

Dakota biotechnology limited liability company located in Fargo, North Dakota. Id. ¶ 7. Aldevron, among other things, acts as a biotechnology manufacturer and is in the business of providing products and services to companies and research institutions, including plasmid and minicircle DNA production, protein production, and antibody generation. Id.

At issue in this case is a specific patent assigned to the University. On March 17, 2020, United States Patent Number 10,590,435 (the “’435 Patent”) was issued and ultimately assigned to the University. Id. ¶ 12; Doc. No. 1-1. Through a series of licenses, sublicenses, and assignments, REGENXBIO holds an exclusive worldwide right and license to the ’435 patent, including all past, present, and future infringement claims. Id. ¶¶ 13-17.

The ’435 Patent, titled “Adeno-associated virus (AAV) serotype 8 [(AAV8)] sequences, vectors containing the same, and uses therefor[“],” protects cultured host cells containing recombinant nucleic acid molecules with sequences encoding AAV8 capsid protein(s) and a heterologous non-AAV sequence. Id. ¶¶ 1, 32. As stated in the Complaint:

The ’435 Patent provides nucleic acid and amino acid sequences, with each unique sequence accompanied by a sequence identification number (“SEQ ID NO”). The claims of the ’435 Patent specifically cover host cells containing a recombinant nucleic acid that (a) either (1) encodes for AAV8 capsid proteins with an amino acid sequence as defined by SEQ ID NO: 2 in the ’435 Patent (or subset thereof) or (2) has a sequence as defined by nucleotides 2121 to 4334 so SEQ ID NO: 1 in the ’435 Patent (or subset thereof) and (b) contains a heterologous non-AAV sequence. The ’435 Patent also covers host cells containing nucleic acids at least 95% identical to nucleotides of SEQ ID NO: 1 and host cells containing nucleic acid molecules encoding capsid proteins having an amino acid sequence at least 95% identical to SEQ ID NO: 2, and a heterologous non-AAV sequence.

Id. For the purposes of this motion, the Court refers to the above as the “’435 Patented Biotechnology.” The ’435 Patent also includes the following independent claims:

1. A cultured host cell containing a recombinant nucleic acid molecule encoding an AAVI vp1 capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 2 (AAV8) or a sequence at least 95% identical to the full

length of amino acids 1 to 738 of SEQ ID NO: 2, wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

7. A cultured host cell containing a recombinant nucleic acid molecule comprising

- (a) nucleotides 2121 to 4334 of SEQ ID NO: 1 or a sequence at least 95% identical to nucleotides 2121 to 4334 of SEQ ID NO: 1,
- (b) nucleotides 2532 to 4334 of SEQ ID NO: 1 or a sequence at least 95% identical to nucleotides 2532 to 4334 of SEQ ID NO: 1, or
- (c) nucleotides 2730 to 4334 of SEQ ID NO: 1 or a sequence at least 95% identical to nucleotides 2730 to 4334 of SEQ ID NO: 1,

wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

(“Independent Claims 1 and 7”). Id. ¶ 51.

REGENXBIO is a client of Aldevron. Id. ¶ 40. As a part of their business relationship, REGENXBIO has ordered, and does order, a variety of plasmids¹ from Aldevron. Id. According to Plaintiffs, the business relationship works as follows. REGENXBIO initially provides a small amount of starting plasmid material to Aldevron. Id. Aldevron then takes and produces host cells that contain specific plasmid material. Id. Once Aldevron makes the host cells, Aldevron functions as a manufacturer and “amplifies,” or mass produces, the same specific plasmid material. Id. Aldevron then returns the amplified plasmid material to REGENXBIO. Id.

As mentioned above, over the course of their business relationship, REGENXBIO has ordered a variety of plasmids from Aldevron and has used Aldevron to amplify a variety of plasmid material. Relevant to this motion, some of the starting plasmid material provided by REGENXBIO to Aldevron to amplify contains the ’435 Patented Biotechnology. Id.

¹ A plasmid is a small, circular piece of DNA found within a cell.

With the background of the two companies' business relationship, the Complaint alleges that after REGENXBIO provided the plasmid material containing the '435 Patented Biotechnology to Aldevron, Aldevron "made and used cultured host cells that contain plasmids comprising recombinant nucleic acid molecules encoding AAV8 capsid proteins and a heterologous non-AAV sequence on behalf of third parties not authorized by REGENXBIO[.]" Id. ¶ 42. Said another way, Plaintiffs allege Aldevron, after having access to the '435 Patented Biotechnology, began producing the same '435 Patented Biotechnology for third parties without authorization.

The Complaint identifies and documents four specific examples of Aldevron producing AAV8 plasmid material for third parties, including (1) Freeline Therapeutics plc and its United States Securities and Exchange Commission ("SEC") Form F-1; (2) the University of Tubingen and its report to the European Commission; (3) an article from Human Gene Therapy Clinical Development by Tobias et al.; and, (4) an article from the American Society of Gene and Cell Therapy by Nathwani et al. Id. ¶ 42. Each of the four examples identifies Aldevron as the large-scale producer of the third party's AAV8 plasmid material. Id. Plaintiffs allege the plasmid material produced by Aldevron for these third parties contains the '435 Patented Biotechnology. Id. ¶¶ 52-53. Specifically, Plaintiffs allege the material produced for the identified third parties infringes on, at a minimum, Independent Claims 1 and 7 of the '435 Patent. Id. Additionally, Plaintiffs allege Aldevron's infringement is continuous and ongoing. Id.

Plaintiffs initiated this patent infringement case against Aldevron on September 16, 2020, alleging a single patent infringement claim in violation of 35 U.S.C. § 271(a). Doc. No. 1. In response to the Complaint, Aldevron filed the instant motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) and/or for a more definite statement under Federal Rule of Civil Procedure 12(e). Doc. No. 18.

II. LAW AND ANALYSIS

Aldevron seeks to dismiss Plaintiffs' Complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). According to Aldevron, Plaintiffs' Complaint fails to plausibly plead a claim for direct patent infringement. Aldevron argues the Complaint "does not provide sufficient factual content to determine what Aldevron products allegedly infringe on the '435 Patent and how any allegedly infringing products correspond to the claims of the '435 Patent." Doc. No. 19. Plaintiffs respond that their Complaint meets the plausibility standard required by Twombly and Iqbal.

A. **Rule 12(b)(6) Standard**

A brief word on the history of the pleading standard for direct patent infringement claims is necessary from the outset. On December 1, 2015, Federal Rule of Civil Procedure 84 and Form 18 were abrogated, and no longer govern the pleading standard for claims of direct patent infringement. Most district courts apply the Twombly and Iqbal pleading standard to claims of direct patent infringement. See Battle Sports Science, LLC v. Shock Doctor, Inc., 225 F. Supp. 3d 824, 835 (D. Neb. 2016) (collecting cases and applying the Twombly and Iqbal plausibility standard for direct patent infringement claims); e.Digital Corp. v. iBaby Labs, Inc., No. 15-CV-05790-JST, 2016 WL 4427209, at *3, *4 (N.D. Cal. Aug. 22, 2016) (noting that a majority of courts have adopted the plausibility standard for direct patent infringement claims). The Court will therefore apply the Twombly and Iqbal standard here.

Federal Rule of Civil Procedure 8(a) requires a pleading only to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Nevertheless, a complaint may be dismissed for "failure to state a claim upon which relief can be granted," and a party may raise that defense by motion. Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion, a

complaint must contain “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). A plaintiff must show that success on the merits is more than a “sheer possibility.” Id.

Plausibility is established when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Threadbare recitals supported by conclusory statements, however, do not suffice to meet the plausibility requirement.

Brookins Hybrid Drive Sys., LLC v. M.A.C., Inc., 3:12-CV-101, 2013 WL 12086636, at *2 (D.N.D. May 2, 2013) (cleaned up). A complaint does not need detailed factual allegations, but it must contain more than labels and conclusions. Bell Atl. Corp. v. Twombly, 551 U.S. 544, 555 (2007).

As noted above, the Court must accept all factual allegations in the complaint as true, except for legal conclusions or “formulaic recitation of the elements of a cause of action.” Iqbal, 556 U.S. at 681. The determination of whether a complaint states a claim upon which relief can be granted is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” Id. at 679. “[T]he complaint should be read as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible.” Wilson v. Ark. Dep’t Human Servs., 850 F.3d 368, 371-72 (8th Cir. 2017). “Specific facts are not necessary; the statement need only give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” Disc Disease Sols. Inc. v. VGH Sols., Inc., 888 F.3d 1256, 1260 (Fed. Cir. 2018) (cleaned up). The burden is on the moving party to prove that no legally cognizable claim for relief exists.²

² When considering a motion to dismiss under Rule 12(b)(6), courts generally must ignore materials outside the pleadings, but they may consider “some materials that are part of the public record or do not contradict the complaint,” as well as materials that are “necessarily embraced by the pleadings.” Porous Media Corp. v. Pall Corp., 186 F.3d 1077, 1079 (8th Cir. 1999) (citation

B. Direct Patent Infringement Claim

Plaintiffs plead a single patent infringement claim in violation of 35 U.S.C. § 271(a) against Aldevron. The statute states, in part: “[W]hoever 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.” 35 U.S.C. § 271(a).

Aldevron primarily argues that the Complaint does not provide enough facts to determine what products allegedly infringe on the ’435 Patent or how any allegedly infringing product corresponds to the claims of the ’435 Patent. The Court disagrees.

At this stage of the litigation, the sole question before the Court is whether Plaintiffs have pleaded a plausible direct patent infringement claim against Aldevron. Accepting as true the allegations in the Complaint, Plaintiffs have provided sufficient facts to put Aldevron on notice of what products are alleged to be directly infringing on the ’435 Patent. Aldevron argues Plaintiffs must identify the specific products that directly infringed on the ’435 Patent. However, “[plaintiffs] need not prove [their] case at the pleading stage.” Nalco Co. v. Chem-Mod, LLC, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (cleaned up). “The complaint must place the ‘potential infringer . . . on notice of what activity . . . is being accused of infringement.’” Id. (quoting K-Tech Telecomms. v. Time Warner Cable, Inc., 714 F.3d 1277, 1284 (Fed. Cir. 2013)).

In this case, K-Tech Telecommunications v. Time Warner Cable and Disc Disease Solutions, Inc. v. VGH Solutions, Inc., 888 F.3d 1256 (Fed. Cir. 2018) are instructive. First, in K-Tech, the complaint identified K-Tech’s patents and its patent-protected material, which consisted

and internal quotation marks omitted). Both parties filed affidavits and documents in support of their respective briefs. The Court finds the affidavits and documents are not “embraced by the pleadings,” and as such, the Court will not consider the documents in deciding the Rule 12(b)(6) motion to dismiss.

of particular identifying systems and methods for modifying major or minor television channel numbers to identify a television program. 714 F.3d at 1284. In its complaint against Time Warner Cable, K-Tech alleged Time Warner Cable and DirecTV infringed on K-Tech's patents by "making, selling, and offering to sell, in this judicial district, systems and methods for modifying a major channel number, a minor channel number, and/or a carrier frequency to identify a television program[.]" Id. The district court granted Time Warner Cable's motion to dismiss for failure to state a claim upon which relief can be granted, but the Ninth Circuit reversed. Id.

Although K-Tech was decided by the Federal Circuit under the now-abrogated Form 18 pleading standard, the rationale explained by the court in reaching its decision holds true here and is helpful in applying the Iqbal and Twombly plausibility standard. The Federal Circuit ultimately concluded K-Tech had met the direct infringement pleading standard because "DirectTV and TWC know what K-Tech's patents claim, and they know what K-Tech asserts their systems do, and why. K-Tech has alleged that DirecTV and TWC must and do modify or 'translate' digital signals they receive, and it has alleged that they do so using K-Tech's methods and systems." Id. at 1287.

So too here. Aldevron knows what Plaintiffs' patent claims; Aldevron also knows what third party-client plasmid material it produced that Plaintiffs claim infringes on the '435 Patent and why. Plaintiffs have alleged that Aldevron, after having access to Plaintiffs '435 Patented Biotechnology, produced the same '435 Patented Biotechnology for four third parties. Accepting as true the allegations in the Complaint, that is enough to state a plausible claim for direct patent infringement.

Additionally, and contrary to Aldevron's arguments, Plaintiffs need not so specifically identify the infringing products. To do so would essentially require proof of direct infringement at the pleading stage, which is not required under Iqbal and Twombly. See Nalco Co., 883 F.3d

at 1350 (citations omitted) (noting a plaintiff need not “prove [their] case at the pleading stage.”).

Moreover, as well-explained by the Federal Circuit in K-Tech:

That K–Tech cannot point to the specific device or product within TWC’s or DirecTV’s systems that translates the digital television signals each receives—especially when the operation of those systems is not ascertainable without discovery—should not bar K–Tech’s filing of a complaint. A defendant cannot shield itself from a complaint for direct infringement by operating in such secrecy that the filing of a complaint itself is impossible.

Id. at 1286. The same is true in this case. Plaintiffs need not provide specific product names or lot numbers they certainly cannot obtain without discovery, and that concern remains despite the abrogation of Form 18. See Air Dynamics Industrial Systems, Inc. v. Lehman, No. 1:19-cv-2073, 2020 WL 6544966, at *6 (M.D. Penn. Nov. 6, 2020) (citing K-Tech and explaining, “We are not troubled that Air Dynamics is, at this juncture, unable to identify by name or description one of defendants’ specific products or features that is allegedly infringing its patents. The parties operate in an industry in which competing products are not available to the general public. The mere inability of Air Dynamics to purchase, analyze, and identify one of defendants’ products before filing suit does not, by itself, bar them from filing suit altogether.”). Plaintiffs have alleged four clients they believe Aldevron produced plasmid product for that contained the ’435 Patented Biotechnology. Indeed, Aldevron should be able to verify through discovery whether the plasmid material produced for those four clients did or did not contain the ’435 Patented Biotechnology.

Even beyond K-Tech, Disc Disease and Air Dynamics further support the Court’s conclusion. As the Federal Circuit explained in Disc Disease, where the court also applied the Twombly and Iqbal standard, a plaintiff “need only give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” The Complaint does that here – it provides Aldevron fair notice of what the claim is and the ground upon which it rests. At its most basic, and accepting as true the allegations in the Complaint, Plaintiffs provided Aldevron with access to its patent-

protected plasmid material. After doing so, Plaintiffs discovered Aldevron began producing similar patent-protected plasmid material for third parties. Plaintiffs identify the third parties for Aldevron and what plasmid material they believe infringes on the '435 Patent, including which independent claims of the patent the material infringes on. That provides sufficient factual detail to plausibly plead a patent infringement claim and to provide Aldevron fair notice of the claim and the grounds upon which it rests. See Air Dynamics, 2020 WL 6544966, at *6 (“Plaintiffs will . . . survive the Rule 12 stage so long as they offer enough information to put defendants on ‘fair notice of infringement of the asserted patents.’”).

Construing the Complaint in the light most favorable to Plaintiffs and drawing all reasonable inferences in their favor, Plaintiffs’ Complaint contains sufficient factual matter, accepted as true, to state a direct patent infringement claim that is plausible on its face. Iqbal, 556 U.S. at 678. Plaintiffs have shown that success on the merits is more than a “sheer possibility.” Id. Thus, after applying the Iqbal and Twombly standard, Plaintiffs have stated a plausible direct patent infringement claim, and the Court denies Aldevron’s motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

C. Failure to State a Claim for Indirect Patent Infringement

Aldevron also challenges Plaintiffs’ claim for indirect infringement. The Complaint mentions indirect infringement solely in its prayer for relief. Doc. No. 1, ¶ B. Plaintiffs are agreeable to striking the “or indirectly” language from the Complaint pursuant to Federal Rule of Civil Procedure 12(f), subject to reserving their right to amend the Complaint should discovery reveal indirect infringement. Given the parties agreement on this issue, the Court will strike the words “or indirectly” from the Complaint pursuant to Federal Rule of Civil Procedure 12(f). This

does not prevent Plaintiffs from exercising their right to amend the Complaint should discovery reveal the need to do so.

D. More Definite Statement

In the alternative, Aldevron moves for a more definitive statement under Federal Rule of Civil Procedure 12(e). Rule 12(e) states:

A party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response. The motion must be made before filing a responsive pleading and must point out the defects complained of and the details desired. If the court orders a more definite statement and the order is not obeyed within 14 days after notice of the order or within the time the court sets, the court may strike the pleading or issue any other appropriate order.

Fed. R. Civ. P. 12(e).

Given the Court's analysis above, Plaintiffs' Complaint is not "so vague or ambiguous" that Aldevron cannot reasonably prepare a response. Indeed, Plaintiffs identify the four clients it believes Aldevron produced patent-infringing material for. Aldevron knows what the '435 patent claims, it knows what products Plaintiffs allege infringe and why. That is not "so vague or ambiguous" as to warrant a more definite statement under Rule 12(e).

E. Motions for Hearing

Aldevron and Plaintiffs requested oral argument on Aldevron's instant motion to dismiss. Doc. Nos. 17, 32. However, the Court finds that the issues have been well briefed, and there is no need for oral argument. Thus, the Court denies the motions for hearing.

III. CONCLUSION

For the reasons discussed above, Aldevron's "Motion to Dismiss Under Rule (12)(b)(6) and/or for a More Definite Statement Under Rule 12(e)" (Doc. No. 18) is **DENIED** in part and

GRANTED in part. Aldevron's Motion for Hearing (Doc. No. 17) and Plaintiffs' Motion for Hearing (Doc. No. 32) are **DENIED**.

IT IS SO ORDERED.

Dated this 16th day of February, 2021.

/s/ Peter D. Welte
Peter D. Welte, Chief Judge
United States District Court