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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SANDOZ INC., a New Jersey corporation, Plaintiff, vs. AMGEN INC., a Delaware corporation and HOFFMANN-LA ROCHE INC., a New Jersey corporation, Defendants.	Case No. 3:13-cv-02904-MMC **Notice of Motion and Motion by Defendants, Amgen, Inc. and Hoffmann-La Roche, Inc. to Dismiss for Lack of Subject-Matter Jurisdiction or, Alternatively, to Decline to Exercise Declaratory Judgment Jurisdiction** **Date: September 20, 2013** **Time: 9:00 a.m.** **Place: Courtroom No. 7, 19th Floor** **(Honorable Maxine M. Chesney)** **[Declaration of Vernon M. Winters filed concurrently herewith]**

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Notice of Motion and Motion to Dismiss

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on September 20, 2013, at 9:00 a.m. or as soon thereafter as counsel may be heard in the above Court, defendants, Hoffmann-La Roche, Inc. ("Roche"), and Amgen Inc. ("Amgen"), will and hereby do move this Court to dismiss the declaratory judgment complaint of plaintiff, Sandoz, Inc. ("Plaintiff"). This motion will be and is based upon Rule 12(b)(1) of the Federal Rules of Civil Procedure ("Rule 12(b)(1)"), N.D. Cal. Civil L.R. 7, the memorandum below, the accompanying declaration in support of the motion, the complete record of this proceeding, evidence and argument presented at the hearing on this motion, and all matters of which the Court may or must take judicial notice.

Issues to Be Decided and Relief Sought

This motion presents two issues: (1) on the date that Plaintiff filed its complaint, did the Court have subject-matter jurisdiction; and (2) even if it did, would it be appropriate for the Court to exercise its discretion to decline declaratory judgment jurisdiction?

Roche and Amgen seek an Order dismissing Plaintiff's complaint for lack of subject-matter jurisdiction; alternatively, Roche and Amgen seek an order dismissing this case in the exercise of this Court's recognized discretion to decline declaratory judgment jurisdiction.

Points and Authorities in Support

I. Summary

Plaintiff purportedly brings this declaratory judgment action essentially seeking to invalidate two Roche patents that will block Plaintiff from selling a "biosimilar" of Amgen's Enbrel® (etanercept) product in the U.S. several years from now. Plaintiff asserts that it brought this action at this time because it is currently making an investment in initiating a large clinical trial necessary to obtain approval from the U.S. Food & Drug Administration ("FDA") to sell its product. In fact, however, this action comes too soon because Plaintiff is just beginning the determinative phase of the clinical trial process and many uncertainties remain as to if and when Plaintiff's alleged biosimilar will ever be approved and ready to market in the U.S. Plaintiff's clinical candidate could fail to show sufficient safety and efficacy to be approved by the FDA and require changes or further

studies before approval is sought. Plaintiff is proceeding with its clinical studies at sites in Eastern Europe without waiting for a determination on the future effect of these two patents and so is suffering no immediate harm that requires redress. Neither Amgen nor Roche has made any threats to Plaintiff. Thus, there is not any controversy between the parties that has sufficient immediacy or reality to invoke this Court's declaratory judgment jurisdiction. This action is simply an attempt to obtain an advisory opinion on two of several patents owned by or licensed to Roche and/or Amgen that may be problems for Plaintiff should its biosimilar candidate survive further clinical testing. If Plaintiff ultimately produces sufficient experimental evidence (pre-clinical, clinical, and quality) to support the filing of an application for FDA approval of a biosimilar etanercept product, a patent dispute will likely ripen—but that point is years away and will likely involve other relevant patents, and may involve additional parties.

* * * *

Amgen sells a therapeutic biologic product called Enbrel®, which contains as its active ingredient a recombinantly-engineered fusion protein called etanercept. Plaintiff wishes one day to market and sell an Enbrel® "biosimilar"—a term the FDA has coined to refer to a biologic that is "highly similar" to a large molecule biologic reference product (as opposed to a "generic," which is a precise copy of a small-molecule pharmaceutical reference product). Plaintiff is in the very early stages of putting together a large-scale human trial, called a "Phase III clinical trial," of its purportedly biosimilar clinical candidate. Without at least one successful trial in sick patients (as compared to healthy adults), Plaintiff will not be in a position to file an application (called a "Biologics License Application" and commonly referred to as a "BLA") with the FDA for approval to market and sell any eventual biosimilar product in the United States.

Many things must happen between now and any BLA filing. This is not merely a question of the passage of time. Instead, it is a question of whether certain events will occur, or not, and whether certain facts will develop, or not. Some of the events that can change and thereby cause Plaintiff's BLA to be delayed in filing, or not to be filed at all, include:

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- Plaintiff's Phase III clinical trial enrollment is insufficient or delayed;
- Plaintiff cannot conduct that trial because it is unable to manufacture the clinical candidate in sufficient quantity and with the required consistency;
- The clinical candidate fails to demonstrate sufficient safety and efficacy in that trial;
- The FDA requires or Plaintiff sees a need for additional testing;
- Plaintiff submits for FDA approval a formulation (that is, the combination of active and inert ingredients) different from that clinical trial candidate;
- The manufacturing process is changed, resulting in potential differences in the product submitted for approval as compared to the candidate tested in that trial; and
- Plaintiff's molecule requires a new method of administration to patients.

The point is that there is no way to know, at the start of the first Phase III clinical trial, whether any or all of these events will occur. And here the Plaintiff is only at the very beginning of that trial.

On the date that Plaintiff filed its complaint, it had enrolled only 1 patient in its clinical trial. Its study design calls for 372. There is a real doubt as to whether Plaintiff will be able to meet its projected timetable for its clinical trial. Although the complaint alleges that Plaintiff "expects" to file its BLA in the year and date specified in ¶ 3 of its unredacted complaint, Plaintiff told U.S. regulatory authorities something entirely different (a "primary completion date" of April 2015) and provided an even later date to EU regulatory authorities.[1] In any event, more than a month after it filed its complaint, Plaintiff had started recruiting patients in only 4 of its 47 clinical trial sites.

Even if Plaintiff succeeds in timely enrolling enough patients, it cannot be known whether its Phase III clinical trial will succeed. One estimate predicts that biosimilars will fail Phase III clinical trials between 20 and 50% of the time, and there have been some noted biosimilar Phase III failures. The press release announcing this very Phase III clinical trial warns that it could yield "unexpected" results. In certified filings to the U.S. Securities and Exchanges Commission, Plaintiff's parent, Novartis, warns that there is a "substantial risk" that any clinical candidate under study "will not meet the requirements" of a Phase III trial, so that Plaintiff would be unable to "progress further"

[1] A "primary completion date" is the date the final subject is examined or receives an intervention for the purposes of final collection of data for the primary outcome. It is not to be confused with the even-later "study completion date" which is the final date on which the data is expected to be collected.

and "may be required to abandon a [clinical candidate] in which we have made a substantial investment." Phase III clinical trials of pioneering biologic products fail more than half the time.

Although the complaint argues that Roche's patents threaten that investment, Plaintiff has not acted as if this litigation will alter that investment. Rather, the complaint reflects that Plaintiff has proceeded, and will continue to proceed, with its development plan irrespective of Roche's two patents, one of which issued in November 2011; the other, in April 2012. Nothing in the complaint suggests their issuance caused Plaintiff to alter or even slow down its investment in its clinical candidate. To the contrary, the complaint shows that Plaintiff continued its efforts unabated. This is understandable, because—although absent from the complaint—Plaintiff has elsewhere admitted that it consulted with the EU regulatory authorities in designing its program and is conducting its clinical trial principally at trial sites in the EU. The EU market for Enbrel® has been estimated at more than a billion dollars a year. Nothing in the complaint rebuts the notion that Plaintiff would have made its investments simply to seek approval to sell its product in the EU.

In any event, subject-matter jurisdiction cannot be purchased: the choice to invest, even substantially, cannot create subject-matter jurisdiction where it does not otherwise exist. It is not Amgen or Roche's conduct which has caused the investment risk, but rather the uncertain nature of the human biotherapeutics. Whether or not Roche's patents were ever granted, Plaintiff would have to make the investment in product development (including Phase III clinical trials and scale up) to determine whether its clinical candidate would work or not.

Plaintiff's justification for litigating now is that it is starting a Phase III clinical trial and other scale-up work. But the EU and U.S. regulatory authorities require that work precisely and only because there is so much uncertainty and so much to prove regarding Plaintiff's clinical candidate and the manufacturing process used to make it. If by simply copying Amgen's Enbrel® product, the safety and efficacy of Plaintiffs' clinical candidate could be assumed, the EU and U.S. regulatory authorities would not require a substantial investment in clinical trials. Plaintiff's "investment" argument only serves to validate the uncertainty surrounding its clinical candidate.

As a matter of law, Plaintiff's voluntary expenses, whatever their level, cannot change the dispositive fact that the parties and the Court cannot currently know, and are a long way from

knowing, facts central to the parties' alleged dispute, including whether the Phase III clinical trial will succeed; whether Plaintiff might be required to engage in additional testing before it can submit an FDA application; what the composition, formulation, method of manufacture, method of administration, and requested indications will be for the eventual product for which Plaintiff might seek FDA approval; and when or even whether Plaintiff will seek FDA approval. No Federal Circuit case has found subject-matter jurisdiction before Phase III clinical trials have ended. And the two most applicable statutory schemes (the Hatch-Waxman statutes and the biosimilars statutes) tie subject-matter jurisdiction to the FDA filing.

Absent a sufficiently concrete warning from the declaratory judgment defendant that it will sue the plaintiff, subject-matter jurisdiction is lacking. Neither the patent-holder, Roche, nor its exclusive licensee, Amgen, has conveyed any such warning. This Court has found no declaratory judgment jurisdiction in the face of asserted statements that were much sharper—for example, that the defendant would seek injunctive relief against any infringer and that it had hired vicious lawyers to do so—than the bland statements alleged here.

To justify its premature lawsuit, Plaintiff alleges it seeks certainty to allow an eventual commercial launch many years hence. But the complaint addresses only two Roche-owned patents, and thus cannot provide that certainty. It is the FDA-approved product that will define the scope of any eventual patent dispute between the parties, not the clinical candidate. Depending on the degree to which an FDA-approved product differs from its clinical candidate (*e.g.*, in structure, formulation, methods of manufacture and administration, and indications) a suit now may be an inefficient use of the courts resources and/or involve the parties in needless litigation.

Finally, the complaint tries to depict Roche and Amgen as delaying the patents' prosecution. Even if true, that would be irrelevant to subject-matter jurisdiction. But it is not true. The applicants repeatedly asked the U.S. Patent and Trademark Office to make faster decisions and to issue the patents. Nor does Roche or Amgen seek undue delay now. The law simply does not allow a copyist to force patent-holders—or the courts—to go through the resource-intensive exercise of patent litigation only to be told, at its end, that Plaintiff has changed its product or decided not to market it because it failed its Phase III clinical trial or could not submit an FDA application.

If at some future point Plaintiff (1) concludes that the nascent clinical trial demonstrated the clinical candidate's efficacy and safety and then (2) prepares a BLA for approval to launch a product in the U.S., a patent dispute with either or both of Roche and Amgen is possible. But those facts do not yet exist, and they may never come to pass.

II. Standards for decision

1. A plaintiff must prove, not merely allege, that subject-matter jurisdiction exists

A plaintiff bears the burden of proving subject-matter jurisdiction. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007). When, as here, a 12(b)(1) motion relies on facts outside of the complaint, a plaintiff cannot rely on the complaint's allegations; it must provide facts. To move beyond the complaint's allegations does not, however, convert the motion to a summary judgment motion. *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Subject-matter jurisdiction is assessed as of the date that the challenged complaint was filed; later events cannot cure a subject-matter jurisdiction defect therein. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1337 (Fed. Cir. 2008). The lack of subject-matter jurisdiction cannot be waived, and it can be raised at any time, including at the appellate oral argument. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 919 (5th Cir. 2001); *Mariuta v. Gonzales*, 411 F.3d 361, 363 (2d Cir. 2005); *U.S. ex rel. P.J. Keating Co. v. Warren Corp.*, 805 F.2d 449, 451-453 (1st Cir. 1986). Patent appeals have been dismissed claims *sua sponte* on appeal. *Metabolite Labs., Inc. v. Lab. Corp. of Am.*, 370 F.3d 1354, 1369 (Fed. Cir. 2004) (Federal Circuit's *sua sponte* dismissal).[2]

2. The declaratory judgment standards

A. The Declaratory Judgment Act does not confer jurisdiction

The Declaratory Judgment Act provides that:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

[2] In *McPherson's Ltd. v. Never Dull, Inc.*, 960 F.2d 156 (Fed. Cir. 1992), a decision not citable as precedent under Federal Circuit Local Rule 47.8(b), the Federal Circuit dismissed a case for lack of subject-matter jurisdiction after the issue first arose at oral argument.

28 U.S.C. § 2201. The Act does not confer subject matter jurisdiction. Rather, it provides a remedy available *only* if the court has jurisdiction from some other source. Article III of the Constitution limits such jurisdiction to the adjudication of "Cases" or "Controversies." *Prasco*, 537 F.3d at 1336.

B. The dispute must have sufficient immediacy and reality

"[T]here is no bright-line rule for determining whether an action satisfies the case or controversy requirement," *Prasco*, 537 F.3d at 1336, and "'it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether this is such a controversy." *Id.* However, the Supreme Court has consistently provided principles that must guide the inquiry. "Our decisions have required 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.' . . . Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient *immediacy* and *reality* to warrant the issuance of a declaratory judgment." *MedImmune Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted; emphasis supplied).

When factual circumstances permit a distinct consideration of the principles of *immediacy* and *reality*, the Federal Circuit has addressed factors that specifically bear upon one principle or the other. In more complex factual circumstances, the interrelated nature of these principles have led the Court to articulate the factors that pertain generally to both. *MedImmune* requires a "totality of the circumstances analysis," *Prasco*, 537 F.3d at 1338, and each approach is relevant and helpful under that analysis. *E.g.*, *id.* at 1335-1336, 1342; *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343-1344 & 1355 (Fed. Cir. 2007); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992).

In considering "immediacy" by itself, the Federal Circuit has most often focused on the degree of uncertainty that exists as to when a future infringement might occur and as to whether a patent suit might actually be brought based on such future infringement. In *Telectronics*, for example, the court "affirmed the district court finding that a defibrillator component manufacturer's

claim for future patent infringement lacked a sufficient allegation of *immediacy* to support a declaratory judgment action since the potentially infringing defibrillator had only recently begun clinical trials and was years away from possible FDA approval." *Benitec*, 495 F.3d at 1346-1347 (discussing *Telectronics*, 982 F.2d at 1527).

In considering "reality" by itself, in the context of patent litigation, the Federal Circuit most often looks to the degree of uncertainty surrounding the infringing technology—the extent to which the technology in question is substantially fixed as opposed to "fluid and indeterminate" at the time declaratory relief is sought. *See, e.g.*, *Sierra Applied Scis. v. Advanced Energy Indus.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). Accordingly, "[t]he greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject—in short, detached from eventual reality." *Id.* The Federal Circuit's case law provides specific examples of the lack of *reality*:

- It has affirmed a dismissal of a declaratory judgment action where clinical trials of the accused device had just begun and "[t]here was no certainty that the device when approved [by the FDA] would be the same device that began clinical trials." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992);
- It has found that jurisdictional reality requirements were not met where development of the power supply in question was "at an early stage" and its design was "fluid and indeterminate" when the complaint was filed. *Sierra*, 363 F.3d at 1379-80; and
- It has found no declaratory judgment basis where the declaratory plaintiff had only a "vaguely defined" plan to expand into animal husbandry and veterinary products and the technology in question was still in a "nascent" stage. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007).

When assessing the totality of the circumstances, all of these factors may be examined to determine if an alleged dispute has the requisite *immediacy* and *reality*.

C. Standing requires injury-in-fact, causation, and redressability

Sometimes the Federal Circuit has assessed immediacy and reality without parsing them; when doing so, it has viewed them "through the lens of standing. To satisfy standing, the plaintiff must allege (1) an injury-in-fact, i.e., a harm that is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's conduct, and (3) redressable by a

favorable decision." *Prasco*, 537 F.3d at 1338 (internal citations and quotations omitted). In *Prasco*, the declaratory judgment plaintiff had continued its investment activities—indeed, it had launched its product—but still claimed a "'paralyzing uncertainty' from fear" that the patent-holder would sue it. *Id*. Noting that the mere existence of a patent does not confer jurisdiction, the court upheld the dismissal concluding that the patent-holder had done nothing to injure the declaratory judgment plaintiff, and that "a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy." *Id*. at 1338-1339 (internal citations omitted).

The standing requirements preclude the notion that subject-matter jurisdiction can be purchased where it does not otherwise exist. Thus, a declaratory judgment plaintiff may well "wish[] to receive the benefit of a ruling on the validity and scope" of patents before it "undertakes any nascent" efforts that involve investing in those efforts—but that does not create an injury-in-fact, causation, or redressability. *Benitec*, 495 F.3d at 1349. In such circumstances, "any adverse economic interest" between the parties is simply "not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction." *Microchip Tech. Inc. v. Chamberlain Grp.*, 441 F.3d 936, 943 (Fed. Cir. 2006).

3. A court need not accept declaratory judgment jurisdiction

The Act vests district courts with "unique and substantial discretion in deciding whether to declare the rights of litigants." *MedImmune*, 549 U.S. at 136 (citation omitted). In particular, even when a plaintiff has proved—or even firmly proved—that the court has subject-matter jurisdiction, it can nonetheless decline to hear the matter. *Id.* The declaratory judgment jurisprudence provides no compulsion to exercise that jurisdiction. *See, e.g.*, *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1289-90 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993). A district court's decision to decline jurisdiction is not reversed unless (1) it was clearly unreasonable, arbitrary or fanciful, (2) it was based on an erroneous conclusion of law, (3) the court's findings were clearly erroneous, or (4) the record contains no evidence upon which the court rationally could have based its decision. *Telectronics*, 982 F.2d at 1527.

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III. Facts

1. The alleged dispute lacks immediacy

A. Plaintiff may not meet its enrollment timetable

The facts surrounding the Phase III trial are uncertain. According to Plaintiff its clinical trial will finish by the date specified in ¶ 3 of its unredacted complaint. But Plaintiff told U.S. regulatory authorities that the trial would not even reach its primary completion date until April 2015 and told the EU authorities that it did not expect the clinical trial to end before November 2015. Declaration of Vernon M. Winters Ex. 1 (U.S. clinical trials website) and Ex. 2 (EU clinical trials website).[3]

Whichever estimate is accurate, Plaintiff's Phase III clinical trial has barely begun. On June 24, 2013 (the lawsuit's filing date, on which subject-matter jurisdiction must be assessed), insofar as Plaintiff's complaint discloses, it had enrolled only 1 patient for that trial. Cmplt. ¶ 42. Its study design calls for 372 patients, and in particular for 300 adults between the ages of 18 and 64, and 72 adults over age 65. WD Ex. 2 (EU clinical trials website). The study requires that each patient (1) have had chronic plaque-type psoriasis diagnosed for at least 6 months before the start of the study, (2) have at least 10% of his or her body surface area affected by plaque-type psoriasis, (3) not have previously taken Enbrel®, (4) have completed wash-out periods for certain medications, and (5) take twice-weekly subcutaneous injections of the clinical candidate. *Id.* The Phase III clinical trial will occur at 72 different trial sites in 12 different countries outside the U.S. *Id.; see also* WD Ex. 3 (US clinical trials website). According to a government website, as of August 10, 2013, Plaintiff had begun recruiting at only 8 trial sites, and had not started recruiting at all in Germany, Poland, Romania, the Russian Federation, South Africa, the Ukraine, or the United Kingdom. *Id.*

Separate and apart from those specific facts, as a general matter it can be difficult to enroll patients to meet a Phase III trial timetable. Reportedly, 80% of all Phase III trials in the U.S. fail to enroll patients on time. WD Ex. 4 (*firstcrestclinical.com*). Indeed, the certified SEC filings of Plaintiff's parent warns that there is a "substantial risk" that Plaintiff will have "difficulty enrolling patients in clinical trials" and, separately, a "substantial risk" that there will be "delays or clinical

[3] All further cites to Exhibits to that declaration will be simply labeled herein as "WD Ex. []."

trial holds at clinical trial sites." *E.g.*, WD Ex. 6 at numbered p. 8 (Novartis SEC Form 20-F 2010). Those filings further warn that Plaintiff's parent could not "reasonably estimate the timing [or] completion dates . . . of our drug development program . . . of *any* particular [experimental biologic]." WD Ex. 7 at numbered p. 164 (Novartis SEC Form 20-F 2011). One drug development treatise has observed that "obtaining a sufficient enrollment number for clinical trials can often be a slow and difficult process, and it can be difficult to obtain the breadth and diversity necessary to ensure results are well balanced." WD Ex. 8 at numbered p. 248 (treatise on bringing drugs to market in the EU).

B. Plaintiff's clinical candidate could credibly fail its Phase III trial

Pharmaceuticals "consist of known chemical compounds that can be easily identified and replicated. By contrast, biotech drugs are produced by genetically modified, living cells that secrete proteins—and come with all the unpredictability of life." WD Ex. 9 at p. 2 (*Wall Street Journal*). That is among the reasons why, in the context of biologics, attempted copies are called "biosimilars," rather than "generics." *Id.* As a senior biologics researcher has explained, "[t]hese genetically modified 'cells are very finicky,' . . . . 'There's a lot more places for variation,'" and even "slight irregularities could potentially change how patients respond." *Id.* The FDA's Director of the Office of Medical Policy has observed that "[w]ith generics, 'we have confidence of sameness,'" but that "[b]iosimilars are different.'" *Id.* The FDA has likewise cautioned that "[u]nlike small molecule drugs, whose structure can usually be completely defined and entirely reproduced, proteins are typically more complex and are unlikely to be shown to be structurally identical to a reference product. Many potential differences in protein structure can arise." WD Ex. 10 at numbered p.4 (FDA Document: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product"). This is one of the reasons why, if the biological product is administered more than once to an individual, "an applicant must provide sufficient information to demonstrate [that] . . . the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." *Id.*

The statistics bear these descriptions out. According to one prediction, the biosimilars failure

rate in Phase III clinical trials is expected to be between 20 and 50%.[4] WD Ex. 11 at numbered slide 16 (*ephmra.org*). One study calculated that the historical failure rate for all biologics in Phase III trials was 57.6%. WD Ex. 12 (*avance.ch*). Another found it was 21%. WD Ex. 13 at p. 2 (*Forbes.com*). A third found that Phase III trials of biologics by large companies, such as Plaintiff's parent, failed 38% of the time. WD Ex. 14 at numbered slide 9 (MedImmune presentation). Although these latter three studies included novel biologics, which many regard as harder to develop than biosimilars, and looked at different study populations, the consistently high failure rate for all biologics does not point to a low failure rate for biosimilars. And there have been some noted Phase III clinical failures in the biosimilar area, notwithstanding that the biosimilars legislation passed only in 2010. For example, Teva Pharmaceutical Industries halted a Phase III clinical trial on a biosimilar of one of the world's top three biologic drugs, which has a worldwide market of $6.6 billion. WD Ex. 15 (*gabionline.net*). Samsung Bioepis Co., Ltd., part of the Samsung conglomerate (in 2013, one of the world's 15 largest companies), halted a high-profile biosimilar Phase III clinical trial and reportedly had to re-start its clinical trial program. WD Ex. 16 (*gabionline.net*).

The CEO of Plaintiff's parent has therefore cautioned that developing biosimilars is "not easy" and that Plaintiff tries to manage that risk by targeting "treatments that are top-sellers and that will have few other competitors." WD Ex. 9 at p. 2 (*Wall Street Journal*). Likewise, Plaintiff's parent's SEC filings warn that, separate and apart from the risk of failing to meet the timetable of a Phase III clinical trial, there is a "substantial risk" that any clinical candidate under study "will not meet the requirements" of a Phase III trial, such that Plaintiff would be unable to "progress further" and "may be required to abandon a [clinical candidate] in which we have made a substantial investment." WD Ex. 6 at numbered p. 49 (Novartis SEC Form 20-F 2011).

C. Plaintiff may not be able to file an FDA application

Even if plaintiff successfully completes its Phase III clinical trial, it is uncertain whether it would thereafter be in a position to file an FDA application. The biosimilars statute is new—passed only in 2010—so data specific to biosimilar failures to progress from Phase III to a filed FDA

[4] The U.S. legislation authorizing biosimilars was passed only in March 2010. *See* 42 U.S.C. § 262(k)).

application are still developing. However, a 2011 study by the Biotechnology Industry Organization of all therapeutics, both biologic and pharmaceutical, concluded that even therapeutics with successful Phase III clinical trials sometimes fail to progress to a filed FDA application in the range of 30 to 55% of the time, depending on the period studied and other variables. WD Ex. 31 at slide 8 (BIO study: "PIII to NDA").

This may be because an FDA application requires much more than simply evidence of a successful Phase III trial. A typical FDA application runs tens of thousands of pages. An FDA application must demonstrate that "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(II); 42 U.S.C. § 262(k)(2)(A)(i)(V). The application must show that the manufacturing facility complies with "good manufacturing practices," a statutory term of art that comprises a complex set of regulations making up five chapters in the Code of Federal Regulations. 21 C.F.R. § 601.20(a) (application must show compliance with "the requirements prescribed in the regulations in this chapter including but not limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820 of this chapter."). The application must show compliance with a variety of regulatory requirements pertaining to building and facility qualification, personnel qualification, equipment qualification, production and process controls, packaging and labeling controls, holding and distribution controls, records and reporting systems, sample testing and retention, and preventive and corrective measures. *See, e.g.*, 21 C.F.R. §§ 211.1-211.198, 600.2-22.

2. The alleged dispute lacks reality

A. Plaintiff's hoped-for product may differ from its clinical candidate

Plaintiff maintains at ¶ 3 of its complaint that it "expects" to file and receive approval for its current clinical candidate, a product that it describes with no great specificity than "a biological drug containing etanercept." Understandably, the complaint is silent regarding that "biological drug's" (1) particular formulation (that is, the combination of the active and inert ingredients), (2) method of manufacture, (3) methods of administration, and (4) intended indications. This is because Plaintiff is not yet in a position itself to know how these variables will resolve. Likewise, Plaintiff is not in a

position to know what "its product" will be, as Plaintiff asserts that it intends to market that product in the U.S. only upon FDA approval.

Within limits, the formulation of a proposed "biosimilar" might be different from the reference product (here, Enbrel®); under the "k" pathway, the FDA only requires that the two be "highly similar," not identical. 42 U.S.C. § 262(k)(2)(A)(i)(I)(aa); WD Ex. 17 at numbered p. 6(FDA document: "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product) (manufacturing process affects protein structure). And if, based on either necessity or choice, Sandoz ultimately employs a formulation that differs substantially from the reference product, Sandoz could simply pursue the traditional "a" pathway instead. 42 U.S.C. § 262(a). In any event, Sandoz has the statutory flexibility to seek FDA approval for an eventual product different from its current clinical candidate.

Plaintiff's current method of manufacturing a clinical candidate may also be different from its eventual method of manufacturing its submitted product. During clinical trials, biologics are not manufactured at commercial scale, as Plaintiff's complaint acknowledges in ¶ 43. A BLA seeking approval to market and sell a biologic must, however, include information about the facilities for commercial manufacture (which the FDA will inspect). 42 U.S.C. § 262(a)(2)(C)(II); id. § 262(k)(2), (3)(B); *see also* 21 C.F.R. § 601.20(a); 21 C.F.R. §§ 211.1-211.198, 600.2-22. The FDA has cautioned that manufacturing changes "may alter a protein product in a way that could affect the safety or effectiveness of the product." WD Ex. 10 (FDA document: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product"). Indeed, such changes can occur even when the FDA has already approved the smaller facility and production process. For example, when Genzyme scaled up an approved biologic's production, differences developed in the protein structure that required Genzyme to submit an entirely new FDA application. WD Ex. 18 (*Nature*). It is even harder to scale up from an unapproved facility to an approved facility. WD Ex. 10 at numbered p. 5 (FDA document: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product"). But it is a necessary part of the development, testing, and approval process.

Plaintiff is not yet in a position yet to say what its scaled-up manufacturing processes might entail, how its product's potency might be different, how those processes and potencies might

ultimately affect dosing, administration, and indications, and how all of those facts may affect the patents that may or may not be implicated in an eventual lawsuit. *Id*. at numbered pp. 5-6.

B. The two Roche patents have been irrelevant to plaintiff's investment

The complaint alleges that the two Roche patents cover Amgen's Enbrel®, a blockbuster biologic used to treat five serious, long-term inflammatory diseases, including the only indication that Plaintiff is investigating: moderate to severe chronic plaque-type psoriasis. Cmplt. ¶ 2; WD Ex. 5 (Sandoz press release). According to Plaintiff, it has been studying the Enbrel® patent estate for years, and built its development program around the study of that estate. Cmplt. ¶ 35.

In November 2011, the '182 Patent issued to Roche; Amgen issued a press release about it, noting that this licensed patent was "related to Enbrel®." WD Ex. 22 (Amgen press release). Shortly thereafter, *Forbes* magazine wrote an article about it and its relation to Enbrel.® WD Ex. 30 (*Forbes.com*). So did *The Pharma Letter*, a widely read biotech publication. WD Ex. 32 (*thepharmaletter.com*). The '522 Patent, which issued from the same application that produced the '182 Patent, followed; it issued and thus became publicly available on April 24, 2012, over a year before Plaintiff filed its complaint.

Plaintiff increased its investment in its development program after the '182 Patent issued, conducting not just one but two clinical trials, at substantial cost. Cmplt. ¶ 41. (A Phase I clinical trial is the "[f]irst clinical trials of a new [therapeutic], generally performed in a small number of healthy human volunteers, to assess the clinical safety, tolerability as well as [the therapeutic's] metabolic and pharmacologic properties." WD Ex. 7 at numbered p. 33 (Novartis SEC Form 20-F 2011). Plaintiff transferred its processes to large-scale production to perform those Phase I trials. Cmplt. ¶ 36, lines 2-3. It conducted analysis and process development to prepare for the Phase III clinical trials, at the cost specified in ¶ 38 of the unredacted complaint. *Id.* ¶¶ 37-38. It continued to meet with the FDA. *Id.* ¶ 40. And, even while bringing this suit, Plaintiff has begun, and claims that it will try to complete, its Phase III clinical trial, and will try to prepare and file regulatory submissions in both the U.S. and elsewhere. *Id.* ¶ 42-43; WD Ex. 23 at p. 3 (*Pink Sheet*).

Indeed, in an article in the biopharma industry publication *The Pink Sheet* published two days before Plaintiff filed this lawsuit, Plaintiff's head of biopharmaceuticals admitted that the two Roche

patents would not change its investment strategy. In commenting on Plaintiff's planned challenge to these two patents, he opined that "if we're unsuccessful and these patents are upheld," then "patients in the U.S. won't have access to [Plaintiff's] product until long after it's been made available in other countries." WD Ex. 23 at p. 3 (*Pink Sheet*).

C. Plaintiff is pursuing a global market, not just the U.S. market

Although not in the complaint, Plaintiff has elsewhere disclosed that its "global clinical program" for its experimental formulation "was developed in consultation with regulatory authorities in the U.S. *and* EU," and that "the results of this clinical trial are expected to support regulatory submissions in *both* the U.S. and the EU." WD Ex. 5 at p. 1 (Sandoz press release) (emphasis supplied). Notably, most of Plaintiff's Phase III clinical trial sites are in Europe, and none are in the United States. WD Ex. 3 at printout pp. 3-5 (*clinicaltrials.gov*). Plaintiff's head of biopharmaceuticals has stated that it has been working with both the FDA and European regulatory authorities in order to "ensure[] that we have a global program that will work." WD Ex. 23 at p.2 (*Pink Sheet*). In the press release announcing the beginning of what it described as the "global" Phase III clinical trial, a senior official of Plaintiff asserted that it "has a strong track record in developing and commercializing biosimilars around the world" and that Plaintiff "will leverage this experience and our industry-leading capabilities to bring a biosimilar version of etanercept to patients and physicians around the world." WD Ex. 5 (Sandoz press release). The EU market for Enbrel® has been estimated to exceed two billion dollars annually. WD Ex. 25 at p. 2 (*gabionline.net*). Plaintiff's manufacturing facility, currently under construction, is not in the U.S.; it is in Austria. WD Ex. 23 at numbered p. 3 (*Pink Sheet*). Plaintiff has estimated that by 2016, Enbrel® will be the 4th largest therapeutic in the world, with global sales of over $7 billion. WD Ex. 24 at slide 9 (Novartis investor presentation).

3. Plaintiff lacks standing

A. Neither Roche nor Amgen has threatened to sue Plaintiff

The complaint does not allege that Amgen or Roche has threatened to sue Plaintiff for infringement of the two patents Plaintiff singles out (or other patents, for that matter), previously sued or indeed threatened to sue anyone on those two patents.

Instead, the complaint notes in ¶¶ 49-51 and 61-64 that Amgen's Annual Reports state that the two exclusively licensed patents are important to its success, and that Amgen officials have since 1990 episodically stated that it is important for a biotechnology company to defend its patents and products. Plaintiff's parent's filings say something similar. WD Ex. 7 (Novartis SEC Form 20-F 2011). In 2007, the Biotechnology Industry Organization presented testimony to Congress that "patents are the life-blood of the biotechnology industry." WD Ex. 20 at numbered p. 2 (*bio.org*). The complaint also alleges in ¶¶ 52-60 statements by Amgen or its representatives that the two Roche patents protect Enbrel® and provide it with market exclusivity to the extent of those patents. Also invoked in ¶ 65 is the fact that Amgen has previously sued competitors—after they have filed an FDA application. Finally the complaint notes in ¶¶ 68-69 that the defendants were unable to respond to Plaintiff's letter, which Amgen received on June 17, 2013, demanding an unlimited and broad covenant not to sue (Plaintiff sued just 7 days later). WD Ex. 21 (Sandoz demand letter).

B. Neither Roche nor Amgen has injured Plaintiff

Neither Roche nor Amgen have done anything to injure Plaintiff. Plaintiff's clinical development has proceeded without interference or complaint. Neither Roche nor Amgen have sought to stop Plaintiff's Phase III clinical trial or interfered with its efforts to produce its clinical candidate. They have not interfered with its efforts to construct production facilities for manufacture of an eventual product. And they have not interfered with Plaintiff's meetings with regulatory authorities in the EU or the U.S. To the contrary, Plaintiff admits that it continues to do all these things notwithstanding Roche, Amgen, and the two patents alleged to be the basis of a dispute.

4. The eventual dispute may also involve different patents

Plaintiff's complaint singled out only two patents, both owned by Roche: the '182, entitled "Human TNF Receptor Fusion Protein," and the '522, entitled "Human TNF Receptor." But there are other patents owned by Amgen, not Roche, as (for example) Amgen's 2012 Annual Report discloses. There, Amgen describes its material patents regarding Enbrel®, the trade name for etanercept, as follows:

Our outstanding material patents for etanercept are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Methods of treating psoriasis	8/13/2019
U.S.	Aqueous formulation and methods of treatment using the formulation[(1)]	6/8/2023
U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028
U.S.	DNA encoding fusion protein, and methods of making fusion protein	4/24/2029

WD Ex. 26 a numbered p. 6 (Amgen 2012 Annual Report). The complaint quotes this in ¶ 50, and it includes patents beyond the two that Plaintiff singled out. A patent dispute regarding Plaintiff's attempt to seek approval for and launch any eventual product may involve those two patents; or different patents owned or licensed by Roche or Amgen; or some combination thereof. The patents at issue will depend on the eventual product's structure, formulation, method of manufacture, recommended method of administration, and indication, all of which would be disclosed in Plaintiff's eventual FDA filing.

IV. Discussion

Subject-matter jurisdiction is absent. Even if it were present, this Court's considerable discretion is best exercised by declining, as is its right, to hear the matter.

1. Plaintiff's alleged dispute lacks immediacy and reality

A. Its alleged future activities are not immediate or determinable

On the long journey to product approval, one must travel an obstacle-laden path through acres of uncertainty before ever arriving at a dispute of sufficient immediacy and reality. A multitude of facts that do not yet exist must all come to pass. Plaintiff must meet its Phase III trial completion date—a difficult proposition given the state of Plaintiff's recruiting efforts and the strict requirements of its study. That Phase III trial must succeed. The Plaintiff must submit an application to the FDA. And that application must be approved.

The uncertainties cannot be ignored. As the Supreme Court has observed, "even at late stages in the development of a new drug, scientific testing is a process of trial and error. In the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments. That is the reason they conduct the experiments." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206

(2005). A non-trivial number of therapeutic candidates that succeed in Phase III do not mature into an FDA filing, as Plaintiff's parent has readily admitted. And no one can predict how the FDA will respond to any given regulatory submission.

The hard truth that Plaintiff seeks to avoid is that the Federal Circuit has never found declaratory judgment jurisdiction for a therapeutic where no FDA application has been filed and the requisite clinical trials have not yet been completed. The case law consistently concludes that on such facts, subject-matter jurisdiction is absent.

Although addressing a medical device, not a biologic, *Telectronics Pacing Systems, Inc. v. Ventritex, Inc*., an appeal from the Northern District of California, is instructive. There, as here, FDA approval was required to market and sell the regulated research item at issue. *Telectronics*, 982 F.2d at 1521. And there, as here, the product was still undergoing clinical testing and had the potential to be modified prior to approval. *Id.* at 1526-27. On those facts, the panel unanimously affirmed this court's dismissal for lack of subject-matter jurisdiction, determining that the matter lacked a "sufficient allegation of immediacy and reality" and emphasizing that, at the time the lawsuit was filed the challenger's regulated device had "only recently begun clinical trials, and was years away from potential FDA approval." *Id.* (internal citations and quotation omitted).

Likewise, in *Benitec Austrl., Ltd. v. Nucleonics, Inc.*, the patent challenger had not completed its Phase III clinical trial or submitted an FDA application; nevertheless, it sought to maintain claims for declaratory judgment of non-infringement and invalidity. *Benitec*, 495 F.3d at 1346-47. The Federal Circuit affirmed the District Court's dismissal for want of subject matter jurisdiction, precisely because the challenger had not successfully finished its Phase III clinical trial or submitted an FDA application. Following *Telectronics*, the panel emphasized that the fact that the challenger "may" file an application "in a few years" simply did "not provide the immediacy and reality required for a declaratory judgment." *Id.*

In addition, the *Benitec* panel underscored that, without more, a mere "expectation" of action fails to support jurisdiction. This applies here: Sandoz's allegations about its possible future actions fall short on their own, without resort to facts outside the complaint. Sandoz's complaint does not allege that it *will* file an FDA application. It alleges merely that it "*expects*" and is thus preparing to

file one. But *Benitec* held that that exact language—that the challenging party "expects" to take certain action—fails to create jurisdiction, cautioning that "to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent." *Id.* at 1349.

B. Its clinical candidate has not been threatened with suit

The alleged Roche and Amgen "threats" in this case are the sort of generalized statements that are typical of biotechnology companies when discussing their patents. That, for example, patents and products are important and should be defended. What is a biotech company supposed to say—that patents and products are best left undefended? Plaintiff also divines a threat in Amgen's statements that patents confer exclusivity. But the U.S. Constitution reminds that inventors are given "the exclusive Right to their . . . Discoveries." U.S. Const. Art. I, § 8, cl. 8. And the patent statutes provide that "[e]very patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process." 35 U.S.C. § 154(a). As this Court has previously confirmed in *Impax Laboratories v. Medicis Pharm Corp*., No. C-08-0253 MMC (N.D. Cal. April 16, 2008), attached as WD Ex. 27, an immediate and real dispute requires much more than the statements Plaintiff invokes here. Indeed, the statements in *Impax*, though sharper, more specific, and more threatening, were still insufficient to bolster the requisite immediacy and reality.

There, the patent-holder's CEO told investment analysts in an Earnings Conference Call that it had "hired a couple of [law] firms that I think are vicious in their enforcement and protection of patents, because we want to send a very strong message that this needs to be an impenetrable defense around this brand"—in short, that it had hired great trial lawyers and was ready to, and would, sue. *Id.* at p. 2 & n.1 (*Impax* slip opinion). The patent-holder's Vice President of Corporate Development told attendees at an equity conference that it "would 'aggressively prosecute the patents," and even went so far as to tell them that the patent-holder would "go after preliminary injunctions to ward off

any infringers.'" *Id.* (*Impax* slip opinion). Other officials of the patent-holder had made similar statements in a variety of contexts. *Id.* And, as here, the copyist asked the patent-holder for a covenant not to sue but rushed into court shortly thereafter (there, 4 instead of, as here, 7 days later), filing a declaratory judgment action. *Id*. at p. 3.

This Court granted the patent-holder's motion to dismiss for lack of declaratory judgment jurisdiction. Even though the declaratory judgment plaintiff had already filed its FDA application, this Court concluded (citing the law that Roche and Amgen discuss above) that the parties lacked a dispute that was sufficiently current, immediate, and real "to warrant the issuance of a declaratory judgment"— notwithstanding the patent-holder's threats of seeking an injunction, hiring vicious lawyers, and building an impenetrable defense. *Id.* at p. 6 (*Impax* slip opinion) (internal citation and quotation omitted). As the asserted statements here are much milder, general, and bland than the statements in *Impax*, it follows that jurisdiction is absent here, too.

On similar facts, other cases have reached similar conclusions. For example, in *Bridgelux, Inc. v. Cree, Inc.*, as here, the declaratory judgment plaintiff asserted that jurisdiction had been created by the patent-holder's various statements (there, in press releases and industry meetings) that it would defend its patents. WD Ex. 28 (*Bridgelux* slip opinion). This Court swiftly rejected that assertion, explaining that the fact that a patent-holder would publicly state that it would defend its patents "is unremarkable. The same could be said of many patent-holders." *Id.* at p. 13.

In short, under the applicable law neither Roche nor Amgen have ever threatened Plaintiff or otherwise done anything to create a dispute of sufficient immediacy and reality to warrant a declaratory judgment action.

C. Its global investment choices are not connected to the two Roche patents

Plaintiff's complaint demonstrates that its investment choices are not connected to the two Roche patents. The complaint avers that Plaintiff has been studying the Enbrel® patent estate for years—indeed that Plaintiff built its development efforts around that study. The '182 Patent issued in November 2011, and the '533 Patent followed in April 2012. And in the time between those dates and the date that plaintiff filed its complaint in late June 2013, the complaint says nothing—not a word—about stopping or slowing down any of its investment efforts. Instead, according to the

complaint, during that time Plaintiff spent money planning for Phase III clinical trials; designing and starting to build production facilities; meeting with regulatory authorities in the EU and the US; and so on. Plaintiff is attempting to convert its investment risk into an "adverse legal interest" through argument on the equities. But the facts demonstrate that the Roche patents have had no connection to Plaintiff's investment choice and there is no injury-in-fact. Roche's patents have been wholly irrelevant to Plaintiff's investments choices. Plaintiff's investment risk, as substantial as it may be, thus cannot be the basis for declaratory judgment jurisdiction any more than could adverse economic interests. *Cf. Microchip Tech, Inc. v. Chamberlain Grp., Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006).

There is a common-sense reason for the disconnect between Plaintiff's investment choices and the two Roche patents: the EU market, estimated at over $2 billion per year, is very attractive to Plaintiff, and Plaintiff wants to capture it—or, more precisely, to convert Enbrel® customers in the EU into customers of Plaintiff's eventual product. Plaintiff is currently able to do, and has been doing, exactly what it wants to do, irrespective of the two Roche patents.

This circumstances of this case are like those in *Prasco*, *supra*, 537 F.3d 1329. There, the declaratory judgment plaintiff had continued its investment activities—indeed, it had launched its product—but still claimed a "'paralyzing uncertainty' from fear" of suit. *Id*. at 1338. Noting that the mere existence of a patent does not confer jurisdiction, the court upheld the dismissal concluding that the patent-holder had done nothing to injure the declaratory judgment plaintiff, and that "a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy." *Id*. at 1338-39.

2. Even if this were a close call, jurisdiction would appropriately be declined

Even if this Court were to conclude that subject-matter jurisdiction existed, the better course would be for this Court to exercise its considerable discretion to decline the matter.

A. This lawsuit could not resolve the parties' full likely dispute

Adjudication of the validity and infringement of the Roche patents would be unlikely to finally and conclusively resolve all underlying controversies that might be created by Sandoz's importation, use, offer for sale or sale of an etanercept product upon FDA approval (as Plaintiff defines the precipitating act in the Complaint). The breadth of the controversy will be defined by the

approved product's structure, formulation, method of manufacture, recommended method of administration, and indication—none of which are yet determinable. While the patent dispute may then involve the two Roche patents, it may also involve other patents owned or licensed by Amgen and/or Roche. It would be contrary to the efficient use of declaratory judgment jurisdiction to permit a litigant to use such an action to obtain piecemeal adjudication of patents that would not finally and conclusively resolve the underlying controversy precipitated by its "expected" actions.

B. To accept this case at this juncture would set a dangerous precedent

To accept this case at this juncture would set a bad precedent in a variety of ways. In a time of decreasing judicial resources and increasing caseloads, it would encourage resource-consuming patent litigation that could be wholly mooted by either (1) a Phase III clinical trial failure; (2) the declaratory judgment plaintiff's inability, for whatever reason, to submit an FDA application; or (3) the FDA's refusal to approve a product submitted for approval. In light of Plaintiff's decision to rush to file only seven days after sending its demand for a broad covenant not to sue, to accept this case would, as this Court has counseled in similar circumstances, "promote the premature filing of declaratory judgment actions and reduce the incentives for potential infringers to communicate with patentees before filing suit." WD Ex. 27 at p. 6 (*Impax* slip opinion); *see also Fresenius USA Inc. v. Transonic Sys., Inc*., 207 F. Supp. 2d 1009, 1012-1013 (N.D. Cal. 2001) (declaratory judgment suited filed before response to pre-suit letter; suit dismissed).

To accept this case would also substantially lower the bar regarding what kinds of corporate statements about patents will create a dispute of sufficient immediacy and reality. The statements that Plaintiff has alleged created such a dispute are the kinds of statements that high-technology, biopharma, and biotechnology companies and their representatives commonly make. If those statements suffice, the litigation floodgates will open.

C. The statutory scheme for biosimilar patent disputes is instructive

As this Court considers whether to exercise its discretion to accept or decline this matter, it is worth noting that the statutory schemes for resolution of patent disputes involving biologics seeking approval pursuant to the "biosimilar" pathway, as well as the statutory scheme for resolution of patent disputes involving generic pharmaceuticals, set the triggering act for statutory jurisdiction at

the filing of an application for FDA approval to market the product candidate. 42 U.S.C. § 262(l)(6) (biosimilars; specifying the timing of a patent litigation by "the reference product sponsor"). So, too, does the Hatch-Waxman statutory framework. 21 U.S.C. § 355(j)(5)(B)(iii) (generic pharmaceuticals; patent holder has 45 days from FDA filing to sue); *id.* § 355(j)(5)(C) (disallowing prior declaratory judgment suit by the generic).

These statutory schemes reflect the Congressional judgment that the appropriate time for the courts to have jurisdiction to resolve patent disputes is at the filing of an FDA application, coincident with the applicant's representation to the FDA that it has completed sufficient clinical testing and analysis of its product candidate to justify FDA approval. There is nothing unique about the circumstances of this case—not the parties, not the investment costs or risks, not the products, or the patents—that compels jurisdiction at this time.

V. Conclusion

Courts are not empowered to issue an advisory opinion about what the parties' rights would be based on a hypothetical set of facts. But that is precisely what Plaintiff's complaint seeks. Indeed, that is all that Plaintiff's complaint seeks. In such circumstances, subject-matter jurisdiction is absent. Even if subject-matter were present—which, emphatically, it is not—given all the circumstances, the better course is to exercise this Court's discretion not to take this case.

Depending on how a series of future events turn out, there may one day be a dispute between the parties concerning an etanercept "biosimilar." But today is not that day.

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