UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., et al., Plaintiffs, v. GENENTECH, INC., et al., Defendants.	Case No. 18-cv-00274-JSW Re: Dkt. No. 53
CELLTRION, INC., et al., Plaintiffs, v. GENENTECH, INC., et al., Defendants.	Case No. 18-cv-00276-JSW **ORDER GRANTING DEFENDANTS' MOTIONS TO DISMISS** Re: Dkt. No. 47

Now pending before the Court are two motions to dismiss filed by Defendants Genentech, Inc., Hoffman La-Roche, Inc., and City of Hope ("Defendants" or "Genentech") to dismiss the first amended complaint filed by Plaintiffs Celltrion, Inc., Celltrion Healthcare, Co. Ltd., Teva Pharmaceuticals International GMGH, and Teva Pharmaceuticals USA, Inc. ("Plaintiffs" or "Celltrion"). The Court has considered the parties' papers, relevant legal authority, and the record in this case, and the Court finds both motions suitable for disposition without oral argument. *See* N.D. Civ. L.R. 7-1(b). For the reasons set forth below, the Court HEREBY GRANTS Defendants' motions to dismiss, but will afford Plaintiffs leave to amend.

BACKGROUND

A. "Biologic" and "Biosimilar" Drugs.

These cases concern a portion of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). 42 U.S.C. § 262(*l*). The BPCIA concerns, in part, approval of "biologic" and "biosimilar" drugs by the Food and Drug Administration ("FDA").

"Biologic" drugs (drugs derived from natural biological sources rather than chemically synthesized) may only be sold to consumers following approval and licensure by the FDA. *Sandoz Inc. v. Amgen Inc.*, ___ U.S. ___, 137 S. Ct. 1664, 1669-70 (2017). A biologic licensed by the FDA is known as a "reference product," and the party who manufactures the reference product is known as the "sponsor" or "reference product sponsor." *Id*. at 1670. "Biosimilar" drugs, in essence, are products "highly similar" to biologic products the FDA has already approved. *Id.* at 1669. Under the BPCIA, a party who wishes to manufacture a biosimilar drug may apply to the FDA and, upon a showing that there are no "clinically meaningful differences" between the biosimilar drug and the biologic drug, may "piggyback" off of the biologic drug's license and procure FDA approval for the biosimilar drug. *Id.* at 1670. Applying to the FDA in order to "piggyback" is technically patent infringement. *See* 35 U.S.C. § 271(e)(2)(C).

B. BPCIA Process for Biosimilar Drugs.

Reference products may be covered by multiple patents, and 42 U.S.C. § 262(*l*) ("Section (*l*)") prescribes a detailed mechanism for resolving infringement claims arising between the reference party sponsor and the biosimilar applicant. *Sandoz*, 137 S. Ct. at 1670. Colloquially, attorneys practicing in this space refer to these steps as the "patent dance."

First, within twenty days of receiving notice that the FDA has accepted its biosimilar application for review, the applicant (here, Celltrion) must send to the reference product sponsor (here, Genentech) (i) the biosimilar application and (ii) information about the processes for manufacturing the biosimilar product (collectively, the "2(A) Disclosure"). 42 U.S.C. § 262(*l*)(2)(A). Sixty days after the reference product sponsor receives the 2(A) Disclosure, it must provide the applicant with a "list of patents" the reference product sponsor believes the biosimilar drug infringes (the "3(A) Disclosure"). *Id.* § 262(*l*)(3)(A)(i). The

reference product sponsor must also identify which patents in the 3(A) Disclosure it would be willing to license to the applicant. *Id.* § 262(*l*)(3)(A)(ii).

Within sixty days of receiving the 3(A) Disclosure, the applicant must send the reference product sponsor its (i) claim-by-claim arguments for noninfringement, invalidity, and/or unenforceability of the patents identified in the 3(A) Disclosure; (ii) a response regarding the reference product sponsor's willingness to license certain patents; and, if applicable (iii) a statement that the applicant does not intend to begin commercial marketing of the biosimilar before certain patents expire (collectively, the "3(B) Disclosure"). *Id.* § 262(*l*)(3)(B). The applicant may also augment the reference product sponsor's 3(A) Disclosure by identifying additional patents the reference product sponsor could assert against the biosimilar drug. *Id.* § 262(*l*)(3)(B)(i). Within sixty days of receiving the 3(B) Disclosure from the applicant, the reference product sponsor must respond, claim-by-claim, to the applicant's noninfringement, invalidity, and unenforceability arguments ("3(C) Disclosure"). *Id.* § 262(*l*)(3)(C).

Following the exchange of the 3(A), (B), and (C) Disclosures, the applicant and the reference product sponsor must engage in "good faith negotiations" to reach an agreement identifying which patents will be the subject of "immediate" patent infringement litigation. *Id.*§ 262(*l*)(4)(A), (*l*)(6). The negotiations kick off the so-called "Phase I" patent litigation. *Sandoz*, 137 S. Ct. at 1671. Once these negotiations begin, the reference product sponsor and the applicant have fifteen days to reach agreement. 42 U.S.C. § 262(*l*)(4)(B). If they cannot agree on a list of patents for Phase I "within" that window, the parties must simultaneously exchange lists of patents each believes should be immediately litigated (the "5(B) Lists"). *Id.* § 262(*l*)(4)(B), (*l*)(5)(B)(i), (*l*)(6). However, before the parties exchange 5(B) Lists, the applicant must identify the *number* of patents it will identify on its own 5(B) List (the "5(A) Number"). *Id.* § 262(*l*)(5)(A). The applicant's proffered number caps the number of patents the reference product sponsor may include on its 5(B) List.[1] *Id.* § 262(*l*)(5)(B)(ii). The reference product

[1] In the event the applicant indicates it will identify no patents, the reference product sponsor may always include at least one patent on its 5(B) List.

sponsor then has thirty days after the exchange of the 5(B) Lists to bring patent infringement claims regarding all patents on those lists. *Id.* § 262(*l*)(6)(B).[2]

"Phase II" litigation, meant to address patents included on the 3(A)-(C) Disclosures but "not litigated" in "Phase I," begins when the applicant serves the reference product sponsor a "notice of commercial marketing," which it must do at least 180 days before marketing the biosimilar. *Id.* § 262(*l*)(8)(A); *Sandoz*, 137 S. Ct. at 1671-72.

The parties' available remedies are contingent upon their compliance with these steps. If an applicant fails to provide its 2(A) Disclosure, it may not bring an action for declaratory judgment for noninfringement, validity, or enforceability of any patent covering the biologic drug. 42 U.S.C. § 262(*l*)(9)(C). If an applicant provides its 2(A) Disclosure, then neither party may bring a declaratory judgment action regarding infringement, validity, or enforceability of a subset of the patents at issue[3] before the applicant serves its notice of commercial marketing (the initiation of Phase II litigation). *Id.* § 262(*l*)(9)(A). Finally, if an applicant: (i) fails to serve its 3(B) Disclosure[4], 5(A) Number, 5(B) List, or notice of commercial marketing; (ii) timely notify the FDA of an ensuing patent lawsuit; or (iii) supplement its 3(B) Disclosure in response to newly issued or licensed patents the reference product sponsor identifies, the applicant may not bring an action for declaratory judgment. *Id.* § 262(*l*)(9)(B).

C. Genentech and Celltrion's BPCIA "Patent Dance."

1. "Herceptin" and "Herzuma."

Genentech is the reference product sponsor for a biologic called "Herceptin." *See* First Amended Complaint, No. 18-cv-000274-JSW ("Herceptin FAC") ¶ 36. On May 30, 2017,

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[2] The reference product sponsor must file for patent infringement for any patent appearing on either its or the applicant's 5(B) Lists.

[3] This subset includes patents on the 3(A) *or* (B) Disclosures, but not encompassed by (i) any agreement the parties reach regarding patents suitable for "immediate" litigation *or* (ii) itemized on the 5(B) Lists.

[4] The only components of the 3(B) Disclosure necessary to avoid Section (l)(9)(B)'s prohibition are (i) the applicant's arguments on invalidity, unenforceability, and/or noninfringement and (ii) any statement by the applicant that it does not intend to begin commercial marketing of the biosimilar before the expiration of certain patents.

pursuant to 42 U.S.C. § 262(k), Celltrion applied for FDA approval to market a biosimilar of Herceptin called "Herzuma." *Id.* ¶¶ 5, 37. The FDA notified Celltrion on July 28, 2017 that its application had been accepted for review. *Id.* On August 11, 2017, well within the statutory deadline, Celltrion sent its 2(A) Disclosure to Genentech.[5] *Id.* ¶¶ 5, 15, 39; 42 U.S.C. § 262(*l*)(2)(A).

On October 10, 2017, Genentech provided Celltrion with its 3(A) Disclosure, listing 40 patents it believed Herzuma would infringe, and, on November 7, 2017, Celltrion responded with its 3(B) Disclosure. Herceptin FAC ¶¶ 5, 15, 41, 42; 42 U.S.C. § 262(*l*)(3)(A), (B). On January 5, 2018, Genentech timely sent its 3(C) Disclosure to Celltrion. Herceptin FAC ¶¶ 5, 15, 46; 42 U.S.C. § 262(*l*)(3(C). Simultaneously, Genentech, evidently intending to begin the statutorily mandated "good faith negotiations," proposed the parties agree to litigate a discrete number (fewer than all)[6] of the patents under discussion. Herceptin FAC ¶ 48; 42 U.S.C. § 262(*l*)(4)(A). Celltrion responded by stating that it wished to litigate a larger number of patents than Genentech's opening offer: namely, *all* patents listed on the 3(A) Disclosure. Herceptin FAC ¶ 49; 42 U.S.C. § 262(*l*)(4)(A).

Celltrion then served a notice of commercial marketing on Genentech. Herceptin FAC ¶¶ 6, 16, 49; 42 U.S.C. § 262(*l*)(8)(A). Celltrion did not provide Genentech with the 5(A) Number or engage in simultaneous exchange of 5(B) Lists with Genentech. *See generally* Herceptin FAC; 42 U.S.C. § 262(*l*)(5). Celltrion filed a declaratory judgment lawsuit regarding these patents (the "Herceptin Lawsuit" or "Herceptin Complaint") on January 11, 2018. Dkt. 1.

2. "Rituxan" and "Truxima."

Genentech is also the reference product sponsor for a biologic called "Rituxan." *See* First

[5] The Court is aware that Genentech contests the sufficiency of Celltrion's 2(A) Disclosures for both biosimilars. Celltrion alleges, in each complaint, it served complete 2(A) Disclosures. As explained below, the Court's analysis is properly limited to the allegations in the complaint. The Court therefore declines to address the sufficiency of Celltrion's 2(A) Disclosures at this time.

[6] The specific information regarding Genentech's proposal is the subject of a motion to seal.

Amended Complaint, No. 18-cv-000276-JSW ("Rituxan FAC") ¶ 41. On April 28, 2017, pursuant to 42 U.S.C. § 262(k), Celltrion applied for FDA approval to market a biosimilar of Rituxan called "Truxima." *Id.* ¶¶ 6, 42. The FDA notified Celltrion on June 27, 2017 that its application had been accepted for review. *Id.* On July 17, 2017, Celltrion sent its 2(A) Disclosure regarding Truxima to Genentech. *Id.* ¶¶ 6, 44; 42 U.S.C. § 262(*l*)(2)(A).

On September 14, 2017, Genentech provided Celltrion with its 3(A) Disclosure for Rituxan, listing 40 patents it believed Celltrion's biosimilar would infringe, and, on November 7, 2017, Celltrion responded in kind with its 3(B) Disclosure. Rituxan FAC ¶¶ 5, 46, 47; 42 U.S.C. § 262(*l*)(3)(A), (B). On January 5, 2018, Genentech timely sent its 3(C) Disclosure to Celltrion. Rituxan FAC ¶¶ 6, 51; 42 U.S.C. § 262(*l*)(3(C). On January 11, 2018, evidently as part of Section (*l*)4's "good faith negotiations," Celltrion indicated it wished to litigate all forty patents on Genentech's 3(A) Disclosure. Rituxan FAC ¶ 53; 42 U.S.C. § 262(*l*)(4)(A). Celltrion then served a notice of commercial marketing on Genentech. Rituxan FAC ¶¶ 7, 54; 42 U.S.C. § 262(*l*)(8)(A). Celltrion did not provide Genentech with the 5(A) Number or engage in simultaneous exchange of 5(B) Lists with Genentech. *See generally* Rituxan FAC; 42 U.S.C. § 262(*l*)(5). Celltrion filed a declaratory judgment lawsuit regarding these patents (the "Rituxan Lawsuit" or "Rituxan Complaint") on January 11, 2018. Dkt.1.

ANALYSIS

A. Applicable Legal Standard.

In its motions to dismiss, Genentech seeks to dismiss both the Herceptin and Rituxan Lawsuits for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim. The Court finds that Genentech's motions are both properly construed as motions to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

Federal courts have subject matter jurisdiction over "all civil actions arising under the Constitution, laws, or treatises of the United States." 28 U.S.C. § 1331. Additionally, a specific statutory grant of jurisdiction gives federal district courts subject matter jurisdiction over "any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). This Court therefore incontrovertibly has subject matter jurisdiction over the patent disputes in both the

Herceptin and Rituxan Lawsuits.

Despite this mandate, Genentech contends that Celltrion's failure to perform the BPCIA's "patent dance" deprives this Court of jurisdiction. The Supreme Court, however, has repeatedly admonished courts to avoid "drive-by jurisdictional rulings" which fail to properly distinguish between a lack of subject matter jurisdiction and a plaintiff's failure to state a claim. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 511 (2006). To discourage inappropriate challenges to subject matter jurisdiction, the Supreme Court developed the "clear statement" rule: courts should treat statutory requirements as nonjurisdictional unless there is a clear legislative statement to the contrary. *Id.* at 515-16.[7] Here, Genentech has cited no "clear statement" by Congress suggesting that Congress intended the BPCIA's requirements to be jurisdictional prerequisites. Rather, a review of the BPCIA reveals that the "patent dance" is a series of statutory conditions an applicant must satisfy before bringing an action for declaratory judgment. *See Castillo v. U.S. I.R.S.*, No. 13-cv-00517-AWI, 2014 WL 1270548, at *4 (E.D. Cal. Mar. 26, 2014) ("Such claim processing rules are not jurisdictional unless Congress specifically attached jurisdictional consequences to such rules."); *cf. Yagman v. Pompeo*, 868 F.3d 1075 (9th Cir. 2017) (finding Freedom of Information Act's exhaustion requirements not "jurisdictional" in nature).

Accordingly, the Court treats Genentech's motions as seeking dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Under this standard, courts construe complaints in the light most favorable to the non-moving party. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986).[8] The plaintiff need only provide a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). This requires the

[7] In subsequent opinions, the Supreme Court has telegraphed a consistently conservative approach to classifying rules as jurisdictional. *See, e.g.*, *Sebelius v. Auburn Regional Medical Center, et al.*, 568 U.S. 145, 153 (2013) ("Tardy jurisdiction objections can therefore result in a waste of adjudicatory resources and can disturbingly disarm litigants.")

[8] Even if Genentech's arguments did constitute proper challenges to subject matter jurisdiction, this Court's analysis would not change. The disagreement between the parties is not whether key actions giving rise to this Court's jurisdiction occurred, but the meaning and effect of actions alleged in the complaints: facial, not factual, challenges. *See Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004) (observing defendant's argument concerned adequacy, not accuracy, of allegations).

plaintiff to provide "more than labels and conclusions:" mere "recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). The Court may consider the facts alleged in the complaint, documents attached to the complaint, documents relied upon but not attached to the complaint (when the authenticity of such documents is not questioned), and other matters of which the Court can take judicial notice. *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). Unless amendment would be futile, the Court should freely grant leave to amend. *Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990).

C. Celltrion's Declaratory Judgment Actions Fail Under Section (*l*)(9)(B) of the BPCIA.

Examining the complaints, and drawing all reasonable inferences in Celltrion's favor, Celltrion fails to state a claim for relief in either the Herceptin or Rituxan Complaint. Because Celltrion did not complete its obligations under Section (*l*)(5), Celltrion may not file actions for declaratory judgment with respect to the patents at issue.

1. Celltrion Did Not Complete the Statutorily Required Patent Dance.

In the Herceptin and Rituxan Complaints, Celltrion alleges that the parties completed their respective Section 2(A), 3(A), 3(B), and 3(C) Disclosure obligations. *See* Herceptin FAC ¶¶ 39, 41, 42, 46; Rituxan FAC ¶¶ 44, 46, 47, 51. In the Herceptin FAC, Celltrion then alleges that the parties began Section (*l*)(4)'s "good faith negotiation" process, but were unable to agree on which patents were suitable for "immediate" Phase I litigation. *See* Herceptin FAC ¶¶ 48, 49. At this juncture, the express terms of the BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5). *See* 42 U.S.C. § 262(*l*)4, (*l*)(5). Yet, Celltrion never alleges that it either (i) sent its 5(A) Number to Genentech, or (ii) that the parties simultaneously exchanged 5(B) lists.

The Rituxan FAC is similarly deficient. Celltrion's allegations reveal that Celltrion began the Section (*l*)(4) negotiation process by indicating that it wanted to litigate all the patents contained on Genentech's 3(A) Disclosure, but then did not wait for Genentech to respond. *See* Rituxan FAC ¶¶ 53, 54. There are no allegations that Celltrion sent its 5(A) Number or exchanged 5(B) Lists with Genentech. Instead, Celltrion contends that it served Genentech with a notice of

commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) and then filed suit. *Id.* ¶ 54.

Section (*l*)(9)(B) provides: "If [an applicant] fails to complete an action required . . . under . . . paragraph (5) . . . the reference product sponsor, *but not the* [*applicant*], may bring an action . . . for a declaration of infringement, validity, or enforceability of any patent included in the list described in [the Section 3(A) Disclosure]." 42 U.S.C. § 262(*l*)(9)(B) (emphasis added). Thus, "when an applicant . . . fails to complete a subsequent step [in the patent dance] . . . the [reference product] sponsor, but not the applicant, may bring a declaratory-judgment action with respect to any patent included on the sponsor's [list of relevant patents]." *Sandoz*, 137 S. Ct. at 1672; *see also Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, 14-cv-2256-PAC, 2014 WL 6765996, at *2 (S.D.N.Y. Dec. 1, 2014) ("Neither party may bring a declaratory judgment action while the process is under way; if the applicant fails to comply with these procedures, the reference product sponsor may bring a declaratory judgment action, but the applicant may not."). Celltrion fails to allege, in either complaint, that it provided Genentech with its 5(A) Number or simultaneously exchanged 5(B) lists with Genentech. In these circumstances, the BPCIA is clear: Celltrion may not bring a declaratory judgment action with respect to any patent on Genentech's Section 3(A) Disclosures.

2. Celltrion's Arguments Conflict with the Plain Meaning of the BPCIA.

Celltrion's arguments as to why its failures to comply with the BPCIA's requirements do not bar this suit are unavailing.

First, Celltrion suggests it may streamline its obligations under the statute and satisfy several steps at once. In support of the Herceptin Complaint, Celltrion argues that it is absolved of the responsibility to comply with Section (*l*)(5) because it told Genentech it "wished" to litigate all patents on Genentech's 3(A) Disclosure. Celltrion contends that this statement both fulfilled its obligations to engage in "good faith negotiations" under Section (*l*)(4) and made the exchange of the 5(A) Number and 5(B) Lists "redundant."

This argument, however, improperly conflates Sections (*l*)(4) and (*l*)(5). The parties' obligations under Section (*l*)(5) only arise if the parties are unable to agree, after fifteen days of good faith negotiations, on a final and complete list of patents to litigate in Phase I. *See* 42 U.S.C.

§ 262 (*l*)(4)(B). Given the plain language of this provision, and the relationship between Sections (*l*)(4) and (*l*)(5) more generally, the Court concludes that no single statement or gesture can satisfy the requirements of both sections simultaneously. Celltrion's assertion that it "wished" to litigate all the patents on Genentech's 3(A) Disclosure was merely a response to Genentech's initial proposition and therefore part of the Section (*l*)(4) negotiation process.

In defense of the Rituxan Complaint, Celltrion argues that it completed its obligations under Section (*l*)(4) by indicating it wished to litigate all listed patents because Genentech had, in its 3(A) Disclosure, "reserved its rights" to litigate all patents. Thus, according to Celltrion, there was nothing left to negotiate. In so arguing, Celltrion suggests that the 3(A), (B), and (C) Disclosures are somehow part of the Section (*l*)(4) negotiations, when they are, in fact, distinct statutory steps which the parties must complete before commencing the Section (*l*)(4) negotiations. 42 U.S.C. § 262(*l*)(4) ("*After* receipt by the [applicant] of the [3(C) Disclosure], the reference product sponsor and the [applicant] shall engage in good faith negotiations to agree on which, if any, patents listed [in the 3(A), (B), and (C) Disclosures] shall be the subject of an action for patent infringement under paragraph (6)." (emphasis added)). The statutory procedures do not allow an applicant to collapse its multiple distinct obligations into one or two perfunctory actions.

Moreover, Celltrion's arguments in support of both complaints presuppose that, once the Section (*l*)(4) good faith negotiations began, any disagreement (or presumed disagreement) as to the desired scope of Phase I patent litigation permitted Celltrion to unilaterally terminate negotiations and end the patent dance. Yet, Celltrion provides no authority for the proposition that Section (*l*)(4) or (*l*)(5) requirements are excused if one party believes continued negotiation is futile. Further, Celltrion's position runs counter to the principles and realities of negotiation. Negotiation would be entirely unnecessary if the initial positions of the reference party sponsor and the applicant were identical: the aim of negotiation, not the starting point, is agreement.

Even assuming, *arguendo*, that Celltrion's characterizations of its obligations under Section (*l*)(4) were correct, Celltrion failed to follow any statutorily prescribed path. If, after

completing Section (*l*)(4)'s "good faith negotiations," the parties had agreed[9] upon the patents they wanted to litigate in Phase I, the statute directed the reference product sponsor Genentech—not applicant Celltrion—to file a patent infringement lawsuit. 42 U.S.C. § 262(*l*)(6)(A). On the other hand, if, at the end of "good faith negotiations" the parties had not agreed on the scope of Phase I patent litigation, Celltrion was obligated to offer its 5(A) Number and then exchange 5(B) Lists. Even under this circumstance, the BPCIA commands Genentech—not Celltrion—to file a patent infringement action. *Id.* § 262(*l*)(6)(B). Neither path permitted Celltrion to file these declaratory judgment actions.

Second, Celltrion argues that it is not obligated to offer its 5(A) Number or exchange 5(B) Lists because it filed this lawsuit nine days before the expiration of the fifteen-day period Section (*l*)(4) allots for good faith negotiation. By this argument, Celltrion suggests that the filing of this declaratory judgment action was permissible *because* it skipped required statutory steps, where the non-occurrence of those statutory steps explicitly bars Celltrion from filing this action—an unpersuasive legal Catch-22[10]. Celltrion was obligated to complete all required procedures before filing this lawsuit, and it did not.

Finally, Celltrion argues that the notices of commercial marketing it served for Herzuma and Truxima enable it to file these declaratory judgment actions, regardless of its compliance with other portions of the BPCIA. The Court disagrees.

Section (*l*)(9) contains three separate, independent statutory bars, each of which applies to

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[9] Of course, it is not at all clear from the Rituxan Complaint that the parties were "in agreement" in wanting to litigate all patents on Genentech's 3(A) Disclosure. In fact, the complaint suggests the exact opposite. Genentech's 3(C) Disclosure demonstrates it was then focusing its attention upon a considerably smaller number of patents than it had originally set forth in its 3(A) Disclosure. Rituxan FAC ¶¶ 46-53. Celltrion's position, after receiving the 3(C) Disclosure, was to press for litigation of all patents on the 3(A) Disclosure.

[10] "There was only one catch and that was Catch-22, which specified that a concern for one's safety in the face of dangers that were real and immediate was the process of a rational mind. Orr was crazy and could be grounded. All he had to do was ask; and as soon as he did, he would no longer be crazy and would have to fly more missions. Orr would be crazy to fly more missions and sane if he didn't, but if he was sane he had to fly them. If he flew them he was crazy and didn't have to; but if he didn't want to he was sane and had to." Joseph Heller, *Catch-22* 46 (Simon & Schuster 2004) (1961).

distinct factual circumstances where applicants fail to comply with certain steps. Section (*l*)(9)(C) applies when an applicant has not completed a 2(A) Disclosure. 42 U.S.C. § 262(*l*)(9)(C). Section (*l*)(9)(B) applies where an applicant has failed to complete any *one* of five specifically identified statutory steps (including Section (*l*)(5)). *Id.* § 262(*l*)(9)(B). And Section (*l*)(9)(A) imposes a temporary statutory bar that begins when a reference product sponsor receives an applicant's 2(A) Disclosure and ends when an applicant serves a notice of commercial marketing. *Id.* § 262(*l*)(9)(A).

Celltrion contends that because a notice of commercial marketing lifts the ban on declaratory judgment actions described in Section (*l*)(9)(A), a notice of commercial marketing should also lift Sections (*l*)(9)(B) and (C)'s prohibitions. By the explicit text of the statute, however, serving a notice of commercial marketing lifts the prohibition imposed by Section (*l*)(9)(A)—and Section (*l*)(9)(A) alone. *See Sandoz*, 137 S. Ct. at 1672 (reasoning Section (*l*)(9)(B) applies when "an applicant provides the application and manufacturing information but fails to complete a subsequent step"); *see also Amgen, Inc. v. Apotex, Inc.*, 827 F. 3d 1052, 1057 (Fed. Cir. 2016) (Section (*l*)(9)(B) addresses applicants "that begin but do not complete" the Section 262(*l*) processes).

The Central District of California considered and rejected a similar argument in *Amgen v. Genentech, Inc.*, 17-cv-7349-GHW, 2018 WL 910198 (C.D. Cal. Jan. 11, 2018). There, the applicant served a notice of commercial marketing and filed a declaratory judgment lawsuit before the parties had completed the 5(A) Number and 5(B) List exchanges. *Id.* at * 3-4. The court, discussing *Sandoz*, observed that to allow an applicant to bring suit after serving its notice of commercial marketing but before completing the rest of the BPCIA's Section (*l*)(5) exchanges would "override congressional intent and do away with the 'carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement' set out in the BPCIA." *Id.* (citing *Sandoz*, 137 S.Ct. at 1670); *see also Sandoz*, 137 S.Ct. at 1675 (BPCIA's "carefully crafted and detailed enforcement scheme" provides "strong evidence" Congress did not intend to imply extra-statutory loopholes) (citation omitted). In other words, a notice of commercial marketing only opens the door for an applicant to file a declaratory judgment action if the applicant complies

with the rest of the statute. A notice of commercial marketing is no *carte blanche*, and Celltrion points to no authority that offers a contradictory interpretation.

As Celltrion has failed to state a claim, the Court declines to address the issue of whether it would exercise its jurisdiction under the Declaratory Judgment Act.[11]

CONCLUSION

For the foregoing reasons, the Court GRANTS both motions to dismiss. The Court will, however, afford Plaintiffs leave to amend, to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11. Should Celltrion choose to file an amended complaint, it shall do so by June 10, 2018.

IT IS SO ORDERED.

Dated: May 9, 2018

JEFFREY S. WHITE
United States District Judge

[11] In 18-cv-00274-JSW, Celltrion seeks to seal the first complaint, first amended complaint, and its opposition to Genentech's motion to dismiss. Dkts. 5, 39, 66. In turn, Genentech requests sealing of its motion to dismiss and reply brief in support. Dkts. 52, 70. In 18-cv-00276-JSW, Celltrion seeks to seal the first amended complaint and its opposition to Genentech's motion to dismiss. Dkts. 39, 62. Genentech requests sealing of its motion to dismiss and reply brief in support. Dkts. 49, 69. The Court grants all requests to seal.