. *See, e.g.*, *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (reversing

finding of fraud on the Patent Office because patentee's failure to disclose a reference, despite it being "so important to patentability," did not prove "deceptive intent"); *Correct Craft IP Holdings, LLC v. Malibu Boats, LLC*, 2010 WL 598693, at *4 (M.D. Fla. Feb. 17, 2010) (dismissing claim for failure to "allege the requisite mental state" where plaintiff alleged "prior art submitted during the prosecution of [a] patent was not disclosed during the prosecution of other related patents").

Finally, to survive dismissal, Plaintiffs would have to plead *Walker-Process* fraud for ***each and every*** one of AbbVie's 100+ patents—a task they declined to undertake. Just ***one*** non-fraudulent patent can lawfully exclude competitors from the market. *See, e.g.*, *In re Terazosin Hydorchloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004) (Section 2 claim failed as a matter of law where one patent "would have prohibited [ ] entry into the marketplace"). And yet Plaintiffs failed to adequately plead the requisite fraud for ***any*** AbbVie patent.

C. The *Noerr–Pennington* Doctrine Immunizes AbbVie's Alleged Conduct.

Plaintiffs' patent thicket theory also fails for a third independent reason: It is barred by the *Noerr–Pennington* doctrine. *Noerr–Pennington* immunizes a party from "antitrust liability for petitioning the government for redress, in light of the First Amendment right to petition the government." *United Food & Commercial Workers Unions v. Novartis Pharms. Corp.*, 902 F.3d 1, 4 (1st Cir. 2018).[7] The immunity applies to both prosecuting patents before the Patent Office and enforcing them in court—further barring Counts V and VI as a matter of law. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 273 (3d Cir. 2017) ("Petitions to administrative agencies are ... immune from antitrust liability."); *id.* at 272 ("Filing a lawsuit essentially petitions the government for redress and is therefore generally protected from antitrust liability").

[7] *Noerr–Pennington* also applies to Plaintiffs' state law claims. *See Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 615 (D.N.J. 2000) (state antitrust and consumer protection claims "cannot rest upon allegations of conduct immunized from the federal antitrust laws"); *Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 900 & n. 18 (10th Cir. 2011) (affirming dismissal); *Davaric Me. Corp. Rancourt*, 216 F.3d 143, 147 (1st Cir. 2000); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1059 (9th Cir. 1998).

Relying on *Noerr–Pennington*, at least one court rejected the exact "patent thicket" theory Plaintiffs advance here. In *Procter & Gamble Co. v. Paragon Trade Brands*, P&G sued Paragon for patent infringement, and Paragon counterclaimed with a Section 2 claim. 61 F. Supp. 2d 102, 106 (D. Del. 1996). As here, Paragon alleged "P&G 'ha[d] a wrongful policy of soliciting and obtaining United States letters patents which [were] excessive in number and virtually inextricable from each other and from the prior art.' This patent 'thicket' allegedly ha[d] the effect of decreasing competition and creating barriers to entry and continued participation in the market.'" *Id*. The court dismissed the Section 2 counterclaim, concluding the "***accrual of a patent 'thicket' [does] not constitute a Section 2 violation because it would be immune under the* Noerr–Pennington *doctrine***." *Id.* at 110 (emphasis added). The same result should follow here.

Plaintiffs cannot avoid *Noerr–Pennington* under its "sham" petitioning exception. That exception applies only when (1) petitioning activity is "objectively baseless in the sense that no reasonable [petitioner] could realistically expect success on the merits," and (2) "the baseless [petition] conceals 'an attempt to interfere *directly* with the business relationships of a competitor' through the 'use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *Prof'l Real Estate Inv., Inc. v. Columbia Pictures Indus.* (*PRE*), 508 U.S. 49, 60-61 (1993). The Complaint never alleges the sham exception applies here, and the Court need not consider this argument any further. Nor could Plaintiffs plead it in any event.

First, Plaintiffs do not allege facts suggesting that any of AbbVie's 100+ patent applications were "objectively baseless." *See id.* Given that AbbVie's applications were ***successful***, no such claim can be made. The Patent Office issued patents to AbbVie following a "thorough" and "rigorous" examination process, *see Hyatt v. U.S. Patent & Trademark Office*, 146 F. Supp. 3d 771, 774 (E.D. Va. 2015); *In re Muth Mirror Sys., LLC*, 379 B.R. 805, 815 (Bankr. E.D. Wis. 2007), and the patents enjoy a statutory presumption of validity "based in part 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); *Cross Med. Prods., Inc. v. Medtronic Sofamore Danek, Inc.*, 2005 WL 5239259, at *11 (C.D. Cal. Apr. 11, 20015) ("Patent examiners are presumed to do their job correctly and to know what claims they are allowing."); *see* 35 U.S.C. § 282(a) ("A patent shall be presumed valid."). And nine AbbVie patents survived IPR challenges. Ex. 1-13. Courts hold that allegations like Plaintiffs'—including their assertions that AbbVie's patents are "weak"—do not satisfy the objective prong of the sham petitioning test. *See, e.g.*, *Braintree Labs., Inc. v. Schwartz Pharma, Inc.*, 568 F. Supp. 2d 487, 497 (D. Del. 2008) (party entitled to *Noerr–Pennington* immunity even where it "appreciates that its '183 patent is 'weak,'" as "[e]ven a potentially 'weak' patent enjoys a presumption of validity"); *Intellectual Ventures*, 2013 WL 6682981 at *7 (plaintiff entitled to *Noerr–Pennington* immunity despite allegations that "patents are ... either unenforceable or so weak that ... they have limited commercial value").

Second, Plaintiffs have not alleged that the BPCIA exchanges or litigations were "objectively baseless." *PRE*, 508 U.S. at 60. As the Federal Circuit explained, "it will be a rare case [when] 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." *Tyco Healthcare Grp. v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014). The standard is one of probable cause, which "requires no more than a '***reasonabl[e]*** belie[f] [by AbbVie] that there is a ***chance*** that [a] claim ***may*** be held valid upon adjudication.'" *See PRE*, 508 U.S. at 62 (emphases added; citation omitted). In fact, "if the court concludes that the antitrust defendant had probable cause to file suit," then the court "cannot find that the defendant engaged in sham litigation, ***even if the litigant filed suit without any expectation of success***." *Intellectual Ventures*, 280 F. Supp. 3d at 709-10 (emphasis added); *see Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992-93 (N.D. Ill 2003) (Posner, J., sitting by designation) (granting motion to dismiss, stating

that "the private thoughts of a patentee ... about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case").

Plaintiffs have not pleaded and cannot plausibly plead that "no reasonable litigant could realistically expect success on the merits." *See PRE*, 508 at 51. AbbVie had every reason to file suit against the biosimilar Defendants. The Amgen and Sandoz litigations each involved one patent for which the PTAB ***denied institution*** of IPR, and the BPCIA exchanges each involved ***eight*** patents for which the PTAB also ***denied institution***,[8] which, as noted *supra* at page 6, has a lower standard for institution (reasonable likelihood) than the litigation standard for invalidity (clear and convincing evidence). That fact alone confirms that AbbVie's BPCIA exchanges and litigations were not "objectively baseless." *See E-Watch, Inc. v. Lorex Canada, Inc.*, 2013 WL 5425298, at *2 (S.D. Tex. Sept. 26, 2013) (where patent claims "survive the reexamination intact," they have done so under scrutiny of the Patent Office's "expertise regarding the validity of the patents"). And even if a court later deemed AbbVie's patents invalid, "[t]he possible invalidity of a patent does not, in and of itself, establish that the litigation asserting it was objectively baseless." *United Food & Commercial Workers Unions v. Novartis Pharms. Corp.*, 2017 WL 2837002, at *11 (D. Mass. June 30, 2017) (dismissing antitrust claims), *aff'd*, 902 F.3d 1 (1st Cir. 2017). The same is true for a noninfringement finding. *See C.R. Bard*, 157 F.3d at 1369 ("[T]he bringing of an unsuccessful suit to enforce patent rights" does not "subject[ ] the suitor to antitrust liability.").

Finally, to nullify *Noerr–Pennington* immunity, Plaintiffs also must plead that AbbVie's "subjective motivation" in enforcing its patents was "to interfere *directly* with the business relationships of a competitor." *PRE*, 508 U.S. at 60-61 (quotation omitted; emphasis in original).

[8] In the litigation against Amgen, U.S. Patent No. 8,916,157, *see* Ex. 1; in the litigation against Sandoz, U.S. Patent No. 9,187,559, *see* Ex. 13. In the BPCIA exchanges, U.S. Patent Nos. 8,916,157; 8,916,158; 9,114,166; 8,802,100; 9,512,216; 8,911,737; 8,974,790, and 9,187,559. *See* Ex. 14 at Ex. A (BPCIA exchange with Amgen).

Plaintiffs make no effort to satisfy that pleading standard. *See GEICO v. Hazel*, 2014 WL 4628655, at *19 (E.D.N.Y. Aug. 11, 2014) (*Noerr–Pennington*'s subjective prong not met where plaintiff did not allege that the defendant "was indifferent to the outcome of its lawsuit," that the lawsuit "cannot be explained by economic considerations," or that the defendant "sued primarily for the benefit of collateral injury that the cost of litigation would inflict"). Moreover, in the patent context, pleading *Noerr–Pennington*'s subjective prong requires allegations that the "original [patent infringement] plaintiff had ***actual knowledge*** that the patent-in-suit was invalid." *Datascope Corp. v. Vascular Solutions, Inc.*, 165 F. Supp. 2d, 933, 936-37 (D. Minn. 2001) (emphasis added). The Complaint is devoid of such allegations.

II. PLAINTIFFS' SECTION 1 CLAIMS FAIL AS A MATTER OF LAW

Plaintiffs also claim that the patent settlement agreements between AbbVie and the biosimilar Defendants were unlawful. Specifically, Plaintiffs contend that those agreements violate Section 1 in three ways: (1) they constitute unlawful reverse payments by granting each biosimilar Defendant "early entry in the European market" in exchange for delayed entry into the U.S. market, Compl. ¶ 263; (2) they unlawfully divide the market for adalimumab between the United States and Europe, *id.* ¶ 280; and (3) AbbVie's agreement with Amgen provides an unlawful reverse payment in the form of five-months of exclusivity in the United States, *id.* ¶ 262. Because all three theories fail, Counts I and III should be dismissed with prejudice.

A. Plaintiffs Have Not Pleaded A Reverse Payment Based On European Entry

Plaintiffs contend that each Defendant entered into pay-for-delay arrangements by which they delayed US market entry in exchange for "early" European market entry. But far from pleading unlawful agreements, the Complaint's allegations about "early" EU entry state only conduct that the Supreme Court expressly sanctioned in *Actavis*: "[A]llowing the generic

manufacturer to enter the patentee's market prior to the patent's expiration." 570 U.S. at 158. Nothing about the settlements at issue runs afoul of that straightforward language.

1. *Actavis* And The Reverse-Payment Framework

In *Actavis*, the Supreme Court considered the lawfulness of a patent settlement in which the alleged infringers agreed to delay market entry for several years, allegedly in exchange for cash payments of tens of millions of dollars. *See id.* at 145. The Court set forth a framework for assessing the lawfulness of these so-called "reverse payment" patent settlements, i.e., settlements in which "the patentee [agrees] to pay the alleged infringer, rather than the other way around." *Id.* at 141; *see id.* at 152 ("A, the plaintiff, pays money to defendant B purely so B will give up the patent fight"). The Court took care to distinguish between settlements whose only term is an early-entry license and those involving a potentially unlawful reverse payment:

> [T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in ***other ways***, 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 (emphasis added). "Other ways," of course, means that early-entry-only settlements are different than reverse-payment settlements—not a species of them—and are exempt from antitrust scrutiny. *See id.* (distinguishing "settlement[s] on terms permitting the patent challenger to enter the market before the patent expires" and "payment[s] in return for staying out of the market").

Courts applying *Actavis* agree that the Supreme Court set aside early-entry-only settlements as being categorically different from reverse-payment settlements and, thus, not requiring antitrust review. *See, e.g.*, *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407-08 (3d Cir. 2017) ("[T]he *Actavis* Court expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb[.]"); *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22,

2015) ("At their core, the settlements at issue simply granted the Generic Defendants a compromise date of generic entry—***the very type of settlement sanctioned by the* Actavis *Court***." (emphasis added)), *aff'd in part, vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017); *FTC. v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015) ("Abbott, Unimed, and Besins simply allow[ed] Teva to enter the AndroGel market almost six years prior to the expiration of the '894 Patent. ... *Actavis* specifically states that such an agreement does not run afoul of the antitrust laws."); *United Food*, 74 F. Supp. 3d at 1066-67 ("As the Supreme Court noted [in *Actavis*], a patent infringement settlement does not raise antitrust concerns if it allows '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.").

Notably, ***no court*** has held that a license to enter different geographic markets at different times is a reverse payment or might violate the antitrust laws, even in cases involving early-entry arrangements that resulted from "near-global litigation settlement[s] ... regarding scores of patent litigations around the world." *See Lipitor*, 868 F.3d at 244.[9] Instead, to subject an agreement to antitrust scrutiny, there always has been some form of alleged payment to the patent defendant other than mere early entry, which, as discussed below, is not alleged here. *See id.* at 247 (agreement by brand manufacturer not to market an authorized generic version of drug ("no AG agreement")); *see also King Drug*, 791 F.3d at 393 (same); *In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 382 (D. Mass. 2013) (same); *Loestrin*, 261 F. Supp. 3d at 321 (no AG agreement plus exclusivity agreement, among other payments).

[9] Unlike the challenged settlements here, where the sole alleged source of value to the biosimilar Defendants is the licensed entry dates, *Lipitor* involved allegations that the patent plaintiff effectively paid the patent defendant hundreds of millions of dollars by releasing a damages claim secured by a $200 million injunction bond for only $1 million. 868 F.3d at 253-54.

2. AbbVie's Early-Entry Settlements Do Not Merit Antitrust Scrutiny

Plaintiffs allege no conduct by Defendants that triggers antitrust scrutiny under *Actavis*. The Complaint alleges that AbbVie's U.S. agreements licensed the biosimilar Defendants to enter the U.S. market in 2023—more than a decade before AbbVie's latest-expiring U.S. patents expire in 2034. *See* Compl. ¶ 91. It also alleges that AbbVie's European agreements licensed the biosimilar Defendants (but not all biosimilar companies) to enter the European market in 2018 for certain patented indications—ahead of the expiry dates of AbbVie's European patents for those indications. *See id.* ¶ 190. Reasoning backwards, Plaintiffs contend that the European license agreements ***must*** amount to a reverse payment because they enabled early entry "worth tens or hundreds of millions of dollars to each [biosimilar] defendant." *Id.* ¶ 263. But the fact that the biosimilar Defendants have the potential to earn revenue in Europe before they do in the United States does not mean that AbbVie "paid" them. Where, as here, a complaint alleges "global, complex settlement agreements," the court must "look[ ] at each component of the [agreements] to determine whether they were 'adequately alleged as unlawful reverse payments." *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 331 (D. Mass. 2017) (quotation omitted). Where no individual component amounts to a reverse payment, the antitrust inquiry ends. *See id.*[10]

Here, in settling, AbbVie received less than it would have had it prevailed in the patent disputes insofar as the biosimilar Defendants can enter the U.S. market before AbbVie's U.S. patents expire. And for Europe, the settlements gave the biosimilar Defendants certainty, allowing them to enter the market for all indications on dates certain before AbbVie's EU patents in using

[10] The FTC has recognized that the simultaneous settlement of two separate pharmaceutical patent litigations is not unlawful if, as here, each settlement, standing alone, is merely an early-entry settlement. *See FTC v. Cephalon, Inc.*, No. 08-cv-2141 MSG (E.D. Pa. 2019), Dkt. No. 410 (Stipulated Settlement) at pp. 8-9 (§ 38(c): "[A]n agreement to settle or resolve a different litigation claim" is not a prohibited "Payment by the [branded drug company] to the Generic" company "so long as the that separate agreement independently complies with the terms of this [Stipulated Settlement]."). In other words, under the applicable antitrust law, two rights cannot make a wrong.

adalimumab to treat ulcerative colitis, Crohn's disease, hidradenitis suppurativa, and rheumatoid arthritis expired. To be sure, the settlement also gave the biosimilar Defendants less than they would have liked, which was immediate, royalty-free market access upon receiving regulatory approval. But such compromises of claims are "not uncommon" and are "not ... subject to antitrust scrutiny." *Actavis*, 570 U.S. at 151-52 (describing $100 million damages claim that settles for $40 million). The Supreme Court calls this a "traditional" settlement that does not trigger antitrust concerns, which stands "in contrast" to reverse payment settlements. *See id.* at 152 ("In the traditional example[ ] ... a party with a claim ... for damages receives a sum equal to or less than the value of its claim. In reverse-payment settlements, ***in contrast***, a party with no claim for damages ... walks away with money simply so it will stay away from the patentee's market." (emphasis added)). The Complaint does not allege a reverse payment at all, even if the biosimilar Defendants could extract value by selling their products earlier to consumers.

The fact that Defendants entered into two different sets of early-entry settlements simultaneously, one resolving the patent litigation in Europe and the other resolving the patent litigation in the United States, does not somehow transform these settlements into unlawful reverse payments. The *Actos* court rejected a similar theory that one early-entry settlement could function as an unlawful "payment" in exchange for another. 2015 WL 5610752, at *17. In that case, plaintiffs alleged that the compromise entry date for one product (ACTO*plus*) caused the patent defendants to accept a later date for another related product (ACTOS). As the court explained, the contemporaneous settlement of two patent disputes is not an unlawful reverse payment: "Both the early-entry ACTOS and ACTO*plus* licenses were permissible settlement terms under *Actavis*, and the simultaneous grant of both does not render either license unlawful." *Id.*

Judge Posner's holding in *Asahi Glass* is also instructive.[11] There, similar to here, the patent holder licensed a generic company to sell a drug "in Puerto Rico beginning immediately and in the rest of the United States as soon as any other generic version ... came on the market." 289 F. Supp. 2d at 989. Noting that "there is a difference between [a] reverse-payment case and other forms of settlement," Judge Posner explained that where competition itself forms the basis of the alleged "payment," any resulting value is not a "payment" at all. *See id.* at 994 ("Another way to put this is that in this case there is only a 'payment' to the settling defendant when competition breaks out. The 'payment' of Puerto Rico to Pentech [the generic] increased the competition there, and the 'payment' in the form of free paroxetine occurred as a byproduct of increased competition."). Here, too, any alleged "payment" is just the result of competition in the EU market, not of any reverse payment. The fact that the biosimilar Defendants may profit from competing for European sales does not make their early entry a "payment" that triggers antitrust review. *See Asahi Glass*, 289 F. Supp. 2d at 994; *see also AbbVie*, 107 F. Supp. 3d at 436 ("[T]he benefit flowing to Teva is also a benefit flowing to consumers who will now be able to purchase the generic form of TriCor at a reduced price.").

Moreover, the face of the Complaint confirms that the earlier European entry is not a result of AbbVie paying the biosimilar Defendants "so [they] will give up the patent fight," *Actavis*, 570 U.S. at 152, but rather results from AbbVie's varying patent coverage across the globe. Plaintiffs allege AbbVie has "more than 100" U.S. patents that are a bar to market entry in the United States, Compl. ¶¶ 4, 11, and that some of those patents do not expire until the 2030s, *see id.* ¶ 91. By contrast, AbbVie has only ***three*** European patents that "remain in force today," *id.* ¶ 190, *see supra* note 2, which protect indications for adalimumab for only four diseases, leaving at least five other diseases for which Humira is approved unguarded by patents in Europe. Under these allegations,

[11] Courts continue to rely on *Asahi Glass* after *Actavis*. *See, e.g.*, *Actos*, 2015 WL 5610752, at *14.

and as a matter of law, the biosimilar Defendants could enter the European markets for all but four diseases in 2018, when AbbVie's "main European Humira patents" are alleged to have expired. *Id.* ¶ 208. And, as a practical matter, lawful entry for non-patented indications could result in entry for all based on cross-label dispensing.[12] Under these circumstances, the agreements allowing entry into Europe as of 2018 are not unlawful under the Sherman Act.

Further supporting that Plaintiffs' theory of a reverse payment is not plausible is the fact that not all the settling biosimilar manufacturers are alleged even to have received "early" European entry. Plaintiffs do not allege that nonparties Mylan and Boehringer received licenses from AbbVie to sell their biosimilars in Europe for patented indications prior to the expiration of relevant patents, yet Mylan and Boehringer still are alleged to have agreed to a U.S. license date in the same 2023 range as the biosimilar Defendants who ***did*** receive a European license date. *See* Compl. ¶ 211. The European entry date thus could not plausibly have induced a delayed U.S. entry date if companies that did not even receive a European entry date nonetheless agreed to similar U.S. entry dates. This allegation debunks Plaintiffs' reverse-payment theory.

At its core, Plaintiffs' complaint appears to be that AbbVie and the biosimilar Defendants did not negotiate an even ***earlier*** entry date in the United States, as they did in Europe. But a settlement does not violate antitrust laws simply because a plaintiff might prefer "some other approach [that] might yield greater competition." *Trinko*, 540 U.S. at 415-16. Indeed, the Supreme Court has cautioned against premising antitrust liability on theories that require the courts to

[12] The European Federation of Pharmaceutical Industries and Associations defines "cross-label" use as "[t]he dispensing of a generic medicine for an indication for which the innovating company still holds a patent and for which the generic medicine has not been authorised/labelled." *See New Indications & Cross-Label Dispensing* (Nov. 11, 2015), https://www.efpia.eu/media/15425/new-indications-cross-label-dispensing-november-2015.pdf; *see also UIRC-GSA Holdings, Inc. v. William Blair & Co., LLC*, 2018 WL 6573226, at *2 (N.D. Ill. Dec. 13, 2018) (taking judicial notice of definitions from websites on motion to dismiss); *Oracle Am., Inc. v. CedarCrestone, Inc.*, 938 F. Supp. 2d 895, 901 (N.D. Cal. 2013) (taking judicial notice of "an online article" in support of motion to dismiss).

second-guess the legitimate business judgments of competing firms or to regulate the terms on which they must deal with one another. *Id.* at 408, 414-15. If Plaintiffs' argument were correct, it would lead to the conclusion that a drug company could never settle a pharmaceutical patent dispute on a multi-national basis without antitrust exposure, unless it had the same patent estate in every country and agreed to the same entry date everywhere. No case suggests this result. Such a result would undercut *Actavis*'s holding that parties can lawfully resolve litigation risks without the influence of a cash or other payment, i.e., with an entry date that reflects the strength of the patents and the patent challenges. Forcing the parties to agree on a single entry date applicable to multiple jurisdictions, upon pains of antitrust liability, would complicate the parties' assessment of litigation risk and interfere with their ability to accomplish what the Court found lawful.

Plaintiffs' effort to allege a "payment" where there was none should be rejected. As Judge Posner explained in *Asahi Glass*, "any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." 289 F. Supp. 2d at 994.

B. Plaintiffs' Attempt To Recast The Settlements As A "Market Division" Fails

Plaintiffs also implausibly describe AbbVie's settlements with the biosimilar Defendants as a horizontal market division that violates the antitrust laws on a *per se* basis. Compl. ¶¶ 11, 206, 281. But Plaintiffs cannot end-run *Actavis*'s express sanctioning of the early-entry-only settlements under the rule of reason by recasting the patent settlements as "market allocation" agreements. *See In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *4 (S.D.N.Y. Aug. 15, 2019). Indeed, as the court in *Novartis & Par* recently made clear in rejecting allegations in a similar context, "[b]ecause the alleged conduct unfolded in the context of and depended on an intricate statutory regime, the Supreme Court's teaching [in *Actavis*] on that regime applies, and

not general principles of market allocation agreements." *Id.*; *see id.* ("case law uniformly supports the application of *Actavis* and the rule of reason approach" to patent-settlement claims). And as a matter of law, there can be no market division where the market is not divided.

Critically, Plaintiffs never contend that AbbVie is ***not*** currently selling Humira and competing in Europe; to the contrary, the Complaint includes numerous allegations about AbbVie's European pricing and its competition with biosimilars in Europe. *See, e.g.*, Compl. ¶¶ 51, 207-09. That is the beginning and end of the market-division analysis. A market division agreement among companies requires "***[e]ach*** agree[ing] not to compete in the other's territories." *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (cited in Compl. ¶ 280 n. 91). *Palmer*, for example, involved an agreement where one company "received [the Georgia] market, while [the other] received the remainder of the United States." *Id.* In other words, the parties "reserve[d] one market for one and another [market] for the other." *Id.* at 50; *see id.* at 47 ("The parties agreed that HBJ would not compete with BRG in Georgia and that BRG would not compete with HBJ outside of Georgia."). This is how an unlawful market allocation agreement works—companies agree to "***never compete[ ] in the same market***." *Id.* at 49 (emphasis added).

That is not the situation alleged here. There is no allegation that the United States and Europe are "mutually exclusive territories," *see United States v. Sealy, Inc.*, 388 U.S. 350, 351 (1967), as between AbbVie and the biosimilar Defendants, whereby Defendants agreed that AbbVie would operate only in one market and the biosimilars only in another. Plaintiffs' repeated reference to the biosimilar Defendants' "European market entry" as the basis for their market-division claim, *see* Compl. ¶ 206, ignores the other half of the equation for market ***division***—namely, that AbbVie has not exited the European market and continues to compete by selling Humira in Europe. *See id.* ¶¶ 51, 206-07. AbbVie and the biosimilar Defendants did not agree that ***any*** market would be "reserve[d]" for the biosimilar Defendants, because AbbVie competes

in both. *See Palmer*, 498 U.S. at 49; *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 477, 492-93 (N.D. Ill. 2019) ("[M]arket-division agreements are agreements between 'competitors to stay out of each other's territories[.]"); *see, e.g.*, *Laumann v. Nat'l Hockey League*, 907 F. Supp. 2d 465, 487 (S.D.N.Y. 2012) (complaint failed to state horizontal market division where "it is clear that [competitors] compete with each other" in the alleged market).

Finally, even if Plaintiffs could plead a market-division claim (and they cannot), it should not be evaluated under the quick look analysis or as *per se* unlawful, as Plaintiffs assert. *See* Compl. ¶¶ 281-82. The Supreme Court in *Actavis* "directed district courts to apply the rule of reason analysis to patent settlements." *United Food*, 74 F. Supp. 3d at 1075. Many plaintiffs have tried to end-run *Actavis*'s rule of reason analysis by recasting their reverse-payment claims as a "market allocation," but courts have rejected those attempts at the pleadings stage. *See, e.g.*, *Novartis & Par*, 2019 WL 3841711, at *4 (rejecting *per se* treatment); *In re Zetia Antitrust Litig.*, 2019 WL 1397228, at *19 (E.D. Va. Feb. 6, 2019) (dismissing *per se* count despite allegation that the settlement agreement "includes a horizontal market allocation"), *R&R adopted*, — F. Supp. 3d. —, 2019 WL 3761680, at *4 (E.D. Va. 2019); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 WL 8620989, at *6-8 (E.D. Pa. Dec. 14, 2015) (rejecting *per se* treatment). That approach has long been the law in this Circuit too. *See Moraine Products v. ICI Am, Inc.*, 538 F.2d 134, 145 (7th Cir. 1976) (applying rule of reason to patent licensing arrangement among competitors who allegedly "conspired to divide the market").

* * *

Ultimately, whether styled as a "reverse payment" or a "market division agreement," Plaintiffs have failed to allege anything more than early-entry patent settlements authorized by *Actavis*, thus requiring dismissal of their Section 1 claims with prejudice.

C. Plaintiffs Have Not Plausibly Alleged A Reverse Payment To Amgen

Plaintiffs' third attempt at establishing a Section 1 violation fares no better than their first two. Plaintiffs claim that the AbbVie-Amgen agreement included a reverse payment in the form of a promised period of "exclusivity" for Amgen's adalimumab biosimilar. Compl. ¶ 151. In particular, they allege that, as part of the settlement, AbbVie induced Amgen to accept a later U.S. entry date—although one still well before AbbVie's patents expire—by agreeing "not to settle with any other manufacturers on terms that would let them enter the market at the same time as Amgen, or for five months thereafter." *Id.* ¶ 153. But this purported contractual term is completely made up by Plaintiffs—the AbbVie–Amgen agreement, which is integral to Plaintiffs' claim, does not provide for any period of exclusivity and unambiguously contradicts Plaintiffs' baseless assertions. The parts of Counts I and II based on an alleged promise of exclusivity to Amgen must be dismissed.

As a threshold matter, the Complaint plainly puts at issue the terms of the AbbVie–Amgen U.S. agreement. Compl. ¶¶ 151, 153, 262, 264. As a result, the court may consider the contents of the agreement (Exhibit 14) "without converting [this] 12(b)(6) motion to a motion for summary judgment." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012); *Hartford Fire Ins. v. Henry Bros. Constr. Mgmt. Servs., LLC*, 2011 WL 3563138, at *4 (N.D. Ill. Aug. 10, 2011) ("[C]ourts may consider a document attached to a defendant's motion to dismiss but not attached to the complaint if the document is referred to in the plaintiff's complaint and [is] central to her claim. The Seventh Circuit has held that '[t]his exception is aimed at cases interpreting, for example, a contract.'"). Indeed, where, as here, a patent settlement agreement is "integral to and explicitly relied on in [a] Complaint" to allege a reverse payment under *Actavis*, a court can properly consider the terms of the agreement in assessing whether the allegations are plausible. *Zetia*, 2019 WL 3761680, at *5. And where the agreement "unambiguously contradicts

the allegations of the Complaint[ ]," dismissal is appropriate. *Id.*; *see also LaSalle Bank Nat'l Ass'n v. Paramont Props.*, 588 F. Supp. 2d 840, 848 (N.D. Ill. 2008) ("[W]here an exhibit conflicts with the allegations in the complaint, the exhibit typically controls"); *Bogie v. Rosenberg*, 705 F.3d 603, 609 (7th Cir. 2013) ("When an exhibit contradicts the allegations in the complaint, ruling against the non-moving party on a motion to dismiss is consistent with our obligation to review all facts in the light most favorable to the non-moving party.").

Here, any claim that AbbVie promised Amgen a period of exclusivity is unambiguously contradicted by the terms of the U.S. AbbVie–Amgen agreement. The agreement provides Amgen with a license permitting U.S. entry on January 31, 2023, in the absence of certain events that may trigger an earlier entry date. Ex. 14 § 6.1. It does not prevent AbbVie from granting to one or more other biosimilar manufacturers an entry date on or before January 31, 2023. To the contrary, the U.S. agreement [redacted]

Id. § 5.5 (emphasis added). AbbVie thus remains free to grant to other biosimilar manufacturers the same entry date or an even ***earlier*** entry date than Amgen received, and other biosimilar manufacturers remained free to attempt to negotiate an earlier entry date. The agreement, which by its terms represents [redacted]

[redacted] simply does not promise Amgen a head start over other biosimilars or any period of exclusivity. *Id.* § 10.4.[13]

The terms of the AbbVie–Amgen agreement thus render not merely implausible, but false, any allegation that AbbVie granted Amgen "valuable exclusivity" to settle the patent dispute, and Counts I and II based on that allegation should be dismissed. *See, e.g.*, *Colander v. Metro. Life Ins.*, 2017 WL 3816100, at *5 (N.D. Ill. Aug. 31, 2017) (dismissing claim where the terms of contract on which it is based, which was referenced in but not attached to complaint, "make clear that plaintiff's claim is not plausible."); *Curran v. JP Morgan Chase, N.A.*, 633 F. Supp. 2d 639, 644 (N.D. Ill. 2009) ("[I]f this document is the 'contract' plaintiff asserts in her amended complaint, her breach of contract claim fails."); *Orlando v. United of Omaha Life Ins.*, 2007 WL 2875241, at *5 (N.D. Ill. Sept. 30, 2007) (dismissing claim because otherwise sufficient allegations were "plainly contradicted" by documents attached to or referenced in complaint).

The alleged pattern of later entry dates for other biosimilars cannot change this result. Compl. ¶ 211. The terms of the AbbVie–Amgen agreement squarely contradict any claim that AbbVie promised Amgen any period of exclusivity. Putting that aside, the fact that AbbVie entered into settlements with other biosimilar manufacturers and agreed to early-entry dates later-in-time than Amgen's, standing alone, does not support a reasonable inference of an unwritten, unidentified agreement between AbbVie and Amgen granting to Amgen any period of *de facto* exclusivity. The Complaint (and common sense) makes clear that AbbVie had an independent incentive to seek as late an entry date as possible in each agreement. Compl. ¶¶ 83-85. As the Complaint shows, the AbbVie–Amgen U.S. agreement established a compromise entry date for Amgen, the first biosimilar applicant, well before the patents that AbbVie was asserting in

[13] The U.S. agreement likewise makes clear that no [redacted] Ex. 14 § 10.4.

litigation against Amgen expire, not to mention the additional patents that AbbVie still could assert in subsequent litigations. *See id.* ¶ 148. Moreover, even after settling with Amgen, AbbVie continued to prevail before the PTAB—victories that strengthened its hand against later applicants and justified later entry dates for subsequent settlers. *See* Ex. 8-13.

"Allegations of facts that could just as easily suggest rational, legal business behavior by the defendants as they could suggest an illegal conspiracy are insufficient to plead a violation of the antitrust laws." *In re Potash Antitrust Litig.*, 667 F. Supp. 2d 907, 934 (N.D. Ill. 2009) (citing *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1049 (9th Cir. 2008)), *vacated and remanded on other grounds*, *Minn-Chem, Inc. v. Agrium Inc.*, 675 F.3d 650 (7th Cir. 2011); *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554-570 (2007) (affirming dismissal of antitrust claim where conduct alleged was consistent with the independent interests of the defendants absent conspiracy); *Jones v. Micron Tech. Inc.*, — F. Supp. 3d —, 2019 WL 4232417, at * (N.D. Cal. Sept. 3, 2019) (same). Just as allegations of parallel pricing among competitors combined with conclusory allegations of conspiracy are insufficient to state a Section 1 claim as a matter of law, *Twombly*, 550 U.S. at 556-57, the allegations concerning the later entry dates to which AbbVie and the other biosimilar Defendants agreed, together with a conclusory allegation that they reflect an unlawful agreement between AbbVie and Amgen, is not enough to state such a claim—particularly in light of Plaintiffs' demonstrably wrong allegations about an exclusivity agreement.

III. PLAINTIFFS FAIL TO PLEAD ANTITRUST INJURY

Not only do Plaintiffs fail to plead conduct that is subject to antitrust scrutiny, they also fail to plead antitrust injury, providing an independent ground to dismiss Counts I-VII.[14] "Antitrust

[14] The antitrust injury requirement applies to Plaintiffs' federal claim for injunctive relief, as well as their state-law claims. *See Supreme Auto Transport, LLC v. Arcelor Mittal USA, Inc.*, 902 F.3d 735, 743 (7th Cir. 2018) ("[P]roximate causation is an essential element that plaintiffs must prove in order to succeed on any of their [state antitrust, consumer fraud, and common-law] claims."); *Sw. Suburban Bd.*

injury" is injury "that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). "Antitrust injury is a threshold requirement for private antitrust plaintiffs," *Int'l Equip. Trading, Ltd. v. Illumina, Inc.*, 2018 WL 3861575, at *8 (N.D. Ill. Aug. 14, 2018), and appropriately resolved on a motion to dismiss. *See, e.g.*, *McGarry & McGarry, LLC v. Bankr. Mgmt. Solutions, Inc.*, — F.3d —, 2019 WL 4197546, at *4-5 (7th Cir. Sept. 5, 2019) (affirming dismissal for failure to plausibly plead antitrust injury); *Midwest Gas Servs., Inc. v. Ind. Gas Co.*, 317 F.3d 703, 712-13 (7th Cir. 2003) (same).

"Antitrust injury involves a causation requirement": Plaintiffs must plausibly plead that the alleged antitrust violation was both the cause-in-fact and proximate cause of their injuries. *See Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 395 (7th Cir. 1993). In other words, Plaintiffs must plead "that 'but for' the violation, the injury would not have occurred." *See id.* If Plaintiffs' purported "injury" would have occurred ***regardless*** of Defendants' conduct, then there is no causation and the plaintiff has not suffered an antitrust injury. *See id.* at 402-04.

Here, that means Plaintiffs must plausibly allege that, but for AbbVie's alleged unlawful patent "thicket" and the settlements, biosimilar companies could have and would have sold adalimumab biosimilars in the United States before 2023. The Complaint does not plead ***any*** facts indicating that any biosimilar company would have entered the U.S. market earlier in the "but-for world." Counts I-VII should be dismissed for failure to plead antitrust injury.

A. Plaintiffs Do Not Plausibly Plead That Any Biosimilar Could Have Lawfully Launched In The Face Of AbbVie's Patents

Plaintiffs allege that AbbVie has "more than 100 (and maybe as many as 130 or more)" U.S. patents related to adalimumab, Compl. ¶ 4, which by law are presumed to be valid, 35 U.S.C. § 282. And yet, as discussed above, Plaintiffs attempt to allege invalidity or "omissions and

of Realtors, Inc. v. Beverly Area Planning Ass'n, 830 F.2d 1374, 1377 (7th Cir. 1987) ("The antitrust injury requirement is ... applicable to antitrust actions seeking injunctive relief.").

misstatements" as to only a subset. *Supra* at pages 14-16. Plaintiffs do not allege ***any*** basis to invalidate or find unenforceable AbbVie's other adalimumab patents, including patents that expire after 2023. If even a single valid patent claim would preclude biosimilar entry in the but-for world, Plaintiffs cannot plausibly plead that AbbVie's alleged illegal conduct, as opposed to a lawful patent, caused them to pay allegedly higher prices for adalimumab. *See In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 165-70 (3d Cir. 2016); *United Food*, 296 F. Supp. 3d at 1155-66. In other words, Plaintiffs fail to allege that the biosimilar Defendants would have been able to lawfully launch—i.e., that they would have sold adalimumab biosimilars without infringing a valid AbbVie patent—in the but-for world. "It is not enough for [Plaintiffs] to show that [a generic manufacturer] wanted to launch its drug"—which Plaintiffs did not plead here—"they must also show that the launch would have been legal." *Wellbutrin*, 868 F.3d at 165. Plaintiffs do not even try to shoulder this burden.

Terazosin is instructive. The plaintiffs there alleged that the defendants brought a series of "sham" patent lawsuits to prevent generic competition. 335 F. Supp. 2d at 1341. The court held that even if a lawsuit based on ***one*** of defendants' patents would not have prevented the generic's market entry in the but-for world, a lawsuit based on ***another*** patent still "would have prohibited [generic] entry into the market place." *Id.* Finding that the plaintiffs failed to "show a causal link between the alleged antitrust violation and the alleged antitrust injury of preventing generic entry," the court awarded summary judgment to defendants on the issue of antitrust injury. *Id.* That principle applies with equal force here: As described above, while Plaintiffs cast aspersions on a few of AbbVie's patents, they do not attempt to plead a basis to challenge ***all*** AbbVie patents.

Moreover, Plaintiffs do not allege that any biosimilar Defendant could have, or would have, overcome each and every one of AbbVie's patents in litigation. As the *Wellbutrin* court made clear, a plaintiff must plead that potential market entrants "would have been more likely than not

to prevail" in litigation against the patent holders. 868 F.3d at 169. But Plaintiffs allege the opposite: They claim that AbbVie's patents were "impassable." Compl. ¶ 9. The PTAB denied petitions for IPR ***13 times*** when biosimilar Defendants tried to challenge AbbVie's patents. Ex. 1-13. Plaintiffs do not allege anything to suggest, much less plausibly plead, that any biosimilar Defendant could have or would have ***successfully*** litigated its way past these battle-tested patents to market entry. And without an allegation that a biosimilar Defendant could have prevailed in litigation against AbbVie, Plaintiffs cannot plead antitrust injury. *See, e.g.*, *Wellbutrin*, 868 F.3d at 169 (plaintiffs who failed to demonstrate that generic manufacturer "would have been more likely than not to prevail" in patent litigation did not suffer antitrust injury); *see also In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 788-92 (8th Cir. 2006) (where federal legislation would have precluded importation of low-priced drugs in the but-for world, plaintiffs failed to plead antitrust injury).

B. Plaintiffs Do Not Plausibly Allege That Any Biosimilar Defendant Would Have Launched, Or Was Even Planning To Launch, At Risk

Not only must Plaintiffs plausibly plead that the biosimilar companies could have lawfully launched, they also must plead that, "in the absence of the [challenged conduct], [they] ***would have*** launched" prior to their settlement entry dates. *See Wellbutrin*, 868 F.3d at 165 (emphasis added). For good reason, they fail to do so here.

Plaintiffs do not allege that any biosimilar Defendant (or Boehringer) would have launched "at risk" of infringing AbbVie's patents before 2023—much less that an at-risk launch would have led to sustained biosimilar entry. In fact, Plaintiffs do not even allege that any biosimilar manufacturer sent statutory notice to inform AbbVie of an intent to market a biosimilar, which the BPCIA requires to provide the reference product sponsor (AbbVie) with time to move for a preliminary injunction. *See* 42 U.S.C. § 262(*l*)(8)(A) & (B).

Far from alleging imminent launch, the Complaint shows the ***opposite***. Amgen and Boehringer, the only two biosimilars who had FDA approval prior to entering into licensing agreements, chose not to attempt to launch while their litigations with AbbVie were pending. Indeed, each refrained from launching for over a year after obtaining FDA approval—in the case of Boehringer, more than ***20 months***—while they litigated with AbbVie. *See* Compl. ¶¶ 149, 151, 182, 184. *Compare, e.g.*, *Niaspan*, 42 F. Supp. 3d at 756 ("[P]laintiffs have alleged not only that Barr planned to launch at-risk before the conclusion of the infringement litigation, but also ... that Barr planned to launch its generic extended-release niacin' at the very first opportunity: ***'as soon as the FDA gave the final green light***.'" (emphasis added)).

A conservative approach by the biosimilar companies is hardly surprising, given the presumed validity of AbbVie's patents and AbbVie's repeated success before the PTAB. Courts recognize that "launching a generic at-risk during the midst of patent litigation is risky; if the court subsequently finds the subject patent(s) valid, enforceable, and infringed, the generic company may face substantial damages from its sales of an infringing product." *Niaspan*, 42 F. Supp. 3d at 756 (brackets and quotation marks omitted). Plaintiffs agree, asserting that "[a] manufacturer that launches at risk ... risks having to pay substantial damages to the brand or biologic manufacturer." Compl. ¶ 170. And according to Plaintiffs, in the case of Humira, the potential damages go beyond "substantial"; they would be "crushing." *Id*. ¶¶ 86, 97. It is no wonder that the Complaint lacks any allegation that a biosimilar Defendant planned to, or did, launch at risk, nor provides any other plausible, non-conclusory allegation of how early entry could or would have occurred in the but-for world.

Of course, even a hypothetical at-risk launch leads right back into the problem outlined above: AbbVie's presumptively valid patents. Plaintiffs must show that a theoretical at-risk launch "would have been legal." *See Wellbutrin*, 868 F.3d at 165. "If [a biosimilar] launch were

stopped" because it violated AbbVie's patents, "then the [Plaintiffs'] injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch." *Id*.; *see Nexium*, 842 F.3d at 62 ("[T]he argument that Ranbaxy would have incurred the risk of launching at risk ... depends on the theory that AstraZeneca's Nexium patents were invalid or not infringed by a generic version."). Plaintiffs do not allege that any biosimilar Defendant would have launched at risk ***and*** overcome AbbVie's patents. That is fatal to Counts I-VII.

IV. PLAINTIFFS' STATE LAW CLAIMS FAIL AS A MATTER OF LAW ON MULTIPLE GROUNDS

Finally, Plaintiffs assert an array of antitrust and consumer protection claims. *See* Compl. ¶¶ 269-78 (Count II), *id*. ¶¶ 286-94 (Count IV) (state antitrust and consumer protection claims against all Defendants); *id*. ¶¶ 301-08 (Count VI) (state antitrust and consumer protection claims against AbbVie); *id*. ¶¶ 309-406 (Count VII) (state consumer protection and unjust enrichment claims against AbbVie). These claims all have fatal pleading defects and must be dismissed.

A. Plaintiffs' State Law Antitrust Claims Should Be Dismissed

1. Plaintiffs' State Antitrust Law Claims Fail On The Same Grounds As Their Federal Antitrust Claims

In Counts II, IV, and VI, Plaintiffs assert claims under the antitrust laws of 27 states based on the same allegations as their federal antitrust claims. In 26 of these states, the antitrust statute is interpreted in harmony with federal antitrust law, either generally or in relation to claims such as these—meaning state antitrust claims rise or fall with federal claims.[15] While there appears to

[15] *See Bunker's Glass Co. v. Pilkington, PLC*, 75 P.3d 99, 102-03 (Ariz. 2003) (Ariz.); *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015) (Cal.); CONN. GEN. STAT. ANN. § 35-44b (Conn.); HAW. REV. STAT. ANN. § 480-3 (Hawaii); 740 ILL. COMP. STAT. ANN. 10/11 (Ill.); *Mueller v. Wellmark, Inc.*, 861 N.W.2d 563, 567-68 (Iowa 2015) (Iowa); KAN. STAT. ANN. § 50-163(b) (Kan.); *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 542 (N.D. Ill. 2019) (Me.); MD. CODE ANN., COM. LAW § 11-202 (Md.); MICH. COMP. LAWS § 445.784(2) (Mich.); *Minn. Twins P'ship v. State ex rel. Hatch*, 592 N.W.2d 847, 851 (Minn. 1999) (Minn.); *Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So. 2d 331 (Miss. 2004) (Miss.); NEB. REV. STAT. ANN. § 59-829 (Neb.); NEV. REV. STAT. ANN. § 598A.050 (Nev.); N.H. REV. STAT. ANN. § 356:14 (N.H.); *Romero v. Philip Morris Inc.*, 242 P.3d 280, 291 (N.M. 2010) (N.M.); *In re Cheese Antitrust Litig.*, 2015 WL 3988488, at *4 (N.D. Ill. June 29, 2015) (N.Y.);

be no statute or decision directly addressing the issue in North Dakota, the North Dakota Attorney General has invoked harmonization principles in applying the North Dakota statute, *James M. Vukelic*, N.D. Att'y. Gen. Op. No. 81-35 (April 2, 1981), 1981 WL 156902, and the North Dakota Supreme Court has cited federal precedent in interpreting it, *Ag Acceptance Corp. v. Glinz*, 684 N.W.2d 632, 639-40 (N.D. 2004). Plaintiffs' state antitrust claims under all 27 states should be dismissed alongside Plaintiffs' flawed federal antitrust claims. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) ("[S]ince Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed.").

2. The Court Should Dismiss Claims Brought Under The Antitrust Laws Of States That Require Conduct With a Significant Nexus To The State

Certain of Plaintiffs' state antitrust claims also should be dismissed because Plaintiffs fail to allege a sufficient nexus to that jurisdiction. Mississippi, North Carolina, Tennessee, Wisconsin, and the District of Columbia antitrust statutes require the purported anticompetitive conduct to have a significant nexus to the jurisdiction. *See, e.g.*, *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 266-67 (S.D.N.Y. 2019) ("[T]he antitrust law of Mississippi focuses on the location where the anticompetitive conduct occurred rather than the effects of such anticompetitive conduct."); *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 549 (N.D. Ill. 2019) (North Carolina antitrust statute "reaches only conduct causing a 'substantial' in-state injury, not merely an 'incidental' one. When plaintiffs do not allege that any wrongful conduct occurred in North Carolina, allegations that indirect purchasers [paid] inflated

Microsoft Corp. v. Computer Support Servs. of Carolina, Inc., 123 F. Supp. 2d 945, 955 (W.D.N.C. 2000) (N.C.); OR. REV. STAT. ANN. § 646.715 (Or.); R.I. GEN. LAWS ANN. § 6-36-2(b) (R.I.); S.D. CODIFIED LAWS § 37-1-22 (S.D.); *Bailey's, Inc. v. Windsor Am., Inc.*, 948 F.2d 1018, 1032 (6th Cir. 1991) (Tenn.); UTAH CODE ANN. § 76-10-3118 (Utah); W. VA. CODE ANN. § 47-18-16 (W. Va.); *Dealer Mgmt. Sys.*, 362 S. Supp. 3d at 544 (Wis.); D.C. Code Ann. § 28-4515 (D.C.).

prices are not sufficient."); *In re Vitamins Antitrust Litig.*, MDL No. 1285, 2001 WL 849928, at *6 (D.D.C. Apr. 11, 2001) (dismissing Tennessee claim due to a "notable lack of allegations regarding any part of the conspiracy that took place in Tennessee, other than the purchase of vitamin supplements by indirect purchasers"); *Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 549 (Wisconsin antitrust statute requires pleading that "actionable conduct ... occurred within the state" or "the conduct complained of 'substantially affects' the people of Wisconsin and has impacts in this state"); *Sun Dun, Inc. v. Coca-Cola Co.*, 740 F. Supp. 381, 396 (D. Md. 1990) (D.C. Code § 28-4501 does not apply to claims that "though bearing some connection to the District of Columbia, are in fact interstate in nature and are thus regulated by federal antitrust provisions").

Plaintiffs do not allege actionable conduct that occurred in Mississippi, North Carolina, Tennessee, Wisconsin, or the District of Columbia. Nor do they allege that any of Defendants' challenged conduct had a "substantial effect" in those jurisdictions. None of the Plaintiffs purports to reside in any of those jurisdictions, and none purports to have any connection to them beyond having allegedly "purchased, paid and/or provided reimbursement for some or all of the purchase price" of some unknown quantity of Humira there (and no Plaintiff even alleges that with regard to Wisconsin). *See* Compl. ¶¶ 13-17. Such bare allegations that "indirect purchasers [paid] inflated prices are not sufficient to establish a substantial, in-state injury." *Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 549 (applying North Carolina law).

3. Plaintiffs' Alaska And Illinois Antitrust Claims Are Barred

Plaintiffs cannot bring class action antitrust claims on behalf of indirect purchasers under Alaska or Illinois law. Plaintiffs, who are indirect purchasers of Humira, Compl. ¶ 225, "seek damages and multiple damages," *id*. ¶¶ 278, 294, 308. However, "[o]nly the [state] attorney general ... may seek monetary relief for injury indirectly sustained for a violation of" the Alaska Restraint of Trade Act. Alaska Stat. § 45.50.577(i); *see In re Dynamic Random Access Memory*

(DRAM) Antitrust Litig., 516 F. Supp. 2d 1072, 1108 (N.D. Cal. 2007) ("[I]n Alaska, only the attorney general may sue for money damages on behalf of indirect purchasers as a result of antitrust violations."). Similarly, the Illinois Antitrust Act provides that "no person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General …" 740 Ill. Comp. Stat. § 10/7(2). Courts evaluating this limitation in light of the Supreme Court's decision in *Shady Grove*,[16] have held it to be a substantive bar to indirect purchaser claims brought in federal class actions. *See In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 722-23 (N.D. Ill. 2016); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 833 (E.D. Pa. 2019) (dismissing claim and concurring with the "prevailing view of the District Courts that have considered this issue within this Circuit [ ] that the Illinois Antitrust Act prohibits indirect purchaser class actions"); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 539 (E.D. Pa. 2010) ("Plaintiffs are prohibited from asserting claims under the Illinois Antitrust Act, because the Act does not provide relief to indirect purchasers through class actions.").

4. Plaintiffs' Lack Standing Under Utah's Antitrust Statute

Plaintiffs' Utah antitrust claim fails under the Utah *Illinois Brick* repealer statute. In *Illinois Brick v. Illinois*, 431 U.S. 720 (1977), the Supreme Court held that only direct purchasers can recover damages under federal antitrust law. Since that ruling, Utah enacted a so-called "*Illinois Brick* repealer" statute creating standing for indirect purchasers under its state antitrust law, but "only if they are citizens or residents of Utah." *Opana ER*, 162 F. Supp. 3d at 725 (citing Utah Code § 76-10-3109). Here, no Plaintiff purports to be a citizen or resident of Utah. Their claims under the Utah Antitrust Act should be dismissed. *Id.* (dismissing Utah antitrust claim brought by indirect purchaser that was not a Utah citizen or resident); *In re Effexor Antitrust Litig.*, 2018

[16] *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010).

WL 6003893, at *17 (D. N.J. Sept. 18, 2018) (dismissing Utah antitrust claim and noting that "[t]he majority of courts that have been presented with this statute require at least one Utah citizen or resident be a named plaintiff."); *Sergeants Benevolent Ass'n. Health & Welfare Fund v. Actavis PLC*, 2018 WL 7197233, at *24 (S.D.N.Y. Dec. 26, 2018) (same).

B. Plaintiffs' State Law Consumer Protection And Unjust Enrichment Claims Should Be Dismissed

In Counts II, IV, VI, and VII, Plaintiffs repurpose their federal antitrust claims as violations of the consumer protection laws of 17 states,[17] along with an unjust enrichment claim under California law. These claims all fail as a matter of law and should be dismissed.

1. Plaintiffs' State Consumer Claims Depend On Their Federal Antitrust Claims And Must Fall Lockstep With Them

As an initial matter, if Plaintiffs' federal antitrust claims fail to state a claim, so too do their state consumer protection claims. There can be no question that Plaintiffs' consumer protection claims are based on the same allegations as their federal antitrust claims, given that each and every claim that AbbVie "has engaged in unfair acts and practices" is based on "the conduct alleged herein." *See generally* Compl. ¶¶ 276, 292, 306, 309-406. But then the converse is also true: If "the conduct alleged herein" fails to allege an antitrust violation, then AbbVie has not committed any "unfair acts [or] practices," and the Court should dismiss their consumer protection claims.

This result makes sense, given that Plaintiffs have inextricably linked their consumer protection claims to Defendants' alleged antitrust violations. Federal courts faced with similar allegations have not hesitated to dismiss ancillary state law claims in their entirety on this ground. *See, e.g.*, *R.J. Reynolds Tobacco Co. v. Philip Morris, Inc.*, 199 F. Supp. 2d 362, 396 (M.D.N.C.

[17] Alaska, California, Florida, Georgia, South Carolina, and Vermont law in Counts II, IV, and VI, and consumer protection claims against AbbVie alone under the laws of Alaska, Arizona, Florida, Georgia, Illinois, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, South Carolina, Utah, and West Virginia, and the District of Columbia in Count VII.

2002) ("Because Plaintiffs do not allege any facts that suggest that Defendant's conduct is unlawful beyond the conduct that is the basis for their federal claims, Plaintiffs' state common law and statutory claims fail as well."); *In re Androgel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371, 1375, 1382 (N.D. Ga. 2010) (dismissing claims that "Defendants violated the common law and antitrust laws of about forty states" upon finding that plaintiffs failed to state a plausible claim under federal antitrust law, because "the factual allegations for both types of claims are the same"). The claims against AbbVie also fail because the alleged patent-related conduct is entitled to *Noerr–Pennington* immunity. *See, e.g.*, *Green Mountain Realty Corp. v. Fifth Estate Tower, LLC*, 161 N.H. 78, 87 (2010) (dismissing consumer protection claim under *Noerr–Pennington*).

2. Plaintiffs' Consumer Protection Claims Fail To Meet Rule 8

Plaintiffs' consumer protection claims also fail as a matter of law because they lack sufficient factual allegations to show that AbbVie or the biosimilar Defendants violated consumer protection laws, and instead rely on bare legal conclusions. Under Rule 8, pleading "must contain a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "[L]abels and conclusions or formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678.

Yet Plaintiffs' claims do no more than that for each state's consumer protection statute. Take just one example. In Count VII, for their District of Columbia claim, Plaintiffs allege that "[b]y reason of the conduct alleged herein"—meaning, the allegations supporting the federal antitrust claims—"AbbVie has engaged in unfair trade practices in connection with consumer transactions." Compl. ¶ 334. Plaintiffs then claim "AbbVie is a 'merchant' within the meaning of" the D.C. statute, *id.* ¶ 335, and that "AbbVie's unlawful conduct substantially affected the District of Columbia's trade and commerce," *id.* ¶ 336. But each of these assertions is devoid of

supporting facts and, more importantly, is a legal conclusion for the Court to make.[18] And for Counts II, IV, and VI, Plaintiffs do not even attempt to recite the statutory elements—let alone facts establishing those elements—and instead merely assert in conclusory fashion that Defendants' agreements and conduct violate a copy-and-pasted, bulleted list of six state consumer protection laws. *See* Compl. ¶¶ 276, 292, 306.

In so pleading, Plaintiffs essentially tell the Court, "take our word for it, Defendants broke these laws." But "[t]he bald assertion that [ ] alleged antitrust conduct violates dozens of non-antitrust laws ... is not entitled to deference, because 'the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.'" *Opana*, 162 F. Supp. 3d at 726 (quoting *Iqbal*, 556 U.S. at 678). Indeed, Plaintiffs "have *listed* claims under very many state laws, but they have not truly *pleaded* claims under those laws sufficient to show their entitlement to recovery under them, as required by Rule 8." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255 (D. Conn. 2015). Hence, district courts dismiss as improperly pleaded federal antitrust allegations couched as state consumer protection claims when lumped together without factual support, as Plaintiffs do here. *See, e.g.*, *Opana*, 162 F. Supp. 3d at 726 (dismissing state consumer protection claims where the complaint "pleaded federal antitrust claims and the factual foundation for them," but "merely alleged that those claims are also actionable under general consumer-protection laws and as unjust enrichment."); *Aggrenox*, 94 F. Supp. 3d at 255-56 (same). This Court should do the same.

[18] Plaintiffs' remaining consumer protection claims, all of which refer back to facts underlying their federal antitrust claims, fare no better. *See, e.g.*, Compl. ¶ 318 (Alaska); *id.* ¶ 323 (Ariz.); *id.* ¶ 328 (Cal.); *id.* ¶¶ 348 (Ga.); *id.* ¶ 352 (Ill.); *id.* ¶ 357 (Neb.); *id.* ¶ 361 (Nev.); *id.* ¶ 368 (N.H.); *id.* ¶ 374 (N.M.); *id.* ¶ 381 (N.C.); *id.* ¶ 386 (N.D.); *id.* ¶ 393 (S.C.); *id.* ¶¶ 396, 398 (Utah); *id.* ¶ 403 (W. Va.).

3. Plaintiffs Cannot Circumvent *Illinois Brick* by Loosely Asserting Consumer Protection Claims Based on Antitrust Allegations

Several of Plaintiffs' consumer protection claims further fail because they are improper attempts to circumvent the *Illinois Brick* indirect purchaser bar, *supra* at page 41, by recasting their federal antitrust claims as state consumer protection claims. As the district court in *Aggrenox* observed, when dismissing consumer protection claims brought by indirect purchasers:

> The problem for the indirect purchasers is that indirect-purchaser rule of *Illinois Brick* blocks them from recovery under federal antitrust law. In an effort to get in on the *Actavis* game, they attempt to build a Frankensteinian equivalent of *Actavis* to reach the very same conduct but without that formidable obstacle, by stitching together a hodge-podge of state-law claims.

94 F. Supp. 3d at 255. For this reason, district courts often reject such claims alleged under the laws of states that have not passed full *Illinois Brick* repealers. *See, e.g.*, *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 539 (E.D. Pa. 2010) ("Because the indirect purchaser class action claims in this case would be precluded under the Illinois Antitrust Act, they cannot be brought under the ICFA instead; to allow otherwise would constitute an end run around the Illinois legislature's determination."); *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1163 (N.D. Cal. 2015) (dismissing indirect purchaser's "attempt to circumvent the *Illinois Brick* bar by reliance on the more general Alaska Consumer Protection statute.").

4. Plaintiffs' Consumer Claims Suffer From Various Pleading Defects

Finally, Plaintiffs' consumer protection claims against AbbVie contain an assortment of state-specific pleading defects requiring their dismissal. AbbVie discusses these additional defects in its Supplemental Motion to Dismiss Plaintiffs' State Consumer Protection Claims.

CONCLUSION

The Consolidated Complaint should be dismissed with prejudice in its entirety.

Dated: October 11, 2019

/s/ Thomas B. Quinn
Thomas B. Quinn
Ronald S. Safer
Sondra A. Hemeryck
RILEY SAFER HOLMES & CANCILA LLP
70 West Madison Street, Suite 2900
Chicago, Illinois 60602
Telephone: (312) 471-8700
Facsimile: (312) 471-8701

Ian Simmons (admitted *pro hac vice*)
Benjamin G. Bradshaw (admitted *pro hac vice*)
Stephen J. McIntyre (admitted *pro hac vice*)
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006
Telephone: (202) 383-5300
Facsimile: (202) 383-5414

Counsel for Defendant Samsung Bioepis Co., Ltd.

/s/ Diana M. Watral
James F. Hurst, P.C.
Diana M. Watral
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, Illinois 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

Damon C. Andrews (*pro hac vice pending*)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004
Telephone: (202) 389-5000
Facsimile: (202) 389-5200

Counsel for Defendants AbbVie Inc. and AbbVie Biotechnology Ltd

/s/ Bruce R. Braun
Bruce R. Braun
David C. Giardina
Steven J. Horowitz
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, Illinois 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

Counsel for Defendant Amgen Inc.

/s/ Stephen Weismann
Stephen Weissman (admitted *pro hac vice*)
Michael Perry (admitted *pro hac vice*)
William Lavery (admitted *pro hac vice*)
Christopher Wilson
Elisa Beneze (admitted *pro hac vice*)
BAKER BOTTS LLP
1299 Pennsylvania Avenue NW
Washington, D.C. 20004-2400
Telephone: (202) 639-7700
Facsimile: (202) 639-7890

Counsel for Defendant Sandoz, Inc.

CERTIFICATE OF SERVICE

I certify that on October 11, 2019, I filed the foregoing using the Court's electronic CM/ECF filing system. Notice of this filing will be transmitted to all counsel of record who are registered users of the Court's electronic case filing system.

/s/ Diana M. Watral
Diana M. Watral

Counsel for Defendants AbbVie Inc. and AbbVie Biotechnology Ltd