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11 Attorneys for Defendant
MEDICIS PHARMACEUTICAL CORP.

12
13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA
15

16 IMPAX LABORATORIES, INC.,

17 Plaintiff,

18 v.

19 MEDICIS PHARMACEUTICAL CORP.,

20 Defendant.
21
22

Case No. C08-00253 MMC

MEDICIS' MOTION TO DISMISS

Date: April 11, 2008
Time: 9:00 a.m.
Ctrm: #7, 19th Floor

The Honorable Maxine M. Chesney

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on April 11, 2008 at 9:00 a.m. or as soon thereafter as counsel may be heard in the above Court, Defendant Medicis Pharmaceutical Corp. ("Medicis") will and hereby does move this Court to dismiss the declaratory judgment complaint of Plaintiff IMPAX Laboratories, Inc. ("IMPAX"). This motion is based upon the memorandum below, the accompanying declarations in support of the motion, the proposed order, the complete record of this action, evidence and argument presented at the hearing on this motion, and all matters of which the Court may take judicial notice.

RELIEF REQUESTED

Medicis respectfully seeks an Order dismissing IMPAX's declaratory judgment complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. In the alternative, Medicis requests that this Court exercise its discretion to decline declaratory judgment jurisdiction.

**I.
INTRODUCTION**

This declaratory judgment action by IMPAX is a premature and impermissible effort to obtain an advisory opinion from this Court on the validity and infringement of a patent owned by Medicis where IMPAX does not have regulatory authorization to commercially market its product, and where Medicis has not used its patent to cause IMPAX injury. IMPAX's declaratory judgment complaint asserts that IMPAX has filed an Abbreviated New Drug Application ("ANDA") seeking approval from the Food and Drug Administration ("FDA") to commercially manufacture and sell a generic copy of Medicis' proprietary acne drug, Solodyn®, and that IMPAX is entitled to a declaration that Medicis' patent directed to Solodyn® (U.S. Patent No. 5,908,838 ("the '838 patent")) is not valid or infringed.

But IMPAX's ANDA has not been approved by the FDA, and IMPAX is thus not allowed to sell its generic drug. Moreover, unlike the typical ANDA situation, Medicis has no ability to obtain a statutory stay on FDA approval. Without such approval, any injury that IMPAX might suffer under Medicis' patent is purely hypothetical, and IMPAX lacks standing to

1 bring this suit. In MedImmune v. Genentech, Inc., 127 S.Ct. 764, 771 (2007), the Supreme Court
2 held that a justiciable Article III controversy is required to establish declaratory judgment
3 jurisdiction. A justiciable Article III controversy exists only if IMPAX has suffered "actual or
4 imminent injury caused by the defendant [Medicis] that can be redressed by judicial relief and
5 that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' "
6 Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1338 (Fed. Cir. 2007). Because
7 IMPAX's complaint fails on its face to show such a justiciable controversy, it should be
8 dismissed. And, in the alternative, public policy and the totality of circumstances centered around
9 the hypothetical nature of this dispute counsel strongly in favor of this Court exercising its
10 discretion to decline jurisdiction.

11 II.

12 STATEMENT OF FACTS

13 A. Medicis Cannot Obtain Any Stay on FDA Approval

14 The statutory backdrop of this case is the "Hatch-Waxman Act," formally entitled
15 The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98
16 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). This Act governs
17 the approval of new and generic drugs and is designed to promote the dual incentives of
18 encouraging innovator companies such as Medicis to develop new drugs, while permitting
19 generic companies such as IMPAX to incur less costs in bringing their drugs to market. See
20 Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). The Act thus permits
21 generic companies through the filing of an ANDA (an "abbreviated" new drug application) to rely
22 on the safety and effectiveness data of the innovator product by simply showing that their product
23 is "bioequivalent" to the innovator product, rather than going through the costly exercise of
24 developing their own data. In exchange for such benefits, the Act provides specific protections
25 for the patent rights of innovator companies and specific mechanisms that ensure the ability of
26 drug patent holders to protect their rights. See 21 U.S.C. § 355(j).

27 These patent protections are triggered by what is known as a "paragraph IV
28 certification." A paragraph IV certification arises from the statutory requirement that new drug
29 developers list patents related to their new drugs in the FDA's "Orange Book," formally titled

1 "Approved Drug Products with Therapeutic Equivalence Evaluations." 21 U.S.C. § 355(b)(1).
2 This Orange Book listing requires any generic company that files an ANDA to make one of four
3 "certifications" as to each listed patent. A "paragraph IV certification" is required by the ANDA
4 filer where the ANDA filer asserts that it should be permitted to market its generic drug before
5 the patent expires because it believes that the listed patent is invalid and/or will not be infringed.
6 See 21 U.S.C. § 355(j)(2)(A)(I)-(IV). Where a paragraph IV certification is made, the ANDA
7 filer is required to provide notice of it to the patent owner along with a detailed explanation of the
8 factual and legal bases for the applicant's opinion that the patent is invalid or will not be
9 infringed. 21 U.S.C. § 355(j)(2)(B).

10 Upon receiving such a paragraph IV certification, the patent owner has an
11 exclusive 45-day period in which to determine whether and where to file a suit for patent
12 infringement against the ANDA filer. 21 U.S.C. § 355(j)(5)(C). The result of commencing such
13 a suit within the 45-day period is that the FDA is automatically precluded from approving the
14 generic company's ANDA for a period of 30 months, or until the patent infringement litigation
15 has been resolved. 21 U.S.C. § 355(j)(5)(B)(iii). The effect of this "30-month stay" is to ensure
16 that there will be no commercial manufacturing or selling of the generic product while the patent
17 litigation is ongoing (up to 30 months). However, if the patentee or NDA holder does not bring
18 an infringement suit within 45 days after receiving notice of a paragraph IV certification, the
19 Hatch-Waxman Act provides that the ANDA applicant may bring a declaratory judgment action
20 seeking a declaration that the patent at issue is invalid or will not be infringed by the generic drug
21 for which the ANDA was submitted. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5) (federal
22 courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over
23 declaratory judgment actions in paragraph IV ANDA cases).

24 None of these paragraph IV patent protections are available for Medicis' Solodyn®
25 product, however, as Solodyn® is one of a relatively very small number of drugs to which the
26 paragraph IV certification requirements do not apply. That is because Solodyn® contains an
27 antibiotic ingredient that was part of a drug that was originally (and required to be) approved
28 under 21 U.S.C. § 357, a now-repealed provision of the Federal Food, Drug, and Cosmetic Act

1 relating to antibiotics. Drug manufacturers such as Medicis who utilize such antibiotic
2 ingredients are not permitted, under FDA's interpretation of the law, to list relevant patents in the
3 Orange Book. See P.L. 105-115 (1997), Section 125(d)(2). ANDA applicants for such products
4 (such as IMPAX) are accordingly not required to comply with the typical paragraph IV
5 certification requirements, and the innovator is not entitled to the statutory protections that would
6 otherwise arise from such certifications.

7 The result of this anomalous situation is that Medicis was not permitted to list its
8 Solodyn® '838 patent in the Orange Book, and IMPAX was not required to file a paragraph IV
9 certification as to the '838 patent in its ANDA. And because there was no paragraph IV
10 certification, Medicis cannot obtain the typical 30-month stay on approval of IMPAX's ANDA.
11 Instead, the FDA can approve IMPAX's ANDA as soon as it otherwise determines that the
12 regulatory requirements have been satisfied. Although, significantly, that has not happened.

13 **B. IMPAX's Premature Declaratory Judgment Complaint**

14 Medicis first learned of IMPAX's ANDA filing in January 2008 when Medicis
15 first reviewed a letter from IMPAX advising Medicis that it had filed an ANDA for a generic
16 version of Solodyn®, asserting the invalidity and noninfringement of the '838 patent, and
17 requesting a covenant from Medicis not to sue IMPAX for infringement.¹ Wu Decl. Ex. 1 (Dec.
18 20, 2007, Ltr. from R. Chin to J. Shacknai). Medicis responded to IMPAX that in view of the
19 holidays it had only just received the letter and would provide a substantive response within two
20 weeks. Wu Decl. Ex. 2 (Jan. 11, 2008, Ltr. from S. Rodner to R. Chin). Rather than wait for the
21 promised response, however, IMPAX filed this lawsuit four days later.

22 IMPAX does not allege any cognizable injury in its complaint, and asserts only
23 that: (1) IMPAX has submitted an ANDA application to manufacture and sell generic Solodyn®,
24 Compl. at ¶ 7; (2) Medicis claims that the use of Solodyn® is covered by the '838 patent, generic
25 competitors face risk of a suit for infringement, and Medicis intends to enforce the '838 patent, id.
26 at ¶¶ 9-11; and (3) Medicis has not provided IMPAX with a covenant not to sue, id. at ¶ 12.

27
28 ¹ The IMPAX letter is dated December 20, 2007. Because of the holidays, the letter was not
reviewed at Medicis until January 2008 when Medicis sent its January 11, 2008 letter to IMPAX.
Wu Decl. Ex. 2 (Jan. 11, 2008, Ltr. from S. Rodner to R. Chin).

1 Based on these allegations, IMPAX claims that a justiciable Article III controversy exists.

2 **III.**

3 **ARGUMENT**

4 **A. A Justiciable Article III Controversy Does Not Exist Over IMPAX's
Premature and Preemptive Complaint**

5 The Declaratory Judgment Act provides that, "in the case of actual controversy
6 within its jurisdiction . . . any court of the United States, upon the filing of an appropriate
7 pleading, may declare the rights and other legal relations of any interested party seeking such
8 declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The
9 statutory requirement of an "'actual controversy' refers to the type of 'Cases' and 'Controversies'
10 that are justiciable under Article III." Teva, 482 F.3d at 1337. The Supreme Court held in
11 MedImmune that Article III "require[s] that the dispute be definite and concrete, touching the
12 legal relations of parties having adverse legal interests; and that it be real and substantial and
13 admit of specific relief through a decree of a conclusive character, as distinguished from an
14 opinion advising what the law would be upon a hypothetical state of facts." MedImmune, 127
15 S.Ct. at 771 (citations omitted).

16 Under MedImmune, "all the circumstances" must demonstrate the existence of a
17 justiciable Article III controversy "of sufficient immediacy and reality to warrant the issuance of a
18 declaratory judgment." Id. "A justiciable Article III controversy requires the party instituting the
19 action to have standing and the issue presented to the court to be ripe." Teva, 482 F.3d at 1337
20 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The constitutional
21 requirement of standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the
22 defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." Allen
23 v. Wright, 468 U.S. 737, 751 (1984). "Of the three standing requirements, injury-in-fact is the
24 most determinative: whatever else the case or controversy requirement embodies, its essence is a
25 requirement of injury in fact." Teva, 482 F.3d at 1337 (citations omitted). An injury-in-fact must
26 be 'personal,' 'concrete and particularized,' and 'actual or imminent.'" Id. (citing Lujan, 504 U.S.
27 at 560). These standing requirements are not met here.²

28 ² This motion represents a facial attack that the allegations in IMPAX's complaint, even if

1 **1. IMPAX's ANDA Does Not Confer Standing on IMPAX**

2 While an ANDA filing is a "technical" act of infringement, it cannot by itself
3 confer jurisdiction over IMPAX's complaint. IMPAX must still satisfy the injury-in-fact standing
4 requirement of Article III, as Congress "cannot expand standing beyond the Article III
5 jurisdiction of federal courts." Teva, 482 F.3d at 1338; see also Lujan, 504 U.S. at 576 ("ignoring
6 the concrete injury requirement" is unconstitutional). There is no actual injury to IMPAX here
7 because it has not obtained FDA approval to market its generic drug. Because IMPAX is not
8 engaging in any commercial manufacture or sales of its product, it is not at risk of incurring
9 damages for patent infringement. Moreover, because there is no paragraph IV certification, there
10 can be no 30-month stay on FDA approval, and IMPAX cannot suffer any injury that might be
11 alleged to arise from such a stay.

12 The absence of jurisdictional injury is shown by Teva v. Novartis, the Federal
13 Circuit's only post-MedImmune ANDA case. There the Federal Circuit made clear that it is not
14 the filing of an ANDA that establishes the required jurisdictional injury for purposes of sustaining
15 a declaratory judgment, but the patentee's subsequent actions in enforcing less than all of the
16 Orange Book listed patents while obtaining a 30-month stay on FDA approval on the entire
17 ANDA. Teva, 482 F.3d at 1343, 1340, n.5 (Novartis' actions caused injury-in-fact to the generic
18 company by "placing into actual dispute the soundness of Teva's ANDA and Teva's ability to
19 secure approval of the ANDA."). In finding the required jurisdictional injury based on the
20 uncertainty caused to the ANDA filer by the 30-month stay, the Federal Circuit specifically
21 distinguished a situation like here where there is no 30-month stay and nothing precluding market
22 entry:

23 [The patentee's] selective [infringement] suit creates uncertainty as
24 to [the generic's] legal rights under its ANDA. *Ordinarily, a*
25 *potential competitor in other fields is legally free to market its*
26 *product in the face of an adversely-held patent.* In contrast, under
27 the Hatch-Waxman Act an ANDA filer in [the generic's] situation
28 is not legally free to enter the market because federal statutes

assumed to be true, are insufficient on their face to establish subject matter jurisdiction. See Safe
Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004) ("In a facial attack, the
challenger asserts that the allegations contained in a complaint are insufficient on their face to
invoke federal jurisdiction. By contrast, in a factual attack, the challenger disputes the truth of the
allegations that, by themselves, would otherwise invoke federal jurisdiction.").

1 prohibit it [by providing a statutory stay on ANDA approval]. See
2 21 U.S.C § 355(j)(5)(B)(iii).

3 Id. at 1345 (emphasis added). In this case there can be no 30-month stay and thus IMPAX has
4 not suffered any injury as it remains "legally free to market its product in the face of an adversely-
5 held patent." Id.

6 The absence of jurisdiction is further underscored by the Hatch-Waxman Act's
7 limited situation in which an ANDA filer is permitted to seek a declaratory judgment.
8 Specifically, the Hatch-Waxman Act ensures that NDA/patent holders have the first opportunity
9 to determine whether and where to enforce patents protecting their drugs. See 149 Cong. Rec.
10 S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee;
11 the "sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-
12 name drug company the first opportunity to begin patent litigation"). It is only when this
13 exclusive 45-day period has expired and the patentee receiving a paragraph IV certification has
14 not brought suit that the Hatch-Waxman Act provides the ANDA filer with the opportunity to file
15 an action for a declaratory judgment "to obtain patent certainty." 35 U.S.C. § 271(e)(5). This
16 section requires that (1) a paragraph IV certification has been filed, and (2) the patentee has failed
17 to sue the ANDA filer for patent infringement within 45 days of receiving notice of the paragraph
18 IV certification. Id. Neither statutory requirement is met here.

19 **2. No Other Alleged Medicis Conduct Can Create Jurisdictional Injury** 20 **Here**

21 Beyond its filing of an ANDA, the only other allegations made by IMPAX to
22 support its claim of jurisdiction are that Medicis has claimed that the use of Solodyn® is covered
23 by the '838 patent, that it intends to enforce the '838 patent (Compl. at ¶¶ 9-11), and that Medicis
24 did not provide IMPAX with a covenant not to sue under the '838 patent. Id. at ¶ 12. These
25 circumstances cannot confer jurisdictional standing.

26 Medicis has not engaged in any acts of aggression that have caused injury to
27 IMPAX. Any statements by Medicis that it intends to defend its patent cannot create the required
28 jurisdictional injury. In Bridgelux, Inc. v. Cree, Inc., for example, this Court rejected such an
argument and dismissed a declaratory judgment complaint, concluding that the patent holder's

1 press releases were not sufficiently "definite and concrete" to warrant a conclusion that
2 defendants had inflicted an "actual and imminent injury" on Bridgelux. Wu Decl. Ex. 3 at *9
3 (Bridgelux, Inc. v. Cree, Inc., No. C 06-6495 PJH, 2007 WL 2022024 (N.D. Cal. July 9, 2007)).
4 "The fact that Cree stated publicly in press releases or at industry meetings that it would defend
5 its patents is unremarkable. The same could be said of many patent-holders." Id.

6 Neither can Medicis' marking of Solodyn® with the '838 patent nor its alleged
7 refusal to provide IMPAX with a covenant not to sue establish the required actual and imminent
8 injury. It simply cannot be the case that marking a product with a patent and not providing any
9 demanding party with a covenant not to sue on that patent are sufficient to force the patentee to
10 defend, and a court to adjudicate, hypothetical questions of patent validity and infringement. Any
11 other result would permit any apprehensive manufacturer to force courts to issue advisory
12 opinions, and subject patentees to unfair harassment. While a particular manufacturer may wish
13 to mitigate its future risk, such a generalized interest in invalidating patents cannot constitute the
14 require actual and concrete injury for establishing standing.

15 This is exemplified in Prasco v. Medicis, where the district court dismissed a
16 declaratory judgment complaint in similar circumstances and held that even if "the marking of
17 products with the patents-in-suit were analogous to a listing of patents in the Orange Book, the
18 court in Teva was clear that this conduct alone is not sufficient to establish an Article III
19 controversy." Wu Decl. Ex. 4 at *3. (Prasco v. Medicis, No. 1:06cv313, 2007 WL 1974951
20 (S.D. Ohio July 3, 2007)). The court further concluded that "Medicis' refusal [to] grant a
21 covenant not to sue holds little weight under the circumstances." Id. at *3. The same conclusions
22 are compelled here.

23 The Supreme Court's decision in MedImmune is consistent with this result. In
24 MedImmune, the party seeking declaratory relief was able to prevent injury only by complying
25 with a demand from the defendant. 127 S. Ct. at 777. The Supreme Court held that a plaintiff
26 was permitted to seek a declaratory judgment that it was not infringing a patent at the same time
27 that it was forestalling a potentially devastating infringement action by paying royalties to the
28 patent holder. Id. Unlike the defendant in MedImmune, Medicis has not asked IMPAX to

1 comply with any demands. IMPAX is not making any payments to Medicis or taking any other
2 actions at Medicis' behest. Nor has Medicis forced IMPAX to forbear from any desired activity
3 in order to avoid liability. Rather, IMPAX is refraining from marketing a generic form of
4 Solodyn®, not because of any actions by Medicis, but because FDA has not approved its ANDA.
5 There is no justiciable Article III controversy in these circumstances, and the Court should
6 accordingly dismiss IMPAX's complaint.

7 **B. In the Alternative, This Court Should Exercise its Discretion to Decline**
8 **Declaratory Judgment Jurisdiction**

9 The Declaratory Judgment Act confers discretion on courts to decline to exercise
10 jurisdiction by providing that judges "*may*" declare the rights and other legal relations of any
11 interested party, not that they *must* do so. See 28 U.S.C. § 2201(a) (emphasis added). "This text
12 has long been understood to confer on federal courts unique and substantial discretion in deciding
13 whether to declare the rights of litigants." MedImmune, 127 S. Ct. at 776-77. It is the district
14 courts which should be vested with this discretion in the first instance "because facts bearing on
15 the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are
16 peculiarly within their grasp." Id. at 776 (citing Wilton v. Seven Falls Co., 515 U.S. 277, 289
17 (1995)). Therefore, even if there is an otherwise justiciable controversy, this Court has the
18 discretion to decline declaratory judgment jurisdiction. Public Svc. Comm'n v. Wycoff Co., 344
19 U.S. 237 (1952); see MedImmune ("We leave the equitable, prudential, and policy arguments in
20 favor of such a discretionary dismissal for the lower courts' consideration on remand.").

21 The purposes of the Declaratory Judgment Act and the principles of sound judicial
22 administration counsel against exercising jurisdiction here. As discussed above, IMPAX does not
23 have regulatory approval to sell its drug, and Medicis has done nothing with its '838 patent to
24 cause any actual or imminent injury to IMPAX. In addition, rather than provide Medicis with a
25 meaningful opportunity to respond to its letter advising of the ANDA, as Medicis requested,
26 IMPAX filed this preemptive strike. Allowing IMPAX to proceed in these circumstances would
27 frustrate the Hatch-Waxman Act's purpose of ensuring that the patent holder has the first
28 opportunity to determine whether and where to enforce its patent rights, and permitting a

