UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2020

(Argued: April 7, 2021 | Decided: August 25, 2021)

Docket No. 20-1994-cv

UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated, PLUMBERS & PIPEFITTERS LOCAL 178 HEALTH & WELFARE TRUST FUND, 199 SEIU-NATIONAL BENEFIT FUND, FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, CROSBY TUGS, LLC, INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 132 HEALTH AND WELFARE FUND, A.F. OF L. - A.G.C. BUILDINGS TRADE WELFARE PLAN, individually and on behalf of all others similarly situated, PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, Individually and on Behalf of All Others Similarly Situated, NECA-IBEW WELFARE TRUST FUND, individually and on behalf of all others similarly situated, CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of all others similarly situated, MINNESOTA AND NORTH DAKOTA BRICKLAYERS AND ALLIED CRAFTWORKERS HEALTH FUND, on behalf of themselves and all others similarly situated, GREATER METROPOLITAN HOTEL EMPLOYERS-EMPLOYEES HEALTH AND WELFARE FUND, on behalf of themselves and all other similarly situated, LOCAL 17 HOSPITALITY BENEFIT FUND, on behalf of itself and all others similarly situated, NEW ENGLAND ELECTRICAL WORKERS BENEFIT FUND, Individually and on behalf of all others similarly situated, DENNIS KREISH, on behalf of himself and all others similarly situated, MAN-U SERVICE CONTRACT TRUST FUND, on behalf of themselves and all others similarly situated, TEAMSTERS UNION LOCAL 115 HEALTH & WELFARE FUND, on behalf of themselves and all others similarly situated,

Plaintiffs-Appellees,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA AMERICA HOLDINGS, INC., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC.,

Defendants-Appellants.[†]

Docket No. 20-2002-cv

MEIJER, INC., MEIJER DISTRIBUTION, INC., CESAR CASTILLO, INC., Individually and on behalf of all those similarly situated,

Plaintiffs-Appellees,

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated,

Plaintiff,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA AMERICA HOLDINGS, INC., TAKEDA PHARMACEUTICALS, U.S.A., INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC.,

Defendants-Appellants.

[†] The Clerk of the Court is directed to amend the official caption as set forth above. Of note, the docket sheet currently lists the Takeda entities as "plaintiff[s]-appellant[s]," which is likely a consequence of their having initially petitioned this Court to hear an interlocutory appeal. However, because the Takeda entities were defendants below, they should remain so in the merits appeal. *See* Fed. R. App. P. 12(a).

Before:

LIVINGSTON, *Chief Judge*, WESLEY, CARNEY, *Circuit Judges*.

Purchasers of brand diabetes drug ACTOS brought suit against the manufacturer ("Takeda") for improperly describing its patents to the Food and Drug Administration, in effect extending the duration of its patent protection over ACTOS and delaying generic competition. The district court denied Takeda's motion to dismiss, concluding that the alleged patent descriptions were incorrect under the Hatch–Waxman Act and pertinent regulations. On this interlocutory appeal, we hold that under the "Listing Requirement" of 21 U.S.C. § 355(b)(1), a combination patent does not "claim" any of its component drug substances past their individual patent expiration dates. We further hold that the purchasers were not required to allege that Takeda's interpretation of the Listing Requirement was unreasonable in order to plead a monopolization claim under the Sherman Act. **AFFIRMED** and **REMANDED**.

STEVEN A. REED, Morgan, Lewis & Bockius LLP, Philadelphia, PA (R. Brandan Fee, Morgan, Lewis & Bockius LLP, Philadelphia, PA; Scott A. Stempel, Morgan, Lewis & Bockius LLP, Washington, DC; Alexander J. Scolnik, Morgan, Lewis & Bockius LLP, New York, NY, *on the brief*) *for Defendants-Appellants*.

STEVE D. SHADOWEN, Hilliard & Shadowen LLP, Austin, TX (Jayne A. Goldstein, Shepherd Finkelman Miller & Shah LLP, Ft. Lauderdale, FL; Kenneth A. Wexler, Wexler Wallace LLP, Chicago, IL; Michael M. Buchman, Motley Rice LLC, New York, NY, *on the brief*), *for Plaintiffs-Appellees* United Food and Commercial Workers Local 1776 et al.

THOMAS SOBOL, Hagens Berman Sobol Shapiro LLP, Cambridge, MA (Gregory T. Arnold, Hagens Berman Sobol Shapiro LLP, Cambridge, MA; Linda P. Nussbaum, Nussbaum Law Group,

P.C., New York, NY, *on the brief*), *for Plaintiffs-Appellees* Meijer, Inc. et al.

WESLEY, *Circuit Judge*:

Defendants-Appellants in these tandem cases (collectively, "Takeda") are a brand pharmaceutical manufacturer and related entities that began producing and marketing the Type-2 diabetes drug ACTOS in 1999. To lawfully market ACTOS, Takeda obtained the patent rights for pioglitazone hydrochloride ("pioglitazone"), the lone active ingredient in the drug. The pioglitazone patent expired on January 17, 2011. Takeda also secured rights to two patents that combined pioglitazone with other substances, yielding novel synergies that ACTOS alone did not offer. These "combination patents" both expired in June 2016.

On November 5, 1999, and January 3, 2002, in applications submitted to the Food and Drug Administration ("FDA"), Takeda described the combination patents as "claiming" the drug ACTOS. Those representations triggered a series of procedural safeguards under the Hatch–Waxman Act regarding the production of ACTOS-based drugs. Most fundamentally, they delayed the ability of generic drug manufacturers to offer consumers cheaper bioequivalent alternatives to ACTOS and thereby compete with Takada.

Plaintiffs-Appellees purchased ACTOS between January 2011 (when the pioglitazone patent expired) and February 2013 (when substantial generic competition began). They allege that during this period, Takeda sold ACTOS at monopolistic prices under the patent protection secured by mischaracterizing the scope of the combination patents to the FDA. Takeda responds that its characterization was proper and, even if not, it was made pursuant to a reasonable interpretation of the relevant statutes and regulations.

We hold that under the "Listing Requirement" of 21 U.S.C. § 355(b)(1), a combination patent does not "claim" any of its component substances past their individual patent expiration dates. We further hold that the purchasers were not required to allege that Takeda's interpretation of the Listing Requirement was unreasonable in order to plead a monopolization claim under the Sherman Act. We therefore affirm the district court's denial of Takeda's motion to dismiss and remand for further proceedings consistent with this opinion.

BACKGROUND[1]

I. The Hatch–Waxman Act and the Listing Requirement

[1] Citations to "App'x" refer to the Appendix, citations to "Supp. App'x" refer to Plaintiffs-Appellees' Supplemental Appendix, and citations to "S.A." refer to the Special Appendix.

As explained in a prior appeal, "[a]lthough the violations of which plaintiffs ultimately complain are antitrust violations, they occur in the context of the pharmaceutical regulatory scheme governed by the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (the 'Hatch–Waxman Act'), and various rules promulgated thereunder." *In re Actos End-Payor Antitrust Litigation*, 848 F.3d 89, 93 (2d Cir. 2017). Thus, an overview of the relevant statutory framework may be helpful.

Under the Federal Food, Drug, and Cosmetic Act, brand-name drug manufacturers must obtain FDA approval to sell a new drug. 21 U.S.C. §§ 301–399. To do so, a manufacturer needs to file a New Drug Application ("NDA"), which includes among other information "a full list of the articles used as components of such drug" and "a full statement of the composition of such drug." 21 U.S.C. § 355(b)(1). If the new drug either is or contains a patented substance, the pharmaceutical company that owns the patent enjoys market exclusivity for the drug co-extensive with the patent's protection.

Meanwhile, the Hatch–Waxman Act "simplifie[s] the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy

and costly NDAs." App'x 105 (citing Pub. L. No. 98-417, 98 Stat. 1585 (1984)). As a result, generic manufacturers need only file an Abbreviated New Drug Application ("ANDA"), which allows the applicant to rely on the FDA's previous safety and effectiveness findings for the brand drug they wish to replicate and bring to market. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). Still, generics are prohibited from infringing the brand's patents; when a generic competitor submits an ANDA, it must provide a "certification" with respect to each unexpired patent related to the brand drug's production. The certification alerts the FDA to the relevant patent and explains why the proposed generic would not infringe it.

The Hatch–Waxman Act envisions two types of certifications, each providing a separate regulatory route for the production of a generic drug despite a brand pharmaceutical company's patent related to the drug. The first is commonly referred to as a "Paragraph IV" certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This certification states that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." *Id.* The second is a "section viii" certification. 21 U.S.C. § 355(j)(2)(A)(viii). A section viii certification is appropriate where the generic company seeks only to market an unpatented *method* of using a substance in the public domain and certifies that it

will "carve out" patented methods from its drug's production and labeled uses. *Id.*; *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, ---F.4th----, 2021 WL 3412496, at *18 (Fed. Cir. Aug. 5, 2021) (Prost, *J.*, dissenting).

Relevant to this case, Paragraph IV certifications activate powerful rights and restrictions on behalf of the patent-holding company. As an initial matter, it triggers a "highly artificial act of infringement," permitting the brand manufacturer to sue the ANDA applicant. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). If the brand chooses to sue, the FDA is automatically prevented from approving the ANDA for the earlier of thirty months or the outcome of the litigation. The wait may be worth it, however, because the statute awards a 180-day period of market exclusivity to the first generic Paragraph IV ANDA applicant who is either not sued or who proves the patent invalid or not infringed by the generic. The exclusivity period begins to run "after the date of the first commercial marketing of the drug" by that generic applicant. 21 U.S.C. § 355(j)(5)(B)(iv). This imposed delay oftentimes creates a bottleneck effect of generic competitors who are ready and willing—but legally unable—to enter the market.

The consequences of filing a section viii certification, on the other hand, are much less dramatic. The process entails neither a 30-month litigation stay nor a

180-day exclusivity period. Thus, a generic manufacturer that files a section viii certification can more easily enter the market without delay.

Whether the generic manufacturer files a Paragraph IV certification or a section viii certification depends on *how* the brand drug manufacturer identifies the object patent(s) to the FDA. During the period relevant to this case, the specific language that a brand looked to in making this decision was found in the Hatch–Waxman Act's so-called "Listing Requirement" of 21 U.S.C. § 355(b)(1).[2] In relevant part, that section provided:

> The applicant shall file with the application the patent number and the expiration date of any patent *which claims the drug* for which the applicant submitted the application or *which claims a method of using such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. (emphases added). Related to the statutory Listing Requirement, an FDA regulation provides:

> An applicant . . . must submit to its NDA the required information . . . for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably

[2] As discussed below, Congress recently amended this statute to clarify its meaning. Because the events of this case transpired while the previous version of the statute was in effect, we will deal primarily with that formulation. In any event, the changes in the statute would not have led us to a different outcome even had that language been in effect during the relevant period.

> be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.
> …
>
> > *For patents that claim a drug product*, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA.
> >
> > *For patents that claim a method of use*, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA. The applicant must separately identify each pending or approved method of use and related patent claim(s).

21 C.F.R. § 314.53(b)(1) (reformatted and emphases added).

If the brand manufacturer lists the patent as claiming the drug itself, a generic manufacturer must make a Paragraph IV certification asserting that the patent is invalid, expired, or otherwise will not be infringed by the generic version. For if the patent at issue is valid and current (and actually *claims the drug*), there is no way to produce a bioequivalent generic without infringing the patent. But if the brand manufacturer lists the patent as claiming a method of using the drug, the section viii certification affords the generic manufacturer an avenue to

immediately produce its proposed drug provided only that the generic does so in a manner different from the patented method.

Because the FDA "lacks both the expertise and the authority to review patent claims," rendering "its own role with respect to patent listing ministerial," it does not "independently assess the patent's scope or otherwise look behind the description authored by the brand." *Caraco Pharm Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406–07 (2012) (internal quotation marks omitted). The use of improper designations during this process "therefore throws a wrench into the FDA's ability to approve generic drugs." *Id.* at 419.

II. Factual Background[3]

In 1999, the FDA approved Takeda's Type-2 Diabetes drug ACTOS, a treatment tablet containing only one active ingredient—pioglitazone. In its NDA for ACTOS, Takeda listed U.S. Patent 4,687,777 (the "'777 Patent"), which "consisted of pioglitazone and its pharmacologically acceptable salts," as claiming the drug ACTOS. Direct Purchasers Br. at 16 (citing App'x 115).[4] The '777 Patent was set to expire on January 17, 2011, and, in 2007, the Federal Circuit upheld the

[3] As alleged in the complaint and supplemented by the parties' briefs.

[4] The '777 Patent was originally "issued to inventors Kanji Meguro and Takeshi Fujita on August 18, 1987"; they later assigned it to Takeda. App'x 115.

patent's validity, thus definitively preventing generic entry into the pioglitazone market until after that expiration date. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

Takeda twice supplemented its NDA—in 1999 and 2002—with information about newly-acquired patents: U.S. Patents 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent"), respectively. Both patents, each set to expire in 2016, cover unique compounds containing pioglitazone *and* another active ingredient that, together, yield novel synergies not offered by pioglitazone alone. Specifically, the '584 and '404 Patents are "[p]harmaceutical composition[s] which comprise[] an insulin sensitivity enhancer[5] in combination with other antidiabetics . . . which shows a potent depressive effect on diabetic hyperglycemia[6]." Supp. App'x 89, 106 (footnotes our own). Because they are amalgams of separately identifiable constituent parts, both '584 and '404 are properly called "combination patents." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961).

[5] *I.e.*, pioglitazone.

[6] *I.e.*, high blood sugar. *Hyperglycemia (High Blood Sugar)*, CLEVELAND CLINIC (Aug. 4, 2021), https://my.clevelandclinic.org/health/diseases/9815-hyperglycemia-high-blood-sugar.

In its supplements for the ACTOS NDA, Takeda told the FDA that these combination patents both *claim the drug* ACTOS in addition to *claiming methods of using* ACTOS. Under normal circumstances, this would have compelled generic drug makers seeking to compete in the ACTOS market to file Paragraph IV certifications because one would have to undermine the validity of the '584 and '404 patents for the FDA to grant the ANDA.[7] Complicating matters in this case, however, when the FDA published Takeda's supplemental patent information in its Orange Book—the "go-to source of brand patent information"—it listed the '584 and '404 Patents only as method-of-use patents.[8] *In re Actos End-Payor Antitrust Litigation*, 848 F.3d at 98–99. Presumably, then, there was no reason at that time for a generic ACTOS maker to believe that a Paragraph IV certification was required for FDA approval.

---

[7] That course being necessary because once a brand indicates that its patent claims the drug itself, only a showing that the patent is expired, invalid, or does not actually claim the drug will permit the FDA to approve the generic's ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[8] This was not a one-off mistake but rather the result of a "significant flaw" in the FDA's standard Orange Book procedure. *In re Actos End-Payor Antitrust Litigation*, 848 F.3d at 98. Until August 2003, the Orange Book "could reflect only one description (*i.e.*, drug substance, drug product, or method of use) per patent. If a brand indicated that a patent claimed both a method of using a drug and the drug product itself, the Orange Book would only list it as a method-of-use patent." *Id.* at 98–99.

Nevertheless, in 2003, three generic manufacturers[9] seeking to introduce a bioequivalent pioglitazone drug filed ANDAs containing Paragraph IV certifications with respect to patents '584 and '404. These companies agreed to share "first filer" status for purposes of the exclusivity period in marketing a generic version of ACTOS. Although their motivations for making this unnecessary certification remain unconfirmed, the competitive advantage from being a first filer under Paragraph IV for a generic ACTOS drug certainly provided a valuable incentive for doing so. Takeda thereafter sued the three generics for patent infringement. After a trial, the district court entered judgment for Takeda solely based on the '777 Patent's continuing validity and enforceability but did not address the validity or enforceability of the combination patents. *Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, No. 03-cv-8250, 2006 WL 618424, at *1–2 (S.D.N.Y. Mar. 13, 2006).

Other generics, however, "refused to make paragraph IV certifications to the purported drug product claims and instead addressed only the method-of-use claims using section viii statements." Direct Purchasers Br. at 19; App'x 237. For example, Teva Pharmaceuticals filed a section viii certification in July 2004, hoping

[9] Mylan Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., and Ranbaxy Laboratories, Inc.

that doing so would permit it to manufacture a non-infringing generic ACTOS "without regard to any 180-day exclusivity [period]." App'x 237. This would have allowed Teva to "come to market immediately upon the '777 patent's expiration, while the [Paragraph IV] certification filers would have to wait." Direct Purchasers Br. at 19.

Yet another generic drug manufacturer, Sandoz, Inc., filed a "citizen petition" with the FDA, asserting that Takeda had "improperly caused the FDA to list the '584 and '404 patents in the Orange Book as drug product patents for ACTOS."[10] App'x 224. It therefore asked that the FDA require all ANDA filers to make Paragraph IV certifications in order to level the playing field among generics. At the FDA's behest, Takeda responded to the petition by reaffirming that it correctly listed the two patents as claiming both ACTOS as well as specific methods of its use. In light of Takeda's response, the FDA granted Sandoz, Inc.'s

[10] This accusation appears to be incorrect considering the Orange Book's limitations during the relevant period. *See* footnote 7 above. In fact, the FDA listed the '584 and '404 Patents *only* as claiming methods of using ACTOS despite Takeda identifying them as also claiming the ACTOS drug itself. Nevertheless, the citizen petition's claim may have just inartfully reflected the fact that Takeda had elsewhere represented that those patents claimed ACTOS.

citizen petition and ruled that it would not approve a generic ACTOS ANDA that did not contain a Paragraph IV certification.[11]

Plaintiffs-Appellees allege that, as a result of these events, "robust generic competition for Actos" was improperly delayed for almost two years past January 17, 2011, when the '777 Patent expired. Direct Purchasers Br. at 22.

III. Procedural History

The instant appeal addresses two cases brought in the Southern District of New York by separate plaintiff groups—the "End Payors" and the "Direct Purchasers" of ACTOS. Both plaintiff groups initially alleged that Takeda inhibited competition by means of its representations in the ACTOS NDA. *See In re Actos End-Payor Antitrust Litigation*, 848 F.3d at 92. On Takeda's first 12(b)(6) motion, the district court (Abrams, *J.*) dismissed all monopolization claims brought by the End Payors, reasoning that "plaintiffs failed to identify a viable regulatory route for generic drug approval that would have avoided the 180-day bottleneck, and that even if they had, they failed to plausibly allege how the generic manufacturers would have avoided Takeda's infringement lawsuits, all of which were voluntarily settled." *Id.* at 93. The district court's reasoning was

[11] Recall that the FDA's role in Orange Book listings is purely ministerial and depends predominantly on the brand's representations.

largely directed at the fact that "the 584 and 404 patents were properly listed in the Orange Book by Takeda as claiming methods of using ACTOS." *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *21–22. "Accordingly," it concluded, "each ANDA filer would have been required to submit an appropriate certification for those patents" anyway. *Id.* at *22.

On a previous appeal, this Court affirmed that dismissal in part, but adopted an alternative theory for why causation was lacking. *In re Actos End-Payor Antitrust Litig.*, 848 F.3d at 98–99. That panel reasoned that the Orange Book wrongly reflected that Takeda identified the '584 and '404 Patents *only* as method-of-use patents, severing the link between (a) the assertion in Takeda's NDA that those patents also claimed ACTOS and (b) the generics' decision to go down the Paragraph IV path. Because the complaint contained "no allegations from which we [could] infer that the generics were aware of the alleged false patent descriptions," the claims derived from the delay of those generics' entry into the pioglitazone market had to be dismissed. *Id.* at 99.

That was not the case for Teva Pharmaceuticals, however. As discussed above, Teva initially refused to make Paragraph IV certifications and ultimately capitulated only *after* Takeda responded to Sandoz, Inc.'s citizen petition. We

concluded that this order of events made it "highly plausible" that Takeda's later representation caused Teva's delayed entry into the generic ACTOS market. *Id.* at 100 ("A plaintiff could hardly ask for a clearer causal connection.").

Upon remand, both the End Payors and the Direct Purchasers (who had been closely following the End-Payor appeal) amended their complaints to their present form. Takeda separately moved to dismiss both, arguing that its listing of the '584 and '404 Patents as claiming ACTOS was proper and, even if not, was based on a reasonable interpretation of the Hatch–Waxman Act, which should shield Takeda from antitrust liability.

The district court analyzed the End Payors' case first. After confirming that Takeda had market power, it observed that the antitrust claim "turns on whether [Takeda] willfully sought to maintain . . . [its] monopoly in violation of § 2" of the Sherman Act. *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 361 (S.D.N.Y. 2019) (internal quotation marks omitted). That question, in turn, depended upon whether "the [Listing] provision requires an NDA applicant for a drug made up of a single active compound, like ACTOS, to *describe patents containing claims directed to compositions of the active compound, in combination with other active compounds, as 'drug product' patents.*" *Id.* (emphasis added).

Takeda argued that such drug-product claims were proper so long as (1) the listed patent "include[s] at least a component" of the NDA drug, and (2) one could reasonably anticipate that the unauthorized sale of the NDA drug would infringe that claim. *Id.* at 362–63. Therefore, according to Takeda, because a component of both '584 and '404 is pioglitazone (the active ingredient in ACTOS), and the unauthorized production of ACTOS could reasonably infringe those patents "[s]ince the label for ACTOS encourages" its ingestion in conjunction with metformin or insulin (functionally creating the compounds protected by '584 and '404), those patents are properly listed as *claiming the drug* ACTOS. *Id.*

The district court rejected Takeda's theory. In parsing the language of 21 U.S.C. § 355(b)(1), the court concluded that there were multiple meanings of the word "claims" in effect:

> The applicant shall file with the application the patent number and the expiration date of any patent which [1] *claims* the drug for which the applicant submitted the application or which [2(a)] *claims* a method of using such drug and with respect to which a [2(b)] *claim* of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

(emphases and bracketed numbers added). According to the court, then, "the plain meaning of 'claims' in § 355(b)(1) applies in the phrase 'claims the drug,' but

the infringement meaning of 'claims' applies in the phrase 'claims a method of using such drug.'" *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d at 369. This interpretation largely followed from the court's belief that the phrase "with respect to which a claim of patent infringement could reasonably be asserted" (*i.e.*, the "Infringement Clause") was relevant only to method-of-use claims and not to drug-product claims. *Id.* Thus, because the combination patents did not "claim the drug" ACTOS in the plain-meaning sense—which is to say that neither '584 nor '404 protects any standalone inventions that are contained within or "read on" ACTOS—Takeda's contrary response was improper under the Listing Requirement. *Id.* at 363, 365–66, 369. Finally, the court determined that the End Payors need not allege bad faith to state a claim under § 2 of the Sherman Act.[12]

The district court subsequently applied the same reasoning to deny Takeda's motion to dismiss the Direct Purchasers' complaint. *In re Actos Direct Purchaser Antitrust Litig.*, 414 F. Supp. 3d 635, 642 (S.D.N.Y 2019) ("For the reasons

[12] Not at issue in this appeal, the district court also permitted Plaintiffs-Appellees to extend the Teva causation theory we endorsed in our prior decision to the non-Teva generics, thereby reviving an additional route for Takeda's antitrust liability. The rationale for that ruling was that the complaints had "plausibly allege[d] that the non-Teva generics would have withdrawn their Paragraph IV certifications as to the patents' drug product claims" had Takeda told the FDA that the patents were improperly listed in the NDA as claiming ACTOS as a drug product. *Id.* at 375.

provided in *End Payor III*, [the Direct Purchasers] have plausibly alleged that Takeda's January 2010 statements to the FDA, in response to the Sandoz Citizen Petition, constituted anti-competitive conduct.").

We granted Takeda's petition for interlocutory appeal of those decisions pursuant to 28 U.S.C. § 1292(b).

DISCUSSION

Takeda argues that the district court erred in two respects: first, that its interpretation of the Listing Requirement was incorrect; second, that it was wrong not to dismiss Plaintiffs-Appellees' monopolization claims when their complaints contained no allegations that Takeda's interpretation of the Listing Requirement was unreasonable. These are both issues of law that we review *de novo*. *See Simmons v. Roundup Funding, LLC*, 622 F.3d 93, 95 (2d Cir. 2010).

I. Listing Requirement

A long line of Supreme Court case law confirms that a combination patent, in general, does not "claim" its constituent parts. In *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 664 (1944), the owner of a combination patent "covering a domestic heating system which comprises three main elements—a motor driven stoker . . . a room thermostat . . . and a combustion stoker switch," sued Mercoid for the unlicensed manufacture and sale of combustion stoker switches for use in

the patented heating system. *Id.* It was undisputed that there was "no use for the accused devices other than in the . . . combination patent." *Id.* Nevertheless, the Court held that "[t]he patent is for a combination only . . . [and] [s]ince none of the separate elements of the combination is claimed as *the invention*, none of them when dealt with separately is protected by the patent monopoly." *Id.* at 667 (emphasis added). Notably, the fact that "the combustion stoker switch [was] the 'heart of the invention'" was of no consequence in deciding the case. *Id.*

Seventeen years later, in *Aro Mfg. Co.*, 365 U.S. at 337–39, the Court reaffirmed the *Mercoid Corp.* principle in a case that saw the owner of a combination patent for a "Convertible Folding Top with Automatic Seal at Rear Quarter" bring an infringement suit against a company that made and sold replacement fabrics for the convertible tops. The Court rejected the patent owner's contention that the "'essentialness' of the fabric element to the combination" rendered it separately protected. *Id.* at 344. Instead, it concluded that "the fabric is no more than an unpatented element of the combination which was claimed as the invention, and the patent did not confer a monopoly over the fabric or its shape." *Id.* at 339–40. *Cf. Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920–22 (2014) (holding that because a "method patent . . . is not infringed

unless all the steps are carried out," a competitor did not induce direct infringement of a method patent merely by "carr[ying] out some steps constituting a method patent and encourag[ing] others to carry out the remaining steps").

At first blush, then, we can be reasonably certain that Takeda's '584 and '404 combination patents do not provide any protection over the standalone drug substance pioglitazone or drug product ACTOS. Pioglitazone is but a single active chemical among the several that comprise those patents, analogous to a stoker switch in a heating system or the fabric of a convertible car top. Although *Aro Mfg.* and *Mercoid Corp.* both dealt with components that were themselves unpatented (unlike pioglitazone), we perceive no difference in the analysis here considering that once the pioglitazone patent expired in 2011, it became eligible for generic production.

The plain meaning of the word "claims"—as in "*claims* the drug"—supports this result as well. "Claim" is a term of art "peculiar to patent law." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996). For a patent to "claim" something means that the "patentee is entitled the right to exclude" that thing's unauthorized production. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115–16 (Fed. Cir. 2004). A claim "functions to forbid not only exact

copies of an invention, but products that go to the heart of an invention but avoid[] the literal language of the claim by making a noncritical change." *Markman*, 517 U.S. at 373–74 (internal quotation marks omitted).

As a definitional matter, patent claims "are the numbered paragraphs which 'particularly point out and distinctly claim the subject matter which the applicant regards as his invention.'" *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989) (quoting 35 U.S.C. § 112 (alterations omitted)). "The words of the claims themselves define the scope of the invention, and are given their ordinary and customary meaning, unless the patentee has chosen to use terms in some other manner." *Allen Engineering Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1344 (Fed. Cir. 2002). The nuanced description of each claim amounts to "a series of limiting words or phrases (limitations)" that establish the "metes and bounds of the right which the patent confers." *Corning Glass Works*, 868 F.2d at 1257–58. By extension, a patent "claims" an invention "when each of the claim limitations 'reads on,' or in other words is found in," the invention. *Allen Engineering Corp.*, 299 F.3d at 1345; *see also Corning Glass Works*, 868 F.2d at 1258 ("In the determination of infringement, the words of the claim must . . . be 'read

on' the accused structure to determine whether each of the limitations recited in the claim is present in the accused structure." (internal citation omitted)).

Applying these concepts to the pharmaceutical context, the Federal Circuit has previously held that the patent for 1–hydroxy–tacrine did not claim a tacrine hydrochloride-based drug even though tacrine hydrochloride metabolizes into 1–hydroxy–tacrine after ingestion. *See Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 757, 759 (Fed. Cir. 1997). Therefore, although Hoechst, the patent owner, may have been "entitled to exclude others from administering tacrine hydrochloride" under a method-of-use framework,[13] "this right to exclude would not arise from the fact that Hoechst ha[d] claimed tacrine hydrochloride." *Id.* at 759 & n.4.

And in *Apotex, Inc. v. Thompson*, the Federal Circuit reaffirmed that to "claim[] the drug for which the NDA was submitted" means that "a patent must be listed if it *contains a product claim that reads on the drug that is the subject of the NDA* . . . ." 347 F.3d 1335, 1343–44 (Fed. Cir. 2003) (emphasis added). This is

[13] As the court in that case noted, such a method-of-use theory would be rather attenuated considering "Hoechst's '286 patent . . . claim[ed] a method of using 1–hydroxy–tacrine rather than a method of using tacrine hydrochloride." *Hoechst-Roussel Pharms., Inc.*, 109 F.3d at 759 n.4.

precisely how the court below interpreted the phrase "claims the drug" in evaluating Plaintiffs-Appellees' complaints. Because the relevant claims in the '584 and '404 Patents are broader than and different from the scope of ACTOS, the district court determined that those claims do not "read on"—and thus do not claim—that drug.[14] We agree.

Takeda nonetheless maintains that the Hatch–Waxman Act permitted (in fact, required) it to list the '584 and '404 Patents as claiming ACTOS for Orange Book purposes. The primary bases for its contention are that: (1) because those combination patents "could be infringed by an unauthorized generic version of Actos," Takeda Br. at 13, they necessarily claim ACTOS; (2) the Infringement Clause applies to *both* instances of the word "claims" in the Listing Requirement and therefore, to avoid redundancy, "claims the drug" must mean something other than "reads on the drug," which phrase entails the same consequences as the

[14] There is no dispute that ACTOS is properly considered a "drug" under 21 U.S.C. § 355(b)(1) and, even more specifically, a "drug product" under 21 C.F.R § 314.53(b)(1). *See* 21 C.F.R. § 314.3(b) ("*Drug product* is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients."). Takeda raises the point that the '584 and '404 Patents are *also* drug product patents, Takeda Br. at 22, which seems to us a reasonable observation, but that does not change the fact that neither combination is "the drug [product] *for which the applicant submitted the application*," 21 U.S.C. § 355(b)(1) (emphasis added).

Infringement Clause; and (3) industry practice supports Takeda's understanding of the Listing Requirement. We are unpersuaded for several reasons.

The problem with Takeda's proposed interpretation of the Listing Requirement is that it would render multiple statutory terms and concepts unnecessary, obliterating the presumption that "statutes do not contain surplusage." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 299 n.1 (2006). Most alarmingly, it would "collapse[] method-of-use . . . claims into drug product claims." Direct Purchasers Br. at 30. In fact, were risk of infringement the only relevant listing factor, there would be no need to separately identify *either* type of claim on the NDA drug. But the distinction between drug claims and method-of-use claims serves a central purpose in the regulatory scheme: to indicate for generic manufacturers whether to make a Paragraph IV or a section viii certification, a decision that will thereafter guide the path of generic drug competition for a given pharmaceutical. Takeda's reading would undermine the "delicate balance" between rewarding innovation and stimulating generic market entry that the Hatch–Waxman Act sought to effect. *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 342 (Fed Cir. 2020) (Williams, *J.*, dissenting).

Takeda's related argument from statutory construction fares no better. It proceeds in three steps: Takeda first posits that the so-called Infringement Clause of 21 U.S.C. § 355(b)(1) ("and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug") applies to both drug claims and method-of-use claims. Next, Takeda presumes that "reads on" is fundamentally equivalent to the phrase, "with respect to which a claim of patent infringement could reasonably be asserted." From there, Takeda concludes that the term "claims the drug" must necessarily be broader than "reads on the drug" because, otherwise, the Infringement Clause would be redundant as applied to drug claims.[15] In other words, because *any* unauthorized use of a patent that reads on the drug will *ipso facto* infringe the patent, "claims the drug" must mean something other than "reads on the drug" in order to avoid surplusage alongside the

[15] As Takeda sees it, should we apply the plain meaning of "claims," the Listing provision would essentially say: the applicant should list "any patent *with respect to which a claim of patent infringement could reasonably be asserted*. . . and *with respect to which a claim of patent infringement could reasonably be asserted* . . . ." Indeed, that would be repetitive. However, as explained herein, just because a patent claim reads on a drug, it does not necessarily follow that its unlicensed production will always reasonably support a claim for infringement.

Infringement Clause. Although this is a closer call, on balance we conclude otherwise.

In light of Congress's recent amendment to the Hatch–Waxman Act, we may assume the Infringement Clause was intended to modify § 355(b)(1)'s "claims the drug" language. Section 355(b)(1) now reads in relevant part:

> Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—
> …
> (viii) the patent number and expiration date *of each patent for which a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
> (I) *claims the drug* for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> (II) *claims a method of using such drug* for which approval is sought or has been granted in the application.

Orange Book Transparency Act of 2020, Pub. L. No. 116–290, § 2, 134 Stat. 4889 (2021) (emphases added). There is thus no doubt that, at least as it now stands, NDA applicants must identify patents that claim the NDA drug *only* if they are reasonably at risk of being infringed by the unlicensed production of the drug.

But it does not automatically follow from that premise that Congress must have intended something broader than the traditional definition of "claims." As an initial matter, although the concepts are closely related, "the plain meaning of

'claims' is not the same as the plain meaning of infringement." *Hoechst-Roussel Pharms., Inc.*, 109 F.3d at 759. Indeed, as the Federal Circuit pointed out in *Hoechst-Roussel*, a functionally identical product may infringe a given patent "even though the product does not fall within the scope of the patent's claims." *Id.* (explaining the doctrine of equivalents). Conversely, there are a handful of situations in which a patent may literally "claim" an invention and yet a cause of action for patent infringement could *not* be reasonably asserted. Two examples are where "the patentee had learned that the patent was invalid or had been procured by fraud." End Payors Br. at 61–62; *see, e.g.*, *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (known fraud); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 149–51, 153, 158 (E.D.N.Y. 2018) (known invalidity). Therefore, despite the relationship between patent claims and patent infringement, there is enough space between them to dispense with Takeda's accusation of redundancy.

In any event, defining "claims" in the manner Takeda suggests would yield consequences at odds with the Hatch–Waxman Act's main goals. As explained above, were all patents for which infringement is reasonably likely automatically considered to "claim the drug," there would be little-to-no room left for method-

of-use claims. Takeda responds that the distinction between the two would rest on whether the patent claim "explicitly include[s] the active ingredient" of the NDA drug, citing *In re Latnus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020), for that proposition. Takeda Br. at 17. But the *Latnus* opinion expressly rejected that analysis, holding that because the patent at issue "does not claim or even mention" the NDA drug, it "does not claim [the drug], *nor even a method of using*" it. *Latnus*, 950 F.3d at 8 (emphasis added). As a result, a patent claim that fails to explicitly include the drug actually makes *neither* type of claim on the drug. The Federal Circuit drew a similar conclusion in *Hoechst-Roussel*, where it reasoned that the patent at issue did not claim a method of using tacrine hydrochloride despite the fact that it claimed the substance into which tacrine hydrochloride transformed upon ingestion. 109 F.3d at 759 n.4; *see also* footnote 11 above.

Moreover, as a practical matter, permitting a brand manufacturer to list a patent as "claiming the drug" when it does not read on that drug is incongruent with the process and remedy prescribed for Paragraph IV certifications. When a generic makes a Paragraph IV certification to the FDA, it is signaling to the agency and the brand its belief that the relevant patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

And if, during subsequent litigation, the generic proves that the patent is either invalid or does not claim the drug, it (and later-following generics) may thereafter freely produce and market the drug. *See id.* § 355(j)(5)(B)(iii)(I). However, if the patent *is* valid and truly *does* "claim the drug," then there is no lawful avenue for a generic to produce an unlicensed version of that drug prior to the patent's expiration. Only a "reads on" interpretation logically comports with such severe, black-and-white consequences.

By contrast, a patent that claims a method of using a drug compels the generic applicant to file a section viii certification. Unlike its more protective sibling, section viii statements "assert[] that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents." *Caraco Pharm. Labs., Ltd.*, 566 U.S. at 406. In other words, it permits the generic, under certain limitations, to market the drug *despite* the patent's claim. Tellingly, as the Supreme Court has observed, "[a] section viii statement is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug," as was roughly the scenario here. *Id.* Furthermore, in both its briefing and at oral argument, Takeda conceded that a generic would potentially be able to lawfully produce an ACTOS

bioequivalent if it were not marketed as a combination therapy along with "metformin or an insulin secretion enhancer." *See, e.g.*, Takeda Br. at 18. We therefore conclude that the proper certification for the hopeful ACTOS generics would have been under section viii, which applies to method-of-use patents only.

It bears mentioning that it was not until 2003 that "the FDA published a new regulation in which it took the position that the Hatch–Waxman Act allows only one 30-month stay for each ANDA." *Apotex, Inc.*, 347 F.3d at 1341. Prior to that rule taking effect, it was an open question whether a brand could supplement its approved NDA with later-filed patents, subjecting ANDA submissions to repeated, unforeseeable litigation stays for new patents that "claim" a particular drug. *See id*. Presumably in light of the limited possibility for multiple patents to "read on" a single drug, *id.* at 1344, the FDA acknowledged that "it is reasonable to have multiple 30-month stays (the old rule), and equally reasonable not to allow them (the new rule)," *id.* at 1353 n.1 (Plager, *J.*, concurring) (citing 68 Fed. Reg. 36,675 (June 18, 2003)). But Takeda's view would have intolerably stretched that allowance because a brand manufacturer could have patented novel combinations incorporating the NDA drug *ad infinitum* and then separately asserted each against aspiring generic manufacturers, generating endless delay. Congress could not

have intended such a perverse opportunity for abuse and the FDA would never have characterized it as an "equally reasonable" alternative.

Finally, we do not accept that "Takeda's listing is consistent with industry practice and understanding." Takeda Br. at 24. The main proof cited for this remark is that, despite the Orange Book originally reflecting only that the '584 and '404 Patents claimed methods of using ACTOS, "nine generic drug companies still filed Paragraph IV certifications." *Id.* But Takeda ignores that there were eight other generic manufacturers who *did not* make Paragraph IV certifications until after Takeda responded to Sandoz, Inc.'s citizen petition. Moreover, the competitive advantages of being a first filer under 21 U.S.C. § 355(j)(5)(B)(iv) provided a significant incentive for the generics to make Paragraph IV certifications regardless of what the Orange Book said. Although the timing may ultimately convince a jury that causation was wanting as between Takeda's initial representation and the actions of the first-filing generics, it is at best weak corroboration of industry understanding. In fact, according to Plaintiffs-Appellees, "but for the Actos product, Takeda has refrained from describing other combination patents it holds as claiming the corresponding stand-alone product." Direct Purchasers Br. at 52; *see also* Brief of Sanofi-Aventis U.S., LLC as Amicus

Curiae in Support of Neither Party at 4 ("[T]he correct interpretation of the term 'claims' . . . in the phrase 'claims the drug' in 21 U.S.C. § 355(b)(1) is its plain and ordinary patent-law meaning of 'reads on.'").

Takeda also cites an academic article expressing that "[m]edicine products may be associated [with and] . . . covered by patents . . . covering . . . combinations of known chemical compounds." Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012). We fail to see how the idea that a combination patent may "cover" a medicine product distinguishes direct drug-product claims from method-of-use claims. In fact, it is almost certain that the article was specifically referencing the latter given that the authors note further that: "These patents are generally termed secondary because they are assumed to come later in the sequence of innovation, *and to offer less robust protection than a chemical compound claim*." *Id.* (emphasis added). Moreover, the article's Supplementary Table 1 notes that method-of-use patents are appropriate "particularly where the product itself cannot be claimed independently due to lack of novelty," as was precisely the case here.

Lastly, Takeda points to statements from pharmaceutical companies and trade associations that "support broad disclosure of patent rights" for listing in the Orange Book. Takeda Br. at 27–28. Nothing in this decision should be read to undermine that goal; we seek only to ensure that the broadly disclosed patent claims are characterized correctly.

For the above-stated reasons, we hold that under the "Listing Requirement" of 21 U.S.C. § 355(b)(1), the '584 and '404 Patents do not "claim the drug" ACTOS.

II. Monopolization Pleading Standard

Faced with the possibility that it misinterpreted the Listing Requirement (as we have now held), Takeda alternatively contends that "[a]ppellees' claim fails because they cannot show that [the] conduct was improper without allegations that the listing decision was unreasonable." Takeda Br. at 31–32. In other words, because "claims the drug" might reasonably[16] be read to permit the listing of any patent at plausible risk of infringement by the production of generic ACTOS, Plaintiffs-Appellees' monopolization claims must necessarily falter. We disagree.

"The offense of monopoly under [Section 2] of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the

[16] According to Takeda.

willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). The latter element requires a plaintiff to establish that "the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition." *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 108 (2d Cir. 2002). Takeda seems to derive its reasonableness argument from the principle that the conduct § 2 prohibits must be both willful and improper—therefore, Takeda concludes, § 2 only prohibits conduct that is *willfully improper*.[17] Takeda misconstrues the standard.

Although the "willfulness element certainly requires proof of intent," *U.S. Football League v. National Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988), it is sufficient under the Sherman Act that a company had the "mere intent to do the act," *United States v. Aluminum Co. of America*, 148 F.2d 416, 432 (2d Cir. 1945).

[17] Takeda's reasoning also requires an additional, unspoken inferential step—that as long as the proffered interpretation is objectively reasonable, even a purposeful misinterpretation of the statute cannot be willfully improper. Because we conclude that objective reasonableness in the first place does not preclude Plaintiffs-Appellees' monopolization claim, we need not address a scenario in which a defendant knew that an objectively reasonable statutory meaning was improper and yet still heeded it.

Thus, absent some anomalous accident or involuntary spasm of industrial consequence, an "[i]mproper exclusion (exclusion not the result of superior efficiency) is always deliberately intended" regardless of any colorable evidence of good faith. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 603 (1985) (quoting Robert Bork, The Antitrust Paradox 160 (1978)). Simply put, "benign intent does not shield anticompetitive conduct from liability" in a monopolization claim. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017).[18]

For this reason, Plaintiffs-Appellees were not required to aver that "the listing decision was unreasonable" in order to allege a monopolization claim; they

---

[18] Of note, however, is that a claim for *attempted* monopolization does depend upon a firm's targeted desire to harm competition. The United States Supreme Court explained this distinction in *Aspen Skiing Co.*, 472 U.S. at 602:

> In *Lorain Journal*, the violation of § 2 was an "attempt to monopolize," rather than monopolization, but the question of intent is relevant to both offenses. In the former case it is necessary to prove a "specific intent" to accomplish the forbidden objective—as Judge Hand explained, "an intent which goes beyond the mere intent to do the act." *United States v. Aluminum Co. of America*, 148 F.2d 416, 432 (CA2 1945). In the latter case evidence of intent is merely relevant to the question whether the challenged conduct is fairly characterized as "exclusionary" or "anticompetitive"—to use the words in the trial court's instructions—or "predatory," to use a word that scholars seem to favor. Whichever label is used, there is agreement on the proposition that "no monopolist monopolizes unconscious of what he is doing."

need only have plausibly alleged that Takeda had market power and that it incorrectly listed its combination patents as claiming ACTOS, causing their antitrust injuries.

CONCLUSION

We **AFFIRM** the district court's denial of Takeda's motions to dismiss and **REMAND** the cases for further proceedings.