UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CELLTRION HEALTHCARE CO., LTD. and CELLTRION, INC., Plaintiffs, v. KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH, Defendant.	:	Civil Action No.: 14-cv-2256 (PAC)

DEFENDANT KENNEDY TRUST'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF CELLTRION'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION PURSUANT TO FED.R.CIV.P. 12(b)(1), OR TO STAY THE ACTION

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I. INTRODUCTION

Celltrion has brought an action seeking a declaratory judgment of the invalidity of three Kennedy patents when (a) all of Kennedy's issued U.S. patents comprise claims which either no longer exist, are on appeal to the Federal Circuit, or have never been the subject of a threat of infringement against anyone, (b) Celltrion admittedly has no product to sell and doesn't know when or if it ever will be able to sell a product in this country or how that product will be marketed, and (c) Kennedy has never threatened to sue Celltrion under these U.S. patents and would prefer to grant Celltrion a license if one is needed. This case is about as far from a ripe controversy as any case could possibly be, even now, months after the March 31, 2014 date on which subject matter jurisdiction should be assessed. There is no real dispute and the case should be dismissed.

If the Court does find subject matter jurisdiction, then a stay should be issued until the conclusion of post-issuance proceedings concerning Kennedy's patents. Such a stay will allow the parties to address those claims which may potentially have relevance to Celltrion's possible future activities, and will not cause any additional uncertainty or prejudice to Celltrion.

Celltrion relies heavily upon *MedImmune v. Genentech* (Opposition at 1, 7). However, that case is not applicable because it involves the right of a patent licensee to challenge validity of the patent while maintaining its license. Celltrion is not a licensee, has paid no royalties to Kennedy, and has no such protection. That right was an issue in the Kennedy -- AbbVie cases, but is not an issue here.

II. CELLTRION CANNOT GROUND SUBJECT MATTER JURISDICTION ON POST-COMPLAINT FACTS AND HOPES FOR THE FUTURE

Celltrion admits, albeit in a footnote, that "the jurisdiction of the court depends upon the state of things at the time of the action brought." Opposition at 19, n. 12, *quoting Grupo Dataflux v. Atlas Global Grp., L.P.*, 541 U.S. 567, 570 (2004). Yet Celltrion, in its attempt to show that there exists

a dispute of sufficient immediacy and reality to support subject matter jurisdiction, relies on numerous facts occurring after the March 31, 2014 filing date of the complaint.

For instance, (1) the number of foreign countries which have approved Remsima or in which Remsima has been sold, as of Celltrion's September 29, 2014 opposition date (Opposition at 4, 9; Park Decl. at ¶¶ 12-13); (2) Celltrion's April 28, 2014 "detailed guidance from the FDA regarding the contents of its application" (Opposition at 5; Park Decl. at ¶19) (3) Celltrion's August 8, 2014 application with the FDA to market Remsima in the U.S., and which indications of Remsima are specified in that application (Opposition at 4-5, 9; Park Decl. at ¶¶ 21, 24; Johnston Decl. at ¶ 39); and (4) The number of plants Celltrion uses to manufacture Remsima, as of September 29, 2014, and its September 29, 2014 plans with respect to future plants, as well as Celltrion's current beliefs as to whether its current and future manufacturing facilities are (or will be) FDA-compliant and able to manufacture enough product to meet demand (Opposition at 5, 9, 13, 14; Park. Decl at ¶¶ 27-28), and (5) Kennedy's attorney's (mischaracterized) comments at the August 13, 2014 pre-motion conference regarding Kennedy's future plans (Opposition at 1, 16).

Focusing on the March 31, 2014 date of filing the complaint, Celltrion had no FDA application, incomplete guidance as to how to file an FDA application, and had received no threat of suit. Unsurprisingly, Celltrion cannot point to a single case allowing a declaratory judgment suit relating to a drug patent, let alone a biologic drug patent, to proceed under such circumstances. Celltrion cites a number of cases declining a bright-line rule to preclude declaratory judgment jurisdiction (*see* Opposition at 8-10), but these cases are inapplicable.

While the cited *Cat Tech LLC v. TubeMaster, Inc.* did not require "actual manufacture or sale of a potentially infringing product" for declaratory judgment jurisdiction, in that case, declaratory plaintiff Cat Tech already had conducted, a month before the patent's issuance, otherwise

potentially infringing activity, and was ready to commit additional potentially infringing activity as soon as it received a purchase order for additional devices. 528 F.3d 871 at 877, 882. Importantly, the product did not require FDA approval. Celltrion, unlike Cat Tech, is incapable of imminent infringement.

Celltrion neglects that *Gelmart Indus., Inc. v. Eveready Battery Co.* is a trademark case, which was important to the *Gelmart* court's determination. 2014 WL 1512036, at *4 ("Because declaratory judgment actions are particularly useful in resolving trademark disputes the finding of an actual controversy should be determined with some liberality.") (internal quotation marks and citation omitted). Declaratory plaintiff Gelmart planned to sell underwear (of course, without FDA approval) using the trademark "Skintimates" and filed an application to register that trademark. *Id.* at *1. Defendant Eveready opposed this registration before the USPTO, claiming that the sale would infringe its own "Skintimate" trademark, and also sent Gelmart two cease-and-desist letters. *Id.* Gelmart alleged in its complaint that it had the ability to "supply product to the U.S. market-place within weeks" and was "poised to effectuate full product launch, [but] such plans have been affected by the actions of Everready …". *Id.* at *5. The trademark owner's claims of trademark infringement, coupled with the potential for infringement within weeks and the "liberal[]" trademark declaratory judgment standard, readily distinguish that case.[1]

Infinitech, Inc. v. Vitrophage, Inc. likewise is distinguishable. Despite a lack of FDA approval, the declaratory defendant patentee nonetheless had repeatedly accused declaratory plaintiff Infinitech of having already infringed the patent at issue, for example, purported

[1] Celltrion cites *Gelmart* in arguing that a "bright line" rule that "declaratory judgment is *never* appropriate pre-approval" is inappropriate. (Opposition at 11). Not only is *Gelmart* a trademark case having nothing to do with FDA approval, but no "bright-line" rule is required to reject declaratory judgment jurisdiction in this case. Kennedy has made no explicit charge of infringement, and, as of the complaint filing date, no FDA application was on file. "All the circumstances" weigh against declaratory judgment jurisdiction.

infringement resulting from Infinitech's application for FDA approval.[2] 842 F.Supp. 332 at 334. The *Infinitech* court noted that, with such an actual charge of infringement of the patent at issue, "there is, *necessarily*, a case or controversy adequate to support jurisdiction […]" *Id.* at 335, *citing Cardinal Chem. Co. v. Morton Intern., Inc.*, 113 S.Ct. 1967, 1975 (1993). Conversely, as of the March 31, 2014 complaint filing date here, Celltrion had neither filed an application for FDA approval nor been charged with infringement of the patents-at-issue by Kennedy. Thus Kennedy, unlike Vitrophage, is not subject to a legal fiction that possible infringement has already occurred.

As in *Infinitech*, in *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, an FDA application had been filed before the complaint. 456 F.Supp.2d 267 at 271, n.1. And, similar to *Infinitech*, the patentee had, on several occasions, announced its certainty that the product-at-issue infringed its patents and its intention to defend those patents. *Id.* at 278. Moreover, in exercising its discretion to maintain declaratory judgment jurisdiction over the future infringement, the *Amgen* court found it important that it would also be addressing Amgen's properly pleaded claims of *present* infringement, stemming from Roche's current importation of an infringing drug. *Id.* at 279. In contrast, Kennedy's method-of-use patents cannot be infringed under §271(a) by mere drug importation.[3]

Celltrion insists it alleged, in its complaint, its intention to sell a drug containing cA2, because "Celltrion's complaint alleges that Remsima's antibody sequence is identical to that of Remicade's antibody". (Opposition at 13, *citing* Compl. ¶¶ 3, 26, 40 and Park Decl. ¶ 3). Celltrion's complaint

[2] Contrary to the ANDA standard of recognizing the filing of an application for FDA approval as a fictional act of infringement, there is no such standard for biologics.

[3] Celltrion also cites, in footnote 2, *Arkema Inc. v. Honeywell Int'l, Inc.* and *Biogen, Inc. v. Schering AG*. *Arkema* involved air conditioners (not subject to FDA review), "Honeywell ha[d] already asserted claims against Arkema in the United States for infringement of other patents covering the same technology" before new method patents issued, and there was no question that Honeywell believed Arkema would be infringing its new method patents. 706 F.3d 1351 at 1355, 1357, 1358. In *Biogen*, Schering had stated that the patent-at-issue gave it "exclusive rights" to Biogen's process and that it could "block Biogen". 954 F.Supp. 391, 393. Biogen had filed its FDA application about a year before the complaint (the application being approved two weeks after the complaint was filed). *Id.* at 393-94.

contains no such allegation. It merely alleges that Remsima is "biosimilar" and "comparable in safety and efficacy" to Remicade, a drug containing cA2. But two drugs can be "bio***similar***" and "comparable in safety and efficacy" without having "identical" compositions. Even supposing the sequence is identical, despite there being no pleading to that effect, an identical sequence does not necessarily result in an identical product. And, as this Court knows, all claims of the '120 and '442 patents that have not been held invalid specifically require cA2. *See* Zivin Decl. in support of MTD, Exh. 3, ¶ 5, Exh. 4, ¶ 6.

Moreover, although Celltrion attempts to focus this Court on the *composition* of the product it hopes one day to sell, the Kennedy patents at issue are method-of-use patents, which no biologic, standing alone, can infringe. *See* Opposition at 6 (falsely stating that "Kennedy has claimed that [an] *antibody* infringes its [foreign] patent rights") and at 8 ("Remsima's formula is fixed … Kennedy has repeatedly asserted its patent rights to block the Remsima *antibody* in foreign jurisdictions") (emphasis added). To be clear, for there to be a possibility of eventual patent infringement, as of the time of the complaint, not only would Celltrion have to proceed to file an FDA application for a follow-on perhaps identical product, and become the first ever such biosimilar to receive FDA approval, but Celltrion would also have to include a particular infringing indication of that biologic in that FDA application, receive approval for that indication, and then choose to market its biologic for that indication (a choice that would depend on its production and marketing capabilities, and the market for the drug for that indication, at that time). Moreover, as to the '120 and '537 patents, all of these contingencies would have to occur prior to the August 1, 2016 expiration date of those two patents.

III. CELLTRION'S BPCIA INVOLVEMENT WITH JANSSEN, THE "REFERENCE PRODUCT SPONSOR," ELIMINATES ANY IMMEDIACY

Celltrion makes a number of technical and policy-based arguments about how the BPCIA is not jurisdictional, and how it does not affect its ability to bring a declaratory judgment suit against Kennedy, because Janssen, not Kennedy, is the "reference product sponsor". (Opposition at 18-20). But this argument misses the forest for the trees. Celltrion admits that Janssen holds two of its own patents, purportedly covering Remicade, which may cause Celltrion to delay entering the market; Celltrion is challenging Janssen's patents in another case. Case No. 14-11613 (D. Mass.), Dkt. 1, ¶¶ 5, 13-14, Celltrion's Complaint for Declaratory Judgment [against Janssen]. Celltrion must address these Janssen patents, both through the BPCIA procedures and through the courts, before it will be able to enter the market. If Celltrion is not able to successfully do so, then the status of Kennedy's patents become moot. This is one additional contingency, and one additional delay, which, under the "all the circumstances" analysis, further cuts against declaratory judgment jurisdiction with respect to Kennedy's patents.

IV. THERE IS NO REAL AND SUBSTANTIAL DISPUTE

Celltrion tries to make out a "real and substantial dispute" based on foreign patent litigation.[4] (Opposition at 14-16). But it provides no legal support for doing so. Celltrion mischaracterizes the *Arkema* Court as relying solely on a German lawsuit as "a sufficient affirmative act on the part of the patentee for declaratory judgment purposes". Opposition at 15, *citing Arkema*, 706 F.3d at 1358. Rather, the "affirmative act" was also based on "Honeywell

[4] Celltrion asserts that "proving a reasonable apprehension of suit is … sufficient … to establish declaratory judgment jurisdiction." Opposition at 14, n. 9, *citing Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008). This mischaracterizes *Prasco*. Even supposing a reasonable apprehension of suit, the lack of immediacy of Celltrion's potentially infringing activity must still be considered in the jurisdictional analysis. *Prasco*, 537 F.3d at 1336, n. 4. In *Prasco*, that element was not in contention, as Prasco was selling the potentially infringing product.

ha[ving] already asserted claims against Arkema in the United States for infringement of other patents covering the same technology." *Id.* at 1357, 1358. Celltrion selectively cites *Teva Pharm. USA, Inc. v. Abbott Labs.* for the proposition that foreign litigation can be considered. Opposition at 15, *citing* 301 F. Supp. 2d 819, 822. But the Illinois *Teva* decision recognized that this Court has held, to the contrary, that a "threat of suit for infringement of a United States patent cannot be inferred from the actual fact of suit on a corresponding foreign patent." *Teva,* 301 F.Supp. 2d at 822, *citing Dr. Beck & Co. G.M.B.H. v. General Electric Co.*, 210 F.Supp. 86, 92 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 538 (2d Cir. 1963).[5]

It is inappropriate for Celltrion to rely on statements made during U.K. settlement negotiations. Opposition at 15; Fed. R. Evid. 408. In any event, Kennedy disputes that it "refused" to grant a license to Celltrion during those negotiations. Celltrion likewise mischaracterizes a statement by Kennedy's attorney as meaning that it is "crystal clear that upon FDA approval, Kennedy believes Celltrion will infringe and owe royalties in the United States". Opposition 15, *citing* Pre-Hearing Conference Tr. at 6-7. Kennedy's attorney simply was addressing a hypothetical question from the Court as to what remedies might be available if Kennedy believed there was infringement and decided to bring suit. Tr. at 6.

The U.S. litigation mentioned by Celltrion (*see* Opposition at 16-17) cannot contribute to a reasonable apprehension of suit, as it involved different parties and products, (*see* MTD at 15-16) and, effectively, patents. Celltrion's statement regarding counterclaims being asserted by Kennedy against AbbVie "on all three of the patents-at-issue here" is not accurate. (Opposition at 16-17). This Court did not permit the compulsory counterclaims. The patents-at-issue are not

[5] In *Electro Med. Sys. S.A. v. Cooper Lasersonics, Inc.*, another Illinois decision, "reasonable apprehension" was based in part on the declaratory plaintiff's potential U.S. distributors having been threatened with a suit for infringement of the U.S. patents at issue. 617 F. Supp. 1036 at 1037-38.

what they used to be. The '442 patent, subject to a combined reissue and reexamination, has had all its claims not requiring cA2 held invalid, and the original cA2 claims have been cancelled or rewritten; it contains only new claims which may or may not be granted. *Abbvie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust*, 956 F.Supp.2d 429 (S.D.N.Y. 2013), *aff'd* 764 F.3d 1366 (Fed. Cir. 2014). The '120 patent, also subject to a reexamination, has had all claims not requiring cA2 held invalid; the invalidated claims are on appeal; it also contains new claims which may or may not be granted. *Abbvie v. Kennedy*, 13 CIV. 1358 PAC, 2014 WL 3360722 (S.D.N.Y. July 9, 2014). The '537 patent is subject to a reissue application, and has never been litigated; it also contains new claims which may or may not be granted. *See* Zivin Decl. in support of MTD, Exh. 4.

V. ABSENT DISMISSAL, A STAY SHOULD BE GRANTED

Celltrion is incorrect that a stay pending the ongoing post-issuance PTO proceedings will not simplify the proceedings before this Court. (*See* Opposition at 23). As explained above, significant changes to the claims are occurring in these proceedings. Such post-issuance changes to the claims *per se* create a simplification of issues such that they weigh in favor of a stay. *See VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1310, 1314 (Fed. Cir. 2014) ("This fact [that there was a motion in the post-issuance proceeding to amend claims], if considered, could only weigh further in favor of granting the stay so as to avoid unnecessary claim construction of what could potentially be a moving target in terms of claim language"; finding district court abused its discretion in not issuing a stay).[6]

[6] Celltrion is also incorrect that Section 112 rejections (written description, enablement, and indefiniteness) cannot occur during reexamination. Presentation of new or amended claims during reexamination triggers examination for compliance with Section 112. 37 C.F.R. 1.552(a); MPEP § 2258(II).

While the complaint has not yet been answered, Celltrion pretends this case is not in its early stages because of its optimism about summary judgment (Opposition at 23). But, even supposing Celltrion's optimism were warranted, the factor at issue is "the stage of the proceedings," not "likelihood of success". Celltrion points to no case in which a pre-answer stage of a proceeding was such a late stage that it weighed against a stay.

Celltrion argues it is prejudiced by Kennedy's belief that "some" of the claims may be confirmed by the PTO as patentable. (Opposition at 24). Celltrion anticipates that, after the post-issuance PTO proceedings, "the parties will end up back in this Court, litigating the invalidity of ***all*** claims-at-issue." *Id.* (emphasis added). But Kennedy's hopes or beliefs that "some" of its claims may be spared cannot alter the fact that the post-issuance PTO procedures are amending and/or eliminating claims, making future litigation over "all" claims improbable. Indeed, all claims of the original '442 patent have been cancelled or amended.

Litigating now would waste resources, including Celltrion's, causing it prejudice. Litigating an original claim now could help Celltrion only if: (1) Celltrion successfully obtains FDA approval for a product used in a method covered by that claim; (2) Celltrion chooses to market for that indication, given its capabilities and the conditions of the market; (3) that claim is not cancelled, finally held invalid, or amended during the current post-issuance proceedings; (4) Celltrion successfully invalidates that claim (and all other original Kennedy claims allegedly posing a threat); (5) no Janssen claim prevents or delays Celltrion from entering the market, rendering Kennedy's patents moot; and (6) Kennedy actually would have chosen to sue Celltrion for infringement of that claim, despite having never threatened to do so. Perhaps most tellingly, even if all six conditions were met, should Kennedy obtain new or amended claims during reissue and/or reexamination that delay or affect Celltrion's sales, then any invalidation of the original

claims would be of no benefit to Celltrion. Additionally, as the '537 and '120 patent expire on August 1, 2016, litigating those patents now would prove unnecessary if potential infringement does not occur prior to that date. Addressing the declaratory judgment action now, against a host of Kennedy's patent claims that may never harm Celltrion, rather than at the conclusion of the post-issuance proceedings, will almost certainly waste significant resources and provide no corresponding advantage to Celltrion. While Celltrion alludes to prejudice it may suffer from "uncertainty," (Opposition at 25, *quoting In re Columbia Univ. Patent Litig.*, 330 F. Supp. 2d 12, 17 (D. Mass. 2004)) Celltrion's current uncertainty regarding Remsima is due to numerous factors that cannot be eliminated through immediately litigating this declaratory judgment action. A stay should be granted if the case is not dismissed.

VI. CONCLUSION

As of the filing date of the complaint, numerous contingencies stood in the way of Celltrion launching a potentially infringing product. And, as of the filing date of the complaint, Kennedy had not taken any affirmative action to put Celltrion in reasonable apprehension of suit. Neither later facts identified by Celltrion, nor case law mischaracterized by Celltrion, can change this and retroactively create declaratory judgment jurisdiction.

If this Court nonetheless finds that there is declaratory judgment jurisdiction, a stay should be granted until the conclusion of post-issuance proceedings. Only at that point will it be clear which of Kennedy's original claims will even exist. There certainly will be none for the '442 patent. As this case has just begun, the complaint not having yet been answered, a stay will save all concerned significant resources fighting over claims that may prove irrelevant to Celltrion's activities. Celltrion, subject to significant uncertainty with or without a stay of this declaratory judgment action, will not be prejudiced by such a stay.

Respectfully submitted,

COOPER & DUNHAM LLP

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing

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was electronically mailed to counsel of record on October 14, 2014 through the Court's ECF notification system.

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