No. 2014-1693

In the United States Court of Appeals for the Federal Circuit

SANDOZ INC.,
PLAINTIFF-APPELLANT,

V.

AMGEN INC. AND HOFFMANN-LA ROCHE INC.,
DEFENDANTS-APPELLEES.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA CASE NO. 3:13-CV-02904, JUDGE MAXINE M. CHESNEY

NONCONFIDENTIAL REPLY BRIEF OF PLAINTIFF-APPELLANT SANDOZ INC.

JAMES F. HURST
MAUREEN L. RURKA
JAMES M. HILMERT
Winston & Strawn LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600
jhurst@winston.com

Counsel for Plaintiff-Appellant Sandoz Inc.

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CERTIFICATE OF INTEREST

Pursuant to Circuit Rule 47.4, undersigned counsel for Plaintiff-Appellant Sandoz Inc., certifies the following:

1. The full name of every party or amicus represented by us is:

   Sandoz Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

   Not applicable; the party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party represented by us are:

   Novartis AG, the ultimate parent company of Sandoz Inc., owning 100 percent of Sandoz Inc., and trading on the New York Stock Exchange under the ticker symbol NVS.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or expected to appear in this court are:

   Winston & Strawn LLP (James F. Hurst, Maureen L. Rurka, James M. Hilmert, Merritt D. Westcott, Elizabeth J. Thompson, Ian J. Nomura, Melinda K. Lackey, K. Joon Oh).

Dated: June 13, 2014

/s/ James F. Hurst
JAMES F. HURST

Counsel for Plaintiff-Appellant Sandoz Inc.

INTRODUCTION

In its four-page order, the district court issued an erroneous statutory construction that threatens serious damage to the nascent biosimilars industry and has broad ramifications for the public at large. According to the court, the BPCIA—a statute enacted to *facilitate* "price competition" in biologics—actually *bars* the courthouse doors to any biosimilar company seeking to resolve a patent dispute at any time before the FDA approves its product. That ruling, if undisturbed, would ensure low-cost biologics will be delayed for years simply due to delays in resolving patent disputes, at a cost of billions to patients, insurers, and the U.S. government. Because this result is directly contrary to the text and purpose of the BPCIA, the district court's judgment should be reversed.

Contrary to the district court's erroneous belief and Amgen's unsupported assertions, the BPCIA is *not* the exclusive mechanism for resolving patent disputes involving biologic drug products. To be sure, the BPCIA creates one potential mechanism to resolve patent disputes, by amending 35 U.S.C. § 271(e) to create a new infringement action based on the "artificial" activity of parties exchanging patent contentions. However, nothing in the BPCIA says that a § 271(e) action is the *only* way to resolving biologic patent disputes. The BPCIA does not purport to deprive federal courts of jurisdiction where it would otherwise exist under the Patent Laws, such as for declaratory judgments filed under §§ 271(a)-(c).

By their express terms, the BPCIA's sole limitations on a declaratory judgment remedy apply ***after*** a subsection (k) application is filed, and then, only "***if***" a subsection (k) applicant first "***fails***" to cooperate in prescribed informational exchanges, 42 U.S.C. §§ 262(*l*)(9)(B)-(C), or does not identify particular patents on a final list, § (*l*)(9)(A). Sandoz is not a "subsection (k)" applicant; it has not "failed" to comply with any obligations; and thus, no provision of the BPCIA bars Sandoz's Complaint.

Those simple facts should have ended the district court's inquiry, because "[w]hen the statutory language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). Amgen never bothers to quote the BPCIA's provisions it argues "bar" Sandoz's Complaint. Instead, Amgen paraphrases them contrary to their express terms. In Amgen's hands, the BPCIA's provisions for mutual exchanges of patent information become statutory "prerequisites," such that any declaratory judgment is barred "unless and until" they are completed. But the statute says no such thing. Congress' words must be faithfully applied as written—not as Amgen or the district court might have drafted them.

To avoid the statute's plain language, Amgen must show that applying Congress' language as written would lead to an "absurd" "disposition." *Arlington,*

548 U.S. at 296. Amgen fails to do so. Certainly, Sandoz's Complaint would not "abrogate" the BPCIA's provisions, as Amgen suggests. After a subsection (k) filing, Sandoz will comply with its obligations under the BPCIA, and Amgen will have every opportunity to bring suit against Sandoz under 35 U.S.C. § 271(e).

Far from being "absurd," permitting a declaratory judgment remedy is *essential* for the BPCIA's structure to work as it is designed in cases like this one, where a reference product's regulatory exclusivity has long expired. Congress envisioned that once a product's 12-year exclusivity expires, a biosimilar company could obtain FDA approval and market its product without further delay—a goal that cannot be accomplished if patent claims remain unresolved. A declaratory judgment action permits resolution of patent disputes in a timely manner, where a § 271(e) infringement suit does not serve that purpose. The district court's ruling obstructs that goal.

Finally, the district court's analysis affirmatively disrupts the BPCIA's exclusivity structure. The district court misinterpreted a provision intended to provide notice to *resolve patent disputes* before an anticipated commercial launch as an *exclusivity* provision. Even worse, under the court's interpretation, that provision—entitled "Notice of Commercial Marketing and Preliminary Injunction"—*automatically* tacks on an extra 180 days of exclusivity *beyond* the prescribed 12-year period *even when no relevant patent exists*. While Amgen

embraces this unforeseen windfall, it presents no argument excusing the district court's extraordinary departure from the statute's clear language. For all of these reasons, the district court's erroneous statutory construction should be vacated.

Amgen next seeks to defend the district court's ruling that there is no justiciable case-or-controversy under Article III of the Constitution. But what case would present a justiciable controversy, if not this one, where Sandoz invested tens of millions over nine years, only to be faced with a potentially huge commercial delay due to Amgen's saber-rattling about excluding competition with submarine patents? The district court's two-paragraph jurisdictional analysis—which failed to apply the controlling legal standards —reached exactly the wrong conclusion.

Amgen does nothing to justify that ruling. First, Amgen attempts to avoid scrutiny of the judgment by suggesting this Court should defer to putative "fact findings," which the district court never made. Far from resolving factual disputes, the district court declined to address any of the disputes the parties raised in their multiple briefs below. This Court owes no deference to the district court's opinion, which does not satisfy Federal Rule 52 nor implicate its "clearly erroneous" standard of review.

Second, Amgen argues there is no dispute because it has not threatened Sandoz or caused it harm. To even make this argument, Amgen must ignore its repeated assertions that its submarine patents claim the "protein that is etanercept"

and permit Amgen to "exclude" all biosimilar competition to Enbrel®, including Sandoz. Under the totality of the circumstances, Amgen has shown a "preparedness and a willingness to enforce its patent rights," which is "enough to establish subject matter jurisdiction." *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1332 (Fed. Cir. 2014). Moreover, it has placed Sandoz in the position of proceeding at the risk of pursuing infringing activity or shelving its product—"precisely the type of situation that the Declaratory Judgment Act was intended to remedy." *Id.*

Third, Amgen urges this Court to adopt a rigid rule that completion of all Phase III clinical studies is a jurisdictional prerequisite to a declaratory judgment action. Amgen's suggestion is contrary to law, contrary to its contentions in other litigation, and completely inappropriate in the context of biosimilar drugs. The FDA's chief drug administrator has explained that biosimilar clinical trials are "only confirmatory," A1572, and the FDA's guidance states that the "foundation" of biosimilar development consists of the *pre-clinical* analytical testing of the biosimilar drug and the reference product. A3062. Here, Sandoz laid this essential foundation through nearly a decade of work, including extensive analytical testing and successful human clinical trials, resulting in a final product that cannot change in any relevant way. These facts are more than sufficient to satisfy the minimal requirements that the dispute be "definite and concrete."

The district court erred in dismissing this case. Its judgment should be reversed and the case remanded for further proceedings.

ARGUMENT

I. The District Court Misconstrued the BPCIA as a Jurisdictional Bar to Sandoz's Complaint.

When statutory language is plain, as here, courts must "enforce it according to its terms," *Arlington*, 548 U.S. at 296, unless "the plain language of the statute would lead to *patently absurd* consequences, that Congress could not *possibly* have intended," *Public Citizen v. U.S. Dept. of Justice*, 491 U.S. 440, 470-71 (1989) (Kennedy, J. O'Connor, J., and Rehnquist, C.J. concurring) (emphasis added). Nothing in the BPCIA makes a § 271(e) action the *only* way to resolve patent disputes involving biologics, and the district court was not at liberty "to rewrite the statute that Congress has enacted" to eliminate alternative declaratory judgment actions under §§ 271(a), (b), and (c). *Dodd v. United States*, 545 U.S. 353, 359 (2005). Far from an "absurd" consequence, those alternatives are *required* to effectuate the BPCIA's underlying policies.

A. The district court's interpretation of the BPCIA is inconsistent with the statutory text.

The judgment below hinges on the notion that the BPCIA precludes any declaratory judgment action "unless and until" the parties complete the exchanges of patent information outlined in Paragraphs (2) through (6). A3. That is wrong. By their terms, the BPCIA's only restrictions on declaratory judgments apply *after*

a subsection (k) application is filed; and even then, only *after* certain contingencies occur. As a matter of law, these limitations do not apply to Sandoz's Complaint.

1. The BPCIA does not require patent exchanges to be completed prior to a declaratory judgment action.

While Amgen repeatedly *asserts* that the BPCIA's information exchanges are "prerequisites" for declaratory judgment actions, Amgen fails to *quote* a single provision of the BPCIA supporting that assertion in its 80-page brief. That is true for a simple reason: no such provision exists. The only restrictions on declaratory judgments are set forth in Paragraphs (9)(A) to (9)(C), and they are triggered only "if" certain contingencies occur that indisputably have *not* occurred here.

The BPCIA's specific text is clear. Paragraph (9)(C) only applies "*[i]f* a subsection (k) applicant *fails to provide the application* and information *required under paragraph (2)(A)*." 42 U.S.C. § 262(*l*)(9)(C) (emphasis added). Paragraph (9)(B), entitled "Subsequent failure to act by subsection (k) applicant," only applies "*[i]f* a subsection (k) applicant *fails to complete an action required of the subsection (k) applicant* under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(B) (emphasis added). Paragraph (9)(A) only applies to certain patents "*[i]f* a subsection (k) applicant *provides the application and information required under paragraph (2)(A),*" *if* the subsection (k) applicant has not provided notice of commercial

marketing, *and if* the parties' final patent lists do not identify those patents for litigation. 42 U.S.C. § 262(*l*)(9)(A) (emphasis added).

If Congress intended completion of patent exchanges to be prerequisites to any declaratory judgment, it would have drafted a provision saying so. Congress easily could have said that "no action may be brought for declaratory judgment by a subsection (k) applicant *unless and until* it has completed the process outlined in Paragraphs (2) through (6)." Congress knew how to draft such "prerequisites." When limiting the availability of a declaratory judgments in the Hatch-Waxman context, Congress did so in precisely that manner:

> *No action may be brought under section 2201 of title 28 by an applicant* referred to in subsection b(2) of this section for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (c) *unless* . . . .

21 U.S.C. § 355(c)(3)(D)(i)(I) (emphasis added). This language stands in stark contrast to the BPCIA's provisions.

Congress' decision to frame the BPCIA's declaratory judgment provisions in a much different way reflects an intent *not* to require the completion of patent exchanges before a declaratory judgment action is filed. By framing the statute as it did, Congress left open the possibility that a declaratory judgments may be filed *before* a subsection (k) application and remain pending *while* the parties complete patent exchanges.

Amgen does not identify any coherent reason why the BPCIA must be interpreted—contrary to its plain terms—to bar all declaratory judgments until *after* patent exchanges are completed. Indeed, Amgen completely disregards the exclusivity structure of the BPCIA, which explains why Congress drafted Paragraph 9 in the manner it did.

Unlike Hatch-Waxman, the BPCIA provides no stay of FDA approval when a brand company files a § 271(e) infringement claim. Instead, the BPCIA provides for a 12-year exclusivity period—regardless of patent coverage—as an incentive for an RPS to develop a new biologic product, while permitting the approval and marketing of a biosimilar product immediately after that period expires. In order to prevent the 12-year period from being extended due to unresolved disputes, it is essential to resolve patent disputes before approval. As Amgen's own counsel testified before Congress, "[n]early all stakeholders agree" on the importance of "identifying and resolving patent disputes implicated by the structure of a biosimilar product and how it is made *before the biosimilar product is approved and put on the market*." *See* Sandoz Opening Br. at 42-43.

Where a product enjoys exclusivity, the BPCIA provides up to *eight years* for the parties to identify and litigate § 271(e) infringement actions before the FDA may approve the biosimilar product. 42 U.S.C. §§ 262(k)(7)(A)-(B). In that circumstance, which will predominate in the future, the BPCIA's patent exchange

process will be sufficient in most cases to resolve patent disputes before commercial marketing of the biosimilar product, with declaratory judgment actions being a secondary option.

The BPCIA's exclusivity structure explains why Congress did not require § 271(e) actions to be the exclusive mechanism for resolving patent disputes. Where there is no remaining reference product exclusivity—the case for all products approved in the 1990s, including Enbrel®—the biosimilar drug can be approved in as little as *ten months* after a subsection (k) filing is made. A1303. If a justiciable dispute already exists between the parties, it makes no sense to bar the courthouse doors until after the parties complete a protracted series of information exchanges designed to identify disputes in the first place. All that would accomplish is delaying litigation of the pre-existing dispute, preventing it from being resolved prior to FDA approval, delaying the availability of the biosimilar medication to the public, and as a practical matter, extending the 12-year exclusivity period.

By making Paragraphs (9)(B) and (9)(C) applicable only when a subsection (k) applicant "fails" to perform a task, the BPCIA permits the filing of declaratory judgment actions in appropriate cases where Article III jurisdiction already exists. The BPCIA thus provides a flexible approach, allowing a party to bring a declaratory judgment case to obtain patent certainty before commercial launch,

where appropriate, while ensuring the declaratory judgment plaintiff engages in the information-exchange process once the application is filed.

Contrary to Amgen's complaints, a constitutionally sufficient declaratory judgment action filed prior to a subsection (k) application does not "abrogate" the BPCIA's provisions, nor does it detract from any right that an RPS enjoys. Br. at 45. Far from it. Upon filing the subsection (k) application, the applicant still participates in the patent exchanges. Likewise, the RPS retains its right to sue under § 271(e), subject to the subsection (k) applicant's ability to limit the number of patents, and retains the remedies that a § 271(e) suit allows.

Without closely analyzing the statute's structure or purpose, the district court leapt to the conclusion Congress must have intended only one way to resolve patent disputes under the BPCIA—through a § 271(e) action after the completion of information exchanges. No provision says so. In reality, Congress crafted a flexible system allowing declaratory judgments to resolve urgent patent disputes, while also enabling dispute resolution through a § 271(e) infringement action. The district court's one-size-fits-all approach eviscerates the flexibility reflected in the actual text of the BPCIA.

2. The three specific limitations on declaratory judgment do not apply to Sandoz's Complaint.

As properly construed, none of the BPCIA's specific limitations on declaratory judgment actions apply here. First, Sandoz is not a "subsection (k)

applicant." Second, the triggering conditions stated in the BPCIA's declaratory judgment limitations have not occurred, nor are they likely to ever occur.

a. Sandoz is not a "subsection (k) applicant."

The BPCIA's limitations on declaratory judgments only apply to an RPS or a "subsection (k) applicant." 42 U.S.C. §§ 262(*l*)(9)(A)-(C). Sandoz has no such status with respect to its etanercept product. Therefore, the BPCIA's specific limitations cannot apply. That simple conclusion should have ended the district court's inquiry under the BPCIA, and the sole question should have been whether Sandoz's Complaint complied with Article III's case-or-controversy requirements.

Amgen argues that Paragraph 9 should apply because the district court found, as a "matter of fact," that Sandoz subjectively intended to file a subsection (k) application, rather than a subsection (a) application. Br. at 30, 37-38. That is irrelevant. The correct interpretation of Paragraph 9 does not depend on the intentions of a *potential* subsection (k) applicant. Under any rational interpretation, Sandoz would become a "subsection (k) applicant" only upon filing its subsection (k) application. No other interpretation is workable.

Indeed, the district court's erroneous construction threatens to extend inapplicable provisions to subsection (a) filers. As Amgen pointed out below, biosimilar applicants can reasonably file for FDA approval under *either* subsection (k) or subsection (a), A1016-17, and sometimes, that choice will be made only

shortly before an FDA filing. Because subsection (a) contains no provisions on declaratory judgments at all, the district court's holding threatens to extend a nonexistent statutory bar to the subsection (a) pathway. Amgen offers no argument to justify this anomalous result.

Amgen says that Sandoz cannot argue that the dispute is justiciable "because it is availing itself of the BPCIA's abbreviated regulatory pathway for biosimilars, yet avoid the BPCIA's limitations on declaratory judgment because it is merely a 'prospective' (k) applicant." Br. at 32. That argument attacks a straw man. Sandoz has not claimed the dispute is justiciable merely because it intends to file a subsection (k) application. The dispute would be justiciable regardless of whether Sandoz filed a subsection (k) or (a) application. The supposed contradiction Amgen posits does not exist.

Contrary to Amgen's invective, this case does not present a situation where Sandoz seeks to obtain the benefits of the BPCIA while disregarding its obligations under the BPCIA. Br. at 45-46. This is a situation where Sandoz fully intends to comply with all statutory obligations—*at the appropriate time when those obligations accrue*—while availing itself of a statutory remedy to resolve an existing patent dispute with Amgen. It was unreasonable and unlawful for the district court to deprive Sandoz of that opportunity.

b. Sandoz has not "failed" to comply with Paragraph 9.

Even if Sandoz were a "subsection (k) applicant," none of the BPCIA's declaratory judgment provisions would bar Sandoz from filing the present action.

Amgen focuses primarily on Paragraph (9)(C), which provides, "*[i]f* a subsection (k) applicant *fails* to provide the application and information required under paragraph (2)(A)," the subsection (k) applicant may not bring suit for declaratory judgment. 42 U.S.C. § 262(*l*)(9)(C) (emphasis added); Br. at 43. Clearly, Sandoz has not "failed" to comply with Paragraph (2)(A). The time for Sandoz to comply with this paragraph is *20 days after* the FDA notifies Sandoz its subsection (k) application is "accepted for review." 42 U.S.C. § 262(*l*)(2). Sandoz cannot be punished for "failing" to comply with that obligation, which has not yet accrued. Likewise, Sandoz cannot be punished for "failing" to comply with any requirements of Paragraph (9)(B), which also accrue only after the filing of a subsection (k) application. 42 U.S.C. § 262(*l*)(9)(B).

Amgen claims that applying the statute according to its terms would create "internal inconsistencies" and "effectively abrogate" the BPCIA's limitations on declaratory judgment. Br. at 45. But, setting aside its empty rhetoric, Amgen identifies no inconsistency, much less a "patently absurd" result caused by a literal application of the statute's text.

As its supposed "inconsistency," Amgen asserts that any declaratory judgment action brought by a potential subsection (k) applicant would have to be dismissed under Paragraph 9(A) when an application is filed, "at the twenty-day deadline for providing the biosimilar application and process information to the RPS," creating what Amgen deems to be an "absurd" situation. Br. at 47. Amgen is mistaken. Paragraph 9(A) does not "require" dismissal of any previously filed action, much less 20 days after a subsection (k) application is filed.

Paragraph 9(A) only applies to declaratory judgment actions implicating patents "*described in clauses (i) and (ii) of paragraph (8)(B)*." 42 U.S.C. § 262(*l*)(9)(A). These patents are defined as patents **(i)** that the parties identify in their patent disclosures, but **(ii)** are *not* included on the final list of patents to be litigated under Paragraphs (4) or (5). 42 U.S.C. §§ 262(*l*)(8)(B)(i)-(ii). To the extent any such patents would exist in any given case, the prohibition stated in Paragraph (9)(A) would spring into effect only *after* the lists "described in clauses (i) and (ii) of paragraph 8(B)" are generated. *See* 42 U.S.C. § 262(*l*)(9)(A).

Critically, a subsection (k) applicant—unlike an RPS—has the unfettered right to identify whatever patent it wants on the final patent list. *See* 42 U.S.C. § 262(*l*)(5)(A)-(B). Since Paragraph 9(A)'s restriction only applies to patents *omitted* from the final lists, and since the subsection (k) applicant can list whatever patents it wants, the subsection (k) applicant has total control over whether

Paragraph (9)(A) imposes a restriction on any given patent. Where a subsection (k) applicant has filed a declaratory judgment action challenging a patent, there is no reason the applicant would choose to omit that patent from the final list.

Further still, Paragraph (9)(A) does not apply after a subsection (k) applicant provides notice of its intended commercial marketing of its product. Sandoz has already provided notice of its intended commercial marketing, which is effective to remove any restriction Paragraph (9)(A) ever could have had on Sandoz's Complaint. Thus, the supposedly "absurd" circumstance that Amgen posits is not "required" by Paragraph (9)(A); it does not exist in this case; and it is not likely to ever exist in any other case.

B. The district court's judgment contradicts the purpose of the BPCIA and Declaratory Judgment Act.

Through its erroneous construction, the district court eviscerated any meaningful role a declaratory judgment action could play in resolving disputes to biosimilar drug products. Still worse, the district court manufactured a new exclusivity period that has no basis in the statute, providing a windfall to reference product sponsors regardless of their patent position.

1. The district court's judgment eviscerates the prescribed role of a declaratory judgment.

Amgen concedes the district court's construction of the BPCIA would prevent a subsection (k) applicant from filing for a declaratory judgment until *after*

its product has already been approved by the FDA. Br. at 11, 33, 49-50. While it fully embraces this result, Amgen provides no serious explanation for why it makes sense in the context of either the Declaratory Judgment Act or the BPCIA.

Requiring a biosimilar applicant to wait for product approval to begin a declaratory judgment action makes that remedy essentially useless. The whole point of a declaratory judgment is "to provide the allegedly infringing party relief from *uncertainty and delay* regarding its legal rights." *Micron Tech. Inc. v. Mosaid Techs., Inc*., 518 F.3d 897, 902 (Fed. Cir. 2008) (emphasis added). By requiring an otherwise justiciable controversy to wait until after FDA approval, the district court *causes* the very delay the Declaratory Judgment Act is intended to *alleviate*.

Amgen also does not dispute the practical reality of the district court's judgment is to delay biosimilar medications to the American public. Indeed, the dilemma Sandoz faces is likely to occur repeatedly over the next few years. Virtually all of the major biologic products were originally approved in the 1990s, and lack any remaining exclusivity. Subsection (k) applicants will not, as a practical matter, launch such products at the risk of infringement liability. Thus, delaying the start of a declaratory judgment action until after product approval means a *de facto* extension of the 12-year exclusivity period for years after the RPS would otherwise be forced to face biosimilar competition.

Amgen shrugs off this problem, claiming it must have been Congress' intent. Amgen notes that in the Hatch-Waxman Act, Congress adopted a 30-month stay for litigation to conclude, so Congress must have accepted the possibility of litigation delays for biosimilars too. Br. at 53-54. Amgen's observation proves the opposite point. Unlike Hatch-Waxman, the BPCIA does *not* contain provisions for the stay of approval pending the outcome of patent litigation. Instead, Congress concluded that a *12-year* exclusivity period was sufficient to effectuate the purpose of encouraging innovation and to allow the resolution of patent disputes prior to approval. Clearly, Congress did not intend to confer additional exclusivity for *old products* such as Enbrel®, nor did it intend for the 12-year period to extend for an indefinite period of time while delayed patent claims work their way through the federal courts.

Amgen also suggests Congress intended to limit declaratory judgment actions until after product approval because, at that point, the biosimilar product is no longer subject to change. Br. at 53. Amgen cites nothing from the text of the statute or its legislative history to support that speculation. There is none.

Finally, Amgen argues that a § 271(e) infringement action provides an adequate remedy for a biosimilar applicant. Br. at 54-56. While that may be true in some circumstances, it is not here. Section 271(e) creates a "technical" act of infringement to allow litigation of disputes during a long period of exclusivity. A

§ 271(e) action is no substitute for a declaratory action in this case, and the BPCIA does not require it to be.

2. The district court's judgment erroneously creates an additional six-month exclusivity period.

Congress clearly envisioned the use of declaratory judgments to resolve urgent patent disputes, because Paragraph (9)(A) only applies "prior to the date notice" of the subsection (k) intended commercial marketing "is received under Paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A).

In this case, Sandoz's notice to Amgen should have been sufficient to remove that limitation, even assuming Paragraph (9)(A)'s limitation applied, which it did not. Instead, the district court misinterpreted the notice provision to require applicants to await FDA approval before providing notice. In the process, the court created an additional 180-day exclusivity period all of its own.

Lacking any serious argument to justify that error, Amgen erects a straw man and tears it down. Amgen spends a page arguing that the phrase "product licensed" in Paragraph 8(A) must refer to a product approved by the FDA. Br. at 49-50. Of course it does; a product clearly must be "licensed" by the FDA in order to be subjected to "commercial marketing," as the provision states. But that is not the issue. The issue is whether *notice* of commercial marketing must await FDA approval. The statute never says that notice can *only* be provided *after* licensure. It contains no restriction on when the notice can be given:

> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A). The only restriction is that the subsection (k) applicant provide 180 days' notice *before* the date of commercial marketing.

Amgen suggests Congress rationally could have intended for "courts to resolve expedited requests for preliminary injunctive relief under disputed patents after licensure of the biosimilar product." Br. at 57. But Amgen ignores that the district court's interpretation requires the subsection (k) applicant to wait an additional 180-day period after approval, *irrespective of whether there are even relevant patents covering the product*. Amgen does not explain how a provision intended to provide notice to resolve patent disputes should be interpreted to confer an additional six months' exclusivity for an RPS, in every case, regardless of whether a relevant patent even exists.

In the end, the district court's construction of the BPCIA conflicts with its express terms, its purpose, and Congress' policy judgment. For all of these reasons, the district court's statutory construction should be vacated.

II. The District Court Erred in Holding There Is No Justiciable Case or Controversy.

To meet Article III's case-or-controversy requirements, the Supreme Court requires only that the dispute be "definite and concrete, touching the legal relations

of parties having adverse legal interests; and that it be real and substantial and admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). Amgen does nothing to justify the district court's erroneous analysis, which neither cited *MedImmune*, applied its standard, nor reached the correct conclusion.

A. The district court did not make "factual findings."

Initially, Amgen tries to bolster its position by claiming the court made "factual findings" in its favor. Br. at 31-32. Amgen then suggests the extended recitation of "facts" in its opposition—which the district court did not even mention—are entitled to deference. *E.g.*, Br. at 73, 75-76, 78, 80. That is nonsense. The district court did not make any "factual" findings, much less adopt the misleading recitation Amgen presents in its brief.

Under the Federal Rules, "the court must find the facts specially and state its conclusions of law separately," but "is not required to state findings or conclusions when ruling on a motion under Rule 12 or 56[.]" Fed. R. Civ. P. 52(a)(1), (3). Thus, when ruling on Amgen's motion to dismiss, the district court made no specific findings. Its opinion contains three paragraphs of "Background" and a "Discussion" section where it makes a *sua sponte* interpretation of the

BPCIA followed by two paragraphs of legal conclusions regarding jurisdiction. Because the district court did not "find the facts specially" nor state them "separately," the court did not make any findings subject to clear error review. *Id.*

The record, moreover, belies any suggestion the district court did so. In its moving papers below, Amgen submitted 32 exhibits (mostly hearsay statements to which Sandoz objected); Sandoz submitted two declarations and 25 other exhibits; Amgen submitted 14 exhibits in reply, including a putative expert declaration; and Sandoz submitted another nine exhibits in its surreply brief. *See* A15; A17-19; A22. The district court's memorandum referenced *none* of these documents. A1-A5. Far from resolving factual disputes, the court's order declined to address Sandoz's objections to Amgen's evidence or Amgen's evidentiary motions. A1-5; A19. Clearly, this Court owes the district court's opinion no deference.

B. There is a "definite and concrete" dispute "touching the legal relations of parties having adverse legal interests."

The district court held, as a matter of law, that jurisdiction was absent because "defendants state they have never advised Sandoz they intend to sue Sandoz" and have not subjected Sandoz to any "imminent threat." A4. That holding contradicts *Medimmune* and multiple controlling cases from this Court. Most recently, this Court explained: "Article III does *not* mandate that the declaratory judgment defendant have threatened litigation or otherwise taken action to enforce its rights before a justiciable controversy can arise. . . ." *Danisco,*

744 F.3d at 1330 (emphasis added). Indeed, "the Supreme Court has *repeatedly* found the existence of an actual case or controversy even in situations in which there was *no indication* that the declaratory judgment defendant was preparing to enforce its legal rights." *Id.* (emphasis added).

Having convinced the district court to dismiss the case based on a blatantly erroneous legal argument, Amgen does nothing to justify that error. First, Amgen mischaracterizes its own actions prompting this dispute, arguing that it only made "bland" statements repeating "basic statutory law" that "patents protect a product within the scope of their claims and confer exclusivity." Br. at 78-79. Clearly, Amgen did not make generic statements about the patent laws; it made a *specific claim* of a *specific* exclusionary right under a *specific patent* against a *specific product* on *the very day that patent issued*. A1357. Amgen then restated its claims at numerous industry conferences attended by its biosimilar competitors. *See* A1448; A1464; A1473; A1484; A1492; A1504. All the while, Amgen gave every indication it intended to enforce its patents to protect its $4 billion/year Enbrel® franchise—just as it had in previous cases when it sued its competitors before they had made an FDA filing, and just as its CEO threatened to do in the future. A1063-65 (¶¶ 27-31); A1547-52 (¶¶ 35-40); A1528.

By any measure, Amgen has "put[] [Sandoz] in the position of either pursuing arguably illegal behavior or abandoning that which [it] claims a right to

do." *SanDisk Corp. v. STMicroelectronics, Inc*., 480 F.3d 1372, 1381 (Fed. Cir. 2007). And by any measure, Amgen "engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights." *Danisco*, 744 F.3d at 1332 (citation omitted). As this Court has stated: "That is *enough* to establish subject matter jurisdiction." *Id.* (emphasis added).

Amgen suggests it must know the amino acid sequence of Sandoz's product for a dispute to exist. Br. at 77. But Amgen knows full well that the use of etanercept's sequence is required for any biosimilar version of Enbrel®. Amgen claimed its submarine patent gave it the right to exclude *all* biosimilar competition precisely because it knew any potential competitors would need to use the specific amino acid sequence for that protein, which Amgen claimed was "cover[ed]" by its patent. A1357; A1442; A1448; A1464; A1473; A1484; A1492; A1504.

Amgen also argues there is no controversy because it did not single out Sandoz when claiming it had the right to exclude all biosimilar competition. Br. at 78-79. However, jurisdiction does not require Amgen make a personalized message where it already took an express position that its patents "cover[] the fusion protein that is etanercept" and allow it to exclude all biosimilar competition for another decade or more. *Id.* Regardless, Amgen's activities demonstrate it has "engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights," *Danisco*, 744 F.3d at 1332 (citation omitted). When

Sandoz apprised Amgen that it disputed Amgen's exclusionary claims, A1556-57, a justiciable controversy existed between the parties.

Finally, Amgen claims Sandoz lacks standing because Sandoz has not been harmed by Amgen's patent claims, since Sandoz proceeded with its product. Br. at 70-75. On the contrary, because of Amgen's acquisition and trumpeting of the submarine patents, Sandoz will be faced with the quandary of launching its product (and thus risking patent damages) or delaying its launch to await the resolution of delayed litigation (and thus delaying any return on its investment). The Court has repeatedly held that this quandary justifies declaratory judgment relief, and indeed is "precisely the type of situation that the Declaratory Judgment Act was intended to remedy." *Danisco*, 744 F.3d at 1332.

That justiciable controversy is confirmed, not undermined, by Sandoz's continued investment, including the planned REDACTED expansion of its manufacturing facilities. A2056 (¶ 18); A2074. While Amgen blithely claims Sandoz would be unharmed by potentially wasting REDACTED under the cloud of potential infringement, the law is to the contrary. *E.g. Sandisk*, 480 F.3d at 1381; *see also Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357-58 (Fed. Cir. 2013) (finding immediate "controversy" where manufacturer placed in position of proceeding with commercialization or abandoning its plans).

C. The dispute is sufficiently "definite and concrete" for jurisdiction.

Ignoring the actual legal standards, Amgen argues that Sandoz cannot establish that "*no uncertainty remains*" in the development of its product. Br. at 60 (emphasis added). Amgen proceeds to fault Sandoz's witnesses for not swearing that Sandoz's etanercept product will, without doubt, succeed in its final clinical trial, or that the etanercept product will, without doubt, never change. Br. at 61. Contrary to Amgen's suggestions, Article III jurisdiction does not require such absolutes.

As this Court has explained, the relevant standard for "reality" focuses on whether Sandoz's product is "*substantially fixed*," and thus, unlikely to change in ways relevant to the patents. *Cat Tech LLC v. TubeMaster, Inc*., 528 F.3d 871, 882 (Fed. Cir. 2008) (emphasis added). This Court's standard for "immediacy" inquires whether Sandoz has engaged in "*meaningful preparation*" for infringement, as compared to seeking an advisory opinion "on whether it would be liable for patent infringement if it were to *initiate some merely contemplated activity*." *Id.* at 881 (emphasis added).

This Court has never required a showing that "no uncertainty remains." In *Cat Tech*, the Court held a product was sufficiently "fixed" where the plaintiff "*does not expect* to make *substantial* modifications to its loading device designs." *Cat Tech*, 528 F.3d at 882 (emphasis added). Here, Sandoz's witness testified that

Sandoz does not expect to make any changes to its product, given the development and testing it has performed for nearly a decade. A2062 (¶ 16). Of course, one cannot say a product will "never" change or that "no uncertainty remains." But the law does not require absolute certainty.

Significantly, Amgen does not identify any potential change that could be relevant to the submarine patents. According to Amgen, those patents claim "the fusion protein that is etanercept" along with methods of making it. A1357; A1442; Br. at 70. Sandoz's product has been and will remain etanercept, as it must be in order to qualify as a biosimilar. Thus, even if the product could change, it could not change in a way making the dispute "unreal" for jurisdictional purposes.

Amgen next claims that "Phase III success is a predicate to subject-matter jurisdiction." Br. at 62. That is not the law. On the contrary, the Supreme Court has stressed that Article III requires an inquiry into "all the circumstances." *Medimmune*, 549 U.S. at 118. Certainly, the clinical status of a product is one factor to consider in determining whether the dispute is "definite and concrete" under *Medimmune*. But no case has held that jurisdiction *depends* on the successful completion of all Phase III clinical trials, and federal courts are not equipped to assess whether a clinical trial is or is not a "success."

As support for its proposed rule, Amgen relies on this Court's decisions in *Benitec* and *Telectronics*, which Sandoz addressed in its opening brief. Br. at 62-

65; Sandoz Op. Br. at 59-60. Neither case bears the weight Amgen places on it. *Telectronics* involved a medical device that had "only recently begun clinical trials"—presumably meaning *Phase I* clinical trials—since the Court noted that it was still subject to change and its potential approval was "years away." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992). *Benitec* involved a "vaguely defined" plan to expand "nascent" technology into veterinary products; thus, the product had not started *any* clinical trials, much less Phase III. *See Cat Tech*, 528 F.3d at 882 (discussing *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007)). The Court's rulings under these facts simply do not support Amgen's proposed requirement that the successful completion of Phase III clinical trials is a jurisdictional prerequisite.

Amgen's rigid proposal also ignores the limited role of Phase III trials in the context of biosimilars. Because the BPCIA states an "accelerated" pathway for FDA approval, the clinical development component is less significant for biosimilars than it is for a new biologic drug (as in *Benitec*) or a new medical device (as in *Telectronics*). Rather, by far the most significant part of a biosimilar product's development involves the "extensive structural and functional characterization of both the proposed product and the reference product," which according to the FDA, "serves as the *foundation* of a biosimilar development program." A3062 (emphasis added).

Contrary to Amgen's assertions, a biosimilar product need not independently prove safety and efficacy in Phase III trials. As the FDA has explained, the purpose of biosimilar development is "*not* to *independently* establish safety and effectiveness of the proposed product," since the reference product already showed that. A1635 (emphasis added). Clinical trials of biosimilars, to the extent they are required at all, are "only confirmatory" of the pre-established biochemical similarity. A1572. Since Enbrel® has already demonstrated safety and efficacy in Phase III trials, there is no reason to doubt that Sandoz's product will also succeed, since it has the same amino acid sequence and has proven to be highly similar in prior clinical trials. A2053-54 (¶¶ 6-9); A2060-61 (¶¶ 9-10); (A2061-62 (¶ 14).

In the end, this case clearly presents a "definite and concrete" dispute. At the time this case was filed, Sandoz's etanercept product was at the end of nine years of development. REDACTED Exhaustive analytical testing, animal studies, and human studies showed that Sandoz's etanercept is highly similar to Enbrel®. A2052 (¶ 2); A2053-54 (¶¶ 5-7, 9-10); A2060-61 (¶¶ 9-11); A1061-62 (¶ 14). When it filed this suit, Sandoz had started a final, confirmatory trial of its product, REDACTED . A2061 (¶¶ 10-11); A2054 (¶ 10); A2055 (¶ 14); A2062-63 (¶ 18). Amgen's repeated disparaging references to Sandoz's etanercept product as a mere "candidate" do not change the

fact that Sandoz has engaged in "'meaningful preparation' to conduct potentially infringing activity." *Cat Tech*, 528 F.3d at 879; *see also Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1571 (Fed. Cir. 1997) (finding standard met where accused infringer was "systematically attempting to meet the applicable regulatory requirements while preparing to import its product").

Stated differently, Sandoz does not seek an advisory opinion "on whether it would be liable for patent infringement if it were to *initiate some merely contemplated activity*." *Cat Tech*, 528 F.3d at 881 (emphasis added). The dispute involves a very real course of conduct that Sandoz has undertaken for nearly a decade at a cost of REDACTED of dollars.

Finally, Amgen raises the question "[w]hat relief could Amgen and Roche have sought" if the shoe were on the other foot. Br. at 74. The answer, of course, is precisely the same relief that Amgen successfully obtained in previous litigation affirmed by this Court, when it sued Roche for a declaration of "future infringement" six months *before* an FDA filing was made. In that case, Amgen asserted that a dispute may be sufficiently "real" and "immediate" under this Court's precedent "even though *clinical trials had not yet begun* and approval was *years* away." A1047 (emphasis added) (citation omitted); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276-278 (D. Mass. 2006), *aff'd* 580

F.3d 1340 (Fed. Cir. 2009). Amgen's feigned confusion does nothing to support its position or to justify the district court's erroneous judgment.

CONCLUSION

The district court's judgment should be reversed, and the case remanded for further proceedings.

Dated: June 13, 2014

Respectfully submitted,

/s/ James F. Hurst
James F. Hurst
Maureen L. Rurka
James M. Hilmert
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, Illinois 60601
(312) 558-5600
jhurst@winston.com

Counsel for Plaintiff-Appellant Sandoz Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2014, I caused the foregoing NONCONFIDENTIAL REPLY BRIEF OF PLAINTIFF-APPELLANT SANDOZ INC. to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on the counsel for Defendants-Appellees Amgen Inc. and Hoffmann-La Roche Inc.

Dated: June 13, 2014

/s/ James F. Hurst
James F. Hurst

Counsel for Plaintiff-Appellant Sandoz Inc.

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1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,999 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

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Dated: June 13, 2014

/s/ James F. Hurst
James F. Hurst

Counsel for Plaintiff-Appellant Sandoz Inc.