UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

No. 1:24-cv-00913

Merus N.V.,
Plaintiff,
v.
Xencor, Inc.,
Defendant.

OPINION AND ORDER

Defendant moves to dismiss this patent-infringement action, arguing that its accused use of plaintiff's patented antibody technologies is activity "reasonably related" to obtaining FDA regulatory approval and thus not infringing under 35 U.S.C. § 271(e). As explained below, the court grants the motion to dismiss.

I. Hatch–Waxman's double-sided change to patent rights

In the Hatch–Waxman Act, Congress addressed a problem at the intersection of the patent promise and regulatory delay. In return for disclosing an invention, a patent holder receives a time-limited exclusive right to practice the invention. But if the patent holder wants to sell a drug or product whose commercialization is regulated by the Food and Drug Administration (FDA), the drug or product must undergo safety testing through lengthy clinical trials. That testing generally occurs after the patent is filed, while the patent term is running. So, for instance, a pharmaceutical company might spend many years conducting preclinical studies, clinical trials, and navigating FDA review before a drug is cleared for the market. But the company would earn no revenue from its patented drug while it awaits market clearance.

The other half of the patent promise is that the patentee must disclose the invention so that competitors can make and use it after the patent expires. But potential competitors face their own obstacle in using an invention at that point: their own, competing products also need lengthy clinical trials for premarket regulatory

approval. Waiting for the patent to expire before even starting that safety testing would mean that the patent holder's monopoly on the invention is effectively extended for the length of the competitors' premarket approval process.

The Hatch–Waxman Act tries to address both sides of that timing problem. It extends the term of certain patents to account for delay in approving the patent holder's own drug or product for sale while the patent term is running. In an effort at balance, the Act then allows competitors to use the patented invention to get premarket approval of their own drugs or products, so that competitors can enter the market when a patent expires.

Specifically, the Act offers a patent-term extension of up to five years based on the length of the premarket-approval process. 35 U.S.C. § 156. Term extension is available only for patents covering a defined "product"—generally products subject to safety trials before they are approved for sale. One such product is "a human biological product." 35 U.S.C. § 156(f)(2)(A); *see* 42 U.S.C. § 262(i)(1) (defining biological product).

The Act then allows others to use a patented invention, without facing infringement liability, for the sole purpose of premarket regulatory clearance:

> 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 [with one exception not relevant here] solely for uses reasonably related to the development and submission of information under [a qualifying regulatory regime].

35 U.S.C. § 271(e)(1). Without that immunity, of course, those activities are infringing during a patent's term:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

Id. § 271(a).

Section 271(e) immunity has two requirements: (1) mandatory premarket approval of the accused infringer's product by a specified regulator and (2) a reasonable relationship between the allegedly infringing use and that regulatory end. In other words, the safe harbor has both an ends test and a means test.

A. The ends test

Subsection (e) creates immunity from the same liability that subsection (a) creates—for making, using, or otherwise infringing a "patented invention." "The phrase 'patented invention' . . . is defined to include all inventions, not drug-related inventions alone." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–70 (1990). So the phrase "patented invention" does not narrow the scope of immunity beyond the scope of liability.

But three other statutory phrases do: (1a) "reasonably related to" (2a) "the development and submission of information under" (2b) a federal "law which regulates," as relevant here, "drugs." *Eli Lilly* interpreted phrases 2a and 2b. Those phrases constrain which uses are eligible for immunity, in contrast to phrase 1's constraint on the means used, or how those uses objectively relate to obtaining federal regulatory premarket approval.

First, *Eli Lilly* held that the "development and submission of information under" a specified federal law means that the law must have a "requirement of premarket approval" for the putative infringer's product. *Id.* at 674 n.6. It is not enough that the law regulates the alleged infringer's product generally. *Id.* Only a premarket-approval regime causes "the need for development and submission of information" as used in § 271(e). *Id.*

Second, *Eli Lilly* held that a "law which regulates" includes regulation even in part. So if any part of an act of Congress requires premarket approval of drugs—the relevant statutory test—then any other product (like medical devices or infant formula) that is also subject to premarket approval under that same act allows recourse to the safe harbor. *Id.* at 666–67, 674 & n.6.

Applying that interpretation, *Eli Lilly* held that a company's alleged use of patented components in a medical device was

eligible for immunity. *Id.* at 664, 674. The ends test was satisfied because the Federal Food, Drug, and Cosmetic Act (FDCA) regulates drugs and also regulates, and requires premarket approval of, medical devices. *Id.*

Eli Lilly did not address the means test imposed by the phrase "reasonably relating," as the trial court had not decided whether the accused infringer's use was closely related enough to mandatory regulatory testing of its product. *Id.* at 664, 674. *Eli Lilly* also assumed that an accused infringer's product would usually be the same type of product as the patented invention and thus subject to the same premarket-approval regime. *Id.* at 674 n.6. But *Eli Lilly*'s explanation that its interpretation of § 271(e) immunity would often lead to symmetry with § 156 term extension was predictive, not a new legal test. *Eli Lilly* did not require symmetry in regulatory treatment between the patented invention and the accused product. *Id.*; *see Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) (rejecting the argument that "statutory symmetry . . . is required" because § 271(e) "contains no such limitation").

Eli Lilly thus held that § 271(e) immunity *is* available even if the alleged infringement is of a patent ineligible for term extension. Specifically, infant formula is not defined as a "product" eligible for patent-term extension. *Id.* at 674 & n.6. But the FDCA does require premarket approval before selling infant formula. *Id.* So although infant-formula patentees cannot receive term extension for their patents, their competitors can use those patents to develop testing data for premarket approval of the competitors' own products. *Id.*

Eli Lilly observed that, as of the Court's decision, every other product as to which the FDCA requires premarket approval is a "product" eligible for Hatch–Waxman Act term extension. *Id.* That "appears to create" a tight fit between (i) the § 271(e) immunity for using a patented invention in a way reasonably related to premarket approval of a competitor's product and (ii) the patent holder's § 156 products or methods eligible for patent-term

extension. *Id.* at 674; *see* 35 U.S.C. § 156(a) ("method of using a product" and "method of manufacturing a product" also eligible for patent-term extension). That close-but-not-perfect de facto fit between an immunity-eligible § 271(e) use of a patented invention and an extension-eligible § 156 product or method patent covering the invention has sometimes been described as creating a narrower meaning, "for purposes of section 271(e)(1), [of the term] 'patented invention.'" *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

The court will avoid that imprecise shorthand here because it is confusing. *Eli Lilly* held that the term "patented invention" in § 271(e) means "all inventions"—as it does in all of § 271. 496 U.S. at 665. Rather than defining that term narrowly, *Eli Lilly* simply defined which of *an accused infringer's* potential products can provide a basis for immunity: products subject to mandatory premarket approval under a federal law that regulates drugs. That is the "ends" part of the safe harbor test.

B. The means test

Section 271(e) immunity requires that use of a patented invention be "reasonably related to" submission of data for premarket approval under a qualifying statute like the FDCA. "Though the contours of this provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

Immunity is broadly applied to uses of a patented invention "on the road to regulatory approval." *Id.* at 206. Naturally, that includes developing information in clinical testing of the accused infringer's drug or product, the final step in the premarket approval process. *Id.* at 202. The "road to regulatory approval" also includes developing information meant to earn FDA approval to perform such clinical testing in the first place. *Id.* at 203. That includes testing not just for safety but for other characteristics—

like drug effectiveness—that may influence the FDA's balancing decision in whether to issue approval. *Id.* at 204.

Immunity on the "road to regulatory approval" also extends to the initial search for drugs or products with effects good enough to start the FDA-approval process, at least if there is "a reasonable basis for believing" that the search could lead to data on a specific product that is submitted to the FDA. *Id.* at 207. If so, use of a patented invention in that search is "reasonably related" to the required end regardless of whether the search is ultimately successful or leads to an FDA submission. *Id.* At the outer edges, however, immunity does not apply to all experimental activity that at some point, however attenuated, may lead to an FDA premarket approval application. *Id.* at 205.

The Federal Circuit has put further meat on the bones of the "reasonably related" means test in two ways relevant here. First, that test looks objectively at the accused infringer's use. If that use creates data appropriate for an FDA submission, it is "reasonably related" to that end regardless of any subjective intent to also spread awareness of the accused infringer's product. *AbTox*, 122 F.3d at 1030; *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, 96 F.4th 1347, 1356 (Fed. Cir. 2024).

Second, use of a patented *method* can be reasonably related to developing information to gain regulatory approval of a product. *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1338–39 (Fed. Cir. 2019). For example, using a patented method to manufacture a drug can be reasonably related to submitting testing data on that drug. *Id.* Immunity attaches only to uses of the method to manufacture a drug for testing that may be relevant to FDA approval, not simply to testing for advertising purposes. *Id.* at 1339. But approval-related submissions can include data that may also have commercial importance, such as data on drug effectiveness. *Merck*, 545 U.S. at 204.

II. The technologies and dispute here

Antigens and antibodies underlie this case. An antigen is a toxin or other foreign substance that induces an immune response

in the human body. Examples are a virus or a bacterium. An antibody is a disease-fighting protein produced by the immune system to identify and neutralize antigens. It works by binding to an antigen receptor (epitope) and either directly neutralizing the antigen or tagging it for destruction by other immune cells.

Scientists have discovered methods of producing antibodies that mimic the body's natural antibodies. Two types exist: monoclonal and multispecific (heterodimeric). Monoclonal antibodies are designed to bind to one antigen. Multispecific antibodies have multiple heavy chains that let them bind to two (bispecific) or three (trispecific) different antigen receptors simultaneously.

Monoclonal antibodies have been used for years in lab settings to help evaluate the efficacy of drug compounds. Now, monoclonal and bispecific antibodies are used as therapeutic drugs to fight cancers and other diseases.

Plaintiff Merus owns three U.S. patents concerning these technologies: Number 9,944,695 concerns a method of making an antibody through transgenic mammals, such as mice into which human DNA has been introduced (making them transgenic). Numbers 9,358,286 and 11,926,859 claim a method of making multispecific antibodies and the antibodies themselves, respectively. The patents are described in more detail below.

A. The '695 patent

Nucleic acids are large biomolecules that store genetic information. That genetic information encodes sequences that are directions for how the body should make important proteins for the immune system, like antibodies that neutralize antigens and other toxins. For instance, DNA encodes information, and RNA uses that information to make amino-acid chains that connect to form important proteins for the body's immune system. DNA is the recipe book, and RNA is the chef.

The '695 patent is titled "Antibody Producing Non-Human Mammals." It teaches how to encode human nucleic-acid chains in a nonhuman mammal (like a mouse) to make cells (B cells) that then produce human antibodies to be extracted and put back into

humans to target specific antigens. Because it uses human genes in a different species to create therapeutic antibodies for humans, it is called transgenic therapy.

The '695 patent claims "[a] method of obtaining an antibody that binds to an antigen" by "immunizing a transgenic mouse with the antigen" to obtain "a population of B cells producing antigen specific antibodies" to ultimately obtain "an antibody which binds to the antigen." Plaintiff alleges that its patented method protects its own product, the Merus Mouse, which has human genes that allow its use to create new, multispecific antibodies targeting tumor cells among others. Doc. 1 at 3. Specifically, plaintiff alleges that its patented method protects the manufacture of Zeno and Peto—two of plaintiff's bispecific antibodies. *Id.* at 8.

The FDCA requires premarket approval for therapeutic antibodies. In the language of the statute, they are a "biologic": a drug derived from animals. 42 U.S.C. § 262(i)(1); *see Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 6 (2017). Manufacturers earn a license to sell biologics by submitting an application detailing the product's safety, efficacy, and manufacturing details. 42 U.S.C. § 262(a); 21 C.F.R. § 601.2(a).

Defendant is Xencor, Inc., a company that engineers therapeutic antibodies. Plaintiff alleges that defendant infringes the '695 patent through each of the following acts:

- "obtaining [multispecific] antibodies that bind to an antigen," Doc. 1 at 9;
- collaborating with a third-party "to obtain and/or use" a product called the "RenLite mouse" as a "platform for bispecific antibody discovery," *id.* at 9–10;
- immunizing the "RenLite mice with antigens" to obtain "B cells that produce antibodies specific to those antigens," *id.* at 13;

- incorporating the third party's process "to create and obtain antigen-specific antibodies," *id.* at 15; and
- making "multispecific antibodies that bind to" cancerous proteins, as disclosed in Xencor's patent application number U.S. 2023/0383012. *Id.* at 9, 15.

Defendant Xencor allegedly infringes during "the antibody generation and discovery process" that occurs before any antibody is advanced as a candidate for regulatory review. *Id.* at 16.

B. The '286 and '859 patents

Both the '286 patent and the '859 patent are titled "Methods and Means for the Production of Ig-Like Molecules." Ig-like molecules are proteins that contain immunoglobulin domains—versatile protein structures with a distinctive fold that have a wide range of functions in the body, including but not limited to the immune system. The patents specify that the Ig-like molecules claimed relate to therapeutics for treating various diseases.

The '286 patent is a method patent. It claims a method of producing a multispecific antibody by harvesting the antibody from a culture—an artificial laboratory condition that encourages cellular growth, which promotes production of antigen-specific antibodies. The '859 patent is a product patent. It claims a multispecific antibody in which the amino acids comprising the antibody are preferentially charged, i.e., one positive and one negative charge, to encourage specific protein folding. Put differently, it claims a product that allegedly "allows for preferential and stable pairing of different antibody heavy chains to create a desired heterodimer, including as part of forming a multispecific antibody of interest." Doc. 1 at 7. Plaintiff alleges that the '286 and '859 patents cover plaintiff's own Zeno and Peto antibodies and their method of manufacture. *Id.* at 8.

Plaintiff alleges that defendant Xencor infringes the '286 and '859 patents through each of the following acts:

- making "stable bispecific antibodies" by Xencor's "XmAb bispecific platform," which is a set of methods to create antibodies with specific properties in a protein structure known as the Fc domain, *id.* at 17;
- changing the charge of two amino acids from neutral to one positive charge and one negative charge to "drive preferential pairing" and "create stable bispecific antibodies," *id.*; and
- generating "early discovery," "preclinical," and "clinical . . . multispecific antibodies." *Id.* at 18.

Xencor allegedly infringes long before any antibody is selected as a possible candidate for regulatory review or approval. *Id.* at 19.

III. Procedural posture

Defendant moves to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that its alleged conduct is either immunized from infringement liability under § 271(e) or else not infringing at all because it does not produce an antibody.

The Federal Circuit applies the regional circuit's law when reviewing a motion to dismiss for failure to state a claim. *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1092 (Fed. Cir. 2016). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a district court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, "accept[ing] all of the complaint's well-pleaded facts as true, but . . . disregard[ing] any legal conclusions." *Id.* at 210–11. Second, the court determines whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

Assessing plausibility, the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). "To decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). "However, an exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered . . . ." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (cleaned up).

The safe-harbor provision is an affirmative defense. *Galderma Labs., L.P. v. Medinter US, LLC*, No. 1:18-cv-01892, 2020 WL 871507, at *2 n.2 (D. Del. Feb. 14, 2020). "The Court may dismiss a claim pursuant to a Rule 12(b)(6) motion in light of an affirmative defense . . . only where the well-pleaded factual allegations in the complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense." *Id.* (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007), and *Kabbaj v. Google, Inc.*, No. 1:13-cv-01522, 2014 WL 1369864, at *2 n.2 (D. Del. Apr. 7, 2014)). Plaintiff argues that a motion to dismiss is not the place to address the safe-harbor affirmative defense. But the Federal Circuit has affirmed a Rule 12(b)(6) dismissal under the § 271(e) safe harbor. *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 586 F. App'x 585 (Fed. Cir. 2014) (per curiam; unpublished), *aff'g* 993 F. Supp. 2d 569 (D. Md. 2014).

IV. Infringement of the patents in suit

The alleged uses by defendant of all three patents in suit meet § 271(e)'s two tests for immunity or simply do not establish infringement liability in the first place.

A. The ends test

1. Plaintiff first disputes whether defendant's alleged conduct meets the ends test for § 271(e) immunity as to the '695

patent. Plaintiff accuses defendant of making "multispecific antibodies that bind to" three specific cancerous proteins. Doc. 1 at 15. On plaintiff's allegations, defendants infringed the '695 patent by conducting experiments with specific antibodies that target specific antigens. The resulting antibodies are not mere research tools but products subject to premarket FDA approval. *See* Doc. 1 at 8 (disclosing that plaintiff's own Zeno antibody is subject to premarket approval under the FDA's biologics license application).

All but one of plaintiff's allegations include producing or obtaining antigen-specific antibodies. Those are products subject to premarket FDA approval, just as are plaintiff's Zeno and Peto products. *Id.* The remaining infringement allegation concerns collaborating with a third-party, not named as a defendant here, to conduct "antibody discovery." *Id.* at 9–10. Even assuming that antibody discovery does not include obtaining an antibody, plaintiff's allegation still fails to show infringement. The '695 patent claims (at col. 163 ll. 38–39) a "method of obtaining an antibody that binds to an antigen." So if defendant's alleged activity is mere general research, i.e., defendant does not obtain an antibody, then it is not infringing activity in the first place.

Plaintiff's argument is inconsistent with the '695 patent claim limitations at column 163, line 40 through column 164, line 52, which require "immunizing a transgenic mouse with the antigen," "obtaining a population of B cells producing antigen specific antibodies," and "obtaining an antibody which binds to the antigen." To infringe the '695 patent, defendant thus must have used a specific antigen. Such a method to obtain an antigen-specific antibody is not a mere research tool. It is the kind of trial-and-error that falls within the safe harbor. *Merck*, 545 U.S. at 205–07 ("Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval.").

2. For the same reasons, the alleged infringement of the '286 patent and '859 patent concern regulated products allowing

access to § 271(e) immunity: multispecific antibodies subject to premarket approval under the FDCA.

The '286 patent claims (at column 71, lines 38–62) a "method for producing a heterodimeric antibody" that includes "produc[ing] a heterodimeric antibody" and "harvesting said heterodimeric antibody." The '859 patent claims (at column 69, lines 33–38) a "heterodimeric antibody" wherein the amino acid at position 364 is positively charged and the amino acid at position 368 is negatively charged. In both patents, the defendant must harvest, possess, or create a multispecific antibody to infringe. So, again, if defendant's accused conduct does not create a multispecific antibody, it is not infringing in the first place. And if defendant's accused conduct does create a multispecific antibody, that opens access to § 271(e) immunity because such antibodies are biologics subject to FDA premarket approval. Doc. 1 at 8.

Plaintiff itself claims that the '286 patent covered Zeno and Peto, plaintiff's leading therapeutic candidates. *Id.* ("Elements of Zeno and Peto, as well as their *creation and production*, are covered by [plaintiff's '695, '286, and '859 patents].") (emphasis added). If the '286 patent protects plaintiff's therapeutic antibodies that are subject to FDA premarket approval, then defendant's alleged use of that patented method to produce therapeutic antibodies is also subject to premarket FDA approval. *See* 21 C.F.R. § 601.

B. The means test

Judging solely from the face of complaint, the accused infringement meets the means test for § 271(e) infringement immunity. It is "reasonably related" as a matter of law to developing data for FDA premarket approval of defendant's antibodies.

1. As discussed above, to infringe the '695 patent, the defendant must immunize a transgenic mouse (or other non-human mammal) to obtain an antigen-specific antibody. Under *Merck*, when an accused infringer "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, that use is reasonably related" to that potential submission. 545 U.S. at 207.

Defendant's accused infringement involves specific cancerous proteins to be targeted by desired antibodies. So defendant allegedly infringes with "the intent to develop a *particular* drug" or with "a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce." *Id.* at 205–06. That makes the accused infringement "reasonably related" to premarket FDA approval. *Id.* at 205–07.

Plaintiff argues that defendant infringes the '695 patent "at an even earlier stage of research than the 'basic scientific research on a particular [antibody]' that [*Merck*] excludes" because infringement occurs before defendant has "develop[ed] a . . . particular antibody." Doc. 20 at 20. But that argument does not help plaintiff given the claims of the '695 patent, which at column 163, line 40 through column 164, line 52 require development of an antigen-specific antibody.

Merck works directly against plaintiff's argument. The Supreme Court held that "[t]here is simply no room in [§ 271(e)] for excluding certain information from the exemption on the basis of the phase of research in which it is developed." *Merck*, 545 U.S. at 202–03 (holding that the safe harbor applies to preclinical *in vivo* and *in vitro* studies because it may be the only "way in which a drugmaker may obtain" the necessary information for premarket approval). Here, defendant is allegedly studying and developing antibodies that target specific antigen receptors. Doc. 1 at 15. That activity is beyond mere general research; it is the "process of trial and error" inherent in scientific testing. *Merck*, 545 U.S. at 206; *see also Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) ("§ 271(e)(1) is sufficiently broad to leave adequate space for *experimentation* and failure on the road to regulatory approval") (emphasis added; cleaned up).

Plaintiff directs the court's attention to two decisions denying a motion to dismiss under the safe harbor, *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 1:20-cv-01226, 2022 WL 609141

(D. Del. Jan. 4, 2022), and *BlueAllele Corp. v. Intellia Therapeutics, Inc.*, No. 1:24-cv-00791, 2024 WL 5046278 (D. Del. Dec. 9, 2024). But those decisions are distinguishable.

In *REGENXBIO*, the patent claimed "cultured host cells" that did not require premarket approval. 2022 WL 609141, at *4. In contrast, the antibodies here are biologics that do require FDA premarket approval—as do plaintiff's antibodies. That explains the different result here than there.

In *BlueAllele*, the court held that the accused infringement was not immunized by § 271(e) because the defendant's gene-editing technology was eligible for immunity at certain stages of product development and research but not others. 2024 WL 5046278, at *2–4. When used for "basic research" the gene-editing technology was not subject to a premarket regulatory regime. But when the technology was incorporated into an infringing product, it was subject to premarket regulatory approval. That is again different than here. The court there also refused, at the motion to dismiss stage, to accept the defendant's claim that the infringement occurred before the patent issued because that claim conflicted with the complaint. *Id.* Here, in contrast, the plaintiff's complaint by itself shows that the accused activity is § 271(e) immune.

Plaintiff argues that the alleged infringement occurred long before a specific antigen was chosen based on the desired therapeutic goal, so it could not be "reasonably related" to producing information for the FDA. Docs. 1 at 16, 20 at 14–15. But the '695 patent is not infringed until a specific antigen is selected for targeting. Plaintiff cannot allege infringement of a claim that requires "obtaining a population of B cells producing *antigen specific antibodies*" while arguing that infringement occurs earlier, regardless of a specific antigen. *See BotM8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1354 (Fed. Cir. 2021) ("Where, as here, the factual allegations are actually inconsistent with and contradict infringement, they are likewise insufficient to state a plausible claim.").

2. The same is true for the '286 and '859 patents. To infringe them, defendant must have created or used an antigen-specific

antibody. *See* '286 patent at col. 73, l. 3 (limiting the variable regions in claim 1 to two different target epitopes); '859 patent at col. 70, ll. 42–44 (limiting the heterodimeric antibody to one of pharmaceutical application). Under *Merck*, when an accused infringer "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, that use is reasonably related." 545 U.S. at 207.

Because defendant's accused infringement includes targeted antigens, defendant allegedly infringes with "the intent to develop a particular drug" or "a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce." *Id.* at 205–06. So the accused infringement is "reasonably related" to developing data for premarket approval. *Id.* at 205–07.

Plaintiff argues that defendant has yet to "identify a multispecific antibody for further study" and infringes the '286 patent to "streamline [defendant's] creation of previously unknown multispecific antibodies for potential further study." For the reasons discussed above, that argument is unavailing. Trial and error to discover products appropriate for placing into the FDA approval process is protected activity under the safe harbor. *Merck*, 545 U.S. at 206; *see also Momenta*, 809 F.3d at 619.

Plaintiff argues that the '859 patent "is directed to a heterodimeric antibody scaffold, without any specified variable regions." The alleged "scaffold" nature of the '859 patent is inconsistent with plaintiff's allegation that the patent covers Zeno and Peto and with claim 7. *See* '859 patent col. 70, ll. 42–44 (multispecific antibody must be one of pharmaceutical application, not mere scaffold). Although plaintiff's response brief asserts that the '859 patent is directed to an antibody scaffold, its complaint makes clear that its "patented heterodimerization technology . . . drive[s] preferential pairing of different antibody heavy chains to create stable *bispecific* antibodies." Doc. 1 at 17 (emphasis added).

Bispecific antibodies are antibodies designed to bind to two specific antigen receptors (epitopes). Doc. 1 at 4. Plaintiff argues that defendant's "Moore paper shows that [defendant's] infringing use of the '859[] Patent includes use to test a variety of formats for platform development, not for drug development reasonably related to submission to the FDA." But plaintiff's complaint cites the Moore paper to show that defendant infringes the '859 patent "to make stable bispecific antibodies." *Id.* at 17. Thus, plaintiff's assertion that the '859 patent covers an antibody scaffold has no support in its complaint or the patent. The court "is not compelled to accept assertions in a brief without support in the pleadings." *Chavarriaga v. N.J. Dep't of Corr.*, 806 F.3d 210, 232 (3d Cir. 2015).

Lastly, plaintiff relies on *Isis Pharmaceuticals, Inc. v. Santaris Pharma A/S Corp.*, No. 3:11-cv-02214, 2012 WL 4111157 (S.D. Cal. Sept. 19, 2012). There, the alleged infringement occurred before there was an identified "therapeutic target." *Id.* at *6. Here, in contrast, the antibodies covered by the '286 and '859 patents are antigen specific. *See* '286 patent col. 73, ll. 1–3 (limiting the variable regions in claim 1 to two different target epitopes); '859 patent col. 70, ll. 42–44 (limiting the multispecific antibody to one that may have a pharmaceutical application).

Plaintiff's reliance on *Isis Pharmaceuticals* is thus misplaced. The safe harbor does not require infringement that ultimately results in submission of information under federal law; it extends to activities that are reasonably related to such potential future submission. *Merck*, 545 U.S. at 207. Whether or not defendant will submit the information relating to all bispecific antibodies allegedly generated through infringement is not part of the "reasonably related" analysis. Because information related to defendant's bispecific antibodies is of the sort objectively appropriate for submission under federal law in a biologics license application, the alleged infringing activity is "reasonably related" under § 271(e)(1). *See Edwards Lifesciences*, 96 F.4th at 1355–56.

V. Conclusion

Defendant's motion to dismiss the complaint is granted. Plaintiff has not previously amended its complaint, so plaintiff's contingent request for leave to amend is granted. Plaintiff must file any amended complaint within 21 days of this order. If plaintiff does not do so, the clerk of court is directed to close the case.

So ordered by the court on September 30, 2025.

J. CAMPBELL BARKER
United States District Judge