IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

VIVEVE, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	
	§	CASE NO. 2:16-CV-1189-JRG
THERMIGEN, LLC;	§	
THERMIAESTHETICS, LLC; AND RED	§	
ALINSOD, M.D.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendants Thermigen, LLC; ThermiAesthetics, LLC; and Dr. Red Alinsod, M.D.'s (collectively "Defendants") Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) and 35 U.S.C. § 101. (Dkt. No. 15.) On February 22, 2017, the Court held a hearing at which the parties presented oral argument on said motion. After considering the briefing and argument of the parties, and for the reasons set forth below, the Court finds that Defendants' motion should be and is **DENIED**.

I. BACKGROUND

On October 21, 2016, Plaintiff Viveve, Inc. ("Plaintiff" or "Viveve") filed its original complaint for infringement of U.S. Patent No. 8,961,511 (the "'511 patent") against Defendants. (*See* Dkt. No. 1.) The '511 patent is titled "Vaginal Remodeling Device and Methods," and claims a method for remodeling female genital tissue by applying heat to certain target tissue. (*Id.* at 4.) As the abstract of the '511 patent states, "[t]he effect of the applied heat is to remodel genital tissue by tightening it." ('511 patent, Abstract.) "The tightening may be a consequence of thermal denaturation of collagen as well as a longer term healing response in the tissue that includes an

increased deposition of collagen." (*Id.*) The method covered by the '511 patent provides an alternative to the prior art, which indicated that invasive surgical procedures were required to bring about the desired remodeling. (*See id.* at col. 2:1–21.)

Plaintiff alleges that Defendants infringe "one or more claims of the '511 Patent, including, but not limited to, Claim 51 . . . ." (*Id.* at 7.) Claim 51 is a method claim, which recites:

> A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:
>
> heating the target tissue, and
>
> remodeling the therapeutic zone of target tissue, wherein the heating includes heating a mucosal surface of the labia minora.

('511 patent, at col. 18: 21–28.)[1] Thus, the method covered by claim 51 essentially covers two discrete steps: (1) "heating the target tissue," and (2) "remodeling the therapeutic zone of target tissue." (*Id.*)

On December 19, 2016, Defendants filed their motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure and 35 U.S.C. § 101, arguing that the '511 patent is invalid as directed to non-patentable subject matter. (Dkt. No. 15 at 1.) Specifically, Defendants assert that the '511 patent is directed to the natural phenomenon that collagen is remodeled through exposure to heat (a phenomenon that allegedly has previous, well known applications in treating tissue generally) and that it simply applies this phenomenon to a discrete area of the human body (i.e., female genital tissue). (Dkt. No. 15 at 1.)

II. LEGAL STANDARD

A. 35 U.S.C. § 101

Section 101 of the Patent Act defines the scope of patent eligible subject matter:

[1] Defendants allege that claim 51 is representative of the other independent claims asserted. Given that the Court perceives no real dispute as to this point, this order primarily (though not exclusively) focuses on claim 51.

> Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101. The Supreme Court has held that there are three specific exceptions to patent eligibility under § 101: laws of nature, natural phenomena, and abstract ideas. *Bilski v. Kappos*, 561 U.S. 593, 601 (2010). "The concern underlying these judicial exclusions is that patent law not inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity." *Rapid Litigation Mgmt. Ltd. v. Cellzdirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quotations and citations omitted).

In *Mayo*, the Supreme Court articulated a two-step test for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296–97 (2012)).

Step One: The first step of *Mayo* requires a court to determine if the claims are directed to a law of nature, natural phenomenon, or abstract idea. *Alice*, 134 S. Ct. at 2355. If the answer to this inquiry is "no," then the inquiry is over and the claims pass muster under § 101. At this first step of the analytical framework, the Federal Circuit has cautioned against "describing the claims at such a high level of abstraction and untethered from the language of the claims," lest "the exceptions to § 101 swallow the rule." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016). Some courts have nicknamed the effort by defendants to describe claims at such a high level of abstraction in order to prevail on a motion to dismiss under § 101 as "reductionist simplicity." *See Verint Syst. Inc. v. Red Box Records Ltd.*, -- F.3d --, 2016 WL 7156768, at *1

(S.D.N.Y. Dec. 7, 2016). "Courts faced with [such motions seeking to oversimplify claims] must scrutinize reductive descriptions with great care." *Id.*

The Federal Circuit recently addressed "reductionist simplicity" in a case involving method claims allegedly directed to natural phenomena. *See Rapid Litigation Mgmt.*, 827 F.3d at 1049. There, the Federal Circuit proclaimed: "[t]hat one way of describing [the process claimed] is to describe the natural ability of the subject matter to undergo the process does not make the claim directed to that natural ability." *Rapid Litigation Mgmt.*, 827 F.3d at 1049. If such were otherwise, producing a new compound, treating cancer with chemotherapy, and treating headaches with aspirin, would all be unpatentable as simply directed to the ability of the subject matter to undergo such processes. *Id.* Rather, as courts examining the natural phenomena exception at step one have observed, claims are most commonly directed to a patent ineligible concept when they amount to nothing more than *observing* or *identifying* the ineligible concept itself. *See, e.g., Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1373–74 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74 (Fed. Cir. 2015).

Step Two: A court applies the second step, per *Mayo*, only if it finds as part of the first step that the claims are directed to a law of nature, natural phenomenon, or abstract idea. *Alice*, 134 S. Ct. at 2355. This second step requires the court to determine if the elements of the claim individually, or as an ordered combination, "transform the nature of the claim" into a patent-eligible application. *Alice*, 134 S. Ct. at 2355. "At step two, more is required than 'well-understood, routine, conventional activity already engaged in by the scientific community,' which fails to transform the claim into 'significantly more than a patent upon the' ineligible concept itself." *Rapid Litigation Mgmt.*, 827 F.3d at 1047 (citing *Mayo*, 132 S. Ct. at 1298, 1294).

As the Supreme Court recognized in *Mayo*, the *Diehr* and *Flook* cases provide guidance on the issue of patent eligibility when a process embodies the equivalent of natural laws. *Mayo*, 132 S. Ct. at 1298. In *Diehr*, the Court "found [that] the overall process [was] patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole." *Mayo*, 132 S. Ct. at 1298 (citing *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)); *see also Mayo*, 132 S. Ct. at 1300 ("It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional."). On the other hand, in *Flook*, the Court found that a process was patent-ineligible because the additional steps of the process amounted to nothing more than "insignificant post-solution activity." *Diehr*, 450 U.S. at 191–92 (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

Following this guidance, a claim may become patent eligible when the "claimed process include[s] not only a law of nature but also several unconventional steps . . . that confine[] the claims to a particular, useful application of the principle." *Mayo*, 132 S. Ct. at 1300. However, a claim is patent ineligible if it describes only "'post-solution activity' that is purely 'conventional or obvious.'" *Mayo*, 132 S. Ct. at 1299.

Resolving § 101 Before Claim Construction: "Where it is clear that claim construction would not affect the issue of patent eligibility, there is no requirement that the court go through that exercise before addressing the eligibility issue." *Pres. Wellness Techs. LLC v. Allscripts Healthcare Sols.*, No. 2:15-CV-1559-WCB, 2016 WL 2742379, at *6 (E.D. Tex. May 10, 2016) (Bryson, J.) (citing *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1274 (Fed. Cir. 2012)). Such is the case here.

B. Rule 12(b)(6)

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides defendants with a vehicle to urge dismissal of a claim for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss under Rule 12(b)(6), the court must assume that all well-pleaded facts are true and view those facts in the light most favorable to the plaintiff. *Bowlby v. City of Aberdeen*, 681 F.3d 215, 218 (5th Cir. 2012). Additionally, the Court may consider "the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint." *Lone Star Fund V (U.S.) L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010). Further, when a Rule 12(b)(6) motion is based on a challenge to a patent's validity under § 101, the Court may properly take note of "technological developments" in the art. *See Affinity Labs of Texas, LLC v. Amazon.com Inc.*, 838 F.3d 1266, 1270 (Fed. Cir. 2016).

III. ANALYSIS

The Court finds that the '511 patent is not invalid as claiming unpatentable subject matter. In applying the *Mayo* two-step framework, the Court finds that Defendants' arguments fail at step one—the '511 is not directed to a natural law or phenomenon. Further, even if it were directed to a natural law or phenomenon, the Court finds that under step two of the *Mayo* framework, the '511 patent improves an existing process for bringing about the tightening of female genital tissue.

A. Step One

As previously mentioned, claim 51 covers a method of remodeling certain target tissue and contains at least two steps: (1) heating the tissue, and (2) remodeling the therapeutic zone.

Defendants first argue that claim 51 is directed to unpatentable subject matter because it is covers a law of nature: namely, "the natural phenomenon that heat denatures collagen and causes

remodeling – i.e., tightening, or *any* change in the structure – of the heated tissue." (Dkt. No. 15 at 7) (emphasis in original). As further support for their argument, Defendants point to the specification of the patent, which they assert acknowledges, "that the remodeling of the tissue is a phenomenon of thermal contraction of collagen." (*Id.*) In response, Plaintiff argues that "[re]modeling [] is not a law of nature, and is not simply the result of heating as [Defendants] suggest to support [their] overgeneralization." (Dkt. No. 23 at 8.) Rather, remodeling is a process comprising a doctor's application of specific concrete steps to specific tissue under particularized conditions, which is simply predicated on the ability of collagen to be physically transformed by heat. (*Id.*) On this point, the Court agrees with Plaintiff.

When analyzing patentable subject matter, the Federal Circuit has recently observed that it is "sufficient to compare claims at issue to those claims already found to be directed to an abstract idea in previous cases." *Enfish, LLC v. Micrososft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016). Accordingly, when determining whether the '511 patent is directed to a natural phenomenon this Court may look to earlier decisions that have scrutinized similar claims under § 101. Significantly, the Federal Circuit recently took up the patentability of similar method claims in *Rapid Litigation Management Ltd. v. Cellzdirect*. There, the Federal Circuit addressed whether method claims covering a process for subjecting hepatocyte liver cells to multiple freeze-thaw cycles (a process called "cryopreservation") used to preserve the cells for later use in various testing, diagnostic, and treatment purposes was directed to a law of nature. *Rapid Litigation Mgmt.*, 827 F.3d at 1045. The prior art indicated that the cryopreservation process could damage hepatocytes, and "prevailing wisdom was that hepatocytes could be frozen only once and then had to be either used or discarded." *Id.* The inventors of the patent in suit discovered that some hepatocytes were capable

of surviving multiple freeze-thaw cycles, and obtained a patent claiming a process comprising three steps:

(A) Subjecting previously frozen and thawed cells to density gradient fractionation to separate viable cells from non-viable ones;

(B) Recovering the viable cells; and

(C) Refreezing the viable cells.

Id. This process has certain advantages over the prior art, such as preserving the hepatocyte cells longer without loss of viability and allowing for the creation of pooled hepatocyte preparations (i.e., hepatocyte preparations comprised of cells from multiple donors) more easily. *Id.*

On appeal, the Federal Circuit reversed the district court's ruling that "the patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles." *Id.* at 1047. Under step one of the *Mayo* framework, the Federal Circuit held that the patent was not directed to a law for nature, because it required "an artisan to carry out a number of concrete steps to achieve the desired preparation." *Id.* In reaching this conclusion, the Federal Circuit cautioned: "[t]hat one way of describing the 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." *Id.* at 1049 (emphasis in original). "If that were so, we would find patent-ineligible methods of, say, producing a new compound (as directed to the individual components' ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin)." *Id.* The Federal Circuit's holding also emphasizes the distinction between method claims and product claims, noting that "[i]t is the *process* of

preservation that is patent eligible here, not necessarily the end product." *Id.* at 1050 (emphasis their own).

The Court finds the Federal Circuit's reasoning and holding in *Rapid Litigation Management* controlling in the present case. Like the court in *Rapid Litigation Management*, here the Court is presented with a method patent comprising concrete steps, premised upon a discovery of natural law rendering the relevant subject matter amenable to certain processes.

In *Rapid Litigation Management*, the patent was predicated upon the ability of hepatocytes to be frozen and thawed multiple times. Here, the '511 patent is predicated upon the ability of collagen to be denatured by heat. In *Rapid Litigation Management*, the patent required an artisan to carry out concrete steps, including (1) subjecting previously frozen and thawed cells to density gradient fractionation, (2) recovering the viable cells, and (3) refreezing the viable cells. *Rapid Litigation Mgmt.*, 827 F.3d at 1045. Here, claim 51 the '511 patent requires a doctor to perform two steps, including (1) heating the target tissue; and (2) remodeling the therapeutic zone. ('511 patent, 18:21–28.) Claim 51, in addition to the other claims of the '511 patent, further provides specificity outlining how and where the method should be performed. For example, claim 51 specifies the particular treatment area and tissues (the "mucosal surface of the labia minora") on which the steps should be performed. (*Id.*) Claims 1, 35, and 43 also specify the various treatment areas on which the particular method should be performed. (*Id.* at 15:47–55; 17:12–21; 17:42–49.) Dependent claims 52, 53, and 54 specify the particular temperature ("between 45 degrees C. and 80 degrees C.") at which the steps outlined in claim 51 should be performed, how that temperature is regulated (with "feedback control"), and how the heat is applied to the tissue (via a "treatment tip"). (*Id.* at 18:29–31, 32–34, 35–37.) These claims provide examples of how the '511 patent dictates, with specificity, the concrete steps which a doctor should take in performing the claimed

method. Finally, like the patent in *Rapid Litigation Management*, the ’511 patent provides certain advantages over the prior art, which indicated that invasive surgery was required to bring about the tightening of the relevant tissue.

The ’511 patent stands in stark contrast to those patents which the Federal Circuit has invalidated as directed to a natural law or natural phenomenon. In those cases, the patents typically encompass the pure observation or identification of the natural law at issue. *See, e.g., Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1373–74 (Fed. Cir. 2016) (involving a claim amounting to nothing more than identifying “information about a patient’s natural genetic makeup”); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74 (Fed. Cir. 2015) (involving claims directed to identifying the presence of cffDNA in a patient’s bloodstream). In this case, however, the claims outlined above demonstrate that the ’511 patent claims more than the observation or identification of a natural law or phenomenon—it claims the application and synthetization of a natural law into a concrete process, which builds upon the subject matter’s capability of undergoing the process. “This type of constructive process, carried out by an artisan to achieve a ‘new and useful end,’ is precisely the type of claim that is eligible for patenting.” *Rapid Litigation Mgmt.*, 827 F.3d at 1048.

B. Step Two

Even if the Court was persuaded that the ’511 patent was “directed to” a natural law or natural phenomenon (which it is not), the ’511 patent recites an inventive concept, rendering it subject matter patent eligible. At step two of the *Mayo* framework, claims directed to a patent ineligible concept are nevertheless not deficient under § 101 if they “improve an existing technological process.” *Alice*, 134 S. Ct. at 2358. “Well-understood, routine, conventional activity

previously engaged in by researchers in the field" does not satisfy the "inventive concept" requirement of step two. *See Mayo*, 132 S. Ct. at 1294.

Here, the Court finds that the claims of the '511 patent recite an improved treatment technique that is inventive over known techniques in the prior art. While the denaturation of collagen through application of heat was known and used for medical and cosmetic purposes in the prior art (*see* '511 patent, 1:39–61), the only known methods for tightening the relevant tissue required invasive surgical procedures which carried with them the risk of scarring. (*Id.* at 2:9–21.) When viewed in this light, the method covered by the '511 patent constitutes an improvement over the prior art.

Defendants' arguments that the methods claimed in the '511 patent claim routine, conventional activity are belied by the statements made by Dr. Red Alinsod (a named Defendant, practicing medical doctor, and executive at ThermiAesthetics LLC) in reference to "vulvoaginal rejuvenation with devices harnessing laser or radiofrequency (RF) energy." In a study funded by ThermiAesthetics, Dr. Alinsod stated that the use of RF energy for female rejuvenation is "a fairly new concept," "game changing," and "the New Paradigm in gynecology." (Dkt. No. 1-2.) These statements cannot be reconciled with Defendants' present arguments. Defendants cannot honestly extoll the "game changing" virtues of the process at issue in the marketplace, yet argue in the courtroom that the same procedure lacks an inventive element. Particularly at the pleading stage, when all factual inferences are drawn in Viveve's favor, these statements further bolster the Court's conclusion that the '511 patent improves an existing process. *See Bowlby v. City of Aberdeen*, 681 F.3d 215, 218 (5th Cir. 2012) (standing for the proposition that the court must assume that all well-pleaded facts are true and view those facts in the light most favorable to the plaintiff).

IV. CONCLUSION

For the reasons explained above, Defendants' Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) and 35 U.S.C. § 101 is **DENIED**.

So ORDERED and SIGNED this 20th day of April, 2017.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE