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

IN RE: HUMIRA (ADALIMUMAB) ANTITRUST LITIGATION	No. 19 CV 1873 Judge Manish S. Shah

MEMORANDUM OPINION AND ORDER

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

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

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

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

I. Legal Standards

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

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

II. Facts

A. Humira and the '382 Patent

Humira is an anti-inflammatory biologic (a drug derived from living organisms that helps slow down overactive immune systems). [109] ¶¶ 2, 32, 77.[1] Originally developed for rheumatoid arthritis, Humira is now used to treat a variety of auto-immune disorders ranging from Crohn's disease to plaque psoriasis. *Id.* ¶ 81.

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

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

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

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

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

B. The Patent System

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

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

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

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

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

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

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