United States Court of Appeals
For the First Circuit

No. 17-1714

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; LABORERS HEALTH AND WELFARE TRUST FUND FOR NORTHERN CALIFORNIA, on behalf of themselves and others similarly situated; AFSCME HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; MINNESOTA LABORERS HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of themselves and others similarly situated; LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY, d/b/a Blue Cross and Blue Shield of Louisiana, on behalf of themselves and others similarly situated,

Plaintiffs, Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS CORPORATION; NOVARTIS AG,

Defendants, Appellees.

No. 17-1776

RXDN, INC., on behalf of itself and on behalf of the Direct Purchaser Class,

Plaintiff, Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS CORPORATION; NOVARTIS AG,

Defendants, Appellees.

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Allison D. Burroughs, U.S. District Judge]

Before

Lynch, Kayatta, and Barron,
Circuit Judges.

Thomas M. Sobol, with whom Hannah W. Brennan, Hagens Berman Sobol Shapiro LLP, John D. Radice, Radice Law Firm, P.C., Noah Rosmarin, Adkins, Kelston & Zavez, P.C. were on brief, for appellants.

Saul P. Morgenstern, with whom David K. Barr, Mark D. Godler, Laura S. Shores, Arnold & Porter Kaye Scholer LLP, William A. Zucker, Wyley S. Proctor, McCarter & English LLP, Grant J. Esposito, Jessica Kaufman, and Morrison & Foerster LLP were on brief, for appellees.

August 21, 2018

BARRON, Circuit Judge. In these consolidated appeals from orders dismissing two putative antitrust class actions, purchasers of a brand-name, prescription drug allege that the drug maker unlawfully delayed the entry of generic versions of the drug into the United States market. Specifically, the plaintiffs allege that the drug maker committed antitrust violations by obtaining through a fraud on the United States Patent and Trademark Office ("Patent Office") a patent for a particular form of a component necessary to manufacture a drug to treat leukemia and by then seeking to enforce that patent through "sham" infringement litigation against manufacturers trying to enter the market with generic versions of that drug.

The drug maker moved to dismiss the antitrust actions on the ground that there was no fraud and that it was immune from antitrust liability for merely enforcing its patent through litigation. The drug maker claimed this immunity based on the Noerr-Pennington doctrine. See United Mine Workers of Am. v. Pennington, 381 U.S. 657, 669 (1965); E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961). That doctrine provides a party immunity from antitrust liability for petitioning the government for redress, in light of the First Amendment right to petition the government. And it is clear that the petitioning activity within this doctrine's protection includes enforcing one's intellectual property rights in court.

See Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc. ("PREI"), 508 U.S. 49, 63-65 (1993) (applying Noerr-Pennington immunity to copyright infringement litigation); Amphastar Pharm. Inc. v. Momenta Pharm., Inc., 850 F.3d 52, 56-58 (1st Cir. 2017) (applying Noerr-Pennington immunity to patent infringement litigation).

The District Court agreed with the drug maker that Noerr-Pennington immunity applied to its alleged conduct and, on that basis, dismissed the putative class actions under Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim. The District Court acknowledged that Noerr-Pennington immunity has two exceptions. An antitrust defendant may not enjoy the immunity in enforcing its patent if it obtained that patent through a fraud on the Patent Office, Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177-78 (1965), or if its suit to enforce the patent is a "sham" for impermissible anti-competitive conduct, PREI, 508 U.S. at 51. The District Court held, however, that the purchasers had not plausibly alleged that either exception applies here. We now affirm.

I.

The putative class actions at issue in these consolidated appeals were brought against Novartis, which distributes and holds the patents for Gleevec, a prescription drug

for treating leukemia.[1] Health plans that purchased Gleevec on behalf of their beneficiaries -- so-called end payers -- are the plaintiffs in the first action. A party standing in the shoes of a direct purchaser of the drug is the named plaintiff in the other action.

The suits arise from the following events. In 1996, Novartis obtained the original patent for Gleevec, or Patent No. 5,521,184 ("Patent '184"). This patent claimed Gleevec's active ingredient -- a compound called "imatinib" -- as well as the compound's "corresponding salts." That patent's expiration date was July 4, 2015.

Four years after obtaining that patent, Novartis filed an application for another one. This application sought a patent that pertained to one of the compound's "corresponding salts," the "mesylate" salt of imatinib. Specifically, Novartis's patent application claimed a particular crystalline form of that salt -- namely, the non-needle or "β-crystalline" form.

According to the complaints filed in each of the antitrust actions against Novartis, chemists commonly modify compounds from "free base" to "salt" form during the pharmaceutical process in order to enhance the drug's properties, such as its

[1] "Novartis" refers collectively to all three Novartis entities that are defendants: Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG.

solubility. The complaints further point out that, although a salt can be left amorphous, chemists often crystallize salts in various shapes to further select for favorable properties. For this reason, a patent for a particular crystalline form of one of imatinib's corresponding salts, such as the one Novartis claimed, could be quite valuable.

The patent examiner rejected Novartis's patent application for the β-crystalline form of imatinib mesylate. The examiner concluded that this form of imatinib mesylate was not patentable in consequence of the requirements set forth in 35 U.S.C. § 102, which provides that an invention is not patentable if it is entirely anticipated by a single item of prior art, and 35 U.S.C. § 103, which provides that an invention is not patentable if, from a body of prior art, "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains."

With reference to § 102, the patent examiner ruled that the β-crystalline form of imatinib mesylate was "anticipated" by Patent '184. With reference to § 103, the patent examiner ruled that Novartis failed to carry its burden to "show that employing routine procedures" would not produce the β-crystalline form of the salt.

Novartis appealed the patent examiner's ruling to the Patent Trial and Appeal Board ("Board"), which reversed. With respect to § 102, the Board "assume[d] arguendo, without deciding," that Patent '184, which was set to expire in 2015, anticipated the mesylate salt of imatinib. But, the Board ruled, Patent '184 "contains insufficient disclosure to support a finding of anticipation" of the β-crystalline form of imatinib mesylate that Novartis claimed in its application for the new patent. With respect to § 103, the Board concluded that the patent examiner had erroneously "shift[ed] the burden of persuasion to applicants to establish that the β-crystalline form recited in their claim 'cannot be made following routine conditions.'" Moreover, the Board explained, "on this record, the examiner has not adequately explained how a person having ordinary skill would have been led from 'here to there,' i.e., from [imatinib mesylate] to the . . . β-crystalline form of that compound."

The next month, the patent examiner issued a "notice of allowance," which issues "[i]f, on examination, it appears that the applicant is entitled to a patent" and which specifies the fees that must be paid to obtain the patent. 37 C.F.R. § 1.311. Thereafter, Novartis made a supplemental disclosure of two prior art references that disclosed the mesylate salt of imatinib (but not the β-crystalline form of imatinib mesylate for which Novartis sought the patent).

The Patent Office finally issued Novartis's patent for the β-crystalline form of imatinib mesylate, or Patent No. 6,894,051 ("Patent '051"), on May 17, 2005, with an expiration date in 2019.[2] Novartis then submitted that patent to the Food and Drug Administration ("FDA") for inclusion in what is known as the "Orange Book" -- which lists FDA-approved drugs along with their corresponding patents -- as one of the patents, along with the as-yet-unexpired original '184 patent, that covers Gleevec.

In 2006, a generic drug manufacturer named Sun Pharma filed an abbreviated new drug application ("ANDA") with the FDA. Sun Pharma's ANDA sought to market a generic version of Gleevec in the United States. In its ANDA, Sun Pharma certified that Novartis's second patent for Gleevec, Patent '051, was invalid. Sun Pharma thus sought the FDA's approval for marketing generic Gleevec as soon as the original Gleevec patent, Patent '184, expired on July 4, 2015, even though Novartis's second Gleevec patent, Patent '051, would not expire until 2019.

Several years later, in 2013, while waiting for Patent '184 to expire, Sun Pharma sued Novartis in federal court seeking a declaratory judgment that the second Gleevec patent, Patent '051,

[2] Novartis also applied for and obtained a third patent for Gleevec -- Patent No. 7,554,799, later reissued as Patent No. RE 43,932 -- which the complaints allege is invalid for the same reasons that Patent '051 is invalid. The plaintiffs discuss only Patent '051, however, on appeal.

was indeed invalid. Novartis counterclaimed, alleging infringement of Patent '051 and seeking a declaratory judgment that the patent was valid.

In May of 2014, before any substantive rulings in that litigation, Sun Pharma and Novartis settled. The parties to that settlement did not disclose its terms, except to announce that Sun Pharma would be permitted to launch its generic version of Gleevec on February 1, 2016, some seven months after the expiration of the original Gleevec patent, Patent '184.[3]

The two putative class actions at issue here were filed in the wake of that settlement in the United States District Court for the District of Massachusetts. Each action alleged that Novartis had "engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly for Gleevec and its generic substitutes" in the United States market. The complaints in each case alleged that Novartis carried out this monopolistic

[3] The plaintiffs allege that other generic drug manufacturers also filed ANDAs for generic versions of Gleevec, each of which certified that Novartis's second patent for the drug, Patent '051, is invalid. Because Novartis sued each of these generic drug manufacturers for patent infringement within forty-five days of receiving notice of such certifications, Novartis obtained automatic thirty-month stays of FDA approval as to each of those ANDAs. See 21 U.S.C. § 355(j)(5)(B)(iii). The plaintiffs represent on appeal that all of these additional infringement suits have been dismissed without prejudice.

scheme in the following way in order to delay generic Gleevec's entry into the United States market.

First, the complaints alleged that Novartis fraudulently procured Patent '051 from the Patent Office by falsely representing that the prior art did not disclose imatinib mesylate and that the discovery of its β-crystalline form was "surprising[]." Second, the complaints alleged that Novartis listed Patent '051 in the Orange Book.[4] And, third, the complaints alleged that Novartis then pursued infringement litigation against manufacturers of generic versions of Gleevec to enforce Patent '051 that was a "sham" for anticompetitive conduct -- given that Novartis could not reasonably expect the patent to withstand an invalidity defense.

The direct purchaser alleged its monopolization claim in its suit under the federal Sherman Act, 15 U.S.C. § 2, while the end payers alleged their monopolization claim under the antitrust laws of twenty-three states and the District of Columbia. See Ill. Brick Co. v. Illinois, 431 U.S. 720, 730 (1977) (holding that indirect purchasers generally lack standing to enforce federal antitrust laws). The plaintiffs in both actions sought monetary

[4] The plaintiffs clarified in their papers below that they "do not assert the Orange Book listings as a basis for antitrust liability." They explained that they instead asserted them as the basis of a third exception to Noerr-Pennington immunity. However, they have not pressed this argument on appeal.

damages as well as class certification on behalf of similarly situated direct purchasers and end payers respectively.

Novartis moved to dismiss the end-payers complaint under Rule 12(b)(6). Proceedings in the direct-purchaser action were stayed pending adjudication of Novartis's motion to dismiss. Novartis contended in that motion that, under Noerr-Pennington, it could not incur antitrust liability for exercising its right to enforce Patent '051 in court against an infringer. Novartis did acknowledge that there are "two relevant exceptions" to Noerr-Pennington immunity -- namely, the exceptions based on a showing of Walker Process fraud and "sham" litigation. But, Novartis argued in its motion that the plaintiffs had failed plausibly to allege that either exception applied.

In their opposition to the motion to dismiss, the plaintiffs accepted that Novartis would be entitled to Noerr-Pennington immunity unless at least one exception to that immunity applied. The plaintiffs asserted, however, that they had plausibly alleged that both exceptions did apply. The plaintiffs contended that their suit should therefore proceed to discovery, given that Novartis was not entitled to Noerr-Pennington immunity and that Novartis had not otherwise contested their allegations of "the traditional elements of an antitrust claim: causation, antitrust injury, and market power."

The District Court rejected the plaintiffs' arguments about the application of the exceptions and agreed with Novartis that it was entitled to Noerr-Pennington immunity. On that basis, the District Court granted Novartis's motion to dismiss the end-payers action. The direct-purchaser plaintiff next moved for entry of a judgment of dismissal in its own action "in accordance with the orders entered in the end payors' case," which the District Court granted.

The plaintiffs in both actions then appealed.[5] In pressing these appeals, the plaintiffs contend that the District Court erred in holding that they had not plausibly alleged that Novartis had engaged in either fraud within the meaning of Walker Process in obtaining Patent '051 or "sham" litigation in enforcing that patent and thus that the District Court erred in dismissing their suits on the ground that Novartis was immune from antitrust liability for enforcing Patent '051. Novartis counters that the District Court's ruling with respect to Noerr-Pennington immunity was correct, though Novartis does not dispute the plaintiffs' assertion that they have otherwise plausibly alleged the elements of an antitrust claim. We thus now address the plaintiffs' position against Noerr-Pennington immunity by considering the

[5] The end-payer plaintiffs have filed an unopposed motion to amend their notice of appeal, which we provisionally granted and now finally grant.

strength of their arguments pertaining to whether Novartis had engaged in fraud within the meaning of Walker Process in obtaining the patent at issue or in "sham" litigation in enforcing that patent.

II.

In Walker Process, the Supreme Court held that "the enforcement of a patent procured by fraud on the Patent Office may be violative of [federal antitrust law] provided the other elements necessary to a[n] [antitrust] case are present." Walker Process, 382 U.S. at 174.[6] The plaintiffs rely on the following alleged misrepresentations in Novartis's patent application to support their contention that Novartis fraudulently obtained Patent '051 from the Patent Office: (1) that the prior art did not disclose imatinib mesylate and (2) that Novartis's manufacture of the non-needle or β-crystalline form of imatinib mesylate was "surprising[]."

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[6] Walker Process concerned antitrust liability under the federal Sherman Act. 382 U.S. at 173. The parties assume that the Walker Process doctrine applies to the state antitrust laws at issue in the end-payers action as well.

We note that the Supreme Court has, since Walker Process, reserved the question "whether and, if so, to what extent Noerr permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations." PREI, 508 U.S. at 61 n.6 (citing Walker Process, 382 U.S. at 176-77). Neither party suggests to us, however, that, in light of PREI, Walker Process is not an available exception to Noerr-Pennington. So we proceed on the assumption that it is.

The plaintiffs' complaints allege that Novartis made these allegedly false representations "[w]ith intent to mislead or deceive" the Patent Office, "but for which the '051 patent would not have issued." Accordingly, the plaintiffs contend that they have sufficiently alleged the elements of intent and materiality in asserting that they are entitled to take advantage of the Walker Process-based fraud exception to the usual rule that a patent holder cannot incur antitrust liability for enforcing its patent. See Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1364-65 (Fed. Cir. 1998).

Novartis counters that the District Court rightly concluded that the plaintiffs have failed plausibly to allege that either of these allegedly false representations by Novartis in its application for Patent '051 was material to the issuance of that patent or that Novartis made either of these representations with the requisite intent to deceive the Patent Office. Accordingly, Novartis contends that the plaintiffs have failed plausibly to allege Walker Process fraud.

We do not need to reach the issue of whether the plaintiffs have plausibly alleged that Novartis made either of the representations at issue with the requisite fraudulent intent. And that is because we agree with Novartis and the District Court that the plaintiffs have failed plausibly to allege that either

representation, even if false, was material to the issuance of the patent. Our review of whether the plaintiffs have sufficiently alleged materiality is de novo. SEC v. Tambone, 597 F.3d 436, 441 (1st Cir. 2010) (en banc).

A.

The materiality requirement is a meaningful one. "The heightened standard of materiality in a Walker Process case requires that the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." Dippin' Dots, 476 F.3d at 1347 (emphasis added) (citing C.R. Bard, 157 F.3d at 1364).

In addition, "[l]ike all fraud-based claims, Walker Process allegations are subject to the pleading requirements of Fed. R. Civ. P. 9(b)." MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958, 967 (Fed. Cir. 2005), rev'd on other grounds, 549 U.S. 118 (2007). That means that the party alleging the fraud, with respect to elements not bearing on the "conditions of a person's mind," "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

B.

We consider first the plaintiffs' allegations regarding Novartis's representation in its patent application that the prior art did not disclose the mesylate salt of the imatinib compound. Novartis does not dispute that this representation was false. But,

Novartis contends, the plaintiffs have failed plausibly to allege that this representation was material to the Patent Office's decision to issue Patent '051 and so cannot provide the predicate for their allegations of fraud under Walker Process. We agree.

Cutting against the alleged materiality of this statement in the patent application is the fact that Patent '051 covers only a particular form of imatinib mesylate, the β-crystalline form, and not the mesylate salt itself. That feature of the patent application is significant to our assessment of the plaintiffs' allegations concerning materiality because the Board reversed the patent examiner's initial rejection of Novartis's claim to the β-crystalline form even though the Board appears to have assumed that the mesylate salt of the imatinib compound had been previously prepared. In such circumstances, we find it difficult to conclude that, but for Novartis's inaccurate representation that the prior art did not disclose the mesylate salt of the imatinib compound, the patent would not have issued.

But there is also another reason to reach that conclusion, which, at least when combined with the one that we have just given, is fatal to the plaintiffs' claim that they have plausibly alleged the materiality of the representation at issue. And that reason is that, as the District Court observed and as even the plaintiffs accept, Novartis eventually actually did submit prior art to the Patent Office that disclosed imatinib

mesylate, although Novartis did so -- to use the plaintiffs' word -- "belatedly."

Specifically, Novartis submitted this prior art to the Patent Office via form PTO-1449. And there is no basis for disputing that the patent examiner, in issuing Patent '051, then considered this subsequently submitted prior art. The patent examiner initialed and signed form PTO-1449, and these "initials when placed adjacent to the considered citations . . . on a form PTO-1449 . . . provide a clear record of which citations have been considered by the Office." U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 609 (8th ed. May 2004). In addition, Patent '051 itself lists the publications referencing the prior art disclosing imatinib mesylate among the publications that the examiner considered in issuing the patent. See id. § 1302.12 ("All references which have been cited by the examiner during the prosecution . . . will be printed in the patent.").[7]

It is true that the patent examiner had already issued the notice of allowance for Patent '051 by the time that Novartis

[7] The complaints allege that there was additional prior art disclosing imatinib mesylate that was never provided to the Patent Office. But, the plaintiffs do not contend that these references disclosed anything of relevance to Novartis's patent application other than the mesylate salt of imatinib that the submitted references had already disclosed. See Rothman v. Target Corp., 556 F.3d 1310, 1326 (Fed. Cir. 2009) ("A piece of prior art is not material to patent prosecution when it is cumulative of information already before the examiner." (citing 37 C.F.R. § 1.56(b))).

had submitted this prior art. But, the plaintiffs make no argument that the examiner could not have withdrawn this allowance in light of the submission of this prior art and the disclosure of the corresponding salt that it made. In fact, the notice of allowance stated, while citing to 37 C.F.R. § 1.313, that "this application is subject to withdrawal from issue at the initiative of the office or upon petition by the applicant."

Simply put, the record shows that the patent covers only a particular form of imatinib mesylate, that the Board reversed the patent examiner's initial ruling denying the patent even after assuming that the mesylate salt of the imatinib compound had been previously prepared, that Novartis ultimately did submit prior art disclosing that salt, and that the patent examiner considered that prior art in ultimately issuing the patent for a particular form of that salt. In light of these features of the record, we do not see how Novartis's earlier allegedly false representation that the prior art did not disclose imatinib mesylate to the Patent Office could plausibly be said to be material to the Patent Office's ultimate decision to issue the patent for the particular crystalline form of the salt.

C.

We next turn to the plaintiffs' allegations concerning a section of Novartis's patent application titled "BACKGROUND TO THE INVENTION," in which Novartis stated that "[i]t has now been

surprisingly found that a crystal form may under certain conditions be found in the [mesylate] salt of [the imatinib] compound, which is described hereinafter as β-crystal form" (emphasis added). The plaintiffs contend that Novartis's description of its manufacture of the β-crystalline form of imatinib mesylate as "surprising[]" was false. The plaintiffs further contend that Novartis made the statement "in order to avoid the inevitable conclusion that the non-needle form of imatinib mesylate was obvious" and that the statement was material to the Patent Office's decision to issue Patent '051.[8]

The District Court disagreed. The District Court noted that it is "unclear whether such a statement qualifies as a misrepresentation." The District Court explained in this regard

[8] At oral argument, the plaintiffs asserted that Novartis's representation in this portion of its patent application from 2000 as to the timing of the β-crystalline discovery -- namely, that it had just "now" been made and that it was thus a "new" crystalline form -- also effected a fraud on the Patent Office, independent of the use of the word "surprisingly." The plaintiffs argue that the use of the words "now" and "new" meant Novartis was presenting a false chronology, given the complaints' allegation that the β-crystalline form, "upon information and belief, was used by Novartis from August 1993 forward." But, although the plaintiffs' opposition brief below did allude to that allegation, the plaintiffs did not sufficiently raise below a Walker Process argument that, but for Novartis's use of the words "now" and "new," the patent would not have issued. See United States v. Slade, 980 F.2d 27, 30 (1st Cir. 1992) (explaining that "[p]assing allusions are not adequate to preserve an argument"). Nor was this argument developed in their briefs to us. See Shell Co. (P.R.) Ltd. v. Los Frailes Serv. Station, Inc., 605 F.3d 10, 19 (1st Cir. 2010) (holding that an argument developed at oral argument but not in a party's briefs is deemed waived).

that "[t]he examiner was free to reach [her] own opinion about whether such a discovery was in fact 'surprising' based on the prior art that was available to her before the patent issued." The District Court went on to explain that the plaintiffs "have not sufficiently alleged that if Novartis had avoided using the word 'surprising,' the patent would not have issued in light of the relevant prior art."

In arguing on appeal that the District Court erred in finding that Novartis's use of the word "surprising" was not material to the patent's issuance, the plaintiffs assert that it would have been obvious to any pharmaceutical chemist of ordinary skill how to convert the mesylate salt from its non-needle to needle form through "routine" steps and that the process might even occur naturally. The plaintiffs thus suggest that Novartis's representation misled the Patent Office into concluding that the crystalline form of the salt at issue was not obvious, when it was.

But, the plaintiffs have not shown that Novartis's characterization of the existence of the crystalline form of that salt as "surprising" was anything more than an assertion of non-obviousness. And the bare assertion that an invention is not obvious -- which, of course, is implicit in any patent application -- is not in and of itself a material misrepresentation for purposes of Walker Process. Rather, it is merely a legal assertion

that the patent examiner is free to assess in light of the prior art that is available to the examiner. See Akzo N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("The mere fact that [a patent applicant] attempted to distinguish [its claim] from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the [claim] based on the art in front of him.").

The case on which the plaintiffs rely to contend that the use of the word "surprising" was more than a standard assertion of non-obviousness, Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123 (Fed. Cir. 2006), is readily distinguishable. For one thing, that case concerned a claim that a patent was invalid because it was obtained through "inequitable conduct" in violation of a patent applicant's "duty to prosecute patents in the [Patent Office] with candor and good faith." Id. at 1128. And, at that time, the materiality standard for an inequitable-conduct claim was lower than the but-for standard that we must apply here. See id. at 1129, 1132.

In addition, Purdue Pharma did not purport to hold that a patent application's isolated description of a drug's new form as "surprising[]" could, standing alone, constitute a material misrepresentation under circumstances like those at issue here. The patent application at issue in Purdue Pharma described the

improved effects of a drug's new dosage-release mechanism, where those effects constituted "a prominent, and at times, the only, argument in favor of [the drug's] patentability." Id. at 1130 (internal quotation marks omitted). The Federal Circuit explained that, in the context of a patent application of that sort, the applicant, by consistently representing to the Patent Office that the effects were a "surprising discovery," was clearly representing that the alleged effects were "based on the results of clinical studies," when that was not in fact true. Id. at 1131. In fact, in finding no clear error in the trial court's conclusion that these representations were therefore material to patentability, id., the Federal Circuit emphasized that Purdue Pharma was an "unusual" case, in which -- by "repeatedly rel[ying] on that discovery to distinguish its invention from other prior art . . . while using language that suggested the existence of clinical results" -- the patent applicant "did much more than characterize [its invention] as a surprising discovery." Id. at 1133.

Here, by contrast, Novartis's use of the word "surprising" gives rise to no similarly misleading implication. The representation at issue in Novartis's application concerns only the existence of the salt's crystalline form; it does not concern the form's "effects." Thus, Novartis's use of the word "surprising," in this context, does not suggest the presence of

underlying clinical data in the way that the use of that word, in the Purdue Pharma context, was found to have falsely implied the same.

For these reasons, the plaintiffs' second Walker Process argument, like their first one, fails to provide a basis from which we could conclude that the plaintiffs have satisfied the but-for materiality standard. And thus, this Walker Process argument fails as well.

D.

In a final attempt to challenge the District Court's Walker Process ruling, the plaintiffs contend that Novartis's inclusion in its patent application of each of the alleged misrepresentations that we have just addressed amounted to the type of "egregious misconduct" that, like "the filing of an unmistakably false affidavit," makes the inclusion of such representations per se material to a patent's issuance. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc); see also Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339, 1342 (Fed. Cir. 2013) (explaining that an "unmistakably false" declaration "alone establishes materiality" if not cured). But, we do not agree.

Novartis correctly points out that the plaintiffs forfeited this argument by not making it to the District Court, and the plaintiffs do not contend that the issue was preserved or

that the District Court plainly erred. See Chestnut v. City of Lowell, 305 F.3d 18, 20 (1st Cir. 2002) (en banc) (per curiam) (describing the four prongs of plain error: "error, plainness, prejudice, and miscarriage of justice or something akin to it"). Moreover, the alleged misrepresentations here, which the complaints allege to be merely "misleading, if not false," do not rise to the level of an "unmistakably false" affidavit or declaration. Intellect Wireless, 732 F.3d at 1342; Therasense, 649 F.3d at 1292. And so, for this reason, too, we reject this attempt by the plaintiffs to show that they have plausibly alleged the element of materiality in alleging Walker Process fraud.

III.

Independent of Walker Process, the plaintiffs separately contend that Novartis is subject to antitrust scrutiny for enforcing Patent '051 on the ground that its patent infringement litigation was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Noerr, 365 U.S. at 144 (emphasis added). But, we do not agree.

A.

The Supreme Court has announced a two-part test for determining whether a suit to enforce intellectual property rights is a "sham" that is not entitled to Noerr-Pennington immunity from antitrust scrutiny. PREI, 508 U.S. at 60. First, "the lawsuit

must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. If the challenged suit is objectively baseless, a court then proceeds to consider the alleged monopolist's "subjective motivation" under the second part of the test. Id. Under this second prong, "the court should focus on whether the baseless lawsuit 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.'" Id. at 60-61 (quoting Noerr, 365 U.S. at 144; City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 380 (1991)).

In order to make a "sham" showing with respect to a suit to enforce an intellectual property right, a plaintiff must allege that both prongs of the test are met. Id. Novartis's motion to dismiss the plaintiffs' antitrust claim challenged the plaintiffs' "sham" litigation argument by contending only that the plaintiffs had failed to plausibly allege that Novartis's litigation to enforce Patent '051 was "objectively baseless." We thus focus on the plausibility of the plaintiffs' allegations with respect to the "objectively baseless" prong, as the parties agree that, at least under PREI, the antitrust actions cannot go forward

unless the plaintiffs have plausibly alleged that Novartis's litigation to enforce Patent '051 was objectively baseless.[9]

B.

Wholly apart from their allegations concerning Walker Process fraud, the plaintiffs argue, for the following reasons, that the only reasonably foreseeable outcome of Novartis's infringement litigation was dismissal on patent-invalidity grounds and thus that the infringement litigation was "objectively baseless." The plaintiffs contend that Novartis's patent was clearly invalid on either anticipation or obviousness grounds because "the non-needle crystal was an inherent characteristic of imatinib mesylate or else entirely obvious." See 35 U.S.C. §§ 102, 103. In this regard, the plaintiffs point to their complaints' "key factual allegation," as described by the District Court: "that the two techniques Novartis described in its patent application,

[9] In addition to invoking this "objectively baseless" test from PREI, the plaintiffs also urge us to apply the test from California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972), which they argue is a different test that applies to allegations that a pattern of petitioning activity, as opposed to a single petition, was a "sham." The plaintiffs contend that this case involves such a pattern because their complaint alleges that Novartis sued not only Sun Pharma but also other generic manufacturers that had filed ANDAs for generic versions of Gleevec. However, the plaintiffs concede in their reply brief that "Novartis rightly points out that the end payers did not argue below that California Motor should apply." And, contrary to their assertion otherwise, our recent decision in Puerto Rico Telephone Co. v. San Juan Cable LLC, 874 F.3d 767 (1st Cir. 2017), does not excuse the forfeiture of that argument, which was no less available to them to make before that decision.

which produced the β-crystalline form, were commonly known methods for developing alternate crystalline forms at the time."

Our review of whether the plaintiffs have plausibly alleged "sham" litigation is de novo. Tambone, 597 F.3d at 441. We proceed on the understanding that a suit to enforce a patent, like a suit to enforce any intellectual property right, could be "objectively baseless." See PREI, 508 U.S. at 63-65 (considering whether the underlying copyright infringement litigation in the case was potentially a "sham" because it was "objectively baseless"). But, here, the only ground that the plaintiffs assert to support their contention that Novartis's infringement litigation to enforce Patent '051 was "objectively baseless" is that the patent was invalid on anticipation or obviousness grounds. And that presents a problem for the plaintiffs.

A patent is "presumed valid" and thus its validity can be challenged only with clear and convincing evidence. Microsoft Corp. v. i4i Ltd., 564 U.S. 91, 95 (2011) (quoting 35 U.S.C. § 282). Against that background, we do not see how on this record plaintiffs can satisfy the "objectively baseless" prong in light of the fact that the Patent Office issued the patent following the Board's earlier ruling reversing the patent examiner's rulings as to anticipation and obviousness.

Although the Board did not have all of the prior art before it at the time of its decision reversing the decision of

the patent examiner, the Board had assumed what the subsequently disclosed prior art showed: that imatinib mesylate was known prior to Novartis's claim to the development of its β-crystalline form. And, in ruling for Novartis notwithstanding that assumption, the Board indicated that it was not clear on the face of the prior art either that the β-crystalline form of imatinib mesylate was inherently anticipated or that it was obvious how to get "from here to there" in terms of developing it. That ruling was significant for purposes of determining whether Novartis could have reasonably expected success in its patent infringement litigation, insofar as any defense to that infringement litigation was based on the invalidity of Novartis's patent.

After all, invalidation of a patent on anticipation grounds "requires that every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention." Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1082 (Fed. Cir. 2008). And the plaintiffs do not dispute the District Court's conclusion that the prior art "neither describes the β-crystalline form of the imatinib mesylate salt nor a method to produce it. The prior art only mentions imatinib mesylate itself, . . . which has many different crystalline forms."

Moreover, with respect to obviousness, the analysis involves "several basic factual inquiries":

> [T]he scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17-18 (1966). And, in the face of the Board's ruling and the patent's subsequent issuance, the complaints' mere allegations that "the two techniques Novartis described in its patent application, which produced the β-crystalline form, were commonly known methods for developing alternate crystalline forms at the time" and that a pharmaceutical chemist of ordinary skill would have been motivated to develop an advantageous crystalline form of imatinib mesylate are insufficient to allege plausibly that Novartis was unreasonable in expecting that Patent '051's presumed validity could withstand an obviousness challenge.[10] Rather, those

[10] The plaintiffs do point to the Supreme Court of India's 2013 decision not to issue what they describe as Novartis's "Indian equivalent" of Patent '051. But, this effort fails. As indicated by a copy of that decision in the record, the India Supreme Court was applying a different patentability standard than under United

allegations merely demonstrate that Novartis would have been subject to a serious defense to its infringement litigation, as Novartis would have had to demonstrate that, despite those allegations, it was not obvious how, as the Board had put it in reversing the patent examiner's ruling as to obviousness, to get "from here to there," i.e., from the mesylate salt of imatinib to its β-crystalline form.

Nor have the plaintiffs identified any authority to support their contention that their allegations are sufficient to plausibly allege that, despite the Board's ruling and the patent's issuance, Novartis's litigation to enforce that patent was a sham. In fact, the plaintiffs have not identified a single precedent that permitted an antitrust "sham" litigation claim to go forward based on an allegation that the infringement litigation was objectively baseless because the underlying patent was alleged to be invalid due to anticipation or obviousness.

We therefore reject the plaintiffs' contentions that they have plausibly alleged that they may take advantage of the "sham" litigation exception to Noerr-Pennington immunity

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States law. As the court explained there, under Indian law, "the mere discovery of a new form of a known substance" is not a "new product" "unless they differ significantly in properties with regard to efficacy." By contrast, under our law, a patent may be obtained so long as the differences between the claimed invention and the prior art were not so minimal that the invention was "obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103.

recognized in PREI. And thus, in light of our rejection of the plaintiffs' Walker Process-based arguments for subjecting Novartis to antitrust scrutiny, we see no reason to disturb the District Court's ruling dismissing the plaintiffs' antitrust suits for failure to state a claim.

IV.

For the foregoing reasons, the judgments of the District Court in both actions are **affirmed**.