

United States District Court
Northern District of California

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

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,
Plaintiffs,

v.

SANDOZ INC., et al.,
Defendants.

Case No. [14-cv-04741-RS](#)

**ORDER ON CROSS MOTIONS FOR
JUDGMENT ON THE PLEADINGS
AND DENYING MOTION FOR
PRELIMINARY INJUNCTION**

I. INTRODUCTION

This dispute arises from conflicting interpretations of the Biologics Price Competition and Innovation Act (“BPCIA”), which established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market (“biosimilars”) to receive Food and Drug Administration (“FDA”) license approval. *See* 42 U.S.C. § 262(k), (l). The BPCIA allows a drug maker who demonstrates the biosimilarity of its product to one which has already received FDA approval (the “reference product”) to rely on studies and data completed by the reference product producer (“reference product sponsor”), saving years of research and millions in costs. Through its amendments to both 42 U.S.C. § 262 and 35 U.S.C. § 271, the BPCIA also enabled a process for resolving patent disputes arising from biosimilars, whereby applicants and sponsors may participate in a series of disclosures and negotiations aimed at narrowing or eliminating the prospect of patent litigation. While engagement in the process creates a temporary safe harbor from declaratory judgment actions, a party’s failure to participate

1 permits the opposing party to commence patent litigation.

2 Plaintiffs Amgen, Inc. and Amgen Manufacturing, Ltd. (collectively “Amgen”) have
 3 produced and marketed the biologic product filgrastim under the brand-name Neupogen since
 4 1991. They aver that defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH,¹
 5 who in July 2014 applied to the FDA to receive biosimilar status for their filgrastim product in
 6 order to begin selling it in the United States, behaved unlawfully under 42 U.S.C. § 262 by failing
 7 to comply with its disclosure and negotiation procedures. Amgen alleges these transgressions give
 8 rise to claims under California’s Unfair Competition Law (“UCL”) and for conversion, as well as
 9 patent infringement as to U.S. Patent No. 6,162,427 (“’427 patent”). Sandoz counterclaims for
 10 declaratory judgment adopting its interpretation of the BPCIA and finding its conduct permissible
 11 as to Amgen’s UCL and conversion claims; and for noninfringement and invalidity of the ’427
 12 patent. The parties each filed cross-motions for partial judgment on the pleadings.² Amgen, in
 13 addition, requests a preliminary injunction to forestall Sandoz’s market entry until a disposition on
 14 the merits has issued.³

15 While there is no dispute that Sandoz did not engage in 42 U.S.C. § 262’s disclosure and
 16 dispute resolution process, its decision not to do so was within its rights. Amgen’s motion for
 17 partial judgment on the pleadings or partial summary judgment in the alternative is, accordingly,
 18 denied, and its UCL and conversion claims are dismissed with prejudice. As the BPCIA does not
 19 bar Sandoz’s counterclaims for noninfringement and invalidity of the ’427 patent, these claims
 20 may advance. In addition, Amgen’s motion for preliminary injunction is, accordingly, denied.

21 _____
 22 ¹ Of the named defendants, only Sandoz, Inc. has responded to Amgen’s suit thus far. Sandoz,
 23 Inc. will be referred to herein simply as “Sandoz.”

24 ² Amgen notes that, while the standards under these rules are similar, it brings its motion under
 25 both Rule 12(c) and Rule 56 to account for conflicting case law as to whether a court may rule
 only as to certain claims, but not others, on a motion for judgment on the pleadings.

26 ³ Since then, however, the parties stipulated that Sandoz would not market its product until the
 27 earlier of either a partial judgment on the pleadings in its favor, or April 10, 2015. Sandoz further
 agreed that, should it receive a favorable ruling before April 10, 2015, it will give Amgen five
 days’ notice before launching its product.

II. BACKGROUND

A. Relevant Provisions of the BPCIA

The dispute presented in the pending motions exclusively concerns questions of law—specifically, of statutory interpretation, as to several provisions in 42 U.S.C. § 262 and 35 U.S.C. § 271(e), both amended in 2010 via Congress’s enactment of the BPCIA. The Act’s stated purpose was to establish a “biosimilars pathway balancing innovation and consumer interests.” Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). At issue in particular are two central provisions of 42 U.S.C. § 262: (1) paragraphs (1)(2)-(1)(6), which lay forth the disclosure and negotiation process that commences with an applicant sharing its Biologic License Application (“BLA”) and manufacturing information with the reference product sponsor within twenty days of receiving notice that the FDA has accepted the application for review; and (2) paragraph (1)(8), requiring an applicant to give the sponsor at least 180 days’ advance notice of the first commercial marketing of its biosimilar. Understanding these particular provisions requires a review of the statutory context.

Subsection (a) of 42 U.S.C. § 262 sets forth standards for FDA approval of biologic products. Among other requirements, applicants must demonstrate that their products are safe, pure, and potent. Subsection 262(k) establishes an abbreviated pathway by which a product “biosimilar” to one previously approved under subsection (a) (a “reference product”) may rely on the FDA’s prior findings of safety, purity, and potency to receive approval. According to subsection (k), any entity which demonstrates its biologic product is sufficiently similar to a reference product may apply for an FDA license to market its biosimilar product. Applications must include publicly available information as to the FDA’s prior determination of the reference product’s safety, purity, and potency, and may include additional publicly available information. 42 U.S.C. § 262(k)(2)(A).

The FDA may not approve a biosimilarity application until twelve years after the date on which the reference product was first licensed under subsection (a); in other words, reference products are entitled to twelve years of market exclusivity. Biosimilarity applicants are precluded

1 from even submitting applications under subsection (k) until four years after the licensing of the
2 reference product. 42 U.S.C. § 262(k)(7)(A), (B).

3 Subsection 262(l) sets forth a process and timeline by which an applicant and reference
4 product sponsor “shall” participate in a series of informational exchanges regarding potential
5 disputes over patent validity and infringement. As long as both parties continue to comply with
6 these disclosure and negotiation steps, neither may bring a declaratory action regarding patent
7 validity, enforceability, or infringement against the other until the applicant provides notice of its
8 upcoming first commercial marketing. 42 U.S.C. § 262(l)(9)(A)-(C).

9 The BPCIA also added to 35 U.S.C. § 271, which governs patent infringement, a provision
10 rendering it “an act of infringement to submit” a subsection (k) application based on a patent the
11 reference product sponsor identified (or could have identified) as infringed by the applicant’s
12 biosimilar product under subsection (l)’s disclosure and negotiation procedures. 35 U.S.C. §
13 271(e)(2)(C). In addition to enabling a reference product sponsor to initiate an infringement
14 action for an applicant’s reliance on its product, subsection 271(e) sets forth remedies for instances
15 in which liability for infringement is found. Where the sponsor identified or could have identified
16 the infringed patent on its initial disclosure to the applicant under 42 U.S.C. § 262(l)(3), injunctive
17 relief may be granted to prevent such infringement, while damages or other monetary relief may
18 only be awarded if there has been commercial manufacture, use, offer to sell, or sale within the
19 United States of an infringing product. Other than attorney fees, these are “the only remedies
20 which may be granted by a court for [infringement of such a patent].” 35 U.S.C. § 271(e)(4)(B)-
21 (D). Where, however, the infringed patent appears on the parties’ agreed-upon list of patents that
22 should be subject to an infringement action, 42 U.S.C. § 262(l)(4), or their respective lists of such
23 patents, 42 U.S.C. § 262(l)(5)—and the sponsor did not sue within the time frame prescribed in
24 subsection (l), had its suit dismissed without prejudice, or did not prosecute its suit to judgment in
25 good faith—the “sole and exclusive remedy” for infringement “shall be a reasonable royalty.” 35
26 U.S.C. § 271(e)(6).

27 Together, 42 U.S.C. § 262(l) and 35 U.S.C. § 271(e) reflect an integrated scheme that

1 provides consequences for the choice either party makes at each step of subsection (l)'s
2 information exchange to carry on the process, or end it and allow patent litigation to commence.
3 At one step in this series of tradeoffs, for example, the applicant has sixty days to respond to a list
4 of patents the sponsor flagged in the prior step as potential grounds for an infringement suit. The
5 applicant, according to 42 U.S.C. § 262(l)(3)(B)(ii), must provide the factual and legal basis for its
6 beliefs that any patents flagged by the sponsor are invalid, unenforceable, or not infringed by its
7 biosimilar. If the applicant does not complete this step, however, the sponsor may bring a
8 declaratory judgment action for any patents it flagged in the prior step. 42 U.S.C. § 262(l)(9)(B).
9 Conclusion of the process yields a list of patents on which a sponsor may bring suit within thirty
10 days. 42 U.S.C. § 262(l)(6). Should the sponsor elect not to do so, it may collect only a
11 reasonable royalty. 35 U.S.C. § 271(e)(6)(A). Thus, to continue the process or to terminate it
12 confers advantages and disadvantages the parties must weigh at each step.

13 **B. Procedural Background**

14 Since 1991, Amgen has produced and marketed the biologic product filgrastim under the
15 brand-name Neupogen as a result of the FDA's approval of Amgen's application for a license to
16 market the product pursuant to BLA No. 103353. Neupogen was originally approved for
17 decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with
18 nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a
19 significant incidence of severe neutropenia with fever. The FDA subsequently approved
20 additional therapeutic indications for the drug, such as aiding faster engraftment and recovery for
21 bone marrow transplant patients.

22 On July 7, 2014, Sandoz received notice that the FDA had accepted for review its BLA for
23 approval of a biosimilar filgrastim product under subsection (k). The next day, it mailed a letter to
24 Amgen offering to share a copy of its BLA under the protection of a proposed Offer of
25 Conditional Access; notifying Amgen that it believed it would receive FDA approval in the first or
26 second quarter of 2015; and stating its intent to market its biosimilar product immediately
27 thereafter. Sandoz sent Amgen a second letter on July 25 again offering conditional access to its

1 BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (l)'s procedures,
2 and that Amgen could instead procure information via an infringement action. Amgen, it appears,
3 declined both offers to view Sandoz's biosimilarity BLA under Sandoz's proposed terms. Only
4 after a protracted dispute did the parties, on February 9, 2015, enter a stipulated protective order
5 providing Amgen protected access to Sandoz's BLA and related application materials. They did
6 not engage in any further patent information exchanges.

7 Amgen initiated this action on October 24, 2014, asserting claims of (1) unlawful
8 competition under Cal. Bus. & Prof. Code § 17200 et seq. based on two alleged violations of the
9 BPCIA; (2) conversion; and (3) infringement of Amgen's '427 patent. According to Amgen,
10 failure to comply with subsection (l)'s disclosure and negotiation procedures and its interpretation
11 of subparagraph (l)(8)(A)'s 180-day notice requirement each comprise an unlawful business
12 practice actionable under the UCL. In addition, Amgen contends, Sandoz's use of Amgen's FDA
13 license for Neupogen in its biosimilarity BLA without abiding by subsection (l)'s procedures rises
14 to an act of conversion.

15 Alongside its answer, the following month Sandoz asserted seven counterclaims seeking
16 declaratory judgments in favor of its interpretation of the BPCIA, as well as non-infringement and
17 invalidity of the '427 patent. Specifically, these counterclaims are for the following declaratory
18 judgments: (1) subsection (k) applicants may elect not to provide their applications to the
19 reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(l)(9)(C); (2)
20 the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection
21 (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to
22 comply with 42 U.S.C. § 262(l)'s disclosure, negotiation, and notification provisions; (4) the
23 BPCIA renders remedies under UCL and conversion claims unlawful and/or preempted; (5) a
24 reference product sponsor does not maintain exclusive possession or control over its biologic
25 product license; (6) noninfringement of the '427 patent; and (7) invalidity of the '427 patent.

26 Amgen now moves for partial judgment on the pleadings, or partial summary judgment in
27 the alternative, as to the two bases in the BPCIA for its UCL claim, and for declaratory judgment

1 barring Sandoz’s sixth and seventh counterclaims. Sandoz cross-moves for partial judgment on
 2 the pleadings granting declaratory judgment in favor of its first through fifth counterclaims, for
 3 dismissal with prejudice of Amgen’s UCL and conversion claims, and for denial of Amgen’s
 4 motion.

5 III. LEGAL STANDARDS

6 While the Federal Circuit is the court of appeal for all cases raising claims under patent
 7 law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. 1338(a); *Holmes*
 8 *Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs.*
 9 *v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Ninth Circuit law therefore governs the
 10 disposition of the parties’ cross-motions.

11 Rule 12(c) of the Federal Rules of Civil Procedure provides that “[a]fter the pleadings are
 12 closed—but early enough not to delay trial—a party may move for judgment on the pleadings.”
 13 Such a motion, like one brought under Rule 12(b)(6), challenges the “the legal sufficiency of the
 14 opposing party’s pleadings.” *Qwest Communications Corp. v. City of Berkeley*, 208 F.R.D. 288,
 15 291 (N.D. Cal. 2002). Accordingly, “a plaintiff is not entitled to judgment on the pleadings when
 16 the answer raises issues of fact that, if proved, would defeat recovery.” *General Conference Corp.*
 17 *of Seventh–Day Adventists v. Seventh–Day Adventist Congregational Church*, 887 F.2d 228, 230
 18 (9th Cir. 1989). A defendant’s sufficient pleading of an applicable affirmative defense likewise
 19 will defeat a plaintiff’s motion. *Id.* Regardless of what facts or affirmative defenses may be
 20 raised by an answer, however, a plaintiff’s motion may not be granted absent a showing that he or
 21 she “is entitled to judgment as a matter of law.” *Hal Roach Studios, Inc. v. Richard Feiner & Co.,*
 22 *Inc.*, 896 F.2d 1542, 1550 (9th Cir. 1989).

23 Rule 56(a) of the Federal Rules of Civil Procedure provides that a “court shall grant
 24 summary judgment if the movant shows that there is no genuine dispute as to any material fact and
 25 the movant is entitled to judgment as a matter of law.” The party who seeks summary judgment
 26 bears the initial responsibility of identifying the absence of a genuine issue of material fact.
 27 *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this initial

1 burden, it shifts to the non-moving party to present specific facts showing that there is a genuine
 2 issue for trial. *Celotex*, 477 U.S. at 324. “Only disputes over facts that might affect the outcome of
 3 the suit under governing law” are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248
 4 (1986). A genuine issue exists if the non-moving party presents evidence from which a reasonable
 5 factfinder, viewing the evidence in the light most favorable to that party, could resolve the
 6 material issue in his or her favor. *Id.* at 248–49.

7 IV. DISCUSSION

8 As noted above, this dispute hinges on the interpretation of two portions of subsection 42
 9 U.S.C. § 262(l) of the BCPIA. According to Amgen, Sandoz acted unlawfully because it (1)
 10 failed to comply with subsection (l)’s disclosure and negotiation procedures; and (2) intends to
 11 market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least
 12 180 days thereafter. These actions, Amgen avers, constitute the predicate wrongful behavior to
 13 sustain its claims under the UCL. Sandoz also committed conversion, avers Amgen, by making
 14 use of Amgen’s FDA license for Neupogen in its biosimilarity BLA.⁴

15 Sandoz contends its actions have comported with the letter and spirit of the BPCIA,
 16 necessitating, therefore, the denial of Amgen’s motion and dismissal of its UCL and conversion
 17 claims. As the analysis below demonstrates, Sandoz’s reading of the statute is the more coherent
 18 of the two, and merits granting, in part, Sandoz’s motion.

19 The interpretation of a statute is a question of law whose answer begins with an
 20 examination of the plain meaning of the statute. *United States v. Gomez–Osorio*, 957 F.2d 636,
 21 639 (9th Cir. 1992). Words not otherwise defined take on their ordinary, common meaning. The
 22 court must, however, read a statute’s language in context and with regard to its role in the overall
 23

24 _____
 25 ⁴ While Amgen contended at oral argument that the BPCIA enables a private right of action from
 26 which its suit against Sandoz could, alternatively, have arisen, this set of motions does not
 27 properly raise that issue and it, accordingly, will not be addressed. Amgen is left with the
 untenable argument that Congress intended not a self-contained statutory scheme under the
 BPCIA, but rather contemplated a hunt by reference product sponsors through the laws of the fifty
 states to find a predicate by which to litigate a claimed BPCIA violation.

1 statutory framework, looking to legislative history as appropriate. *FDA v. Brown & Williamson*
 2 *Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Morton*, 467 U.S. 822, 828 (1984). If
 3 the statutory language is unambiguous, and the statutory scheme is coherent and consistent, that
 4 should mark the end of a court’s interpretative inquiry. *Miranda v. Anchondo*, 684 F.3d 844, 849
 5 (9th Cir. 2012).

6 A. BPCIA: Disclosure and Negotiation Procedures

7 As noted above, Sandoz elected not to supply Amgen with a copy of its BLA and
 8 manufacturing process description within twenty days from notice that the FDA had accepted its
 9 application for review,⁵ and to engage in subsection (l)’s subsequent series of disclosures and
 10 negotiations regarding potential patent disputes. These acts, Amgen avers, amount to unlawful
 11 transgressions of mandatory requirements for subsection (k) applicants set forth in 42 U.S.C. §
 12 262(l)(2)-(8). Indeed, these paragraphs repeatedly use the word “shall” to describe the parties’
 13 obligations under its prescribed procedures. Subparagraph (l)(9)(B) moreover characterizes lack
 14 of compliance as a “fail[ure] to provide the application and information required.”

15 While such phrasing lends support to Amgen’s reading, Sandoz’s overall interpretation of
 16 the statute’s plain language is more persuasive. While Amgen correctly notes that subsection (l)
 17 uses the word “may” in certain paragraphs, thereby suggesting that the use of “shall” in others
 18 implies an action is required, several countervailing factors reflect otherwise. First, that an action
 19 “shall” be taken does not imply it is mandatory in all contexts. It is fair to read subsection (l) to
 20 demand that, if both parties wish to take advantage of its disclosure procedures, then they “shall”
 21 follow the prescribed procedures; in other words, these procedures are “required” where the
 22 parties elect to take advantage of their benefits, and may be taken away when parties “fail.”

23 That compliance allows an applicant to enjoy a temporary safe harbor from litigation and,
 24 potentially, to resolve or narrow patent disputes outside court proceedings, bolsters this reading.

25
 26 _____
 27 ⁵ Whether Amgen effectively declined access to Sandoz’s BLA within these twenty days pursuant
 28 to Sandoz’s July 2014 letters is a factual matter disputed by the parties, and is not at issue here.

1 Subparagraphs (I) (9)(B) and (C) contemplate the scenario in which an applicant does not comply
 2 at all with disclosure procedures, or fails to follow through after having begun the process. They
 3 allow the reference product sponsor to commence patent litigation immediately in either
 4 instance—removing (or precluding) availability to the applicant of a litigation safe harbor.
 5 Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an
 6 applicant’s failure to disclose information regarding a potentially infringed patent under
 7 subsection (I)’s requirements is immediately actionable, making it clear that such a dispute is ripe
 8 for adjudication.

9 Such an interpretation would not be wholly without precedent; other district courts faced
 10 with a similar question have found that failure to comply with a provision containing “shall” was
 11 not unlawful, where the statute contemplated and provided for such a scenario. See *County of*
 12 *Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff’d*, 776
 13 F.3d 947 (8th Cir. 2014) (finding a statute stating that “[e]very conveyance of real estate shall be
 14 recorded” and that “every such conveyance not so recorded shall be void” was not mandatory
 15 because the statutory language “specifically contemplate[d] that not all conveyances will be
 16 recorded and outlines the consequence of failing to do so.”)

17 Further, while Amgen contends persuasively that use of subsection (I)’s procedures can
 18 serve important public interests, including potential reduction of patent litigation and protection
 19 for innovators, nowhere does the statute evidence Congressional intent to enhance innovators’
 20 substantive rights. In contrast to numerous other federal civil statutes which offer a claim for
 21 relief and specify remedies, here Congress did more than remain silent—it expressly directed
 22 reference product sponsors to commence patent infringement litigation in the event of an
 23 applicant’s non-compliance. Even in subsection (I) itself, subparagraph (I)(8)(B) is clear in
 24 providing the remedy of a preliminary injunction for failure to give the 180-day notice required in
 25 (I)(8)(A). It is therefore evident that Congress intended merely to encourage use of the statute’s
 26 dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor
 27 for applicants who otherwise would remain vulnerable to suit. The statute contains no stick to

1 force compliance in all instances, and Amgen does not identify any basis to impute one.

2 Indeed Sandoz's decision not to comply with subsection (l) reflects how the statute's
3 overall scheme operates to promote expedient resolution of patent disputes. Compliance with the
4 disclosure process affords an applicant many benefits: it allows the applicant to preview which
5 patents the reference product sponsor believes are valid and infringed, assess related factual and
6 legal support, and exercise some control over which patents are litigated and when. An applicant
7 with a high (or unknown) risk of liability for infringement could benefit considerably from this
8 process: it would be able to undergo the information exchange while protected by the statute's safe
9 harbor from litigation, and if necessary, delay its product launch to protect the investment it made
10 in developing its biosimilar.

11 On the other hand, subsection (l) lays out a process that could take up to 230 days—just to
12 commence patent litigation. An applicant who values expedience over risk mitigation may believe
13 that the disclosure and negotiation process would introduce needless communications and delay.
14 Such an applicant may have good reason to believe that no unexpired relevant patents relate to its
15 biosimilar, and that it is likely to prevail if challenged with an infringement suit. The applicant
16 may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and
17 receive information about potentially relevant patents from the reference product sponsor, and
18 instead commence litigation immediately.

19 Perhaps confident in its limited exposure to liability and eager to resolve patent disputes so
20 as not to face delays to market entry, Sandoz opted to invite a suit from Amgen soon after filing its
21 BLA with the FDA.⁶ Had the parties followed subsection (l)'s disclosure and negotiation

22
23 ⁶ While Amgen contends that the path chosen by Sandoz enables biosimilar producers to evade
24 liability for patent infringement because biosimilar producers may keep reference product
25 sponsors in the dark about their biosimilarity BLAs and plans to take their products to market, the
26 180-day notice requirement addressed below mitigates such concerns. With six months' advance
27 notice of a biosimilar producer's intent to commence sales, a reference product sponsor who
28 believes it may have an infringement claim can file suit to access the biosimilarity BLA,
manufacturing process, and other relevant information via discovery—as in any other typical
instance of potential infringement. While Amgen may have preferred that Sandoz share this
information voluntarily, the BPCIA rendered it Sandoz's choice to make.

1 procedures, it is unlikely the present infringement action—filed in October 2014—would have
 2 even commenced until mid-March 2015, given the 230-day timeline over which subsection (l)’s
 3 procedures are designed to unfold. Sandoz therefore traded in the chance to narrow the scope of
 4 potential litigation with Amgen through subsection (l)’s steps, in exchange for the expediency of
 5 an immediate lawsuit. The BPCIA’s plain language and overall statutory scheme support a
 6 reading that renders this decision entirely permissible.

7 **B. BPCIA: One Hundred Eighty Days’ Notice Prior to First Commercial Marketing**

8 The most reasonable interpretation of paragraph (l)(8) of 42 U.S.C. § 262 also favors
 9 Sandoz. As noted above, this provision dictates that an applicant “shall provide notice to the
 10 reference product sponsor not later than 180 days before the date of the first commercial
 11 marketing of the biological product licensed under subsection (k).” 42 U.S.C. § 262(l)(8)(A).

12 Upon receiving such notice, the reference product sponsor may seek a court order enjoining such
 13 market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. §
 14 262(l)(8)(B). It may also initiate a declaratory judgment action. 42 U.S.C. § 262(l)(9)(B).

15 Amgen makes too much of the phrase quoted above from subparagraph (l)(8)(A). It argues
 16 that the word “licensed,” a past tense verb, means an applicant may not give the required 180-day
 17 notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—
 18 resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market
 19 entry. Amgen draws support for this reading from Congress’s use in other paragraphs of the
 20 statute of the phrase “subject of an application under subsection (k)” to refer to biosimilars. *See,*
 21 *e.g.*, 42 U.S.C. § 262(i)(2). Congress employs the distinction between the two phrasings, asserts
 22 Amgen, to signal whether it intends a particular provision to refer to a biosimilar before or after it
 23 has received FDA approval. Amgen contends that the only logical conclusion, therefore, is that
 24 because (l)(8)(A) refers not to the “subject of an application,” but rather a “licensed” product,
 25 FDA approval must be a condition precedent to valid notice.

26 Amgen’s attempt to bolster this interpretation by referencing a prior decision of this
 27 district, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12,

2013), has little effect. In that case, Sandoz sued to obtain a declaratory judgment that two patents were invalid, unenforceable and would not be infringed if Sandoz used, offered to sell, sold, or imported a drug product “biosimilar” to Amgen’s etanercept product Enbrel. Finding for Amgen on Article III standing grounds, the court stated merely in passing that, in addition, Sandoz could not obtain a declaratory judgment prior to filing an FDA biosimilarity application according to the procedures set forth in 42 U.S.C. § 262(l). While Sandoz contended that its suit complied with section 262(l), which permits actions for declaratory judgment once a manufacturer of a licensed biosimilar has provided notice of commercial marketing, the district court—looking only to the language of the statute itself—wrote that “as a matter of law, [Sandoz] cannot have provided a [such notice] because . . . its [biosimilar] product is not ‘licensed under subsection (k).’” *Id.* The Federal Circuit affirmed the district court’s ruling on standing grounds, but expressly declined to address its BPCIA interpretation, which had not been briefed for the district court and was not dispositive in its ruling. This prior case, therefore, has little persuasive authority over the present dispute.

Indeed the more persuasive interpretation accounts for the fact that FDA approval must precede market entry. It would be nonsensical for subparagraph (l)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its “first commercial marketing” a biosimilar must, in all instances, be a “licensed” product. “Before” modifies “first commercial marketing”; “licensed” refers only to “biological product”—not the appropriate time for notice.

Even more problematic with Amgen’s reading is the impact it would have on the overall statutory scheme. Because the FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen’s reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A).⁷ Had Congress intended to make the exclusivity period twelve and one-half years, it

⁷ Amgen contends that because the FDA approval process may entail modifications to a biosimilar’s properties or manufacturing process, allowing applicants to give 180-day notice prior to FDA approval would burden sponsors with the unfair task of having to aim infringement claims at a moving target. While this statutory construction may indeed disadvantage sponsors in some

1 could not have chosen a more convoluted method of doing so. Moreover, Congress presumably
 2 could have been far more explicit had it intended for infringement suits to commence only once a
 3 biosimilar receives FDA approval. It was, therefore, not wrongful for Sandoz to give Amgen its
 4 180 days' notice prior to first commercial marketing pursuant to subparagraph (l)(8)(A) in July
 5 2014, in advance of receiving FDA approval.⁸

6 C. Amgen's State-Law Claims for Unlawful Business Practices and Conversion

7 Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or
 8 wrongful predicate act to sustain Amgen's claims under the UCL and for conversion. A plaintiff
 9 may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates
 10 another law is independently actionable under § 17200. *Cel-Tech Commc'ns, Inc. v. Los Angeles*
 11 *Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that
 12 defendants' conduct is "unfair" within the meaning of the several standards developed by the
 13 courts. *Id.* at 186–87, 83 (finding of unfairness must be "tethered to some legislatively declared
 14 policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless*
 15 *Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to
 16 a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the
 17 challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that
 18 "members of the public are likely to be deceived" by the challenged business acts or practices. *In*
 19 *re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144
 20 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices
 21 are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory,
 22 averring that Sandoz behaved unlawfully by violating both subsection (l)'s disclosure and
 23 negotiation procedures and paragraph (l)(8)(A)'s 180-day notice requirement. As shown above,
 24 _____
 25 respects, such policy considerations are for Congress, not the courts, to address.

26 ⁸ In addition, had Sandoz failed to do so, it would be subject only to the consequences prescribed
 27 in 42 U.S.C. § 262(l)(9)(B)—an action for declaratory judgment regarding patent infringement,
 28 viability, or enforceability.

1 however, Sandoz's actions are within its rights and subject only to the consequences contemplated
 2 in the BPCIA. Because Amgen has not shown that Sandoz violated any provision of law, its UCL
 3 claim fails.

4 Amgen further alleges that Sandoz's reliance on Amgen's FDA license for Neupogen in its
 5 subsection (k) application constitutes conversion. To sustain a claim for conversion, a plaintiff
 6 must demonstrate (1) the plaintiff's ownership or right to possession of the property; (2) the
 7 defendant's conversion by a wrongful act or disposition of property rights; and (3) damages.
 8 *Burlesci v. Petersen*, 68 Cal. App. 4th 1062 (1998).

9 Sandoz's "wrongful act," alleges Amgen, was making use of Amgen's FDA license for
 10 Neupogen without complying with subsection (l)'s disclosure and negotiation procedures. Yet the
 11 BPCIA expressly contemplates that a subsection (k) applicant will rely on the reference product's
 12 license and other publicly available safety and efficacy information about the reference product.
 13 Indeed, as Sandoz's decision to forego the benefits of subsection (l)'s disclosure and negotiation
 14 procedures and instead open itself up to immediate suit for patent infringement was entirely
 15 permissible under 42 U.S.C. § 262, Sandoz has committed no wrongful act. The effect of
 16 Amgen's position—that Congress intended for sponsors to resort to state laws to enforce
 17 mandatory provisions in a federal statute and collect remedies for their violation, in addition to
 18 exacting the consequences written expressly into the legislation itself—is unworkable. Amgen
 19 therefore cannot maintain a claim for either unlawful business practices or conversion, and both
 20 claims are dismissed with prejudice pursuant to Sandoz's motion.

21 D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

22 Amgen contends that 42 U.S.C. § 262(l)(9)(C) bars the counterclaims for declaratory
 23 judgment of noninfringement and invalidity Sandoz alleges in response to Amgen's averment that
 24 Sandoz infringed its '427 patent. Subparagraph (l)(9)(C) states that where, as here, an applicant
 25 has not provided its BLA and manufacturing process information to the reference product sponsor,
 26 "the reference product sponsor, but not the subsection (k) applicant, may bring an action under
 27 section 2201 of title 28, United States Code, for a declaration of infringement, validity, or

1 enforceability of any patent that claims the biological product or a use of the biological product.”
 2 According to Amgen, this provision prohibits Sandoz, a subsection (k) applicant who has not
 3 provided its BLA and manufacturing process information to its sponsor, from raising its
 4 counterclaims for declaratory judgment regarding the ’427 patent.

5 Asserting a counterclaim is not the equivalent of commencing a lawsuit. *See Alexander v.*
 6 *Hillman*, 296 U.S. 222, 241 (1935). The BPCIA addresses only an applicant’s ability to “bring an
 7 action,” not to assert a counterclaim if placed in a position to defend against an infringement suit.
 8 Furthermore, as Sandoz’s counterclaims arise from the same transaction or occurrence that is the
 9 subject of Amgen’s claim—the validity and relevance of Amgen’s ’427 patent—they are
 10 compulsory, and would be waived if not asserted. Barring such claims in particular raises “real
 11 due process concerns.” *See U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d
 12 20, 26 (D.D.C. 2007). Sandoz’s sixth and seventh counterclaims regarding Amgen’s ’427 patent
 13 are, therefore, not barred by the BPCIA.

14 E. Amgen’s Motion for Preliminary Injunction

15 Amgen has claimed it is entitled to both preliminary relief in advance of a decision on the
 16 merits, and, in the event of a decision in its favor, an injunctive remedy placing the parties where
 17 they would have stood had Sandoz fully complied with the BPCIA as Amgen interprets it. To
 18 obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits;
 19 that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the
 20 balance of equities tips in his or her favor; and that an injunction would serve the public interest.
 21 *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies this
 22 standard in reviewing the grant or denial of an injunction where the issues at play are unique to
 23 patent law. Where they are not, it applies the law of the regional circuit (here, the Ninth Circuit).
 24 *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Ninth
 25 Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a
 26 “sliding scale.” *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) (“[T]he
 27 ‘serious questions’ version of the sliding scale test for preliminary injunctions remains viable after

1 the Supreme Court’s decision in *Winter*.”). According to this test, “[a] preliminary injunction is
2 appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were
3 raised and the balance of hardships tips sharply in the plaintiff’s favor,” provided, of course, that
4 “plaintiffs must also satisfy the other [*Winter*] factors” including the likelihood of irreparable
5 harm. *Id.* at 1135.

6 The parties disagree as to which standard is appropriate here. Yet because it cannot
7 demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is
8 foreclosed from injunctive relief under either formulation of the test for injunctive relief.

9 Indeed, the analysis above resolves in Sandoz’s favor the merits as to the issues raised in
10 the parties’ cross-motions. Neither Sandoz’s failure to supply its BLA and manufacturing process
11 information within twenty days of learning the FDA had accepted its application for approval and
12 subsequent decision to forego subsection (*I*)’s disclosure and negotiation procedures,⁹ nor its
13 intention to proceed to market by giving 180-day in advance of FDA approval, constitutes
14 wrongful or unlawful behavior. As Amgen has failed to show otherwise, neither Amgen’s UCL
15 claim nor its conversion claim is, therefore, viable; and it has yet to proceed on its remaining claim
16 for patent infringement.

17 Amgen furthermore does not carry its burden to demonstrate that irreparable harm will
18 result in the absence of injunctive relief. Amgen argues market entry of Sandoz’s biosimilar
19 filgrastim product will cause it irreparable harm in several respects, specifically by: (1) delaying or
20 precluding Amgen (through its sales of biosimilar filgrastim and diversion of revenue from
21 Amgen) from undertaking research and development for new drugs and potentially causing
22 Amgen to lose staff and scientists; (2) diverting Amgen sales representatives’ energy from selling
23 new products to competing with Sandoz for filgrastim market share; (3) causing Amgen to drop
24

25 _____
26 ⁹ Even were the BPCIA to render unlawful an applicant’s failure to supply its BLA and
27 manufacturing process information to the reference product sponsor within twenty days, whether
28 Sandoz made such information available to Amgen in a timely manner is a factual dispute between
the parties that need not be reached here.

1 the price of Neupogen to remain competitive; and (4) damaging Amgen’s customer relationships
 2 and goodwill in the event that the Court compels Sandoz to remove its product from the market,
 3 thereby prompting Amgen to enforce the order or raise its prices to where they were prior to
 4 Sandoz’s market entry.

5 Not only are such harms at best highly speculative; they are based on the as-yet unproven
 6 premise that Sandoz has infringed a valid patent belonging to Amgen. While Amgen has averred
 7 infringement of its ’427 patent and argues that Sandoz’s biosimilar filgrastim has the potential to
 8 infringe some four hundred more, *see* Declaration of Stuart Watt, it has not raised these
 9 contentions for a disposition at this juncture. It must, therefore, be assumed that no such
 10 infringement has occurred. As the twelve-year exclusivity period for Neupogen long ago expired,
 11 there exists no substantive bar to market entry for Sandoz’s biosimilar filgrastim—and,
 12 consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for
 13 disadvantages it may suffer due to market competition from Sandoz.

14 V. CONCLUSION

15 For the all of the aforementioned reasons, Amgen’s motions for partial judgment on the
 16 pleadings or partial summary judgment in the alternative, and for preliminary injunction, are
 17 denied. Its claims under the UCL and for conversion are, furthermore, dismissed with prejudice.

18 Insofar as the above interpretation of the BPCIA is consistent with Sandoz’s first through
 19 fifth counterclaims, judgment is hereby entered in Sandoz’s favor. The BPCIA renders
 20 permissible a subsection (k) applicant’s decision not to provide its BLA and/or manufacturing
 21 information to the reference product sponsor, subject only to the consequences set forth in 42
 22 U.S.C. § 262(l)(9)(C). Such a decision alone does not offer a basis for the sponsor to obtain
 23 injunctive relief, restitution, or damages against the applicant; indeed, 42 U.S.C. § 262(l)(9) sets
 24 out the exclusive consequences for an applicant who elects not to provide its BLA and/or
 25 manufacturing information, or participate in any aspect of subsection (l)’s disclosure and
 26 negotiation process. As the BPCIA contemplates that a subsection (k) applicant will use the
 27 reference product sponsor’s FDA license, and does not declare it unlawful for the applicant to do

1 so without participating in subsection (l)'s disclosure and negotiation process, there exists no
2 predicate wrongful act on which to base Amgen's conversion claim.¹⁰ In addition, the BPCIA
3 poses no bar to Sandoz's sixth and seventh counterclaims for patent noninfringement and
4 invalidity as to Amgen's '427 patent.

5
6 **IT IS SO ORDERED.**

7 Dated: March 19, 2015



8
9 RICHARD SEEBORG
United States District Judge

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
United States District Court
Northern District of California

¹⁰ Whether a sponsor otherwise maintains some exclusive property rights over an FDA license obtained for a biologic product is beyond the scope of this disposition.