

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1 James F. Hurst (admitted *pro hac vice*)  
*jhurst@winston.com*  
2 Maureen L. Rurka (admitted *pro hac vice*)  
*mrurka@winston.com*  
3 James M. Hilmert (admitted *pro hac vice*)  
*jhilmert@winston.com*  
4 WINSTON & STRAWN LLP  
35 West Wacker Drive  
5 Chicago, IL 60601-9703  
Telephone: (312) 558-5600  
6 Facsimile: (312) 558-5700

7 K. Joon Oh (SBN: 246142)  
*koh@winston.com*  
8 WINSTON & STRAWN LLP  
101 California Street  
9 San Francisco, CA 94111-5802  
Telephone: (415) 591-1000  
10 Facsimile: (415) 591-1400

11 Ian Nomura (SBN: 269048)  
*inomura@winston.com*  
12 WINSTON & STRAWN LLP  
333 S. Grand Avenue  
13 Los Angeles, CA 90071-1543  
Telephone: (213) 615-1700  
14 Facsimile: (213) 615-1750

15 Attorneys for Plaintiff  
SANDOZ INC.

17 **UNITED STATES DISTRICT COURT**  
18 **NORTHERN DISTRICT**  
19 **SAN FRANCISCO DIVISION**

20 SANDOZ INC., ) **Case No. 3:13-cv-02904-MMC**  
21 )  
22 Plaintiff, ) **SANDOZ INC.'S OPPOSITION TO**  
23 ) **DEFENDANTS' MOTION TO DISMISS**  
24 v. )  
25 AMGEN INC. and HOFFMAN-LA ROCHE ) **REDACTED**  
26 INC., )  
27 )  
28 Defendants. )

Winston & Strawn LLP  
 101 California Street  
 San Francisco, CA 94111-5802

**TABLE OF CONTENTS**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

	<u>Page</u>
TABLE OF AUTHORITIES .....	ii
STATEMENT OF THE ISSUE.....	1
INTRODUCTION .....	1
FACTUAL BACKGROUND.....	3
A.    Amgen markets Enbrel, claiming patent exclusivity since 1995.....	3
B.    Relying on the upcoming expiration of Amgen’s patents, Sandoz develops and finalizes an etanercept product to compete with Enbrel. ....	4
C.    Sandoz will submit an FDA application for etanercept following the conclusion of a final, confirmatory Phase III trial. ....	5
D.    Just as its patent position is set to expire, Amgen obtains two submarine patents allegedly covering etanercept until 2029.....	7
E.    Amgen engages in a public campaign touting its newfound patent “exclusivity” on etanercept and threatening competition. ....	8
F.    Amgen’s patent position disrupts Sandoz’s settled expectations and places it in a legal quandary.....	9
LEGAL STANDARD.....	10
ARGUMENT.....	10
I.    The Court Has Subject Matter Jurisdiction Over This Action.....	11
A.    Jurisdiction Only Requires The Existence Of An “Actual Controversy.”.....	11
B.    There Is An Actual Controversy Requiring Judicial Resolution. ....	13
C.    The Controversy Is Real And Immediate. ....	16
1.    Sandoz’s product is not subject to change. ....	16
2.    Sandoz has engaged in “meaningful preparation” for allegedly infringing activity.....	18
II.   The Court Should Exercise Its Jurisdiction .....	22
CONCLUSION.....	26

Winston & Strawn LLP  
 101 California Street  
 San Francisco, CA 94111-5802

**TABLE OF AUTHORITIES**

**Page(s)**

**CASES**

1  
2  
3  
4 *3D Sys., Inc. v. Envisiontec, Inc.*,  
5 575 F. Supp. 2d 799 (E.D. Mich. 2008).....19  
6 *ABB Inc. v. Cooper Indus., LLC*,  
7 635 F.3d 1345 (Fed. Cir. 2011).....14  
8 *Alpharma, Inc. v. Purdue Pharma L.P.*,  
9 634 F. Supp. 2d 626 (W.D. Va. 2009) .....13, 14  
10 *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*,  
11 456 F. Supp. 2d 267 (D. Mass. 2006) ..... passim  
12 *Amgen Inc. v. F. Hoffman-La Roche Ltd.*,  
13 580 F.3d 1340 (Fed. Cir. 2009).....20  
14 *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*,  
15 3 F. Supp. 2d 104 (D. Mass. 1998) .....2, 19, 20, 21  
16 *Aria Diagnostics, Inc. v. Sequenom, Inc.*,  
17 2012 WL 761706 (N.D. Cal. 2012) .....15  
18 *Arkema Inc. v. Honeywell Intern., Inc.*,  
19 706 F.3d 1351 (Fed. Cir. 2013)..... passim  
20 *Benitec Austrl., Ltd. v. Nucleonics, Inc.*,  
21 495 F.3d 1340 (Fed. Cir. 2007).....17, 19  
22 *Beyene v. Coleman Sec. Servs., Inc.*,  
23 854 F.2d 1179 (9th Cir. 1988) .....10  
24 *Bridgelux, Inc. v. Cree, Inc.*,  
25 2007 WL 2022024 (N.D. Cal. 2007) .....15  
26 *Capo, Inc. v. Dioptics Med. Prods.*,  
27 387 F.3d 1352 (Fed. Cir. 2004).....24  
28 *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*,  
527 F.3d 1278 (Fed. Cir. 2008).....12  
*Cardinal Chemical Co. v. Morton Intern., Inc.*,  
508 U.S. 83 (1993).....11, 12

Winston & Strawn LLP  
 101 California Street  
 San Francisco, CA 94111-5802

1 *Cat Tech LLC v. TubeMaster, Inc.*,  
 2 528 F.3d 871 (Fed. Cir. 2008)..... passim

3 *Cephalon, Inc. v. Impax Laboratories, Inc.*,  
 4 2012 WL 3867568 (D. Del. 2012) .....25

5 *City of Aurora ex rel. Aurora Water v. PS Systems, Inc.*,  
 6 2008 WL 4377505 (D. Colo. 2008) .....13

7 *Genentech v. Eli Lilly & Co.*,  
 8 998 F.2d 931 (Fed. Cir. 1993).....22

9 *Glaxo, Inc. v. Novopharm, Ltd.*,  
 10 110 F.3d 1562 (Fed. Cir. 1997).....18, 20

11 *Impax Labs., Inc. v. Medicis Pharm. Corp.*,  
 12 2008 WL 1767044 (N.D. Cal. 2008) .....15

13 *Infinitech, Inc. v. VitroPhage, Inc.*,  
 14 842 F. Supp. 332 (N.D. Ill. 1994) .....21

15 *Kamen v. American Tel. & Tel. Co.*,  
 16 791 F.2d 1006 (2d Cir. 1986).....10

17 *MedImmune, Inc. v. Genentech, Inc.*,  
 18 549 U.S. 118 (2007).....2, 12, 14, 22

19 *Micron Tech. Inc. v. Mosaid Techs., Inc.*,  
 20 518 F.3d 897 (Fed. Cir. 2008).....11, 12, 15, 22

21 *Neuralstem, Inc. v. StemCells, Inc.*,  
 22 573 F. Supp. 2d 888 (D. Md. 2008) .....14, 15

23 *Prasco, LLC v. Medicis Pharm. Corp.*,  
 24 537 F.3d 1329 (Fed. Cir. 2008).....15

25 *Reynolds v. Army & Air Force Exch. Serv.*,  
 26 846 F.2d 746 (Fed. Cir. 1988).....10

27 *Safe Air for Everyone v. Meyer*,  
 28 373 F.3d 1035 (9th Cir. 2004) .....10

*SanDisk Corp. v. STMicroelectronics, Inc.*,  
 480 F.3d 1372 (Fed. Cir. 2007).....2, 12, 13, 14

*Shire LLC v. Amneal Pharmaceuticals, LLC*,  
 2013 WL 1932927 (D. N.J. 2013) .....25

*Sierra Applied Scis. v. Advanced Energy Indus.*,  
 363 F.3d 1361 (Fed. Cir. 2004).....17

Winston & Strawn LLP  
 101 California Street  
 San Francisco, CA 94111-5802

1 *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*,  
 2 497 F.3d 1271 (Fed. Cir. 2007).....14

3 *Tasini v. New York Times Co., Inc.*,  
 4 184 F. Supp. 2d 350 (S.D.N.Y. 2002).....18

5 *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*,  
 6 982 F.2d 1520 (Fed. Cir. 1992).....17, 19

7 *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*,  
 8 482 F.3d 1330 (Fed. Cir. 2007).....12, 21

9 **STATUTES**

10 28 U.S.C. § 2201.....11

11 35 U.S.C. § 271(e)(1).....21

12 42 U.S.C. § 262(k)(2)(A)(i)(IV) .....16

13 42 U.S.C. § 262(k)(7)(A)-(B) .....23

14 42 U.S.C. § 262(l)(8)-(9) .....24

15 **OTHER AUTHORITIES**

16 *Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing Before the*  
*Subcomm. On Courts and Competition Policy of the H. Comm. On the Judiciary, 111th*  
*Cong. (2009) .....23*

17 Fed. R. Civ. P. 12(b)(1).....10

18 S. Rep. No. 73–1005 (1934) .....11

19

20

21

22

23

24

25

26

27

28

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**STATEMENT OF THE ISSUE**

Does this Court have declaratory judgment jurisdiction to resolve a dispute regarding two submarine patents Defendants acquired over two decades after their filing dates, where Defendants have taken a particular position under these patents forcing Sandoz to either abandon commercialization of its biologic product, or proceed with further investment at the risk of pursuing infringing activity?

**INTRODUCTION**

For over nine years, Sandoz has researched and developed a biosimilar drug to compete with Amgen’s Enbrel. Sandoz engaged in its product development with the legitimate expectation that Amgen’s patents covering Enbrel—first issued nearly twenty years ago—all would have expired by Sandoz’s anticipated product launch in 2016. Yet, just as Amgen’s patents were expiring and Sandoz’s development was nearing its end, Amgen suddenly announced that the PTO had issued two brand new patents on Enbrel, allowing it to exclude all biosimilar competition until 2029. Amgen’s threats under these new patents, issuing from unpublished submarine applications, have upended Sandoz’s settled expectations and cast uncertainty over its product and business as a whole.

Sandoz’s Complaint identifies precisely the situation the Declaratory Judgment Act was intended to address. After expending many years of effort and tens of millions of dollars, Sandoz has a final product it intends to launch upon FDA approval in three years. Amgen seeks to exclude that product based on patents Sandoz believes are invalid. Sandoz faces the present quandary that further investment—[REDACTED]—could be wasted if it is later found to infringe. And, unless Sandoz obtains clarity of its rights, it will be required to shelve its product or risk the potential for significant liability by launching it. Because Amgen will not license a biosimilar version of Enbrel under any circumstances, this lawsuit is Sandoz’s only realistic hope to obtain clarity of its rights before its intended launch.

Amgen, by its motion, seeks to hold Sandoz’s rights in limbo until Amgen decides the time is right for it to sue for infringement. To that end, Amgen argues this dispute is not sufficiently “real” or “immediate” because—so it claims—Sandoz’s clinical trials might fail or cause a change in its

1 product design or delay its FDA filing. But these concerns are imaginary. Despite making a  
2 “factual attack” on jurisdiction, Amgen does not muster any actual evidence to support its  
3 allegations. Rather, it manufactures a list of hypothetical problems based on a collage of  
4 inadmissible hearsay snippets unrelated to the facts of the case. The only actual evidence of  
5 record—submitted herewith—demonstrates Sandoz’s product is final after nearly a decade of  
6 development; it has *already* been successfully tested in humans; and its sole remaining clinical trial  
7 is merely confirmatory because Sandoz already established a high degree of similarity to Enbrel.

8         Apart from being factually baseless, Amgen’s arguments directly contradict its own  
9 successful arguments in prior litigation. Twice, Amgen has sued its competitors for declaratory  
10 judgments of *future* infringement before any FDA filing had been made. Both times, the court found  
11 jurisdiction existed. *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267 (D. Mass. 2006);  
12 *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). Amgen  
13 successfully argued in the *Roche* case that “future infringement was found to be sufficiently  
14 imminent and real for purposes of declaratory relief jurisdiction under *Lang* even though *clinical*  
15 *trials had not yet begun* and approval was *years* away.” (Ex. 1 at 13) (emphasis added). Where  
16 jurisdiction existed for Amgen to sue for a declaratory judgment in far less compelling  
17 circumstances, jurisdiction also exists for Amgen to be sued for declaratory judgment here.

18         Amgen also argues there is no “controversy,” because it did not make specific threats against  
19 Sandoz’s product in particular. Amgen is clearly wrong. Under the Supreme Court’s *MedImmune*  
20 decision, specific threats of infringement are not required. Rather, a controversy exists “where the  
21 patentee takes a position that puts the declaratory judgment plaintiff in the position of either  
22 pursuing arguably illegal behavior or abandoning that which he claims a right to do.” *SanDisk Corp.*  
23 *v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007). Here, Amgen has trumpeted its  
24 “exclusivity” under its new patents to the entire industry, time and again, and made clear its strategy  
25 for Enbrel depends on excluding all competition. It cannot be heard to threaten the *entirety* of its  
26 competitors, and then claim there is no “controversy” when a *particular* competitor seeks  
27 adjudication of its rights. Indeed, Amgen concedes it intends to enforce its patents against Sandoz—  
28

1 just on its own timeline. (Br. at 2). The law does not require Sandoz to wait for Amgen to sue at its  
2 leisure while Sandoz suffers from the delay.

3 Finally, Amgen urges this Court to exercise its discretion and dismiss the action. There is no  
4 basis to do so. Dismissing this case would frustrate the purpose of the Declaratory Judgment Act by  
5 allowing Amgen to disrupt Sandoz's settled expectations with invalid submarine patents, and then  
6 deny Sandoz the ability to determine its rights. Further, if Sandoz were forced to wait until after  
7 filing its FDA application, the lawsuit could not be [REDACTED] between its FDA  
8 filing and anticipated product launch. By filing now, Sandoz gives the Court adequate time to hold  
9 trial and issue judgment before Sandoz's launch rather than resolve the dispute in an emergency  
10 hearing. Maintaining this action thus advances sound judicial administration.

11 For all of these reasons, this court clearly has subject matter jurisdiction, and it should  
12 exercise its discretion to hear this lawsuit. Amgen's motion lacks merit and should be denied.

### 13 **FACTUAL BACKGROUND**

#### 14 **A. Amgen markets Enbrel, claiming patent exclusivity since 1995.**

15 Enbrel is a widely used biologic drug approved by the FDA for the treatment of autoimmune  
16 conditions. (Compl. ¶¶ 14, 47; Ex. 4). Its active ingredient is a protein called etanercept, which  
17 functions to reduce inflammation in the body by binding to tumor necrosis factor (TNF). (*Id.*, ¶ 14;  
18 Ex. 4). Amgen's predecessor developed Enbrel in the early 1990s, and the FDA originally approved  
19 it in 1998 for the treatment of rheumatoid arthritis. (Compl. ¶¶ 14; Ex. 4). In 2012, Enbrel was  
20 Amgen's second largest product, accounting for 25% of its annual revenues and over \$4.2 billion in  
21 North American sales. (Compl. ¶ 47; Ex. 3 at 62-63, F-22).

22 Ever since its approval in 1998, and before, Amgen and its predecessor have claimed that  
23 Enbrel is protected by U.S. patents. (*Id.*, ¶¶ 14-15). Among other patents, Immunex acquired U.S.  
24 Patent No. 5,395,760 in 1995 and U.S. Patent No. 5,605,690 in 1997 (Ex. 5-6), both of which  
25 Amgen listed on the package insert for Enbrel. (*Id.*, ¶ 18; Ex. 4). Based on these patents, Amgen  
26 has enjoyed exclusivity over Enbrel for fifteen years and counting. The '760 patent expired in 2012,  
27 while the '690 patent expires in 2014. (*Id.*, ¶ 19).

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**B. Relying on the upcoming expiration of Amgen’s patents, Sandoz develops and finalizes an etanercept product to compete with Enbrel.**

Sandoz, a leading developer of generic drugs and biosimilars, began work on its own etanercept product in 2004 and has developed it continuously since that time. (Compl. ¶¶ 35-44; Jankowsky ¶¶ 2-10). Sandoz timed its development so that its commercial marketing would coincide with, or post-date, the expiration of potentially relevant patent rights, including the ‘760 and ‘690 patents. (Compl. ¶ 35; Jankowsky ¶ 16). Thus, Sandoz devoted substantial resources to ensure its product would be ready for a 2016 product launch. (Compl. ¶¶ 3, 35, 43-44; Jankowsky ¶¶ 2, 11, 16).

Sandoz’s work in developing etanercept was both extensive and expensive. (Compl. ¶¶ 35-44; Jankowsky ¶¶ 2-12). Sandoz created a cell line utilizing a complex and iterative process focusing on comparable quality attributes to Enbrel obtaining a final, selected master cell-line, developed a manufacturing process and a suitable formulation of the drug, proved similarity with Enbrel on a molecular basis, developed a pre-filled syringe drug product, and transferred its processes to large scale production for clinical trials. (Compl. ¶ 36; Jankowsky ¶¶ 2-12). Working closely with the FDA, Sandoz has since tested its product in several animal models, in a Phase I clinical trial with healthy human volunteers, and now in an ongoing Phase III clinical trial. (Compl. ¶¶ 39, 41-42). The total costs, through completion of the Phase III trial, are expected to be more than [REDACTED]. (Compl. ¶ 43).

After nine years of systematic efforts, Sandoz now has a final etanercept product. (*Id.*, ¶ 44; Jankowsky ¶ 7). Although Amgen speculates that the product may change in various ways (Br. at 13-14), Amgen is mistaken. Given how FDA regulations operate, there is no way the product could be changed in any material way at this late stage in the process, because any such change would essentially require Sandoz to start over. Sandoz’s product has already been subjected to extensive validation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED] (*Id.*). Sandoz does not intend to rewind a  
5 decade of successful development by changing its product now. (Jankowsky ¶ 7).

6 Likewise, Sandoz’s manufacturing process is fixed. (Jankowsky ¶¶ 12-13). While Amgen  
7 points out that a manufacturing method hypothetically may change as it is scaled up (Br. at 14),  
8 Amgen fails to recognize that [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 (*Id.*, ¶¶ 12-13). [REDACTED]

12 [REDACTED]

13 [REDACTED] (*Id.*, ¶¶ 12-13, 18).

14 **C. Sandoz will submit an FDA application for etanercept following the conclusion**  
15 **of a final, confirmatory Phase III trial.**

16 The current Phase III trial is the final stage in the development of Sandoz’s etanercept  
17 product. (Roth ¶¶ 8, 10). This study, which is intended to support both U.S. approval and European  
18 registration, tests the safety and efficacy of etanercept in a large population of patients suffering with  
19 plaque psoriasis, as compared to Enbrel. (*Id.* ¶ 10). [REDACTED]

20 [REDACTED]<sup>1</sup>

21 While Amgen speculates that Sandoz’s Phase III clinical trial may fail in some unspecified  
22 way (Br. at 11-12), there is no reason to believe that will happen. When testing a brand new  
23 compound for the first time, establishing efficacy in a large patient population can be uncertain. But  
24 that is not the situation here. The clinical trial of a biosimilar drug does not start from a blank slate,  
25 but relies on the safety and efficacy already demonstrated by the reference biologic product in

26 [REDACTED]

27 <sup>1</sup> [REDACTED]  
28 [REDACTED]

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1 treating a given condition. (Roth ¶ 14). Here, Enbrel has already been shown to work in treating  
2 psoriasis. (*Id.*). Sandoz’s etanercept product has been shown to be highly similar to Enbrel on a  
3 molecular basis, which is what matters for biosimilarity. (Jankowsky ¶¶ 4-5). The same dosage  
4 form, method of administration, and strength of etanercept are being tested in Sandoz’s ongoing  
5 trial. (Roth ¶ 14). Thus, the Phase III trial is simply a confirmation that Sandoz’s etanercept product  
6 is similar to Enbrel, as Sandoz already demonstrated in earlier studies. (*Id.*, ¶ 14). Given the  
7 already-established identity between Sandoz’s product and Enbrel, there is no good scientific basis  
8 for expecting anything other than the confirmatory trial will prove successful—just as it was for  
9 Amgen. (*Id.*, ¶ 7, 8, 10, 14-15).

10 Sandoz has developed and marketed three biosimilar products in Europe and one in the  
11 United States. (Roth ¶ 5). None of the Phase III studies for initial filing of these drugs failed. (*Id.* ¶  
12 15). [REDACTED] (*Id.* ¶ 16).  
13 Sandoz’s 100% success rate in these late-stage trials of biosimilar products for initial filing speak  
14 volumes about the likelihood of a successful outcome here. (*Id.*). And, contrary to Amgen’s  
15 baseless assertions (Br. at 3), there is no reason to believe the FDA will require additional clinical  
16 studies. Sandoz designed its Phase III study in close consultation with the FDA for the purpose of  
17 showing biosimilarity under the FDA’s regulations, and understands based on those interactions that  
18 the design is adequate for assessing biosimilarity. (Roth ¶ 10-11).

19 Amgen posits that Sandoz’s clinical trial might be delayed because it will not be able to  
20 successfully enroll patients in its clinical study (Br. at 10). [REDACTED]

21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED] (*Id.*).

25 Amgen also asserts that Sandoz may not be able to assemble its regulatory dossier on time.  
26 (Br. at 12). That is nonsense. Sandoz has a capable, full time staff dedicated to regulatory affairs  
27 with extensive experience in submitting FDA applications. (Roth ¶ 18). Sandoz’s regulatory group  
28 works hand-in-hand with its parent company Novartis, and thus draws on the experiences of one of

1 the world's largest pharmaceutical companies, which makes numerous FDA filings every year.  
2 (*Id.*). There is simply no question that Sandoz will be able to assemble the required paperwork, as it  
3 has done repeatedly in the past.

4 Following the conclusion of its Phase III clinical trial, Sandoz will submit an application  
5 seeking FDA approval. (Roth, ¶ 18; Jankowsky ¶ 14). [REDACTED]

6 [REDACTED] (*Id.*). In  
7 fact, the review period for Sandoz's application may be much quicker. The FDA has publicly  
8 committed to reviewing NDA and BLA applications in a period of 10 months' time. (Ex. 7). And as  
9 Amgen has explained elsewhere, the average time of FDA approval even for new biologic drugs is  
10 "likely 10 to 13 months." (Ex. 1 at 9).

11 **D. Just as its patent position is set to expire, Amgen obtains two submarine patents**  
12 **allegedly covering etanercept until 2029.**

13 While Sandoz was researching, developing, and finalizing its etanercept product in reliance  
14 on Amgen's patent expirations, Amgen was secretly prosecuting applications that would threaten to  
15 extend its monopoly on Enbrel for another seventeen years. (Compl. ¶¶ 2, 5, 26). Amgen  
16 exclusively licensed rights in two patent applications from Roche, which were filed in 1995 and  
17 based on still older applications filed in 1990. (Compl. ¶¶ 21-23, 28-31; Ex. 10 at 1; Ex. 11-12). In  
18 2005, Amgen took over their prosecution and sought to use them as vehicles to obtain additional  
19 patents putatively covering etanercept to extend Amgen's market exclusivity. (Compl. ¶¶ 21-23, 28-  
20 31; Ex. 8-9). The applications were unpublished and unavailable to the public, and thus, Sandoz had  
21 no reason to suspect they even existed. (Compl. ¶¶ 2, 5, 35, 71).

22 On November 22, 2011, just as the '760 patent was expiring, Amgen issued a press release  
23 proclaiming that it had acquired U.S. Patent No. 8,063,182. (Compl. ¶ 53; Ex. 10-11). Amgen  
24 announced that "[t]he patent describes and claims the fusion protein that is etanercept, and by  
25 statute, the '182 patent has a term of 17 years from today"—until November 2028. (Ex. 10). Five  
26 months later, on April 24, 2012, the Patent Office issued U.S. Patent No. 8,163,522, based on the  
27 other submarine application. (Compl. ¶ 28; Ex. 12). Amgen claimed that the '522 patent, like the  
28 '182 patent, is "material" to its Enbrel product. (Compl. ¶ 52; Ex. 3 at 6). According to Amgen, the

1 term of the ‘522 patent is set to expire April 24, 2029—39 years after its original application was  
2 filed. (*Id.*).

3 **E. Amgen engages in a public campaign touting its newfound patent “exclusivity”**  
4 **on etanercept and threatening competition.**

5 Following the issuance of its patents, Amgen trumpeted its newfound “exclusivity” against  
6 all biosimilar competition. For the ‘182 patent, Amgen announced “this newly issued patent to the  
7 fusion protein that is etanercept adds to [existing] patent protection,” “we are confident in our ability  
8 to protect our products,” and thus, “we do not envision Enbrel biosimilar competition in the United  
9 States for the foreseeable future.” (Compl. ¶ 54; Ex. 13 at 1). At an industry conference in  
10 December 2011, Amgen proclaimed: “With a broad patent estate that we have now established for  
11 Enbrel, we feel that the market *exclusivity* for Enbrel is going to be prolonged and we don’t  
12 anticipate *any biosimilar competition* in the foreseeable future.” (Compl. ¶ 55; Ex. 14 at 2). Amgen  
13 sounded the same refrain over and over throughout 2012-13. (Compl. ¶¶ 53-60; Ex. 16-19, *e.g.*, Ex.  
14 18 at 3 (“Given this added *exclusivity* that we now have on Enbrel, we are not expecting *any*  
15 *biosimilar competition* for Enbrel in the foreseeable future.”)).

16 Amgen was already notorious for its aggressive patent enforcement actions. It had  
17 previously sued competitors seeking a declaration of future infringement before any FDA filings  
18 were made. (Ex. 2 at ¶¶ 27-30 Ex. 23 at 14-15). In 2012, while it was boasting about its new  
19 Enbrel patents, Amgen’s CEO stated: “we have consistently demonstrated that we have the will and  
20 the skill to defend our intellectual property, and you should expect that we’ll do that with respect to  
21 our G-CSF franchise as well as our other franchises.” (Ex. 22 at 12). Further, he warned: “you  
22 should expect that we will assert our IP rights, and to the extent that they infringe, you should expect  
23 that we’ll deal with that through the appropriate channel.” (Compl. ¶ 63; Ex. 22 at 12).

24 Amgen’s message to Sandoz and other potential biosimilar competitors is clear. The ‘182  
25 and ‘522 patents cover Enbrel, Amgen will not tolerate biosimilar competition, and it will enforce  
26 the ‘182 and ‘522 patents to protect its market exclusivity.

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

1           **F. Amgen’s patent position disrupts Sandoz’s settled expectations and places it in a**  
2           **legal quandary.**

3           Amgen’s new patent position has disrupted Sandoz’s business expectations. (Compl. ¶¶ 3-5;  
4 Jankowsky ¶¶ 16-20). Sandoz has allocated nine years of product development and [REDACTED]  
5 in reliance on defined patent expiration dates, only to have Amgen suddenly claim the right to  
6 exclude its product for an entire generation based on submarine patents issuing two decades after  
7 their original filing dates, which Sandoz had no way of knowing about. (*Id.*). Sandoz, however, has  
8 no intention of abandoning its product in the face of Amgen’s threats. It believes the patents are  
9 invalid for multiple reasons, unenforceable, and not infringed. (Compl. ¶¶ 4, 26-27, 34, 73-108).  
10 Sandoz intends to file its FDA application at the conclusion of its clinical trials. (Compl. ¶¶ 3-4;  
11 Jankowsky ¶ 14).

12           Amgen’s patent claims place Sandoz in an untenable situation. [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]

17           [REDACTED] Sandoz is thus faced with the present decision to proceed with activities directed  
18 towards allegedly infringing activity or abandoning them. (*Id.*).

19           There is no hope of Sandoz obtaining a license from Amgen. Amgen has repeatedly stated it  
20 intends to exclude biosimilar competition for Enbrel; indeed, its whole business model is premised  
21 on enforcing its patents against competing products. Amgen has grown its Enbrel sales into 25% of  
22 its company’s total through price increases that would be impossible with biosimilar competition.  
23 (Compl., ¶ 48; Ex. 3; *id.* at 62- 63 (15% increase in Enbrel revenues primarily attributable to  
24 increase in sales price)). The ‘182 and ‘522 patents are thus critical to Amgen’s long-term strategy  
25 for Enbrel, which stands to be even more profitable for Amgen once a co-promotion agreement with  
26 Pfizer expires later this year. (Compl. ¶ 49; Ex. 3 (Shareholder Ltr.); Ex. 14 at 2; Ex. 16 at 3; Ex. 17  
27 at 2). Licensing the patents to Sandoz would be contrary to Amgen’s entire business plan for Enbrel.  
28 (*E.g.*, Ex. 17 at 2; Ex. 3 at 44-45 (discussing risk factor of biosimilar competition)).



1 changed. To say the least, Amgen is mistaken. The evidence of record shows that Sandoz’s product  
2 is in the very final stages of development, not subject to change, and proceeding expeditiously to  
3 completion of its final clinical trial, FDA review, and approval.

4 Amgen’s legal arguments are equally meritless. Contrary to its assertions, jurisdiction does  
5 not require Sandoz to have made an FDA filing, nor does it require Sandoz to have completed all  
6 clinical trials, nor does it require Amgen to have made particular threats to sue. Rather, the Act  
7 permits declaratory judgment actions to the greatest extent the Constitution allows—where there is  
8 an *actual controversy* between the parties of sufficient reality and immediacy to support a  
9 declaratory judgment. That is the case here.

10 Ultimately, Amgen seeks to dismiss this case in the hopes of bringing an infringement action  
11 in the future, at a time and place of its own choosing. The Court should decline that request.  
12 Dismissing this action would advance no rational purpose, serve only to delay adjudication of the  
13 parties’ dispute to Sandoz’s prejudice, and require Sandoz’s rights be adjudicated in an emergency  
14 hearing, contrary to sound judicial administration.

15 **I. The Court Has Subject Matter Jurisdiction Over This Action.**

16 **A. Jurisdiction Only Requires The Existence Of An “Actual Controversy.”**

17 The Declaratory Judgment Act provides, “[i]n a case of actual controversy,” the district court  
18 “may declare the rights and other legal relations of any interested party seeking such declaration,  
19 whether or not further relief is or could be sought.” 28 U.S.C. § 2201. Its purpose in patent cases is  
20 “to provide the allegedly infringing party relief from uncertainty and delay regarding its legal  
21 rights.” *Micron Tech. Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). A  
22 “declaratory judgment is ‘especially useful in avoiding the necessity ... of having to act at one’s peril  
23 or to act on one’s own interpretation of his rights, or abandon one’s rights because of a fear of  
24 incurring damages.’” *Arkema Inc. v. Honeywell Intern., Inc.*, 706 F.3d 1351, 1357-58 (Fed. Cir.  
25 2013)) (quoting S. Rep. No. 73–1005, at 2–3 (1934)).

26 The Act’s sole requirement “is that the conflict be real and immediate, *i.e.*, that there be a  
27 true, actual ‘controversy’ required by the Act.” *Cardinal Chem. Co. v. Morton Intern., Inc.*, 508  
28 U.S. 83, 96 (1993) (quotation omitted). The Act thus extends to the greatest scope allowed by

1 Article III of the Constitution. *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278, 1290  
2 (Fed. Cir. 2008) (“It is well established that the phrase “actual controversy” in § 2201(a) includes  
3 any controversy over which there is Article III jurisdiction.”). The Supreme Court has observed that  
4 “[m]erely the desire to avoid the threat of a ‘scarecrow’ patent, in Learned Hand’s phrase, may  
5 therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act.” *Cardinal*  
6 *Chemical Co.*, 508 U.S. at 96.

7 Jurisdiction will exist where “the facts alleged, under all the circumstances, show that there is  
8 a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and  
9 reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549  
10 U.S. 118, 127 (2007). Under this standard, “an ‘actual controversy’ requires only that a dispute be  
11 ‘definite and concrete, touching the legal relations of parties having adverse legal interests’; and that  
12 it be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character,  
13 as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.’”  
14 *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007) (quoting  
15 *Medimmune*).

16 Although the Federal Circuit previously required DJ plaintiffs to have a “reasonable  
17 apprehension” of being sued, the Supreme Court rejected that rule in *MedImmune*, liberalizing the  
18 standard for DJ actions. *See Micron*, 518 F.3d at 902. “[T]he now more lenient legal standard  
19 facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases.” *Id.*  
20 After *MedImmune*, a controversy exists “where the patentee takes a position that puts the declaratory  
21 judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that  
22 which he claims a right to do.” *SanDisk Corp. v. ST Microelectronics, Inc.*, 480 F.3d 1372, 1381  
23 (Fed. Cir. 2007). For instance, a patentee’s refusal to grant a license “suggests that there is an active  
24 and substantial controversy between the parties.” *Arkema*, 706 F.3d at 1358. Likewise, a patentee’s  
25 public statements about its patent position may also demonstrate the existence of a controversy. *See*  
26 *Micron*, 518 F.3d at 901.

1           **B.       There Is An Actual Controversy Requiring Judicial Resolution.**

2           The facts here establish the minimal requirements for an “actual controversy.” Amgen has  
3 clearly “taken a position” that requires Sandoz to pursue allegedly infringing activity or abandon its  
4 product launch plans. *SanDisk*, 480 F.3d at 1381. It has repeatedly announced its two submarine  
5 patents give it the right to exclude all biosimilar competition from the market. Amgen’s allegations  
6 force Sandoz to choose to proceed with, or abandon, substantial investments in preparing its  
7 allegedly infringing product for launch, particularly, [REDACTED] dollar expansion of  
8 manufacturing facilities it needs to meet the expected demand for U.S. commercialization. Further,  
9 without the present litigation, Sandoz will lack certainty of its rights, and would be faced with the  
10 choice of launching its product at the risk of a potentially devastating damages claim or give up what  
11 it believes it has a right to do. These quandaries pose the “quintessential example of a situation in  
12 which declaratory relief is warranted.” *Arkema*, 706 F.3d at 1357; *City of Aurora ex rel. Aurora*  
13 *Water v. PS Sys., Inc.*, No. 07-CV-02371, 2008 WL 4377505, \*11 (D .Colo. 2008) (DJ plaintiff’s  
14 pursuit of allegedly infringing construction project put it in “the untenable position of either pursuing  
15 arguably illegal behavior or abandoning ... the Project altogether, despite the millions of dollars it  
16 has invested already”—“the classic dilemma that the Declaratory Judgment Act is meant to  
17 ameliorate”)

18           Amgen claims that its patents are “irrelevant” to Sandoz’s business because Sandoz has  
19 chosen to forge ahead despite their issuance. (Br. at 21-22). But this argument misses the point.  
20 What is relevant for jurisdiction is that Amgen has placed Sandoz “*in the position* of either pursuing  
21 arguably illegal behavior or abandoning that which [it] claims a right to do.” *Sandisk*, 480 F.3d at  
22 1381 (emphasis added). The law does not require Sandoz to make a particular decision once it is put  
23 in that position. *Id.*; see also *Alpharma, Inc. v. Purdue Pharma L.P.*, 634 F. Supp. 2d 626, 630-31  
24 (W.D. Va. 2009) (finding jurisdiction under *Sandisk* where “plaintiff must *either* continue to  
25 produce a drug that is potentially encompassed by the defendant’s patents *or* reluctantly forgo the  
26 drug’s development.”) (emphasis added). Indeed, if Sandoz simply gave up, Amgen would  
27 presumably claim that Sandoz lacked standing since it would no longer have a product.

1 Amgen suggests its submarine patents have had no effect on Sandoz because Sandoz is  
2 developing its product for European markets. Amgen is wrong. [REDACTED]

3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]

8 Amgen also halfheartedly claims there is no “controversy” between the parties because  
9 Amgen did not threaten litigation against Sandoz in particular. (Br. at 20-21). But this argument  
10 invites legal error. In *MedImmune*, the Supreme Court held a licensee could challenge a patent  
11 without first breaching the license, and thus, without the patentee first threatening suit. 549 U.S. at  
12 128, 137. Following *MedImmune*, the Federal Circuit has repeatedly found “[a] *specific threat* of  
13 infringement litigation by the patentee is *not required* to establish jurisdiction.” *ABB Inc. v. Cooper*  
14 *Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (emphasis added); *see also Arkema*, 706 F.3d at  
15 1358 (“*Nor is it necessary* that a patent holder make *specific accusations* against either the potential  
16 direct infringers or Arkema.”) (emphasis added); *Neuralstem, Inc. v. StemCells, Inc.*, 573 F. Supp.  
17 2d 888, 894 (D. Md. 2008) (rejecting the argument that “an identification of a specific patent and the  
18 allegedly infringing products or activities” was necessary; “[T]he Federal Circuit has acknowledged  
19 that declaratory judgment jurisdiction can exist even where the potential declaratory judgment  
20 defendant cannot sue or has not indicated a willingness to sue”) (citing *SanDisk* and *Sony Elecs., Inc.*  
21 *v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1284 (Fed. Cir. 2007)); *Alpharma, Inc.*, 634 F.  
22 Supp. 2d at 630-31 (“Nevermind that the defendant did not explicitly threaten the plaintiff with  
23 litigation.”).

24 Requiring Amgen make specific threats against Sandoz would serve no rational purpose here.  
25 Amgen has already made its patent position clear to the entire industry, repeatedly, since the first  
26 submarine patent issued. (Compl. ¶¶ 53-60; Ex. 10 at 1). It has stated its claim to “exclusivity”  
27 against biosimilar competition in press releases, business journals, investor conference calls, and at  
28 numerous industry conferences, while its statements and annual reports confirm that its business

1 strategy requires excluding biosimilar competition. (Ex. 10 at 1; Ex. 13; Ex. 14 at 2; Ex. 15 at 9; Ex.  
2 16 at 2; Ex. 17 at 2; Ex. 18 at 3; Ex. 19 at 4; Ex. 3 at 44-45). It has declined to license Sandoz.  
3 (Compl. ¶¶ 67-69). It has aggressively enforced patents on its major products, including by  
4 preemptive DJ actions. (Compl. ¶ 65; Ex. 2 at ¶¶ 27-30; Ex. 23 at 14-15). Its CEO has publicly  
5 boasted about its litigation history and intention to pursue similar litigation in the future (Compl. ¶¶  
6 62-64; Ex. 22 at 12). In sum, Amgen leaves no doubt of its intent to enforce the ‘182 and ‘522  
7 patents against Sandoz. And in its brief, it now confirms that it will enforce these patents and  
8 possibly others against Sandoz. (Br. at 2-3). Under these circumstances, there is a clear dispute  
9 between the parties based on Amgen’s own affirmative actions. Requiring Sandoz to await a  
10 specific threat, while suffering from delay, would be a meaningless formalism contrary to case law  
11 and the purpose of the Declaratory Judgment Act.

12 Amgen cites *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1337 (Fed. Cir. 2008)  
13 and *Impax Labs., Inc. v. Medicis Pharm. Corp.*, No. C-08-0253, 2008 WL 1767044, \*3 (N.D. Cal.  
14 2008) for the proposition that specific threats are required to establish a controversy. In *Prasco*,  
15 however, the patent merely existed and its owner took no position on it. In *Impax*, the court found  
16 there was a real issue whether the patentee would have licensed the defendant’s product had they  
17 negotiated before suit—clearly *not* the situation here. *See* 2008 WL 1767044, \*1, \*4.<sup>2</sup>

18 Since those cases, this Court has found a controversy existed based on a patentee’s general  
19 public statements that *anybody* practicing certain DNA technology would infringe the patent, where  
20 the statements created a barrier to funding for a particular DJ plaintiff’s product. *Aria Diagnostics,*  
21 *Inc. v. Sequenom, Inc.*, No. 11-06391, 2012 WL 761706, \*3 (N.D. Cal. 2012); *see also Micron*, 518  
22 F.3d at 902 (finding controversy based on “MOSAID’s recent public statements and annual reports  
23 [which] confirm its intent to continue an aggressive litigation strategy.”); *Neuralstem, Inc.*, 2008 WL  
24 3929350, \*6 (holding non-specific public statements by patentee, coupled with patentee’s litigious

25  
26  
27 <sup>2</sup> In *Bridgelux, Inc. v. Cree, Inc.*, No. 06-6495, 2007 WL 2022024, \*9 (N.D. Cal. 2007), which  
28 Amgen also cites, the court declined jurisdiction because the plaintiffs’ basis for claiming  
jurisdiction was based on “hearsay or double hearsay.” Moreover, that case did not involve a  
situation—as here—where the patent holder took a particular position about its patent covering a  
particular product.

1 history, established a controversy under the totality of the circumstances). Under all of the  
2 circumstances, the present facts fall well with the scope of the case law affirming jurisdiction.

3 **C. The Controversy Is Real And Immediate.**

4 Amgen argues that this case is not sufficiently “real” or “immediate” to warrant the issuance  
5 of a declaratory judgment. Again, Amgen is wrong.

6 **1. Sandoz’s product is not subject to change.**

7 In patent cases, “the reality requirement is often related to the extent to which the technology  
8 in question is ‘*substantially fixed*’ as opposed to ‘fluid and indeterminate’ at the time declaratory  
9 relief is sought.” *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 882 (Fed. Cir. 2008) (citation  
10 omitted) (emphasis added). Where the technology is substantially fixed, as opposed to “in an early  
11 stage of development,” the reality requirement is satisfied. *Id.*

12 Here, far from being “in an early stage,” Sandoz’s product is in the very final stage of  
13 development. It has been thoroughly validated over the course of *nine years*, shown to be identical  
14 or highly similar to Enbel in a wide array of molecular studies, tested in humans and animals, and  
15 shown to possess equivalent pharmacokinetics and safety to Amgen’s Enbrel in humans.  
16 (Jankowsky ¶¶ 4-5; Roth ¶¶ 7, 9). The product cannot change without rewinding this process, which  
17 Sandoz has no intention of doing. (Jankowsky ¶ 7).

18 Amgen speculates that the route of administration, method of manufacture, or formulation of  
19 Sandoz’s product all could change in unspecified ways (Br. at 3, 22-23). They will not. First, the  
20 route of administration for Sandoz’s biosimilar product is *required by law* to be the same as  
21 Enbrel’s. 42 U.S.C. § 262(k)(2)(A)(i)(IV) (requiring the “route of administration” be “the same” as  
22 “the reference product”). (Roth ¶ 17). Second, contrary to Amgen’s assertions, Sandoz does not  
23 need to scale up its manufacturing process to produce drug product for clinical trials. This activity  
24 has *already occurred* (Jankowsky ¶¶ 12-13), and there is no need for the manufacturing changes  
25 Amgen imagines.<sup>3</sup> Third, Amgen presents no basis for its assertion that Sandoz’s formulation will

26 <sup>3</sup> Amgen’s argument is based on a misreading of Sandoz’s Complaint. In the paragraph Amgen  
27 cites, Sandoz stated that it needs to increase its production capabilities. (¶ 43). It did not say it  
28 needed to scale up its process for clinical trials. Sandoz needs the additional facilities to perform the  
same scaled-up process so it can meet anticipated commercial demand, not make product for clinical  
studies. As to the purported “evidence” that Amgen cites regarding Genzyme’s scale-up, it is blatant  
hearsay that is entirely irrelevant.

1 change, and there is none. Even assuming a change to the formulation occurred, it would be  
2 irrelevant to the patents here, which, according to Amgen, claim “the protein that is etanercept.”  
3 (Ex. 10). Sandoz’s product has always been and will continue to be etanercept, regardless of any  
4 formulation changes, which it has no intention of making.<sup>4</sup>

5 This case presents a far cry from the cases Amgen cites in support of dismissal. In *Sierra*  
6 *Applied Scis. v. Advanced Energy Indus.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004), the plaintiff  
7 presented no evidence that it even built a *prototype* of its product “until at least a year after the  
8 commencement of suit.” *Cat Tech*, 528 F.3d at 881 (discussing *Sierra*). In *Benitec Austral., Ltd. v.*  
9 *Nucleonics, Inc.*, 495 F.3d 1340, 1348-49 (Fed. Cir. 2007) the DJ plaintiff had only a “vaguely  
10 defined” plan to expand its “nascent” technology into veterinary products. *Id.* at 1348-49; *Cat Tech*,  
11 528 F.3d at 881 (discussing *Benitec*). In *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d  
12 1520, 1527 (Fed. Cir. 1992), the product in question was an original medical device that had only  
13 just begun its very first clinical trial, was not similar to any reference product (unlike a biosimilar),  
14 and thus was inherently changeable. As the Federal Circuit later explained, all of these cases  
15 presented extreme situations where the product design was “fluid and in an early stage of  
16 development.” *Cat Tech*, 528 F.3d at 882.

17 Here, by contrast the only competent evidence is that Sandoz’s etanercept product is fixed  
18 after nearly a decade of successful development, and is not subject to further change. (Jankowsky ¶¶  
19 2-12; Roth ¶ 16). These facts are more than sufficient to establish a “real” dispute based on a “real”  
20 product. *Cat Tech*, 528 F.3d at 882 (finding dispute was “real” where the alleged infringer “does not  
21 expect to make substantial modifications to its loading device designs”).

22  
23  
24  
25  
26 <sup>4</sup> Amgen does not identify how any hypothetical change in formulation could be relevant to the  
27 patents in suit. Rather, it claims that a change may be relevant to another patent it has listed in its  
28 annual report. (Br. at 17-18). Amgen will receive discovery about Sandoz’s formulation in this  
case, and may sue on that patent if it has a legitimate basis to do so. Sandoz submits there would be  
no such basis. Regardless, Amgen’s uncertainty about the applicability of other patents does not  
detract from the Court’s jurisdiction over the present dispute.



1 Sandoz or its product (Br. at 12). That hearsay is inadmissible.<sup>5</sup> *E.g., Tasini v. New York Times Co.,*  
 2 *Inc.*, 184 F. Supp. 2d 350, 357 n.8 (S.D.N.Y. 2002) (stating “articles and newspaper clippings do not  
 3 rise to the level of competent evidence” for 12(b)(1) motion); *3D Sys., Inc. v. Envisiontec, Inc.*, 575  
 4 F. Supp. 2d 799, 804 (E.D. Mich. 2008) (“Hearsay statements may not be considered.”). The actual  
 5 evidence is that Sandoz’s biosimilars have never failed an initial late-stage trial, Sandoz’s enrollment  
 6 is ahead of schedule, and there is every reason to believe its final confirmatory trial will succeed in  
 7 light of Sandoz’s extensive proof of molecular and functional similarity in the analytical,  
 8 bioanalytical, pre-clinical and clinical comparison with its reference product Enbrel®. (Roth ¶¶ 8-  
 9 12, 14-16; Jankowsky ¶¶ 4-5, 9).

10 Amgen would have the Court believe no jurisdiction exists unless all clinical trials have been  
 11 completed and an FDA filing has been made. (Br. at 19). But the two cases Amgen cites do not  
 12 support that position. In *Teletronics*, the medical device in question—unlike here—had barely  
 13 started clinical development and FDA submission was still “*years away*.” 982 F.2d at 1527  
 14 (emphasis added). *Benitec* involved an equally extreme situation where “[t]he plaintiff, who sought  
 15 declaratory relief in **2005**, did not anticipate filing an NDA until ‘*at least 2010-2012, if ever*[.],’”  
 16 *Cat Tech*, 8 F.3d at 881 (discussing *Benitec*) (emphasis added). The Federal Circuit resolved the  
 17 cases on those facts, which differ dramatically from the case here, where Sandoz’s product is far  
 18 more advanced and will be subject to FDA approval and commercialization during the pendency of  
 19 this litigation or immediately after it concludes.

20 Not only is Amgen’s proposed rule wrong, it is directly contrary to precedent Amgen itself  
 21 set during prior litigation. Previously, Amgen sued Hoechst for a DJ of future infringement despite  
 22 the fact that Hoechst had not filed for FDA approval or even conducted *any* clinical studies of its  
 23 competitive EPO drug. (Ex. 23, at ¶ 35; Ex. 1 at 13). To justify jurisdiction, Amgen relied on

24 <sup>5</sup> Sandoz specifically objects to the following purported “evidence”: WD 4 (article with hearsay  
 25 statement about patient enrollment); WD 8 (powerpoint slide with hearsay statement about patient  
 26 enrollment); WD 9 (web article printout with hearsay statements); WD 11 (powerpoint snippet with  
 27 hearsay statement about Phase III failure rate); WD 12 (corporate finance article with hearsay  
 28 statements and statistics about clinical trial success rates); WD 13 (internet blog with double hearsay  
 statements about clinical trial success rates); WD 14 (powerpoint presentation with hearsay  
 statements about “Big pharma probability of approval”); WD 15-16 (internet blogs with hearsay  
 about Samsung’s and Teva’s irrelevant product development of rituximab); WD 18 (article with  
 hearsay about Myozyme scale-up process); WD 25 (hearsay market research about etanercept sales  
 in Europe); WD 31 (powerpoint with hearsay about clinical development success rates).

1 *Glaxo*, claiming that the dispute was immediate based on Hoechst’s substantial preparations for  
2 infringement. (Ex. 25 at 5). The court agreed the dispute was sufficiently immediate, despite the  
3 lack of any clinical studies in that case. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d  
4 104, 112 (D. Mass. 1998) (noting Hoechst “plans to market GA-EPO at the earliest opportunity” and  
5 there was no “question about its immediate capacity to do so upon FDA approval.”).

6 A few years later, Amgen sued Roche for a declaratory judgment of future infringement  
7 based on Roche’s development of a competitive EPO drug, claiming Roche’s product, when filed,  
8 approved, and subsequently marketed in the U.S., would infringe Amgen’s patents. (Ex. 2 at ¶¶ 27-  
9 31).<sup>6</sup> Amgen based its arguments on the same type of facts that it now disregards, including Roche’s  
10 intent to market its product and its substantial preparations to do so, such as the construction of a  
11 commercial manufacturing facility. (Ex. 2, ¶ 28; Ex. 1, at 19 (“There is no doubt that Roche plans to  
12 market pegylated EPO at the earliest opportunity and that it has made meaningful commercial  
13 preparations to do so. ***These are the types of activities that courts have found to warrant exercise***  
14 ***of declaratory relief jurisdiction.***”) (emphasis added)).

15 In opposing a motion to dismiss for lack of jurisdiction, Amgen again cited *Glaxo*, 110 F.3d  
16 at 1571, pointing out that the Federal Circuit upheld a DJ lawsuit there, even though infringement  
17 was eighteen months away (Ex. 1 at 12). It then proceeded to rely on the precedent it set in the  
18 *Hoechst* case. Amgen argued, in direct contradiction to its current claims:

19 Like *Glaxo*, this Court’s application of *Lang* in *Amgen Inc. v. Hoechst Marion*  
20 *Roussel, Inc.*, shows that subject matter jurisdiction exists here. Due to defendant  
21 HMR/TKT’s intent and capacity to market the accused product upon FDA approval,  
22 its future infringement ***was found to be sufficiently imminent and real for purposes***  
***of declaratory relief jurisdiction*** under *Lang* ***even though clinical trials had not yet***  
***begun*** and approval was ***years away***.

23 (Ex. 1 at 13) (emphasis added). Relying on Amgen’s arguments, the district court found jurisdiction  
24 existed and denied Roche’s motion to dismiss. *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F.  
25 Supp. 2d 267, 276-78 (D. Mass. 2006). In particular, the court found a controversy existed based on  
26 Roche’s substantial preparations for infringing activity, holding Roche’s expected approval date of  
27

28 <sup>6</sup> Roche filed its FDA application well after suit was commenced.

1 “20 to 24 months away can be considered *sufficiently imminent* by this Court.” *Id.* at 278  
2 (emphasis added).

3 On a later appeal, there was no hint the Federal Circuit perceived a jurisdictional defect. *See*  
4 *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1346 (Fed. Cir. 2009). This is significant  
5 because, as Amgen concedes in its brief (Br. at 6 & n.2), the Federal Circuit will dismiss a case  
6 where subject matter jurisdiction is lacking, even when the parties do not raise jurisdiction as an  
7 issue. Thus, contrary to Amgen’s misstatements (Br. at 19), the “hard truth” is that the Federal  
8 Circuit has indeed upheld jurisdiction over a declaratory judgment action brought prior to an FDA  
9 filing. The court did so in Amgen’s own case involving its most prominent product.

10 If Amgen can sue for future infringement based on a competitor’s substantial preparations to  
11 market a competitive product, it is equally true that Amgen is subject to suit here. The Federal  
12 Circuit has explained: “It logically follows that if such an action creates a justiciable controversy for  
13 one party, the same action should create a justiciable declaratory judgment controversy for the  
14 opposing party.” *Teva Pharmaceuticals*, 482 F.3d at 1342. For declaratory judgments, what is  
15 sauce for the goose is sauce for the gander.

16 Indeed, the facts are more compelling here than the prior *Amgen* cases. The prior *Amgen*  
17 cases involved situations where a patentee sued preemptively for future infringement against  
18 products undergoing development. Such lawsuits disturb the policies behind the statutory safe  
19 harbor, which insulates research related to FDA filings from infringement liability, and protects  
20 biosimilar and generic manufacturers from unwanted patent suits.<sup>7</sup> *See* 35 U.S.C. § 271(e)(1). No  
21 such policy is implicated when an accused infringer—as here—seeks a declaration of its *own* rights  
22 prior to FDA approval. As the court noted in *Infinitech, Inc. v. VitroPhage, Inc.*, “The patent holder  
23 loses nothing by waiting, as the alleged infringer cannot market the product until gaining  
24 government approval,” while “the alleged infringer has *everything to lose* by being forced to shelve  
25 its declaratory judgment suit until after its product receives federal approval.” 842 F. Supp. 332, 337  
26 (N.D. Ill. 1994) (emphasis added).

27  
28 <sup>7</sup> Based on this policy, the *Hoechst* court declined to exercise its jurisdiction, despite finding an  
actual controversy existed. 3 F. Supp. 2d at 112.

1 As in the *Amgen* cases, the *Infinitech* court found there was jurisdiction for an accused  
2 infringer's DJ action, even though FDA approval for the product was still in the future. The Court's  
3 holding describes the situation here perfectly: "While [Sandoz] may not have the present ability to  
4 market [etanercept]," the court noted, "it has embarked upon a protracted and costly process of  
5 obtaining regulatory approval." *Id.* "[Sandoz's] conduct thus evinces the kind of 'concrete steps' or  
6 'meaningful preparation' needed to establish an actual controversy under 'all the circumstances.'" *Id.*  
7 *Id.* at 337-38.

## 8 **II. The Court Should Exercise Its Jurisdiction**

9 The only remaining question is whether this Court should exercise its jurisdiction. It should.  
10 "When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is  
11 discretionary." *Cat Tech*, 528 F.3d at 883. But that discretion, though "broad," is "not absolute."  
12 *Micron*, 518 F.3d at 903. "When there is an actual controversy and a declaratory judgment would  
13 settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual  
14 circumstance the declaratory judgment is not subject to dismissal." *Genentech v. Eli Lilly & Co.*,  
15 998 F.2d 931, 937 (Fed. Cir. 1993). Thus, where "resolving the case serves the objectives for which  
16 the Declaratory Judgment Act was created," the Court should exercise its discretion and retain the  
17 case. *Cat Tech*, 528 F.3d at 883; *Amgen v. Roche*, 456 F. Supp. 2d at 278 ("Given that the test for  
18 the existence of an actual controversy is satisfied, the Court is warranted in exercising jurisdiction  
19 over this declaratory judgment action.").

20 The Act was tailor-made for a case like this. Maintaining the case stands to provide Sandoz  
21 with "relief from uncertainty and delay regarding its legal rights," and thus, would place it in the  
22 position it reasonably expected prior to Amgen's acquisition and trumpeting of its submarine  
23 patents. *Micron*, 518 F.3d at 902. Dismissing the case, on the other hand, would obstruct this  
24 objective by allowing Amgen to upset Sandoz's legitimate business expectations with invalid patents  
25 issuing over two decades after their original filing dates, dissuading Sandoz's legitimate competition  
26 and investment, while depriving Sandoz of the ability to determine its rights.

27 Amgen suggests that accepting this case would cause "litigation floodgates" to be opened,  
28 because it would allow DJ actions where the plaintiff was not explicitly threatened with suit. (Br. at

1 23). That is not a concern here. First, the Supreme Court already rejected the explicit threat  
2 requirement. Accepting this case is entirely consistent with the Supreme Court's precedent and  
3 would not pave new ground. *See Micron*, 518 F.3d at 902 (discussing the "ease of achieving  
4 declaratory judgment jurisdiction in patent cases" following *MedImmune*). Second, the facts of this  
5 case show an undeniable dispute. Amgen has taken an express position about its patent coverage  
6 that puts Sandoz in the typical quandary implicating the Declaratory Judgment Act. Beyond that,  
7 Amgen refuses to license Sandoz and effectively admits that it will sue Sandoz for its etanercept  
8 product later if this case is dismissed. The question is not whether the dispute will be resolved in  
9 court, but *when*.

10 Amgen argues this case should await Sandoz's FDA filing because the Hatch-Waxman Act  
11 and the BPCIA supposedly reflect a Congressional intention to delay patent litigation until after  
12 FDA filings are made. If this statement were true, however, there would be statutory provisions  
13 confirming it. Tellingly, however, Amgen cites no provision in either statute purporting to deprive  
14 the federal courts of subject matter jurisdiction where a case or controversy is already established  
15 prior to the time of an FDA filing. There is none.

16 On the contrary, a declaratory judgment action is necessary to achieve patent certainty prior  
17 to Sandoz's commercial marketing. Here, all regulatory exclusivities for Enbrel have already  
18 expired. Thus, Sandoz can market its etanercept product immediately upon FDA approval, which  
19 could occur in as little as 10-12 months after its filing. Because a complex biologics patent case  
20 cannot be resolved in 10-12 months or even twice that long, the *only way* for the parties to achieve  
21 patent certainty prior to commercial marketing in this case is through a DJ action brought prior to the  
22 biosimilars filing.<sup>8</sup>

23 <sup>8</sup> The BPCIA, which governs biosimilar filings, does not allow the FDA to stay approval of a  
24 biosimilar product pending the outcome of patent litigation. Rather, in the typical case, patent issues  
25 will be resolved during a lengthy period of regulatory exclusivity the BPCIA provides for the  
26 reference biologic drug. For new BLA filings, the BPCIA provides a 4-year exclusivity period in  
27 which the FDA may not accept biosimilar applications and a 12-year data exclusivity period in  
28 which the FDA may not approve a biosimilar. 42 U.S.C. § 262(k)(7)(A)-(B). Thus, the BPCIA  
envisioned a period of time of up to 8 years in which patent disputes can be resolved in the typical  
case. These exclusivities are calculated as of the date the reference product's BLA is filed. *Id.*  
Since the BLA for Enbrel was filed over 12 years ago, Enbrel is not entitled to *any* such regulatory  
exclusivity, and thus, the typical period for resolving patent disputes under BPCIA does not exist  
here.

1 Achieving patent certainty prior to commercial marketing is a necessity. During the  
2 Congressional debate on biosimilars legislation, for example, Jeffrey Kushan, partner at Amgen’s  
3 counsel Sidley Austin LLP, testified “any legislation *must* include a balanced and fair procedure for  
4 identifying and resolving patent disputes implicated by the structure of a biosimilar product and how  
5 it is made *before the biosimilar product is approved and put on the market.*”<sup>9</sup> Indeed, “[n]early *all*  
6 *stakeholders agree* that doing so is better for patients, caregivers, and *both innovator and biosimilar*  
7 *companies.*” To achieve that goal, other witnesses explained, “[w]e need things like declaratory  
8 judgment actions being available to the follow-on applicant.”<sup>10</sup> And consistent with this goal, the  
9 BPCIA provides DJ actions can be filed by either party upon the biosimilar manufacturer’s notice of  
10 commercial marketing, which Sandoz has given here. *See* 42 U.S.C. § 262(l)(8)-(9). (Ex. 24).<sup>11</sup>  
11 This action is thus entirely consistent with the text and the policy of the BPCIA.

12 If this lawsuit had to await a formal FDA filing, as Amgen suggests, it simply could not be  
13 resolved prior to the intended 2016 launch of Sandoz’s product. Previously, Amgen agreed that  
14 courts should accept jurisdiction for precisely this reason. In the *Roche* litigation, Amgen vigorously  
15 urged the court to hear its case because it otherwise could not be resolved by the time of anticipated  
16 commercial marketing. (Ex. 1 at 1, 4, 15-16; *id.* at 15 (arguing “[i]f this case is not allowed to

17 <sup>9</sup> Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing Before the Subcomm. On  
18 Courts and Competition Policy of the H. Comm. On the Judiciary, 111th Cong. (2009) at 46,  
19 available at [http://judiciary.house.gov/hearings/printers/111th/111-73\\_51014.PDF](http://judiciary.house.gov/hearings/printers/111th/111-73_51014.PDF) (emphasis added).  
20 Mr. Kushan testified on behalf of Biotechnology Industry Organization, which represents the rights  
21 of BLA holders such as Amgen.

22 <sup>10</sup> *Id.* at 222 (statement of Teresa Stanek Rea on behalf of the American Intellectual Property Law  
23 Association in response to the question “what is the *best way* to resolve a patent dispute in a world  
24 that involves biosimilar competition”) (emphasis added).

25 <sup>11</sup> Debate on the biosimilars legislation confirmed that Congress recognized at least three years’ time  
26 would be needed to resolve DJ actions in complex biologics cases in advance of commercial  
27 marketing. In a draft of legislation subject to debate in the House, the bill provided a declaratory  
28 judgment procedure that was only available where the action was filed *less* than three years prior to  
commercial launch. This provision was widely criticized during Congressional hearings and  
ultimately removed from the House bill. *See id.* at 205 (statement of Teresa Stanek Rea) (“The  
assumption that a patent infringement litigation can be resolved in 3 years may not necessarily hold  
true.”); *id.* at 35 (December 22, 2008 Letter from Bruce A. Leicher of Momenta to the Federal  
Trade Commission) (“As proposed at the Roundtable, one would anticipate litigation lasting four (4)  
years in a biologic patent.”); *id.* at 21 (“Because this would not provide sufficient time to complete  
litigation, it would extend biologic entry well beyond the 12-14 years data exclusivity period in the  
bill.”). In the Senate bill, which largely reflects the final statutory language, there was never any  
temporal limitation on DJ actions.

1 proceed now, there is *little likelihood that Amgen could obtain adjudication* of its infringement  
2 claims *before market entry*”) (emphasis added). And with good reason. The entire point of the DJ  
3 Act, as Amgen explained, is “to provide relief to entities at a legal risk from an unresolved dispute,”  
4 “especially when the other party wishes to delay the litigation.” (Ex. 1 at 11) (citing *Capo, Inc. v.*  
5 *Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004)). It makes absolutely no sense to delay  
6 the start of a DJ action to a time that no longer fulfills its appointed purpose.

7 Yet that is precisely the result Amgen seeks here. Perhaps Amgen hopes, given its patent  
8 threat, Sandoz will not make the substantial investments needed to effectively compete with Amgen  
9 upon its 2016 commercial launch. Perhaps Amgen hopes that Sandoz will refrain from launching its  
10 product until the case is resolved, for fear of incurring a potential damages claim. In either situation,  
11 Amgen will have extracted an unjustified benefit by holding Sandoz’s rights unresolved. This action  
12 is necessary and appropriate to relieve Sandoz from this potential prejudice.

13 Finally, maintaining this case is appropriate for practical reasons. If this case were delayed  
14 until an FDA filing, the court would have to resolve the parties’ rights in a preliminary injunction  
15 hearing prior to Sandoz’s intended product launch without the benefit of a full record or completed  
16 discovery. Accepting jurisdiction now avoids the need for an emergency hearing, permits normal  
17 case management and discovery, and therefore promotes sound judicial administration. It is also  
18 consistent with a wealth of judicial experience under the Hatch-Waxman act, where courts routinely  
19 schedule trials to allow for patent issues to be resolved prior to the conclusion of the regulatory stay  
20 and intended product launch. *E.g., Shire LLC v. Amneal Pharm., LLC*, No. 11-3781, 2013 WL  
21 1932927, \*7 (D. N.J. 2013) (striking supplemental expert report where the effect of the report would  
22 “disrupt this litigation” by preventing the case from being concluded before 30-month stay expired);  
23 *Cephalon, Inc. v. Impax Lab., Inc.*, No. 11-1152, 2012 WL 3867568, \*2 (D. Del. 2012) (denying  
24 stay request because “the court could not resolve the present dispute within thirty months if the  
25 remaining claims are stayed”).

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CONCLUSION**

For all of these reasons, Defendants' motion should be denied.

Dated: September 13, 2013

By: /s/ K. Joon Oh  
James F. Hurst  
Maureen L. Rurka  
James M. Hilmert  
K. Joon Oh

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802