UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Novo Nordisk Inc., and
Novo Nordisk A/S,

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

Civil No. 10-2199 (DWF/JJK)

MEMORANDUM OPINION AND ORDER

Aric H. Wu, Esq., Austin V. Schwing, Esq., George A. Nicoud, III, Esq., Josh A. Krevitt, Esq., Michael A. Sitzman, Esq., Wayne M. Barsky, Esq., Gibson, Dunn, Crutcher LLP; Chad Drown, Esq., Christopher J. Burrell, Esq., Kenneth A. Liebman, Esq., Faegre & Benson LLP; and W. Todd Miller, Esq., Baker & Miller PLLC, counsel for Plaintiffs.

Justi Rae Miller, Esq., Barbara P. Berens, Esq., Kelly & Berens, PA; and Daniel G. Brown, Esq., Gina R. Gencarelli, Esq., Nicole W. Stafford, Esq., and Seth C. Silber, Esq., Wilson, Sonsini, Goodrich & Rosati PC, counsel for Defendant.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss Count Two of Plaintiffs' Complaint brought by Defendant Paddock Laboratories, Inc. ("Paddock") and a Motion to Enjoin Paddock from Proceeding in the Eastern District of Michigan brought by Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (together, "Novo Nordisk"). For the reasons set forth below, the Court denies Paddock's motion and grants Novo Nordisk's motion.

BACKGROUND

Novo Nordisk filed this two-count action alleging the infringement of United States Patent No. 6,677,358 (the "'358 Patent") and seeking a declaration that Novo Nordisk has not violated the Antitrust Laws of the United States, 15 U.S.C. § 1, *et seq*. (Compl. ¶ 1.) Novo Nordisk holds the '358 Patent, which is directed at and claims a pharmaceutical composition that includes repaglinide in combination with metformin.[1] (Compl. ¶ 12 & Ex. A.) Novo Nordisk holds the FDA-approved New Drug Application ("NDA") for repaglinide, and it manufactures and sells repaglinide under the brand name PRANDIN®. (Compl. ¶ 13.) There are three FDA approved uses for repaglinide in the treatment of type 2 diabetes: "(1) repaglinide by itself (*i.e.*, monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones." (Compl. ¶ 14.)

Novo Nordisk alleges on information and belief that Paddock submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to engage in the commercial manufacture and sale of a generic form of repaglinide. (Compl. ¶ 31.)

[1] Combination therapy with repaglinide and metformin is a treatment for type 2 diabetes mellitus. (Compl. ¶ 10.) The '358 Patent claims "a pharmaceutical composition which includes repaglinide, metformin and a carrier (claim 1) in the form of a tablet (claim 2) or a capsule (claim 3); a method for treating non-insulin dependent diabetes mellitus . . . by administering repaglinide and metformin to a patient in need of treatment (claim 4); and a kit that includes repaglinide and metformin (claim 5)." (Compl. ¶ 11.)

In May 2009, Novo Nordisk submitted a proposed amended use code description for PRANDIN®, which the FDA published in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). (Compl. ¶¶ 18, 26-27.)

On or about April 15, 2010, Paddock sent a letter to Novo Nordisk stating that Paddock's ANDA contains a Paragraph IV Certification alleging that the '358 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Paddock's repaglinide. (Compl. ¶ 33.) In an attachment to the April 15, 2010 letter, Paddock also stated that Novo Nordisk's amended use code for PRANDIN® misrepresents the scope of the '358 Patent and that Novo Nordisk has amended the use code description to unlawfully monopolize the market for repaglinide. (Compl. ¶¶ 33, 41.) On May 13, 2010, Paddock advised Novo Nordisk that if Novo Nordisk were to file a patent infringement action against Paddock based on the '358 Patent, Paddock would file a counterclaim for an antitrust violation against Novo Nordisk and that the resulting antitrust claim would be premised on the change in the use code description for PRANDIN®. (Compl. ¶ 43.)

On May 28, 2010, Novo Nordisk filed the current action, alleging both that Paddock's submission of its ANDA constitutes infringement of the '358 Patent and that an actual controversy exists as to whether Novo Nordisk had engaged in anticompetitive conduct. (Compl. ¶¶ 45, 50.) In particular, Novo Nordisk asserts that "its requests and various petitions to the FDA regarding ANDAs for repaglinide," such as its submission of a Citizen Petition and proposed amended use code for PRANDIN®, are not shams or fraudulent misrepresentations. (Compl. ¶ 56.)

On July 13, 2010, Paddock answered Novo Nordisk's Complaint and asserted an affirmative defense and counterclaim alleging that Novo Nordisk misused the '358 Patent to "unlawfully extend its monopoly on Prandin®." (Answer and Countercl. at 16.) Paddock's allegations of misuse are based on Novo Nordisk's submission of its proposed amended use code for PRANDIN®. (*Id*. at 18, 19.) Specifically, Paddock's counterclaim alleges:

> 16. In view of the March 2009 expiration of RE'035, Novo Nordisk had to act to protect its repaglinide monopoly. While the '358 patent did not expire until 2018, this patent gave Novo Nordisk the right to prevent competitors from using repaglinide only in combination with metformin, and not from using repaglinide itself. In other words, without taking action Novo Nordisk could not prevent competition from ANDA applicants, such as Paddock, seeking to market repaglinide itself.
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> 17. To prevent the erosion of its Prandin® profits through competition with lower-priced generic alternatives, in May 2009, Novo Nordisk deceptively manipulated the use code for the '358 patent.

(*Id*. at 19.)

Also on July 13, 2010, Paddock filed a complaint in the Eastern District of Michigan (the "Michigan Action"). (Compl. ¶ 9; Request for Judicial Notice, Ex. A (Compl. in *Paddock Labs., Inc. v. Novo Nordisk Inc., et al.*, Case No. 10-cv-12760 (E.D. Mich., July 13, 2010 ("Mich. Compl.")).)[2] In the Michigan Action, Paddock alleges that Novo Nordisk unlawfully monopolized the market of repaglinide. Paddock's allegations

[2] Pursuant to Federal Rule of Evidence 201, Novo Nordisk requests that the Court take judicial notice of the Michigan Complaint. The Court grants the request. *See, e.g.*, *Great Plains Trust Co. v. Union Pacific R.R. Co.*, 492 F.3d 986, 996 (8th Cir. 2007) (explaining that court proceedings in other cases are proper subjects of judicial notice).

in the Michigan action are nearly identical to those asserted in its counterclaim in the present action:

> 46. With the March 2009 expiration of RE'035 approaching, [Novo Nordisk] had to act to protect [its] repaglinide monopoly. While the '358 patent did not expire until 2018, this patent gave Novo Nordisk the right to prevent competitors from using repaglinide only in combination with metformin, and not from using repaglinide itself. In other words, without taking action, [Novo Nordisk] could not prevent competition from ANDA applicants, such as Paddock, seeking to market repaglinide itself.
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> 52. Unable to protect [its] repaglinide monopoly through the citizen petition process, Defendants, in May 2009, deceptively manipulated the use code for the '358 patent.

(Mich. Compl. ¶¶ 46, 52.)

Also pending in the Eastern District of Michigan are two additional cases in which Novo Nordisk is a defendant and involve antitrust allegations pertaining to PRANDIN®. (*American Sales Co., Inc. v. Novo Nordisk A/S, et al.*, Case No. 10-cv-12141 (E.D. Mich., May 28, 2010); *Rochester Drug Co-Operative, Inc. v. Novo Nordisk A/S, et al.*, Case No. 10-cv-12235 (E.D. Mich., June 7, 2010).)

Presently before the Court are 1) Paddock's motion to dismiss Count Two of the Complaint, and 2) Novo Nordisk's motion to enjoin Paddock from proceeding in the Eastern District of Michigan.

DISCUSSION

I. Motion to Dismiss

In deciding a motion to dismiss under Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the

light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 579 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 555. As the United States Supreme Court recently reiterated, "[t]he threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Igbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

Paddock asserts that Count Two of Novo Nordisk's Complaint should be dismissed. In Count Two of its Complaint, Novo Nordisk seeks a declaration with regard to Paddock's allegations that Novo Nordisk has engaged in conduct that violates Section

2 of the Sherman Act. (Compl. ¶¶ 48-57.)[3] Paddock asserts that Novo Nordisk has not alleged sufficient facts to allow the Court to reach the conclusion that Novo Nordisk has not engaged in unlawful monopolization. In addition, Paddock requests that the Court exercise its discretion under 28 U.S.C. § 2201(a) and dismiss Novo Nordisk's declaratory judgment claim in favor of the ongoing litigation in the Eastern District of Michigan.

Paddock asserts that in order to state a claim for unlawful monopolization under Section 2 of the Sherman Act, a plaintiff must allege that the defendant possesses monopoly power in a relevant market and has acquired, enhanced, or maintained that power through the use of exclusionary conduct. Paddock then argues that it follows that, to be entitled to a declaration that Novo Nordisk has not engaged in conduct that violates Section 2 of the Sherman Act, Novo Nordisk must demonstrate the *absence* of the factors above. Paddock argues that Novo Nordisk cannot demonstrate the absence of those factors because Novo Nordisk has not adequately alleged the relevant market, an absence of power in the relevant market, or that its conduct was not exclusionary.

Novo Nordisk challenges the notion that is must defeat every element of a Sherman Act violation and contends that it need only defeat any element of a Sherman Act violation. The Court agrees. Courts have held that a party accused of a Sherman Act violation is entitled to summary judgment if the party alleging the violation is unable to

[3] Here, there is no dispute that this Court has jurisdiction to issue the declaratory relief sought by Novo Nordisk.

carry its burden on one element of the Sherman Act claim.[4] *See, e.g., Midwest Radio Co., Inc. v. Forum Pub. Co.*, 942 F.2d 1294, 1297-98 (8th Cir. 1991). Therefore, if Novo Nordisk has adequately pled facts that could defeat any element of a Sherman Act violation, then its claim for declaratory relief related to the Sherman Act violation (Count Two) survives Paddock's motion to dismiss.

Monopolization under Section 2 of the Sherman Act requires a showing of anticompetitive conduct. *Verizon Commc'ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 407 (2004). "Exclusionary conduct under section 2 is the creation or maintenance of monopoly by means other than the competition on the merits." *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 522 (5th Cir. 1999). Novo Nordisk asserts that it has alleged facts that support a finding that it did not engage in exclusionary conduct.

Paddock disputes this and contends that Novo Nordisk has not sufficiently set forth that its conduct surrounding PRANDIN® was not exclusionary or anticompetitive. Specifically, Paddock asserts that the allegations in Novo Nordisk's Complaint do not establish that its conduct surrounding PRANDIN® was not anticompetitive and leaves the Court to speculate on how the facts pled would entitle Novo Nordisk to the declaratory relief it seeks. The Court disagrees.

The two forms of allegedly exclusionary conduct at issue in this case are Novo Nordisk's submission to the FDA of the Citizen Petition and the proposed amended use

[4] In its opposition papers, Paddock explains that it agrees that Novo Nordisk need not disprove every element of a Section 2 claim. (Opp'n. to Pls.' Mot. to Enjoin Def. from Proceeding in the Eastern Dist. of Mich. at 5.)

code.[5] In its Complaint, Novo Nordisk alleges that it submitted a Citizen Petition to the FDA seeking governmental action and that the petition was ultimately denied. (Compl. ¶ 56.) Therefore, accepting Novo Nordisk's allegations as true, Novo Nordisk could demonstrate that its actions in petitioning the FDA were not exclusionary because the petition was denied and, thus, had no effect.[6]

Novo Nordisk further alleges that it submitted a proposed amended use code for PRANDIN® that accurately describes the FDA-approved indication for PRANDIN® (Compl. ¶¶ 26-27), that FDA attorneys did not raise any objection to its proposed amendment to the use code (Compl. ¶ 25), and that Novo Nordisk never represented to the FDA that the '358 Patent covers the use of repaglinide in monotherapy or in combination therapy with thiazolidinediones (Compl. ¶ 54). Novo Nordisk also alleges that in a decision dated April 14, 2010, the United States Court of Appeals for the Federal Circuit addressed a dispute over the amended use code description for PRANDIN® and vacated a district court injunction ordering Novo Nordisk to request that the FDA restore the original use code for PRANDIN®. (Compl. ¶¶ 28-30.)

Accepting Novo Nordisk's allegations as true, one could reasonably infer that Novo Nordisk's conduct with respect to PRANDIN® was not exclusionary. The factual

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[5] These are the two categories of exclusionary conduct that are both addressed in Novo Nordisk's Complaint in this action and alleged by Paddock in the Michigan Action.

[6] The parties dispute whether Novo Nordisk's petitioning the FDA was protected by the *Noerr-Pennington* doctrine. *See generally Eastern R.R. Presidents Conf. v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). The Court need not reach this issue in considering the present motions.

allegations in Novo Nordisk's claim for declaratory relief are sufficient to plausibly suggest that Novo Nordisk is entitled to a declaration that it has not unlawfully monopolized an alleged market for repaglinide. Thus, Count Two of Novo Nordisk's Complaint survives, and Paddock's motion to dismiss Count Two of the Complaint is denied.

Paddock also requests that the Court exercise its discretion to dismiss Novo Nordisk's declaratory judgment claim in favor of the antitrust litigation pending in the Eastern District of Michigan. In support, Paddock argues that the United States District Court in the Eastern District of Michigan is positioned to comprehensively resolve the antitrust issues and that dismissal would serve the interest of wise judicial administration. The Court addresses this issue below in its discussion of Novo Nordisk's related motion to enjoin Paddock from proceeding in the Eastern District of Michigan.

II. Motion to Enjoin Paddock from Proceeding in the Michigan Action

The first-filed rule establishes that in cases of concurrent jurisdiction, "the first court in which jurisdiction attaches has priority to hear the case." *Northwest Airlines, Inc. v. Am. Airlines, Inc.*, 989 F.2d 1002, 1005 (8th Cir. 1993). The purpose of the rule is to conserve judicial resources and avoid conflicting rulings. *Keymer v. Mgmt. Recruiters Int'l, Inc.*, 169 F.3d 501, 503 n.2 (8th Cir. 1999). In addition, "[t]he discretionary power of the federal court in which the first-filed action is pending to enjoin the parties from proceeding with a later-filed action in another federal court is firmly established." *Northwest Airlines*, 989 F.2d at 1004.

The prevailing standard is that in the absence of "compelling circumstances," the first-filed rule should apply. *Northwest Airlines*, 989 F.2d at 1006. In *Northwest Airlines*, the court identified two red flags indicating possible compelling circumstances: (1) when the plaintiff is on notice that the defendant was considering filing suit against it; and (2) when the first-filed suit was for declaratory judgment rather than damages or equitable relief. 989 F.2d at 1007. In addition, the Court considers whether one party is asserting claims in one forum that are not asserted in the other, which forum would be more convenient for parties and witnesses, whether there will be duplicative efforts and costs, the inconvenience to the parties, and the waste of judicial resources inherent in parallel litigation. *Id*.

There is no dispute that Novo Nordisk filed the present action, and that jurisdiction attached, in Minnesota before Paddock filed its action in Michigan. Paddock nonetheless argues that the first-filed rule is not controlling because the *Northwest Airlines* factors weigh against maintaining the current action here in Minnesota and because there are two other antitrust actions against Novo Nordisk pending in Michigan. Paddock also asserts that this suit is an anticipatory suit and an attempt at forum shopping on the part of Novo Nordisk.

First, the record establishes that Novo Nordisk filed the present action six weeks *before* Paddock filed its antitrust complaint in Michigan Action. The record also establishes that Novo Nordisk did not file this action until roughly six weeks *after* Paddock first suggested, in its April 2010 letter, that Novo Nordisk violated antitrust laws. And while the record establishes that on May 13, 2010, Paddock again put Novo

Nordisk on notice that Paddock was considering filing an antitrust claim against Novo Nordisk, the May 2010 notice was that Paddock would file a *counterclaim* against Novo Nordisk if Novo Nordisk sued Paddock for patent infringement.[7] Indeed, Novo Nordisk did sue Paddock for patent infringement when it filed the present action, and Paddock waited six weeks to file its complaint in the Michigan Action.[8] The Court concludes that this is not a case where Novo Nordisk raced to the courthouse, acted in bad faith, or filed an anticipatory lawsuit.

Second, the District of Minnesota is a logical and convenient forum to adjudicate the parties' dispute. Paddock is a Minnesota corporation with its principal place of

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[7] The record demonstrates that the parties met on or around May 17, 2010, to discuss their contemplated claims against one another. Paddock claims that when it asked Novo Nordisk about its response to a settlement proposed by Paddock, Novo Nordisk represented that it would not have a response until Novo Nordisk met with its attorneys on May 25, 2010, and requested that Paddock not file suit until after receiving Novo Nordisk's response. Novo Nordisk, however, denies that it engaged in any bad faith behavior and claims that the parties met because they were both contemplating filing suits against each other. Novo Nordisk also claims that it was under a statutory deadline to bring a patent infringement suit that was triggered by Paddock's April 2010 letter. Novo Nordisk denies that there was an agreement by any party not to file suit against the other or any discussion on the appropriate forum for any lawsuit. The Court has considered the conflicting evidence and concludes that, while perhaps the parties could have had better communication, the record falls far short of demonstrating bad faith on the part of Novo Nordisk.

[8] The present action involves both a patent infringement claim and an antitrust declaratory judgment claim. The declaratory judgment claim mirrors the antitrust counterclaim that Paddock asserted that it would file against Novo Nordisk.

business in Minneapolis.[9] Witnesses and documents at issue are presumably located in Minnesota. Indeed, Paddock has not argued that Minnesota is an inconvenient forum to litigate this action.

Third, the present action provides a "comprehensive solution of the general conflict" between the parties. *See Hyrpo, Inc. v. Seeger-Wanner Corp.*, 292 F. Supp. 342, 344 (D. Minn. 1968). The present case includes both patent and antitrust disputes between the parties, while the Michigan Action involves only the antitrust dispute. Thus, allowing the present action to proceed will provide a solution to all of the pending disputes between the parties. In contrast, Paddock's request to dismiss Novo Nordisk's antitrust declaratory judgment claim in favor of the Michigan Action would lead to duplicative litigation and would not serve the interest of judicial economy. Paddock has asserted both an affirmative defense and a counterclaim in the present action that are premised on the same alleged unlawfully anticompetitive behavior on the part of Novo Nordisk that underlies both Count Two of Novo Nordisk's Complaint and Paddock's claims in the Michigan Action. Thus, the dismissal of Count Two would not narrow the issues before the Court in this case, and both this Court and the court in the Michigan Action would be required to reach the same antitrust issues.

Finally, that there are currently two antitrust actions pending against Novo Nordisk in the Eastern District of Michigan does not create a compelling circumstance

[9] In contrast, neither Paddock nor Novo Nordisk is headquartered in Michigan. (Compl. ¶¶ 2-4.)

warranting a departure from the first-filed rule. Paddock is not a party to either of those actions, neither action was filed before this action, and neither action involves Paddock's alleged patent infringement.

After careful review of the record and the parties' submissions, and for the reasons discussed above, the Court concludes that the first-filed rule applies and that this Court has priority to hear Novo Nordisk's claim for declaratory judgment. In addition, to avoid unnecessary duplicative litigation and to serve the interest of judicial economy, the Court enjoins Paddock from litigating its antitrust claims in the Michigan Action.

CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons set forth above, **IT IS ORDERED** that:

1. Paddock's Motion to Dismiss Count 2 of the Complaint (Doc. No. [18]) is **DENIED**.

2. Novo Nordisk's Motion to Enjoin Paddock from Proceeding in the Eastern District of Michigan (Doc. No. [28]) is **GRANTED** as follows:

   a. Paddock is enjoined from proceeding in the lawsuit captioned *Paddock Laboratories, Inc. v. Novo Nordisk Inc. and Novo Nordisk A/S* pending in the United States District Court for the Eastern District of Michigan, Southern Division, Case No. 2:10-cv-12760-PDB-PJK;

   b. The Clerk of Court shall provide a copy of this Order to the Clerk of Court for the Eastern District of Michigan in relation to the above-referenced action; and

c. This injunction shall remain in effect until a final judgment is entered in this action and all appellate rights are exhausted or until the Court orders otherwise.

Dated: November 30, 2010

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge