UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MEDICAL DIAGNOSTIC LABORATORIES, L.L.C.,

Plaintiff,

v.

PROTAGONIST THERAPEUTICS, INC.,

Defendant.

Case No. 17-cv-05572-EMC

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

Docket No. 25

Plaintiff Medical Diagnostics Labs alleges that Defendant Protagonist Therapeutics, Inc.'s development of a drug called PTG-200 infringes on its patent for polypeptides that bind to IL-23 receptors. These polypeptides, including PTG-200, have therapeutic potential to treat inflammatory and autoimmune diseases. Protagonist has entered into a multi-million dollar agreement with third-party pharmaceutical company Janssen, Inc. to develop the drug, perform testing necessary for regulatory approval, seek regulatory approval, and, if regulatory approval is obtained, to manufacture and commercialize the drug.

Defendant moves to dismiss, arguing that the activities alleged in the complaint all fall under the safe harbor provided by 35 U.S.C. § 271(e)(1). For the reasons below, the Court agrees that all activity alleged—with the exception of future commercialization plans—falls within the safe harbor provision. Insofar as future commercialization may infringe on Plaintiff's patent, however, the issue is not sufficiently concrete or immediate to create a case-or-controversy because several contingencies may never materialize. Thus, the Court **GRANTS** Defendant's motion to dismiss.

I. FACTUAL BACKGROUND

Plaintiff Medical Diagnostic Labs ("MDL"), a reference laboratory, alleges patent infringement by Defendant Protagonist Therapeutics ("Protagonist"), a pharmaceutical company that develops peptide-based chemicals for therapeutic purposes.

MDL owns U.S. Patent No. 8,946,150 ("the '150 patent"), which covers "novel polypeptides that bind to IL-23 receptor and inhibit the binding of IL-23 to its corresponding receptor and cell signaling thereof" and their "use" "to treat IL-23 associated human diseases including, for example, inflammatory bowel diseases, psoriasis and Crohn's disease." Compl. ¶¶ 11-12. These peptides have therapeutic potential, *id.* ¶ 15, which, of course, translates to commercial potential, as "over 10 million people in the United States are affected by IL-23 mediated immune-diseases." *Id.* ¶ 17.

In 2011, MDL filed provisional application No. 61/520,710 ("the '710 application") "covering its IL-23 receptor inhibitor technology." *Id.* ¶ 16. In 2012, it filed U.S. Application No. 13/523,286 ("the '286 application"), which claims priority to the '710 application. The '286 application published on January 31, 2013 as US 2013/0029907 ("the '907 publication"), and issued as to the '150 patent on February 3, 2015. *Id.*

On July 17, 2014, Defendant Protagonist filed provisional application No. 62/025,899 ("the '899 application"), called "Oral Peptide Inhibitors of Interleukin-23 Receptor and Their Use to Treat Inflammatory Bowel Diseases." The '899 application references MDL's '907 publication. *Id.* ¶ 19.

A few months later, in October 2014, scientists from both companies met, during which time MDL shared information about its IL-23 polypeptide research with Protagonist. *Id.* ¶ 20. On February 3, 2015, MDL's '286 patent issued. *Id.* ¶ 21. Two days later, Protagonist sent MDL a nondisclosure agreement so the parties could continue discussing their research. *Id.* ¶ 21. On February 23, Protagonist filed two new provisional applications relating to IL-23 (the '685 and '688 applications). *Id.* ¶ 22. The parties signed the non-disclosure agreement on May 5, 2015, and then held a telephonic conference regarding MDL's IL-23 research on May 29, 2015. *Id.* ¶¶ 25-26. On July 15, 2015, Protagonist filed its '627 application (which later issued as the '268

patent), containing significantly more amino acid sequences than its earlier July 2014 '899 provisional application. *Id.* ¶ 27.

Between July 15, 2015 and October 13, 2015, the parties attempted but failed to negotiate a licensing agreement for Protagonist under MDL's patent. *Id.* ¶¶ 28-30.

Then things took off for Protagonist. After an initial public offering in 2016, Protagonist began publicly announcing in early 2017 its research into PTG-200, a polypeptide hoped to have inhibiting effects on IL-23 receptors. *Id.* ¶ 31. MDL's '286 patent allegedly covering PTG-200 was issued in May 4, 2017. *Id.* ¶ 33. Just a few weeks later, on May 30, 2017, Protagonist announced a major collaboration agreement with Janssen Biotech, Inc. ("Janssen") to develop, manufacture, and commercialize PTG-200 worldwide for the treatment of Crohn's disease and ulcerative colitis (hereinafter "Janssen Agreement"). *Id.* ¶ 34; *see also* Compl. Exs. F-K.

The Janssen Agreement is phased. Under the Agreement, Janssen made an initial payment of $50 million to Protagonist to fund the research. *See* Compl., Ex. J. Protagonist is responsible for Phase 1 clinical trials of PTG-200 at its own expense, while Janssen is responsible for the Phase 2 clinical trial, with Janssen shouldering 80% of the costs. *Id.*

At a couple of critical junctures, Janssen has the option to keep on or drop out. For example, following the completion of Phase 2A of the Phase 2 clinical trial, Janssen must pay Protagonist an additional $125 million if it elects to maintain its license rights and continue the development of PTG-200 in Phase 2B of the clinical trial. *Id.* If Janssen elects to maintain its license rights after Phase 2B, then it must pay Protagonist an additional $200 million. At that point, Janssen would be responsible for the manufacture, continued development of, seeking regulatory approval for, and commercialization of PTG-200 worldwide. Meanwhile, Protagonist would be eligible for up to $615 million in additional payments if unspecified regulatory and sales milestone payments are met, as well as royalties based on Janssen's worldwide net sales. If Janssen opts out after Phase 2A or Phase 2B, then the agreement terminates. *Id.*; *see also* Compl. ¶¶ 36-38.

As of this date, PTG-200 is still in pre-clinical trials and no regulatory approval has been obtained or even sought. Thus, the parties agree that Protagonist may not commercialize or

market the drug at this time.

Though MDL generally alleges that Protagonist has "attempted to advance and sell" MDL's patented technologies, *id.* ¶ 43, the only specific example of a sale alleged are those to Janssen pursuant to the collaboration agreement. *Id.* MDL claims that Protagonist's making, using, selling, and/or offering to sell PTG-200 to Janssen infringes several claims of its '150 patent. *Id.* ¶¶ 51-68.

Additionally, MDL alleges that Protagonist has "booked millions of dollars of revenue from sales and/or use of MDL's patented IL-23 receptor inhibitor technology," and that "such sales and/or use are not reasonably related to the development and submission of information to the FDA for regulatory approval, and therefore are not exempted from infringement by the safe-harbor provision of Section 273(e)(1)." *Id.* ¶ 47. Again, the only sales that have been identified, however, are those to Janssen under the agreement. According to MDL, "on information and belief, the substantial sums received by Protagonist, and the significant future payments contemplated by the Janssen Agreement, constitute commercial revenue that Protagonist uses to fund and develop its business in general." *Id.*

II. DISCUSSION

Defendant moves to dismiss on the basis that all the alleged activities fall within 35 U.S.C. § 271(e)(1)'s safe harbor and because the possibility of future commercialization is too remote to support a case-or-controversy.

A. Whether Section 271(e) Requires Dismissal

1. *Merck KGaA v. Integra Lifesciences, I. Ltd.*

Congress has created a safe harbor for certain acts that might otherwise constitute infringement:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

In *Merck KGaA v. Integra Lifesciences, I. Ltd.*, 545 U.S. 193 (2005), the Supreme Court considered how broadly Section 271(e)(1)'s protections applied. It read the protections broadly. It held that Section 271(e)(1) "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process." *Id.* at 202. The exemption "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Food and Drug Control Act (FDCA)]." *Id.* The protection extends both to preclinical studies and clinical studies. "There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Id.*

Significantly, the Supreme Court held that the safe harbor's protections were broad enough to protect research performed in relation to drugs for which no application or information is ultimately submitted to the Food and Drug Administration. Because "scientific testing is a process of trial and error," the Supreme Court concluded that "[p]roperly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval." *Id.* at 206.

Thus, the question for determining whether the safe harbor applies is *not* whether regulatory approval is ultimately sought from the FDA. Rather, the protection applies "[a]t least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA.'" *Id.* at 206-207. In contrast, "[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the research intends to induce, is surely not 'reasonably related to the development and submission of information to the FDA." *Id.* at 206.

2. All Non-Commercialization Activities Fall Within the Safe Harbor

Merck makes clear that the safe harbor applies broadly to protect research and development reasonably related to the development of information that may be submitted to the FDA in connection with regulatory approval. Here, MDL's allegations leave no doubt that the purpose of the Janssen Agreement is to explore the viability of PTG-200 as a therapeutic drug to

treat certain anti-inflammatory conditions. Indeed, the key pre-commercialization terms relate to the division of financial and oversight responsibilities between Protagonist and Janssen with respect to pre-clinical research, Phase 1 and Phase 2 clinical trials, and the regulatory approval process. At this juncture, the only payment made under the Janssen Agreement is $50 million to fund research.

Although MDL broadly alleges that Protagonist has "attempted to advance and sell IL-23 receptor inhibitor compounds," the only specific examples alleged are the sales to Janssen under the Agreement in connection with clinical trials. Compl. ¶ 43. In the absence of a factual allegation that Protagonist has made sales to a party other than Janssen under the Agreement, or to Janssen for a specific use unrelated to research for the regulatory approval process, MDL's vague allegation of attempted sales fails to support a plausible inference that Protagonist has engaged in activities outside the safe harbor. Indeed, MDL has not identified *any* specific use, sale, or offer to sell the patented technology outside the context of the Janssen Agreement.

At the hearing, MDL advocated a new, more focused argument that was not briefed and therefore was arguably waived. In particular, MDL claimed that, at the very least, Protagonist lacked a "reasonable belief that the compound will cause the sort of physiological effect the research intends to induce," *Merck*, 545 U.S. at 205-206, until Protagonist met with MDL in May 2015, and therefore could not have benefited from the safe harbor before that time. As MDL's counsel put it, Protagonist had a "Eureka!" moment after MDL divulged its secrets at that 2015 meeting. MDL's suspicion is bolstered by Protagonist's disclosure of significantly more amino acid sequences in its '627 application (filed only two months later on July 15, 2015) than in its July 2014 provisional '899 application. According to MDL, the only explanation is that Protagonist used the information it learned at the "Eureka!" meeting to identify the new polypeptides.

MDL's "Eureka!" theory is flawed. First, MDL does not allege anywhere in its complaint that Protagonist lacked a reasonable belief regarding the potential of the drugs it was researching (including the PTG-200), nor does it allege facts that would support that inference. Thus, the complaint, as pled, does not support MDL's theory.

Second, even assuming that Protagonist lacked a reasonable belief *before* the May 2015 meeting with MDL, that "Eureka!" moment would, by definition, have then endowed it with a reasonable belief in the drug's potential. That epiphany *precedes* the Janssen Agreement, and therefore any sales or uses pursuant to the Agreement, by two years; MDL has not alleged any infringing sales or uses prior to the Janssen Agreement. Thus, the "Eureka!" theory now advanced by MDL would, if anything, immunize under Section 271(e)(1) Protagonist's conduct pursuant to the Janssen Agreement.

Third, as a matter of fact, it is highly unlikely that Protagonist lacked a reasonable belief prior to the May 2015 meeting with MDL. As Protagonist's counsel pointed out and MDL's complaint acknowledges, Protagonist had already been developing and researching polypeptides with the specific purpose of locating the four-leaf clover that would inhibit IL-23 receptors, as indicated by Protagonist's July 17, 2014 provisional '899 application. Thus, in light of MDL's own allegations, it is implausible to suggest that, at least as of July 17, 2014, Protagonist lacked a "reasonable belief that the compound will cause the sort of physiological effect the research intends to induce." *Merck*, 545 U.S. at 205-206. Indeed, that was the very purpose of the discussion between MDL and Protagonist.

Plaintiff has therefore failed to plausibly plead that the narrow exception to the safe harbor provision applies here.

3. Plaintiff Fails to Plead That the Allegedly Infringing Activities Were Not Reasonably Related to the FDA Approval Process

Plaintiff also argues that its complaint should survive dismissal because it creates a factual dispute by pleading that "[o]n information and belief, such sales and/or use are not reasonably related to the development and submission of information to the FDA for regulatory approval, and therefore are not exempted from infringement." Compl. ¶ 47. MDL argues in its supplemental brief, "there is a dispute regarding MDL's factual allegations about whether certain of Protagonist's infringing activities are *in fact* reasonably related to obtaining FDA approval." Docket No. 42 at 1 (emphasis in original).

The problem here is that MDL has not alleged any specific sales or uses to begin with, as

explained above, except those pursuant to the Janssen Agreement, which occurred years after the "Eureka!" moment that MDL says gave Protagonist a reasonable belief about the therapeutic potential of PTG-200. Moreover, MDL's revised position that it "has alleged infringement in its complaint based on Protagonist's making and using activities occurring between issuance of the '150 patent on February 3, 2015 and approximately five months later, on July 15, 2015, when Protagonist filed its patent application that led to the '268 patent," Docket No. 42 at 4, is not supported by the complaint because MDL does not identify any "making and using activities" occurring during that time period.

Although whether challenged activity is reasonably related to the development and submission of information for FDA approval may in some circumstances be a fact question, there must be specific facts alleged to create a plausible claim to the contrary in order to escape dismissal under the safe harbor provision. *Aschroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). The complaint does not support a plausible inference that Protagonist used or sold MDL's patented technology in a manner not reasonably related to developing information for submission in connection with the regulatory approval process. The Janssen Agreement centers on and is predicated on the process of obtaining FDA approval, and the initial $50 million payment (the only payment due at this stage of the Agreement) is specifically directed at research leading the clinical trials.

The cases relied on by Plaintiff are inapposite because in those cases there was a factual foundation to challenge whether the uses were reasonably related. *See, e.g., ISIS Pharms., Inc. v. Santaris Pharma A/S Corp.*, 2014 U.S. Dist. LEXIS 26148, at *35 (S.D. Cal. Feb. 27, 2014) (at summary judgment, defendant failed to present any evidence that "at the time it entered into the collaboration agreements, it knew of the 'particular biological process' and 'particular physiological effect'" that the patented compounds would have, whereas here the Janssen Agreement states that it relates to development of PTG-200 "for the treatment of Crohn's disease ('CD') and ulcerative colitis ('UC')"); *Chang v. Biosuccess Biotech Co., Ltd.*, 76 F.Supp.3d 1022, 1036 (C.D. Cal. 2014) (the plaintiff "ha[d] presented *evidence* that supports a claim that [defendant] has imported and used pharmaceutical TPA [the patented compound] for reasons that

go beyond seeking FDA approval" (emphasis added)). No similar factual foundation establishing a lack of reasonable relationship is alleged here.

4. Protagonist's Business Motivations and Janssen's Payments Do Not Deprive Protagonist of Safe Harbor Protection

MDL argues that Protagonist's activities fall outside of the safe harbor because Protagonist has received (or will receive at a later juncture) a large sum of money from Janssen and has used the results from its testing to generate investor interest and to present its findings at various conferences or in press releases, activities not tied directly to research and FDA approval. *See, e.g.*, Compl. ¶¶ 31-35, 47. For instance, some of the funds that may be paid in the future arguably reflect consideration for licensing rights in addition to funding research and clinical trials.

In its reply, Protagonist relies on *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997). In *AbTox*, AbTox—the defendant—counterclaimed that the plaintiff MDT had infringed on one of its patents by "conduct[ing] limited tests consistent with the collection of data necessary for filing an application with the Food and Drug Administration (FDA) for approval of its Class II medical device." *Id.* at 1027. AbTox argued that "the actual *purpose* of these tests was not to secure FDA approval, but was intended, *inter alia*, to promote [a medical device it was developing] to potential customers and induce MDT to purchase the rights to the device, which it did." *Id.* (emphasis added). The Federal Circuit rejected AbTox's argument that the *purpose* of the otherwise protected activity was material. Rather, it explained that "section 271(e)(1) requires only that the otherwise infringing act be performed 'solely for *uses* reasonably related to' FDA approval." *Id.* at 1030 (emphasis in original) (quoting 35 U.S.C. § 271(e)(1)). Because the statute focuses on *uses* of a patented technology, the court held that "[t]he statute . . . does not look to the underlying purposes or attendant consequences of the activity (*e.g.*, tests led to the sale of the patent), as long as the use is reasonably related to FDA approval." *Id.* "In other words, the statutory language allows MDT to use its data from the tests for more than FDA approval." *Id.* at 1030. *See also Intermedics, Inc. v. Ventitrex, Inc.*, 775 F.Supp. 1269, 1277 (N.D. Cal. 1991).[1]

[1] The analysis in *Intermedics* has been expressly endorsed by the Federal Circuit. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 n. 5 (Fed. Cir. 1992)

In its supplemental brief, MDL does not dispute that *AbTox* remains good law, but now claims that "because the parties dispute *whether* certain of Protagonist's infringing activities are reasonably related to obtaining FDA approval, it is inappropriate under *AbTox* to look to the 'underlying purposes or attendant consequences of the activity.'" Docket No. 42 at 1 (emphasis in original). To a certain extent, MDL's argument creates an irony; it is MDL—not Protagonist—that suggested the Court look to Protagonist's business motivations to determine whether the safe harbor applies. *See* Opp. at 9 (arguing that "the substantial payments from Janssen to Defendant" were not reasonably related to providing information to the FDA). Indeed, MDL now goes so far as to argue that "the plain language of § 271(e)(1), as interpreted by *AbTox*, *precludes* consideration of the 'underlying purposes or attendant consequences of [Protagonist's] activit[ies] when making a factual determination about the activities' reasonable relation to obtaining FDA approval." Docket No. 42 at 4 (emphasis added). The Court agrees, but that is a reason for granting, at least in part, not denying, Protagonist's motion.

The only activity alleged to have already taken place so far, however, is Janssen's payment of $50 million to Protagonist to fund the research and initiate the clinical trial process. Compl., Ex. J at 3. This is clearly reasonably related to the development and submission of information for the FDA approval process. Whether Protagonist is ultimately motivated to use that research (or the money) to promote or commercialize the drug is immaterial under *AbTox*.

To the extent MDL alleges that future payments under the Janssen Agreement are not protected by the safe harbor, the Court notes that the clear purpose of the agreement with Janssen revolves around obtaining FDA approval of PTG-200. The agreement is explicitly structured around the stages of FDA approval. Protagonist and Janssen are betting on PTG-200's success as a therapeutic drug, and they are also betting on FDA approval to manufacture and market the drug. Janssen funds Protagonist's research to pave the road to regulatory approval and, in exchange,

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(pointing to *Intermedics* "[f]or a carefully reasoned and exhaustive analysis of the point" made by the Federal Circuit itself that "[i]f Congress intended to make [it more difficult for competitors to raise funds to develop and test their products] by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear").

Protagonist offers Janssen the future option to exercise an exclusive license to Protagonist's patent over PTG-200.

That future contingent payments to Protagonist by Janssen for licensing rights may be characterized as creating an incentive to Janssen to assume risks and incur costs in the development and obtaining FDA approval does not necessarily deprive Protagonist of the safe harbor protection. The activities provided in the Janssen Agreement include, *inter alia*, completion of the Phase 2A and Phase 2B portions of the clinical trials, and Janssen's election at both junctures whether to pursue the agreement, including whether to maintain license rights for sums in the range of $125 and $200 million. *See* Compl., Ex. J at 3. Though the question is not yet ripe for review for the reasons stated below, it is by no means clear that the size of those payments or Protagonist's subsequent use of the money to invest in other research unrelated to PTG-200 is relevant to the safe harbor analysis. As the *Intermedics* court explained, "Congress clearly intended . . . to create a legal environment in which the potential competitors of patent holders would be free, through non-infringing activities like raising capital, to position themselves to enter the market in a commercially significant way just as soon as the relevant patents expired." *Intermedics*, 775 F.Supp. at 1278. In crafting the safe harbor, "Congress understood that in the real world of high-tech medicine, at least, it is 'business purposes' that inspire the kinds of infringing activities that the exemption clearly covers." *Id.* at 1279. Against this backdrop, "[i]t would strain credulity to imagine that Congress was indifferent to the economics of developing and marketing drugs and medical devices when it enacted § 271(e)(1)." *Telectronics*, 982 F.2d at 1525. To the contrary, Congress was surely aware "of the need of competitors to raise funds for developing and testing competing products, and for preparing to enter the market once controlling patents had expired." *Id.* Affording Janssen a potential license as part of the consideration for payments to Protagonist for research and FDA approval appears to be illustrative of "the need of competitors to raise funds for developing and testing products" that Congress had in mind when it enacted Section 271(e)(1). *Telectronics*, 982 F.2d at 1525.[2]

[2] Further, Protagonist's press releases and conference presentations regarding its development of PTG-200 do not deprive the underlying testing activity of protection; *Merck* also involved the

In any event, as explained above, the only uses or sales allegedly covered by MDL's patented technology that have already transpired concern the research phases of the Janssen Agreement following the initial $50 million payment but preceding the completion of Phase 2A and Phase 2B. Defendant's motion is **GRANTED** with respect to those allegations because Plaintiff fails to allege any current activity that falls outside of the Section 271(e)(1) safe harbor. As to Plaintiff's allegation that the safe harbor would not apply to further payments made after the successful completion of future clinical trials if Janssen elects to maintain its licensing rights, and to Janssen's and Protagonist's plan to actually manufacture, market, and commercialize PTG-200, Compl. ¶ 48, the Court need not reach the question whether the safe harbor applies. As explained below, because this and other future activity have not yet happened, the Court must first analyze whether the question is ripe.

B. Whether a Case-or-Controversy Exists

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). To create a real case or controversy, however, the dispute must "be definite and concrete, touching the legal relations of parties having adverse legal interests," and must be "real and substantial and admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). "Basically, the question in each case is whether the facts alleged, under all circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Maryland Casualty Co. v. Pacific*

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publication and presentation of data at conferences, and *AbTox* similarly involved the sharing of test results to promote sales to clients. *See also Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007) ("That the experiments contributed to scientific knowledge does not deprive them of the safe-harbor benefit of § 271(e)(1) when the requirements therefor are met."); *see also Intermedics*, 775 F.Supp. at 1281 (noting that "[t]o raise funds, and to comply with securities laws, [defendant] provided potential investors with information about [its] status and testing").

Coal & Oil Co., 312 U.S. 270, 273 (1941)).

The possibility of future payments under the Janssen Agreement and ultimately commercialization of PTG-200 is too speculative and contingent to create a case or controversy under Article III. Payments beyond the already committed $50 million are contingent on favorable clinical trial results, approvals by the FDA, and discretionary decisions by Janssen to continue moving forward at various phases of the clinical testing process. *See, e.g.*, Compl. Ex. J at 3 (Janssen has the right to opt-out of the agreement either after Phase 2A or Phase 2B of the clinical testing process, before regulatory approval let alone commercialization). No case or controversy arises from such speculative and multiple uncertain contingencies. *See, e.g., Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007) (where plaintiff's present activities were protected by the safe harbor provision, "[t]he fact that [plaintiff] may file an NDA in a few years does not provide the immediacy and reality required for a declaratory judgment"); *cf. Alphamed Pharmaceuticals Corp. v. Arriva Pharmaceuticals, Inc.*, 391 F.Supp.2d 1148, 1160 (S.D. Fl. 2005) (holding that allegations that present safe harbor activities "will lead to 'inevitable commercialization activities'" were insufficient to create a case-or-controversy where the plaintiff did not "allege with any specificity what these activities are and *whether they are imminent*" (emphasis added)). Future payments are not "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty*, 312 U.S. at 273. Entertaining the case would require the Court to proceed based "upon a hypothetical state of facts." *MedImmune*, 549 U.S. at 127.[3]

Because there is no case-or-controversy Article III standing, there is no occasion for the Court to exercise its discretion whether entertaining the action would be appropriate as a matter of prudential standing. *See Gov't Employees Ins. Co. v. Dizol*, 133 F.3d 1220 (9th Cir. 1998)

[3] As explained above, even if the significantly larger payments Janssen is to make to Protagonist after Phase 2A and Phase 2B somehow transform Protagonist's use of Plaintiff's patented technology into having less of a reasonable relationship with the FDA process (which the Court doubts), that question is still not sufficiently imminent to merit review. It is yet unknown if and when Phase 2A will be completed, let alone whether Janssen will at that point opt to pursue the collaboration and make the payments to Protagonist. Similarly, it is unknown whether Janssen will continue after Phase 2B.

(holding that a suit seeking declaratory judgment must first "pass[] constitutional and statutory muster" as presenting a case-or-controversy before the court exercises its discretion whether "entertaining the action is appropriate"). Even if there were such occasion, however, the Court, considering "equitable, prudential, and policy" factors, *see MedImmune*, 549 U.S. at 136, would decline to do so. In the patent context, courts typically permit a plaintiff seeking a declaration of non-infringement to proceed on the understanding that a plaintiff "need not bet the farm, or . . . risk treble damages [for patent infringement] . . . before seeking a declaration of its actively contested legal rights" or force the potential infringer to make "in terrorem choices." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 883 (Fed. Cir. 2008). The circumstances here are reversed: it is Protagonist and Janssen (not MDL) who are betting the farm, so to speak. They are on notice that MDL believes PTG-200 will infringe on its patented technology. Because it is not yet known whether the FDA will approve further clinical trials or ultimately give final approval to PTG-200, whether Janssen and Protagonist will in fact seek such further and final approval, and whether Janssen will opt in at contractually specified junctures, Plaintiff has not identified a clear equitable or policy reason to entertain its request for declaratory relief at this time.

Plaintiff has cited no case-law to the contrary. The Court **GRANTS** Defendant's motion to dismiss the request for declaratory judgment based on future payments or commercialization as not presenting a case-or-controversy at this juncture. Dismissal is without prejudice to re-filing if and when the challenged conduct which MDL contends falls outside the safe harbor becomes imminent or concrete.

III. CONCLUSION

The Court **GRANTS** Defendant's motion to dismiss.

Plaintiff has not adequately pled that Defendant is currently engaging, or has engaged, in any infringing activities that are not protected by the Section 271(e)(1) safe harbor provision. Though Plaintiff did not identify other facts at the hearing or in its supplemental brief pertaining to activities outside of the safe harbor, the Court will grant Plaintiff leave to amend only if it can allege specific sales or uses outside of the Janssen Agreement, or specific uses under the Agreement but which are not reasonably related to seeking FDA approval, with an articulation

why they are not consistent with this Order. If Plaintiff opts to do so, Plaintiff must file the amended complaint within 30 days.

To the extent Plaintiff claims that future payments or commercialization of PTG-200 would fall outside the safe harbor and infringe its patent, that claim is at present too speculative to create a case or controversy under Article III. Nor does it warrant the Court's exercise of its discretion to exercise jurisdiction to issue declaratory relief. Plaintiff does not have leave to amend that claim but may re-file in the future if commercialization becomes imminent or concrete.

This order disposes of Docket No. 25.

IT IS SO ORDERED.

Dated: February 7, 2018

EDWARD M. CHEN
United States District Judge