No. 20-2402

IN THE

United States Court of Appeals for the Seventh Circuit

UFCW LOCAL 1500 WELFARE FUND, et al.,
Plaintiffs-Appellants,

v.

ABBVIE INC., et al.,
Defendants-Appellees.

On Appeal from the
United States District Court for the Northern District of Illinois
Honorable Manish S. Shah
No. 1:19-cv-01873

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF APPELLEES

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INTRODUCTION AND INTEREST OF THE UNITED STATES

The United States, through the Department of Justice, enforces the federal antitrust laws, and has a strong interest in their correct application in both public and private antitrust enforcement actions. This case involves the intersection of antitrust law and patent law, a topic which the United States has long studied and with which it has considerable experience.

The antitrust laws and intellectual property laws are "*in pari materia*," *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964), and "share the common purpose of promoting innovation and enhancing consumer welfare," Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 1.0 (2017) [hereinafter *IP Guidelines*]. These bodies of law promote innovation and consumer welfare "in different ways, both of importance to the nation." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999). Thus, the United States seeks to advance their consistent and correct application so that they "work in tandem to bring new and better technologies, products, and services to consumers at lower prices." U.S. Dep't of

Justice & Fed. Trade Comm'n, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* 1 (2007).

We file this brief, pursuant to Fed. R. App. P. 29(a), to advance this important interest. Plaintiffs-appellants allege that defendant-appellee AbbVie Inc. has maintained its monopoly in the market for the drug Humira by, among other conduct, filing hundreds of patent applications and thereby amassing a "patent thicket." Through this aspect of their theory, plaintiffs effectively would attach antitrust liability to the procurement of a large portfolio of patents, a result contrary to antitrust law and patent law.[1] Accordingly, in the interest of competition and innovation, the Court should exclude AbbVie's patent procurement from the alleged anticompetitive conduct when assessing the adequacy of plaintiffs' claim under Section 2 of the Sherman Act.

[1] This brief addresses the internal development of patents, not the acquisition of patents from third parties. In a number of circumstances, an acquisition of a patent(s) from a third party can give rise to antitrust concerns. *See generally* Herbert Hovenkamp et al., *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 14.03 (3rd ed. 2016) [hereinafter *IP & Antitrust*].

STATEMENT OF ISSUE

Whether patent procurement can constitute anticompetitive conduct for purposes of a private monopolization claim under Section 2 of the Sherman Act where the plaintiff has waived a *Walker Process* theory and instead claims that the patent procurement constitutes sham petitioning.

STATEMENT OF THE CASE

A. Factual and Procedural Background

1. Humira is a biologic drug used to treat a variety of autoimmune disorders. Compl. ¶ 81.[2] Before marketing a biologic, the manufacturer must obtain authorization from the Food & Drug Administration (FDA) in one of two ways. First, for a new biologic, the manufacturer submits a Biologic License Application (BLA) demonstrating that the drug is "safe, pure, and potent." Compl. ¶ 35. Second, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) permits a manufacturer of a generic or "biosimilar" drug to file an Abbreviated Biologic License Application

[2] This factual discussion is drawn from plaintiffs' complaint. Dkt. No. 109. When weighing dismissal under Fed. R. Civ. P. 12(b)(6), courts construe the complaint in the light most favorable to the plaintiff, accept well-pleaded facts as true, and draw all inferences in the plaintiff's favor. *Bell v. City of Chi.*, 835 F.3d 736, 738 (7th Cir. 2016).

(ABLA) that piggybacks on a previously filed BLA (the reference product). Compl. ¶¶ 38-39.

The BPCIA establishes a framework for resolving any claims by a biologic manufacturer that it holds patents covering the reference product. In a "patent dance," the applicant provides the ABLA and other information to the sponsor of the reference product, and the sponsor responds with a list of patents for which a claim of patent infringement could reasonably be asserted against the ABLA applicant. Compl. ¶¶ 62-63. Then, the parties exchange views on whether any of those patents are invalid, unenforceable, or would not be infringed. Compl. ¶¶ 64-65. Finally, the parties litigate any remaining patent disputes. Compl. ¶¶ 67-70.

2. Humira's active ingredient is an antibody called adalimumab. Compl. ¶ 77. In 2000, BASF AG obtained a patent for formulations of adalimumab—U.S. Patent 6,090,382 (the '382 Patent). Compl. ¶ 78. AbbVie's predecessor[3] acquired the '382 patent when it purchased BASF AG's pharmaceutical business in 2001. Compl. ¶ 79.

[3] AbbVie was spun off from Abbott Laboratories in 2013. Compl. ¶ 87.

AbbVie obtained FDA approval for Humira in 2002, and marketed it shortly thereafter. Compl. ¶ 80. Humira became one of the largest-selling drugs of all time in the United States (and worldwide). Compl. ¶ 83. According to plaintiffs, however, AbbVie faced the prospect of competition from biosimilars, which would erode its sales when the '382 patent expired in 2016. Compl. ¶ 2.

To stem this threat, plaintiffs allege, AbbVie undertook an anticompetitive scheme, including (1) pay-for-delay and market-allocation agreements with biosimilar competitors and (2) the creation of a "patent thicket." Compl. ¶ 11. Plaintiffs (end-payors of Humira) alleged that this conduct violated Sections 1 and 2 of the Sherman Act, respectively, as well as various state laws. The district court dismissed the complaint.

B. Plaintiffs' Section 2 Claim

Plaintiffs allege that AbbVie violated Section 2 by amassing and wielding a "patent thicket" to maintain its Humira monopoly. Plaintiffs seemingly have highlighted different aspects of this alleged "scheme" in the district court and on appeal. Nonetheless, AbbVie's filing of over 200

patent applications and procurement of over 100 patents appears to remain a significant part of plaintiffs' claim.

1. In their complaint, plaintiffs allege that AbbVie's "development, acquisition, and enforcement of its patent thicket . . . undertaken and executed without regard to the merits of the patents" violates Section 2 of the Sherman Act. Compl. ¶ 297. AbbVie obtained an "enormous portfolio of patents," by one estimate filing 247 patent applications and procuring 132 Humira-related patents. Compl. ¶¶ 99-100. AbbVie "sought to obtain patents regardless of their merits," and, as a result, "many of its patents do not withstand scrutiny." Compl. ¶ 107.

AbbVie nonetheless threatened protracted litigation against any applicants for a Humira biosimilar. Compl. ¶ 86. "Regardless of the ultimate merits" of AbbVie's patents, "the sheer volume of patents and claims" deterred or delayed entry of biosimilar competitors. Compl. ¶ 85. "[F]ew if any companies could litigate all of AbbVie's patents; indeed, few could even parse through the morass of patents to determine whether any were valid and infringed." *Id*.

Additionally, AbbVie asserted some patents in its portfolio against specific biosimilar manufacturers seeking FDA approval. It identified

allegedly infringed patents during patent dances, and initiated infringement litigations against biosimilar manufacturers. *E.g.*, Compl. ¶¶ 143, 150, 167-70, 181-83.

2. The district court dismissed the Section 2 claim, which the court described as premised on "a new theory of § 2 antitrust liability." A-19; *see also* A-17 (plaintiffs assert a "new kind of [Section 2] claim"). The court held that "the vast majority" of the alleged anticompetitive conduct was protected by the *Noerr-Pennington* doctrine, which protects the petitioning of the government absent special circumstances. A-31. It held that "AbbVie's conduct during the patent dances was not protected by *Noerr-Pennington*." A-29. It concluded, however, that the claim failed "because plaintiffs' theory depends on all the components of AbbVie's conduct as the means to suppress competition." A-31-32.

Additionally, the fact that the claim involved the government-created patent system was, to the court, "all the more reason to decline to recognize plaintiffs' new theory of antitrust liability." A-32. Even if AbbVie was able to exploit deficiencies in the patent system, "the proper fix is not to use antitrust doctrine to launch a collateral attack on [AbbVie's] patents, thirteen *inter partes* review determinations, multiple

patent dance exchanges and at least two patent infringement lawsuits."[4] A-32.

3. On appeal, appellants contend that "AbbVie's baseless patent assertions in the patent dance and litigation violate Section 2 of the Sherman Act." Br. 29. According to appellants, "AbbVie began filing hundreds of patent applications and ultimately obtained over 130 patents, scores of which it asserted baselessly or meritlessly against would-be competitors. AbbVie's goal was to use the sheer number of patents asserted to impose exorbitant costs on its would-be competitors." Br. 2. Appellants state that they "challenge AbbVie's applications to obtain patents as part of the unlawful scheme only if *California Motor* applies" to their claim. Br. 36 n.4.

ARGUMENT

Plaintiffs seek an unwarranted extension of Section 2 liability, endeavoring to base liability, in part, on mere patent procurement. Filing patent applications, even hundreds, can promote innovation and competition, the shared goals of patent and antitrust law. Accordingly,

[4] The district court also held that plaintiffs failed to allege antitrust injury, which provided an independent ground for dismissing the Section 2 claim. A-57-58.

to avoid chilling such procompetitive conduct, courts recognize Section 2 liability for conduct involving patent procurement only in limited circumstances.

Plaintiffs have not alleged such circumstances and have not presented a cognizable theory of liability related to AbbVie's patent procurement. They have not alleged any use of the application *process*—as opposed to the *outcome* of process—to exclude competitors, and therefore have failed to allege sham petitioning with respect to AbbVie's patent procurement. Indeed, the process costs of applying for patents fall entirely on AbbVie. Once the Patent and Trademark Office (USPTO) grants a patent, the patentee, of course, can impose costs on a competitor by asserting the patent, as AbbVie did here in patent dances and in litigation. However, imposing assertion costs is improper only in limited circumstances, e.g., sham litigation or the assertion of a patent obtained by fraud (a *Walker Process* claim). The mere fact of asserting numerous validly obtained patents is not enough to give rise to antitrust liability.

Plaintiffs have waived any *Walker Process* claim. In any event, they have not attempted to allege fraud on the USPTO with regard to the vast majority of the patent procurement. Accordingly, and in order not

to upset the Supreme Court's "suitable accommodation" of antitrust law and patent law, *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 179 (1965) (Harlan, J., concurring), and thereby discourage innovation, the Court should not consider AbbVie's patent procurement, or the mere fact of its numerous patents, as part of plaintiffs' Section 2 claim.

More broadly, the Court should decline plaintiffs' invitation to use antitrust law to redress alleged deficiencies in the patent system and the regulatory framework. As the district court correctly concluded, that is a job for Congress, not the courts.[5]

[5] The United States takes no position on whether *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), or *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993), governs plaintiffs' Section 2 claim. The United States also takes no position on whether plaintiffs have adequately alleged antitrust injury or claims under Section 1 of the Sherman Act or under state law.

I. Plaintiffs Have Failed to Allege That AbbVie's Patent Procurement Constitutes Anticompetitive Conduct

A. The Numerosity of Validly Obtained Patents Cannot Give Rise to Section 2 Liability

1. Ordinarily, "there is no limitation on a company's freedom to generate its own patents."[6] *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir. 1981). Courts therefore have concluded that "[t]he mere accumulation of patents, no matter how many, is not in and of itself illegal."[7] *Automatic Radio Mfg. Co., Inc. v. Hazeltine Rsch., Inc.*, 339 U.S. 827, 834 (1950), *rev'd on other grounds by Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

The reasons for this rule are straightforward, but critical. Put simply, "we do not wish to discourage innovation, even by monopolists."

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[6] *See also* 2 Antitrust Section, Am. Bar Ass'n, *Antitrust Law Developments* 1059 (8th ed. 2017) ("The mere procurement of a patent from the [USPTO] does not violate the antitrust laws."); 1 William C. Holmes, *Intellectual Property & Antitrust Law* § 11.1 (2019) ("numerous judicial decisions have rejected attempts to directly or indirectly challenge the internal creation and exploitation of intellectual property on antitrust grounds"); 1 Irving Scher & Scott Martin, *Antitrust Adviser* § 6:14 (5th ed. 2017) ("The acquisition of patents by internal development is not a violation of the antitrust laws even when the result is monopoly power in the relevant market.") [hereinafter *Antitrust Adviser*].

[7] As noted above, *supra* note 1, the acquisition of patents procured by a third party raises different issues.

Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and their Application* ¶ 704c (4th ed. 2015) [hereinafter *Antitrust Law*]. The prospect of a patent drives innovation, a shared goal of antitrust law and patent law. "Thus, a vigorous research program directed toward improving one's competitive position via the development of patented inventions will not by itself be grounds for antitrust challenge, even if the program ultimately results in the entity achieving a dominant or monopoly position in the field." Scher & Martin, *supra*, § 6:14.

Additionally, imposing liability for the mere accumulation of patents could have unwanted collateral consequences. The patent system is designed to facilitate the disclosure of inventions in exchange for a limited period of exclusivity. This disclosure can facilitate follow-on innovation. Imposing antitrust liability merely for filing large numbers of patent applications may cause innovators to abandon the patent system and instead rely on trade secrets to protect investment in research and development, which could hamper follow-on innovation rather than advance it. *See, e.g.*, W. Nicholson Price II & Arti K. Rai,

Manufacturing Barriers to Biologics Competition and Innovation, 101 Iowa L. Rev. 1023 (2016).

2. Relatedly, a patentee's conduct in obtaining or enforcing a patent generally is protected by the *Noerr-Pennington* doctrine. Under this doctrine, "[t]hose who petition government for redress are generally immune from antitrust liability." *Prof'l Real Estate Inv'rs., Inc. v. Columbia Pictures Indus., Inc.* (*PREI*), 508 U.S. 49, 56 (1993). A person or entity may, "without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors." *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972).

3. "But this immunity is hardly absolute." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1356 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). In particular, a patentee "may be stripped of its immunity from the antitrust laws" if it (1) institutes sham litigation or other sham petitioning to enforce a patent or (2) enforces or attempts to enforce a patent obtained by fraud on the USPTO, commonly

denominated a *Walker Process* claim. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998).

a. *Noerr-Pennington* protection does not apply if a party engages in "sham" petitioning—i.e., if a petition "is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961). "The 'sham' exception encompasses situations in which persons use the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991). "A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay." *Id.* (citing *Cal. Motor*, 404 U.S. 508). The reason liability cannot be premised on the outcome of the process (as opposed to the collateral consequences of the process) is that "'[w]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive

restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (quoting *Noerr*, 365 U.S. at 136).

In the patent context, courts have recognized the availability of antitrust liability where patent holders initiate baseless infringement lawsuits designed not to win in court but to harm competition by imposing costs and delay on competitors forced to litigate. *See, e.g.*, *FTC v. AbbVie Inc.*, 976 F.3d 327, 360-71 (3d Cir. 2020); *see generally IP Guidelines* § 6.[8]

b. The second exception to *Noerr-Pennington* protection occurs when the patent holder so corrupted the governmental process in

[8] In assessing sham-litigation claims, courts have been careful to balance the need for patentees "to test the validity of their patents in court through actions against alleged infringers" against antitrust law's goal of preventing sham claims that harm competition. *See, e.g.*, *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 993 (9th Cir, 1979); *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 849 (1st Cir. 1985). For example, *PREI*'s standard is generally consistent with lower court decisions predating *PREI* that defined antitrust liability for patent-infringement litigation (so-called *Handgards* claims) narrowly so as not to "thwart good faith efforts at patent enforcement." *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 877 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma*, 141 F.3d 1059; *Handgards*, 601 F.2d at 996 (holding "a patentee's infringement suit is presumptively in good faith and that this presumption can be rebutted only by clear and convincing evidence"); *see generally IP & Antitrust* § 11.03 (describing *PREI* as "somewhat stricter" than *Handgards*). The concerns about chilling procompetitive patent activity are even greater at the patent-prosecution stage.

obtaining the patent that the outcome is not valid. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 173 (1965), the Supreme Court held that a private plaintiff could bring a treble-damages Section 2 claim based on "the maintenance and enforcement of a patent obtained by fraud on the Patent Office."

The Supreme Court has limited *Walker Process* claims to instances of fraud and "made clear that the invalidity of the patent was not sufficient." *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012). The knowing assertion of patent procured by fraud is "very specific conduct that is clearly reprehensible," *Nobelpharma*, 141 F.3d at 1071, and recognizing Section 2 liability for such conduct "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure," *Walker Process*, 382 U.S. at 351 (Harlan, J., concurring).

Conversely, a broader standard of antitrust liability "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Nobelpharma*, 141 F.3d at 1069 (quoting *Walker Process*, 382 U.S. at 352 (Harlan, J., concurring)). Patent prosecutions "may be

portrayed as tainted conduct" with "ease," given that "in the usual course of patent prosecution many choices are made, recognizing the complexity of inventions, the virtually unlimited sources of information, and the burdens of patent examination." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1365 (Fed. Cir. 1998). In short, *Walker Process* realizes "a suitable accommodation in this area between the differing policies of the patent and antitrust laws." 382 U.S. at 351 (Harlan, J., concurring).

Walker Process sometimes is viewed as the patent-litigation version of a broader "misrepresentation" exception to *Noerr*. *See, e.g.*, Fed. Trade Comm'n Staff, *Enforcement Perspectives on the* Noerr-Pennington *Doctrine* 23 (2006); *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 842 (7th Cir. 2011). The logic of this exception is that, where government action is procured through intentional fraud, the outcome properly is attributed to the private party whose fraud procured the outcome, not the government actor who unwittingly relied on the fraudulent representation. *See, e.g*, Fed. Trade Comm'n Staff, *supra*, at 23 ("Such misrepresentations differ from traditional sham activities, such as the initiation of baseless litigation, in that the purpose of making the misrepresentations likely *is* to obtain government action.").

In and of itself, however, procuring large numbers of patents does not implicate either the sham or *Walker-Process* exception to *Noerr-Pennington* protection. It therefore follows that, without more, procuring a large portfolio of patents cannot constitute anticompetitive conduct sufficient to ground a Section 2 claim.

B. Plaintiffs Have Not Alleged That AbbVie's Patent Procurement Constituted Sham Petitioning and Have Waived Any *Walker Process* Claim

Plaintiffs have failed to allege that AbbVie's patent procurement constituted anticompetitive conduct because (1) regarding their sham-petitioning theory, they have not alleged any harm to competition from AbbVie's use of the patent-procurement *process*, (2) they waived any *Walker Process* claim, and (3) they have not identified any other viable theory for attaching antitrust liability to AbbVie's patent procurement.

1. Plaintiffs invoke two variations of the sham exception. First, under the two-part test set forth by the Supreme Court in *PREI*, a plaintiff must establish that (1) the petition was "objectively baseless" and (2) the 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." 508 U.S. at 60-61 (internal quotations, citation, and punctation omitted). Second, drawing on *California Motor*, some courts have applied a separate standard when the alleged anticompetitive conduct consists of a series of petitions, instead of a single petition. These courts ask whether the petitions were filed "not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment." *USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO*, 31 F.3d 800, 811 (9th Cir. 1994).

Under either standard, the plaintiff must establish that the defendant filed petitions "for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). For example, courts applying a separate *California Motor* standard have asked whether the petitions were filed "simply to impose expense and delay," *Primetime 24 J.V. v. Nat'l Broad. Co., Inc.*, 219 F.3d 92, 101 (2d Cir. 2000) (quoting *City of Columbia*, 499 U.S. at 380), or constituted a "policy of harassment with

the effect of obstructing [plaintiff's] access to governmental bodies," *Hanover 3201 Realty*, 806 F.3d at 182.

Plaintiffs indeed allege that AbbVie has engaged in petitioning that could impose collateral costs on generic competitors. The conduct they point to in this regard, however, occurred in a patent dance or in patent-infringement litigation. Plaintiffs attempt, unsuccessfully, to fold AbbVie's patent procurement into this theory. *See* Br. 36 n.4 ("Plaintiffs challenge AbbVie's applications to obtain patents as part of the unlawful scheme only if *California Motor* applies."). Plaintiffs, however, have no theory that AbbVie's conduct in the patent-application process imposed any collateral costs on its competitors, and for good reason.

Patent procurement cannot qualify as sham petitioning because the process before the USPTO is *ex parte* and thus cannot impose costs and delay on competitors.[9] To be sure, a successful patent application gives the patentee an exclusionary right—the patent. To the extent having

[9] The USPTO's administrative process of *inter partes* review can involve competitors that petition for review of a patent. *See, e.g.*, Compl. ¶¶ 73-75, 108. However, that is not the applicant interfering with the business of a competitor, but rather the competitor seeking redress from the USPTO.

that patent can be said to harm competition, however, that exclusion arises through "the *outcome* of that process"—not through "use [of] the governmental *process*" itself—and thus cannot qualify for the sham exception to *Noerr*.[10] *City of Columbia*, 499 U.S. at 380.

2. Plaintiffs have waived any *Walker Process* claim. Dkt. 149 at 11 n.4 (Pls.' Opp'n Mot. Dismiss) ("the plaintiffs have not asserted a *Walker Process* claim"). In any event, plaintiffs attempt to allege fraud only in regard to a handful of AbbVie's patent applications. Compl. ¶¶ 114-120. Thus, their attempt to ground their Section 2 claim in part on patent procurement must fail.

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[10] A district court has held that plaintiffs sufficiently alleged that patent prosecution was sham petitioning where the defendant allegedly manipulated the process in order to delay issuance of a patent and thereby obtain a second 30-month stay of FDA approval under the Hatch-Waxman Act. Specifically, the defendant allegedly deliberately omitted information from a patent application, withdrew that application on that basis after the application had been approved, and filed "unnecessary" and unsuccessful continuation applications. *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *4, *19 (D.N.J. Aug. 28, 2009); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 345 n.8, 366 (D.N.J. 2009). Even if the court reached the correct result, plaintiffs' allegations are still insufficient to establish that AbbVie's patent applications were shams. The BCPIA does not provide for a 30-month stay, and plaintiffs have not alleged any analogous anticompetitive use of the process. Additionally, plaintiffs have not alleged that AbbVie filed any particular patent application to impose collateral costs on competitors rather than to obtain a patent.

This Court should not allow plaintiffs to circumvent *Walker Process*'s appropriately high bar for liability simply by denominating their challenge to the patent procurement sham petitioning. If a private plaintiff could allege non-fraudulent patent procurement as anticompetitive conduct simply through artful pleading, it would disturb the "accommodation" the *Walker Process* Court achieved. *Walker Process*, 382 U.S. at 351 (Harlan, J., concurring). The patent laws foster innovation by rewarding inventors with a limited period of exclusivity and by encouraging public disclosure of inventions. Expansive antitrust liability for patent procurement could discourage good-faith patenting, a result that would undermine innovation and competition and a result at loggerheads with patent law and antitrust law. *Cf. Loctite Corp.*, 781 F.2d at 877 (relying on "the public policy of erecting a barrier against thwarting patentees from asserting legitimate patent rights").

Accordingly, the Court should not consider the impact of AbbVie's patent procurement in assessing whether AbbVie's conduct had anticompetitive effect. *Mercatus Grp.*, 641 F.3d at 839 (the Court will not "aggregate the effects of conduct immunized from antitrust liability with the effects of conduct not so immunized"). Additionally, the Court should

not look to the numerosity of AbbVie's validly obtained patents in determining whether AbbVie engaged in a pattern of petitioning sufficient to justify application of a *California Motor* standard. For the same reason that a single patent application does not impose process costs on competitors, nor do multiple patent applications. Once granted, AbbVie can impose process costs on competitors by asserting the patents, but the focus of the pattern question should be on whether AbbVie's assertion of each of its distinct patent rights imposed process costs on competitors. The United States does not express an opinion on the sufficiency of the allegations to establish any *California Motors* claim here.

II. The Court Should Disregard Plaintiffs' Critique of the Patent System and the Regulatory Framework

The Court should decline plaintiffs' invitation to deploy Section 2 to address alleged deficiencies in the patent system and the regulatory framework. Plaintiffs suggest that the patent system allows a patentee to acquire too many patents, which stalls competition. *See, e.g.*, Compl. ¶ 297; Dkt. 149 at 18-19 (arguing that "[c]ourts have addressed the dangers inherent in vast accumulations of patents" and that "[l]arge

accumulations of patents are subject to special scrutiny"). This states a critique of the patent system, not a Section 2 violation.

Plaintiffs contend that AbbVie has exploited deficiencies in the patent system by filing "a seemingly never-ending series of continuation applications of the Humira-related patent applications," resulting in patents that should have never been issued. Compl. ¶ 100. Continuation applications are common, however, and any resulting patent expires 20 years from the date on which the earliest such application was filed, and thus does not extend beyond the term of the original patent. 35 U.S.C. § 154(a)(2); *see also Antitrust Law* ¶ 704b4 ("the pursuit of patent continuations is protected conduct"). Further, as the district court noted, there are rules in place to ensure that obvious variations on an invention would expire with the original patent. A-6. It is also possible that further research leads to innovation, such as improving potency of a drug.

Even assuming that plaintiffs are correct that the continuation process is flawed and AbbVie benefitted, "the antitrust laws were not designed to repair other government regulatory processes, but rather to take these processes as given and strive to further competition consistent with their mandates." *Id.* As the district court correctly stated, perceived

deficiencies in the patent system or the regulatory framework should not be remedied by antitrust law. A-32. Indeed, the patent system itself includes numerous correction mechanisms that tend to discourage abuse of this system. For example, patents can be reevaluated in reexamination and administrative-review proceedings, and accused infringers always have defenses of invalidity, unenforceability, prosecution laches, and undue multiplicity at their disposal. *See, e.g.*, 35 U.S.C. §§ 282(b), 302, 314, 321.

Plaintiffs point out that members of Congress have been critical of AbbVie's conduct and that there are legislative proposals to address perceived deficiencies in the system. Compl. ¶¶ 214-233. If, indeed, reforms to the BPCIA are needed, then Congress can act. The district court properly declined to expand the contours of antitrust law to serve as an alternative remedy. A-32-22. Expanding Section 2 liability beyond the well-established boundaries of antitrust law, while Congress considers changes to the current regulatory framework, would usurp legislative prerogative.

CONCLUSION

Patent procurement, as alleged by plaintiffs, does not constitute anticompetitive conduct, and the Court should affirm the dismissal of plaintiffs' Section 2 claim to the extent that it relies on patent procurement.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(a)(4)(G) and Fed. R. App. P. 32(g)(1), I certify that this brief complies with the type-volume limitation of Circuit Rule 29 and Fed. R. App. P. 32(a)(7)(B) because, excluding the parts exempted by Fed. R. App. P. 32(f), this brief contains 4,967 words.

I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and Circuit Rule 32(b) and the type-style requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in Microsoft Word 2019 using 14-point New Century Schoolbook font, a proportionally spaced typeface.

December 28, 2020

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CERTIFICATE OF SERVICE

I certify that on December 28, 2020, I caused the foregoing to be filed through this Court's CM/ECF filer system, which will serve a notice of electronic filing on all registered users, including counsel of record for all parties.

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