RACHEL KREVANS (CA SBN 116421)
RKrevans@mofo.com
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: 415.268.7000
Facsimile: 415.268.7522

GRANT J. ESPOSITO (admitted *pro hac vice*)
GEsposito@mofo.com
MORRISON & FOERSTER LLP
250 West 55th Street
New York, NY 10019-9601
Telephone: 212.468.8000
Facsimile: 212.468.7900

Attorneys for Defendant
SANDOZ INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH,

Defendants.

Case No. 3:14-cv-04741-RS

DEFENDANT SANDOZ INC.'S NOTICE OF MOTION AND CROSS-MOTION FOR JUDGMENT ON THE PLEADINGS; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF; AND OPPOSITION TO AMGEN'S MOTION FOR JUDGMENT ON THE PLEADINGS

Date: March 12, 2015
Time: 1:30 p.m.
Crtrm: 3, 17th Floor

Judge: The Honorable Richard Seeborg

Date Action Filed: October 24, 2014

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on March 12, 2015, at 1:30 p.m., Defendant Sandoz Inc. ("Sandoz") will and hereby does move this Court for an order pursuant to 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 12(c) that Sandoz complied with the Biologics Price Competition and Innovation Act (BPCIA) and declaring: (1) by providing notice of commercial marketing to Amgen at least 180 days before it will sell its biosimilar, Sandoz followed Section (*l*)(8)(A) of the BPCIA; and (2) the BPCIA permitted Sandoz not to provide Amgen with its biosimilar application within twenty days of acceptance by FDA, and permitted Amgen to bring the declaratory judgment action it filed here. Sandoz also seeks an order denying Plaintiffs' Motion for Judgment on the Pleadings and dismissing Plaintiffs' First and Second Causes of Action with prejudice.

This motion will be based on this Notice, the accompanying Memorandum of Points and Authorities concurrently filed herewith, the pleadings and papers on file with the Court, and such other evidence and argument as may be presented at the hearing.

Dated: January 23, 2015

MORRISON & FOERSTER LLP

By: /s/Rachel Krevans
Rachel Krevans

Attorneys for Defendant
SANDOZ INC.

TABLE OF CONTENTS

		Page
I.	INTRODUCTION	1
II.	LEGAL STANDARD	5
III.	ARGUMENT	5
A.	Sandoz Followed the BPCIA's Notice-of-Commercial-Marketing Provision by Sending Notice More Than 180 Days Before the First Commercial Marketing	6
B.	The BPCIA's Patent Dispute Provisions Expressly Address the Situation, as Here, Where an Applicant Does Not Provide Its Application	9
1.	Interpreting the BPCIA as Providing Flexibility to Resolve Patent Disputes Is the Only Interpretation Consistent With the Entire Statutory Scheme.	10
2.	Amgen's View of Section (*l*) Requires That One Interpret an Act of Congress Solely by Reading a Single Provision in Isolation and Out of Context	13
3.	There Are Good Policy Reasons Why Congress Provided for a Flexible Approach to Resolving Patent Disputes.	15
4.	The BPCIA Created Procedural Mechanisms for Resolving Patent Disputes, Which Amgen Cannot Convert into Substantive Rights	17
C.	Amgen's State-Law Claims Should Be Dismissed	18
1.	The UCL Claim Should Be Dismissed Because Sandoz Did Not Engage in Unlawful Activity and Congress Already Balanced the Relevant Competing Interests	18
2.	Amgen's Conversion Claim Should Also Be Dismissed	21
D.	Sandoz's Sixth and Seventh Counterclaims Should Not Be Dismissed	22
IV.	CONCLUSION	23

TABLE OF AUTHORITIES

Page

CASES

Alexander v. Hillman,
296 U.S. 222 (1935) 22

Banko v. Apple Inc.,
20 F. Supp. 3d 749 (N.D. Cal. 2013) 8, 14

Beaty v. FDA,
853 F. Supp. 2d 30 (D.D.C. 2012) 14

Burlesci v. Petersen,
80 Cal. Rptr. 2d 704 (Ct. App. 1998) 21

Citizens for a Better Env't v. Union Oil Co.,
861 F. Supp. 889 (N.D. Cal. 1994) 14

Cook v. FDA,
733 F.3d 1 (D.C. Cir. 2013) 14

Cortez v. Purolator Air Filtration Prods. Co.,
999 P.2d 706 (Cal. 2000) 19

Davis v. Mich. Dep't of Treasury,
489 U.S. 803 (1989) 10

Duncan v. Walker,
533 U.S. 167 (2001) 14

G.S. Rasmussen & Assocs. v. Kalitta Flying Serv.,
958 F.2d 896 (9th Cir. 1992) 21

Gen. Elec. Co. v. Marvel Rare Metals Co.,
287 U.S. 430 (1932) 22

Gutierrez de Martinez v. Lamagno,
515 U.S. 417 (1995) 13

In re Mercedes-Benz Tele Aid Contract Litig.,
257 F.R.D. 46 (D.N.J. 2009) 20

Lazar v. Hertz Corp.,
82 Cal. Rptr. 2d 368 (Ct. App. 1999) 18

Mazza v. Am. Honda Motor Co.,
666 F.3d 581 (9th Cir. 2012) 20

TABLE OF AUTHORITIES
(continued)

Page

McCann v. Foster Wheeler LLC,
225 P.3d 516 (Cal. 2010) 20

Miles, Inc. v. Scripps Clinic and Research Found.,
810 F. Supp. 1091 (S.D. Cal. 1993) 22

Moore v. Regents of Univ. of Cal.,
51 Cal. 3d 120, 793 P.2d 479 (Cal. 1990) 22

Neitzke v. Williams,
490 U.S. 319 (1989) 5

Norwest Mortg., Inc. v. Super. Ct.,
85 Cal. Rptr. 2d 18 (Ct. App. 1999) 19

Sandoz Inc. v. Amgen Inc.,
No. 2014-1693, 2014 U.S. App. LEXIS 22903 (Fed. Cir. Dec. 5, 2014) 8

Sandoz Inc. v. Amgen Inc.,
No. C-13-2904 MMC, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013) 7, 8

Schnall v. Hertz Corp.,
93 Cal. Rptr. 2d 439 (Ct. App. 2000) 18

Smith v. State Farm Mut. Auto. Ins. Co.,
113 Cal. Rptr. 2d 399 (Ct. App. 2001) 18

Town of Castle Rock v. Gonzales,
545 U.S. 748 (2005) 13

TRW Inc. v. Andrews,
534 U.S. 19 (2001) 14

United States v. Cabaccang,
332 F.3d 622 (9th Cir. 2003) 5

United States v. Reeb,
433 F.2d 381 (9th Cir. 1970) 13

United States v. Wilson,
503 U.S. 329 (1992) 15

Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.,
200 F.3d 795 (Fed. Cir. 1999) 23

TABLE OF AUTHORITIES
(continued)

Page

Washingtonian Publ'g Co. v. Pearson,
306 U.S. 30 (1939) 17

Westwood Apex v. Contreras,
644 F.3d 799 (9th Cir. 2011) 10

STATUTES

28 U.S.C.
§ 2201 5
§ 2202 5

35 U.S.C.
§ 271 ..... 6, 12, 13

42 U.S.C.
§ 262 ..... passim

Cal. Bus. & Prof. Code
§ 17200 ..... passim
§ 17203 19

OTHER AUTHORITIES

Biologics Price Competition and Innovation Act (BPCIA),
Pub. L. No. 111-148, 124 Stat. 804 (2010)
§ 7001 ..... 2, 10
§ 7002 12

Federal Rules of Civil Procedure
Committee Notes on Rules, 2007 Amendment 13
Rule 12 5
Rule 13 22

William L. Stern, *Bus. & Prof. C. § 17200 Practice* 3:53 (Rutter Group 2014) 19

I. INTRODUCTION

At the time of the enactment of the Biologics Price Competition and Innovation Act (BPCIA) in 2010, spending on biologic pharmaceuticals represented 21% of total medication spend ($67 billion of $307 billion), and was expected to increase materially.[1] In response to this challenge, Congress introduced the BPCIA to create both a new regulatory pathway for the approval of biosimilar products, and patent-resolution mechanisms by which the originator of a biological medicine (the reference product sponsor or "Sponsor") and a biosimilar applicant ("Applicant") can resolve potential patent disputes prior to the launch of the biosimilar product, so that patients and the healthcare system could access affordable and effective biosimilar products as soon as possible. In doing so, Congress struck a careful balance in the BPCIA between encouraging innovation and providing consumers with prompt access to lower-cost biosimilars.

Sandoz, as the first Applicant under the BPCIA, has used both the regulatory pathway and the patent-resolution mechanisms of the BPCIA to bring its biosimilar filgrastim product to patients. In particular, Sandoz has used the patent dispute resolution mechanisms provided in the BPCIA to try to resolve any patent issues well in advance of its launch.

Amgen's motion raises two questions about how Sandoz has used those BPCIA mechanisms, namely:

1) When can an Applicant provide its "notice of commercial marketing" to a Sponsor?

2) How do patent disputes between Applicants and Sponsors get resolved when, as Section (*l*)(9)(C) contemplates, an Applicant does not provide the Sponsor with a copy of its application for FDA approval under BPCIA subsection (k) ("Application") within twenty days of acceptance by FDA, as described in Section (*l*)(2)(A)?

[1] *See* Declaration of Stephen D. Keane ("Keane Decl."), Ex. 1 at 4, 6 (IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010*, at 4, 6 (April 2011), *available at* http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf (last accessed Jan. 23, 2015)).

On the first question, the answer resides in the text of Section (*l*)(8)(A) of the BPCIA, which states that the 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)." As Amgen would have this Court answer that question, Section (*l*)(8)(A) creates an additional 180-day exclusivity period for Sponsors. That interpretation finds no support under this notice provision, which says nothing about exclusivity. Rather, prior notice allows the Sponsor, if it wishes, to try to halt commercial marketing by seeking a preliminary injunction well before the biosimilar launches. Amgen is unable to deny that on July 8, 2014, Sandoz gave Amgen notice that it intended to commercially market filgrastim after approval by FDA, which was expected within ten months.[2]

Amgen claims, however, that this notice was not effective under the BPCIA because it was ***too*** early. Amgen argues that effective notice (which is intended to provide a Sponsor with time to assert its patent rights, if any) cannot be given until ***after*** FDA licenses the biosimilar. Such an interpretation cannot be reconciled with the plain language and meaning of the statute.

Moreover, Amgen's attempt to read that notice provision to mean that ***every*** Sponsor would ***always*** effectively obtain an automatic 180-day injunction after ***every*** product approval is contrary to the goals of the BPCIA, which balanced the competing interests of consumer demands for more affordable medical treatments and the need to protect innovation by providing (among other things) clearly defined exclusivity periods to Sponsors. *See* BPCIA § 7001(b), Pub. L. No. 111-148, 124 Stat. 804 (2010) (Congress intended to develop a "biosimilars pathway balancing innovation and consumer interests").[3] In essence, Amgen's reading therefore turns a notice provision into an exclusivity provision.

The second question is how do patent disputes between Applicants and Sponsors get resolved when, as Section (*l*)(9)(C) contemplates, an Applicant does not provide the Sponsor with

[2] *See* Compl. ¶¶ 63, 70.

[3] For the Court's convenience, a copy of the BPCIA is provided. (*See* Keane Decl. Ex. 2.)

a copy of its Application within twenty days of acceptance by FDA, as described in Section (*l*)(2)(A)? The answer is the very claim for patent infringement that Amgen has brought.

The dispute on the second question concerns whether Section (*l*) of the BPCIA provides only one way to resolve patent disputes. It does not. Instead, Section (*l*) provides a roadmap for Applicants and Sponsors as they navigate the resolution of patent disputes, which can differ in material ways depending on the circumstances. Section (*l*) expressly contemplates that in different cases, Applicants and Sponsors will have different objectives and different concerns that affect how to resolve patent issues between them. That Congress wanted Section (*l*) to provide such a flexible framework should come as no surprise, due to the impossibility of predicting the facts that may be in play at the time of patent-dispute resolution, and the myriad ways parties can disagree about intellectual property rights and how to address them.

There will be circumstances where the Applicant will want to provide the Sponsor a copy of the Application within twenty days of acceptance by FDA, and then engage in other Section (*l*) provisions by which the parties try to resolve patent disputes. 42 U.S.C. § 262(*l*)(2)-(4). There will be other circumstances, however, where it makes little sense for the Applicant to provide its Application within that time period. That decision triggers specified consequences—notably including allowing the Sponsor to sue immediately to enforce patents claiming the biological product, or a use thereof. 42 U.S.C. § 262(*l*)(9)(C). Sandoz made such a choice here, the consequence of which is that Amgen had the right to bring a patent infringement action immediately—which it did.

Amgen's view that Section (*l*) provides only one way to resolve patent disputes cannot control, because it is premised on a reading of individual pieces of Section (*l*) in isolation while ignoring the intent and text of Section (*l*) as a whole. Under this interpretation, Applicants must supply their Applications within twenty days of acceptance by FDA to Sponsors in ***all*** circumstances. But Section (*l*) as a whole deals with resolving potential patent disputes. Amgen's view would require an Applicant to provide its Application even when there are no patent disputes to resolve, such as where the Applicant intends to launch only after any relevant patents have expired. Furthermore, Amgen's proffered interpretation would require this Court to

ignore parts of Section (*l*) that expressly contemplate that an Applicant will ***not*** provide a Sponsor with a copy of the Application within the twenty days. 42 U.S.C. § 262(*l*)(9)(C).

In addition, the relief Amgen seeks finds no place in the BPCIA. Section (*l*) does not provide Sponsors substantive rights to force Applicants to resolve patent disputes in the manner Sponsors prefer. Nor does the BPCIA award damages or impose injunctive relief if Applicants choose to resolve patent issues in ways expressly permitted by Section (*l*). Amgen's effort to engraft these remedies onto the BPCIA contravenes the statutory scheme's careful balance between encouraging innovation and providing consumers with prompt access to lower-cost biosimilars. In sum, because Sandoz's view of the BPCIA follows the words of the statute, is consistent with the intent of Congress to provide cost-effective biosimilars to patients in the U.S. in a timely manner, and honors principles of statutory construction, this Court should adopt it.

In its cross-motion, Sandoz seeks an order declaring that its interpretation of the BPCIA controls. Sandoz also moves to dismiss Amgen's unfair competition and conversion claims. Under the correct interpretation of the BPCIA, Sandoz engaged in no unlawful conduct. It simply elected BPCIA provisions for resolving patent disputes different from the provisions Amgen would have preferred. Because that is not unlawful conduct, the predicate act for California conversion and unfair competition claims does not exist and those claims should be dismissed.

Moreover, Amgen cannot obtain relief under its state-law claims. First, relief under California's unfair competition law is equitable, and would require this Court to recalibrate the equities between the parties that Congress already balanced. Second, Amgen's argument would prevent a uniform interpretation of the BPCIA across the country. Because California's unfair competition law is unique, it could not provide a remedy where neither the Sponsor nor the Applicant resides in California. Application of California law would therefore yield different outcomes under the BPCIA depending on where the parties reside. Nothing in the BPCIA suggests that is what Congress intended.

In short, the relief Amgen's motion seeks is inconsistent with the goals of the BPCIA. It would cause unwarranted delay in providing lower-cost, effective drugs to cancer patients, with no countervailing benefits. Amgen already has held a monopoly in the U.S. filgrastim market for

more than two decades, far longer than the twelve years of exclusivity provided for or intended by the BPCIA.[4] Amgen's motion should be denied and Sandoz's cross-motion should be granted.

II. LEGAL STANDARD

The parties agree that the Court should issue a judgment on the pleadings pursuant to Rule 12(c), based upon the existence of a dispositive, but disputed, question of law. *See* Mot. at 8-9; *Neitzke v. Williams*, 490 U.S. 319, 326 (1989) ("Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law.") (citation omitted). Because the key issue here involves statutory interpretation, which is a question of law, under 28 U.S.C. §§ 2201 and 2202 the Court can and should issue a declaratory judgment in Sandoz's favor if it construes the BPCIA in the manner urged by Sandoz. *See United States v. Cabaccang*, 332 F.3d 622, 624-25 (9th Cir. 2003) (the interpretation of a statute is a question of law); *Neitzke*, 490 U.S. at 326.

III. ARGUMENT

Sandoz has fully complied with the BPCIA. Sandoz followed BPCIA Section (*l*)(8)(A) when it provided Amgen with notice on July 8, 2014 of its intent to sell biosimilar filgrastim upon FDA approval. And Sandoz complied with the BPCIA when it elected not to provide Amgen with its Application within the twenty-day period and accepted the risk that Amgen would sue it for patent infringement—as Amgen has now done. Amgen's arguments to the contrary rely on interpretations of the BPCIA that either misread provisions entirely or read them in isolation and without regard to the statute as a whole, as canons of statutory construction require.

Properly construed, Section (*l*) provides procedural mechanisms through which the parties can resolve patent disputes.[5] It offers procedures designed to facilitate discussion prior to litigation, which put limits on who can sue when and under what circumstances. Section (*l*) also recognizes that those procedures will not work in all cases. And when they do not, Section (*l*)

[4] *See* 42 U.S.C. § 262(k)(7)(A).

[5] While the instant motion is largely limited to the meaning of Section (*l*), the BPCIA has other provisions that operate independently of Section (*l*). For example, Section (k) describes the requirements for FDA approval of a biosimilar. *See* 42 U.S.C. § 262(k)(3) (approval requires showing of biosimilarity or interchangeability, as well as Applicant's consent to inspection of manufacturing facility).

lifts those limits that would otherwise prevent immediate patent litigation. Section (*l*) provides a handy roadmap for both Applicants and Sponsors to follow as they try to resolve patent litigation before FDA approval, so that once FDA approves a biosimilar, patients—and state and federal governments and employers that help subsidize their care—can promptly reap the benefits of more affordable medical treatment.

Section (*l*) does many things to help resolve patent disputes. What it does not do, however, is punish an Applicant for pursuing a patent dispute resolution process permitted by the BPCIA just because the Sponsor prefers a different course of action. Section (*l*) does not create a new substantive right that could be enforced under state or federal law; rather, it simply provides procedural mechanisms that, together with an amendment to 35 U.S.C. § 271(e), allow the Sponsor and Applicant to litigate about substantive patent rights. The Sponsor's substantive right to try to delay entry of a biosimilar hinges solely on whether the Sponsor can succeed on a patent infringement claim. In other words, only if the Sponsor succeeds in establishing that its patent(s) are valid and infringed, should the launch of a biosimilar product be delayed.

In any event, because Sandoz fully complied with the BPCIA, Amgen has no proper basis for seeking relief under the state-law claims asserted. For the reasons that follow, Amgen's motion should be denied and Sandoz's cross-motion should be granted.

A. Sandoz Followed the BPCIA's Notice-of-Commercial-Marketing Provision by Sending Notice More Than 180 Days Before the First Commercial Marketing.

Commercial marketing in the United States can commence as soon as FDA approves the biosimilar. Section (*l*)(8)(A) directs an Applicant to notify the Sponsor of its intent to sell "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." BPCIA Section (*l*)(8)(A) states:

> NOTICE OF COMMERCIAL MARKETING.—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).

Thus, the question is whether Sandoz notified Amgen of its intent to sell "not later than 180 days before the date of the first commercial marketing of" biosimilar filgrastim. The answer is yes.

On July 8, 2014—the day after FDA accepted Sandoz's Application—Sandoz notified Amgen that it would begin to sell filgrastim upon FDA approval.

Despite the statute's clear pronouncement, Amgen argues that Section (*l*)(8)(A) means that an Applicant cannot provide notice that it will sell the biosimilar until ***after*** FDA approves the biosimilar. Under Amgen's interpretation, Sponsors will obtain an additional six months of uninterrupted market exclusivity after biosimilar approval while cancer patients wait needlessly for the less expensive version of filgrastim that Congress and FDA promised them. That argument cannot be squared with either the statutory text or the entire statutory scheme. Looking at the statutory text, the "before" modifies "the date of the first commercial marketing." The "licensed" relates to the product that will be commercially marketed, ***not*** the triggering time for the notice.

Amgen makes much of the fact that Section (*l*)(8)(A) uses the phrase "licensed under subsection (k)" while other parts of the BPCIA sometimes refer to a "biological product that is the subject of the subsection (k) application." But that choice of phrase sheds no light on the meaning of Section (*l*)(8)(A). By the time commercial marketing has begun, it is irrelevant whether the marketed product is referred to as "the licensed product" or "the subject of the application"—because, as of the time of marketing, the product must have been approved by FDA, so those phrases refer to the exact same thing. It would have made no difference for Congress to have phrased the provision as "commercial marketing of the biological product that is the subject of the subsection (k) application," because that application has necessarily been approved by the time marketing begins. Thus, contrary to Amgen's arguments, Congress' choice of the phrase "licensed under subsection (k)" reflects only the mundane truth that the product has already been licensed by the time marketing begins.

Amgen's argument as to the timing of when notice of commercial marketing can issue clings to dicta in the Etanercept case, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013). In that case, Amgen never made the argument it advances here. Instead, the district court simply made statements *sua sponte* suggesting that an Applicant cannot provide notice of commercial marketing until after FDA approves the

biosimilar. *See id.* at *6. Although Amgen eventually tried to defend those statements in the Federal Circuit, the Circuit expressly stated that its holding was based on other grounds, and that it did not reach the notice-timing issue. *Sandoz Inc. v. Amgen Inc.*, No. 2014-1693, 2014 U.S. App. LEXIS 22903, at *2 (Fed. Cir. Dec. 5, 2014) ("We do not address the district court's interpretation of the BPCIA"). Amgen's argument here cannot be reconciled with the plain meaning of the statutory provision, which clearly states that notice should precede commercial marketing and says nothing about the timing of such notice relative to FDA approval.

Under Amgen's interpretation, Section (*l*)(8)(A) is no longer a notice provision, but rather an exclusivity provision. When viewed against the intent of the statute, this makes no sense. Congress already decided that Sponsors should have twelve years of exclusivity, and that no biosimilar application could be submitted to FDA for approval until after the Sponsor's product had been on the market for four full years. 42 U.S.C. § 262(k)(7).

Section (*l*)(8)(A) does not provide an additional six months of market exclusivity. Rather, it was intended to provide 180 days for Sponsors to seek an injunction against marketing by proving to a court that they have met the traditional test for a preliminary injunction. But Amgen's view of Section (*l*)(8)(A) would effectively give all Sponsors a six-month preliminary injunction after approval for every biosimilar—even if they have no patents covering the product—without meeting the high burden for obtaining such an injunction. Nothing in the BPCIA dispenses with the need for meeting the rigorous test for judicial approval of a preliminary injunction. Amgen cannot extend its monopoly by waiting for FDA approval and then having an additional six months to assert its patent rights while patients wait on the sidelines and governments and companies continue to endure higher prices to treat their citizens and employees.

If the section read as Amgen urges, Congress would have simply said: "The subsection (k) applicant shall provide notice to the reference product sponsor after FDA approval and cannot begin commercial marketing until 180 days after providing such notice." Congress did not, and Amgen's argument should be summarily rejected. *See Banko v. Apple Inc.*, 20 F. Supp. 3d 749, 757 (N.D. Cal. 2013) (correct interpretation of statute cannot ignore the plain

language of that statute, and "must give effect to the unambiguously expressed intent of Congress") (citation omitted).

It is much more consistent with the goals of the BPCIA to read Section (*l*)(8)(A) as simply calling for no less than six months' notice before marketing, without waiting first for approval. That gives both parties and the judicial system six months to litigate and decide whether a preliminary injunction based on patent rights is warranted ***before*** a biosimilar is approved and would otherwise be ready for launch. If the Sponsor cannot meet the traditional requirements for an injunction, consumers can benefit from the lower-cost biosimilar as soon as it is approved by FDA. On the other hand, if a court decides that an injunction is appropriate, patent rights will be protected and the Applicant will not be able to launch unless and until the injunction is lifted. That outcome reflects the balance struck by Congress in the BPCIA between these competing interests.

Amgen's effort to read into Section (*l*)(8)(A) a further delay in the sale of affordable biosimilars, if adopted, would have far-reaching consequences. Not only would that interpretation improperly force this Court to re-evaluate the balance Congress already struck in providing exclusivity to promote innovation, but it would also impose a massive cost on the healthcare system by needlessly delaying the entry of more affordable medicines that FDA approved for sale. Amgen's effort to amend Section (*l*)(8)(A) to impose such a requirement—especially where the text says nothing about exclusivity—should be rejected.

The Court should therefore hold that (a) Applicants do not have to wait to provide notice of commercial marketing until after FDA approves their biosimilars, and (b) Section (*l*)(8)(A) does not award Sponsors an additional six months of exclusivity.

B. The BPCIA's Patent Dispute Provisions Expressly Address the Situation, as Here, Where an Applicant Does Not Provide Its Application.

Section (*l*) deals with how to resolve patent disputes between Applicants and Sponsors. Those provisions provide flexibility to resolve patent disputes, depending on the circumstances. Contrary to Amgen's argument, Section (*l*) does not impose only a single or exclusive way to resolve patent disputes.

1. Interpreting the BPCIA as Providing Flexibility to Resolve Patent Disputes Is the Only Interpretation Consistent With the Entire Statutory Scheme.

That the BPCIA provides for ways to resolve patent issues besides the approach Amgen prefers in this case is the only reading consistent with the entire statutory scheme. A fundamental canon of statutory construction is that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989) (citation omitted). In interpreting the language of a statute, "it is inappropriate to construe a statute by reading related clauses in isolation or taking parts of a whole statute out of their context. An excerpted clause in a statute cannot be interpreted without reference to the statute as whole . . . ." *Westwood Apex v. Contreras*, 644 F.3d 799, 804 (9th Cir. 2011) (citing *United States v. Morton*, 467 U.S. 822, 828 (1984)). Providing alternate approaches to resolving patent issues reflects Congress' intent to provide the flexibility needed to achieve the BPCIA's primary purpose: striking a balance between protecting consumer interests by efficiently getting biosimilar products to market, and protecting innovation by providing mechanisms to resolve potential patent disputes. *See* BPCIA, § 7001(b), Pub. L. No. 111-148, 124 Stat. 804 (2010) (Congress intended to develop a "biosimilars pathway balancing innovation and consumer interests"). The text of the statute provides for more than one mechanism precisely in order to achieve that balance.

Specifically, Section (*l*) of the BPCIA creates a set of procedures that Applicants and Sponsors can use to resolve potential patent disputes, with different methods of resolution depending on how each elects to proceed under the circumstances. Under the statute, one election that the Applicant can make is to provide the Sponsor a copy of the Application within twenty days of acceptance by FDA under Section (*l*)(2)(A), and then to exchange lists of patents that might be relevant and negotiate any resulting disputes before commencing patent litigation (the "Patent-Exchange Process").[6] An Applicant's provision of its Application to the Sponsor carries

[6] The procedures for identifying and negotiating patent disputes after receipt of the Application are contained in 42 U.S.C. § 262(*l*)(3)-(4).

certain risks and benefits for both the Applicant and the Sponsor. For example, during the Patent-Exchange Process the Sponsor cannot immediately run to court and sue the Applicant for infringing a patent covering its branded drug or how it is used.

But the text of Section (*l*) makes clear that providing the Application within twenty days of acceptance by FDA is not the only way that patent disputes can be resolved. Another election the Applicant can make is ***not*** to provide its Application within that time period. That is the plain meaning of Section (*l*)(9)(C) of the BPCIA, which is entitled "SUBSECTION (k) APPLICATION NOT PROVIDED" and states:

> If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C). If the Applicant proceeds under this provision, different risks and benefits emerge, including the fact that the Sponsor can sue ***immediately*** to enforce valid patents claiming its drug, or its use—as Amgen has done here.

Interpreting the provisions of Section (*l*) as a whole means that ***if*** the Applicant wishes to take advantage of the Patent-Exchange Process described in Sections (*l*)(2)-(6), ***then*** the Applicant ***must*** supply the Application to the Sponsor within twenty days of its acceptance by FDA. But that is not the only way to resolve patent disputes under the BPCIA.

Specifically, Section (*l*) explains how patent litigation between the Applicant and the Sponsor should occur depending on how the Applicant proceeds. Under Section (*l*)(9)(A), if the Applicant shares its Application within twenty days of FDA acceptance and engages in the Patent-Exchange Process—potentially culminating in a limited suit for patent infringement under Section (*l*)(6)—***neither*** party may bring an action for declaratory judgment for infringement, validity, or enforceability of patents before the Applicant provides its notice of commercial

marketing.[7] Under Section (*l*)(9)(B), if the Applicant shares its Application, begins the Patent-Exchange Process, and then chooses not to continue, the Sponsor can bring traditional patent litigation at a time of its choosing.

If, on the other hand, the Applicant does not share the Application within the twenty-day period for whatever reason, Section (*l*) points to the next step in the process to cover that scenario: Section (*l*)(9)(C) authorizes the Sponsor—but ***not*** the Applicant—to bring a declaratory judgment action of infringement, validity, or enforceability at any time, as Amgen has now done. Sections (*l*)(9)(B) and (*l*)(9)(C) put to rest any notion that a Sponsor has the right or the ability to force the Applicant to engage in the Patent-Exchange Process. That is because they expressly acknowledge that the Applicant has the right not to turn over its Application within twenty days of FDA acceptance, which starts the Patent-Exchange Process, as well as the right to walk away from that process even after the Applicant has chosen to begin it. In any event, Sandoz complied with the BPCIA when it refused to give Amgen a copy of its Application within the twenty-day period. And Amgen complied with the BPCIA when it followed Section (*l*)(9)(C) and sued Sandoz for infringement of the '427 patent.

That there are different mechanisms to resolve potential patent disputes under Section (*l*) is further supported by the fact that Congress passed, as part of the BPCIA, a conforming Amendment to 35 U.S.C. § 271(e), which governs patent infringement actions. BPCIA § 7002(c). Specifically, Congress added new subsection (C) to § 271(e)(2) to account for situations like the one before this Court, where the Applicant does ***not*** provide its Application to the Sponsor. That new subsection specifies in pertinent part that "an application seeking approval of a biological product" is an act of infringement "for a patent that could be identified pursuant to [262(*l*)(3)(A)(i)]" "***if the applicant for the application fails to provide the application*** and information required under section [262(*l*)(2)(A)]." BPCIA § 7002(c)(1)(A)(iii), codified at 35 U.S.C. § 271(e)(2)(C)(i)-(ii) (emphasis added).

[7] Declaratory judgment actions under Section (*l*)(9)(A) are limited to patents that were included on the lists the parties shared during the Patent-Exchange Process, but that were not previously asserted against the Applicant under Section (*l*)(6).

This additional act of Congress further demonstrates that Congress considered and addressed ways to resolve patent disputes when Sponsors do not receive those Applications. Together, BPCIA Section (*l*)(9)(C) and the new addition to Section 271(e) create a process for the Sponsor to follow when the Applicant chooses not to provide the Application. Section (*l*)(9)(C) allows the Sponsor to bring an action for declaratory judgment. At the same time, Section 271(e)(2)(C)(ii) ripens the dispute for adjudication by making it an act of infringement to submit an Application if the Applicant elects not to provide that application to the Sponsor. Read as a whole, these provisions make it unmistakably clear that the BPCIA provides more than one way to resolve patent disputes.

2. Amgen's View of Section (*l*) Requires That One Interpret an Act of Congress Solely by Reading a Single Provision in Isolation and Out of Context.

Notwithstanding Congress' clear intent, Amgen clings to a myopic view of Section (*l*)(2)(A), arguing that because the statute contains "shall", Applicants must supply their Applications in all circumstances. Read within the context of the BPCIA as a whole, however, the word "shall" in Section (*l*)(2)(A) simply directs the first step in the Patent-Exchange Process, ***if*** the Applicant chooses that approach to resolve patent issues. The word "shall" is often used to convey permissive conduct, especially when the surrounding context supports that use.[8]

As noted above, Section (*l*)(9)(C) expressly contemplates that some Applicants will not disclose their Applications within the twenty days in every case, and supplies the steps that follow. By suggesting, contrary to the very text of Section (*l*)(9)(C), that Applicants must always

[8] *See Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 (1995) ("Though 'shall' generally means 'must,' legal writers sometimes use . . . 'shall' to mean 'should,' 'will,' or even 'may.'"); *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 760-62 (2005) (provision containing the word "shall" did not require that legal action be taken, in light of policy considerations favoring discretion); *United States v. Reeb*, 433 F.2d 381, 383 (9th Cir. 1970) ("The interpretation of [shall and may] depends upon the background circumstances and context in which they are used and the intention of the legislative body . . . which used them."); Fed. R. Civ. P. Committee Notes on Rules, 2007 Amendment (explaining that the Federal Rules were amended in 2007 to "minimize the use of inherently ambiguous words," including the word "shall," which "can mean 'must,' 'may,' or something else, depending on context. The potential for confusion is exacerbated by the fact that 'shall' is no longer generally used in spoken or clearly written English.").

turn over their Applications, Amgen's argument essentially ignores that provision. But Section (*l*)(9)(C) must be given full effect. *See, e.g.*, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant"); *see also Duncan v. Walker*, 533 U.S. 167, 174 (2001); *Citizens for a Better Env't v. Union Oil Co.*, 861 F. Supp. 889, 903 (N.D. Cal. 1994); *Banko*, 20 F. Supp. 3d at 756-57.[9]

Amgen's tunnel-vision interpretation of "shall" causes it to overlook the fact that the term is used in other places of the BPCIA where it indisputably cannot be interpreted as mandatory, because the broader context describes two alternative scenarios. For example, Amgen describes the final steps of Section (*l*) and claims they "lead[] up to a licensing agreement ***or*** a mandatory subsection 262(*l*)(6) lawsuit." (Mot. at 7 (emphasis added).) Where the Sponsor can choose between a license agreement and a lawsuit, such lawsuit can hardly be deemed "mandatory." Likewise, where, as here, a statute permits the resolution of patent issues through a procedural mechanism that delays litigation, or through a procedural mechanism that allows the Sponsor to move directly to patent litigation, neither approach can be described as "mandatory" and both must be interpreted as legally permitted alternatives.

Amgen's contention that Sandoz's interpretation "renders superfluous . . . the Patent provisions of the BPCIA" (Mot. at 17) is simply wrong. Under Sandoz's interpretation, all provisions of Section (*l*) remain fully intact and available to resolve patent disputes—including the procedures that brought this dispute to this Court, the procedure Amgen wished Sandoz had followed, and whatever other procedures future Applicants and Sponsors may follow as they seek to bridge the patent issues that divide them. Sandoz's view is fully consistent with the flexible approach to carrying out the intent and the express language of Section (*l*).

[9] The cases on which Amgen relies also interpret the word "shall" by looking at the statute as a whole. *See Cook v. FDA*, 733 F.3d 1, 8 (D.C. Cir. 2013) (finding "shall" to be mandatory because such an interpretation "gives meaning to the [statute's] exception to that [mandatory] command"); *Beaty v. FDA*, 853 F. Supp. 2d 30, 38-39 (D.D.C. 2012) (finding "shall" to be mandatory where the statute contained an exception that would have been rendered meaningless if "shall" were interpreted to be permissive).

In addition, under Amgen's reading of the statute, an Applicant would be forced to disclose its highly confidential and valuable information contained in the Application in all cases, even if there were no relevant unexpired patents or if the Applicant decided to avoid the cost of litigation and wait to sell its biosimilar until after the Sponsor's relevant patents expired. Forcing either outcome would illogically burden both parties with additional cost but no additional benefit. Adopting Amgen's interpretation of the statute would thus violate the fundamental principle that a statute should not be interpreted in a manner that yields absurd results. *United States v. Wilson*, 503 U.S. 329, 334 (1992) (citation omitted).

Simply put, Section (*l*) of the BPCIA provides a road map for both Applicants and Sponsors to resolve patent disputes that will arise under different circumstances, in different cases, in different places, and with differing considerations about how best to proceed. The BPCIA permitted Sandoz not to supply its Application. Once Sandoz made that decision, Section (*l*)(9)(C) provided that Amgen could immediately sue for patent infringement, and that patent disputes would be resolved in court. Amgen has done just that; it has at its disposal all of the traditional patent remedies, including the right to seek in discovery Sandoz's Application, and the right to seek a preliminary injunction to protect its patent rights.[10]

This Court should declare that Sandoz acted within its rights under the BPCIA not to provide its Application to Amgen within twenty days of learning that FDA would review filgrastim.

3. There Are Good Policy Reasons Why Congress Provided for a Flexible Approach to Resolving Patent Disputes.

That Congress would want flexibility should not be surprising, due to the difficulty in determining in advance the different facts that may apply in any one case and the myriad ways

[10] Sandoz has been willing to provide its Application to its direct competitor Amgen since July 2014. Amgen, perhaps for tactical reasons, has continually refused to accept it under appropriate confidentiality restrictions. The parties have therefore submitted competing versions of a protective order to the Court, which will resolve what level of confidentiality is appropriate. Amgen has refused Sandoz's offer to provide its Application under terms of confidentiality that Sandoz believes should apply pending the Court's ruling, which calls into question whether Amgen truly wants the Application at all.

parties can disagree about intellectual property rights and how to address them. As an example in this context, the BPCIA prevents Applicants from seeking FDA approval until the reference drug has already been on the market for four years. 42 U.S.C. § 262(k)(7)(B). The BPCIA provides twelve years of exclusivity. *Id.* § 262(k)(7)(A). In some cases, then, the parties will have eight years to work through patent disputes, and that timing will impact how both sides want to proceed. In other cases, however, the time period between seeking approval and expiration of BPCIA exclusivity will be much shorter. Such is the case here, where the Application was filed after the twelve-year exclusivity period had already expired. Countless other factors can be envisioned in which the parties' rights and needs will necessitate differing approaches to resolving patent disputes. Only a flexible approach will address all of these needs. That is the approach Congress adopted.

Many Applicants will opt to supply their Applications and engage in the Patent-Exchange Process because it offers numerous benefits. It allows the Applicant to preview the patents that the Sponsor believes are valid and infringed. It also provides assurances that certain patent-infringement actions must be brought by the Sponsor within a specified timeframe. 42 U.S.C. § 262(*l*)(6). It also allows the Applicant to control to a degree which patents are litigated.

An Applicant's election to forgo that approach to resolve patent disputes therefore brings its own set of consequences. The Applicant forfeits the right to bring certain declaratory judgment actions and to receive full information about potentially relevant patents. This means the Sponsor alone can choose whether and when to file a declaratory judgment action, potentially leaving the Applicant in the dark with respect to its patent rights and forcing another choice: whether to launch with the risk that it will lose a considerable investment and the proceeds from sales if the biosimilar is later found to infringe a valid patent.

An Applicant that evaluates the benefits and drawbacks of the various options may elect not to disclose its Application. That is exactly what happened here. Faced with confidentiality concerns about sharing its Application with Amgen, with whom it competes in the biosimilar space; having evaluated the patent landscape and concluded that Amgen did not have a valid patent covering the product or its use that could keep Sandoz's biosimilar off the market; and

seeking the quickest path to resolving patent disputes before FDA approval, Sandoz elected not to turn over its Application and instead to run the risk that Amgen would sue it over the '427 patent—a risk that was realized when Amgen filed this case. Sandoz's election fully complied with the BPCIA.

4. The BPCIA Created Procedural Mechanisms for Resolving Patent Disputes, Which Amgen Cannot Convert into Substantive Rights.

Amgen argues about what it perceives to be violations of the patent-dispute resolution procedures contained in Section (*l*), as if they, standing alone, could cause an independent injury meriting relief. Section (*l*) of the BPCIA is not, as Amgen suggests, a criminal statute designed to punish non-compliance and to protect citizens from harm. (*Cf.* Mot. at 9.) Rather, Section (*l*) provides a road map and a flexible set of procedures to resolve patent disputes. When Sandoz, as it was permitted to do, did not provide its Application within twenty days of FDA acceptance, Section (*l*) directed Amgen to bring its patent lawsuit, which it has done. Under any permitted scenario, Amgen only suffers cognizable harm here if the '427 patent is valid and Sandoz infringes it.

To the extent Amgen wants to misinterpret the procedural choice Sandoz was free to make as a "violation" of Section (*l*), the procedural "remedy"—i.e., commencing a patent infringement suit—is found in Section (*l*)(9)(C). Amgen nonetheless contends that Section (*l*)(9)(C) is "not remedial." (Mot. at 15.) That is, at best, ironic, given that Amgen has followed Section (*l*)(9)(C) in bringing this lawsuit. Semantics aside, perhaps what Amgen meant to argue is that the "remedy" in Section (*l*)(9)(C) is not to Amgen's liking. But it is the only one Congress provided. Amgen improperly tries to convert the Section (*l*) ***procedures*** for evaluating patent disputes into ***substantive*** rights and then to add a remedy for that supposed "right" by seeking relief not authorized by the statute. Congress could easily have provided for restitution, or authorized an injunction, or directed FDA not to approve the Application until the Applicant provided its Application to the Sponsor. Congress did not, and this Court should not add those remedies or give Section (*l*) "a more drastic effect [that] would tend to defeat the broad purpose of the enactment." *Washingtonian Publ'g Co. v. Pearson*, 306 U.S. 30, 41 (1939) (refusing to read the

Copyright Act of 1909's deposit requirement as a mandatory prerequisite to perfecting a copyright, even though statute contained remedies for failure to deposit). As a result, the Court should enter an Order rejecting Amgen's interpretation of the BPCIA, and accepting Sandoz's interpretation.

C. Amgen's State-Law Claims Should Be Dismissed.

Amgen's state-law claims of unfair competition and conversion are premised on an assumption that Sandoz violated the BPCIA. Because Sandoz provided notice of commercial marketing under Section (*l*)(8)(A), and because BPCIA Section (*l*) provides for Amgen and Sandoz to resolve their patent issues in the exact manner that brought them to this court, Sandoz has not violated any laws. Without the predicate wrongful conduct required by the state-law claims Amgen asserts, those claims, which find no place in this patent dispute, should be dismissed.

1. The UCL Claim Should Be Dismissed Because Sandoz Did Not Engage in Unlawful Activity and Congress Already Balanced the Relevant Competing Interests.

Amgen's claim under California's unfair competition law, Cal. Bus. & Prof. Code § 17200 *et seq.* ("UCL"), assumes that Sandoz engaged in unlawful conduct. But it is well established that an absolute defense to a UCL claim is that the conduct has been authorized by the legislature. *See, e.g.*, *Schnall v. Hertz Corp.*, 93 Cal. Rptr. 2d 439, 451 (Ct. App. 2000) (finding no UCL claim because "where the allegedly unfair business practice has been authorized by the Legislature, no factual or equitable inquiry need be made, as the court can decide the matter entirely on the law").[11] Because, as described above, Sandoz fully complied with the BPCIA, Sandoz has not violated any laws. Therefore, the Court should dismiss Amgen's UCL claim.

Of equal importance, California's UCL is not the proper vehicle for this Court to right the alleged wrongs of which Amgen complains. The California legislature conferred upon courts

[11] *See also Smith v. State Farm Mut. Auto. Ins. Co.*, 113 Cal. Rptr. 2d 399, 414 (Ct. App. 2001) (conduct cannot be "unlawful" for purposes of the UCL where defendant's actions do not violate the law); *Lazar v. Hertz Corp.*, 82 Cal. Rptr. 2d 368, 375 (Ct. App. 1999) (plaintiff failed to state UCL claim based on "unlawful" conduct where court had determined defendant's conduct did not violate the statute at issue).

such authority "as *may* be necessary to prevent the use or employment by any person of any practice which constitutes unfair competition." Cal. Bus. & Prof. Code § 17203 (emphasis added). Courts have characterized this ability to provide relief under the UCL as deriving from "a grant of broad equitable power." *Cortez v. Purolator Air Filtration Prods. Co.*, 999 P.2d 706, 717 (Cal. 2000). To properly fashion this relief, "consideration of the equities between the parties is necessary to ensure an equitable result." *Id.* But this Court does not need to reinvent the wheel by considering the equities between the parties: Congress has already done so. By its own express statement of intent, Congress sought to "balanc[e] innovation and consumer interests." Engrafting UCL remedies onto this statutory scheme would tip the scales in favor of the Sponsor and upset the balance so carefully crafted by Congress.

The UCL is an improper remedy for yet another reason: it is available *only in California*. California's UCL is unique among state unfair and deceptive trade practices acts because it is the only such act that prohibits activity that is allegedly "unlawful" under another statute or regulation. Cal. Bus. & Prof. Code § 17200 ("[U]nfair competition shall mean and include any ***unlawful***, unfair or fraudulent business act or practice" (emphasis added)). This "bootstrapping" is unique to the UCL. *See* William L. Stern, *Bus. & Prof. C. § 17200 Practice* 3:53 (Rutter Group 2014) (UCL unique in permitting cause of action for violation of other law). If Amgen were permitted to enjoy the benefits of an injunction under the UCL, that remedy would be available only because Amgen is a California resident, thereby creating an inconsistent framework of rights dependent on the parties' residence. *See Norwest Mortg., Inc. v. Super. Ct.*, 85 Cal. Rptr. 2d 18, 26-27 (Ct. App. 1999) (UCL cannot reach conduct outside California by non-California resident). Amgen cites no provision in the BPCIA supporting such an outcome.

As for the "consumer interests" that Congress sought to balance, Congress made no statement that the interests of any one state's residents should be given more or less weight than those of another state's. But application of UCL remedies would do just that. If Amgen prevails, sales of Sandoz's biosimilar cancer drug will be delayed only in California. Amgen's drive for profit has blinded it to the fact that the relief it urges here comes at the expense of cancer patients in California—and those who subsidize their care—the only consumers who will not benefit

from prompt access to more affordable biosimilar filgrastim. We respectfully submit that the UCL was not designed to achieve that result.

a. Amgen's Motion Fails to Demonstrate That the California UCL Applies Here.

Under California choice-of-law principles, California applies the three-step "governmental interest analysis": (1) whether the laws of the potentially affected jurisdictions differ; (2) if so, whether there is a "true conflict" given each jurisdiction's interest in the application of its own laws in the facts and circumstances of the case; and (3) if so, which jurisdiction's interests would be most impaired if its laws were not applied. *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 590 (9th Cir. 2012); *McCann v. Foster Wheeler LLC*, 225 P.3d 516, 527 (Cal. 2010). Here, Amgen is a resident of California; Sandoz has its principal place of business in New Jersey and is incorporated in Colorado; and the cancer patients to be treated reside throughout the United States. As *Mazza* recognizes, with respect to statutes such as the UCL, states may appropriately strike different balances between maximizing consumer and business welfare. *Mazza*, 666 F.3d at 592-93.

New Jersey courts have, for example, held that under California choice-of-law rules New Jersey's interest in regulating its corporations warranted the application of New Jersey law. *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 64 (D.N.J. 2009) ("New Jersey's interest in regulating Mercedes, a corporation located within its borders, requires the application of New Jersey law to Plaintiffs' consumer fraud claims under the 'government interest' choice of law test utilized by California and New York."). And both New Jersey and Colorado (and indeed, every state paying medical costs for its citizens) have an evident interest in obtaining lower-cost medications for cancer patients. So do countless companies deciding whether to call California their home. Further, California's interests are not significantly impaired if New Jersey or Colorado law is applied, because Amgen retains its right to enforce its '427 patent against Sandoz under patent law.

2. Amgen's Conversion Claim Should Also Be Dismissed.

Just as Amgen cannot replace the remedy Congress provided to resolve patent disputes with California's UCL, Amgen cannot blue-pencil the BPCIA and add a right to assert a conversion claim. Like the failed UCL claim, a conversion claim cannot survive in the absence of unlawful conduct. Under California law, "[t]he elements of a conversion claim are: (1) the plaintiff's ownership or right to possession of the property; (2) the defendant's conversion by a ***wrongful act*** or disposition of property rights; and (3) damages." *Burlesci v. Petersen*, 80 Cal. Rptr. 2d 704, 706 (Ct. App. 1998) (citations omitted) (emphasis added). Conversion "rests upon the unwarranted interference by defendant with the dominion over the property of the plaintiff from which injury to the latter results." *Id.* Again, because Sandoz's decision not to provide its Application to Amgen was not unlawful, Amgen's claim for conversion necessarily fails and should be dismissed. Further, as discussed above, Amgen has not shown it has suffered any cognizable harm that would warrant a remedy under its common law conversion claim. Any such remedy would circumvent the patent dispute resolution processes that Congress provided in Section (*l*) of the BPCIA.

In any event, Amgen does not and cannot meet the requirements for demonstrating conversion of an intangible property right. The Ninth Circuit has interpreted California law as imposing a three-part test. "First, there must be an interest capable of precise definition; second, it must be capable of exclusive possession or control; and third, the putative owner must have established a legitimate claim to exclusivity." *G.S. Rasmussen & Assocs. v. Kalitta Flying Serv.*, 958 F.2d 896, 903 (9th Cir. 1992). Amgen cannot satisfy the second or third elements with respect to its biologics license application (BLA). That is because the BPCIA expressly permits Applicants to use Amgen's BLA to file their Applications. 42 U.S.C. § 262(k)(2)(A)(iii). If Congress allows Applicants like Sandoz to use Amgen's BLA, Amgen cannot establish an exclusive ownership interest in the BLA, nor can it establish a "legitimate claim to exclusivity."

Further, the California courts have consistently rejected theories that seek to expand conversion law, particularly where the proposed expansion seeks to (a) interfere with the balance struck by a statute, such as the BPCIA, between the interests of the putative owner of intangible

property rights and the interests of the public in the availability of important products and technologies; or (b) end-run the requirements of patent law. *See Miles, Inc. v. Scripps Clinic and Research Found.*, 810 F. Supp. 1091, 1095 (S.D. Cal. 1993) (refusing to expand California law to recognize a cause of action for conversion of the intangible right to commercialization of a cell line); *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 143-44, 793 P.2d 479 (Cal. 1990) (refusing to extend a conversion cause of action to a person's cells where physician's existing statutory disclosure obligations provided plaintiff sufficient protection). As a result, the conversion claim should be dismissed.

D. Sandoz's Sixth and Seventh Counterclaims Should Not Be Dismissed.

Amgen's Complaint alleges that the '427 patent is valid and infringed by Sandoz. As is customary in patent litigation, Sandoz responded with counterclaims seeking declaratory judgment that the '427 patent is neither. Amgen now argues that these counterclaims are barred because, according to Amgen, Section (*l*)(9)(C)—the very section Amgen refuses to honor in full—mandates that only Amgen, not Sandoz, "may file a declaratory judgment action" at this juncture. (Mot. at 24.)

Amgen's argument fails because ***Amgen***, not Sandoz, has brought this action. Section (*l*)(9)(C) states in relevant part that "the reference product sponsor, but not the subsection (k) applicant, may ***bring an action*** under section 2201 of title 28, United States Code, for a [declaratory judgment] . . . ." 42 U.S.C. § 262(*l*)(9)(C) (emphasis added). Once that action is filed, traditional patent litigation rules apply. Courts have long held that the assertion of counterclaims is not "bring[ing] an action." *Alexander v. Hillman*, 296 U.S. 222, 241 (1935) (assertion of counterclaims is not commencement of a suit); *see also Gen. Elec. Co. v. Marvel Rare Metals Co.*, 287 U.S. 430, 435 (1932) ("[O]ne who sues in a federal court of equity to enjoin the infringement of his patent, thereby submits himself to the jurisdiction of the court with respect to all the issues of the case, including those pertaining to a counterclaim . . . ."). Sandoz may file any and all counterclaims relating to the infringement claims against it—and nothing in the BPCIA suggests otherwise. Indeed, because the counterclaims "arise[] out of the transaction or occurrence that is the subject matter of the opposing party's claim," Federal Rule of Civil

Procedure 13(a)(1) makes clear that Sandoz must assert these counterclaims or they will be waived. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 801-02 (Fed. Cir. 1999).

It is curious that Amgen (a) elects not to move for relief under the '427 patent, the only substantive rights Amgen has in this case; and (b) tries to limit Sandoz's proactive ability to reveal this patent for what it is: invalid and not infringed by Sandoz. In any event, like its other arguments, Amgen's argument hinges on a misinterpretation of the BPCIA. Amgen's motion for judgment against Sandoz's Sixth and Seventh Counterclaims should therefore be denied.

IV. CONCLUSION

For all the foregoing reasons, Sandoz respectfully requests that the Court issue an order denying Amgen's Motion for Judgment on the Pleadings, and dismissing Amgen's First and Second Causes of Action with prejudice. Sandoz also seeks an order granting Sandoz's cross-motion, and entering judgment on Amgen's First and Second Causes of Action and on Sandoz's First through Fifth Counterclaims.

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MORRISON & FOERSTER LLP

By: /s/ Rachel Krevans
Rachel Krevans

Attorneys for Defendant
SANDOZ INC.