UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, Plaintiff/Counter-Defendant, v. GRIFOLS DIAGNOSTIC SOLUTIONS INC., GRIFOLS WORLDWIDE OPERATIONS LIMITED, and NOVARTIS VACCINES AND DIAGNOSTICS, INC., Defendants/Counter-Plaintiffs.	)	No. 19 C 6587 Judge Sara L. Ellis

OPINION AND ORDER

Abbott Laboratories ("Abbott") brought this declaratory judgment action against Defendants Grifols Diagnostic Solutions Inc. ("Grifols Diagnostic"), Grifols Worldwide Operations Limited ("Grifols Worldwide"), and Novartis Vaccines and Diagnostics, Inc. ("Novartis"), asserting that the claims of U.S. Patent No. 7,205,101 ("the '101 Patent") are invalid. Defendants deny that the claims of the '101 Patent are invalid, and they brought a counterclaim asserting that Abbott infringes claim 7 of the '101 Patent.[1] Abbott now moves under Federal Rule of Civil Procedure 12(b)(6) to dismiss Defendants' infringement counterclaim on the basis that claim 7 of the '101 Patent is invalid as a matter of law under 35 U.S.C. § 101. Because Abbott has not demonstrated that claim 7 is directed to a patent-ineligible natural phenomenon, the Court denies Abbott's motion to dismiss [53].

[1] For simplicity, the Court does not refer to Defendants' additional designation as Counter-Plaintiffs.

BACKGROUND[2]

The '101 Patent, titled "Human Immunodeficiency Virus (HIV) Nucleotide Sequences, Recombinant Polypeptides, and Applications Thereof," relates to the diagnosis, prevention, and treatment of HIV, the virus that causes acquired immunodeficiency syndrome ("AIDS"). *See, e.g.*, Doc. 1-1 ("'101 Pat.") at Abstract, 1:1–4, 2:56–3:4, 6:8–11; *HIV/AIDS – Symptoms and causes*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/hiv-aids/symptoms-causes/syc-20373524 (last visited Nov. 13, 2020). In particular, the '101 Patent is "directed to nucleotide sequences, such as DNA, encoding human immunodeficiency virus polypeptides, the use of such nucleotide sequences in diagnostic procedures and in the production of recombinant protein, as well as the use of such proteins in diagnostic, prophylactic, and therapeutic applications."[3] '101 Pat. at 1:27–32.

The United States saw its first documented cases of AIDS in 1981, and by 1984, three groups had independently identified HIV as the suspected cause of AIDS. Because an individual infected with HIV can transmit the virus to others while remaining asymptomatic for years, a focus at that time was developing the ability to accurately screen large numbers of asymptomatic individuals (e.g., healthy appearing blood donors) to detect for HIV infection. Researchers

[2] In setting forth the relevant background, the Court has accepted as true all well-pleaded factual allegations from Defendants' counterclaim and drawn all reasonable inferences from those allegations in Defendants' favor. *See Kubiak v. City of Chicago*, 810 F.3d 476, 480–81 (7th Cir. 2016); *see also Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306, 1316–19 (Fed. Cir. 2019) (district court must accept a complaint's "plausible and specific factual allegations" about the patent claims at issue in resolving a § 101 challenge at the motion to dismiss stage). The Court has also considered "documents that are critical to" and referred to by Defendants' counterclaim, such as the '101 Patent; "information that is subject to proper judicial notice"; and any factual allegations set forth in Defendants' opposition brief, "so long as those facts 'are consistent with the pleadings.'" *Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1019–20 (7th Cir. 2013) (citations omitted).

[3] This passage refers to both proteins and polypeptides. Proteins are large polypeptides, and one can use the two terms (proteins and polypeptides) interchangeably. Bruce Alberts et al., *Molecular Biology of the Cell* 125 & G:30 (5th ed. 2008); *see also* Doc. 41 at 18 (¶ 15) (defining polypeptides as "either full or partial proteins").

discovered immortalized cell lines that they could chronically infect with HIV *in vitro*, which enabled them to produce HIV in substantial quantities. This in turn led to the development of immunoassays to detect HIV-specific antibodies in the blood of blood donors or patients suspected of having HIV.[4] Researchers could construct an HIV immunoassay using natural HIV proteins by growing live, fully intact HIV in large quantities; breaking the HIV into pieces; collecting the HIV proteins and sticking them to a surface; and then washing the patient's blood over the surface. If HIV antibodies were present in the blood, they would bind to the HIV proteins and remain attached to them when the blood was washed away from the surface. Researchers could then detect the HIV antibodies by using enzymes that change color or fluorescent markers that emit light in the presence of HIV antibodies.

However, because growing large amounts of live, intact HIV *in vitro* exposed workers to risk of infection and required expensive laboratory facilities, the number of facilities and individuals available to work with the virus was limited. Moreover, although tissue culture could "provide viral polypeptides suitable for use in diagnostic assays, it [was] highly undesirable to employ polypeptides produced by tissue culture in vaccine compositions due to the risk of infectivity posed by live, intact virus." '101 Pat. at 2:22–27.

A potential solution was to produce HIV proteins using recombinant (as opposed to natural) means, and in 1984, scientists began trying to use recombinant DNA technology[5] to

[4] When the human immune system detects the presence of HIV, it responds with HIV-specific antibodies, which are unique molecules formed by the immune system as part of its defense against the virus. The presence of these antibodies in a human blood sample, therefore, indicates a current or prior encounter with HIV or part of the virus.

[5] Recombinant DNA technology involves techniques where scientists combine DNA segments from different sources to make new, non-naturally occurring DNA. *See In re Droge*, 695 F.3d 1334, 1335 (Fed. Cir. 2012) ("The term 'recombinant DNA' generally refers to DNA from one or more sources with a sequence that does not occur in nature."); *Molecular Biology of the Cell* G:15 (genetic engineering

make proteins and partial proteins from HIV's outer layer, called the envelope ("env"). Scientists focused on identifying DNA fragments that encoded HIV env proteins because they suspected that the env layer would react or bind with HIV-specific antibodies.

In the spring of 1984, a team from Chiron Corporation ("Chiron") began working on creating a recombinant DNA env-based immunoassay. By October 1, 1984, Chiron had run sequence reactions on DNA fragments that spanned what has since been determined to be HIV's entire env layer. In connection with this work, Chiron filed U.S. Patent Application No. 06/667,501 ("the '501 Application") on October 31, 1984. Before Chiron filed the '501 Application, the production of recombinant HIV proteins was not possible. Scientists did not know the sequence of HIV nucleotides "that would enable the production of recombinant proteins," nor did they know "whether recombinantly produced viral protein would be sufficiently similar in antigenic properties to native HIV polypeptides so as to be generally useful in diagnostic assays or vaccine production." Doc. 41 at 20 (¶ 22); *see also* '101 Pat. at 2:28–37, 2:49–52.

On April 17, 1995, Chiron filed the patent application that issued as the '101 Patent. This application claims priority, through several divisional and continuation applications, to the '501 Application, which Chiron filed more than a decade earlier. The '101 Patent issued on April 17, 2007. Novartis, which later acquired Chiron, and Grifols Worldwide jointly own the '101 Patent. The '101 Patent has 19 claims, but Defendants only assert claim 7 against Abbott.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir.

(recombinant DNA technology) entry: "Collection of techniques by which DNA segments from different sources are combined to make a new DNA, often called a recombinant DNA.").

1990). In considering a Rule 12(b)(6) motion, the Court accepts as true all well-pleaded facts in the plaintiff's complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *Kubiak*, 810 F.3d at 480–81. To survive a Rule 12(b)(6) motion, the complaint must assert a facially plausible claim and provide fair notice to the defendant of the claim's basis. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Adams v. City of Indianapolis*, 742 F.3d 720, 728–29 (7th Cir. 2014). A claim is facially plausible "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.

Patent eligibility under 35 U.S.C. § 101 "is a question of law based on underlying facts." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 749 (Fed. Cir. 2019). The Court may resolve patent eligibility on a Rule 12(b)(6) motion but only "when the undisputed facts require a holding of ineligibility." *Id.*; *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) ("[P]atent eligibility can be determined at the Rule 12(b)(6) stage . . . only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law."). "If there are claim construction disputes at the Rule 12(b)(6) stage," the Court must either adopt "the non-moving party's constructions" or "resolve the disputes to whatever extent is needed to conduct the § 101 analysis, which may well be less than a full, formal claim construction." *Aatrix*, 882 F.3d at 1125. In addressing a motion to dismiss based on patent eligibility, the Court may consider the patent itself, as well as "plausible and specific factual allegations" in the patent owner's complaint about the patent and its claims. *See, e.g.*, *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368–71 (Fed. Cir. 2020) (considering claim language and the patent's written description); *Cellspin Soft*, 927 F.3d at 1316–19 (considering allegations in the complaint). Ultimately, the party raising a § 101

challenge bears the burden of demonstrating that the patent claim is not eligible for patenting. *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319, 1328 (Fed. Cir. 2020) ("[T]he party challenging the validity of the patents . . . bear[s] the burden of proof on its § 101 challenge[.]"); *see also Cellspin Soft*, 927 F.3d at 1319 ("To the extent the district court . . . conclud[ed] that issued patents are presumed *valid* but not presumed *patent eligible*, it was wrong to do so.").

ANALYSIS

Section 101 of the Patent Act defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. This provision, however, "contains an important implicit exception": "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable subject matter. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (citations omitted); *accord Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1374 (Fed. Cir. 2016); *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.* ("*In re BRCA*"), 774 F.3d 755, 762–63 (Fed. Cir. 2014). At the same time, "an invention is not rendered ineligible for [a] patent simply because it involves" one of these exceptions. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

Abbott asserts that claim 7 of the '101 Patent is invalid because it impermissibly claims a natural phenomenon. In *Alice* and *Mayo*, the Supreme Court set forth a two-part test "[t]o distinguish claims to patent-eligible applications of . . . natural phenomena from claims that impermissibly tie up such . . . phenomena." *Illumina*, 967 F.3d at 1324–25. For step one of the *Alice/Mayo* test, the Court asks whether claim 7 is "directed to" a natural phenomenon. *Id.* If the answer is no, the Court ends its inquiry because the claim is patent eligible. *Id.* at 1329–30; *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016). But if claim

7 is directed to a natural phenomenon, the Court must proceed to *Alice/Mayo* step two, where it "examine[s] whether the limitations of the claim apart from the . . . natural phenomenon, considered individually and as an ordered combination, 'transform the nature of the claim into a patent-eligible application.'" *Illumina*, 967 F.3d at 1324–25 (quoting *Alice*, 573 U.S. at 217). If so, the claim is eligible for patenting; if not, the claim is invalid under § 101. *Compare, e.g.*, *CellzDirect*, 827 F.3d at 1050–52 (finding that even if the claims at issue were directed to a natural law, they would still be patent eligible under step two because they applied the natural law "to achieve a new and useful preservation process"), *with Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376–78 (Fed. Cir. 2015) (finding that the claims at issue were not patent eligible because they were directed to naturally occurring phenomena (step one) and that practicing the claims did "not result in an inventive concept that transforms the natural phenomenon . . . into a patentable invention" (step two)).

"The step one 'directed to' inquiry focuses on the claim as a whole." *Athena*, 915 F.3d at 750. It asks whether the language of a patent claim, considered in light of the patent's specification, is directed to excluded subject matter, such as natural phenomena. *See TecSec, Inc. v. Adobe Inc.*, --- F.3d ----, 2020 WL 6228460, at *10 (Fed. Cir. Oct. 23, 2020); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1368 (Fed. Cir. 2019). It is not enough, however, "to merely identify a [natural phenomenon] underlying the claim;" the Court "must determine whether . . . the claim is 'directed to'" that phenomenon. *CellzDirect*, 827 F.3d at 1050. In answering this inquiry, the Court may consider "whether the claimed advance improves upon a technological process or merely an ineligible concept, based on both the written description and the claims." *Athena*, 915 F.3d at 750. The specification may also help the Court "understand 'the problem facing the inventor' and [] what the patent describes as the invention."

ChargePoint, Inc. v. SemaConnect, Inc., 920 F.3d 759, 767 (Fed. Cir. 2019) (citations omitted). But even though the patent's written description informs the Court's understanding of a claim, *CardioNet*, 955 F.3d at 1368, the focus of the "directed to" inquiry must remain on the language of the claim itself, *see Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1293 (Fed. Cir. 2020) ("The Supreme Court's cases focus on the claims, not the specification, to determine section 101 eligibility. . . . Similarly, we have repeatedly held that features that are not claimed are irrelevant as to step 1 or step 2 of the *Mayo/Alice* analysis."); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016) (explaining, at step one, that "[t]he § 101 inquiry must focus on the language of the Asserted Claims themselves").

When Chiron filed the '501 Application in October 1984, the methods for naturally replicating HIV included chronically infecting immortalized cell lines with HIV *in vitro* and using tissue culture to produce HIV polypeptides. *See* '101 Pat. at 2:1–27. But these methods exposed workers to risk of infection and required expensive laboratory facilities. *Id.* at 2:20–27; Doc. 41 at 20 (¶¶ 20, 21). The inventors of the '101 Patent sought to solve these problems by producing recombinant HIV proteins that "would be generally useful in diagnostic, prophylactic, or therapeutic methods or products." *See* '101 Pat. at 1:27–32, 2:28–52. The only claimed invention from the '101 Patent at issue here is claim 7. This claim—revised to include the language of claim 1, from which it depends—provides:

> A method for replicating DNA specific for HIV, which comprises:
>
> (a) providing a DNA construct comprising an origin of replication recognized by a unicellular microorganism and a DNA sequence comprising at least a 20 bp sequence of a human immunodeficiency virus (HIV) genome; and
>
> (b) growing a unicellular microorganism containing said DNA construct under conditions whereby said DNA sequence is replicated[,]

wherein the unicellular microorganism is a bacterial cell.

Id. at 75:57–66, 76:13–14. Claim 7 provides a two-step method for replicating HIV-specific DNA. First, the "providing" step provides a "DNA construct," which comprises (1) an origin of replication recognized by a unicellular bacterial cell, and (2) a DNA sequence comprising at least a 20 bp (base pair) sequence of HIV genome. Second, the "growing" step grows a unicellular bacterial cell containing the DNA construct under conditions whereby the HIV's DNA sequence replicates.

Abbott first argues that the '101 Patent is directed to a "product of nature," i.e., "the HIV DNA strain identified by the inventors" in Figure 4 of the '101 Patent, "as opposed to a novel process for replicating DNA." Doc. 54 at 9–10; *see also* Doc. 60 at 6 ("[T]he claimed advance of the '101 patent over the prior art is the identification of the sequence of HIV DNA disclosed in Figure 4 of the patent.").[6] According to Abbott, this renders claim 7 invalid under § 101 because "claims covering DNA sequences are not patent eligible subject matter." Doc. 54 at 10.

This argument is not persuasive. At step one, the Court asks what subject matter claim 7—not the '101 Patent—is "directed to." *See Realtime Data LLC v. Reduxio Sys., Inc.*, --- F. App'x ----, 2020 WL 6228818, at *4 (Fed. Cir. Oct. 23, 2020) ("Although the court articulated a 'fair description' of each patent-in-suit, it failed to tie those descriptions to any specific claim or to clarify whether those descriptions are the abstract ideas that the claims are 'directed to' within the meaning of § 101 jurisprudence. *It is, of course, incorrect to consider whether a patent as a whole is abstract. The analysis is claim specific*." (emphasis added) (citation omitted)). The Court may consider the '101 Patent's specification in answering this question, *CardioNet*, 955 F.3d at 1367–68, but the Court's focus must ultimately remain on the language of claim 7, *see*

[6] For the parties' briefs, the Court cites to the page number(s) set forth in a document's ECF header.

Am. Axle & Mfg., 967 F.3d at 1293; *Synopsys*, 839 F.3d at 1149. Here, the plain language of claim 7 does not purport to claim a newly discovered HIV DNA sequence, let alone the particular DNA sequence identified in Figure 4 of the '101 Patent. *See Illumina*, 967 F.3d at 1327–28 (rejecting a similar argument where the claims were "not directed to the cell-free fetal DNA itself"). In fact, Abbott expressly acknowledges as much in its reply: "[t]he claim at issue in this case is . . . not a claim to HIV DNA itself." Doc. 60 at 12. As already noted, claim 7 recites a two-step method for replicating HIV-specific DNA that requires the use of a DNA construct and a unicellular bacterial cell. Thus, claim 7 is not impermissibly "directed to" a particular HIV DNA sequence.

Abbott also contends that claim 7 is "directed to" the replication of HIV DNA, which is a natural phenomenon. But this contention overgeneralizes the claim and fails to consider the claim's language. *See TecSec*, 2020 WL 6228460, at *10 ("[W]e have reiterated the Supreme Court's caution against 'overgeneralizing claims' in the § 101 analysis, explaining that characterizing the claims at 'a high level of abstraction' that is 'untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule.'" (citations omitted)). The fact that the subject matter of the claimed process, HIV DNA, may undergo replication in nature does not make claim 7 "directed to" that ability. *See CellzDirect*, 827 F.3d at 1049 ("That one way of describing the [claimed] process is to describe the natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability.").

A claim is "directed to" a natural phenomenon when it "amount[s] to nothing more than observing or identifying the [phenomenon] itself." *Id.* at 1048. Claim 7 does not fall into this camp. The claim does not recite a method that merely observes the replication of HIV DNA or detects the existence of such replication; rather, it recites a particular two-step method for

replicating HIV-specific DNA that the inventors of the '101 Patent believed was a solution to the problems accompanying the then-existing processes of replicating HIV DNA. *See Illumina*, 967 F.3d at 1326, 1329 (finding method claims patent eligible where they "achieve[d] more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon"); *CellzDirect*, 827 F.3d at 1048, 1050 (finding method claims patent eligible where they were "directed to a new and useful method of preserving" cells and did not simply observe or detect the ability of the cells "to survive multiple freeze-thaw cycles").

That claim 7 of the '101 Patent does not merely detect or observe the replication of HIV-specific DNA distinguishes it from the claims addressed by the Federal Circuit decisions Abbott relies upon for its step-one argument—*Athena*, *Roche*, *Genetic Technologies*, *Ariosa*, and *In re BRCA*. In *Athena*, the claims recited a method for diagnosing certain neurological disorders based on the correlation between the presence of naturally occurring autoantibodies in bodily fluid and the neurological disorders. 915 F.3d at 747, 750. The Federal Circuit concluded that the claims were "directed to" a natural law "because the claimed advance was only in the discovery of a natural law" (the relationship between the autoantibodies and the neurological disorders) and the additional recited method steps "only appl[ied] conventional techniques to detect that natural law." *Id.* at 750–51. In *Roche*, the Federal Circuit found that the method claims were directed to a natural phenomenon because they disclosed a way to detect Mycobacterium tuberculosis ("MTB") based on the observation that the presence of certain naturally occurring nucleotides indicated the presence of MTB in a biological sample. 905 F.3d at 1371–72. The claim in *Genetic Technologies* was similarly directed to a law of nature because it recited a method for detecting a coding region of DNA based on the coding region's relationship with non-coding regions. *Genetic Techs.*, 818 F.3d at 1372–76; *CellzDirect*, 827

F.3d at 1048 (distinguishing *Genetic Technologies*). In *Ariosa*, the claims "were directed to detecting a natural phenomenon after a sample has been prepared or extracted," *Illumina*, 967 F.3d at 1327 (distinguishing *Ariosa*), and detecting or identifying the presence of the natural phenomenon "was merely claiming the [phenomenon] itself," *CellzDirect*, 827 F.3d at 1048 (same); *see Ariosa*, 788 F.3d at 1373–74, 1376. And in *In re BRCA*, the method claims identified alterations of a gene by comparing two gene sequences, which constituted patent-ineligible abstract ideas or mental processes. *In re BRCA*, 774 F.3d at 761–64; *CellzDirect*, 827 F.3d at 1048 (distinguishing *In re BRCA*).

In each of these cases, the method claims at issue used a law of nature, natural phenomenon, or mental process to detect or diagnose something. The Federal Circuit has consistently held such "claims unpatentable as directed to ineligible subject matter." *Illumina*, 967 F.3d at 1325; *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352–53 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc) (citing, among other cases, *Athena*, *Roche*, *Genetic Technologies*, *Ariosa*, and *In re BRCA*). In contrast, claim 7 does not use a patent-ineligible concept to detect or diagnose anything; it provides a particular process for making copies of HIV DNA. This makes claim 7 more akin to a method claim directed to the preparation or production of something, like the claims the Federal Circuit found patent eligible at step one in *Illumina* and *CellzDirect*. *See Illumina*, 967 F.3d at 1326–29 (finding that claims "directed to methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA" were not directed to a natural phenomenon); *CellzDirect*, 827 F.3d at 1047–50 (finding that claims reciting methods for producing a desired preparation of preserved cells were not directed to a natural law).

It is also not enough that the Federal Circuit has found ineligible method claims that included DNA amplification, which Abbott analogizes to claim 7's method of HIV DNA replication, as one of their steps. *See, e.g.*, Doc. 54 at 12–13 (analogizing claim 7 to the method claims in *Roche* and *Genetic Technologies*, which included DNA amplification as a claimed step); Doc. 60 at 11–12 ("[Claim 7] is directed to only the first step of the *Ariosa* method claims found invalid—replication without requiring the next step of detection or testing. Claim 7 cannot be patentable when it is a mere step in an unpatentable method[.]"); *id.* at 13 ("Just like claim 7 of the '101 patent, the method claim at issue [in *Genetic Techologies*] included a step of amplification (e.g., replication) of naturally-occurring DNA."). The step one "inquiry focuses on the claim *as a whole*." *Athena*, 915 F.3d at 750 (emphasis added). Although the claims in *Roche*, *Ariosa*, and *Genetic Technologies* may have included an amplification step, the claims were not, in their entirety, directed to the replication of DNA, as is claim 7 of the '101 Patent.

Furthermore, Abbott does not contend that the particular method of HIV DNA replication recited by claim 7 naturally occurs. Notably, Abbott does not dispute Defendants' contention that the starting point for the claimed method, the DNA construct required by the "providing" step, "is a chimeric, human-made construct *that does not exist in nature*," Doc. 59 at 11 (emphasis added), and the Court accepts that contention for purposes of Abbott's motion, *cf. Aatrix*, 882 F.3d at 1125 (at the Rule 12(b)(6) stage, the Court "must proceed by adopting the non-moving party's [claim] constructions, or the [C]ourt must resolve the disputes to whatever extent is needed to conduct the § 101 analysis" (citation omitted)). Abbott also appears to concede that a unicellular bacterial cell, which is required for the "growing" step, does not naturally replicate HIV DNA. *See* Doc. 60 at 11 ("[B]acteria may not naturally replicate HIV DNA."). And although Abbott contends that "bacteria replicate other types of DNA," *id.*, claim

7 does not recite a method for replicating just *any type* of DNA—only HIV-specific DNA. Because Abbott does not dispute that claim 7 recites a method that (1) begins with the use of a human-made, non-natural DNA construct to initiate the replication of HIV DNA, and (2) ends with the presence of replicated HIV DNA in an environment where HIV DNA does not naturally replicate, the Court does not see how claim 7 can be "directed to" a *natural* phenomenon. *Cf. Ariosa*, 788 F.3d at 1376 (finding that method claims that began and ended with a natural phenomenon were directed to naturally occurring matter).[7]

In sum, the answer to step one of the *Alice/Mayo* inquiry is "no." Abbott has not demonstrated that claim 7 of the '101 Patent is directed to a patent-ineligible natural phenomenon. Accordingly, the Court does not need to reach step two of the *Alice/Mayo* inquiry. *Illumina*, 967 F.3d at 1329 ("[W]e conclude at step one of the *Alice/Mayo* test that the claims are not directed to a patent-ineligible concept, and we need not reach step two of the test.").

CONCLUSION

For the foregoing reasons, the Court denies Abbott's motion to dismiss [53].

Dated: December 1, 2020

SARA L. ELLIS
United States District Judge

[7] This is not to say that the use of a man-made structure in a claimed method necessarily means the claim is directed to patent-eligible subject matter. As Abbott points out in its reply brief, the "use of a man-made molecule in a method claim employing standard techniques *to detect or observe a natural law* may still leave the claim directed to a natural law." *Athena*, 915 F.3d at 752 (emphasis added). But this principle does not apply here because claim 7 does not use the human-made DNA construct or the unicellular bacterial cell "to detect or observe" a natural phenomenon.