**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| LANNETT COMPANY, INC., | ) CIVIL ACTION |
| | ) |
| Plaintiff, | ) No. 08-cv-3920 |
| | ) |
| v. | ) Honorable Timothy J. Savage |
| | ) |
| CELGENE CORPORATION, | ) |
| | ) |
| Defendant. | ) |
| | ) |

**DEFENDANT CELGENE CORPORATION'S MEMORANDUM OF LAW**
**IN SUPPORT OF ITS RENEWED MOTION TO DISMISS**

Defendant Celgene Corporation ("Celgene") hereby respectfully moves the Court to dismiss the Complaint of Plaintiff Lannett Company, Inc. ("Lannett") pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

## INTRODUCTION

This lawsuit represents Lannett's second attempt to obtain an injunction from this Court compelling Celgene to sell to Lannett Celgene's branded thalidomide product, Thalomid®. Like its original suit, Lannett's latest effort to force a sale of this life-saving but highly teratogenic product outside Celgene's FDA-mandated distribution system finds no support in the antitrust statutes or case law. Like that suit, this one is meritless and should be dismissed.

As before, Lannett's current Complaint pleads a single substantive claim for violation of Section Two of the Sherman Act, 15 U.S.C. § 2. Specifically, Lannett alleges that Celgene has refused to provide it with units of Thalomid® so that Lannett may conduct bioequivalence testing to submit to the FDA in connection with a future application to market a

generic version of Thalomid®. Lannett contends that, without Celgene's cooperation and assistance, it will not be able to launch a generic thalidomide product to compete with Celgene's branded product. According to Lannett, in these circumstances, the antitrust laws impose upon Celgene a duty to sell Thalomid® to Lannett so that it may seek to enter the market.

Based on the pleadings, this Court should enter judgment for Celgene under Rule 12(b)(6). Lannett's legal theory flies in the face of a core principle of antitrust law – that no company, even a monopolist, should be forced to deal with its competitors. *Verizon Comm'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). To proceed beyond a motion to dismiss on a duty to deal claim under Section Two, the plaintiff must – at a minimum – allege facts from which the Court could find it plausible that the defendant is a monopolist who terminated a profitable, prior course of dealing with the plaintiff. *See Trinko*, 540 U.S. at 409; *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Here, Lannett has not alleged, and cannot allege, that Celgene has ever sold thalidomide to Lannett or that it would be economically rational for it to do so. Invoking the "essential facilities" doctrine does nothing to save Lannett's claim because – even assuming the doctrine's continuing validity after *Trinko* – the factual circumstances of this case do not fit the requirements of the doctrine.

In the alternative, if the Court does not dismiss the Complaint pursuant to Rule 12(b)(6), it should stay the case until the FDA rules on each of two pending citizen petitions. A premature ruling by this Court granting the relief sought by Lannett would interfere with the FDA's primary jurisdiction.

## STATEMENT OF FACTS

Defendant Celgene is a biopharmaceutical company that develops treatments for cancer and immunological diseases. (Compl. ¶ 12). Celgene is the only U.S. company that has

obtained FDA approval to market thalidomide, which it sells under the brand name Thalomid®. (*Id.* ¶ 21). Celgene holds several patents covering Thalomid® and methods for administering Thalomid® safely to patients after controlled distribution.[1] The last of these patents does not expire until 2023.

Thalidomide is a highly teratogenic drug: ingestion of even a single capsule of thalidomide by a pregnant woman may result in fetal death or serious birth defects. Originally marketed outside the United States for morning sickness, thalidomide was taken off the market in the 1960s after its lethal danger became apparent. (*Id.* ¶¶ 14-15, 17, 20). In 1998, Celgene applied for and obtained FDA approval to market thalidomide for use in treating erythema nodosum leprosum ("ENL"), a complication of leprosy. (*Id.* ¶ 19). As a condition of granting marketing approval for Thalomid®, FDA explicitly required Celgene to adhere to the System for Thalidomide Education and Prescribing Safety program ("S.T.E.P.S.®"), a restricted distribution system developed by Celgene and aimed at achieving zero fetal exposure to thalidomide. (*Id.* ¶ 27; Letter from Gary Buehler, Dir. of the Office of Generic Drugs, FDA, to John Ryman, Lannett (2/12/07) (attached to Complaint as Ex. A ("Compl. Ex. A"))).

The S.T.E.P.S.® system is designed to minimize the chance of fetal exposure by tightly controlling the distribution and administration of Thalomid®. S.T.E.P.S.® requires

[1] The patents covering the formulation of Thalomid®, the use of Thalomid® in the treatment of cancer, and its administration under a restricted distribution program are listed in the FDA's "Orange Book." *See* Office of Generic Drugs, Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations*, at ADA 181-82 (30th ed. 2010) (available at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf). The Court may take judicial notice of the listings in such authoritative government sources. *See* Fed. R. Evid. 201(b) (permitting judicial notice of facts "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned"); *Fellner v. Tri-Union Seafoods, L.L.C.* No. 06-0688, 2010 WL 1490927, at *6 n.8 (D.N.J. Apr. 13, 2010) (taking judicial notice of records maintained on FDA's website). The patents listed in the Orange Book can be independently verified using the U.S. Patent and Trademark Office's website at http://patft.uspto.gov/netahtml/PTO/search-bool.html (enter the patent number in the space provided and click "Search"). Such listings are also subject to judicial notice. *See Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 (3d Cir. 2004) (taking judicial notice of records available on the PTO website).

patients, prescribers, and pharmacists to register with Celgene and to work with Celgene customer care representatives to ensure that patients are educated and tested about the proper use of thalidomide and that prescribers and pharmacies distribute Thalomid® only under controlled conditions. (Compl. ¶¶ 25-30). Several years after Celgene first obtained approval to market Thalomid® for use in treating ENL, it obtained a second FDA approval to market Thalomid® for use in treating multiple myeloma, a cancer of the blood. (*Id.* ¶ 21). Again, FDA expressly conditioned its approval on adherence to the S.T.E.P.S.® program of restricted distribution. The FDA has since deemed S.T.E.P.S.® to be an approved Risk Evaluation and Mitigation Strategy ("REMS") pursuant to 21 U.S.C. § 355-1.

Plaintiff Lannett, a manufacturer of generic drugs, alleges that it has begun working on a generic thalidomide. (*Id.* ¶¶ 5, 34-39). In a letter dated September 6, 2006, Lannett sought FDA's recommendations regarding thalidomide bioequivalence testing. (*Id.* ¶¶ 5, 34-39).[2] On February 12, 2007, FDA responded with a letter stating that "[t]he safeguards included in the S.T.E.P.S.® program were a condition of approval for marketing of THALOMID® and S.T.E.P.S.® was specifically referenced in the July 16, 1998 approval letter to Celgene." (*Id.* ¶ 40; Compl. Ex. A, at 1). However, FDA explained that it "intends to exercise its enforcement discretion to permit Celgene to provide ... 500 units" of Thalomid® to Lannett outside of the S.T.E.P.S.® program "when Celgene has received confirmation in writing" that Lannett "has an IND in effect" or has otherwise established to the FDA's satisfaction that it has

[2] A generic drug manufacturer that submits an abbreviated new drug application ("ANDA") to the FDA must establish, among other things, that its product is "bioequivalent" to the reference product. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

established a protocol "to ensure the safety of the subjects" in the bioequivalence study.[3] (Compl. ¶ 40; Compl. Ex. A, at 2).

On July 26, 2007, Lannett sent a letter to Celgene stating that "the FDA has instructed [Lannett] to purchase 250 [sic] Thalomid® 200 MG Capsules from [Celgene]" for use in bioequivalence testing for a generic thalidomide product. (Compl. ¶ 41).[4] The letter did not provide any indication that Lannett had an IND or an alternative FDA-approved safety protocol in effect. In September 2007, Lannett faxed to Celgene a copy of the FDA letter of February 12, 2007. (*Id.* ¶ 42). On January 8, 2008, Celgene responded that it could not provide Thalomid® to Lannett outside of the S.T.E.P.S.® program unless Lannett provided it with certain safety information and assurances, including information about its intended risk management measures and evidence of insurance coverage. (*See id.* ¶¶ 46-48).

Rather than provide the information requested by Celgene, Lannett filed its first antitrust suit on January 14, 2008. (Compl. ¶ 49). Upon inquiry by the Court, Lannett conceded that it did not have an IND or FDA approval for its proposed bioequivalence study. (*Id.* ¶ 55). On March 18, 2008, following a hearing on Celgene's motion to dismiss, the Court dismissed Lannett's complaint without prejudice. (*Id.*).

Several months after the dismissal of Lannett's first suit, on August 14, 2008, Lannett forwarded to Celgene a letter it had received from the FDA's Office of Generic Drugs ("OGD"). The OGD letter, dated August 11, 2008, stated that OGD found that Lannett's "final protocol (BE-183-THAL-2007, Version 4), consent form, and information materials on the S.T.E.P.S. program include the necessary safety precautions as set forth in the FDA mandated

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[3] An IND is an application to distribute an "investigational new drug." *See* 21 C.F.R. part 312.

[4] Like its original complaint, Lannett's current Complaint misquotes this letter as requesting 250 Thalomid® capsules; Mr. Bedrosian's letter actually requested 600 capsules.

S.T.E.P.S. program for prevention of unrecognized accidental fetal exposure to teratogenic effects with use of thalidomide." (Compl. ¶ 58; Compl. Ex. B). Notably, in issuing this letter, OGD stated its belief that it was reviewing Lannett's "final protocol" for its bioequivalence trial. (*Id.*). The OGD letter also stated that Lannett's protocol was subject to further independent review by an Institutional Review Board ("IRB") and that OGD's approval "should not influence the decision of an IRB to accept the protocol."[5]

Lannett filed this suit on August 15, 2008. Following the filing of the suit, Celgene and Lannett engaged in further communications concerning Lannett's proposed bioequivalence trial for Thalomid®. Those discussions continued until March 5, 2010, when Celgene learned that Lannett had removed significant patient safety protections from subsequent versions of its trial protocol after the FDA reviewed it and without the FDA's consent.[6] At that point, Celgene informed Lannett of its intention to file the present motion.

**STANDARD OF REVIEW**

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. ___, 129 S.Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570); *accord Gelman v. State Farm Mut. Auto. Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009). In determining a claim's plausibility, a court does not have to accept as true "'legal conclusion[s] couched as ... factual allegation[s].'" *Id.* (quoting *Twombly*, 550 U.S. at 555). Although legal conclusions "can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 1949-50.

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[5] The FDA's requirements for IRBs are set forth at 21 C.F.R. part 56.

[6] For informational purposes only, Celgene submits as Attachment 1 hereto a copy of counsel's March 5, 2010 letter to Lannett pointing out the changes in the trial protocol.

"Determining whether a complaint states a plausible claim for relief [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Iqbal*, 556 U.S. at 1949 (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted).

**ARGUMENT**

Lannett's Section Two claim should be dismissed under Rule 12(b)(6) for failure to state a claim for which relief can be granted. Preliminarily, while the Court need not decide this question, the Complaint fails to allege that Celgene is a monopolist in any properly defined market. Lannett asserts, without more, that Thalomid® has a 100% share of the markets for treatment of ENL and multiple myeloma without addressing any of the well-known therapeutic alternatives to thalidomide that are available.[7] Such naked assertions of market share do not adequately allege a Section Two claim. *See Crossroads Cogeneration Corp. v. Orange & Rockland Util., Inc.,* 159 F.3d 129, 141 (3d Cir. 1998); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997).[8]

In any event, however, even assuming for the sake of argument that Celgene is a monopolist, Celgene has no duty to deal with Lannett at all. Unlike the rare cases in which a

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[7] *See, e.g.*, FDA-approved Label for Lamprene®, at 1 (indications include treatment of ENL), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/19500slr010_lamprene_lbl.pdf; FDA-approved Label for Velcade®, at 1 (indications include treatment of multiple myeloma), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021602s019s020lbl.pdf.

[8] Lannett's allegations concerning its alleged exclusion from the putative "market" for treatments of multiple myeloma fail for an additional reason. It is a matter of public record that Celgene's multiple myeloma indication for THALOMID® is protected by "orphan drug status," giving Celgene legal exclusivity until at least the year 2013. *See* FDA, Cumulative List of Designated and Approved Orphan Products, at 97 (2007), available at www.fda.gov/orphan/designat/allap.rtf.

company has been liable under Section Two for refusing to deal with a competitor, here Lannett has made no allegation that Celgene engaged in a prior, profitable course of dealing with Lannett. Absent such a prior course of dealing, Lannett cannot state a viable Section Two claim and its Complaint should be dismissed. In the alternative, if the Court does not dismiss Lannett's Complaint, this action should be stayed while the FDA continues to review citizen petitions that raise issues central to this case and within the core of FDA's regulatory expertise.

## I. LANNETT FAILS TO ALLEGE A VIABLE SECTION TWO CLAIM

Lannett's effort to force Celgene to sell it Thalomid® runs afoul of a bedrock antitrust principle: No company – not even a monopolist – has a duty to aid its competitors. This principle was recently reinforced by the Supreme Court in its decision in *Verizon Communications v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004). In *Trinko*, the Court dismissed on the pleadings a refusal to deal claim brought by a customer of one of the rivals of defendant Verizon. The plaintiff claimed that Verizon, which had until 2006 operated under an exclusive franchise for the provision of local phone service in the New York area, had refused to provide interconnection services to its competitors, including the plaintiff's provider. 540 U.S. at 401. In rejecting the plaintiff's Section Two claim, the Supreme Court noted the "long recognized right" of firms to "exercise [their] own independent discretion as to the parties with whom [they] will deal." *Id.* at 408 (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)). The Court emphasized that it had "been very cautious in recognizing exceptions" to this principle, "because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct" by a single firm. *Id.*

Distinguishing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the Court placed that prior decision "at or near the outer boundary of § 2 liability." *Trinko*, 540 U.S. at 409. In *Aspen Skiing*, the defendant's refusal to cooperate with the plaintiff

was a sudden departure from a long-standing course of dealing. By contrast, the plaintiff in *Trinko* had not alleged that Verizon had "voluntarily engaged in a course of dealing with its rivals, or ever would have absent statutory compulsion." *Id.* Thus, in contrast to the defendant in *Aspen Skiing*, there was no suggestion that Verizon had terminated "a voluntary (*and thus presumably profitable*) course of dealing." *Id.* (emphasis original). Had Verizon done so, its conduct might have "suggested a willingness to forsake short-term profits to achieve an anticompetitive end." *Id.* But, because Verizon had not voluntarily engaged in a prior course of dealing with its rival, its alleged refusal to do so could not support Section Two liability.

By limiting *Aspen Skiing* to its peculiar facts, *Trinko* "severely narrowed the antitrust duty of a monopolist to deal with rivals." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 772d2 (2d ed. & Supp. 2009) (hereafter, "Antitrust Law"). Here, as further explained below, Lannett's claim does not fit within this narrow set of circumstances in which such a duty may arise.[9]

### A. Lannett Does Not, And Cannot, Allege That Celgene Terminated A Prior Course of Dealing

Since *Trinko,* every federal court of appeals to consider the issue has held that a refusal-to-deal claim cannot withstand a motion to dismiss absent allegations that the defendant

[9] Further, courts have held that where, as here, the alleged refusal to deal concerns a patent holder's unwillingness to license or sell a patented product, the right to refuse is nearly absolute. "In the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention *free from liability under the antitrust laws*." *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) (emphasis added); *see also W.L. Gore & Assocs. v. Carlisle Corp.*, 529 F.2d 614, 623-24 (3d Cir. 1976) ("The right to refuse to license is the essence of the patent holder's right under the patent law," and "[a]n effort by a patent holder to defend his valid patent monopoly by exercising the right which he has in common with all others to do business with whom he pleases cannot rationally be regarded as misuse of his patent."); *United States v. CIBA-GEIGY Corp.*, 508 F. Supp. 1118, 1149-51 (D.N.J. 1976) (manufacturer of a patented hypertension drug did not violate Section Two by unilaterally refusing to sell or permit its licensees to sell the product to generic manufacturers because any resulting restraint on competition "inheres in the patent monopoly itself").

unilaterally terminated a prior course of dealing with the plaintiff. *See In re Elevator Antitrust Litig.*, 502 F.3d 47, 52 (2d Cir. 2007) ("[B]ecause plaintiffs do not allege that defendants terminated any prior course of dealing – the sole exception to the broad right of a firm to refuse to deal with its competitors – the [complaint's] allegations are insufficient to state a unilateral-monopolization claim."); *Covad Comm'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 673 (D.C. Cir. 2005) ("An antitrust claim based upon the defendant's refusal to cooperate with its competitor can withstand a motion to dismiss only when it is alleged either that the defendant had previously engaged in a course of dealing with its rivals, or that it would ever have done so absent statutory compulsion." (quotation marks and alterations omitted)); *Covad Comm'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004) ("*Trinko* now effectively makes the unilateral termination of a voluntary course of dealing a requirement for a valid refusal-to-deal claim under *Aspen*.").

Lannett's complaint, however, makes no allegation that Celgene previously engaged in any course of dealing with Lannett. There is no history of Celgene "voluntarily engag[ing] in a course of dealing with its rivals." *Trinko*, 540 U.S. at 409. Indeed, the Complaint makes no allegation that Celgene has ever sold Thalomid® outside of the S.T.E.P.S.® program. Under such circumstances, *Trinko* makes clear that the antitrust laws do not impose a duty upon Celgene to sell Thalomid® to Lannett.

### B. The Complaint Does Not Plausibly Allege That Celgene Has Acted Contrary To Its Legitimate Business Interests

Even if Lannett could allege a prior course of dealing with Celgene, that would not save its antitrust claim. To succeed on a Section Two duty-to-deal claim, a plaintiff must also demonstrate that the course of dealing it seeks to force the defendant to engage in would be a profitable one for the defendant. A defendant's unwillingness to deal profitably with the

plaintiff may reveal an intention to sacrifice short-term gains to obtain long-run monopoly profits. *Trinko*, 540 U.S. at 409. Thus, for example, in *Christy Sports, LLC v. Deer Valley Resort, LTD*, 555 F.3d 1188 (10th Cir. 2009), the court upheld dismissal of plaintiff's Section Two claim, despite the defendant's termination of a prior course of dealing, because the complaint failed to allege that "the defendant terminated a profitable relationship without any economic justification, showing 'a willingness to forsake short-term profits to achieve an anticompetitive end.'" *Id.* at 1197 (quoting *Trinko*, 472 U.S. at 409); *see Four Corners Nephrology Assocs. v. Mercy Med. Ctr. of Durango*, 582 F.3d 1216, 1225 (10th Cir. 2009) ("[T]he key fact permitting liability in *Aspen Skiing* 'was that the defendant terminated a profitable relationship without any economic justification' other than an anticompetitive one." (quoting *Christy Sports*, 555 F.3d at 1197)); *Antitrust Law* ¶ 772d3 ("[B]efore a unilateral refusal to deal is unlawful under § 2, the refusal must be 'irrational' in the sense that the defendant sacrificed an opportunity to make a profitable sale only because of the adverse impact the refusal would have on a rival.")

Nowhere in the Complaint does Lannett allege that Celgene's refusal to sell it Thalomid® outside the protections of the S.T.E.P.S.® program would be "irrational" or without "economic justification." To the contrary, Lannett's own complaint details the horrors caused by uncontrolled use of thalidomide in the 1950s and 1960s. (Compl. ¶¶ 14-6). In the wake of the resulting tragic fetal deaths and deformities, thalidomide was banned worldwide for decades, despite its efficacy in treating certain medical conditions. (*Id.* ¶¶ 17-18). Lannett also correctly alleges that thalidomide became available in the United States only after Celgene expended great effort, working with the FDA, healthcare providers, and patients, to develop S.T.E.P.S.®, a "novel method of delivering Thalomid® (thalidomide) to patients." (*Id.* ¶¶ 20, 26-27).

Likewise, Celgene has invested significant resources in developing Thalomid® as a cancer agent and owns or controls patents to the thalidomide formulation and its use in cancer treatment. S.T.E.P.S.® has been incredibly successful due to its tight monitoring of distribution and compliance: "[O]ver 145,000 individuals have taken advantage of Celgene's S.T.E.P.S.® program in order to receive the potential therapeutic benefits of Thalomid® (thalidomide)." (*Id.* ¶ 31).

These admitted facts refute any attempt by Lannett to argue that its Complaint plausibly alleges that Celgene has forsaken short-term economic gain by refusing to sell Thalomid® to Lannett. Engaging in such a transaction would, by Lannett's own admission, require departing from the effective distribution system Celgene has devised, with FDA approval, to minimize risk of fetal exposure and thereby protect the company. Such a departure would inevitably entail some degree of risk of fetal exposure to thalidomide, which – if it were to adversely affect the health of even one baby – could imperil the entire market for Thalomid®. Celgene's legitimate concern over the safety of Lannett's proposed clinical trial is underscored by Lannett's plan to conduct its trial outside of the country and, therefore, according to Lannett, outside of the FDA's regulatory authority. (*Id.* ¶ 51). In addition to the risks posed to children, their families, and Celgene's business, selling Thalomid® to Lannett also has the potential to impose significant product liability on Celgene, including litigation and other costs.

Finally, a patent holder is entitled to refuse to license or sell a patented product without incurring liability under the antitrust laws, regardless of the patent holder's motivations or its effect on competition. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) ("We … will not inquire into [a patent holder's] subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may

have an anticompetitive effect so long as the anticompetitive effect is not extended beyond the statutory patent grant"); *W.L. Gore & Assocs. v. Carlisle Corp.*, 529 F.2d 614, 623-24 (3d Cir. 1976). Indeed, even where (unlike here) a defendant is alleged to have refused to sell a patented product in order to gain a monopoly in a separate market beyond the scope of the patent, the defendant's "desire to exclude others from its protected work is a presumptively valid business justification for any immediate harm to consumers." *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1218 (9th Cir. 1997) (quotation marks and alteration omitted); *accord Data Gen. Corp. v. Grumman Sys. Corp.*, 36 F.3d 1147, 1187 (1st Cir. 1994).[10]

In sum, even on the face of the Complaint, there are a host of reasons why it makes economic sense for Celgene not to sell Thalomid® to Lannett. Without plausible allegations that Celgene sacrificed short-term profits in refusing to deal with Lannett, the Complaint fails as a matter of law. *See Trinko*, 540 U.S. at 409; *Christy Sports*, 555 F.3d at 1197.

### C. Invoking The Essential Facilities Doctrine Does Nothing To Save Lannett's Claim

Lannett attempts to sidestep its inability to meet *Trinko*'s pleading requirements for Section Two claims by invoking the so-called "essential facilities" doctrine. As a threshold matter, applying the "essential facilities" label relieves Lannett of "no burden [it] would otherwise bear, and constitutes no substitute for a showing that the requirements for a cause of

[10] Likewise, the antitrust laws do not require Celgene to aid Lannett in completing its ANDA submission to the FDA and thereby trigger protracted patent litigation. *See Gore*, 529 F.2d at 623-24 ("It surely cannot be the law that a patent holder must continue to do business with a willful infringer, thereby contributing financially to the ability of the latter to defend against and possibly defeat his infringement suit."); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1358 (Fed. Cir. 1999) ("[N]o case has held that divulgation of proprietary information and the provision of special or privileged treatment to a legal adversary can be compelled on a 'refusal to deal' antitrust premise.").

action under the antitrust laws have been met." *Viacom Int'l, Inc. v. Time, Inc.*, 785 F. Supp. 371, 376 n.12 (S.D.N.Y. 1992).

Moreover, the validity of the doctrine has been seriously questioned. The Supreme Court in *Trinko* expressly disavowed ever having approved of the essential facilities doctrine, which it referred to as a limited exception "crafted by some lower courts." 540 U.S. at 410. At the same time, *Trinko* cited with approval an article by a leading antitrust scholar criticizing the doctrine. *Id.* at 410-11 (citing Phillip E. Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 Antitrust L.J. 841 (1989)). Following *Trinko*, a number of courts and commentators have recognized that, if it has not been completely rejected, the essential facilities doctrine has little vitality left.[11] One decision in this district credited *Trinko* with "call[ing] the use of the [essential facilities] doctrine into question except in the most extreme cases." *Pocono Invitational Sports Camp, Inc. v. NCAA*, 317 F. Supp. 2d 569, 587 n.23 (E.D. Pa. 2004). *See also United Asset Coverage, Inc. v. Avaya, Inc.*, 409 F. Supp. 2d 1109, 1149 (N.D. Ill. 2006) ("[T]he so-called 'essential facilities' doctrine ... has been virtually disclaimed by [*Trinko*].").

Regardless, even if the essential facilities doctrine somehow survived *Trinko*, Lannett's claim fails for each of two reasons. First, to prevail on its claim under pre-*Trinko* case law, Lannett must plausibly allege "[c]ontrol of the essential facility by a monopolist" and Lannett's "inability to practically or reasonably duplicate the essential facility." *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996); *see also MCI Comm'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132-33 (7th Cir. 1983). Here, Lannett does not request

[11] *See, e.g.*, Daniel F. Spulber, Christopher S. Yoo, *Mandating Access To Telecom And The Internet: The Hidden Side Of Trinko*, 107 Colum. L. Rev. 1822, 1869 & n.253 (2007) ("[C]ommentators generally acknowledge that [*Trinko*'s] reasoning certainly casts serious doubts on the [essential facilities] doctrine's continuing vitality.").

access to a "facility" at all. Rather, it asks this Court to require Celgene to sell a product, Thalomid®, to Lannett so that it may conduct bioequivalence testing. Such a request does not fit the mold of the pre-*Trinko* essential facilities cases, which concerned access to physical "facilities," in most cases pipelines, bridges, or networks over which goods or services are transported or delivered. *See MCI Comm'ns*, 708 F.2d at 1132 (telephone services); *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990) (hospital facilities through which patients are sold durable medical equipment); *United States v. Terminal R.R. Ass'n*, 224 U.S. 383 (1912) (railroad bridge); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973) (electric transmission lines).

At its core, the doctrine was intended to prevent a company from extending "power from one stage of production to another, and from one market to another." *MCI Comm'ns*, 708 F.2d at 1132; *see Advanced Health-Care*, 910 F.2d at 150. Here, rather than a request for ongoing access to a network or pipeline to prevent extension of a monopoly from one market into another, Lannett is requesting a sale of Thalomid® capsules in order to permit it to create a product to compete with Thalomid®. Courts have found the "essential facilities" doctrine inapplicable in such situations, and have rejected plaintiffs' requests for the sharing of information so that competitors can create related products.[12]

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[12] *See Intergraph*, 195 F.3d at 1357-58 ("The notion that withholding of technical information and samples of pre-release chips violates the Sherman Act, based on essential facility jurisprudence, is an unwarranted extension of precedent and cannot be supported on the premises presented."); *Clifford Elec., Inc. v. Lo-Jack Corp.*, 1991 WL 216951, at *2 n.1 (9th Cir. 1991) (affirming summary judgment on essential facilities claim explaining that "with only one product involved, there was no separate 'facility,' access to which was being denied"); *see also Daisy Mountain Fire Dist. v. Microsoft Corp.*, 547 F. Supp. 2d 475, 489 (D. Md. 2008) (dismissing case because "the essential facilities doctrine should not be applied in a case involving technological innovations or information"); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp 185, 191-92 (D. Mass. 1991) (rejecting claim that diagnostic program developed by defendant that would aid in maintenance of computers was an "essential facility"); *Berkey Photo, Inc. v. Eastman Kodak, Co.*, 603 F.2d 263, 285 (2d Cir. 1979) (rejecting assertions that a monopolist had a duty to share knowledge of its products with competitor).

Second, to establish an essential facilities claim, Lannett must also allege facts giving rise to a plausible inference that the transaction would be "feasible." *Ideal Dairy*, 90 F.3d at 748; *see MCI Comm'ns*, 708 F.2d at 1132-33. To demonstrate feasibility, Lannett must allege facts showing that the forced sale of Thalomid® would not undermine Celgene's legitimate business interests. *See Cyber Promotions v. Am. Online*, 948 F. Supp. 456, 464 (E.D. Pa. 1996); *Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1380 (9th Cir. 1992). However, for the reasons explained above, Lannett has conspicuously failed to allege that, under the present conditions, it would be feasible for Celgene to provide Thalomid® to Lannett. Indeed, the complaint's allegations demonstrate that the sale of Thalomid® outside of S.T.E.P.S.® involves risks to Thalomid®'s ongoing marketability. Moreover, the forced sale of Thalomid® would also likely impose on Celgene, among other things, significant administrative costs as well as the cost of patent litigation.

The antitrust laws do not require Celgene to accept these risks and costs. *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 400 (7th Cir. 2000); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1359 (Fed. Cir. 1999) ("[A] manufacturer is 'under no duty to help plaintiff or other … manufacturers survive or expand." (quoting *Cal. Computer Prods., Inc. v. Int'l Bus. Mach. Corp.*, 613 F.2d 727, 744 (9th Cir. 1979)). Indeed, Lannett's Complaint is simply a variation on the form of claim rejected in *Goldwasser*: "X is a monopolist; X didn't help its competitors enter the market so that they could challenge its monopoly; the prices I pay X are therefore still too high." 222 F.3d at 400 (quotation marks omitted). These allegations "do[] not state a claim under Section 2," because "the antitrust laws do not impose that kind of affirmative duty, even on monopolists." *Id.*

## II. IF THE COURT DOES NOT DISMISS THE COMPLAINT, IT SHOULD STAY THE CASE PENDING FDA'S FINAL DECISION ON THE RELATED CITIZENS PETITIONS

The doctrine of primary jurisdiction counsels deference to an administrative agency whenever enforcement of a claim in court would "require[] the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *United States v. Western Pac. R.R. Co.*, 352 U.S. 59, 64 (1956); *see also Int'l Assoc. of Heat and Frost Insulators and Asbestos Workers v. United Contractors Assoc., Inc.*, 483 F.2d 384, 400-01 (3d Cir. 1973). Here, if the Court does not dismiss the Complaint, the doctrine of primary jurisdiction counsels that the case be stayed until the FDA issues its decision on two pending citizen petitions that raise core issues before this Court – namely, (i) whether any generic thalidomide product should be approved, and (ii) whether the FDA has been authorized by Congress to require branded drug manufacturers to sell to generic companies for bioequivalence testing drugs that are subject to FDA-mandated distribution restrictions. The answers to either of these questions could be dispositive of Lannett's claims.

**Celgene's Citizen Petition**. In September 2007, Celgene filed a citizen petition with the FDA requesting that the Commissioner refrain from approving *any* application for generic thalidomide.[13] The petition contends that the prospect of generic thalidomide poses "unacceptable safety risks" due to the uniquely dangerous properties of thalidomide, the need to tightly manage its distribution through a single distribution system, and the required labeling omissions for generic thalidomide based on Celgene's orphan drug exclusivity for multiple

[13] The fact that Celgene has filed its citizen petition and no action has yet been taken is a judicially noticeable fact that can be verified in the official FDA docket, administered by the Federal Dockets Management System (FDMS) and located at www.regulations.gov. *See* FDA's Transition to the Federal Dockets Management System, 73 Fed. Reg. 2264 (Jan. 14, 2008) (explaining transition of official FDA docket to FDMS and regulations.gov). Celgene's Citizen Petition and associated documents appear at Docket No. FDA-2007-P-0113. *See Fellner*, 2010 WL 1490927, at *6 n.8 (taking judicial notice of records maintained on FDA's website).

myeloma. (*Id.* at 15-30). Based on these considerations, the petition requests that FDA "refrain from approving any application for a generic thalidomide product." (*Id.* at 1) The FDA has yet to act on Celgene's citizen petition.[14]

Celgene's citizen petition requires the FDA to address a predicate question that is central to Lannett's claim here, *i.e.,* whether any generic thalidomide should be allowed on the market in the United States. Lannett's claim presumes that generic thalidomide products will be permitted and alleges that it has been injured because Celgene has "precluded or substantially delayed Lannett's entry" into the sale of such a product. (Compl. ¶ 71). If the FDA determines that no generic thalidomide products will be allowed – an issue that the FDA is already considering and that it has "special competence" to address – Lannett's claim fails as a matter of law. *See, e.g., Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967) (affirming motion to dismiss where plaintiff's claim presumed drug would be approved for interstate distribution though FDA had not considered the issue).

**Dr. Reddy's Citizen Petition**. In June 2009, generic drug manufacturer Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") filed a citizen petition requesting that the FDA take several actions to force manufacturers of branded drugs subject to FDA-mandated restricted distribution programs, such as S.T.E.P.S.®, to provide their products to generic manufacturers for purposes of bioequivalence testing.[15] In particular, Dr. Reddy's argues that Congress has authorized the FDA to establish procedures that would require branded drug manufacturers to sell their drugs subject to REMS distribution restrictions to generic manufacturers for purposes

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[14] Over a dozen public comments supporting Celgene's petition have been filed with the FDA by a variety of interest groups, including the American College of Obstetricians and Gynecologists, American Medical Women's Association, International Myeloma Foundation, March of Dimes, and National Birth Defects Prevention Network. The comments are attached hereto as Attachment 2 and can be found on FDA's official docket, Docket No. FDA-2007-P-0113.

[15] Dr. Reddy's citizen petition is available on the FDA's official docket, Docket No. 2009-P-0266.

of bioequivalency testing. (*Id.* at 12). Dr. Reddy's further contends that FDA should exercise its authority to bring enforcement actions against brand manufacturers who refuse to sell their products for such purposes, and discusses Thalomid® in particular. (*Id.*).

Celgene believes that Congress granted no such authority to the FDA, and it has filed an opposition with the FDA setting forth the basis for its position. Nonetheless, Dr. Reddy's citizen petition puts the question of FDA's regulatory authority squarely before the agency. Ultimate resolution of the issue could be dispositive of Lannett's Section Two claim. If the FDA were found to have the power to compel the sale of Thalomid®, there would be yet another reason to hold that Lannett has no remedy under the antitrust laws. *Trinko*, 540 U.S. at 411-12 (noting that where a regulatory structure provides for competitor access, it is unnecessary and inappropriate to impose a duty to deal based on the antitrust laws as well).

Accordingly, if the Court denies Celgene's motion to dismiss, it should not permit the litigation to proceed further. Rather, it should stay the case until FDA has acted on the pending citizen petitions.

## CONCLUSION

For all the foregoing reasons, Lannett's Complaint should be dismissed with prejudice for failure to state a claim upon which relief can be granted. Alternatively, if the Court does not enter judgment against Lannett, the case should be stayed until the FDA issues its final decision on the pending citizen petitions of Celgene and Dr. Reddy's.

Respectfully submitted,

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Dated: May 28, 2010

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that a true and correct copy of the forgoing Motion to Dismiss was filed electronically through this Court's ECF System and is available for viewing and downloading from this Court's ECF System. I further certify that an electronic copy of the foregoing was served upon all counsel of record through this Court's ECF System at the e-mail address listed in the Court's database as follows:

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