UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND and LABORERS HEALTH AND WELFARE TRUST FUND FOR NORTHERN CALIFORNIA, on behalf of themselves and others similarly situated, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION, Defendants.	*	Civil Action No. 15-cv-12732
LOUISIANA HEALTH SERVICE AND INDEMNITY COMPANY d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA, on behalf of themselves and others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION, Defendants.	*	Civil Action No. 15-cv-13461
AFSCME HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION, Defendants.	*	Civil Action No. 15-cv-13724

MINNESOTA LABORERS HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION, Defendants.	*	Civil Action No. 15-cv-13725
PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of themselves and others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION, Defendants.	*	Civil Action No. 15-cv-13726

MEMORANDUM AND ORDER GRANTING MOTION TO DISMISS

BURROUGHS, D.J.

I. INTRODUCTION

In this putative class action, Laborers Health and Welfare Trust Fund for Northern California and Louisiana Health Service and Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana ("Plaintiffs") bring state-law claims against Defendants Novartis Pharmaceuticals Corporation, Novartis AG, and Novartis Corporation (collectively, "Novartis"), on behalf of themselves and all others similarly situated, for engaging in an alleged "monopolistic scheme" in connection with Gleevec®, a brand-name prescription drug used to

treat certain types of chronic myeloid leukemia and acute lymphoblastic leukemia. Specifically, Plaintiffs allege that Novartis, which held the patent rights to Gleevec, engaged in illegal, anticompetitive conduct designed to delay the entry of generic forms of the drug into the U.S. market. Presently before the Court is Novartis' Motion to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(b)(1) [ECF No. 111] and End Payer Plaintiffs' Motion for a Rule 26(f) Conference [ECF No. 135]. For the reasons set forth below, the motion to dismiss is GRANTED, and the motion for a conference is DENIED.

II. PROCEDURAL HISTORY

Plaintiffs filed their original Class Action Complaint on June 22, 2015, seeking only declaratory and injunctive relief under federal antitrust law. [ECF No. 1]. In July and August 2015, Novartis filed motions to dismiss. [ECF Nos. 53, 60]. On February 1, 2016, while the motions were pending, a generic form of Gleevec was introduced into the market, thus mooting the request for injunctive relief. On March 24, 2016, the Court denied the motions to dismiss as moot and gave Plaintiffs leave to amend their complaint. [ECF No. 104]. In addition, the Court consolidated the action for pretrial purposes with four other cases involving similar claims against Novartis. On April 8, 2016, Plaintiffs filed the operative Consolidated Amended Class Action Complaint ("CAC"). [ECF No. 105]. The parties stipulated that the CAC would supersede all other complaints filed by any plaintiff in any of the consolidated actions. In contrast to the original complaint, the CAC does not contain any claims arising out of federal antitrust law; instead, it asserts only state-law antitrust and unfair trade practices claims, under the laws of 23 states and the District of Columbia. This Court appears to have diversity jurisdiction pursuant to 28 U.S.C. § 1332.

On May 10, 2016, Novartis filed a motion to dismiss for failure to state a claim and lack of jurisdiction [ECF Nos. 111, 112] and a supporting declaration [ECF No. 113]. Plaintiffs opposed the motion [ECF No. 120] and Novartis filed a reply [ECF No. 121]. On August 1, 2016, the Court held a hearing on the motion. [ECF No. 126].

III. ALLEGATIONS IN THE CONSOLIDATED CLASS ACTION COMPLAINT

The CAC alleges a single claim for relief on behalf of the putative class—that Novartis' conduct amounted to "monopolization and [a] monopolistic scheme" in violation of the laws of 23 states and the District of Columbia. Specifically, Plaintiffs allege that Novartis "engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly for Gleevec and its generic substitutes," and that "as part of this scheme, Novartis: (1) [w]ith intent to mislead or deceive, failed to disclose to the PTO [U.S. Patent and Trademark Office] material information known to it and made material misrepresentations to the PTO, but for which the '051 patent would not have issued; (2) [i]mproperly listed the '051, '799, and RE'923 patents in the Orange Book; and (3) [p]rosecuted sham patent litigation lawsuits against generic manufacturers." Plaintiffs further allege that at all relevant times, Novartis intended to, and did, maintain and extend its monopoly power, which allowed it to continue charging supra-competitive prices for Gleevec without a substantial loss in sales, and that as a direct and proximate result of this conduct, Plaintiffs and other members of the putative class were injured, in that they paid more for the drug than they would have if a generic had been allowed onto the market.

The following facts are derived from the CAC unless otherwise noted.

A. Prosecution of the Polymorph Patents

Defendant Novartis Pharmaceuticals Corporation (a subsidiary of Defendant Novartis AG), with FDA approval, markets and distributes Gleevec in the United States. Defendant Novartis Corporation is the assignee of U.S. Patent No. 5,521,184 ("the '184 Patent"), which is the basic compound patent claiming Gleevec's active ingredient, commonly known as "imatinib." In addition to claiming the imatinib compound in its "free base" form, the '184 Patent also claims certain "salts" of the imatinib compound and their use as tumor-inhibiting agents.[1] The '184 Patent issued on May 28, 1996, and expired on July 4, 2015.

Prior to the expiration of the '184 Patent, Novartis obtained two follow-on patents that claim particular crystalline ("polymorphic") "non-needle" forms of the mesylate salt of imatinib:[2] (1) U.S. Patent No. 6,894,051 ("the '051 Patent") issued on May 17, 2005, and (2) U.S. Patent No. 7,554,799 ("the '799 Patent) issued on June 9, 2009, which was subsequently surrendered and reissued as RE43'932 ("the RE'932 Patent")[3] (collectively, the "Polymorph

[1] Because the "free base" forms of many pharmaceutical compounds often do not exhibit the range of physical properties that are suitable for drug development, chemists sometimes modify the characteristics of the compound by adding an acid to form an "acid addition salt." One common acid addition salt is a salt of methanesulfonic acid, also known as "mesylate." Novartis sells Gleevec with imatinib mesylate in a tablet form.

[2] Once a salt is selected, a drug manufacturer can also select a polymorphic form of the salt. Salts crystallize in a variety of different shapes, depending on conditions like temperature, solvent, and degree of supersaturation. When a salt is to be used in pharmaceutical drugs, some crystalline forms are preferable to others, as the form of the salt can affect drug qualities such as stability, dissolution, and bioavilability. In addition, certain crystalline forms may not be ideal for mass-scale production, in light of the form's flow properties, compressibility, bulk density, and particle sizes. Plaintiffs allege that "[n]eedle-shaped crystals, which are long and very thin . . . are very difficult to handle both in the laboratory and in commercial production." Id. ¶ 41. Accordingly, it is preferable to use a non-needle crystalline form when developing a salt for use in prescription drugs. Id. ¶ 42.

[3] The '051 Patent is alleged to expire November 23, 2019. CAC ¶ 262. The CAC alleges that the '799 Patent, due to the terminal disclaimer, would expire the same day, id. ¶ 293, but Novartis represents that the RE'932 Patent expires on July 16, 2019 [ECF No. 112 at 4 n.6].

Patents"). The CAC alleges that the Polymorph Patents are invalid, although Plaintiffs do not contest the validity of the original '184 Patent.

The application for the '051 Patent, filed in January 2000, purported to disclose and claim the methanesulfonate salt of imatinib, along with a particular polymorphism—namely, the non-needle form, which Novartis referred to as the "β-crystalline" form.[4] In September 2000, the patent examiner issued a non-final rejection of Novartis' claims, concluding that the claims were both anticipated and rendered obvious by the '184 Patent. Specifically, the examiner rejected the claims as anticipated by the '184 Patent's disclosure of the "free form" of imatinib and a "list of intended salts, including the methanesulfonate [mesylate] salt." She also held that the burden was on the applicant to show that the claimed β-crystalline form would not be inherently produced using routine procedures described in the '184 Patent. Although Novartis responded to the examiner's rejections, the examiner nonetheless issued a final office action on July 5, 2001 in which she found that Novartis' patent claims were anticipated and rendered obvious by the '184 Patent.

Novartis appealed this rejection to the Patent Board. On November 24, 2003, the Patent Board reversed the examiner's decision. The Patent Board's decision assumed, without deciding, that the original '184 Patent described the mesylate salt of imatinib. The Patent Board nevertheless held that the '184 Patent "contains insufficient disclosure to support a finding of anticipation of the appealed claims which recite a non-hygroscopic or β-crystalline form of the methanesulfonic acid addition [mesylate] salt of imatinib." See Declaration of Wyley S. Proctor

[4] The Court understands the term "methanesulfonate salt" to be identical to "mesylate salt" in this case, and thus uses them interchangeably.

[ECF No. 113] ("Proctor Decl."), Ex. D.[5] Further, the Patent Board held that the examiner had erred in shifting the burden of persuasion to Novartis "to establish that the β-crystalline form recited in their claims 'cannot be made following routine conditions.'" Id. This, the Patent Board explained, was reversible error, because "before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art." Id. (internal quotations and citation omitted). Because no such evidence or reasoning appeared in the record, the Patent Board reversed the examiner's rejections based on anticipation.

Similarly, the Patent Board reversed the examiner's rejections based on obviousness. Again, the Patent Board assumed, *arguendo*, that the '184 Patent described the mesylate salt of imatinib. Id. The Patent Board, however, disagreed with the examiner that this disclosure would render obvious the claims in the '051 Patent. The Board found that the examiner had not adequately explained how a person having ordinary skill in the art "would have been led from 'here to there,' *i.e.*, from the methanesulfonic acid addition [mesylate] salt of imatinib to the . . . β-crystalline form of that compound recited in the appealed claims." Id.; see also CAC ¶ 244.

On December 31, 2003, six weeks after the Patent Board reversed the examiner's rejections and without conducting any further proceedings, the examiner issued a notice of allowance.[6] Plaintiffs allege that the file wrapper reflects no further developments to the record

[5] Although the Patent Board's decision is not attached to the CAC, it is cited at length therein. Moreover, because documents in the patent's prosecution history are public records, the Court may take judicial notice of their contents. See Beddall v. State St. Bank & Trust Co., 137 F.3d 12, 16–17 (1st Cir. 1998).

[6] "If, on examination, it appears that the applicant is entitled to a patent under the law, a notice of allowance will be sent to the applicant . . . ." 37 C.F.R. § 1.311(a).

following the Board's decision, except a notice that the patent term would be extended by 311 days due to the pendency of the appeal to the Board. In Plaintiffs' view, the Board's decision was based on an incomplete prior art record and that the examiner's subsequent decision allowing the patent to issue was not on the merits.

The CAC alleges that Novartis specifically withheld five prior art references—publications by its own scientists—that disclosed the earlier use of the mesylate salt form of imatinib to inhibit the growth of tumor cells:

(1) A 1996 article published in *Cancer Research* by Novartis scientists Buchdunger, Zimmerman, Lydon, Druker, and others entitled "Inhibition of the Ab1 Protein-Tyrosine Kinase in vitro and in vivo by a 2-Phenylaminopyrimidine Derivative." The article allegedly disclosed that the scientists had made a series of compounds that inhibited tyrosine kinases, and described a single compound (imatinib) that showed potent inhibition of the Abl kinase associated with chronic myeloid leukemia. The article explained that the scientists had also synthesized a methanesulfonate salt form of the compound, and that they did so well before the article was submitted on July 31, 1995. The Court will refer to this article as the "**1996 Buchdunger Article**." See CAC ¶¶ 159–64.

(2) A 1997 article published in *Bioorganic & Medicinal Chemistry Letters* by Zimmerman, Buchdunger, and others from Novartis' Oncology Research Department, entitled "Potent and Selective Inhibitors of the Abl-Kinase: Phenylamino-Pyrimidine (PAP) Derivatives." The article, which was submitted for publication on August 21, 1996, described development and optimization of a new class of phenylamino-pyramidine derivatives that yielded highly potent and selective Bcr-Abl kinase inhibitors. The article advised that in one particular series of the PAP derivatives, "improvement of the aqueous solubility can be accomplished by attachment of a salt forming group on the indole side chain." Thus, the article suggested that the compound might be a development candidate for use in treatment of certain leukemias. The Court will refer to this article as the "**1997 Zimmerman Article.**" See id. ¶¶ 178–80.

(3) A 1996 Article published in *Nature Medicine* by Druker, Buchdunger, Zimmerman, Lydon, and others entitled "Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Ab1 Positive Cells." The article allegedly detailed the design of imatinib and its effect of selectively inhibiting proliferation of Bcr-Abl expressing cells in vitro and in vivo. The Court will refer to this article as the "**1996 Druker Article**." See id. ¶ 172.

(4) A 1995 presentation that Druker gave at the American Society of Hematology's annual meeting in Seattle, entitled "Preclinical evaluation of a selective inhibitor of the Abl tyrosine kinase as a therapeutical agent for chronic myelogenous leukemia." The presentation abstract allegedly disclosed the imatinib compound as a potent and specific inhibitor of the ABL protein tyrosine kinase, and concluded that the compound may be useful in the treatment of certain leukemias. The Court will refer to this as the "**1995 Druker Presentation**." See id. ¶¶ 157–58.

(5) A 1996 Article published in *Bioorganic & Medicinal Chemistry Letters* by Zimmerman, Buchdunger, Lydon, and others entitled "Phenylamino-Pyrimidine (PAP) – Derivatives: A New Class of Potent and Highly Selective PDGF-Receptor Autophosphorylation Inhibitors." In that article, Zimmerman noted that the phenylamino-pyramidine compounds at issue "show poor solubility in water . . . but are soluble under acidic conditions." In a footnote, the authors described a "typical synthesis" of the compounds, which involved filtration, evaporation, and crystallization. The Court will refer to this as the "**1996 Zimmerman Article**." See id. ¶¶ 165–67.

On March 26, 2004, Novartis submitted a Continued Prosecution Application Request and a supplemental Information Disclosure Statement ("IDS") that disclosed, for the first time, two of these prior art references (the 1996 Buchdunger Article and 1997 Zimmerman Article). See id. ¶ 252. Other prior art—the 1995 Druker Presentation, 1996 Zimmerman Article, and 1996 Druker Article—was allegedly never disclosed. Id. ¶¶ 252, 271, 272. Along with the IDS, Novartis filed "remarks," in which it argued that because the Patent Board had presumed that the mesylate salt of imatinib was described in the prior art, yet still reversed the examiner's rejections, principles of *res judicata* required that the patent claims be allowed, even assuming that the prior art disclosed the mesylate salt. Id. ¶ 253; Proctor Decl. Ex. G.

Plaintiffs further allege that during the prosecution of the '051 Patent before the PTO, Novartis made intentional false statements and material omissions, including

> (i) misrepresenting that the mesylate salt of imatinib was not actually prepared in Zimmermann [the '184 Patent], (ii) misrepresenting that obviousness and anticipation depend on whether the salt form compound was actually made in Zimmermann [the '184 Patent] (when the relevant question is whether its preparation is within the knowledge of those of ordinary skill in light of Zimmerman [the '184 Patent]), (iii) failing to disclose that the specific salt, imatinib

> mesylate, had been publicly disclosed in publications authored by Novartis's own scientists, (iv) withholding relevant prior art until after the PTO sent a notice of allowability, thereby failing to disclose information material to patentability during the prosecution of the patent, (v) misrepresenting, when it did finally disclose some material prior art, that the Board had already decided that prior art disclosing the mesylate salt form would not invalidate the patent (when the Board did *not* consider whether other prior art disclosed the mesylate salt, in part because Novartis had not provided the relevant prior art).

CAC ¶ 265.

Plaintiffs additionally claim that Novartis misrepresented in its patent application that the non-needle, β-crystalline form of imatinib mesylate was a recent and "surprising" discovery when, in fact, Novartis scientists had been using the β-crystalline form since August 1993 and anyone skilled in the art would have been both motivated and easily able to formulate a non-needle, crystalline form using routine laboratory procedures.

The PTO ultimately issued the '051 Patent on May 17, 2005. In 2006, Novartis filed and obtained the second follow-on patent, the '799 Patent, which purportedly disclosed the methanesulfonate salt of imatinib and its β-crystalline form. According to Plaintiffs, parts of the '799 Patent application were identical to the '051 Patent application. Novartis again stated that it was "surprised" to find the β-crystalline form in the methanesulfonate salt of the compound, even though the form had been known to have advantageous properties since July 31, 1995 and was the basis of the '051 Patent. Plaintiffs allege that the '799 Patent was broader than the '051 Patent, which claimed the β-crystalline form, because the '799 Patent ultimately also claimed the non-needle crystal of imatinib mesylate. The '799 Patent eventually issued on June 9, 2009. Plaintiffs argue that it is invalid for the same reasons that the '051 Patent is invalid. The '799 Patent was eventually reissued as the RE'932 Patent.

B. The Orange Book Listing

The Orange Book lists FDA-approved drug products along with the corresponding patents that cover the drugs. One objective of the Orange Book is to provide would-be generic manufacturers with notice of any patent rights that are implicated by a brand-name drug. The information published in the Orange Book, however, is based on drug manufacturers' submissions and representations to the FDA. The FDA does not independently determine whether a particular drug product actually reads on a particular patent claim, and it does not examine the asserted patents to ensure their validity.[7]

Novartis submitted all three patents—the original '184 Patent, the '051 Patent, and the '799 Patent—to the FDA to be listed in the Orange Book as covering Gleevec. CAC ¶ 295. Plaintiffs allege that Novartis did so knowing that the Polymorph Patents had "no realistic

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[7] Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a drug manufacturer must obtain FDA approval to market a drug product by filing a New Drug Application ("NDA"). The FDA will approve the NDA if the drug applicant is able to demonstrate that the drug is safe and effective to treat a particular condition. Within thirty days after the FDA approves an NDA, the drug applicant must submit a "Form 3542" to the FDA, in which the sponsor discloses all patents that it believes are implicated by its new drug. Specifically, FDA regulations require the applicant to disclose

> each patent that claims the drug or a method of using the drug that is the subject of the [new drug application] . . . and with respect to 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 product.

21 C.F.R. § 314.53(b)(1). If, however, there are no relevant patents that could reasonably be asserted, the applicant is also required to disclose this information. The regulation provides that

> [i]f the applicant believes that there are no relevant patents that claim the drug substance . . . drug product . . . or the method(s) of use for which the applicant has received approval, and with respect to 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 product, the applicant will verify this information in the appropriate forms.

Id. § 314.53(c)(3). The FDA publishes the patent information provided by the drug applicant in a compendium called *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

likelihood" of ever being able to stand up in court as valid patents, and that those patents would pose an impediment to the launch of generic imatinib mesylate. Id.

C. Litigation and Settlement Between Sun Pharma and Novartis

On June 16, 2006, Sun Pharma ("Sun") filed an abbreviated new drug application ("ANDA"), pursuant to the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, with the FDA, seeking approval to market 100mg and 400mg generic imatinib mesylate tablets, with Gleevec as the brand-name reference.[8] In its ANDA, Sun told the FDA that it would wait until the '184 Patent expired in July 2015 before marketing its drug, but that the follow-on '051 Patent was invalid and would not be infringed. Accordingly, Sun sought FDA approval to market its generic no later than July 5, 2015.

Novartis did not file a Hatch-Waxman infringement suit with respect to the '051 Patent within the period set forth in the statute. Accordingly, no 30-month stay of FDA approval ever

[8] The CAC explains the Hatch-Waxman amendments as follows. See CAC ¶¶ 58–64. In 1984, Congress passed the "Hatch-Waxman" amendments to the FDCA, which were designed to speed the introduction of low-cost generic drugs into the market by permitting generic manufactures to file abbreviated new drug applications. The FDA will approve an ANDA as long as the applicant can show that the proposed generic is therapeutically equivalent to an existing brand-name drug on the market. The Hatch-Waxman amendments also created a mechanism to resolve potential patent disputes between would-be generic manufacturers and brand-name manufacturers before the launch of a generic product. When filing an ANDA, the generic manufacturer must certify, in one of four ways, that its proposed drug will not infringe any patents listed in the Orange Book for the brand-name drug. See 21 U.S.C. § 355(j)(2)(A)(vii). If the generic drug sponsor files a "Paragraph IV Certification," a brand-name manufacturer can sue the ANDA applicant for patent infringement (notwithstanding the fact that the applicant is not yet infringing). The resulting lawsuit, which is commonly known as "Hatch-Waxman Litigation," has the effect of staying the FDA's final approval of the ANDA until the earlier of (1) the passage of 30 months or (2) a court entering final judgment finding that the patent is invalid or not infringed by the generic. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to go to market with its product. In addition, the Hatch-Waxman amendments provide that the first ANDA drug applicant to challenge a patent through a Paragraph IV Certification is eligible for six months of marketing exclusivity after it brings its drug to market.

went into effect for the Sun ANDA, and on November 13, 2009, the FDA granted tentative approval to Sun's ANDA for a generic version of Gleevec.

On June 7, 2013, while Sun was preparing for the timely entry of its generic into the marketplace, Sun filed an action against Novartis in the United States District Court for the District of New Jersey, seeking a declaratory judgment that Sun would not be infringing the '051 Patent and/or that the '051 Patent was invalid or unenforceable. Novartis counterclaimed, alleging infringement of the '051 Patent and seeking a declaration that the '051 Patent was valid and enforceable.[9] Plaintiffs allege that at the time Novartis filed its counterclaims, Novartis knew that the '051 Patent was invalid for obviousness or anticipation and that "Novartis also knew that it had very likely committed inequitable conduct before the PTO during the prosecution of the '051 Patent." CAC ¶ 306.

Sun and Novartis settled the case on May 15, 2014, less than one year after the litigation was filed and before the court issued any substantive rulings in the action. Shortly after the settlement, both parties announced that under their settlement agreement, Sun would be permitted to launch its generic version of Gleevec on February 1, 2016.

D. Litigation And Settlement With Other Generic Manufacturers

In or around 2014, several other generic manufacturers filed ANDAs for generic Gleevec, which included Paragraph IV Certifications as to some or all of the Orange Book-listed patents for Gleevec. In contrast to its approach in the Sun litigation, Novartis immediately filed Hatch-Waxman infringement suits against each of these generics, resulting in 30-month stays of FDA approval as to those ANDAs.

[9] Novartis did not assert the '799 Patent or the RE'932 Patent against Sun.

Two of those cases, one involving Dr. Reddy's Laboratories and the other involving Ranbaxy, have already resulted in settlements, the terms of which are not disclosed in the CAC. Plaintiffs represent that Novartis is still actively pursuing litigation as to six other ANDA filers, including Breckenridge, Roxane/Boehringer Ingelheim, Natco, Amneal, Shilpa Medicare Ltd., and Wockhardt Bio AG. These suits are currently pending in the District Courts for the District of Delaware and the Southern District of New York, with 30-month stays that expire between December 2017 and June 2018.

IV. LEGAL STANDARD

Under the Federal Rules of Civil Procedure, a complaint "must provide 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" Cardigan Mountain Sch. v. N.H. Ins. Co., 787 F.3d 82, 84 (1st Cir. 2015) (quoting Fed. R. Civ. P. 8(a)(2)). This pleading standard requires "more than labels and conclusions," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007), and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. at 678 (quoting Twombly, 550 U.S. at 570).

When evaluating the sufficiency of a complaint, the Court "first must 'distinguish the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited).'" Cardigan Mountain Sch., 787 F.3d at 84 (quoting García-Catalán v. United States, 734 F.3d 100, 103 (1st Cir. 2013)) (further internal quotations and citation omitted). "Second, the court must determine whether the factual allegations are sufficient to support the reasonable inference that the defendant is liable for the misconduct alleged." García-Catalán, 734 F.3d at 103 (internal quotations and citation omitted). In

conducting this analysis, the Court must accept all well-pleaded facts as true and analyze those facts in the light most favorable to the plaintiff's theory, drawing all reasonable inferences in favor of the plaintiff. U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 383 (1st Cir. 2011).

"When considering a motion to dismiss under subsection 12(b)(1) of the Federal Rules of Civil Procedure, the Court should apply a standard of review 'similar to that accorded a dismissal for failure to state a claim' under subsection 12(b)(6)." Menge v. N. Am. Specialty Ins. Co., 905 F. Supp. 2d 414, 416 (D.R.I. 2012) (quoting Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995)).

> When faced with motions to dismiss under both 12(b)(1) and 12(b)(6), a district court, absent good reason to do otherwise, should ordinarily decide the 12(b)(1) motion first . . . . It is not simply formalistic to decide the jurisdictional issue when the case would be dismissed in any event for failure to state a claim. Different consequences flow from dismissals under 12(b)(1) and 12(b)(6): for example, dismissal under the former, not being on the merits, is without res judicata effect.

Ne. Erectors Ass'n of the BTEA v. Sec'y of Labor, Occupational Safety & Health Admin., 62 F.3d 37, 39 (1st Cir. 1995).

V. DISCUSSION

Although Plaintiffs' monopolization claims are based solely on state law, Plaintiffs and Novartis have both raised legal arguments that rely heavily on doctrines developed in federal antitrust cases—specifically, the Noerr-Pennington doctrine, as set forth in E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961) and United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965)—and on the related grounds for antitrust liability—a "Walker Process" theory, as described in Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965), and a sham litigation theory.

The Noerr-Pennington doctrine, which arose in antitrust cases under the Sherman Act, holds that a party petitioning the government for redress is generally immune from antitrust liability based on that conduct. See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993) (hereinafter, "PRE"). Although it appears that the doctrine developed, at least in part, out of First Amendment concerns, see PRE, 508 U.S. at 56 (citing Noerr, 365 U.S. at 138); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503-DJC, 2015 WL 5458570, at *11 (D. Mass. Sept. 16, 2015); Hamilton v. Accu-tek, 935 F. Supp. 1307, 1316 (E.D.N.Y. 1996), the Supreme Court has confirmed that Noerr-Pennington immunity extends to "petitioning" activities before the courts (*i.e.*, litigation), see Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972).

There are exceptions to Noerr-Pennington immunity, however, including when a defendant engages in sham litigation or Walker Process fraud on the PTO, both of which Plaintiffs allege here. The Federal Circuit has held that the sham litigation and Walker Process exceptions "provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws," and that "either or both may be applicable to a particular party's conduct in obtaining and enforcing a patent." Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1071 (Fed. Cir. 1998); see also Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 994 (9th Cir. 1979) (distinguishing sham litigation from Walker Process).

In this case, Plaintiffs' state-law monopolization claims, which closely track the sham litigation and Walker Process exceptions, are based on allegations that Novartis (1) made misrepresentations and omissions when prosecuting the '051 Patent before the PTO; (2) wrongfully submitted the Polymorph Patents for publication in the Orange Book; and (3) initiated alleged sham litigation against Sun and other generic manufacturers. Novartis has

moved to dismiss, asserting that Plaintiffs fail to allege facts supporting either a sham litigation or Walker-Process-type claim. Plaintiffs' opposition brief argues the contrary. Thus, it appears that both parties have presumed that (1) Noerr-Pennington shields parties from liability under all of the state antitrust and unfair competition laws cited in the CAC; and that (2) in order to plead viable claims under these state laws, the Plaintiffs must plausibly allege sham litigation and/or Walker-Process theories of antitrust liability.

The First Circuit has not decided whether the Noerr-Pennington doctrine is applicable to state law claims as a matter of federal law. See Davric Me. Corp. v. Rancourt, 216 F.3d 143, 148 n.7 (1st Cir. 2000). The majority of circuits, however, have recognized that Noerr-Pennington emanated, at least in part, from First Amendment concerns and therefore can apply to certain state law claims as well as federal claims. See, e.g., Coll v. First Am. Title Ins. Co., 642 F.3d 876, 895 (10th Cir. 2011) ("[T]he Noerr-Pennington doctrine is based upon the First Amendment, which applies to [the states] through the Fourteenth Amendment . . . ."); see also VIBO Corp. v. Conway, 669 F.3d 675, 683–84 (6th Cir. 2012) ("Where private actors petition the government for action that would violate antitrust law, the Petition Clause [of the First Amendment] immunizes the actors from litigation in connection with their petitioning."); Kottle v. Nw. Kidney Centers, 146 F.3d 1056, 1059 (9th Cir. 1998) (noting that the Noerr-Pennington doctrine "sweeps broadly and is implicated by both state and federal antitrust claims that allege anticompetitive activity in the form of lobbying or advocacy before any branch of either federal or state government"); John J. Miles, Health Care and Antitrust Law, § 7:8 n.7 (2017) (collecting cases). Further, many states have actually adopted the Noerr-Pennington doctrine and applied it to certain state-law claims. See Coll, 642 F.3d at 895 (noting that "many other states have adopted and apply the Noerr–Pennington doctrine to state antitrust claims, as well as other state-

law claims," collecting cases, and anticipating that the Noerr-Pennington doctrine would be applied to the New Mexico Antitrust Act); Apple, Inc. v. Motorola Mobility, Inc., 886 F. Supp. 2d 1061, 1077 (W.D. Wis. 2012) (applying Noerr-Pennington immunity to bar state-law unfair competition claim); Bayou Fleet, Inc. v. Alexander, 26 F. Supp. 2d 894, 897 (E.D. La. 1998) (dismissing claim under Louisiana Unfair Trade Practices Act as barred by Noerr-Pennington). Accordingly, as both parties have already done, albeit without explicitly addressing the issue, the Court applies the Noerr-Pennington doctrine to Plaintiffs' state-law claims in this case.

In addition to arguing that Plaintiffs fail to allege plausible sham litigation or Walker Process claims, Novartis argues that Plaintiffs lack standing to assert these claims and that their Walker Process claims are preempted by federal patent law.

A. Standing

Novartis argues, first, that Plaintiffs lack standing to challenge the validity of the patents and can therefore not pursue sham litigation claims based on invalidity, and second, that Plaintiffs do not have standing to bring Walker Process claims because they are indirect purchasers. Plaintiffs argue that they have standing to pursue both state-law antitrust claims that involve issues of patent invalidity and Walker Process fraud despite the fact that they are indirect purchasers.

Article III of the U.S. Constitution requires that three conditions be satisfied in order for a plaintiff to have standing. U.S. Const. art. III, § 2, cl. 1. "First and foremost, there must be alleged (and ultimately proved) an 'injury in fact.'" Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998) (quoting Whitmore v. Arkansas, 495 U.S. 149, 155 (1990)). This injury "must be concrete in both a qualitative and temporal sense," "distinct and palpable" as opposed to "abstract," and "actual or imminent" as opposed to "conjectural or hypothetical." Whitmore,

495 U.S. at 155 (internal quotations and citations omitted). Second, standing requires causation, defined as a "fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant." Steel Co., 523 U.S. at 103. Finally, standing requires "redressability—a likelihood that the requested relief will redress the alleged injury." Id.

In addition to the Article III standing requirements, plaintiffs pleading federal antitrust claims must meet two other requirements: "the plaintiff must also allege antitrust injury and must demonstrate, through a series of related factors, that its injuries are more than speculative and that it is well-situated to serve as an 'efficient enforcer' of the antitrust laws." William B. Rubenstein, Newberg on Class Actions § 20:3 (5th ed. 2017); see also Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 535–38 (1983) (establishing factors to consider in assessing antitrust standing). Antitrust standing is generally justified on prudential, rather than on constitutional, grounds. Sullivan v. Tagliabue, 25 F.3d 43, 45 n.5 (1st Cir. 1994) ("It is unquestioned that the requirements of antitrust standing exceed those of standing in a constitutional sense."); see also In re Modafinil Antitrust Litig., 837 F.3d 238, 264 n.30 (3d Cir. 2016), as amended (Sept. 29, 2016) ("Antitrust standing, unlike Article III standing, is not a jurisdictional requirement."); Ethypharm S.A. Fr. v. Abbott Labs., 707 F.3d 223, 232 (3d Cir. 2013).

Although the arguments are somewhat unclear, Novartis seems to challenge Plaintiffs' standing based on antitrust and patent prudential considerations, which relate to Plaintiffs' ability to meet non-Article III standing requirements, rather than challenging their constitutional standing. In any event, the Court finds the Article III standing requirements met here.[10]

[10] Although the Court need not reach the antitrust standing issue because the claims are dismissed on other grounds, it notes that whether Plaintiffs, as indirect purchasers, have antitrust standing to recover under state antitrust statutes in federal court is a question of state law, see

B. Sham Litigation Claims

i. Relevant Legal Standard

In order to bring a sham litigation claim, a plaintiff must plausibly plead that the litigation was:

> (1) 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits'; and (2) subjectively motivated by a desire 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.

Solodyn, 2015 WL 5458570, at * 11 (quoting PRE, 508 U.S. at 60–61). "The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." PRE, 508 U.S. at 62. The Court addresses the two PRE prongs sequentially because "[o]nly if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." Id. at 60.

ii. "Objectively Baseless" Prong

Novartis argues that Plaintiffs have not plausibly alleged that the Sun infringement litigation was "objectively baseless," as required to satisfy the first prong of the PRE test.

Salveson v. JP Morgan Chase & Co., 166 F. Supp. 3d 242, 256 (E.D.N.Y.), aff'd, 663 F. App'x 71 (2d Cir. 2016), cert. denied 137 S.Ct. 1826, (Apr. 24, 2017); see also In re Lithium Ion Batteries Antitrust Litig., No. 13-MD-2420 YGR, 2014 WL 4955377, at *7 (N.D. Cal. Oct. 2, 2014) ("[A]ntitrust standing under state law is just that, a matter of state law."); D.R. Ward Constr. Co. v. Rohm & Haas Co., 470 F. Supp. 2d 485, 494 (E.D. Pa. 2006), that the parties failed to adequately brief. Furthermore, the Court does not understand Novartis' challenge to Plaintiffs' standing to assert claims in states where they do not reside and have not been injured to raise an Article III standing issue that must be addressed now. See Newberg on Class Actions § 2:3; In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions, 148 F.3d 283, 307 (3d Cir. 1998) ("The absentee class members are not required to make a similar [Article III] showing, because once the named parties have demonstrated they are properly before the court, 'the issue [becomes] one of compliance with the provisions of Rule 23, not one of Article III standing.'" (quoting Goodman v. Lukens Steel Co., 777 F.2d 113, 122 (3d Cir. 1985), aff'd, 482 U.S. 656 (1987))).

Novartis asserts that in order to plead a plausible case for "objective baselessness," Plaintiffs need to allege that the patent was either (1) declared invalid by some other court; or (2) that its validity was "tarnished" by an adverse Markman ruling or some other judicial ruling that calls its validity into question. Plaintiffs aver that a prior invalidity finding is not a pre-condition to a sham litigation claim, and that by alleging the patent's invalidity here, they have sufficiently pleaded sham litigation. The Court declines to adopt a bright-line rule requiring that a patent be invalidated or tarnished before a plaintiff can allege a sham litigation claim, but notes that it is difficult to conceive of a scenario in which a sham litigation claim would go forward without the patent having been invalidated or otherwise tarnished.

In support of the "objectively baseless" prong, Plaintiffs argue that the '051 Patent is invalid because it would have been obvious to an ordinary person skilled in the art or inherently anticipated in the prior art and thus not patentable. Specifically, Plaintiffs aver that the prior art—the '184 Patent and at least two articles—disclosed that Novartis had made mesylate salt of imatinib, that an ordinary person with the requisite skill would have been motivated to create a usable crystal form, and that the β-crystal form would have been an obvious choice. Further, Plaintiffs assert that the fact that Novartis failed to sue Sun within the requisite time period to obtain a mandatory 30-month stay, and then agreed to a settlement very favorable to Sun, allowing Sun to share in $7.5 billion in potential Gleevec sales that it otherwise would not have been entitled to unless it succeeded in litigation, all shows that Novartis did not believe that it could win on the merits.

Here, Plaintiffs have not alleged a plausible sham litigation claim. The possible invalidity of a patent does not, in and of itself, establish that the litigation asserting it was objectively baseless. "A firm that has received a patent from the patent office (and not by fraud . . .), and

thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment." Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 992–93 (N.D. Ill. 2003). Absent meeting the PRE criteria, "[n]either the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability." C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998). In other words, even if a patent is ultimately found to be invalid, that does not necessarily prove that the relevant claims, without a prior invalidity finding, were "so baseless that no reasonable litigant could realistically expect to secure favorable relief." PRE, 508 U.S. at 62. Thus, a merely plausible patent invalidity claim is not enough to support a plausible sham litigation claim.

"[T]he determination of whether such a suit is a sham depends not on what the patentee believes but 'on the nature of and the underlying merits of the patentee's case.'" Asahi Glass Co., 289 F. Supp. 2d at 995 (quoting FilmTec Corp. v. Hydranautics, 67 F.3d 931, 936 (Fed. Cir. 1995)). Even on the facts alleged in the CAC, Novartis had a colorable claim that the '051 Patent was valid and enforceable by arguing that it was neither inherently anticipated by nor obvious in the prior art, which is consistent with both the patent examiner's and PTO Board of Appeal's determinations.

To prove invalidity by anticipation, a party must show 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). The prior art, identified by Plaintiffs as belatedly presented or withheld completely from the patent examiner, 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, CAC ¶ 140, which has many different crystalline forms, CAC ¶¶ 35–36. "[D]ifferences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation." Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008). Furthermore, not only did the PTO assume that the prior art disclosed the imatinib mesylate, but the patent examiner also received some of the prior art identified in the CAC, initialed it, and still issued the '051 Patent. Thus, the facts in the CAC show that Novartis had a colorable argument that the '051 Patent was not inherently anticipated by prior art, and Plaintiffs cannot, without more, plausibly allege that the Sun litigation was objectively baseless on that theory of patent invalidity.

With respect to Plaintiffs' theory of patent invalidity based on obviousness, the CAC also establishes that Novartis had a colorable claim that the '051 Patent was not obvious. Section 103 of the Patent Act provides that subject matter cannot be patented if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. The Supreme Court explained how to apply § 103 as follows:

> the scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . 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); see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406–07 (2007) (explaining that Graham "set out a framework for applying the statutory language of § 103" and controls inquiries of whether claimed subject matter is obvious). Furthermore, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results," KSR Int'l Co., 550 U.S. at 416, however, a patent "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art," id. at 418. "Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." Id.

The CAC alleges that any person skilled in the art at the time would have tried to find a crystalline form that was suitable for commercial pharmaceutical production, and thus would have been motivated to find a more stable, less hygroscopic (*i.e.*, one that absorbed less moisture from the air) form. CAC ¶¶ 206–07. It further claims that anyone skilled in the art at the time would have known that the needle-shaped, α-crystalline form of mesylate salt was not suitable for pharmaceutical production and would have tried to find a non-needle form (such as the β-crystalline form). CAC ¶ 208. It also alleges 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. CAC ¶ 211.

The fact that someone might have been "motivated" to discover a crystalline form of a compound that would be more suitable for pharmaceutical production does not on its own

establish that the subject matter was obvious. See In re Armodafinil Patent Litig. Inc., 939 F. Supp. 2d 456, 487 (D. Del. 2013) (explaining that obviousness "requires 'a reasonable expectation of success'" (quoting Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006))). Even following extensive presentation of evidence in trial, analogous arguments involving the obviousness of polymorphic forms have failed to invalidate patents. See id. at 494. Here, the prior art did not disclose the existence or properties of the β-crystalline form or the method by which it could be derived.[11] The CAC largely contains conclusory allegations that deriving the β-crystalline form would have been predictable based on the mere disclosure of the mesylate salt and that the methods used to derive it were routine. Even if this were enough to allege a plausible invalidity claim, it is not enough to show that Novartis' litigation based on the '051 Patent was objectively baseless.

Moreover, the patent examiner considered much of the prior art at issue in the CAC before eventually issuing the patent, and it is not clear that the prior undisclosed art would have altered the examiner's obviousness analysis. Further, it is noteworthy that the '051 Patent had never been previously invalidated or tarnished in any way. See Solodyn, 2015 WL 5458570, at *11.

Finally, the fact that Novartis has obtained settlements involving challenges to the validity of the Polymorph Patents and that these patents have never actually been called into question by a judicial authority, while not dispositive, further undercuts Plaintiffs' ability to

[11] Plaintiffs alleged that the Buchdunger and Druker articles disclosed that scientists used the β-crystalline form of the mesylate salt. CAC ¶ 183. The actual description of these articles calls that allegation into question. The 1996 Buchdunger Article apparently discussed "crystalline derivatives" without describing any specific crystalline form. See CAC ¶¶ 165–67. The 1996 Druker Article only seems to discuss mesylate salt generally, not its crystalline forms. See CAC ¶¶ 159–64. In any event, both were disclosed prior to the issuance of the '051 Patent.

allege objective baselessness, particularly where Plaintiffs have not called the settlements themselves into question. See Asahi Glass Co., 289 F. Supp. 2d at 992 ("If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation."). Although the '051 Patent could ultimately be invalid, that issue is not directly before this Court. Accordingly, Plaintiffs have failed to allege a plausible claim that litigation based on the '051 Patent, and therefore the other Polymorph Patent, was "objectively baseless."

C. Walker Process Fraud Claims

i. Relevant Legal Standard

In Walker Process, the Supreme Court held that if a party obtains a patent "by knowingly and willfully misrepresenting facts to the Patent Office," this is "sufficient to strip [the party] of its exemption from the antitrust laws." 382 U.S. at 177. To adequately allege Walker Process fraud, Plaintiffs must claim "(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted."[12] C.R. Bard, 157 F.3d at 1364; see also

[12] The Federal Circuit has described Walker Process fraud as distinct from inequitable conduct because "[t]he 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, Inc. v. Mosey, 476 F.3d 1337, 1346–47 (Fed. Cir. 2007); see also C.R. Bard, 157 F.3d at 1365 (explaining that "an equitable defense . . . may be satisfied when material information is withheld with the intent to deceive the examiner, whether or not the examiner is shown to have relied thereon"); SanDisk Corp. v. STMicroelectronics, Inc., No. C 04-4379 JF (RS), 2008 WL 4615605, at *5 n.5 (N.D. Cal. Oct. 17, 2008) ("Walker Process fraud essentially is a more egregious version of inequitable conduct."). In Metris U.S.A., Inc. v. Faro Techs., Inc., the court observed that, following a Federal Circuit decision in 2011 that heightened the standard for inequitable conduct, "it appears that Walker Process fraud is

Nobelpharma, 141 F.3d at 1070–71. The fraud must be "knowing and willful." C.R. Bard, 157 F.3d at 1364 (quoting Walker Process, 382 U.S. at 177). Where the fraud is based on omission, "there must be evidence of intent separable from the simple fact of omission." Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1347 (Fed. Cir. 2007).

In addition, a plaintiff must plausibly allege all other required elements of an antitrust claim—causation, antitrust injury, and market power. See Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 459 (1993); see also Ritz Camera & Image, LLC, v. SanDisk Corp., 700 F.3d 503, 506 (Fed. Cir. 2012) (explaining that Walker Process fraud claim requires showing "all the elements otherwise necessary to establish a Sherman Act monopolization charge"); C.R. Bard, 157 F.3d at 1368 ("Unless the patent had been obtained by fraud such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act."). Finally, plaintiffs alleging Walker Process fraud must comply with the heightened pleading requirements of Rule 9(b) as applied by the Federal Circuit. Medimmune, Inc. v. Genentech, Inc., 427 F.3d 958, 967 (Fed. Cir. 2005), rev'd and remanded on other grounds, 549 U.S. 118 (2007); see also Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326–28 (Fed. Cir. 2009) (explaining that Rule 9(b) particularity requirement entails alleging the specific "who, what, when, where, and how").

ii. Misrepresentation/Omission and Materiality

Plaintiffs base their state-law Walker Process fraud claims on the following: (1) the withholding of prior art publications by Novartis' own scientists "that explicitly disclosed the

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now largely coextensive with the new inequitable conduct doctrine." 882 F. Supp. 2d 160, 174 (D. Mass. 2011). Thus, although the Federal Circuit has not clarified how coextensive Walker Process fraud is with inequitable conduct, it seems to remain the case that a plaintiff that fails to allege inequitable conduct, necessarily fails to allege Walker Process fraud. Dippin' Dots, 476 F.3d at 1346–47.

mesylate salt form imatinib that had the desired qualities of kinase inhibition;" (2) that "Novartis misrepresented that the non-needle form of the compound was a recent, 'surprising' discovery, despite the fact that Ciba-Geigy scientists had been using it for years," that "anyone skilled in the art would have been both motivated and easily able to formulate a non-needle crystal form using routine laboratory procedures," and that Novartis' scientists did in fact do that; and (3) that Novartis improperly argued to the patent examiner that the PTO Board of Appeals decision had *res judicata* effect. CAC ¶¶ 5–7.

Novartis argues that three of the five prior art references at issue were not withheld from the PTO and that the remaining two references were cumulative or immaterial. The two prior art references that were ultimately disclosed to the PTO in an IDS and which the examiner herself initialed, see Proctor Decl., Exs. G–H, indicating that she considered them, cannot form the basis of a plausible Walker Process fraud claim, where they were disclosed prior to issuance. See Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1327 (Fed. Cir. 2000) ("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner."). Further, Plaintiffs failed to show how a third prior art reference (the 1996 Druker Article) that was actually cited in the '051 Patent's specification, see Proctor Decl., Ex. A, can support a fraud allegation. See Oracle Corp. v. Drug Logic, Inc., No. 11-00910, 2011 WL 5576267, at *11 (N.D. Cal. Nov. 16, 2011) (holding that, where prior art references were disclosed in patent's specifications, allegations did not support inference that applicant deliberately withheld material information).

Novartis' *res judicata* argument to the patent examiner regarding the prior art that was disclosed post-appeal also cannot support a Walker Process fraud claim because it does not qualify as a material misrepresentation and the patent examiner was not bound by it. See

Rothman v. Target Corp., 556 F.3d 1310, 1328–29 (Fed. Cir. 2009) ("While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct."); Environ Prods., Inc. v. Total Containment, Inc., 951 F. Supp. 57, 61 (E.D. Pa. 1996) ("[T]here is no policy reason which would support the unprecedented expansion of the interpretation of 'material information' to include legal arguments."). Plaintiffs make no argument to the contrary in their opposition brief.

Furthermore, the two prior art references that Novartis admits were withheld—the 1995 Druker Presentation and the 1996 Zimmerman Article—also do not support a Walker Process fraud claim in this case. Plaintiffs' allegations of materiality with respect to the undisclosed prior art do not reach the plausibility threshold. In their brief, they explain that the prior art is relevant as to "whether the mesylate salt had been made or disclosed earlier," but the PTO, on appeal, specifically assumed the mesylate salt of imatinib had been disclosed and, moreover, Novartis did ultimately provide prior art that disclosed mesylate salt to the patent examiner. Plaintiffs also argue that the prior art is relevant as to "whether the β-crystal form could be made following routine conditions." Yet Plaintiffs fail to allege how either the 1995 Druker Presentation or the 1996 Zimmerman Article are material in that respect and, as required by Rule 9(b), how they are material to any particular claim in the '051 Patent. See Exergen Corp., 575 F.3d at 1329 ("[T]he pleading fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the 'what' and 'where' of the material omissions."). Moreover, the Court cannot infer that they plausibly are material where they neither discuss the β-crystalline form of the mesylate salt specifically nor mention methods for creating it.

Finally, Novartis' statement that the discovery of the β-crystalline form was "surprising" does not support a plausible fraud claim. Firstly, it is unclear whether such a statement qualifies as a misrepresentation, particularly where the 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. Cf. LifeScan, Inc. v. Home Diagnostics, Inc., 103 F. Supp. 2d 379, 386 (D. Del. 2000) ("As the Federal Circuit has recognized, the mere fact that a patent applicant attempts to distinguish its patent from the prior art does not constitute a material omission or misrepresentation where the patent examiner has the prior art before him or her, and therefore, is free to make his or her own conclusions regarding the claimed invention."). Further, 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.

Accordingly, Plaintiffs have failed to sufficiently allege that the claimed misrepresentations or omissions were material to the patent examiner's determination.

iii. Fraudulent Intent

"Although 'knowledge' and 'intent' may be averred generally, . . . the pleadings [must] allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." Exergen Corp., 575 F.3d at 1327 (citing Fed. R. Civ. P. 9(b)). The facts alleged, even construed generously, do not support a plausible inference of fraudulent intent. In their opposition brief, Plaintiffs point to no specific factual allegations in the CAC that would permit such an inference, and argue only that "no other inference . . . can be drawn from the facts alleged in the complaint." [ECF No. 120 at 29]. "[T]he simple fact of omission" is insufficient. Dippin' Dots v. Mosey, 476 F.3d 1337, 1347 (Fed. Cir. 2007). Further, Plaintiffs' belated disclosure of certain prior art does not permit this Court, without more, to plausibly infer

that Novartis acted with fraudulent intent. At best, the allegation that the prior art was disclosed after an initial notice of allowance cuts equally in favor of and against Plaintiffs, in that it suggests that Novartis did not intend to hide information as evidenced by the fact that it did, in fact, disclose it. Where the prior art at issue was largely disclosed and the remaining undisclosed prior art is not clearly material in light of the disclosed prior art, the fact that Novartis' scientists authored the prior art does not demonstrate deceptive intent. Lastly, based on all of the above, there are insufficient factual allegations that would allow the Court to infer that the characterization of the β-crystal as "surprising" was intended to deceive the PTO.

Accordingly, the Court concludes that Plaintiffs have failed to adequately plead a state-law Walker Process fraud claim.[13] Moreover, where Plaintiffs have failed to state a claim based on sham litigation or Walker-Process fraud, Plaintiffs' Orange Book listing allegations cannot form a separate basis for liability and therefore fail as well. See Daiichi Sankyo, Inc. v. Apotex, Inc., No. CIVA.030937(SDW-MCA), 2009 WL 1437815, at *9 (D.N.J. May 19, 2009) (noting that "the Orange Book listing was only wrongful if the patent was obtained through fraud or was 'objectively baseless'"); see also Solodyn, 2015 WL 5458570, at *12. Because Plaintiffs have

[13] Novartis also argues that the state-law Walker Process fraud claims should be dismissed because they are preempted by federal patent law. When determining whether state-law claims are preempted by federal patent law, Federal Circuit law controls. Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH, 524 F.3d 1254, 1260 (Fed. Cir. 2008). In Hunter Douglas, Inc. v. Harmonic Design, Inc., the Federal Circuit considered whether federal patent law preempted state law claims for, *inter alia*, state unfair competition law that prohibited tortious activities in the marketplace. 153 F.3d 1318 (Fed. Cir. 1998), overruled on other grounds, Midwest Industries, Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1358–59 (Fed. Cir. 1999). It held that there was no field preemption of state unfair competition law by federal patent law. Hunter Douglas, 153 F.3d at 1334–35. With respect to conflict preemption, Hunter Douglas held that state-law claims were preempted by federal patent law only"[i]f a plaintiff bases its tort action on conduct that is protected or governed by federal patent law." Id. at 1335. Because Novartis' preemption argument does not implicate this Court's jurisdiction, the Court need not address it here. This Court also need not address Defendants' state law-specific arguments for dismissal.

failed to adequately allege claims sufficient to avoid the bar of Noerr-Pennington immunity, their state-law claims must be dismissed.

VI. CONCLUSION

Accordingly, Novartis' motion to dismiss [ECF No. 111] is GRANTED. In light of this ruling, there is no need for a Rule 26(f) conference and that motion [ECF No. 135] is DENIED as moot.

SO ORDERED.

Dated: June 30, 2017

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE